ESTTA Tracking number: **ESTTA613386**
Filing date: **07/02/2014**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	92052897
Party	Plaintiff Thomas SkÃ¶ld
Correspondence Address	ARTHUR E JACKSON MOSER IP LAW GROUP 1030 BROAD STREET, SUITE 203 SHREWSBURY, NJ 07702 UNITED STATES docketing@mtiplaw.com, ajackson@mtiplaw.com
Submission	Testimony For Plaintiff
Filer's Name	Arthur E. Jackson
Filer's e-mail	docketing@mtiplaw.com, mcurcio@mtiplaw.com, ajackson@mtiplaw.com
Signature	/Arthur E. Jackson/
Date	07/02/2014
Attachments	NoticeOfFilingDayDep.pdf(11833 bytes) Day Dep.pdf(1235334 bytes) Exhibit H.pdf(261029 bytes) Exhibit I.pdf(319119 bytes) Exhibit J.pdf(719307 bytes) Exhibit K.pdf(347875 bytes) Exhibit L_Public.pdf(418323 bytes) Exhibit M.pdf(688274 bytes) Exhibit T2_Public.pdf(884855 bytes) Exhibit T8.pdf(421746 bytes) Exhibit T74_Public.pdf(1514176 bytes) Exhibit T143.pdf(1007676 bytes) Exhibit T148.pdf(1546834 bytes) Skold Dep Filing.pdf(12046 bytes) SKold Dep Public P1.pdf(2706115 bytes) SKold Dep Public P2.pdf(3281176 bytes) Skold Ntc Dep Exhs Public.pdf(12344 bytes) Exhibit A_Public.pdf(1573946 bytes) Exhibit B.pdf(1190388 bytes) Exhibit C.pdf(834987 bytes) Exhibit D sized.pdf(966762 bytes) Exhibit E_Public sized.pdf(698188 bytes) Exhibit F_Public sized.pdf(791349 bytes) Exhibit G_Public.pdf(494981 bytes) Exhibit T1.pdf(455955 bytes) Exhibit T2_Pulbic.pdf(884855 bytes) Exhibit T3_Public.pdf(1726174 bytes) Exhibit T6_Public.pdf(440567 bytes) Exhibit T7.pdf(1097445 bytes) Exhibit T8 skd.pdf(421740 bytes) Exhibit T9.pdf(569677 bytes) Exhibit T9 skd.pdf(569677 bytes) Exhibit T11_Public sized.pdf(1139144 bytes) Exhibit T12_Public.pdf(1102586 bytes) Exhibit T15.pdf(310442 bytes) Exhibit T27.pdf(1577813 bytes) Exhibit T27 skd.pdf(1577813 bytes)

	Exhibit T58.pdf(1045365 bytes) Exhibit T59.pdf(1376367 bytes) Exhibit T61_Public.pdf(917680 bytes) Exhibit T69.pdf(627895 bytes) Exhibit T70.pdf(304579 bytes) Exhibit T71.pdf(314937 bytes) Exhibit T73.pdf(740411 bytes) Exhibit T74_Public skd.pdf(1514176 bytes) Exhibit T125.pdf(325878 bytes) Exhibit T126_Public.pdf(651121 bytes) Exhibit T130 sized.pdf(2294616 bytes) Exhibit T132_Public.pdf(1001840 bytes) Exhibit T133_Public.pdf(512223 bytes) Exhibit T143 skd.pdf(1007676 bytes) Exhibit T145_Public sized.pdf(785029 bytes) Exhibit T146_Public.pdf(3036837 bytes) Exhibit T147.pdf(441613 bytes)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the Matter of Registration Nos. 2985751; and 3394514

Dated: August 16, 2005 & March 11, 2008, Respectively

Thomas Sköld, Petitioner v. Galderma Laboratories, Inc., Registrant	))))))))	Cancellation No. 92052897

NOTICE OF FILING OF DAY DEPOSITION

Pursuant to 37 CFR 1.123(h), Petitioner herewith files a true copy of the Deposition of Jeffrey Scott Day, taken 14 November 2013. True copies of the exhibits introduced therewith are being filed under separate cover.

Respectfully submitted,

Date: July 2, 2014 By: /Arthur E. Jackson/

Arthur E. Jackson, Esq.
New Jersey Bar No. 00288-1995
ajackson@mtiplaw.com
MOSER TABOADA
1030 Broad Street, Suite 203
Shrewsbury, NJ 07702
(732) 935-7100
(732) 935-7122
Attorney for Petitioner

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Thomas Sköld, Petitioner, v. Galderma Laboratories, Inc., Registrant	))))))))	Cancellation No. 92052897

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Notice of Filing of Day Deposition and the deposition referenced there in were sent by email on this 2nd day of July, 2014 to:

Jeff.Becker@haynesboone.com

/Arthur E. Jackson/
Arthur E. Jackson

#374042

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the Matter of Registration Nos. 2985751; and 3394514

Dated: August 16, 2005 & March 11, 2008, Respectively

Thomas Skold, Petitioner, v. Galderma Laboratories, Inc., Registrant.	Cancellation No. 92052897

DEPOSITION OF JEFFREY SCOTT DAY, a witness herein, called for examination, taken by and before Ann Medis, Registered Professional Reporter and Notary Public in and for the Commonwealth of Pennsylvania, at the Penn State Hershey Medical Center, University Physician Center, 4th Floor Conference Room, 500 University Drive, Hershey, Pennsylvania 17033, on Thursday, November 14, 2013, commencing at 1:33 p.m.

Job No. 32505

APPEARANCES:

On behalf of Petitioner

MOSER TABOADA
1030 Broad Street, Suite 203
Shrewsbury, New Jersey 07702
732.917.6323
BY: ARTHUR E. JACKSON, ESQ.
ajackson@mtiplaw.com

On behalf of Registrant

HAYNES AND BOONE, LLP
30 Rockefeller Plaza, 26th Floor
New York, New York 10112
212.659.4984
BY: RICHARD D. ROCHFORD, ESQ.
richard.rochford@haynesboone.com

HAYNES AND BOONE, LLP
2323 Victory Avenue, Suite 700
Dallas, Texas 75219
214.651.5262
BY: LISA N. CONGLETON, ESQ.
lisa.congleton@haynesboone.com

Also Present: Thomas Skold

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- - - -

JEFFREY SCOTT DAY,

having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. JACKSON:

Q. Mr. Day, could you put your name on the record.

A. Yes, Jeffrey Scott Day.

Q. Residence?

A. 60 Springdale Road, Warrington ~~Lancaster~~, Pennsylvania 18987.

JSD

Q. Your current work position?

A. President and CEO of Quinnova Pharmaceuticals.

Q. Could you outline your background in the pharma and dermatology business?

A. Yeah. I started my career in dermatology for Allergan. I don't know how specific you want it to be. From there I went on to Ferndale Laboratories. And I started my own company called Rx Pharmaceuticals and moved on, sold the assets of that company to Collagenex. And then most recently started and became CEO of Quinnova Pharmaceuticals.

DAY

My whole life in this career has been based on commercial operations, sales, marketing, distribution, trade, and most recently president and CEO.

Q. Quinnova is spelled Q-u-i-n-n-o-v-a?

A. Correct.

Q. When did you start your career at Allergan about?

A. 1987, around there.

Q. When Collagenex acquired the assets of RX Pharma, you took the position at Collagenex?

A. I did. I came over. They bought the derm assets of my little company, and then I became vice-president of dermatology.

Q. So about what timeframe did you start?

A. For Collagenex?

Q. For Collagenex?

A. The end of 2001, October.

Q. You departed Collagenex about?

A. You're killing me with this. Probably towards the end of 2004, I think.

Q. Do you recall a meeting that you and Thomas Skold had with Collagenex --

MR. ROCHFORD: Object to the form. Go

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ahead. I'll let you finish.

BY MR. JACKSON:

Q. -- on or about 12 September 2001?

A. Yes.

MR. JACKSON: You've objected to form?

MR. ROCHFORD: No.

BY MR. JACKSON:

Q. Do you remember the subject of that meeting?

A. Yes, I do. It was based on the Restoraderm technology.

MR. ROCHFORD: Move to strike that answer, foundation. There was no Restoraderm technology at that time.

BY MR. JACKSON:

Q. And Restoraderm technology, was that originating from Thomas Skold?

MR. ROCHFORD: Object to form, foundation.

A. Yes.

MR. JACKSON: I should apologize. This is the same as yesterday. It's just abbreviated. I've taken pages out.

MR. ROCHFORD: Just describe on the

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record what you're giving us.

MR. JACKSON: What I am giving you is the same exhibit book that was introduced yesterday but with fewer pages. I'm only going to be able to give you the two of you one. I miscalculated.

This is the same exhibit book that was put in the record yesterday except that for purposes of Mr. Day's testimony, there are fewer exhibits that we might reference. So I've removed some pages, some exhibits.

MR. ROCHFORD: So yesterday you marked a book. I'm not sure you marked it, but you referred to some things in a book. And today you're giving us another book.

MR. JACKSON: Yes.

BY MR. JACKSON:

Q. If we could refer to Skold Exhibit T8, which is on page 159.

A. Are you asking me to?

Q. Yeah, if you look at page 159 of the book. And page numbers are down here.

Are you familiar with the subject matter of this document?

DAY

MR. ROCHFORD: Object to form.

A. Yes.

BY MR. JACKSON:

Q. Was the subject matter of this document presented at the approximate 12 September 2001 meeting between Collagenex and Mr. Skold?

A. Yes.

MR. ROCHFORD: Object to form and move to strike the response. No foundation. The form of the question is vague.

A. Yes.

BY MR. JACKSON:

Q. At that meeting was the technology that Mr. Skold was presenting described as Restoraderm technology?

A. Yes.

MR. ROCHFORD: Object to form, foundation and hearsay. Move to strike the response.

BY MR. JACKSON:

Q. Did Mr. Skold in his interactions with Collagenex ship a topical formulation labeled Restoraderm to Collagenex in 2001?

MR. ROCHFORD: Object to form,

DAY

foundation.

A. Yes. Samples of the technology were sent to Collagenex.

BY MR. JACKSON:

Q. And those samples were labeled Restoraderm?

A. Yes.

MR. ROCHFORD: Same objections.

BY MR. JACKSON:

Q. Do you remember in what fashion they were sent to Collagenex?

A. They were sent in small aerosol canisters.

Q. Were further samples delivered to Collagenex at the January Caribbean meeting?

A. Well, they were hand delivered by Thomas at that meeting.

Q. Were they hand delivered to you?

A. They were delivered to me.

Q. They were labeled Restoraderm?

A. That's correct.

MR. ROCHFORD: Object to form. Move to strike. Foundation, form.

DAY

BY MR. JACKSON:

Q. Do you recall what parties from Collagenex were present at the meeting in September 2001?

A. Yes, Brian Gallagher, the president; Rob Ashley; myself and Thomas.

Q. Could you give us a description of what you -- I presume that Mr. Skold was trying to sell something to Collagenex?

A. Correct.

Q. Could you describe what he was trying to sell?

A. Well, he was trying to sell the Restoraderm technology for us to -- to Collagenex to develop the technology products.

Q. Was that a baseline vehicle for more specific products?

A. Well, Restoraderm is a vehicle that is designed to carry active ingredients, and so we talked about many different products, yes.

MR. ROCHFORD: Move to strike that last response as nonresponsive, and while we're on the record, the prior response as lack of foundation and hearsay.

DAY

BY MR. JACKSON:

Q. From the background you told us, and your history in the pharmaceutical industry, could you confirm that the type of service that Mr. Skold was offering is typically sold on an exclusive or a well-defined exclusive field use basis?

MR. ROCHFORD: Objection. Relevance.

A. Yes.

MR. ROCHFORD: And to the form of the question.

A. Yes.

BY MR. JACKSON:

Q. If you didn't present it in that way, one would lose substantial value; would they not?

MR. ROCHFORD: Objection. Form, foundation, calls for expert testimony.

A. In my opinion, you can't go to many, many different companies with the same technology. It just doesn't work. So you do lose value. Just like my own company is based on a unique technology that no one else has.

MR. ROCHFORD: I move to strike the last answer. This witness has not been qualified as an

DAY

expert or disclosed as an expert. We object to all and any opinion testimony based on alleged specialized knowledge of this witness.

BY MR. JACKSON:

Q. In your role at Collagenex, is it clear to you that Mr. Skold would not have established an agreement with Collagenex if he had not shipped sample to Collagenex in late 2001, early 2002?

MR. ROCHFORD: Object to the form of the question. Calls for speculation. Calls for expert testimony. It lacks foundation.

A. In my expert opinion, you're only able to -- in dermatology, in my expert opinion, you have to test products in that process. So if you don't see samples of things -- because it's all about look, feel, smell and how they're applied to the skin. That's what this business is all about.

Yes, it's very, very important to have those samples. That's basically very typical of what occurs.

MR. ROCHFORD: Renew the motion to strike based on the grounds that this is unnoticed and unqualified expert opinion testimony.

DAY

BY MR. JACKSON:

Q. In your affidavit that you signed in this matter in May of 2013, you identified the companies that were the significant players for marketing this kind of technology in the United States in the 2001, 2002 timeframe.

Do you remember the companies you listed?

MR. ROCHFORD: Objection. Form, foundation, relevance, calls for expert testimony.

A. Do you want a list of the ones?

BY MR. JACKSON:

Q. Can you make a list?

A. It's been a while, but I could -- the answer is yes. But it primarily at the time was Ortho and Neutrogena, J & J, obviously Galderma. We had Connectics, Medicis. Who else am I missing at that particular time? Fujisawa. I may be missing one or two.

Q. If I showed you paragraph 10 of your affidavit, would that -- which I will put into the record as Exhibit T148. If I showed you paragraph 10 of your response, would that refresh your memory?

A. No. 10, yes.

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MR. ROCHFORD: Object, first of all, to any responses relating to this list that's been requested on all the grounds previously noted.

BY MR. JACKSON:

Q. Proceed, Mr. Day.

MR. ROCHFORD: I don't view this as an offer of evidence. Just so it's clear, we object to virtually every document that has been identified by Petitioner in this proceeding, and at the appropriate time, if and when any of those are formally offered, we will submit our objections in full.

A. Is the question in my opinion?

BY MR. JACKSON:

Q. Are those the companies that you think are the relevant companies that were most appropriate to market technology in the 2001, 2002 timeframe?

A. Yes.

MR. ROCHFORD: Same objections.

BY MR. JACKSON:

Q. Could you read for the record what those companies are?

MR. ROCHFORD: Same objections.

DAY

A. Johnson & Johnson, Novaritis, Medicis Allergan, Galderma, Fujisawa, Ferndale, Steifel and Connetics.

BY MR. JACKSON:

Q. Could you describe your relationship with Thomas Skold in the fall 2001 timeframe and how you came to collaborate on the Restoraderm technology?

A. Yeah. I have to take a step back due to this history. Thomas and I had been working on the previous technology together. When I was at Ferndale, we launched a product there. I ended up leaving Ferndale, and then he ended up leaving Ponsus.

And at that particular point, he notified me that he was working on a new technology, kind of a new improved technology over Proderm. So that's my relationship to that point.

Q. Were you involved in all key decision making at Collagenex as to dermatology products when you were employed there?

MR. ROCHFORD: Object to form, vague, foundation.

A. Yes. I was involved in all -- in

DAY

decision making and specifically for dermatology at Collagenex.

BY MR. JACKSON:

Q. Were you involved in all promotional activity at Collagenex as to dermatology products?

A. Yes.

Q. In the formation of the -- well, in 2002, was an agreement between Collagenex and Skold formalized?

A. Correct, yes.

Q. In formulating that agreement, from your interactions with people at Collagenex, is it your view that the trademark Restoraderm was exclusively used to refer to the technology brought to Collagenex by Thomas Skold?

MR. ROCHFORD: Object to form, compound question, calls for speculation, foundation, hearsay.

A. It was viewed as one in the same.

BY MR. JACKSON:

Q. During the course of your employment at Collagenex, did the view -- from your interactions with people at Collagenex, did the view that Restoraderm and the technology were one in the

DAY

same change?

A. No.

MR. ROCHFORD: Same objections as to the previous question.

THE WITNESS: I feel like I'm messing up. Should I wait until you respond?

MR. ROCHFORD: No. You can see I'm not being obtrusive, but I have to make a record.

BY MR. JACKSON:

Q. From your interactions with Collagenex during the 2002 to 2004 timeframe that you were employed at Collagenex, was there an expectation by Collagenex that the Restoraderm trademark would return to Skold if Collagenex voluntarily terminated its project with Mr. Skold?

MR. ROCHFORD: Objection to form, lack of foundation, calls for speculation, hearsay, relevance.

A. I think it's -- to me, it's almost the same as the last question, which is we viewed it as one in the same and, yes, returned.

BY MR. JACKSON:

Q. You made efforts to promote Restoraderm to outside collaborators while you were at

DAY

Collagenex, outside corporate collaborators?

MR. ROCHFORD: Object to form.

A. Yes.

BY MR. JACKSON:

Q. In those efforts to promote Restoraderm technology to outside partners, was Mr. Skold consistently named as associated with the technology?

MR. ROCHFORD: Same objection.

A. In most cases, yes, he was involved as the expert in describing the technology and everything else.

BY MR. JACKSON:

Q. Was he frequently named as the inventor of the technology?

A. Yes.

Q. Was Mr. Skold integrally involved in promoting Restoraderm to potential partners?

MR. ROCHFORD: Object to form.

A. Yes.

BY MR. JACKSON:

Q. Did Mr. Skold assist you in making presentations to potential partner companies?

A. Yes.

DAY

Q. Did Mr. Skold provide technical consultations on the Restoraderm product and technical services in preparing the Restoraderm product?

A. Yes.

MR. ROCHFORD: Object to form. There was no product.

A. Yes.

MR. ROCHFORD: Foundation.

BY MR. JACKSON:

Q. Can you recall a meeting concerning Restoraderm with Johnson & Johnson and several of its affiliates on or about September 11, 2001?

A. Yes.

Q. Can you tell us what you remember about that meeting?

A. Well, obviously it was during a very difficult time with the September 11 tragedy. But yeah, we were up at J & J that morning presenting the Restoraderm technology to them when the September 11 events occurred.

MR. ROCHFORD: Move to strike on foundation that last response. There was no Restoraderm technology.

DAY

BY MR. JACKSON:

Q. Did you hear of some indication of the attack before you arrived at J & J?

JSD A. Well, I actually picked up Thomas at the hotel in -- it's ~~It's~~ called Peddlers Village. At the time, the morning, there was -- I guess they reported a small plane hit the towers. I'm sure we all remember that.

We went up to the meeting, and we were notified about halfway through the meeting what happened. Actually I remember perfectly because the building went into lockdown. And so obviously the meeting at that point had kind of ceased about halfway through.

Q. Were Neutrogena and Ortho affiliated with Johnson & Johnson at the time of that meeting?

A. Yes.

Q. Do you recall organizing a meeting concerning Restoraderm with Allergan in the fall of 2001?

MR. ROCHFORD: Object to form.

A. Yes. We actually attempted to have that meeting at the same time that we were doing the

DAY

Medicis meeting, but it just didn't work out. But I personally had a meeting with them at a later date.

BY MR. JACKSON:

Q. Do you recall organizing a meeting with Medicis, helping to organize a meeting with Medicis in the same timeframe concerning the Restoraderm technology?

MR. ROCHFORD: Same objection.

A. Yes.

BY MR. JACKSON:

Q. Did that meeting come to pass?

A. Telephonically.

Q. Where did it occur telephonically from your perspective?

A. Well, it occurred -- the telephonic meeting occurred at the Collagenex office. We obviously were unable to fly down there because of September 11.

Q. Did somebody from Galderma mention -- bear with me.

Did somebody from Galderma mention Restoraderm to you at the 2009 AAD meeting?

A. Yes.

DAY

MR. ROCHFORD: Objection, hearsay, foundation, relevance.

BY MR. JACKSON:

Q. What is the AAD meeting?

A. It's the American Academy of Dermatology.

Q. What did they tell you about Restoraderm?

MR. ROCHFORD: Same objection.

A. It was communicated to me -- and by the way, at that meeting, just to make it a little better understanding for everybody, I was there for Quinnova. It was at a later point. I was supposed to be in a meeting with Art, and he was unable to make it. And I ended up meeting with a European. It's Chris somebody. I can't remember his last name. But he headed up business development for the European group.

He had mentioned to me at that time they had no interest in the technology, but were going to keep the name.

MR. ROCHFORD: Move to strike for all the reasons indicated earlier; hearsay, lack of foundation, form, relevance.

DAY

BY MR. JACKSON:

Q. The Art you mentioned, was that Art Clapp?

A. Yes.

Q. And his position at Galderma was?

A. He's head of business development.

Q. At the time?

A. I still think he is today.

Q. Was it clear to you that the person, the Galderma person at that meeting understood that Restoraderm was the same as the technology until that point?

MR. ROCHFORD: Same objections, foundation, form, hearsay, relevance.

A. The way it came across to me, I would have to say yes.

MR. ROCHFORD: Also calls for speculation. Move to strike on the additional basis.

BY MR. JACKSON:

Q. From your long association with the dermatology formulation community, do you recall interactions that establish that the term Restoraderm was viewed as equating to the

DAY

technology of Thomas Skold?

MR. ROCHFORD: Objection. Calls for expert testimony that has neither been properly noticed, nor has there been any attempt to qualify this witness properly. So I object on that basis. We also object on relevance grounds, that it calls for hearsay, calls for speculation.

A. Yes. And in several of the publications, the studies that were done were done with my participation, the Jim Fowler study and the Ruby Ghadially study. In fact, I introduced Bill Abramovitz to Thomas. He's an expert in skin restoration, the treatment and use of ceramides.

BY MR. JACKSON:

Q. These studies were published?

A. Well, the Ruby Ghadially study was published and the Jim Fowler study was published, but Bill Abramovitz was just lecturing on utilizing the name Restoraderm.

MR. ROCHFORD: Move to strike that response as nonresponsive and lacking foundation, hearsay, relevance.

BY MR. JACKSON:

Q. If we look at page 469 of the exhibit

DAY

book, Skold Exhibit T143, page 469.

A. Yes.

Q. Could you describe that document?

MR. ROCHFORD: I'm going to object on relevance grounds, foundation, hearsay.

A. This is actually the poster itself for the Joe Fowler study.

BY MR. JACKSON:

Q. By Joe Fowler study, you mentioned that he's listed as the lead author.

A. That's correct.

Q. Could you read the title of the study?

A. "A Comparator Study of An Adjunctive Dermal Lipid Replacement Foam (Restoraderm) in the Management of Refractory Hand Contact Dermatitis."

MR. ROCHFORD: Same objections to this entire line relating to what's been marked for identification as T143, and that is this study.

BY MR. JACKSON:

Q. In Skold Exhibit T143 -- I apologize for how hard this is to read, Mr. Day. But if you could --

A. I'll do my best.

DAY

Q. If you could read -- and I'm sorry it's covered over in part -- in the abstract portion of Exhibit T143, the second paragraph under the abstract beginning with the word Restoraderm.

MR. ROCHFORD: Same objections.

A. "Restoraderm is composed of an exclusive nonalcoholic water-based formulation of lipids that mimic the body's own natural skin barrier system. It contains ceramides, cholesterol, palmitic and two biologic precursors, mevalone" -- and I'm not even going to try to say the next word, hydroxy whatever.

BY MR. JACKSON:

Q. That's fine.

Are you familiar with the product Cetaphil Restoraderm?

A. Yes, by name and what it does. It's a moisturizing agent.

Q. Do you believe it contains ceramides, cholesterol and palmitic acid?

MR. ROCHFORD: Object. Calls for an expert conclusion, hearsay, foundation.

MR. JACKSON: I'm going to ask for a break. I'm potentially near finished, but I might

have one more question or one more series of questions.

MR. ROCHFORD: Okay. Off the record.

(There was a recess in the proceedings.)

BY MR. JACKSON:

Q. You mentioned that your career in dermatology has been since approximately 1987.

A. Correct, yes.

Q. During the course of your career, have you managed the development of dermatology products?

A. Yes, not from an R & D standpoint, but product development standpoint, yes.

Q. By which you mean?

A. So I come up with the idea of developing a product and am part of the process of deciding on the product, designing what we want. But when it comes to sample and designing a clinical study, that's not me. Mine start from the idea to commercializing it.

Q. During the course of that commercial development work, have you frequently dealt with outside consultants on those more scientific elements?

DAY

JSD

A. Absolutely. We're a small company, and so was Collagenex -- small companies always use the consultants to do our work. We don't do much internally.

Q. If you could let us know your post-high school education.

A. College graduate from Indiana University of Pennsylvania.

Q. Oh. That's a confusing name.

What was your major?

A. Marketing.

Q. Is there a difference between a platform technology and products made from that platform technology?

MR. ROCHFORD: Objection, form, foundation, calls for expert testimony.

A. You have to explain a little bit more than that.

BY MR. JACKSON:

Q. For instance, as I understand, Restoraderm was a technology in which you were going to make more specific products.

A. Correct.

Q. Is it fair to call Restoraderm a

DAY

platform technology?

A. Yes.

MR. ROCHFORD: I'm going to object to this string of questions on the grounds it calls for expert testimony, form, foundation, relevance.

BY MR. JACKSON:

Q. Have you in your experience since 1987 worked with, developed products from other platform technologies?

A. Yes. In fact, the company I'm CEO of is based on a technology called Proderm technology, which is a similar concept. If you look at our stuff, everything is -- whatever, our product Hydro 35 utilizes Proderm technology. So we use that vehicle -- you call it a platform -- as the chassis for just carrying active ingredient.

MR. ROCHFORD: Object and move to strike, form, foundation, expert testimony and relevance.

MR. JACKSON: Our testimony is closed. We can go off the record for our side. We will, if we need to, seek to have Mr. Day qualified as an expert.

So you're welcome to cross on that point if

DAY

you wish.

MR. ROCHFORD: Well --

MR. JACKSON: It is what it is.

MR. ROCHFORD: You're going to have to make some kind of application. We'll oppose it. I don't think you can you can do it at this point. There's all sorts of rules, like Federal Rule 26, that governs, and I think you're too late. I'll say that for the record.

MR. JACKSON: It's in your interest to.

MR. ROCHFORD: Let me note we do object to any expert testimony as not having been noticed under Rule 26 as required by the rules of the TTAB. There hasn't been any expert report as is also required. Therefore, we are, to the extent necessary, proceeding under protest here and reserve all rights to recall Mr. Day in the event that TTAB allows some belated attempt at qualification.

(There was a recess in the proceedings.)

MR. ROCHFORD: We're back on the record.

CROSS-EXAMINATION

BY MR. ROCHFORD:

Q. We're back on the record.

DAY

Mr. Day, I introduced myself previously. I'm Rich Rochford representing Galderma. I'm from the Haynes and Boone law firm here with my colleague, Lisa Congleton. I'll be asking you some questions.

MR. ROCHFORD: Let me note before I start the questions two things. First, as indicated prior to the break, we're proceeding with this cross-examination under protest on the expert issue that we identified at that time.

Secondly, because of the nature of these proceedings before the TTAB where we lodge our objections now, but they're not ruled on until later in the proceeding, the cross-examination may involve some offers of proof relating to matters that we have objected to, and we do not waive any objection by proceeding with those matters.

BY MR. ROCHFORD:

Q. Mr. Day, you go back quite a ways with Mr. Skold; isn't that correct?

A. Yes.

Q. Have you had any recent contact with Mr. Skold?

A. I stayed with him for one night in

DAY

Sweden when I was over for business. My technologies are licensed from a company in Sweden.

Q. When was that?

A. I don't know the date. Couple months ago, three, four months ago.

Q. And you socialized with him at that time?

A. Yes. We had dinner.

Q. Is that the last time you saw Mr. Skold before today?

A. Yeah.

Q. Did you see him today at all before coming in for your testimony?

A. We met as a central point and drove over. They followed me in the car.

Q. Did you discuss this case at all with him today?

A. No.

Q. Do you know Professor Marks?

A. Very well.

Q. Have you discussed this case with Professor Marks at any time?

A. No. In fact, I haven't seen Jim since

DAY

the last meeting last year.

Q. When you say Jim, you mean Jim Marks?

A. Jim Marks.

Q. Have you discussed the case with Mr. Jackson?

A. I did talk to him a couple of weeks ago just to get my bearings straight. I've never been through this type of deposition before.

Q. Was that a meeting or a phone conversation?

A. It was a very brief meeting.

Q. Where did that occur?

A. In New Jersey.

Q. How long was the meeting?

A. Twenty-five, 30 minutes. I can't remember.

MR. JACKSON: I can't testify.

A. Twenty-five, 30 minutes I would imagine.

BY MR. ROCHFORD:

Q. What did you talk about?

A. Just getting myself, my head together as to prepare for this.

Q. Did you look at any documents?

A. We did talk about a couple of questions

DAY

that were going to be answered on what I had signed under -- whatever I signed.

Q. Your declaration?

A. Declaration.

Q. So you reviewed the declaration you submitted in this case, which I believe was marked as an exhibit during your direct testimony as T148?

A. Right.

MR. ROCHFORD: Do we have that, counsel? Is that out there, the original?

MR. JACKSON: Yeah. I had it. I brought it over. Yeah, I have a copy here.

BY MR. ROCHFORD:

Q. Showing you, Mr. Day, Exhibit what's been marked for identification T148, is that the declaration you're referring to that you discussed with Mr. Jackson?

A. Correct.

Q. Do you recall anything specific about the discussion of your declaration?

A. It was more to solidify what I had signed and to be prepared to get questioned on it.

Q. Now, in that process as you reviewed it,

DAY

is there anything you would change about your sworn testimony in T148?

A. Nothing more than what I said to him was, this is a long time ago. So if I can't come down to an exact hour or day of time, I'll do my best. That's the only thing. I feel very good about what's on here, what I signed, but this was a long time ago.

Q. So you can't be entirely sure of your recollections; is that your testimony?

A. Maybe on specific dates or times, yes.

Q. Is there anything else relating to T148 that you would change, having reviewed it recently?

A. Absolutely not.

Q. I'm sorry?

A. No.

Q. What else did you discuss with Mr. Jackson during that meeting?

A. That was it. That's a lie. Where we're going to meet today.

Q. In terms of your relationship with Mr. Skold, that goes back to about 1997?

A. Yeah, probably right.

DAY

Q. At that time you were working for Ferndale?

A. That's correct.

Q. And he was working for Ponsus?

A. Yes.

Q. At that time you collaborated and your companies collaborated with respect to some Ponsus product; isn't that correct?

A. That's correct.

Q. When did that occur?

A. I can't exactly remember when we launched, but we launched a product called Pro-Q, and I'm assuming that would be, I would say -- bear with me on this. I would say it's probably late '90s, say '97, '98, '99. I'm guessing on that, to be honest with you.

But we launched a product called Pro-Q, which is based on the Proderm technology, which was a Ponsus technology.

Q. Since that time in the late '90s, you've been friends with Mr. Skold?

A. Yeah.

Q. Close enough friends that you would stay at his house?

DAY

A. Yeah.

Q. Does he socialize with you in the U.S.?

A. He's never stayed with me in the U.S., but we have met in the U.S. over the years, of course. He comes over for business, and we'll have dinner, those types of things.

Q. And you consider him a close friend?

A. I do.

Q. Now, you indicated that you left Ferndale and started your own company. That company was called Rx-Pharma?

A. Rx Pharmaceuticals, yes.

Q. When did you leave Ferndale and start Rx Pharmaceuticals?

A. I'm struggling with dates. Probably '99, 2000, that timeframe. That business was about two years. So it was probably about '99. I can validate that for you if you want me to.

Q. What did you do at Ferndale?

A. I was -- I don't remember what my direct title was. I did two things. I did trade relations, sales and marketing. So I headed up the derm sales force, and I headed up the trade relations team.

DAY

Q. Throughout your career, your work has been, as you indicated earlier, on the sales side of the business, correct?

A. I'm a commercial guy, so sales and marketing, trade relations and business development.

Q. As we saw when you were trying to read the Fowler poster there -- I think that's T143 -- you stumbled on the technical terms. So you are not a technical guy, are you, sir?

A. I am not. Why don't you take it one step further and ask what type of technical guy. If you're asking me if I'm a chemist, no, I'm not.

Q. I take it that you're not comfortable with chemical terminology?

A. No, that's not true. That particular word I stumbled with, yes, but I think I'm pretty confident when it comes to some, much of the technical side.

Q. But you never worked on that side of the business?

A. I'm not an R & D guy, that's the truth, yes.

Q. You don't have any engineering or

DAY

science background in the industry?

A. No, I do not.

Q. And your undergraduate degree was in marketing?

A. That's correct.

Q. So it's your recollection that you started Rx-Pharma in about 1999?

A. I'm guessing, yes. Off the top of my head, I can't remember the exact date, but that's probably very close.

Q. And you founded Rx-Pharma?

A. Yes.

Q. You were the CEO?

A. That's correct.

Q. Did you own Rx-Pharma in entirety?

A. Yes.

Q. Were there any officers besides yourself?

A. No.

Q. Any employees besides yourself?

A. No, not direct employees of that company, no.

Q. Were there indirect employees?

A. Yes. I had a contract sales force.

DAY

Q. That sales force also carried products from other companies?

A. That's correct.

Q. They were independent contractors?

A. They were not independent contractors, but they were employed by the contract sales group.

Q. And that contract sales group was an independent entity that you dealt with to --

A. That's correct, yes.

Q. -- sell products?

What products did Rx-Pharma market or sell?

A. Well, it was two primary products. One was Pro-Q. The product was a Proderm technology product. And I also licensed a topical steroid as well.

Q. What was the topical steroid called?

A. It was Pandel.

Q. Pro-Q product, was that something you had license rights from Ponsus to market or sell?

A. It was a Ponsus-licensed product to Ferndale, and Ferndale ended up getting it licensed to me. It wasn't licensed to me. It was -- I acquired the inventory of the existing

DAY

product that was there.

Q. From Ferndale?

A. From Ferndale.

Q. And in turn attempted to market and sell that product?

A. Not attempted, but marketed the product, yes.

Q. Then you also marketed and sold this topical steroid product at Rx?

A. On a co-marketing arrangement, that's correct.

Q. Did Rx-Pharma market or sell any other products during the time it existed?

A. No, no.

Q. Did it develop any products?

A. No. We did not develop any.

Q. You didn't have the resources to develop products at Rx-Pharma, did you, sir?

A. No, not without raising money, correct.

Q. You moved from Rx-Pharma to Collagenex; isn't that correct?

A. Yes. Collagenex acquired the assets of Rx-Pharma.

Q. Was that according to a formal

DAY

agreement?

A. Um-hum.

Q. "Yes" or "No" for the record.

A. Yes.

Q. When did that occur?

A. In the latter part of 2001. I think it was October or November, one or the other.

Q. You joined Collagenex at that time as vice-president of dermatology; is that correct?

A. Correct, yes.

Q. You were at Collagenex until approximately September of 2004?

A. Correct.

Q. And you maintained the same title during your time there?

A. Correct.

Q. And among your duties is you helped promote Mr. Skold's concept; isn't that correct?

A. Yeah. There was many different duties on it, but one of them was the development of a line of products based on the Restoraderm technology, correct.

Q. Now, there was no Restoraderm technology at the time you joined Collagenex in late 2001,

DAY

was there, sir?

A. No.

Q. It was an idea at that point?

A. It was a technology that was introduced to me. I don't know what you consider an idea.

Q. When I think of a technology -- let's see if we can agree on a definition -- I think of something that's already been developed, whereas an idea is something that is a concept that might lead to a product, but it's still on the drawing board.

A. Well, when it was introduced to me, it was Restoraderm technology. That was an entity. It was a product in itself.

Q. So a product existed that Mr. Skold had created as of September 2001?

A. Well, it's interesting. This technology, again, which is very similar to my Proderm technology which I market, the technology itself is a product which is a product for dry skin. It's also a delivery chassis for active ingredients. So that product itself, the entity, the vehicle which is a product in its own was developed.

DAY

What was the future products which we're using as a delivery compound, I guess you may be right there. Those were products that we were looking to develop.

Q. But, Mr. Day, there was no product that had been developed using the idea that Mr. Skold discussed with you in September 2001, was there?

A. Well, explain yourself further.

Q. Was there any type of product that could be sold to the public as of September 2001?

A. Not to be sold to the public. Yes, you're right. The answer to that is right, there was nothing to be sold to the public.

Q. In fact, there wasn't any product using the formulation that Mr. Skold had on the drawing board that had even been subjected to stability testing; isn't that correct?

A. At that point, probably not, correct.

Q. So I'm correct that no stability testing had been done on any formulas?

A. I had not seen any stability testing at that particular point, correct. There was lab testing that was being done, but if you want to say an official lab site GMP vendor facility,

DAY

probably not.

Q. What lab testing was being done on Mr. Skold's concept in September of 2001?

A. Well, when you develop a product --

Q. Let me finish.

A. Oh, I'm sorry.

Q. I don't want to hear about hypothetically. What work in the way of lab testing --

A. If you'd let me be finish --

Q. Let me ask my question.

What type of lab testing was being done on Mr. Skold's formulation as of September 2001 of your personal knowledge?

A. Really what you're looking at is ~~physical~~ feel, smell and touch, and that's it. No official lab testing, stability testing was done at that point.

Q. So no lab testing was occurring at that time?

A. Yes, I guess you're right on that.

Q. So you left Collagenex in about September of 2004?

A. That's about right.

DAY

Q. At that time did you form Quinnova?

A. Quinnova, correct.

Q. What's your role at Quinnova?

A. I'm president and CEO.

Q. Have you been at Quinnova as president and CEO since that time in 2004?

A. Correct.

Q. What does Quinnova do?

A. We're a specialty dermatology pharmaceutical business.

Q. Are you involved with any particular products?

A. Yeah.

Q. What products?

A. You want a list of them? We have a brand called Neosalus. We have Hydro 35, Hydro 40, Salvax, Tersi foam and another line, Atrapro. All of them except for the latter are all based off of a technology called Proderm technology.

Q. So all of those products came from the Ponsus Proderm technology; is that correct?

A. Correct.

Q. Do you have a license arrangement with Ponsus relating to that product line?

DAY

A. Yes.

Q. Mr. Skold assisted you in making that arrangement with Ponsus; isn't that correct?

A. Yes.

Q. In fact, your involvement with Mr. Skold led to your joining Collagenex in September 2001; isn't that correct?

A. Repeat that.

Q. Your relationship with Mr. Skold led to you joining Collagenex in September 2001, correct?

A. Not specifically Thomas himself. He's not the only reason why I took that job at Collagenex.

Q. He was a significant factor in your receiving that opportunity, correct?

A. No. I mean, that's not true. I decided to take that job. My relationship with him had nothing to do with that job other than being a reference.

Q. Now, you were asked some questions during your direct testimony relating to the time period in September 2001; is that correct?

A. Um-hum, yes.

Q. You were arranging meetings for

DAY

Mr. Skold to discuss his concept with several U.S. companies at that time; isn't that correct?

A. That is correct.

(Galderma Exhibit H was marked.)

BY MR. ROCHFORD:

Q. Mr. Day, I'm showing you what's been marked as Galderma Exhibit H, which is an email previously produced as Skold 1841, and it includes in that document an email message from Jeff Day to Thomas Skold dated September 4, 2001.

Are you familiar with this document, sir?

A. Yes.

Q. Exhibit H indicates that you have confirmed several meetings, a Monday meeting with Collagenex, a Tuesday morning meeting with Neutrogena Orthoderm and Tuesday afternoon departing for Phoenix, a Wednesday meeting with Medicis.

Am I reporting your message correctly?

A. Yes.

Q. You also note that you're still waiting for Allergan to confirm; isn't that correct?

A. That is correct.

Q. You were arranging these meetings so

DAY

that Mr. Skold could present his concept to these companies at that time, correct?

A. Yes, Restoraderm technology to those companies.

Q. Well, there's nothing in here that says Restoraderm in this message, is there, sir?

A. There's nothing in here, but that's what was inferred. That's what we were planning on doing.

Q. What you're talking about is something that later became known as Restoraderm, correct?

A. I knew it at that particular point as Restoraderm from discussions and communications with Thomas.

MR. ROCHFORD: Move to strike the nonresponsive response.

BY MR. ROCHFORD:

Q. Why were you planning these meetings, Mr. Day? Didn't you have a job?

A. No. I didn't have a job at that particular point yet anyway. Second of all, if you were my friend and looking for help, I would have helped you as well. I've been in this industry a long time, and I know a lot of people.

DAY

Quite frankly, too, if something would come of it -- maybe financially there would have been something in it for me.

Q. And Mr. Skold told you there would be something in there for you, correct?

A. Yes.

Q. What did he tell you specifically?

A. I don't even remember what it was, to be honest with you. We never had a formal agreement. It was just basically done on a handshake.

Q. Based on that handshake agreement that you would be rewarded, you set up these or attempted to set up these meetings, correct?

A. I wouldn't say rewarded. It would be earned.

Q. Now, as it turned out, no meeting with Allergan occurred in September of 2001, correct?

A. That's correct.

Q. As to Medicis, there was a brief telephone call rather than a meeting; isn't that correct?

JSD

A. It was a teleconference, correct.

Q. And as to Neutrogena and Orthoderm, I believe you testified that that proposed meeting

Ortho Derm.

JSD DAY

also included Johnson & Johnson?

A. Ortho Derm. ~~Orthoderm~~ and Neutrogena are J & J. They're two companies based under the J & J umbrella. They're the derm groups.

Q. So when we talk about the J & J in this proceeding, we're also talking about Neutrogena and Ortho Derm. ~~Orthoderm~~, correct?

JSD A. That's correct.

Q. And it was one meeting, all of those?

A. That's correct.

Q. In fact, that meeting was canceled, correct?

A. No, it was not canceled.

Q. It's your testimony after the planes hit the World Trade Centers across the river from J & J, you all proceeded with the meeting on a concept?

A. Yeah, actually we did. The meeting took place. The building went into lockdown. Halfway through the meeting it was stopped, that's correct.

Q. Are you aware that Mr. Skold has previously indicated to people at J & J that that meeting had been canceled?

DAY

A. I don't -- I'm unaware of any of that.

Q. Weren't you calling your friends and neighbors to see if they were okay at that time, on September 11, 2001?

A. When we left that facility, of course. We didn't even know what was going on at that particular point. The building went into lockdown. We were trying to figure out what was going on ourselves.

That morning, if you remember yourself, there was a small plane that went into the side of the building. That's all we basically knew at that point.

Q. But, in fact, you did have a meeting with Collagenex on September 12, 2001, correct?

A. Correct.

Q. At that meeting -- let me show you a document that's been marked as T8. I think it's in your book here.

A. T8 it's marked as?

MR. JACKSON: Page 59.

BY MR. ROCHFORD:

Q. Do you have what's been marked for identification as T8 in front of you, Mr. Day?

DAY

A. Yes.

Q. That reads at the top "A Theory of the 'Mode of Action' Concerning This New Technology, 5 November 2001."

Did I read that correctly?

A. Um-hum.

Q. "Yes" or "no."

A. Yes.

Q. Now, I believe on your direct examination you indicated that the substance of what's in T8 was discussed with Collagenex and Mr. Skold on September 12, 2001.

Was that your testimony, sir?

A. Yes.

Q. So that was an oral presentation by Mr. Skold relating the theory of the mode of action, correct?

A. That's correct.

Q. You don't recall any document being given to anyone at Collagenex at that time?

A. I do not recall, that's correct.

Q. And whatever was described by Mr. Skold during that meeting related to his theory or concept, correct?

DAY

A. I guess you'd have to say yes on that.

Q. From the time you joined Collagenex in September or October of 2001, at that time Mr. Skold and Collagenex were engaged in private confidential discussions and negotiations towards an agreement, weren't they?

A. Say it again. I'm sorry.

Q. At the time you joined Collagenex in September, October of 2001, Mr. Skold and Collagenex were engaged in private confidential negotiations towards a deal, correct?

A. Well, if they were private and confidential, I wasn't part of it. I'm sure there were discussions. But I don't know it to the extent what he was doing on his own.

Q. But you weren't involved in the -- from the Collagenex side in the negotiations?

A. Yes, I was.

Q. I'm showing you a document.

MR. ROCHFORD: Is this in his book, Mr. Jackson, T74?

MR. JACKSON: Yes. We had so much trouble finding it last time. It's T74.

MR. ROCHFORD: I believe so.

DAY

MR. JACKSON: It's page 313. That will be the second volume.

A. I have it. It's page 313. Is this what you're looking for?

BY MR. ROCHFORD:

Q. Yes.

So T74 is a document that reads "Flowchart with Trigger Events, LipoDerm/RestoDerm/EpiLip Technology."

Did I read that properly, Mr. Day?

A. Yes.

Q. Mr. Skold prepared this document and sent it to you around October of 2001; isn't that correct?

A. It was sent to Collagenex itself, I would imagine.

Q. Do you recall seeing this before?

A. I have seen it, but I don't recall that it was sent directly to me.

Q. Do you recall when you first saw it?

A. I can't remember.

Q. You'll see at the top that this is refers to a LipoDerm, RestoDerm, EpiLip technology; isn't that correct?

DAY

A. I see that, yes.

Q. So those were the terms that Mr. Skold was using to describe his concept in late 2001, correct?

A. I guess so, yeah.

Q. At some point after T74 was sent, Collagenex chose to use Restoraderm going forward as the name, and that was fine with Mr. Skold, correct?

A. Yes.

Q. Now, you testified this morning about some experimental samples that Mr. Skold sent to you in late 2001 and early 2002. Do you recall that?

A. I do.

Q. And those samples at that time, as we've talked about, hadn't been tested, correct?

A. I don't know to the extent of what they were tested. So I guess you're right on that.

Q. They certainly weren't usable or approved for personal use, right?

A. They were designed for sample testing for ourselves, that's correct.

Q. You don't recall if those samples had

DAY

any labels on them, do you, sir?

A. They were labeled as Restoraderm.

Q. How do you know that?

A. Well, he handed the ones right directly to me at the Caribbean Derm meeting.

Q. So it's your testimony that at the Caribbean Derm meeting, you received samples from Mr. Skold that bore a label that said what precisely? What were the exact words?

A. The Restoraderm technology. And this, if I'm not mistaken, was the base vehicle product.

Q. Those were the only words on the label?

A. I can't remember anything else on it, to be honest with you.

Q. But you do remember that?

A. Yeah. I mean, that's what it is. It was Restoraderm technology.

Q. Well, are you just saying that because Collagenex decided to use that name previously? Do you think those samples said that, or do you have a very clear recollection?

A. I'm very confident, because I sent samples actually back to Thomas at one point, a few years after that point. So I feel confident

DAY

that they said Restoraderm on them.

Q. But they might have said other things?

A. They could have had other stuff on it, yes.

Q. They could said Lipoid, Lipoderm?

A. I think I would remember that.

Q. You didn't keep any copies of those, did you, sir?

A. Of the samples?

Q. Yes.

A. They were sent back to Thomas.

Q. So if they exist, Thomas would have them?

A. Yes.

Q. At the time you saw those samples at the Carib Derm meeting in January 2002 --

A. Let me go back on something. I actually do have samples still, but I don't know when they were sent to me. So I'm not sure if it references this particular timeframe. I'd have to go back and look. Sorry to interrupt you.

Q. That's okay.

(Galderma Exhibit I was marked.)

DAY

BY MR. ROCHFORD:

Q. So, Mr. Day, we're showing you what's been marked as Galderma Exhibit I. It's an email string previously produced as Skold 1847 from February 17 and February 18, 2002. The first message is from Thomas Skold to you and then your response.

Are you familiar with this document, sir?

A. Yes. Let me --

Q. Take your time to read it.

(Witness reviewed the exhibit.)

A. Okay.

BY MR. ROCHFORD:

Q. You'll see at the bottom of Mr. Skold's February 17, 2002 message to you, the last line of that reads, "Enclosed please find the Restoraderm formula including two important names."

Did I read that properly?

A. Yes.

Q. Does that refresh your recollection that that's the initial base formulation sent after execution of the cooperation agreement between Skold and Collagenex?

A. Repeat, please.

DAY

(The record was read back.)

A. Yes, I guess Restoraderm, yes, yes.

BY MR. ROCHFORD:

Q. And that first formulation Mr. Skold said included two important names, correct?

A. Yes. That's what it reads here.

Q. Do you recall what those names were?

A. I do not.

Q. That indeed was the first time that samples included names; isn't that correct?

A. I'm not really sure where you're going with this.

Q. It's a straightforward question. That time, as of February 17, is the first time that a sample sent from Mr. Skold to Collagenex included names, correct?

A. Are you talking about specific product names or the technology name?

Q. Any name.

A. No. As I said to you earlier, the Restoraderm name was part of the original samples that came in.

Q. Then why would Mr. Skold at this point highlight that he was sending you formula that

DAY

included two important names?

A. I don't know what that means.

MR. JACKSON: I'll object to the mischaracterization of what that line says.

A. It could have been names of specific products that we were looking at. I don't know.

BY MR. ROCHFORD:

Q. Now, there came a time in late 2001 when Collagenex and Mr. Skold entered into a signed Letter of Intent; isn't that correct?

A. Yes.

Q. That, I believe, is marked is Galderma Exhibit B. I'll put that in front of you.

MR. JACKSON: As it turns out, I don't have a copy unless it's in the book.

MR. ROCHFORD: You're welcome to look over his shoulder. I only have a few questions on this.

A. Let me look at it, please.

BY MR. ROCHFORD:

Q. Take your time to read it.

(Witness reviewed the exhibit.)

MR. JACKSON: I'm going to object to this line of questioning, I think, as beyond the

DAY

scope of the direct pending the question, of course.

A. Okay.

BY MR. ROCHFORD:

Q. So this Letter of Intent marked as Galderma Exhibit B was signed by Collagenex, by Mr. Ashley, and accepted and agreed by Mr. Skold; isn't that correct?

A. Yes.

Q. If I could direct your attention to the top of page 2 --

MR. JACKSON: Again, beyond the scope of direct. Objection.

BY MR. ROCHFORD:

Q. You'll see that clause there. Let me read it, "All trademarks associated with the drug delivery system, the proposed intellectual property, products deriving therefrom and products marketed or to be marketed by Collagenex and/or any commercial partner of Collagenex anywhere in the world, shall be applied for and registered in the name of Collagenex and be the exclusive property of Collagenex."

Did I read that correctly, sir?

DAY

A. Yes.

Q. And that indicates that Collagenex owned all trademarks associated with the drug delivery system, et cetera, correct?

MR. JACKSON: Further object on the basis that the document speaks for itself and that it requires a legal conclusion on the part of Mr. Day.

BY MR. ROCHFORD:

Q. Mr. Day, you understand the concept of exclusive property, correct?

A. Correct.

Q. This indicates that all trademarks are the exclusive property of Collagenex, correct?

A. That's what's written.

MR. JACKSON: Objection. It's the same objections.

BY MR. ROCHFORD:

Q. There then came a time in February of 2002 where the parties entered into -- by the parties I mean Collagenex and Skold -- entered into a Cooperation, Development and Licensing Agreement; is that correct?

A. Yes.

DAY

Q. I believe that's at T2 in your book. It's a long document. You're welcome to read it all, but I only have a question about a provision --

A. To save me a second, what page is it, please?

MR. JACKSON: It starts at page 3 in terms of the bulk of the document.

BY MR. ROCHFORD:

Q. Let me tell you the portion I'm going to ask you about. You can decide how much you want to read before I ask you the substantive question. I'd like you to take a look at 4.2.1.

MR. JACKSON: My objections will be the same as before, beyond the scope, calls for a legal conclusion. That's basically it.

BY MR. ROCHFORD:

Q. Mr. Day, this Cooperation, Development and Licensing Agreement marked for identification as T2 was signed by both Collagenex and Mr. Skold; isn't that correct?

A. Yes.

Q. In that Section 4.2.1, this agreement reads, "All trademarks applied for ~~are~~ or registered JSD

DAY

(including Restoraderm) shall be in the sole name of Collagenex and be the exclusive property of Collagenex during the term and thereafter (the trademarks)."

MR. JACKSON: Same objection.

BY MR. ROCHFORD:

Q. Did I read that properly?

A. Yes.

Q. This agreement ratifies the Letter of Intent in terms of all trademarks being the exclusive property of Collagenex, correct?

A. That's how it's written.

MR. JACKSON: Same objection.

BY MR. ROCHFORD:

Q. There came a time that Skold and Collagenex entered into another agreement in 2004; isn't that correct?

A. Yes.

Q. You discussed that agreement briefly in your sworn declaration, what's been marked for identification as T148, at paragraph 9, if I could direct your attention there.

A. Yes.

Q. At the beginning of that paragraph, you

talk about Collagenex's motive for changing the 2002 agreement to create the 2004 agreement and you indicate that they were financial motives involved; isn't that correct?

A. That's what I understand, yes.

Q. You further state in that same paragraph that the substance of the agreement, that being the 2002 agreement, other than the timing of payments, was intended to remain the same; isn't that correct?

A. That's what I understand, yes.

If you have to go off the record in a minute, please do.

MR. ROCHFORD: Let's take a short break. That's fine. The witness' needs are always important. We'll take just a couple of minutes, and I should be able to conclude very quickly.

(There was a recess in the proceedings.)

BY MR. ROCHFORD:

Q. Mr. Day, back on the record. I'll ask you to take a quick look at T143 for identification, which is that Fowler study Mr. Jackson asked you about.

A. You're talking about this one?

DAY

Q. So you have that in front of you, T143, the poster of the Fowler study?

A. Yes.

Q. When was that poster prepared?

A. I don't know the exact date, to be quite honest with you.

Q. 2005?

A. I don't think it would be. It would be -- I'm trying to get my bearings on the dates. I would have to say it would be -- I know the study was conducted, if I'm not mistaken, in 2002 or early 2003.

Q. I'm not asking you to guess. If you don't know --

A. I don't know the answer.

Q. As to that particular work that's referenced in T143, Collagenex sponsored that work; isn't that correct?

A. That's correct.

Q. Now, we talked a little bit about the experimental samples that Mr. Skold sent over to you and to Collagenex in late 2001 and early 2002. Those were sent confidentially to Collagenex, correct?

DAY

A. That's correct. Versus what else? Are you asking any -- I'm not really sure.

Q. That's all.

(Galderma Exhibit J was marked.)

BY MR. ROCHFORD:

Q. There's an email string on here, Mr. Day, on what's been marked as Galderma Exhibit J. The message I'd like to direct your attention to is the second one there, the March 10, 2003 message from Mr. Skold to you. You're welcome to read the entire page, if you wish.

A. Yeah. Bear with me here.

(Witness reviewed the exhibit.)

A. Okay.

BY MR. ROCHFORD:

Q. Directing your attention to the March 10, 2003 message from Mr. Skold to you, you'll see the first paragraph there. It says, "Sounds like a good challenge to present the technology for Ortho and Neutrogena. The fact that they called gives us some sort of advantage, I think. It will be extremely interesting since it is my first time talking about it to a company."

DAY

Did I read that correctly?

A. Yeah, you did.

Q. Does that refresh your recollection that that was the first time Mr. Skold presented technology to a company?

A. Well, that's what it says here, but that's not what the case was because I presented that technology with him to Ortho on September 11.

Q. But that's what the document says.

A. That's what the document says, but I'm not sure why it says that.

Q. Maybe because something had been developed by March 10, 2003?

A. That's up to you to talk to Thomas about.

MR. ROCHFORD: I'd like these next two marked as the next two in line.

(Galderma Exhibit K and Exhibit L were marked.)

BY MR. ROCHFORD:

Q. Let's start with K.

MR. JACKSON: Objection. Beyond the scope of the direct.

MR. ROCHFORD: I think his relationship with Mr. Skold is certainly at issue here.

DAY

BY MR. ROCHFORD:

Q. Mr. Day, I'm showing you what's been marked as Galderma Exhibit K, which is some emails between yourself and Mr. Skold from September 28, 2010.

You've had a chance to look at that document?

A. Yes.

Q. That indicates that you are involved in some type of development effort relating to Mr. Skold's at that time what you referred to as Restoraderm information, correct?

A. That's what it says, yes.

Q. What was that about? What were you doing at that time?

A. I have to be honest with you. I don't remember. I cannot answer the question. After looking at this, I cannot remember what it was about.

Q. So you don't recall attempting to engage in some joint development activity with Mr. Skold as of September 2010?

A. I'm drawing a blank. I'm sorry.

Q. Let's take a look at Exhibit L, Galderma Exhibit L, which is an email string between

DAY

yourself and Mr. Skold. This is you -- let me start over for the record.

L is an email from you to Thomas Skold dated February 1, 2013; isn't that correct?

A. Um-hum.

Q. Yes?

A. Yes.

Q. You've had a chance to look at that?

A. I have.

Q. And this refers to a possible development deal that you are pursuing with a prospective company; is that correct?

A. Yes.

Q. You had sent some items on Mr. Skold's, as you call it, technology to a prospective company; isn't that correct?

A. That's correct.

Q. Did this go any further than this email, this opportunity?

A. No.

Q. Did Mr. Skold, in fact, ever respond to you regarding this opportunity?

A. I don't remember.

Q. Have you attempted to develop any other

opportunities relating to Mr. Skold's technology, as you call it?

A. No.

Q. Are you aware that Mr. Skold has recently entered into a deal relating to his technology?

A. I don't know any specifics on it. Are you talking between your client?

Q. No.

A. Other deals I don't know anything about.

(Galderma Exhibit M was marked.)

BY MR. ROCHFORD:

Q. Mr. Day, I've put in front of you what's been marked as Galderma Exhibit M, which is a screenshot from the Quinnova.com website from November 9, 2013, and it's the executive management page.

I take it you're familiar with this page?

A. Yes.

Q. This includes your bio and the biographies of the other members of executive management at Quinnova?

A. A snapshot of.

Q. So they're snapshot bios of yourself and

DAY

several other individuals; is that correct?

A. Right.

Q. You highlight your involvement with Restoraderm in your snapshot bio; isn't that correct?

A. Along with other things as well, correct.

Q. Clearly the most prominent thing in here is your discussion of your involvement with Restoraderm, correct?

A. That's your opinion, but I don't think so. That's one of the items that's in here.

Q. Now, let me read a portion of your bio in Exhibit M.

"In 2000, Mr. Day founded Rx-Pharma Pharmaceuticals, Inc., a specialty pharmaceutical business with two licensed products, Pandel and Pro-Q and a delivery platform technology Restoraderm."

Did I read that correctly?

A. Um-hum.

Q. Yes?

A. Yes.

Q. Now, no delivery platform Restoraderm

DAY

existed in 2000, did it, sir?

A. Repeat the question.

Q. No delivery platform technology Restoraderm existed in the year 2000, did it?

A. I struggled with the dates on that earlier. Really I guess it came from -- no. It was between discussions with Thomas and I.

Q. In 2000?

A. I can't remember the exact date. I'm sorry.

Q. Well, from our testimony today, we talked about Mr. Skold's initial idea being presented to you in September of 2001; isn't that correct?

A. Regarding -- as part of the Collagenex deal, correct.

Q. That was the first time that there had been any discussion between you and Mr. Skold regarding the delivery platform that later became known as Restoraderm; isn't that correct?

A. Pertaining to Collagenex, correct.

Q. Had it ever come up in any other context prior to September?

A. In discussion, yes.

DAY

Q. So it's your testimony that you had discussed the delivery platform of Mr. Skold's that later became known as the Collagenex project Restoraderm prior to September 2001?

A. I just can't remember. Sorry. I do not know the dates on that.

Q. But you'd agree with me that there certainly was no delivery platform technology Restoraderm in the year 2000?

A. I don't know. That's something you're going to have talk with Thomas about.

Q. To your knowledge, did any delivery platform technology known as Restoraderm exist in the year 2000?

A. I just told you that I'm not a hundred percent sure on the date. You can ask me a hundred different ways. I just can't remember the exact date.

Q. Going on in your snapshot bio, it reads as follows: "After building a sales force and developing several products utilizing the Restoraderm platform, he successfully negotiated and consummated the sale of Rx-Pharma to Collagenex Pharmaceuticals, Inc., assuming the

DAY

position of Vice President, Dermatology, Collagenex."

Did I read that correctly?

A. You did.

Q. Now, no products utilizing the Restoraderm platform were developed while you were at Rx-Pharma, were there, sir?

A. That's correct.

Q. So that's an incorrect statement in your bio?

A. Technically you're correct, I guess.

Q. I don't know about technically. In reality I'm correct, right? There were no Restoraderm products, no products utilizing the Restoraderm platform while you were at Rx Pharmaceutical, were there?

A. That's true.

MR. ROCHFORD: I have nothing further.

MR. JACKSON: You marked the Day declaration an exhibit number?

MR. ROCHFORD: I thought you did. I thought it was 148.

MR. JACKSON: Yeah, I did. I don't think I introduced it.

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MR. ROCHFORD: I don't think you've introduced anything.

REDIRECT EXAMINATION

BY MR. JACKSON:

Q. On redirect, if we look at Exhibit Skold T148, it sounds like from your testimony that if we would look on paragraph 4 --

A. What?

Q. Paragraph 4, that overlaps page 1 and 2, it sounds like you're no longer as confident that you saw Trial Exhibit T8 at the September 11 meeting in 2001.

MR. ROCHFORD: Objection. Mischaracterizes testimony.

A. T8 which is?

BY MR. JACKSON:

Q. In the book T8 which is the mode of action document.

A. I actually feel very confident that a document was there and seen and also that information was presented.

Q. If you would look at --

MR. ROCHFORD: Move to strike that response as nonresponsive and speculation.

JSD

DAY

BY MR. JACKSON ~~ROCHFORD~~:

Q. If we look at Galderma Exhibit I --

A. Got it.

Q. -- the last sentence before the "See you soon," could you read that?

A. "Enclosed please find the Restoraderm formula including two important names."

Q. What's a formula?

A. A formula is just the ingredient list of a particular product.

Q. It's not a product, is it?

A. The formula?

Q. Yeah.

A. Not by name it's not.

Q. In your quick bio from the Quinnova web page, Exhibit M, you did work with, in your bio, in the early 2000s a platform technology called Restoraderm?

A. I worked with Thomas on Restoraderm, yes.

MR. ROCHFORD: Object. Move to strike that answer and the question as form, foundation.

MR. JACKSON: I'm going to leave it at that, and I'm going to go off the record.

DAY

MR. ROCHFORD: Are you done?

MR. JACKSON: Yeah, I'm done.

MR. ROCHFORD: Give me one second. No questions at this time.

MR. JACKSON: So that closes us.

(Whereupon, at 3:44 p.m., the taking of the instant deposition ceased.)

STATE OF Pennsylvania

) :ss

COUNTY OF Bucks)

I, JEFFREY SCOTT DAY, the witness herein, having read the foregoing testimony of the pages of this deposition, do hereby certify it to be a true and correct transcript, subject to the corrections~~, if any, shown on the attached page~~ clearly marked above the original testimony set forth in the above pages and, for each insertion or substitution, initialed ("JSD") by me

JEFFREY SCOTT DAY

Sworn and subscribed to before me, this 20 day of December, 2013.

Notary Public

NOTARIAL SEAL
AMIE L TAYLOR
Notary Public
NEWTOWN BORO, BUCKS COUNTY
My Commission Expires Mar 22, 2015

1

2 COMMONWEALTH OF PENNSYLVANIA)

3 COUNTY OF DAUPHIN) SS:

4 C E R T I F I C A T E

5 I, Ann Medis, Registered Professional

6 Reporter, Certified Livenote Reporter and Notary

7 Public within and for the Commonwealth of

8 Pennsylvania, do hereby certify:

9 That JEFFREY SCOTT DAY, the witness

10 whose deposition is hereinbefore set forth, was

11 duly sworn by me and that such deposition is a

12 true record of the testimony given by such

13 witness.

14 I further certify the inspection,

15 reading and signing of said deposition were not

16 waived by counsel for the respective parties and

17 by the witness.

18 I further certify that I am not related

19 to any of the parties to this action by blood or

20 marriage and that I am in no way interested in the

21 outcome of this matter.

22 IN WITNESS WHEREOF, I have hereunto set

23 my hand this 26th day of November, 2013.

24

25 _____

Notary Public

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

E R R A T A

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WITNESS' SIGNATURE DATE

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204

Arthur Jackson

From: Thomas Sköld [skold@ponsus.se]
Sent: Wednesday, September 05, 2001 3:39 AM
To: Thomas Sköld
Subject: FW: Schedule

-----Original Message-----
From: Jeff Day [mailto:jday@myexcel.com]
Sent: Tuesday, September 04, 2001 10:10 PM
To: Thomas Sköld
Subject: Schedule

I have confirmed several meetings:

Monday: Arrival into Newark
Meeting with CollaGenex
Tuesday: AM meeting with Neutrogena / Ortho Derm
PM - Depart for Phoenix
Wednesday: 9:00 AM - 11:30 Medicis

I am still waiting for Allergan to confirm, and if we go there we will also meet with OMP (Direct to Physcian sales organization), located outside of Los Angeles.

Jeff Day

PENGAD 800-631-6989
EXHIBIT
Cancellation
92052897
Skold v Galderma

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EXHIBIT
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Galderma

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Arthur Jackson

208

From: Jeffrey Day [jday@collagenex.com]
Sent: Monday, February 18, 2002 7:59 AM
To: 'Thomas Sköld'
Subject: RE: In the States

Thomas,
I hope you are feeling better! I will contact you later this AM, most likely someone will pick you up around 11:30.
Follow up:

1. Terry Cobb - I wanted to make sure you got this message to call him this AM.
2. John Kinzell – Did you recieve this email as well. John was Pres of Optime (Liposomal Delivery Co.) and just left looking for new opportunities, he might be a great person to call for; money and US expertise. If you don't have his number, call me this AM!
3. Have you followed up with Bruce Simpson?

Jeff Day

-----Original Message-----
From: Thomas Sköld [mailto:skold@mbox312.swipnet.se]
Sent: Sunday, February 17, 2002 8:12 PM
To: Jeff Day
Subject: In the States

Good morning Jeff,

Wanted to let you know that I made it here to the Brick.

I have had a stomach disease since Friday so the flight could have been more pleasant. How ever, I am getting better so I should be alright by the time we meet for lunch.

Enclosed please find the RestoraDerm Formula including two important names.

See you soon.

Regards,
Thomas

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Arthur Jackson

216

From: Jeffrey Day [jday@collagenex.com]
Sent: Monday, March 10, 2003 10:58 AM
To: 'Thomas Sköld'
Subject: RE: Yesterdays meeting

Let me know the date the new product will be available.

-----Original Message-----
From: Thomas Sköld [mailto:thomas-skold@telia.com]
Sent: Monday, March 10, 2003 3:02 AM
To: 'Jeffrey Day'
Subject: RE: Yesterdays meeting

Good morning Jeff,

Sounds like a good challenge to present the technology for Ortho-Neutrogena. The fact that they called gives us some sort of advantage I think. It will be extremely interesting since it is my first time talking about it to a company.
Should we try to set the meeting up for 9:00 am? We could have breakfast at our hotel.

I will keep you posted about the progress with Investor. I am fairly sure that the management will listen to Thomas, which means we have to agree on the price and how it should be paid. Since Pathfinder wants to re-sign an agreement due to their acquisition of Sea & Ski we need to get as much info as possible to be able to make up projections that you will use as a base to value the company.

Regards,
Thomas

-----Original Message-----
From: Jeffrey Day [mailto:jday@collagenex.com]
Sent: Sunday, March 09, 2003 5:26 PM
To: 'Thomas Sköld'
Subject: RE: Yesterdays meeting

Let me know when I can get the new completed samples. I need to prepare for several meetings and studies.

Note: Ortho-Neutrogena called to set up a meeting at teh AAD! I will set up for Fri or Sat. Try to set up the meeting with Bernie on Sunday (except 12-2:30)

Jeff Day

-----Original Message-----
From: Thomas Sköld [mailto:thomas-skold@telia.com]
Sent: Friday, March 07, 2003 11:46 AM
To: 'Jeffrey Day'
Subject: RE: Yesterdays meeting

Hi Jeff,

Sure thing.
I will send him an E-mail requesting a phone call at his earliest convenience.

By the way I didn't proper congratulate you to what is about to see day light in 6½ month.
Congratulations to you and your family.

Have a great weekend.

Regards,
Thomas

Ps. We are starting the BPO developing work on Tuesday. On Tuesday evening we will fill the propellant in both clobetasol-aerosol products and vehicle-aerosol products

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EXHIBIT
Cancellation
92052897
Skold v. Galderma

PENGAD 800-631-6989
EXHIBIT
J
Galderma

SKOLD-001860

-----Original Message----
From: Jeffrey Day [mailto:jday@collagenex.com]
Sent: Friday, March 07, 2003 5:20 PM
To: 'Thomas Sköld'
Subject: RE: Yesterdays meeting

Thomas,
It was great seeing you!

Can you do me a favor, really important! Joe Fowler is starting up two studies (Pin Prick versus Elamax and Hand Dermatitis for new Restoraderm Foam), in fact the Pin Prick has started.
Can you call him over the weekend to discuss both of these studies to make sure you are okay with them, and you can get his initial feelings?

Lidocaine: Pin Prick versus Elamax (to simply see if we are as efficasious for pain relief and in on-setl)
Restoraderm: Enhanced Pro-Q study versus Aquaphor

Jeff Day

-----Original Message-----
From: Thomas Sköld [mailto:thomas-skold@telia.com]
Sent: Friday, March 07, 2003 4:55 AM
To: Jeff Day; Nancy Broadbent; Robert A. Ashley
Subject: Yesterdays meeting

Dear friends,

I'm finally home in Sweden after this quick but very productive trip.
I'm happy to say that Thomas really liked what he saw and he will be working in our favor to make this happen.
He also mentioned that he would be the one (from Investor) responsible for a CollaGenex investment based on a share swap but also for any future investment. He got a good impression of the company and very important also of you personal. Thank you all for a very good meeting.

Have a great weekend.

Regards,
Thomas

Arthur Jackson

From: JEFF DAY [jday60@comcast.net]
Sent: Tuesday, September 28, 2010 2:45 PM
To: Thomas Sköld
Subject: Thanks

~~SKOLD-001969~~

Thanks for a great call today. I look forward to getting the Restoraderm information as we prepare for the NIH grant... Good luck tomorrow with Lars and Mats. Put pressure on Lars to get this done on his side.
-I am working with attorneys; cap tables, stock purchase agreements, license agreement templates.... This should all be ready in 7-10 days.
Jeff

-----Original Message-----
From: Thomas Sk@ld <thomas-skold@telia.com>
Sent: Tuesday, September 28, 2010 8:43 AM
To: jday60@comcast.net
Subject: SV: SV: SV: Emailing: Cetaphil@ Brand Launches Cetaphil@ Restoraderm@ -- a new Line of Products to... -- FORT WORTH, Texas, Sept. 14 -PRNewswire- --.htm

Ok, will do!

Fr@n: jday60@comcast.net [mailto:jday60@comcast.net]
Skickat: den 28 september 2010 14:27
Till: Thomas Sk@ld
@mne: Re: SV: SV: Emailing: Cetaphil@ Brand Launches Cetaphil@ Restoraderm@ -- a new Line of Products to... -- FORT WORTH, Texas, Sept. 14 -PRNewswire- --.htm

Call my cell 9:15

Hotel Room 407-996-1000 room 508

use cell as back up 215-534-4549

EXHIBIT
Cancellation
92052897
Skold v. Galderma
PENGAD 800-631-6989

EXHIBIT
K
Galderma
PENGAD 800-631-6989

Arthur Jackson

From: [redacted]net
Sent: Friday, February 01, 2013 11:37 AM
To: Thomas Sköld
Subject: Possible Development Deal (Restoraderm)

~~254~~ 255

Thomas,
I am following up on the meeting I had last week with the prospective company; utilizing Restoraderm to develop a line of [redacted]n [redacted]e [redacted]s. I have sent them the Fowler study and a few items on the technology. They did ask for the Patent #, but I dont have it. Can you send me the Patent number so they can review?

Keep you posted.
[redacted]

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ABOUT
Quinnova Vision
Executive Management
Advisory Board
Our Technologies
News

Executive Management

JEFFREY S. DAY
(President & CEO, Founder)

Mr. Day is a commercial development specialist, whose primary focus and expertise is the dermatology marketplace. He has held strategic sales, marketing, and management positions with major pharmaceutical companies, including Allergan Pharmaceuticals and Ferndale Laboratories. In 2000, Mr. Day founded Rx-Pharma Pharmaceuticals, Inc., a specialty pharmaceutical business with two licensed products ("Pandel" and "Pro-Q") and a delivery platform technology, "Restoraderm." After building a sales force and developing several products utilizing the Restoraderm platform, he successfully negotiated and consummated the sale of Rx-Pharma to CollaGenex Pharmaceuticals, Inc., assuming the position of Vice President, Dermatology at CollaGenex. A key to Mr. Day's success in the pharmaceutical industry is his strong ongoing relationships with the members of the dermatology community and capitalizing on their experience and expertise during the development, launch, and sales of new products. These ongoing working relationships are the basis for building invaluable Advisory Boards, and Steering Committees and aid tremendously in the successful launch of unique prescription drug products.

KIMBERLY GLACKEN REIF
(Senior Director of Finance & Controller)

Ms. Reif has over 13 years of progressive experience in the life-sciences industry. She joined Quinnova Pharmaceuticals in 2007 prior to the launch of their first commercial product, at which time she established the company's financial infrastructure. Today she directs the activities of finance, corporate accounting, risk management and corporate affairs.

Prior to joining Quinnova Ms. Reif was the Controller of multiple early stage bio-technology companies. She also held financial positions in Fortune 500 wholesale and retail apparel companies. Ms. Reif holds an Executive MBA from Drexel University, a BS in Accounting from Longwood University, and is a Certified Public Accountant in Pennsylvania.

GLENN SCHLOEFFEL
(Vice President, Sales)

Mr. Schloeffel has more than 15 years of sales and sales management related experience in the medical and pharmaceutical industry. He began his career with Johnson & Johnson in their Diagnostic Hospital Division and progressed to a specialty sales position. He joined Ferndale Laboratories, a specialty pharmaceutical company in 1997 and advanced quickly into a Regional Sales Director. During his tenure with Ferndale Laboratories, Mr. Schloeffel was part of more than 7 new OTC and branded prescription drug product launches and built multiple sales teams as the company grew from 14 to 80 sales representatives across the country. He has expertise in building new sales forces and sales management teams and related operations, optimizing sales performance, as well as overseeing sales force training. Mr. Schloeffel is a Navy veteran with 21 years of service, retiring from the Naval Reserves in 2001.

STEVEN W. SMITH
(Vice President, Marketing)

With more than 20 years of sales, marketing, new products and business development experience, Mr. Smith has spent the past 17 years in specialty pharmaceutical and medical device markets. His expertise lies in building organizations, launching products, product portfolio and lifecycle management, and organizational leadership. While his experience in dermatology is extensive, Mr. Smith has also worked in podiatry, pediatrics, plastic surgery, orthopedics, and primary care markets. Beginning as a dermatology sales representative with Johnson & Johnson, Mr. Smith held several positions of increasing responsibility including sales leadership, marketing, and business development. In addition to his recent role as Regional Vice President at Stiefel, a GSK company, he has served in the capacities of Marketing Director and National Sales Director at two start-up specialty pharmaceutical companies, playing critical roles in the commercial launch of both organizations and several prescription pharmaceutical products.

JAMES A. HAVILAND
(Vice President, Quality Assurance, Regulatory Compliance & Regulator Affairs)

Mr. Haviland draws upon over 30 years of product development and commercial experience in the pharmaceutical and medical device industry. Jim has held executive leadership positions in Quality Assurance and Regulatory Affairs for both large and small pharma companies including Johnson & Johnson, Genta, and Barrier Therapeutics. His extensive experience in dermatology is complemented by work in oncology, wound care, and animal health products. He has been instrumental in establishing quality systems within R&D and commercial operations on an international basis, as well as providing regulatory leadership throughout the entire product life cycle.

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Galderma

Exhibit T 2
Skold v. Galderma
Cancellation No. 92052897

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~~CONFIDENTIAL~~

Public

Sköld v. Galderma
Cancellation No. __
Re Registration Nos. 2985751 and 3394514

CO-OPERATION, DEVELOPMENT AND LICENSING AGREEMENT

THIS AGREEMENT ("the Agreement") is made and effective the 11th day of February, 2002 by and between:-

1. COLLAGENEX PHARMACEUTICALS INC., a company organised and existing under the laws of the State of Delaware, United States of America and having its principal place of business at 41 University Drive, Newtown, Pennsylvania 18940, United States of America (hereinafter "CollaGenex");

   and

2. THOMAS SKOLD, a citizen and resident of Sweden of Bjorno Gard, S-761 41 Norrtalje, Sweden (hereinafter "Skold").

(A) WHEREAS Skold is developing, will continue to develop and has rights to the Technology (as defined hereafter) and the potential Products (as defined hereafter) resulting there from and desires to develop said technology in conjunction with CollaGenex in accordance with the terms and conditions hereof; and

(B) WHEREAS CollaGenex is desirous to participate in and control the development of the technology as defined herein and to obtain all rights thereto in accordance with the terms and conditions hereof;

NOW, THEREFORE, in consideration of the premises and mutual covenants and agreements hereinafter contained, the parties hereto, intending to be legally bound, hereby undertake and agree as follows:-

1. DEFINITIONS

1.1. The term "Affiliate" shall mean any entity in which the party has a direct or indirect equity interest or income interest ownership of at least fifty per cent (50%) or more, or any entity which, directly or indirectly, through one or more intermediaries, controls or is controlled by, or is under common control with the party.

1.2. The term "Confidential Information" shall mean any and all information or any portion thereof howsoever disclosed to or otherwise acquired or observed by either party or its employees, agents or Affiliates (each individually referred to as a "Recipient") either directly or indirectly from the other party, including, but not limited to, the technology and/or the products resulting there from as defined herein, enhancements, modifications, discoveries, claims, formulae, processes, apparatuses, research, development, patents, Confidential Information, Know-how as defined herein, trade secrets, knowledge, [redacted] designs, specifications, drawings, concepts, data, reports, methods, documentation, methodology, pricing, marketing and sales plans, customer lists, collaborators, salaries or business affairs and any other information or knowledge owned or developed or controlled by either party except for information which the Recipient can demonstrate:-

   (a) was at the time of disclosure to such Recipient part of the public domain or thereafter becomes part of the public domain through no act or omission by such Recipient; or

   (b) was lawfully in such Recipient's possession as evidenced by written records prior to disclosure by the disclosing party and without any obligation of confidentiality; or

(c) was lawfully received by such Recipient after disclosure from a third party without obligation of confidentiality and without violation by said third party of any obligation of confidentiality to another party; or

(d) was required to be disclosed by law or court order; or

(e) was independently developed by the Recipient without reference to or reliance on any of the Confidential Information.

1.3. The term [redacted]

1.4. The term [redacted] defined h[redacted] Affiliates. [redacted]

1.5. The term [redacted]

1.6. The term [redacted]

1.7. The term "Net Sales" shall mean [redacted]

1.8. The term [redacted]

1.9. The term [redacted]

1.10. The term [redacted]

1.11. The term "the Term" shall mean the term of this Agreement and any extension thereto as defined herein.

1.12. The term "the Territory" shall mean [redacted]

2. GRANT OF RIGHTS

2.1. (a) [redacted]

(b) [redacted]

2.2. [redacted]

2.3. [redacted]

records, ledgers, books and laboratory to verify Skold's compliance with the terms of this Agreement.

2.4. [redacted]

2.5. [redacted]

3. PAYMENTS FOR RIGHTS

3.1. [redacted]

a) [redacted]

i. [redacted]

ii. [redacted]

iii. [redacted]

[redacted]

c) [redacted]

d) [redacted]

e) [redacted]

f) [redacted]

g) [redacted]

h) [redacted]

i) [redacted]

3.2. [redacted]

3.3. [redacted]

(a) [redacted]

(b) [redacted]

(c) all payments by CollaGenex to Skold will be in United States dollars.

(d) [redacted]

(e) [redacted]

3.4. [redacted]

(a) [redacted]

(b) [redacted]

(i) [redacted]

(i) [redacted]

(ii) [redacted]

(iii)

(c) [redacted]

4. INTELLECTUAL PROPERTY

4.1. Patents

4.1.1. [redacted]

4.1.2. [redacted]

4.1.3. [redacted]

4.1.4. [redacted]

(a) [redacted]

(b)

(c)

[redacted]

4.2. Trade Marks

4.2.1. [redacted]

4.2.2.

4.2.3.

5. REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE PARTIES

5.1. CollaGenex represents and warrants to Skold that:-

(a) CollaGenex Pharmaceuticals, Inc. is a corporation duly organised, validly existing and in good standing under the laws of the State of Delaware, United States of America and that it has full corporate power and authority to conduct the business in which it is now engaged and as contemplated by this Agreement; and

(b) [redacted]

(c) [redacted]

(d) [redacted]

[redacted]

5.2. Skold hereby warrants and represents to CollaGenex that:-

(a) he is a citizen and resident of Sweden and in good standing in that country; and

(b) [redacted]

(c)

(d)

(e)

(f)

(g)

6. [redacted] INSURANCE

[redacted]

[redacted]

7. MARKETING AUTHORISATIONS

[redacted]

8. CONFIDENTIALITY

8.1. [redacted]

8.2. [redacted]

(a) [redacted]

(b)

8.3. The parties acknowledge and agree that the financial terms contained in this Agreement shall be considered as Confidential Information hereunder.

8.4. [redacted]

9. TERM AND TERMINATION AND REVERSION OF RIGHTS

9.1. [redacted]

9.2.

9.3.

(a)

(b)

9.4. [redacted]

9.5.

9.6. [redacted]

10. FORCE MAJEURE

10.1. [redacted]

10.2.

10.3.

10.4.

10.5.

11. OTHER PROVISIONS

11.1. [redacted]

11.2.

Any notice shall be deemed to have been given on day of delivery or receipt. Notices shall be delivered to the parties at the following addresses until a different address has been designated, by notice, to the other party:-

If to CollaGenex	CollaGenex Pharmaceuticals, Inc., 41 University Drive, Suite 200, Newtown, Pennsylvania 18940, United States of America. Telefax : (001) 215 579 8577 Attention : Senior Vice President
If to Skold	Thomas Skold, Bjorno Gard, S-761 41 Norrtalje, Sweden. Telefax : (0046) 176 22 4420

11.3. This Agreement is executed in two counterparts each one of which is deemed an original and which taken together shall constitute one and the same instrument.

11.4. [redacted]

11.5.

11.6.

11.7.

11.8.

11.9.

11.10.

11.11. Except where the context otherwise permits or requires, words denoting the singular include the plural and vice versa; wording denoting one gender include all genders; words denoting persons include firms and corporations and vice versa.

11.12. [redacted]

11.13. [redacted]

IN WITNESS WHEREOF, THE PARTIES HAVE CAUSED THIS AGREEMENT TO BE SIGNED BY THEIR DULY AUTHORISED REPRESENTATIVES THE DAY AND YEAR FIRST ABOVE WRITTEN :

COLLAGENEX PHARMACEUTICALS, INC.

by.....
Brian M. Gallagher Ph.D.,
Chairman, President & Chief Executive Officer

THOMAS SKOLD

.....

Exhibit T8
Skold v. Galderma
Cancellation No. 92052897

A theory of the "mode of action" concerning this new technology

5 November, 2001

The vehicle is designed in its choice of and share of lipids to resemble the normal lipid organisation of the stratum corneum. Thus the administered vehicle will easily penetrate the lipid bilayer of the skin and in doing so create a temporary and reversible state of enhanced atrophy among the bilayer.

The enhanced atrophy in itself should then give rise to a) enhanced energy levels, said energy could promote active transport of the to-be-carried substances into the skin, and/or b) naturally and reversibly occurring holes and disorganised patches in the lipid bilayer, through which the active substances could then pass more easily.

It is very well feasible that the temporary disarray in the lipid bilayer will temporarily break up the organised structure of the bilayer and create micelles of lipids with areas between them/ surrounding them through which lipophobic/hydrophilic substances and compositions can enter the stratum corneum.

As the content of the vehicle resembles the natural lipid build-up of the skin, the so introduced new lipids will after a short span of creative chaos easily blend in with the natural lipid building stones of the lipid bilayer and thus not permanently damage the skin.

Thomas Sköld

LipoDerm Lipoid Restoraderm Technology

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Public

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FLOW CHART WITH TRIGGER EVENTS
LipoDerm/RestoDerm/EpiLip Technology

Exhibit T 74
Skold v. Galderma
Cancellation No. 92052897

November 2001 – February 2002

1, Practical formulation work (base product = vehicle)

2, Patent formulation and registration

3, Start formulation work on one or two more products (OTC)

Total cost, $ [redacted]

February 2002 – June 2002

1, 3 month stability study on base formulation

2, Start stability work on the other potentially two products

Total cost includes in the above cost

March 2002 – June 2002

1, Lipid study (tape stripping human skin measuring lipid content after appl.)

2, Tewl study (trans epidermal water loss study)

Total cost approx. $ [redacted]

May 2002 – October 2002

1, Chronic hand dermatitis study with the vehicle

2, Study on the second OTC product

3, Study on the third OTC product

Total cost, $ [redacted]

[redacted]

1

September 2002 – December 2002

At this point I anticipate that the purchase of the rights is done and taken care of, which means that CollaGenex will now pay for actual costs for technical feasibility studies. Since most of the groundwork by this time is conducted, costs might be a bit lower that the $ 70.000 per technical feasibility study previous paid by CollaGenex.

I also anticipate that we will start at least one Rx technical feasibility study and perhaps one or two products for other companies. Potential partners and products could be Allergan with a lies product and Fujisawa with an immune modulator (instead of a steroid but with the same indication, namely Tacrolimus). Could also be with Taisho, or how the spell their name, and that would be one or more steroid products.

Total costs except for the work between Sept and Dec will be approx. $ 340.000 except for the $ [redacted]0 as a cash down payment for the technology.

Pretend that we will launch only two products during 2002, which will at least do 100.000 units each just to fill a tiny pipeline in a few chains. [redacted]0 [redacted] a price of $ [redacted] per unit and a marginal of approximately 70% in the beginning would create revenue of around $ [redacted] and a profit of $ [redacted]. So launching only two products in late 2002 will pay for the full cash investment during that same year.

Once again I would like to mention that I think that we should have our eyes open for the progress within Ponsus and potentially be ready to act if the opportunity occurs. If it would, I guess that it would not occur before March next year. My suggestion, if that would be a reality, would be that CollaGenex puts in $ [redacted] same time as I arrange, from some of the other owners, agreements to convert their shares with CollaGenex. CollaGenex would then become a majority owner of Ponsus. The benefits would be to gain access to a skilled organisation, four major partners and something to put on NASDAQ with a good profit after taking advantages of what fits CollaGenex at the time.

SKOLD v. Galderma, Cancellation No. 92052897, Exhibit Book p. 469

A Comparator Study of an Adjunctive Dermal Lipid Replacement Foam (Restoraderm™) in the Management of Refractory Hand Contact Dermatitis

Fowler JF, Perryman JH; University of Louisville, Louisville, Kentucky

ABSTRACT

Background: Dermatitis (irritant, allergic, or both) is the most common occupational skin disease. Although many "barrier creams" with high concentrations of petrolatum are sold, none have shown consistent effectiveness.

Restoraderm is composed of an exclusive non-alcohol, water-based formulation of lipids that mimics the body's own natural skin barrier system. It contains ceramides, cholesterol, palmitic acid and two biologic precursors, mevalonic acid and hydroxycholecalciferol. It does not contain petrolatum, and is a non-greasy formulation. Many occupational hand dermatitis patients find it difficult to work when using a product with petrolatum as its greasy residue can negatively affect grip and impair the protection of latex gloves.

Objective: To measure the effectiveness of Restoraderm in reducing or eliminating chronic hand contact dermatitis. The primary endpoints were mean percent change from baseline in the Clinician's Global Assessment Score and mean change in frequency of topical steroid use.

Methods: Thirty-one patients were randomized to receive either Restoraderm or a comparator (ointment or lotion) at the baseline visit. Each patient received Restoraderm for a 3 week period followed by comparator or vice versa. There was a two-week washout between study phases.

Results: Restoraderm proved to be effective in reducing or eliminating chronic hand contact dermatitis caused by occupational exposures. It was preferred by patients over the comparators. The non-greasy foam formulation of Restoraderm may contribute to compliance, ease of use, and patient satisfaction in patients with chronic hand dermatitis.

INTRODUCTION

Dermatologic conditions account for the majority of reported occupational illness in the United States. Dermatitis (irritant, allergic, or both) is the most common occupational skin disease. Although many "barrier creams" are sold none have shown consistent effectiveness in preventing occupational hand dermatitis. Some occupational hand dermatitis patients, such as beauticians, nurses, mechanics, and culinary workers, are not able to work when using a product with a high concentration of petrolatum to treat the condition. Petrolatum leaves a greasy residue which can negatively effect grip and render latex gloves ineffective in bacterial protection.

Restoraderm (CollaGenex Pharmaceuticals) is a dermal lipid replacement foam composed of an exclusive non-alcohol, water-based formulation of lipids that mimics the body's own natural skin barrier system. Restoraderm does not contain petrolatum. Restoraderm is a non-greasy formulation.

OBJECTIVE

The objective of this study is to measure the effectiveness of Restoraderm in reducing or eliminating irritant and/or allergic contact dermatitis of the hands in patients with chronic hand dermatitis caused by occupational exposures. The primary endpoints were mean percent change from baseline in the Clinician's Global Assessment Score and mean change in frequency of topical steroid use from baseline.

METHODS

Study Design: Prospectively randomized, cross-over design

Inclusion Criteria: Normal healthy males or females with chronic hand dermatitis verified by a score of 3 to 8 on the Clinician's Global Assessment Scale (Table 1).

Table 1. Clinician's Global Assessment Scale

0	Clear
1	Almost Clear: Minimal scattered erythema and/or scaling (<10% involved)
2	Minimal Dermatitis: Minimal scattered scaling and/or erythema (<50% involved)
3	Mild Dermatitis: Mild scattered scaling with mild to minimal erythema (<50%)
4	Mild to Moderate Dermatitis: Same as #3 but more extensive, ± a few papules or vesicles
5	Moderate Dermatitis: Moderate scaling with moderate erythema, some papules, vesicles, and/or early fissures (<50%)
6	Moderate Dermatitis: Same as #5 but more extensive
7	Moderate to Severe Dermatitis: Scaling and deeper fissures and/or confluent papules, vesicles and moderate to severe erythema (<50%)
8	Moderate to Severe Dermatitis: Same as #7 but more extensive
9	Severe Dermatitis: Severe scaling and fissures, papules, and/or vesicles with erythema (<50%)
10	Severe Dermatitis: Severe scaling and fissures and/or vesicles and crusting with erythema, covering most of the hand surface

Week 0: Thirty-one patients randomized to receive Restoraderm Foam or a comparator (Aquaphor Ointment or Lubriderm Lotion) for a 3-week period

Week 3 - Week 5: Washout period

Week 5: Patients on Restoraderm receive either of the two comparators and individuals on comparator receive Restoraderm for an additional 3-week period

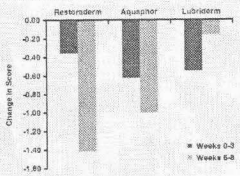
Week 8: Last observation

Investigator Evaluation: Occurred at weeks 0, 3, 5, and 8. Parameters evaluated on a scale of 0-5: erythema, scaling, cracking and fissuring, vesicles. Nail changes indicted as either present or absent. Location of activity noted. Global evaluation on a scale of 0-10 recorded.

RESULTS

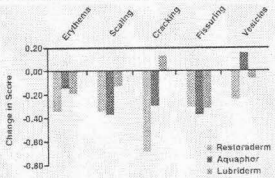
- Patients who received Restoraderm during the second treatment period exhibited a significant improvement in Global Assessment Score vs comparator groups (Figure 1).

Figure 1. Investigator Global Assessment Score – Change From Baseline



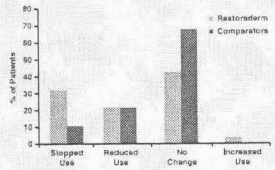
- Patients who received Restoraderm exhibited consistent improvement in all five categories and significant improvement in erythema and cracking vs comparator groups (Figure 2).

Figure 2. Skin Irritancy Scores – Cumulative Change From Baseline Following Both Treatment Periods



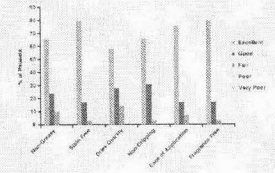
- Patients who received Restoraderm were 3-fold more likely to stop concomitant use of steroids vs comparator groups (Figure 3).

Figure 3. Steroid Usage – Cumulative Change From Baseline Following Both Treatment Periods



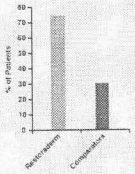
- Restoraderm received an excellent rating from at least 60% of patients in all characteristics (Figure 4).

Figure 4. Rating the Cosmetic Characteristics of Restoraderm



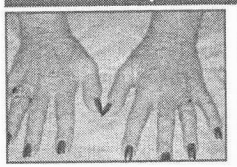
- Restoraderm was preferred by 71% of patients vs 29% for comparators (Figure 5).

Figure 5. Overall Patient Preference For Restoraderm and Comparators

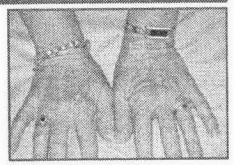


- Photos of one patient in the study are displayed in Figure 6.

Figure 6. Overall Patient Preference For Restoraderm and Comparators



Baseline



After 3 weeks of treatment with Restoraderm foam

CONCLUSIONS

- Restoraderm proved to be effective in reducing or eliminating chronic hand contact dermatitis caused by occupational exposures.
- Restoraderm users exhibited an overall improvement in Skin Irritancy & Global Assessment Scores.
- Restoraderm users were more likely to stop steroid usage than those receiving comparators.
- Restoraderm received excellent ratings in 5 major cosmetic categories from the majority of patients.
- The non-greasy foam formulation of Restoraderm may contribute to compliance, ease of use, and satisfaction in patients with chronic hand dermatitis.
- Restoraderm was preferred by patients by a margin greater than 2:1 vs comparators.

Disclosure or Support: Dr. Fowler has received consulting fees from CollaGenex Pharmaceuticals. This study was supported by an unrestricted grant from CollaGenex Pharmaceuticals, Inc.

Exhibit
T 143
Skold v. Galderma
Cancellation No. 92052897

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the Matter of Registration Nos. 2985751; and 3394514

Dated: August 16, 2005 & March 11, 2008, Respectively

Exhibit T 148
Skold v. Galderma
Cancellation No. 92052897

Thomas Sköld, Petitioner, v. Galderma Laboratories, Inc., Registrant	))))))))	Cancellation No. 92052897

DECLARATION OF JEFFREY S. DAY

I, Jeffrey S. Day, declare as follows:

1. I am over the age of eighteen (18) and am competent to make this declaration.
2. I have personal knowledge of the matters which are the subject of this declaration.
3. I have been employed in the pharmaceutical industry, with a particular focus on dermatology, since the late 1980s. Soon after 12 September 2001, Collagenex Pharmaceuticals, Inc. acquired the assets of a dermatology products company that I founded, Rx-Pharma Pharmaceuticals, Inc., and I became vice president, dermatology at Collagenex. remained in that position until about September 2004. Since 2005, I have been a founder and the CEO of Quinnova Pharmaceuticals, Inc. (originally named Princeton Pharmaceuticals), which since December 2010 has been an affiliate of Amneal Enterprises, LLC. Quinnova focuses on dermatology. I have, and in 2001 and 2002 I had, expertise is the dermatology marketplace.
4. I attended a meeting between Thomas Sköld and Collagenex at Collagenex's Newton, Pennsylvania location on or about 12 September 2001, the day after the

memorable day of 11 September 2001. In the meeting, Sköld presented the Restoraderm topical formulation technology, his services in developing specific Restoraderm formulations, and his availability to provide specific formulations within the technology, for example formulations carrying specific drugs. I recall seeing, in connection with that meeting, a document with content substantially the same, if not identical to, that attached hereto as Sköld Decl. Exhibit E (SKÖLD-000011, Mode of Action, associated herewith when I executed this Declaration), and which used the term "Restoraderm" to identify the topical formulation technology. Ex. E = Trial Ex. T8, p. 59

5. In November and December of 2001 Sköld transported samples of skin-care formulations labeled "Restoraderm" to Collagenex. Some of the samples were transported from Sweden by Sköld, and some were mailed to me from Sweden. Sköld further delivered such samples to me and Collagenex at the Caribean Derm. meeting in Puerto Rico, which meeting occurred on or about 18 January 2002..
6. Primary participants of the 12 September 2001 meeting were Sköld, Brian M. Gallagher, president of Collagenex, Robert A. Ashley, senior vice president, Commercial Development, of Collagenix, and myself. These officers remained together at Collagenex through at least about mid-year 2004.
7. The services and product Sköld was selling at the 12 September 2001 meeting were for formulation of new dermatology products in the new vehicle he invented. This type of service is to be sold on an exclusive or a well-defined exclusive field-of-use basis, or would be without substantial value. Accordingly, it is normal in the industry

that selling of the services is to a limited number of entities. It is normal that limited samples are provided (if at all) in selling presentations.

8. I am familiar with the process that lead to the 2002 Agreement between Sköld and Collagenex, and I am certain that Sköld would not have gained the 2002 contract with Collagenex if he had not, as he did, send samples to Collagenex in November and December 2001.

9. Collagenex's motive for changing of the 2002 Agreement to create the 2004 Agreement were financial motives such as outlined in the Sköld Decl. Exhibit D (Ashley Email dated 9 December 2003, associated herewith when I executed this Declaration). The substance of the agreement, other than the timing of payments, was intended to remain the same. Ex. D = Trial Ex. T12, p. 84

10. In the late 2001, early 2002 time frame, the number of financially credible dermatology development companies in the United States was limited. My recollection is that the following were the significant players:

    1, Johnson & Johnson, Neutrogena, Ortho Derm (related, treated as one);
    2, Novartis Pharmaceuticals;
    3, Medicis;
    4, Allergan;
    5, Galderma;
    6, Fujisawa;
    7. Ferndale Laboratories;
    8, Stiefel; and
    9. Connetics;

11. At the time, Collagenex was just emerging into the group of significantly credible dermatology development companies. At the outside, if I have forgotten any players,

the number of significantly credible dermatology development companies in the United States cannot have exceeded 15 in late 2001 or early 2002.

12. During the 12 September 2001 meeting, and during all of my subsequent work at Collagenex, the term "Restoraderm" was inextricably connected to the topical formulation technology being developed for Collagenex by Sköld. I am familiar with the negotiations between Sköld and Collagenex, and I am sure that there was no expectation by Collagenex that if it declined to further develop the Restoraderm technology that it could keep title to the Restoraderm trademark.

13. At I declare, under penalty of perjury under the laws of the United States of America and 28 U.S.C. § 1746, that the foregoing is true and correct, and that this declaration was executed this 15th day of May 2013 in New York, New York, United States of America.

Respectfully submitted,

Date: 5/15/13

By: _____
Jeffrey S. Day

Attachments:
Sköld Decl. Exhibit E, SKÖLD-000011, Mode of Action
Sköld Decl. Exhibit D, Ashley Email dated 9 December 2003, SKÖLD-000036

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the Matter of Registration Nos. 2985751; and 3394514

Dated: August 16, 2005 & March 11, 2008, Respectively

Thomas Sköld, Petitioner v. Galderma Laboratories, Inc., Registrant	))))))))	Cancellation No. 92052897

SKÖLD NOTICE OF FILING SKÖLD DEPOSITION

Pursuant to 37 CFR 1.123(h), Petitioner herewith files a true copy of the Deposition of Thomas Sköld, taken 13 November 2013. True copies of the exhibits introduced therewith are being filed under separate cover.

Respectfully submitted,

Date: July 2, 2014 By: /Arthur E. Jackson/

Arthur E. Jackson, Esq.
New Jersey Bar No. 00288-1995
ajackson@mtiplaw.com
MOSER TABOADA
1030 Broad Street, Suite 203
Shrewsbury, NJ 07702
(732) 935-7100
(732) 935-7122
Attorney for Petitioner

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Thomas Sköld, Petitioner, v. Galderma Laboratories, Inc., Registrant	))))))))	Cancellation No. 92052897

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Sköld Notice of Filing Sköld Deposition and the Public Version of the deposition referenced there in were sent by email on this 2nd day of July, 2014 to:

Jeff.Becker@haynesboone.com

And that the Trade Secret/Commercially Sensitive version of the deposition referenced therein were sent by mail to:

Jeff Becker, Esq.
Haynes and Boone, LLP
2323 Victory Avenue - Suite 700
Dallas, TX 75219

/Arthur E. Jackson/
Arthur E. Jackson

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the Matter of Registration Nos. 2985751; and 3394514

Dated: August 16, 2005 & March 11, 2008, Respectively

Thomas Skold, Petitioner, v. Galderma Laboratories, Inc., Registrant.	Cancellation No. 92052897

DEPOSITION OF THOMAS SKOLD, the Petitioner herein, called for examination, taken by and before Ann Medis, Registered Professional Reporter and Notary Public in and for the Commonwealth of Pennsylvania, at the Harrisburg Hilton, 1 North Second Street, Harrisburg, Pennsylvania 17101, on Wednesday, November 13, 2013, commencing at 8:05 a.m.

Job No. 32504

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APPEARANCES:

On behalf of Petitioner

MOSER TABOADA
1030 Broad Street, Suite 203
Shrewsbury, New Jersey 07702
732.917.6323
BY: ARTHUR E. JACKSON, ESQ.
ajackson@mtiplaw.com

On behalf of Registrant

HAYNES AND BOONE, LLP
30 Rockefeller Plaza, 26th Floor
New York, New York 10112
212.659.4984
BY: RICHARD D. ROCHFORD, ESQ.
richard.rochford@haynesboone.com

HAYNES AND BOONE, LLP
2323 Victory Avenue
Suite 700
Dallas, Texas 75219
214.651.5262
BY: LISA N. CONGLETON, ESQ.
lisa.congleton@haynesboone.com

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3 THOMAS SKOLD PAGE

4 DIRECT EXAMINATION BY MR. JACKSON 7
CROSS-EXAMINATION BY MR. ROCHFORD 71
5 REDIRECT EXAMINATION BY MR. JACKSON 144

6 * INDEX OF PETITIONER EXHIBITS *

NO.	DESCRIPTION	PAGE
7 Exhibit T1	Email chain, 8/18/04 from D. Glazer to T. Skold, subject: RE: Asset Purchase Agreement (page 56)	9, 56
9 Exhibit T2	Cooperation Development and Licensing Agreement (page 2)	9, 26
11 Exhibit T3	Asset Purchase Agreement, 8/19/04. (page 27)	9, 57
12 Exhibit T6	Consulting Agreement (page 51)	9, 65
13 Exhibit T7	Email chain, 9/4/01, from J. Fowler to T. Skold, subject: Re: Some info (page 57)	9, 34
15 Exhibit T8	A theory of the 'Mode of Action' concerning this new technology. SKOLD-000011 (page 59)	9, 17
17 Exhibit T9	"LipoDerm Restoraderm a vehicle technology for topical use" (page 60)	9, 35
19 Exhibit T11	License and Feasibility Study Agreement between EpiTan, Collagenex and Skold (page 63)	9, 66
21 Exhibit T12	Email, 12/9/03, from R. Ashley to F. Ruffo, et al., subject: Minor Amendments (page 59)	9, 68
23 Exhibit T15	Email, 7/19/04, from J. Day to T. Skold, subject: Ph Level (page 101)	9, 70 ~~69~~

Exhibits T4-5, T10 T13-14, T16-26, T28-57, T60, T62-68, T72, T75-124, T127-129, T131 T134-142 and T144

As described in Exhibit T145, introduced in the Deposition at p. 7, with these Exhibits discussed at p. 9

9,

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* INDEX OF PETITIONER EXHIBITS (Continued) *

NO.	DESCRIPTION	PAGE
Exhibit T27	Email chain, 7/15/09 from Q. Cassady to T. Skold, subject: RE: Restoraderm and October (page 129)	9, 34
Exhibit T58	Email, 6/2/09, from Q. Cassady to T. Skold, subject: Restoraderm Update (page 283)	9, 39
Exhibit T59	Email chain, 6/17/09, from Q. Cassady to T. Skold, subject: RE: Restoraderm (page 287)	9, 47
Exhibit T61	Thomas Skold/Restoraderm Technology (page 291)	9, 59
Exhibit T69	Email chain, 9/5/01, from T. Skold to J. Day, subject: RE: Products for Medcis (page 306)	9, 34
Exhibit T70	Email chain, 9/5/01, from T. Skold to J. Day, subject: RE: Products for Medicis (page 306)	9, 35
Exhibit T71	Email chain, 9/5/01, from J. Day to T. Skold, subject: Re: Schedule (page 309)	9, 34
Exhibit T73	Email chain, 9/6/01, from T. Skold to J. Day, subject: FW: USA biljetter som budas nu (page 311)	9, 34
Exhibit T74	Flowchart with Trigger Events (page 313)	9, 36
Exhibit T125	Companies Promoted to During the ~~Collagenex-Skolk~~ Collagenex-Skold, Galderma-Skold Collaboration (Collagenex-Tied Promotions (page 417)	9, 10
Exhibit T126	Skold recollection of companies for promotion of Restoraderm in period after collaborative relationship with Collagenex (page 418)	9, 50

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Exhibit T130	U.S. Patent No. 8,029,810 (page 424)	~~127~~ 9, 128
Exhibit T132	Recollections of Promotional Meetings (page 449)	~~12~~ 9,
Exhibit T133	Restoraderm Technology Projects and Products Worked on by Skold since 2001 (page 450)	~~12~~ 9,
Exhibit T143	"Comparator Study of an Adjunctive Dermal Lipid Replacement Foam (Restoraderm) in the Management of Refractory Hand Contact Dermatitis" (page 469)	~~145~~ 9, 146
Exhibit T145	Document Authentication	7
Exhibit T146	Declaration of Thomas Skold	~~13~~ 9,
Exhibit T147	Letter, 3/3/10, from T. Skold to Galderma enclosing Assignment of Patents GAL-000001 - 000002	~~58~~ 9,

- - - -

GALDERMA NO.	DESCRIPTION	PAGE
Exhibit A	Email chain, 1/13/08, from J. Willis to T. Skold, subject: RE: Derm delivery system SKOLD-000164 - 000166	102
Exhibit B	Letter, 12/12/01, from R. Ashley to T. Skold, Letter of Intent GAL-000005 - 000006	112
Exhibit C	Email chain, 5/1/02, from R. Ashley to T. Skold, subject: RE: Visit to ATS SKOLD-001850 - 001851	115
Exhibit D	Water-Based Topical Delivery System	124

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* INDEX OF GALDERMA EXHIBITS (Continued) *

GALDERMA NO.	DESCRIPTION	PAGE
Exhibit E	Asset Purchase and Product Development Agreement by and between Collagenex Pharmaceuticals Inc. and Thomas Skold, dated as of August 19, 2004	133
Exhibit F	Asset Purchase and Product Development Agreement by and between Collagenex Pharmaceuticals Inc. and Thomas Skold, dated as of _____ __, 2004 SKOLD-000241 - 000775	134
Exhibit G	Email, 2/1/13, from J. Day to T. Skold, subject: Possible Development Deal (Restoraderm) SKOLD-002042	142

- - - -

THOMAS SKOLD,

having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. JACKSON:

Q. Mr. Skold, would you please set forth your name, place of residence and age.

A. Thomas Skold, Bjorno Gard, Norrtalje, Sweden.

Q. Could you outline your current professional status?

A. Oh, gee. I've been retired since 2001 taking care of my home and doing research on initially on a basis or taking care of my technologies.

private

Q. I'm going to hand you what we've designated Exhibit T145, and also with this exhibit, we're going to attempt to authenticate these documents, these documents set forth in what we've labeled as Skold Deposition Exhibit 145.

You've had a chance to review both the exhibit in detail and the exhibit workbook; have you not?

A. Yes, I have.

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SKOLD

Q. If we go to Exhibit T145 and the second page, if you'd read the first paragraph.

A. Let me ask, since I'm not a deposition guy, is it appropriate to give a copy to the --

Q. What is T145?

MR. ROCHFORD: Describe on the record what you're doing.

MR. JACKSON: It's Mr. Skold authenticating all these documents in the workbook. We talked about authenticating from Galderma and did not have success. It's the Group A documents that I think Galderma could have authenticated. As the Group B documents, as I put them, that Mr. Skold probably could only authenticate. The next two are fairly self-authenticating. Basically we're seeking to authenticate. Since Mr. Skold pulled them all from his records, he can authenticate ~~then~~ them.

MR. ROCHFORD: I suspect we're going to have numerous objections, but I'll let you proceed with your foundation testimony.

BY MR. JACKSON:

Q. If you'd read the first paragraph.

A. "From review of the Skold deposition

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SKOLD

exhibit workbook, Skold will be asked to affirm as to each of the following Group A documents, which should be available to Registrant from its corporate files, and Group B documents that, A, it is a true copy of the documents, as found in Skold's physical files, and B, Skold stored the ~~Skold~~ document in the ordinary course of business, as Skold does with comparable important business documents."

Q. Do you affirm those statements are true?

A. Yes, I did.

Q. Could you read the second paragraph?

A. "Of the Group C documents, Skold will be asked to affirm that each is a recordation of Skold's recollection on the subject matter thereof."

Q. Do you affirm that statement?

A. I do.

Q. And then finally the third paragraph?

A. "The Group D documents comprise official records or publications. Of these Skold will be asked to affirm that the SEC 10-K statement and the press release match Skold's recollection."

Q. Do you affirm that?

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SKOLD

A. Yes, I do.

Q. If we go to page 9 of Exhibit T145, as to Exhibit T125, could you read the notes?

A. "These are Skold recollections of" --

Q. We should probably pull out Exhibit T125.

A. "These are Skold recollections of companies to whom Skold assisted in promoting the Restoraderm technology during the term of Skold's collaborative relationship with Collagenex. In parentheses are listed some of the people with whom Skold interacted. For companies marked with an X, corroborating emails can be found as listed above. All of Skold's discussions with these companies involve personnel from Collagenex."

Q. Do you affirm that statement?

A. Yes.

Q. Exhibit 126, have you looked over the text?

A. I do.

MR. ROCHFORD: Counsel, did you prepare Exhibit 145, or did the witness?

MR. JACKSON: Collaborative.

MR. ROCHFORD: The notes, language

SKOLD

you're reading, is that your language?

THE WITNESS: Yes.

A. You want me to read?

BY MR. JACKSON:

Q. Sure.

A. "This is a listing of companies Skold recollects promoting the Restoraderm technology to in the period after his collaborative relationship with Collagenex. Also listed are Skold recollections of some of the individuals from the companies with whom Skold interacted. Further listed is location of the company headquarters. Of the ex-U.S. companies, at least Ponsus Pharma, Basilea, Midas ~~Medicis~~ Pharma, Ferndale Lab, Merck-DE, and Q-Med had in the relevant timeframe a ~~of~~ substantial presence in the United States. Except for Leo, Merck-DE and Q-Med, with all the listed companies, discussions were in the U.S. or with someone in the U.S. For the companies listed in bold, corroborating emails can be found as listed above."

Q. Do you affirm that statement?

A. Correct, yes.

Q. If I didn't ask, do you affirm the

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SKOLD

statement in T125?

A. Absolutely.

Q. Proceeding as to the paragraph on Exhibit T132, page 49.

A. "This is a listing of Skold's recollections of meetings Skold undertook to promote Restoraderm technology. For the companies listed in bold, corroborating emails to/from the company or principals thereof can be found as listed above."

Q. You affirm?

A. I do.

Q. Finally, as to this Exhibit T133 on the next page, if you'd read the notes after you refreshed on the exhibit.

A. "This is a listing of drugs for which Skold recollects having supervised the formulation in Restoraderm technology, with an indication of stability for many."

Q. Do you affirm that statement?

A. I do.

Q. When and how did the project that came to be known as Restoraderm come into being?

A. Already during 2000 I decided to retire

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SKOLD

and --

Q. Retire from what position?

A. As the CEO.

MR. ROCHFORD: Note my objection to the form of the question. No foundation.

A. In 2000 I decided to resign and retire from my position as the CEO. I had one year to think about things because I wasn't supposed to end my position until the summer of 2001. And during the spring and the summer is when the idea to develop a technology based on things I learned long before. And it wasn't until August when I really got started on the project, 2001.

BY MR. JACKSON:

Q. When was the earliest that you manufactured a Restoraderm product?

MR. ROCHFORD: Object to form. Vague, foundation.

A. In its real form, I would say October of 2001.

BY MR. JACKSON:

Q. I have here an exhibit that we designated T146 with your declaration of May 2013.

A. Um-hum.

SKOLD

Q. Exhibit T146 is the same as the declaration that you signed in May 2013 except in an obvious manner, a correlation between the exhibits, two of the exhibits cited there and the exhibits as denoted for trial.

MR. ROCHFORD: I'm not following that explanation, counsel. What are you referring to?

MR. JACKSON: If you look, say, at the bottom of page 1 of the declaration where we refer to the Exhibit E that was filed with the declaration, Exhibit E equates to Trial Exhibit 8, and you'll see the same correlation on page 5 where Exhibit D corresponds to Trial Exhibit T12.

MR. ROCHFORD: Where is T8 in your 145 document?

MR. JACKSON: T8 is page 59.

MR. ROCHFORD: How about your appendix, where is T8 referenced? I see it. It's on page 6 under Group B. T8 is a theory document?

MR. JACKSON: Yes.

MR. ROCHFORD: I'm trying to understand your terminology. Then you're saying the document that was Exhibit D to his declaration, T146, is the same as your Trial Exhibit T12?

SKOLD

MR. JACKSON: Page 84 of the book. You'll see at the front of the book there's an index.

MR. ROCHFORD: And that's T12 on page 2 of T145. Okay.

BY MR. JACKSON:

Q. Mr. Skold, could you read paragraph 4 of your declaration.

A. "I first met with Collagenex Pharmaceuticals" --

MR. ROCHFORD: You've got to ask him a question. You can't just ask him to read prior testimony.

MR. JACKSON: All right.

BY MR. JACKSON:

Q. When did you first meet with Collagenex Pharmaceuticals?

A. September 12, 2001.

Q. Is there any context that helps you remember that date?

A. Well, of course, the September 11, 2001 event.

Q. At that meeting did you present the Restoraderm ~~technologies.~~ Technology?

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SKOLD

A. Yes, I did.

Q. Your services?

MR. ROCHFORD: Object to the form. Foundation.

BY MR. JACKSON:

Q. At that meeting did you present your services in developing specific formulations of the Restoraderm technology?

MR. ROCHFORD: Same objection. There was no Restoraderm technology at that time.

A. Yes, I did.

BY MR. JACKSON:

Q. Did you present your availability to provide and make specific formulations within the technology?

A. Yes, I did.

MR. ROCHFORD: Same objection.

MR. JACKSON: Noted.

BY MR. JACKSON:

Q. Did that include formulations with specific drugs?

A. Yes.

MR. ROCHFORD: Objection. Foundation.

SKOLD

BY MR. JACKSON:

Q. At that meeting did you show Collagenex a document substantially the same as, not identical to that found as Trial Exhibit T8?

A. Yes, I did.

Q. You remember that, but do you want to look it up at page 59.

A. I just looked it up.

MR. ROCHFORD: Same objection, move to strike.

BY MR. JACKSON:

Q. In that meeting, did that meeting lead to an agreement to work collaboratively with Collagenex?

A. Yes, it did.

MR. ROCHFORD: Objection. Foundation.

A. A Letter of Intent in December 2001 and an agreement, licensing agreement in February 2002.

BY MR. JACKSON:

Q. So during what period did you work collaboratively with Collagenex on the Restoraderm technology?

MR. ROCHFORD: Object to form.

SKOLD

A. Except for the meeting in September, I would say from the second week of October 2001 and actively collaborated until mid 2006.

BY MR. JACKSON:

Q. During that period in September, did you come to the United States in an effort to promote the Restoraderm technology?

MR. ROCHFORD: Object to form. There was no such technology?

A. Yes, I did, and there were meetings set up with three different companies.

BY MR. JACKSON:

Q. What companies were those?

A. J & J for the 11th, September 11, Medicis in Phoenix September 12. I imagine Allergan was the following day or one day after that.

Q. In Exhibit T8, do you use the phrase Restoraderm technology?

MR. ROCHFORD: What page is that again, counsel?

MR. JACKSON: Fifty-nine.

A. Yes, I do.

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SKOLD

BY MR. JACKSON:

Q. Did you use the phrase Restoraderm technology when you met with Collagenex?

A. Yes, I did.

MR. ROCHFORD: Object to form, foundation. Move to strike.

BY MR. JACKSON:

Q. Did you use the phrase Restoraderm technology when you met with J & J, Johnson & Johnson?

A. Yes, I did.

MR. ROCHFORD: Object to form, move to strike, both on form and foundation grounds and note my hearsay objection to the same colloquy relating to Collagenex.

BY MR. JACKSON:

Q. Did Johnson & Johnson have more than one of its internal entities at the meeting that you had with it?

A. Can you repeat that?

Q. Were there representatives of Neutrogena and Ortho and McNeil at the Johnson & Johnson meeting?

A. Yes. I believe there were probably 10

or 12 people in the room when we presented.

Q. Did the planned meeting with Medicis in Phoenix occur?

A. No, it did not.

Q. Was there a substitute meeting?

A. There was a phone call on September 12 instead of flying out on September 11 since there was no flights flying that evening.

Q. So there was a discussion with Allergan about the technology in that teleconference?

A. Medicis.

Q. Medicis?

MR. ROCHFORD: Objection. Leading, foundation, hearsay.

A. But that is correct.

BY MR. JACKSON:

Q. Did Medicis have before, in your words or in documents sent to it, the terminology Restoraderm technology?

MR. ROCHFORD: Objection. Compound, leading, foundation, hearsay.

A. Yes, they did.

BY MR. JACKSON:

Q. Did the meeting with Allergan come to

SKOLD

pass?

A. It never took place in 2001.

Q. And that was because?

A. First of all, we weren't able to fly out of the east coast at the date when we were supposed to meet, and due to the September 12 meeting with Collagenex, I decided to go to length to finalize an agreement with them rather than talking to other potential clients.

Q. With "them" being Collagenex?

A. Correct.

Q. Did you present, provide to Allergan in paper or in telephone discussion a phrase, Restoraderm technology?

MR. ROCHFORD: Object to form, compound also foundation, hearsay.

A. Yes.

BY MR. JACKSON:

Q. Did you in late 2001 transport samples of a topical formulation that you labeled Restoraderm to Collagenex?

A. Yes, I did during --

MR. ROCHFORD: Objection, foundation, form, hearsay.

SKOLD

A. November and December it was labeled Lipoderm Restoraderm technology to be accurate.

BY MR. JACKSON:

Q. Could you explain your conception of the trademark Lipoderm?

MR. ROCHFORD: Object to form, foundation.

A. Lipoderm was in mid 2001 supposed to become a brand for a specific product, not the technology, but for the SBR, the skin barrier repair, product. I offered both Restoraderm and Lipoderm to Collagenex. They wanted Restoraderm technology for the technology. But the Lipoderm they turned down in favor of a name they came up with themselves, which was ~~Cetaphil~~ Ceracel. 75

BY MR. JACKSON:

Q. Did you further deliver to Collagenex samples labeled Restoraderm at the Caribbean Derm meeting in January 2002?

A. Yes, I did.

MR. ROCHFORD: Object to form, foundation.

A. At this time they said Restoraderm and not -- Lipoderm was taken away from them.

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SKOLD

MR. ROCHFORD: What was that?

THE WITNESS: Lipoderm in the delivering of samples in 2001, the label said Lipoderm Restoraderm technology, so both the product name and the technology name, and in 2002 January it only said the Restoraderm technology.

MR. ROCHFORD: Object, move to strike. Foundation.

BY MR. JACKSON:

Q. Did that Caribbean Derm meeting in Puerto Rico, did that occur on or about January 18, 2002?

A. Yes, it did, and about a week after.

Q. That meeting, fair to say it proceeded for about a week?

A. Proceeded for a week, correct.

Q. The samples that you you've spoken of, the samples you delivered to Collagenex in 2001 and January 2002, were they formulated in Sweden?

A. Yes, they were. The 2001 formulations were made in my laboratory, and the 2002 were manufactured at something called the Institute of Surface Chemistry which is part of the Royal Institute of Technology in Stockholm, Sweden.

SKOLD

Q. Were they formulated under your direction?

A. Correct.

Q. Who assisted you?

A. Mats ~~Matt~~ Silvander, and we had two more assistants. I don't recall their names.

Q. When you met with Collagenex on or about September 12, 2001, who participated in the meeting?

A. Except Jeff Day who set up everything, it was Brian Gallagher and Rob Ashley, the two founders of Collagenex.

Q. Later in your interaction with Collagenex, did Jeff Day's role change?

A. One week prior to September 11 week, Jeff had interviewed for a position at Collagenex which he accepted or they both came to an agreement, at least, in the first week of October 2001. I don't know. I don't remember the date.

Q. What was his title later in 2001 and 2002?

A. It was VP of dermatology since Collagenex wasn't a dermatology company at that

PUBLIC

SKOLD

time. It was periodontal.

Q. Could you give us the background on your role in the dermatology community before these dates that we've been discussing?

A. I was the CEO of a company in Sweden called Ponsus Pharma from 1995, I believe, up until 2001, and most of our activities were actually taking place within the U.S.

Q. Did Ponsus deliver, develop dermatology products?

A. Yes, they did, and they do.

Q. In your relationship with Collagenex, there were a number of agreements. Could you outline those agreements?

A. Sorry. Please repeat.

Q. In your relationship with Collagenex, there were several agreements that defined your relationship. Could you --

A. Over the years.

Q. Yes. Could you outline some of those?

A. I think the first thing we had on a piece of paper was a Letter of Intent December 2001, licensing agreement in February 2002 ~~202~~, consulting agreement February 2002, an asset

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purchase agreement 2004, another consulting agreement in 2004. Did I have anything more? I signed the patents over to them as well, which we did in writing.

Q. Under the regime of the 2002 licensing agreement, you were paid in what range of monies for that relationship?

MR. ROCHFORD: Object to form. There's no 2002 agreement, no less a licensing agreement.

BY MR. JACKSON:

Q. Would that be the one you're referring to as the licensing agreement, Mr. Skold?

A. Correct.

Q. Would that be the agreement that is Exhibit T2 of the Exhibit book that recites it is a Cooperation, Development and Licensing Agreement?

A. Cooperation, Development and Licensing Agreement, correct.

Q. Under that agreement, were you paid monies by Collagenex?

A. Yes, both for consulting and some milestone ~~sum~~ payments.

Q. Did you under that agreement provide and

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supervise provision of the formulation that was labeled Restoraderm?

A. Yes, I did.

MR. ROCHFORD: Object to form, foundation.

BY MR. JACKSON:

Q. Do you recall roughly what kinds of monies you were paid under the 2002 licensing agreement that is Trial Exhibit T2?

A. Do we not have that as an exhibit somewhere, so I can feel more comfortable about numbers?

Q. I believe you can refresh your memory from it.

A. From this one?

MR. ROCHFORD: He can't refresh his memory unless you ask him to so it's clear on the record what he's doing.

BY MR. JACKSON:

Q. Are you refreshing your memory from Exhibit T146?

A. Yes, I am. But it feels like the numbers I'm reading right now are the total amount generated under both agreements, I think. That's

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confused

why I'm a little bit -- I would think from the 2002 licensing agreement it would be much less, but there's supposed to be -- I think I've seen an exhibit with the amounts.

Q. Let's move on rephrase the question. Under all of your agreements, do you recall how much you were paid in consulting fees?

A. Well, about [redacted], and that was according to the Andrew Powell response on February 12, 2008 where he also confirms the same amount.

Q. That would be the total amounts paid; would it not?

A. Yes.

Q. For consulting fees, could you refresh your memory at in Trial Exhibit T146 at line 3 of page 4?

MR. ROCHFORD: Please note my objection for this entire chain about payments to Mr. Skold under agreements from 2002 on relevance grounds.

A. Those seems to be accurate and correct.

BY MR. JACKSON:

Q. And the total amount of monies that were milestone or milestone-like payments in your

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relationship with Collagenex, that amount was?

A. About [redacted].

Q. Did, in answering that question, you refresh your memory by referring to Exhibit T146?

A. That is correct.

MR. ROCHFORD: Same objections.

BY MR. JACKSON:

Q. In your opinion, would you have formalized finalized the agreement with Collagenex if you had not delivered to Collagenex sample of the formulation?

A. I believe not.

MR. ROCHFORD: Objection. Foundation. Relevance.

BY MR. JACKSON:

Q. In the 2001, 2002 timeframe, were the companies that were -- the United States companies that were credible for developing dermatology products, was that a limited pool of companies?

MR. ROCHFORD: Objection, form.

A. I would say they were.

BY MR. JACKSON:

Q. About how many companies do you think that was in that timeframe?

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A. About ten or a little bit above.

MR. ROCHFORD: Also object on relevance and materiality grounds to this chain of questions about U.S. companies.

BY MR. JACKSON:

Q. Is the list that is found on page -- overlapping page 4 and 5 of Trial Exhibit T146, is that an accurate reflection of your memories of some of those ten or so companies?

A. Yes.

MR. ROCHFORD: Same objections. Form, lack of foundation. Lack of qualification to provide anything in the form of expert testimony. Lack of notice under the applicable rules of any attempt to offer expert testimony as well as relevance and materiality and competence.

BY MR. JACKSON:

Q. From your interactions with Collagenex, did you understand -- were you given the motive for changing the 2002 agreement to the 2004 agreement?

MR. ROCHFORD: Object to form.

A. It was brought up by Rob Ashley. I guess it is the T12 that I just looked up, isn't

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it? Page 84.

BY MR. JACKSON:

Q. It is page 84.

MR. ROCHFORD: Where are these page numbers you're referring to, counsel?

MR. JACKSON: There's a string.

MR. ROCHFORD: Oh, I see. The exhibit book string at the bottom?

MR. JACKSON: Yes.

A. So that -- page 84 would be a little bit what started it, and that was during 2003, and Collagenex struggled with how they would put money that they spent and they didn't want them to hit the P & L. And then came also -- what was that the name -- the Enron business in the U.S., Enron I think it was. So they wanted to restipulate the agreement so that they could -- for better bookkeeping management.

MR. ROCHFORD: Move to strike as nonresponsive, relevance, materiality, foundation.

BY MR. JACKSON:

Q. Could you --

MR. ROCHFORD: Competence.

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BY MR. JACKSON:

Q. Could you set forth what you meant by P & L?

A. That any money that would either go to me as a milestone, consultant fee or clinical study, at the first agreement would hit the P & L, the profit and loss, instead of -- I'm not sure what the terminology is here, but for us back home, it puts it on the balance sheet rather than the P & L.

MR. ROCHFORD: Same objections and to the previous extent I did not enter a hearsay objection.

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BY MR. JACKSON:

Q. Could you outline your September 11, 2001 meeting with J & J and how it differed from the planned meeting?

A. Well, Jeff Day and I came up. The meeting was supposed to start at 9:00 and go on, more or less, the entire day. And due to the event, I think we ended up just having a meeting for about two hours. Everyone was relieved from their work.

People went into the cafeteria and watched the television rather than doing anything else. J & J was kind enough to arrange a hotel at the Peddlers Inn that evening since I was supposed to stay in Phoenix that night.

Q. But you did have a meeting with J & J that day?

A. Yes, we did. That was ongoing also in 2002.

Q. That meeting was more abbreviated than the meeting that had been planned?

MR. ROCHFORD: Objection. Leading.

A. Very much so.

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BY MR. JACKSON:

Q. During the course of your relationship with Collagenex, where was the Restoraderm formulation formulated?

MR. ROCHFORD: Object to form.

A. 2001 at my lab. 2002 in the beginning, at the Institute of Surface Chemistry and further on also during 2002 at something called the Swedish Apoteket, a government-owned lab and pharmacy company, 12,000 employees.

BY MR. JACKSON:

Q. Were the formulations that you spoke of in Sweden conducted under your direction and supervision?

A. Yes, they were, at least up until 2005; 2004, 2005.

Q. I've previously asked you to review Trial Exhibit T7, paragraph 1 of the narrative text of the September 3 email there and that's at page 57, the narrative text, meaning the text after the heading and greeting; Exhibit T69 at page 306 and 7, the second volume.

A. You said 306 and 7?

Q. Yeah.

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MR. ROCHFORD: Counsel, it sounds like a compound question. Do you want to break it up?

BY MR. JACKSON:

Q. Still I'd like to in the interest of time do some consolidation. I'm going to put on the record the exhibits I'm speaking of. The exhibits we're speaking of and you previously viewed, Mr. Skold, T7, particularly the first paragraph of the narrative text, T69 in its entirety, Exhibit T27, paragraph 2 of the narrative text; T71, T73 the entire. If you recall these as you reviewed them, do these texts confirm your planned meetings with Johnson & Johnson, Medicis and Allergan?

A. That's basically what they do.

MR. ROCHFORD: Object to form, compound question, vague.

BY MR. JACKSON:

Q. Does Exhibit T70 at page 308 -- you already have it --

MR. ROCHFORD: These are all hearsay exhibits that are being referred to. Let me note that objection.

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BY MR. JACKSON:

Q. Does that exhibit indicate your effort to promote to Bi-Coastal ~~bicoastal~~ pharma?

MR. ROCHFORD: Objection. Foundation.

A. That's true.

BY MR. JACKSON:

Q. Were your promotion efforts successful with respect to Restoraderm?

A. Yes, they were.

MR. ROCHFORD: Object to form foundation.

BY MR. JACKSON:

Q. If we look at Exhibit T9 at page 60 of the book --

A. Yes.

Q. -- was that text or the substantial equivalent used in your meetings with Johnson & Johnson and Collagenex?

MR. ROCHFORD: Object to form, foundation, hearsay.

A. Yes.

MR. ROCHFORD: You're talking about T9 on page 60?

MR. JACKSON: Page 60, yes.

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A. Yes.

BY MR. JACKSON:

Q. Is the phrase "Restoraderm technology" used in Exhibit T9?

MR. ROCHFORD: Object to form.

A. That was -- yes, it is.

BY MR. JACKSON:

Q. Was that phrase used in your meetings with Johnson & Johnson and Collagenex?

A. Yes, they were.

MR. ROCHFORD: Object to form, foundation, hearsay.

BY MR. JACKSON:

Q. When and why was the flowchart that is Exhibit T74 put together? That is at page 313 and 314.

A. I believe this was produced by myself in late October, early November.

Q. Of what year?

A. 2001, to become a small preliminary business plan and budget for the same that I sent to Jeff Day and Collagenex.

Q. Does that exhibit use the phrase "Restoraderm technology"?

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A. Yes, it does.

Q. You've already explained to us what Lipoderm is. What is EpiLip?

A. Honestly I don't remember. Probably a product idea that we had at the time.

Q. In I forget which one, but in one of Exhibits T8, T9 or T74, you've used the phrase "Lipoid." Could you give us a context on what that means?

MR. ROCHFORD: Object to form foundation.

A. That I remember a little bit better. That was also a product idea for a surface anesthetical product, but it got dropped. And Collagenex wanted to go with ~~Lightra~~ Lytra instead.

Q. Is it your impression, based on your interaction with Collagenex, that at Collagenex the trademark Restoraderm was exclusively used to refer to your technology and the products thereof?

MR. ROCHFORD: Object to form, foundation, hearsay.

A. Yes, absolutely.

MR. ROCHFORD: Competence.

A. I think it's clear from everything and

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from everybody at Collagenex.

BY MR. JACKSON:

Q. Based on your interactions with Galderma, was it your impression early in the transition from Collagenex to Galderma the trademark Restoraderm referred to your products?

MR. ROCHFORD: Object to form, foundation, relevance, competence.

A. From March 2008, just a few number of days after it got official that Galderma acquired Collagenex, it was referred to as the Restoraderm technology up until late 2009 on each communication which is... obvious

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BY MR. JACKSON:

Q. During the period of -- if you look at Exhibit T24, which is at page 121, does Samira Shaimi use the term Restoraderm in a fashion that is clearly meant to identify your technology.

MR. ROCHFORD: Object, relevance.

A. Yes, on more than one occasion.

BY MR. JACKSON:

Q. Who was, to your recollection, Samira Shaimi?

A. She was a project manager at Galderma's

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R & D facility in France.

Q. If we look at Exhibit T58.

A. 283.

Q. Thank you. Does Quintin Cassady refer to the Restoraderm project?

MR. ROCHFORD: Objection, relevance. I note this is a document from 2009.

A. This is from June 2, 2009, correct, and subject "Restoraderm Update," and he talks about being more involved in the Restoraderm project.

BY MR. JACKSON:

Q. Does he speak of at the bottom of the page plans for Restoraderm?

A. Yeah, and he is also referring to the topical dermatology technology known as the Restoraderm.

MR. ROCHFORD: Same relevance objections.

BY MR. JACKSON:

Q. Who was Quintin Cassady in the June 2009 timeframe?

A. I believe he was the legal counsel.

Q. For?

A. Galderma.

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Q. If you look at Exhibit T125 at page 417, second volume -- we've already done this. My apologies.

A. Yes, we have.

Q. Let me ask in a different way. Does that confirm your recollections that you aided Collagenex in promoting the technology?

MR. ROCHFORD: Objection. Relevance by way of incorporated hearsay, foundation.

A. That's correct.

BY MR. JACKSON:

Q. In those promotions that Collagenex did, as you recall from your interactions with Collagenex and the parties being promoted to, were you presented by Collagenex as the inventor and technical resource on Restoraderm technology?

A. Yes, I was.

MR. ROCHFORD: Object to form, hearsay.

A. Yes, I was.

BY MR. JACKSON:

Q. Just for the record, I'm going to ask you to identify some of the people that you interacted with.

In the 2001, timeframe, what was Rob Ashley

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at Collagenex?

A. He was director of commercial development and the second man, second person in command after Brian Gallagher.

Q. In that 2001-2004 timeframe, who was Jeff Day at Collagenex?

A. VP of dermatology.

Q. Who was Greg Ford at Collagenex?

A. Greg Ford was business development. He started, I think, 2004.

Q. Was he head of business development?

A. Yes.

Q. Who was Andrew Powell at Collagenex?

A. Legal counsel at Collagenex.

Q. Chief legal counsel?

A. Yes.

Q. Who was Art Clapp at Galderma?

A. Business development.

MR. ROCHFORD: Objection, foundation.

BY MR. JACKSON:

Q. Who was Brad Zerler at Collagenex?

A. Research and development at Collagenex and a project manager.

Q. Could you provide us with your view of

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how your relationship with Collagenex proceeded over the years, 2002 to 2008?

MR. ROCHFORD: Objection, relevance, foundation.

A. We worked very closely for the first number of years, from 2002 up until 2005, 2006. But in 2004, 2005 there was a management shift, and after that, they had difficulties in deciding what they were about to do not just with Restoraderm technology, but also with other things.

We got, more or less, stonewalled from one period or one year to another where they shifted gears numerous times. And that restrained our relationship. Up until the point where I had to ask my attorney in New York to write a letter, I believe, in 2006, which is part of the exhibits, I don't remember, and to the point where we during 2007 discussed this on a frequent basis; ended up meeting Greg Ford, the business development manager in July, August 2007 in New York at the AAD meeting. We had dinner together, where I realized, reading between the lines, that Collagenex would probably not continue the

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development of Restoraderm technology.

BY MR. JACKSON:

Q. The AAD meeting, what's that stand for?

A. American Academy of Dermatology.

Q. Was there any particular language that Greg Ford used in that conversation that sent you the signal that you spoke of?

MR. ROCHFORD: Objection, hearsay, relevance.

A. I'm saying that I read between the lines, but it was fairly clear from what he told me. And we -- in the fall, I believe in October 2007, we had a phone conference where he more -- how do you say -- more officially told me that this was the case, that they would not pursue the Restoraderm technology. And I asked him then to get that in writing because I had the sense already six months before that there would not be anything going on with Restoraderm technology to the point where I in January 2008 wrote a termination letter to Collagenex and got a ~~respond~~ response letter in February 2008 where Andrew is stating how much, in spite of everything, they had actually added to the assets.

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BY MR. JACKSON:

Q. Andrew being?

A. Andrew Powell, legal counsel of Collagenex.

Q. Could you provide us a view of your relationship with Galderma from when it acquired Collagenex in 2002 until November 2009 when they terminated the agreement?

MR. ROCHFORD: Did you mean to say 2002 counsel?

MR. JACKSON: No. 2008.

MR. ROCHFORD: Can you start over so I can get a clean question.

BY MR. JACKSON:

Q. Could you provide us with your view of your relationship with Galderma from when it acquired Collagenex in 2008 until it sent you a termination letter for the 2004 agreement in November 2009?

MR. ROCHFORD: Objection, relevance, foundation.

A. I contacted Art Clapp, since I met him in 2004 when Galderma had an interest in Restoraderm technology. I did so in March, so

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just a few days or a few weeks after it got official they acquired Collagenex.

Art told me that, ~~fortunately~~ unfortunately, Restoraderm technology was not part of their due diligence when they acquired Collagenex. So they probably needed up to six months, three to six months to get back to me whether or not they would keep Restoraderm technology or return the asset back to me.

MR. ROCHFORD: In addition to previously noted objections, move to strike the response on the same grounds.

A. And in summer, after the summer, August, September, they organized the few days for me to go down to their R & D facility in France to work with a project group, head up by this Samira that we recently spoke about, to review.

And after that, after September 2008, it was only words and email that went back and forth. They couldn't make up their mind, according to the emails at least.

And in March 2009, I was told that Collagenex had -- Galderma, I should say, had decided internally to drop the Restoraderm technology but

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to keep the trademark.

MR. ROCHFORD: Just so it's clear, I move to strike the last response on grounds of hearsay, relevance, foundation, speculation.

A. I heard this in early March.

MR. ROCHFORD: You should probably wait for a question.

A. I thought I was still answering you about the relationship.

And so I got a little bit upset; however, I got an email two weeks later, one to two weeks later from Art Clapp stating that their legal division of Galderma was right now working on some kind of a contract proposal to me. But since nothing happened with that, I contacted Quintin.

MR. ROCHFORD: Move to strike the last unprovoked response on all the same grounds.

BY MR. JACKSON:

Q. If we look at Exhibit T59, at page 287, in your email of December 16, 2009, on page 288, you mention that --

MR. ROCHFORD: Counsel, I'm not sure you have the right date there. I want to make sure the record is clear. You're referring to

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December ~~2008~~ 2009. My page 288 refers to June 16.

BY MR. JACKSON:

Q. June 16, 2009.

In the last full paragraph of that, were you mentioning to Quintin Cassady the rumor that you had heard that Galderma was going to take the trademark alone and not the technology?

MR. ROCHFORD: Object to form, calls for speculation, document speaks for itself.

A. Yes. That is what I'm saying at the last part of this email.

BY MR. JACKSON:

Q. On page 287 of this exhibit book, on the second paragraph of the email from Quintin Cassady of June 17, 2009, is Mr. Cassady responding to that part of your email?

MR. ROCHFORD: Object to form. Calls for speculation. Also relevance objection to this line of questions.

A. He is responding, but in a strange manner where he is avoiding the subject.

BY MR. JACKSON:

Q. In a conversation that you had on the telephone with Mr. Cassady, did he expand on his

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answer?

MR. ROCHFORD: Objection. Calls for hearsay, relevance.

A. On the conference call he denied that that was the case.

MR. ROCHFORD: Move to strike as nonresponsive.

BY MR. JACKSON:

Q. If we look at Exhibit T132, page 449, the smaller of the exhibit books, is this your recollection? I think I'm repeating, but I'm going to do it just out of caution.

Is this your recollection of the meetings, the promotional meetings you had on Restoraderm technology during the period 2001 to 2010?

A. Yes, it is, at least the vast majority of it.

MR. ROCHFORD: Object to this on relevance grounds, foundation, form, materiality. And I think it also incorporates a hearsay objection.

BY MR. JACKSON:

Q. At these meetings referenced in Exhibit T132, did you consistently use the term

Restoraderm to refer to your technology and the products made from it?

A. Absolutely.

MR. ROCHFORD: Object to form, foundation, relevance hearsay.

BY MR. JACKSON:

Q. Among the scientific meetings referenced in Exhibit T132, were many of the major opinion leaders in dermatology well represented there?

MR. ROCHFORD: Object to form, calls for expert testimony, and there's been no foundation laid. Calls for speculation, calls for expert testimony.

A. Majority of them were.

MR. ROCHFORD: And relevance.

BY MR. JACKSON:

Q. At the scientific meetings, did you discuss in those Restoraderm technology, identifying it as Restoraderm technology with numerous such leading opinion leaders in dermatology?

MR. ROCHFORD: I'll have the same objections, just the same.

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BY MR. JACKSON:

Q. Go ahead.

A. Correct.

Q. In Exhibit T132 the meetings with [redacted], these meetings that you did promoting Restoraderm technology independent of Collagenex or Galderma, correct?

A. That is correct.

MR. ROCHFORD: Object to form, foundation, hearsay, relevance, competency, materiality.

BY MR. JACKSON:

Q. At page 418, Exhibit T126 --

A. What page was it again?

Q. 418. Does this listing represent companies you remember making promotional efforts to in the 2007-2013 timeframe?

MR. ROCHFORD: Objection, relevance, foundation, form.

A. Yes, it does.

BY MR. JACKSON:

Q. From your interactions with these

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companies, can you say that the headquarters of the companies listed in Exhibit T126 are correct?

MR. ROCHFORD: Objection. Relevance.

A. Yes, I can.

BY MR. JACKSON:

Q. And Exhibit T133, which unfortunately I did not correlate to a page -- at page 450, does that listing represent formulations of Restoraderm that you have prepared or supervised the preparation of in the time period of 2001 till the current day?

MR. ROCHFORD: Objection, relevance, form, speculation. There's no details here.

A. In reading it, it is correct, because it states products developed in collaboration with Collagenex, products developed independently of Collagenex, which is also correct. Products developed independently by myself is also correct. The launchable products is also correct.

BY MR. JACKSON:

Q. Could you tell us of your more recent efforts to promote Restoraderm technology?

MR. ROCHFORD: Objection, relevance, form, foundation.

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A. With the fact that I did not get, as I refer to it, the IP, the patents back in ~~in~~ the beginning of 2010 and the entire portfolio was a mess, I had to focus for at least six months to get those in shape. And not until May of this year, 2013, the last patent out of the patent portfolio got granted, which made life a little bit easier for me to collaborate with others.

[redacted]

BY MR. JACKSON:

Q. [redacted] company?

A. [redacted]

Q. There's further promotional efforts that you want to discuss, outline?

A. [redacted]--

MR. ROCHFORD: Same objections.

A. [redacted]

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BY MR. JACKSON:

Q. [redacted]

A. [redacted]

MR. ROCHFORD: Same relevance objection.

MR. JACKSON: That's trade secret, by the way.

BY MR. JACKSON:

Q. In your efforts, more recent efforts that you spoke of, you referred to the technology as Restoraderm?

A. I did and so did they.

MR. ROCHFORD: Object, move to strike as hearsay, relevance.

BY MR. JACKSON:

Q. Are you supervising the formulation of Restoraderm product for these recent efforts?

MR. ROCHFORD: Object to form.

A. Yes, I am.

BY MR. JACKSON:

Q. Where is the formulation being conducted?

A. Predevelopments in my laboratory. Stability and clinical batches are manufactured ~~is~~ at

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the Swedish Apoteket, same company as I was working with with Collagenex.

MR. ROCHFORD: Also move to strike on relevance grounds this entire chain.

BY MR. JACKSON:

Q. [redacted]

A. Yes.

MR. ROCHFORD: Object to form, relevance, speculation, authentication.

BY MR. JACKSON:

Q. [redacted]

A. [redacted]

Q. In your promotional efforts for Restoraderm after your relationship with Collagenex ceased, ceased to be cooperative in roughly 2006, were there obstacles to your promotional efforts?

MR. ROCHFORD: Object to form, foundation, relevance.

A. Yes, there were.

BY MR. JACKSON:

Q. Could you outline some of those

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obstacles?

MR. ROCHFORD: Same objections.

A. Major ones were that they weren't able to make up their mind trying to be within the agreement of 2004, which was why they kept shifting gears every six months.

BY MR. JACKSON:

Q. After you received the patents back from Galderma, were there still obstacles to your promotional efforts?

MR. ROCHFORD: Same objections.

A. Yes. As I mentioned before, the patent portfolio was not functionable for various reasons, and so I had first to take care of that. And the credibility out in the community wasn't really there in the early days. Neither I went out and declared the termination, nor did Galderma.

So there were very, very few people that did have any knowledge, which was very confusing. And also companies didn't feel comfortable without knowing the details of the relationship between myself and Galderma, still to this day actually.

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BY MR. JACKSON:

Q. If we look at Exhibit T1 at page 1 of the exhibit book, if we look at Mr. David Glazer's email of August 17, 2004 and your response of August 18, is there something more that we should know about that discussion between you and David Glazer?

MR. ROCHFORD: Object to the form of this. Let me take a minute to read what you're talking about.

I object to any hearsay response.

A. I probably should say that David was not part of the group that worked on this, the agreement from the beginning. Her name was Karen, and Karen was on vacation this week. So David had to step in to do the schedules.

So David wrote to me on August 17 asking if I had any more patents that I wanted to include in the asset or trademarks, that we should include in the trademark. He's also making a comment where he's saying also Collagenex has informed me that it already owns the Restoraderm trademark.

And due to this email, we had a conference call on the 18th to discuss, and there were no

more patents which we included in the asset. There were no more trademarks to include in the asset. And David confirmed that the trademark was part of the asset.

Before I responded on the email back to David, I also consulted my attorney in Sweden, and after he agreed that both parties acknowledged that it was part of the asset, that I could say that we are in agreement.

MR. ROCHFORD: I'm going to move to strike that all as hearsay and as unintelligible.

BY MR. JACKSON:

Q. Irrespective of David saying in the teleconference or Nancy saying in the teleconference, did you take the agreement set forth the Restoraderm trademark was part of the asset defined in that agreement?

MR. ROCHFORD: I'm going to object to hearsay, object to form, object to foundation. It's all the terminology that's being used here without definition.

A. Yes, and, therefore, I confirmed that we are in agreement.

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BY MR. JACKSON:

Q. If we look at Exhibit T147 which isn't in the book, I'm about to hand out, could you explain this exhibit to us, Mr. Skold?

A. It is from February 22, 2010, and it's a document showing that Galderma/Collagenex are assigning over the patents to me.

Q. Those are the patents that --

A. The patents application. Sorry.

Q. That relate to Restoraderm?

A. The Restoraderm technology, correct.

Q. And the letter from you to Galderma dated March 3, 2010?

A. "Dear Nora, enclosed please find a signed version of our assignments of patents. I hope with this that all matters relating to IP are settled."

Q. Could you explain your interpretation of the term IP as you understood it, as you were using it at the time?

MR. ROCHFORD: I'm going to object, calls for speculation, the document speaks for itself.

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BY MR. JACKSON:

Q. Continue, Mr. Skold.

A. To me IP was patent-related items, as I also saw that terminology in both agreements, as separate from trademarks and know-how.

Q. Both agreements, you mean the 2002 and 2004 agreements?

A. Yes.

Q. We'll refresh our memory. Bear with me. If we will look at Exhibit T3 at page 27, look at Section 1.20.

A. Um-hum.

Q. Could you read that for us, Mr. Skold?

A. "'Restoraderm intellectual property' means all Restoraderm patents rights, Restoraderm know-how and any rights in any jurisdiction to limit the use or disclosure thereof, rights to sue and recover damages or obtain injunctive ~~adjunctive~~ relief for past and future infringements, dilution, misappropriation, violation or breach thereof."

Q. If we look at -- could we look at Exhibit T61 on page 291 of the exhibit book. Did you send page 291, 292, did you send this listing to Galderma?

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MR. ROCHFORD: I'm going to object to form, foundation.

A. Page 291 and 292, yes, I did, shortly after the termination on November -- which was November 27th of 2009. I did put together the Restoraderm technology asset and what was supposed to be reverted back to me.

MR. ROCHFORD: Note, in addition, my relevance objection to the entire line around the Galderma issues.

BY MR. JACKSON:

Q. Does Exhibit T61 separately list patents and trademarks?

MR. ROCHFORD: Same objections.

A. Yes, and it lays out in regards to development studies and published data. That also can be related to our contract.

BY MR. JACKSON:

Q. Exhibit T58 at page 283.

MR. ROCHFORD: What page, counsel?

MR. JACKSON: 283, larger book.

BY MR. JACKSON:

Q. And it's paragraphed numbered 1 and it's section numbered 1 of three types of studies; is

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that correct?

MR. ROCHFORD: Objection, relevance.

A. "Galderma is currently conducting the following studies using its own protocols: Technical manufacturing feasibility study, stability studies, and skin barrier recovery tests."

BY MR. JACKSON:

Q. When you received returns from Galderma pursuant to Section 8.5 of the 2004 agreement, did you receive any results of these studies?

MR. ROCHFORD: Same objection, relevance.

A. No. I did not receive anything that had been ongoing from 2008 up until November 27, 2009 except for the emails between myself and the R & D facility in France.

BY MR. JACKSON:

Q. If we look at Exhibit T3, page 41, the portion at page 41 in the exhibit book and we look at subsection (b)(iii), could you read that for us, Mr. Skold.

A. "Collagenex shall transfer to Skold the purchased assets and additional records relating

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to such terminated products. Such transfer shall be accompanied by documentation, data and information related to the purchased assets that can be transferred by Collagenex."

Q. If we look at Exhibit T3, Section 1.3 which is found at page 24 of the exhibit book...

MR. ROCHFORD: Move to strike the last question and answer on relevance grounds.

What page, counsel?

MR. JACKSON: Page 24.

BY MR. JACKSON:

Q. Could you read Section 1.3?

A. "'Additional records' means any and all records or documentation in whatever form pertaining to the development, marketing or sales of a product and originating from or generated by Collagenex under this agreement such as, but not limited to, batch protocols, sterility protocols, clinical trial documentation, specification over raw materials and marketing materials."

MR. ROCHFORD: Same objection, relevance.

BY MR. JACKSON:

Q. Based on these requirements of the

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contract and your not receiving any data from the alleged studies, what was your conclusion?

MR. ROCHFORD: Same objection.

A. That it was difficult to believe that anything had been going on.

MR. JACKSON: Much to my amazement, I am partly done. I might want to organize for a half hour to see if I'm done.

MR. ROCHFORD: Why don't we take a break and you can keep the record open. We'll come back at 10:15.

MR. JACKSON: That sounds like a good plan.

MR. ROCHFORD: We're off the record.

(There was a recess in the proceedings from 9:44 to 10:27 a.m.)

BY MR. JACKSON:

Q. Mr. Skold, during your last year as CEO of ~~Pondus~~ Ponsus in 2001, approximately what were the gross sales for ~~Pondus~~ Ponsus?

MR. ROCHFORD: Objection, relevance.

A. Not much. I would imagine 2, maybe $3 million.

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BY MR. JACKSON:

Q. If we would turn to Exhibit T3 and particularly the part at page 27 of the exhibit book, could you read Sections 1.21 and 1.23?

A. In a row?

Q. Yes.

MR. ROCHFORD: I'll object. Relevance, document speaks for itself, foundation.

A. "1.21, 'Restoraderm Know-how' means any and all know-how owned or controlled by Skold or its affiliates as of the effective date relating to the Restoraderm technology.

1.23, 'Restoraderm Technology' means the topical drug delivery technology developed by Skold and covered by the patent applications recited in Schedule 1.22. For the avoidance of doubt, technology for oral, nasal or intravenous use shall not, when used in this agreement, be embraced by the term topical." 73

BY MR. JACKSON:

Q. Does this language confirm your impression that you gained in discussions with Collagenex that the term Restoraderm equates to the technology?

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A. Always.

MR. ROCHFORD: Object to form, calls for speculation, hearsay.

A. Always.

BY MR. JACKSON:

Q. If we turn to Exhibit T6, page 51, if we look at the paragraph numbered 1, could you read the second full sentence thereof beginning "Restoraderm technology..."?

A. "...means the topical drug delivery technology developed by Skold and covered in provisional application filed on March 13, 2002."

MR. ROCHFORD: Objection, speaks for itself, relevance, foundation.

BY MR. JACKSON:

Q. That's sufficient reading, Mr. Skold.

Does that language confirm your impression from your discussions with Collagenex that the term Restoraderm was exclusively used to refer to the technology?

MR. ROCHFORD: Object to form, hearsay relevance, foundation.

A. Yes, it does.

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BY MR. JACKSON:

Q. Thank you.

If we turn to Exhibit T11 at page 63 of the exhibit book, if you could read Section C of the background that is -- could you explain what that document is first?

A. Bear with me. Yep. This is the second page on an agreement for License and Feasibility Study Agreement between three parties, EpiTan Limited, Australia; Collagenex Pharmaceuticals, Pennsylvania; Thomas Skold in Sweden.

Q. If you could read Section C of the background at page 63.

MR. ROCHFORD: I'll object. The document speaks for itself, relevance, foundation.

A. "On 12 February 2002 Skold and Collagenex, a specialty pharmaceuticals company, entered into a cooperation, development and licensing agreement (the Skold license agreement as defined in this agreement) under which, amongst other things, Skold agreed to grant an exclusive worldwide license to Collagenex for certain Restoraderm (as defined in this agreement)."

Q. Does that language confirm your view

based on your discussions with Collagenex that the term Restoraderm was exclusively used to refer to your technology?

MR. ROCHFORD: Objection, relevance, calls for a hearsay response, foundation.

A. Yes, it does.

BY MR. JACKSON:

Q. If we would turn to page 66 also in the same exhibit, T11, if you would Section 1.1 which starts earlier, if you would read the definition of Restoraderm?

MR. ROCHFORD: Same objections.

A. "Restoraderm means the water-based lipid topical drug delivery and skin barrier restoration technology (lipoid technology) that is the subject of the Skold licensing agreement."

BY MR. JACKSON:

Q. Does this language confirm your view based on your discussions with Collagenex that the term Restoraderm was exclusively used to refer to your topical technology?

MR. ROCHFORD: Same relevance objections. The document speaks for itself, calls for a hearsay response.

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A. Yes, it does.

BY MR. JACKSON:

Q. If we would look at Exhibit T12 at page 84, if you would read from the first line to the second line of the bulk text of the email. First explain what that document is, Mr. Skold.

A. This document was brought up recently since it is an email from Rob Ashley, Collagenex, referring to that we have to rework the agreement.

Q. Did someone at Collagenex forward this email to you soon after its e-mailing?

A. Yes.

Q. Could you read from line 1 of the bulk of that through line 2, the text that begins "Skold is the inventer..."

A. Not from here.

Q. The body of the email after "Gentlemen," the first line.

MR. ROCHFORD: I'm going to object on relevance grounds.

A. "Appended is the Skold agreement with a couple of additional minor amendments. Paul and Colin, Skold is the inventor and developer of Restoraderm."

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BY MR. JACKSON:

Q. Does this document confirm your view that you formed from your discussions with Collagenex that the term Restoraderm was exclusively used to refer to your topical dermal technology?

MR. ROCHFORD: Same objections, form, foundation, relevance, hearsay.

A. Among other things, yes.

BY MR. JACKSON:

Q. Could you look at Exhibit T15 at page 101. Could you explain what this document is?

A. This is an email from Jeff Day, the VP of dermatology at Collagenex, sent July 19, '04 to me where he is asking what the pH level range is for Restoraderm.

Q. Is that fairly much a direct quote? Does he say, "What is the pH level for Restoraderm?"

A. Correct.

MR. ROCHFORD: Objection, relevance, the document speaks for itself.

BY MR. JACKSON:

Q. Does this document confirm your view

based on your discussions with Collagenex that the term Restoraderm was exclusively used by Collagenex to refer to your topical dermal technology?

MR. ROCHFORD: Same objections, relevance, foundation, hearsay.

A. Yes.

BY MR. JACKSON:

Q. I think that's a sampling of that. That's enough.

MR. JACKSON: So we're done for now.

MR. ROCHFORD: Off the record.

(There was a recess in the proceedings from 10:38 a.m. to 12:43 p.m.)

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MR. ROCHFORD: Back on the record, counsel?

MR. JACKSON: Good with us.

MR. ROCHFORD: On the record. Let me initially note that due to the nature of this proceeding, we will be through cross-examination making offers of proof relative to some evidence that we have objected to since objections are not ruled on until later on in the proceeding. We do not waive any objections by virtue of taking these matters up during cross-examination or otherwise. I just wanted to be clear.

CROSS-EXAMINATION

BY MR. ROCHFORD:

Q. Good afternoon, Mr. Skold. I introduced myself earlier. I'm Rich Rochford. I'm going to ask you some questions on behalf of Galderma.

Jeff Day is a close friend of yours, correct?

A. And has been so since I think '97; how close you can be with living that far away, but you would probably say that we are fairly close friends, not that I know he's friends, so not that close.

Q. But in terms of the personal

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relationship between yourself and Mr. Day, it's a close one?

A. I would probably say so. I don't really know the terminology of good friends in that perspective.

Q. You consider him a good friend?

A. I do.

Q. For what that's worth?

A. Yeah.

Q. You said you've known him since '97?

A. I believe it's '97 when he was working up at Ferndale.

Q. How did you come to meet him?

A. Because we were working with Ferndale.

Q. When you say "we" --

A. Ponsus Pharm in '97, and I think I met him at one of the sales conferences or something like that.

Q. Did you end up doing business with Mr. Day in the period before you left Ponsus U.S. in 2001?

A. Ponsus, they were doing some businesses, not developments or anything like that. He was taking care of some of the Ferndale inventories to

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sell. You could say there was a relationship between Day or at least the company and Ponsus, but came in from the Ferndale relationship that he had.

Q. The products that Ponsus was making during that time were aerosol ~~formulated~~ formulations? TS

A. They were exclusively aerosol.

Q. How did Mr. Day end up at Collagenex?

A. I don't know.

Q. You know that he interviewed there in early September of 2001?

A. I know that he was interviewing about a week prior to September 11, and I know that because he told me so driving me to my hotel at Peddlers Inn on the evening of September 11. At that time no cell phone worked. Everything was dead. And I wanted to be somewhere where I could use the phone. And then he told me we could perhaps use the Collagenex phone. He said " I know the people. I was up there interviewing about a week ago" TS TS

Q. Mr. Day was responsible for setting up the meeting you had on September 12, 2001 at Collagenex; isn't that correct?

A. I believe he called -- I'm not sure --

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it could have been Rob Ashley, I imagine it would be Rob Ashley to ask if we could use their conference room. The following meeting at the same time wasn't planned.

Q. I had understood that during the first week of September 2001, Mr. Day set up meetings for you in the United States. Let's start there. Is that correct, did he perform that function?

A. Yes.

Q. Why did he do that?

A. You'll have to ask him. I would say that it was partly on a personal basis, and I imagine he was hoping that something would be in it for him in the end.

Q. Was there anything in it for him in terms of a financial incentive in early September 2001?

A. Nothing on a piece of paper.

Q. What did you discuss with him?

A. That he would be remembered.

Q. Anything more specific than that?

A. No, no, not what I recall at least.

Q. Was he, in fact, remembered at any point for his efforts in helping you?

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A. Not financially since he found himself getting a position at Collagenex. So there were no reason for that.

Q. So you believe that your discussions with Collagenex with Mr. Day there helped him in terms of acquiring a job at Collagenex?

A. I can't speculate about that.

Q. Did you ever discuss it with him?

A. I don't think so.

Q. Was Mr. Day working in early September 2001?

A. I believe he was working for himself.

Q. Was he involved with an outfit called Rx Pharmaceutical at that time?

A. I think that was one of the things he was into.

Q. That was his own business?

A. I believe so.

Q. But he was no longer at Ferndale at that time?

A. No. I'm pretty sure he wasn't at Ferndale at that time.

Q. And it was through Mr. Day's involvement that your concept ended up at Collagenex for

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development; isn't that correct?

A. You could say that if Jeff on my behalf ~~had~~ hadn't called Collagenex to ask if we could use or I could use their conference room to call Medicis, if that would be the reason, then yes.

Q. I'm a little confused. Are you saying there was no meeting scheduled at Collagenex, you were just using their conference rooms?

A. Yes.

Q. But weren't there discussions or emails between you and Mr. Day the prior week about a Collagenex meeting?

A. No, not to my knowledge.

Q. So it's your recollection and testimony that you were using Collagenex facilities for a conference call with Medicis and that led to an opportunity to speak to individuals at Collagenex while you were there?

A. That is correct, because that particular day people were not forced to work. They could come in if they wanted. Everyone was sort of on leave. The phones weren't ringing. There weren't any emails to respond to. So there was probably only I would say -- I'm guessing now -- about

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50 percent of the workforce there. And I remember in the meeting that led to a meeting, I believe we probably talked for a while about the event, because Brian Gallagher was having a financial meeting at the Waldorf and was able to get out just in time before they closed all the bridges and tunnels and everything.

Q. So your meeting at Collagenex on September 12 was impromptu?

A. What do you mean by impromptu?

Q. It was impromptu, it was not previously scheduled?

A. Correct.

Q. At that time you met with Mr. Day, Mr. Gallagher and Mr. Ashley?

A. That's correct.

Q. You spent some time with them during which you discussed the events of the day before as well as your concept; is that correct?

A. Yes.

Q. So you hadn't provided Collagenex with any material relating to your concept prior to September 12, 2001, had you, sir?

A. No.

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Q. And do you recall providing anything to them on that day?

A. Not more than what I brought with me that I was supposed to talk about seeing J & J, Medicis and Allergan.

Q. What was that?

A. At that time I only had two documents that I had picked out myself.

Q. Take a look at T8, which I think is in your book. Let me say referring to the document that's been marked for identification by Petitioner as T8, and I'll use that same numbering when I can when I use it as a reference.

A. Yes.

Q. So this was a confidential document of yours, right, this document here?

A. I'm not sure. I'm not sure how confidential it was.

Q. Do you see where it says "Confidential" on the top?

MR. JACKSON: We can stipulate that's part of this endeavor. That's not part of the original.

SKOLD

BY MR. ROCHFORD:

Q. Well, you still consider it confidential, sir; isn't that correct?

A. Well, I would still say there's important pieces missing to throw out for a patent application. So I don't think I saw this as confidential.

Q. Because it was incomplete?

A. It left out some details for people that if they wanted to steal something, it didn't have enough for them.

Q. And this document T8 bears the date 5 November 2001, correct?

A. It says November 5, yeah.

Q. That's when you created it?

A. No. I believe that's when I amended it.

Q. So it's your testimony today that you created some version of T8 prior to November 5, 2001?

A. The first version was drafted during the summer in 2001.

Q. But you don't have that version, do you, sir?

A. No.

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Q. That version doesn't exist?

A. No, not to my knowledge.

Q. So there's no way to tell as to when exactly you created the original in this document; isn't that correct?

A. There is no way to say when before November 5, 2001 it was first drafted, no.

Q. But it's your testimony today that you gave some version of this to people at Collagenex on September 12, 2001?

A. Yes.

Q. Now, looking at T8, in the big letters on the top it says "A theory of the 'Mode of Action' concerning this new technology." Did I read that properly?

A. Um-hum.

Q. "Yes" or "No."

A. Correct.

Q. So what you were laying out here is some conjecture about how the vehicle that you describe works; isn't that correct?

A. Correct.

Q. Do you recall how you might have changed this document on November 5 from any prior

version?

A. Not exactly.

Q. But it's your testimony that what you gave to Collagenex on September 12, 2001 was substantially similar, if not identical, to this document; isn't that correct?

A. Substantially similar.

Q. And by that, by "substantially similar," you mean that the substance of the content was very much the same, correct?

A. I believe there is a little bit more detail in this version and the version got more and more detailed for every year that went by, but it still says theory because not even today we can be a hundred percent that this is actually what is going on and why we see such good results.

Q. But at that point you didn't have any results, did you, sir, 2001?

A. No clinical data if that's what you mean.

Q. Well, you hadn't done any stability testing, isn't that correct, as of September 2001?

A. I would say no.

Q. You hadn't done any penetration testing?

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A. No.

Q. You hadn't done any feasibility testing?

A. No.

Q. Certainly no in vivo testing?

A. No. Feasibility is, of course, something you can do on a piece of paper also. So I would say that what's been done before was more reviewing -- we have to understand that I have been working with lipids for a number of years and for two years together with a Professor ~~Bugh~~ Bo Forslind that specialized in, more or less, what this is all about.

So it would be wrong to say that it wasn't anywhere. But it was -- I would still say that during the summer and the short period thereafter, it was still on the drawing board.

Q. Looking at the first paragraph of T8, it starts by saying, "The vehicle is designed in its choice of and share of lipids..." Did I read that properly? Just "Yes" or "no."

A. You probably know that as well as I do, maybe even better.

Q. I'm just going to ask you if I'm reading things correctly for purposes of the record. Then

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I'm going to ask you a question about it.

You say, "The vehicle is designed in its choice of and share of lipids..." You don't specify the choice of or the particular share of lipids that are used in the vehicle here, do you, sir?

A. No. If you though would know what kind of normal lipids we find in stratum corneum and the cells, then you would know that it's limited to a very few.

Q. But it's not specified here?

A. It's not specified.

Q. Nor is the share of lipids specified, correct?

A. That's correct.

Q. Looking two lines down, it refers to "...the administered vehicle will easily penetrate..."

That hadn't been confirmed at that time, that it would easily penetrate the lipid bilayer, had it, sir?

A. Well, I would say that we were theoretically very convinced of that fact due to earlier work.

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Q. In the next line it says, "...and in doing so will create a temporary and reversible state of enhanced atrophy..."

Do you know how long that temporary state or did you know in September of 2001 how long that temporary state might be?

A. We did not, and we don't know today either.

Q. Do you know if it's reversible?

A. We have strong reasons to believe that.

Q. It refers to enhanced atrophy. How much is enhanced? Did you know in September of 2001?

A. It's partly individual from one ~~scheme~~ person to another.

Q. But you don't provide any details in this document, do you, sir?

A. No.

Q. Then the next paragraph begins, "The enhanced atrophy in itself should then give rise..."

You use the word "should" meaning you don't know, but that's what you expect to happen; isn't that correct?

A. Well, if you go up to the top, it's

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still a theory. This entire document is about the theory. So I cannot go out and be saying that I know for sure everything.

Q. Right. And to that point, in the next sentence you say, "...said energy could promote active transport..."

That's again a theoretical choice of words, correct?

A. Right.

Q. And it refers in the line after that to-be-carried substances. Those are not specified in this document, are they, sir?

A. They are not.

Q. Then you use the words "and/or" to indicate that it might work the way you described it in subsection (a), or it might work in the way you described it in subsection (b) perhaps, or both or neither. You don't know; isn't that correct?

A. I don't know today either.

Q. In the next paragraph you say, "It is very well feasible that the temporary disarray in the lipid bilayer will temporarily break up..."

When you say "very well may," you're saying

possible, correct?

A. Would it be the same, possible. I think possible is probably a little bit too weak.

Q. In any event, it was unproven at that time, it was theoretical, correct?

A. It is theoretical.

Q. Then the last paragraph reads, "As the content of the vehicle resembles the natural lipid buildup of the skin, the so introduced new lipids will after a short span of creative chaos easily blend in with the natural lipid building stones of the lipid bilayer and thus not permanently damage the skin."

That's a somewhat vague expression of the concept, right, Mr. Skold?

MR. JACKSON: That's a fairly argumentative form for an argumentative question. Taking on the vague, I'd be okay with no problem answering the question.

A. Let me read it myself. Would you please repeat the question.

BY MR. ROCHFORD:

Q. This last paragraph here above your name indicates or describes a somewhat vague concept of

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your theory, correct?

MR. ROCHFORD: And I'll note counsel's objection.

A. I don't see in what way it would be vague.

BY MR. ROCHFORD:

Q. You don't say how the vehicle resembles the buildup of the skin. You don't specify that in that paragraph, do you, sir?

A. For a skilled artisan, it would be fairly obvious I would say.

Q. But you don't define it, do you, sir?

A. Not on this piece of paper.

Q. You don't define what the short span of creative chaos is in the second line, do you, sir?

A. Time-wise, as answered before, we don't know exactly, and it's very individual from one person to another.

Q. You don't even explain what creative chaos is, do you, sir?

A. Creative chaos is the same. It's what I would -- it may be a word easier to understand for some than enhanced atrophy, because those two means the same thing.

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Q. And you say it won't permanently damage the skin, but you don't say if there's temporary damage and for how long in that paragraph, do you, sir?

A. We're saying that it's temporary because we know the lipids are bending in with the existing lipids in the skin after some time.

Q. Now, in this theory document at the bottom, you have the phrase "LipoDerm Lipoid Restoraderm Technology."

Did I read that correctly?

A. Yes.

Q. That was added to the November 5 version of this document.

A. I don't think so. I think it was there before, but I'm not a hundred percent sure.

Q. There's no way of checking, correct?

A. No, not to my knowledge.

Q. But it's your testimony that some version, substantially similar version of T8 was provided to Collagenex on September 12?

A. Absolutely.

Q. Of that concept theory document.

That's the only material you provided to

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Collagenex at that meeting; isn't that correct?

A. I believe there was another document.

Q. Why?

A. I think there was a more easy version for what this all stand for, stands for. Wasn't there?

Q. Do you have a specific recollection of a particular document that you provided Collagenex with ~~without~~ just from your memory, sir?

A. It was probably just something that described this in more easy words.

Q. You are reviewing your files.

A. I believe ~~I've~~ I have seen it

MR. JACKSON: We could refresh Mr. Skold on this morning's testimony that it was Exhibit T9.

MR. ROCHFORD: You can't coach the witness, counsel.

MR. JACKSON: You knew.

MR. ROCHFORD: I'm entitled to test his memory. And obviously he doesn't remember it.

A. Here it is. I didn't remember what page it was. It's Exhibit -- it's on page 60.

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BY MR. ROCHFORD:

Q. So being coached by your counsel and reviewing and reviewing your book, you've concluded that document T9 --

MR. JACKSON: I'm going to object to the characterization of that. The morning testimony was that it was T9.

MR. ROCHFORD: Counsel, any more coaching and I'm going to shut this down.

BY MR. ROCHFORD:

Q. So it's now your testimony that you also produced or provided T9 to Collagenex on September 12, ~~2005~~ 2001?

A. I presented that as well.

Q. I'm sorry?

A. I presented that as well.

Q. High ~~per sent~~ percent?

A. I presented that.

Q. This document T9 is not substantially the same as T8, is it, sir?

A. No. It describes things in a little bit more detail.

Q. Do you recall signing a sworn declaration in this case?

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A. Yes.

Q. I think you have in front of you a loose copy of T146. Do you have that in front of you?

A. Is this the declaration?

Q. Where it says Declaration.

A. Yeah.

Q. And you signed that under oath; am I correct, Mr. Skold?

A. Yeah.

Q. On May 14, 2013, correct?

A. Correct.

Q. Now, if you look at paragraph 4 of your declaration on page 1, you'll see several sentences down it reads as follows, "At the meeting, I showed Collagenex a document substantially the same as, if not identical to, that attached here to as Skold declaration Exhibit E."

And as counsel has noted on this T146, it's marked for identification Exhibit E equals Trial Exhibit for identification T8, which we were just looking at.

A. Correct.

Q. So your testimony in May, your sworn

testimony was that you showed Collagenex a version of T8. Now, there's nothing in there about showing, in your declaration, about showing Collagenex any other document, is there, sir?

A. No. It doesn't say so.

Q. And your declaration was submitted in the context of responding to a motion to have your case dismissed for lack of proof; isn't that correct?

A. I believe you're right.

Q. So when you signed this declaration, you were trying to submit all the proof that you believed would support your position; isn't that correct?

A. I'm not sure I believe you're correct, but at least the ones we thought was crucial. Otherwise, I believe this document would have been a little bit thicker.

Q. So you don't consider the T9 document to be crucial to your position, sir?

A. Apparently not at this point.

Q. Looking at T9, there's no date on this document, is there, sir?

A. What page was it again? Sixty? No.

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Q. Now, this has also some description of your theory, correct, sir?

A. Yes.

Q. Rather than going over the same vague concepts, let me cut to the last sentence before the word studies. So it reads as follows: "this can be explained in more technical terms, but future studies can give a more thoroughly explanation/description of what is happening." Did I read that correctly?

A. Yes.

Q. So at the point that T9 was created, you needed future studies to explain or describe your concept or theory adequately, correct?

A. I think a better word would be "to better explain ~~describe~~" and not "describe".

Q. And you don't have a dated copy of this document, T9?

A. Apparently not.

Q. Wasn't it your practice to date documents like you did with T8?

A. I cannot answer that because I don't know.

Q. While we're looking at T9, in T9 you've

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got an alternative name. In T8 you refer to your theory or concept as the LipoDerm Lipoid Restoraderm and then T9 you refer to it as LipoDerm Restoraderm, correct?

A. Correct.

Q. You say you were handing these both out at the same time to people?

A. Yes.

Q. At Collagenex?

A. Yes.

Q. Now, you left -- I believe your testimony this morning with respect to Ponsus was that you had worked there from '95 to 2000; is that correct?

A. 2001.

Q. And you retired at that time in 2001?

A. Yes, sir.

Q. And since that time when you retired, when was that in 2001?

A. Summer.

Q. So before August?

A. I think the new CEO ~~sale~~ didn't come until August. So I might have held out one or two days and even during the summer if anything was -- I

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mean, if there was something that needed someone's attention that had the experience with it. But I basically left at the summer break.

Q. And the summer break in Sweden?

A. Is mid summer, so mid June, end of June.

Q. Since you retired from Ponsus, the work you've done you've done under your own name, Thomas Skold; isn't that correct?

A. Correct.

Q. So any type of consulting or formulation work you've done, you've done as Thomas Skold; is that correct?

A. That's correct.

Q. Now, this meeting with Collagenex on September 12, that was a confidential meeting; was it not?

A. There was nothing signed that it was confidential.

Q. Did you have any expectation that people at Collagenex could discuss the theory document you gave to anyone else?

A. I don't think I actually thought about that at all at the time.

Q. What was Mr. Day's role at that meeting

SKOLD

you had at Collagenex on September 12?

A. I believe he didn't have a role.

Q. Was he in attendance?

A. Yeah, I would say so.

Q. You don't recall for sure?

A. I mean, he was there, but he didn't have a role. He was in the room.

Q. But he didn't say anything?

A. I don't think he had that much to say, not what I recall, and especially not for this case.

Q. Did the subject of Mr. Day's employment at Collagenex come up during that meeting?

A. I don't remember.

Q. Now, you also have testified that you had scheduled other meetings for September of 2001; isn't that correct?

A. Um-hum, that's correct.

Q. And the meeting with Allergan that had been discussed was canceled; was it not?

A. That's correct.

Q. And you didn't provide any materials to Allergan, did you, sir?

A. I'm very uncertain ~~under certain~~ what Allergan got

TJ

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or didn't get.

Q. So you can't testify to any more than that?

A. I can't be a hundred percent sure.

Q. Now, as to Medicis, instead of a meeting, you had a brief conference call with people at Medicis. When did that occur?

A. I would imagine it was a bit after lunchtime, 1:00 or 2:00.

Q. On which day, sir?

A. You're talking about the phone call with Medicis?

Q. Yes.

A. September 12.

Q. So while you were at Collagenex, you called Medicis after your morning meeting with Collagenex; is that correct?

A. No. My meeting with Collagenex was afterwards, as I recall it.

Q. So you had an afternoon meeting with Collagenex after you called Medicis. And that was a brief call with Medicis; is that correct?

A. That was probably not more than -- I'm guessing again -- but I would say 30 minutes.

SKOLD

Q. And you didn't provide any materials to Medicis in connection with that call, did you, sir?

A. It was -- how would I do that? Except verbally.

Q. So they didn't get any documentation from you. You just explained your theory to Medicis during that call?

A. Well, with Medicis, I can't say for sure exactly when and how and maybe even if, but I'm fairly certain that they had received more info for us to talk about and not just something that I had in my briefcase to show them.

Q. What is your basis for that view?

A. I wouldn't know why they would see me if they didn't know anything more, but that's why I'm saying what I'm saying. But I'm not a hundred percent sure exactly.

Q. So you don't know for sure if Medicis had any material or prior information about your concept?

A. Prior information they absolutely did, but what kind of documents they had, I can't say. But we had -- there was numerous calls with

SKOLD

Medicis before and after this meeting.

Q. But the call on September 12 is when you described your theory to people at Medicis; isn't that correct?

A. No. The theory they already knew before. It wasn't like I was going --

Q. Had you talked to them before about your theory?

A. Yes.

Q. That hasn't been mentioned previously in this proceeding. Do you have any records of any such calls or meetings?

A. It's only ~~calls~~ emails that we've reviewed this morning.

Q. Are you sure it wasn't somebody else who talked to Medicis, or is it your testimony you spoke to them prior to September?

A. I know I spoke to them prior, but it also could be that it's been Jeff Day that has had part of that relationship.

Q. So you can't say for sure?

A. I can't say for sure.

Q. And I believe you mentioned and you testified to this fact, that after the first round

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of discussions in the meeting with Collagenex, you proceeded after the mid-September timeframe only with Collagenex, isn't that correct, with respect to your theory?

A. I believe that I didn't come back home until about a week after. So it must have been 16th, 18th, something like that, Sunday, Sunday after, at least, I know. And I remember taking most of that following week off. And then it wasn't more than a few days until Jeff Day announced that he had now started working at Collagenex.

I do not believe I had any further -- not sure, but I do not believe that I had any contact with Rob in between the meeting of September 12 and when Jeff Day started working for Collagenex.

Q. You mean Rob Ashley?

A. Rob Ashley, correct.

Q. So you picked up with Collagenex after you were back in Sweden and Mr. Day had joined the company; isn't that correct?

A. More or less.

Q. And you didn't speak to anyone else once those discussions began in earnest with

SKOLD

Collagenex, correct?

A. I probably spoke a lot with Jeff during those ~~that~~ two weeks.

Q. I mean anyone outside of Collagenex.

A. No, I don't think so, because I know I made a promise to myself not to go to anyone else before Collagenex had ~~had~~ the time to make a decision of their own. So on the basis of that, I would say no.

Q. Mr. Skold, as it turned out -- let's step back.

You've indicated that Johnson & Johnson, Ortho and Neutrogena were, in effect, one entity for purposes of considering your theory; is that correct?

A. Yes.

Q. And you were scheduled to meet with them on September 11, 2001, correct?

A. Correct.

Q. As it turned out, that meeting was canceled, correct?

A. It got canceled during the meeting.

Q. Didn't it, in fact, get canceled in full?

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A. No.

Q. Isn't it true that on your way in to J & J, the first aircraft hit the towers and the presentation was canceled even though you stayed watching it all on TV in the cafeteria for the entire day?

A. Not the entire day. We stayed for some time after our introduction and presentations before the crowd and Jeff Day brought me in his car down to the hotel where I stayed afterwards, which was something that J & J people booked for me while we were watching the television.

(Galderma Exhibit A was marked.)

BY MR. ROCHFORD:

Q. Let me show you what's been marked as Galderma Exhibit A.

(Witness reviewed the exhibit.)

A. Are we supposed to read it?

BY MR. ROCHFORD:

Q. Yeah. I'm watching you read it.

MR. JACKSON: Are we focusing on the first page?

MR. ROCHFORD: Yes, we are.

SKOLD

BY MR. ROCHFORD:

Q. Have you had a chance to read the first page?

A. No.

Q. Why don't you please do that.

MR. JACKSON: If you'll trust that I won't be coaching, I'll sit close enough.

MR. ROCHFORD: You can sit close.

A. Okay.

MR. ROCHFORD: Let me just identify this on the record. What's been marked as Galderma Exhibit A is a string of emails originally produced under Skold Bates No. 00164 and 165 and 166, and I'd like to direct the witness' attention now that he's had a chance to read it, to the January 12, 2008 email from Thomas Skold to Joe Willis.

BY MR. ROCHFORD:

Q. Now, Mr. Willis was employed by Johnson & Johnson at that time; isn't that correct Mr. Skold?

A. Sorry. Again?

Q. Mr. Willis was employed by Johnson & Johnson?

SKOLD

A. When?

Q. As of January 2008 when you sent this email.

A. I believe so.

Q. And you are sending him a message regarding a derm delivery system, and you state in paragraph 2 or 3 of that message, "What is kind of interesting is that on September 11, 2001, I was scheduled to present my early findings of my development efforts for your people in your New Jersey office. On my way in to your office, the first aircraft hit one of the towers and the presentation got canceled (even though I stayed watching it all on TV in your cafeteria for the entire day)."

Did I read that correctly, sir?

A. Right.

Q. Does that refresh your recollection that the presentation to J & J, Ortho and Neutrogena on September 11, 2001 was canceled?

A. No. It was not canceled.

Q. Is this a false statement?

A. It's not a false statement, but it's not a correct statement.

SKOLD

Q. I have to say, Mr. Skold, I don't know anyone who doesn't remember that day or that morning with absolute clarity.

A. I do remember it with absolute clarity.

Q. As of January 12, 2008, your recollection was the presentation got canceled?

A. It doesn't necessarily have to be so, but I still stated it, so...

Q. So even though you said in 2008 that the presentation had been canceled, it's your testimony now that there was some type of abbreviated introduction?

A. For a few hours.

Q. For a few hours?

A. I would say we probably were doing it between 9:00 and at least after 10:00, 10:30.

Q. So the first aircraft hit one of the towers in New York City between 8:00 and 9:00 a.m. that morning; isn't that correct?

A. I believe you're correct.

Q. J & J's office are basically across the river from that site; isn't that correct?

A. We even saw it from there.

Q. It's your testimony J & J proceeded with

SKOLD

a meeting to hear about your theory as that event was unfolding?

A. Yes.

Q. Do you think anyone was paying attention?

A. Not as much as you --~~that~~ as the presenter wanted them to be, because they actually had speakers that announced things on a frequent basis.

Q. Now, is it also your testimony that some version of T8 was presented to J & J in these other companies?

A. Yes.

Q. On September 11, 2001?

A. Yes.

Q. After September 11, 2001, you didn't have any further contact with J & J or Ortho or Neutrogena with respect to your theory, did you, sir?

A. I did not personally have contacts with them. I'm fairly certain that Jeff Day and some of his colleagues did, but I did not personally have.

Q. And you don't know what those contacts

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that Jeff Day might or might not have had were, do you, sir?

A. No. I don't know that.

Q. So as you've testified a few minutes ago, after mid September of 2001, you proceeded with private confidential negotiations with Collagenex towards reaching an agreement to develop your theory; isn't that correct?

A. Yes.

Q. Let me show you what's been marked for identification as T61. I think that's in your book.

MR. JACKSON: 291.

BY MR. ROCHFORD:

Q. I thought T61 was the flowchart. Did I have the wrong number?

MR. JACKSON: I think you do.

A. But I've seen that.

BY MR. ROCHFORD:

Q. We discussed it this morning.

A. We did.

MR. JACKSON: I just have to find where that is.

SKOLD

BY MR. ROCHFORD:

Q. It's T206 perhaps.

MR. JACKSON: Page 206? Page 313.

MR. ROCHFORD: T74 is the number that was the marked for identification number.

MR. JACKSON: It's 313.

BY MR. ROCHFORD:

Q. Let me start over after that colloquy so we get the right number on the record.

Mr. Skold, I'm going to ask you some questions about what has been marked for identification as T74. Do you have that in front of you, the flowchart?

A. Yes I do.

Q. And it's your testimony that you prepared this in October of 2001 and sent it to Jeff Day at Collagenex at that time?

A. That is correct. I even had discussed things with him before putting it together. But yes, that's correct.

Q. And you've described this as your preliminary business plan; is that correct?

A. Yeah, I would probably say that, but also attached with what kind of financials are needed

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to get there, but very short term.

Q. So according to this business plan, you're talking about working on a base formulation and having some testing started to be concluded by June 2002; is that correct?

A. Correct.

Q. And that would be the first stability work that would be done on any material created according to your theory, correct?

A. Not necessary. It could also be improvements, adjustments.

Q. But as of October -- let me strike that.

So I note here under the title Flowchart with Trigger Events, you refer to the LipoDerm/~~Restoraderm~~ RestoDerm/EpiLip Technology. Did I read that correctly?

A. That's what I'm reading, too.

Q. So those were all alternative names you were using to describe your theory at that time; is that correct?

A. Not the theory, but for various products and projects, yes.

Q. Well, there were no products at that time, were there?

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A. How do you define products in this case?

Q. I define products in the normal usage, something that could be delivered to a consumer.

A. But we are not talking about any products that are supposed to be delivered to a consumer.

Q. At this point in September of 2001, there weren't any physical manifestations of your theory, were there, sir?

A. Again, what do you mean?

Q. Any.

A. Yes, there were.

Q. You didn't have a base formulation as of October 2001, did you, sir?

A. As of October, some time in October I did have, but I wouldn't call it a base formulation.

Q. No. What you had was an initial stab on the drawing board of a sample; isn't that correct?

A. Well, at least up until September, that's correct.

Q. And whatever you came up with prior to March of 2002, none of that had been subjected to any form of testing, had it, sir?

SKOLD

A. Well, I think you need to see things a little bit different because this is not -- we are not trying to produce a product that we're supposed to hand out to any consumer at this point in time. It's a delivery vehicle. It doesn't have anything to do with a finished product at all at this time. It's not the nature of the business.

Q. It was ~~skill~~ still in a conceptual stage, correct?

A. That is not what I said. It needs someone that you are working with that needs to designate how they would like to see the finished product. So you could only do examples, is probably a better word, for them to review, but it still needs in this case Collagenex to make a decision on what kind of product would they like to use with this technology.

Q. So the first samples you provided to Collagenex in late 2001 and early 2002 were these experimental examples; isn't that correct?

A. That was examples that I had produced myself.

Q. And they were experimental in nature,

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weren't they?

A. Well, you could probably say it's been experimental up till 2009, ~~29th~~ November 27th almost, because there was nothing coming out of it. And unless nothing came out of it, it is still experiments.

Q. And the phrase you used to describe your concept in Exhibit for identification T74 is LipoDerm/~~Restoraderm~~ RestoDerm/EpiLip, correct?

A. Correct.

Q. Now, there came a time that you entered into a Letter of Intent with Collagenex; isn't that correct?

A. I believe it was mid December of 2001.

(Galderma Exhibit B was marked.)

BY MR. ROCHFORD:

Q. Mr. Skold, Galderma Exhibit B is a December 12, 2001 letter addressed to Thomas Skold called the Letter of Intent, and it is two pages. It's previously been marked in this case as GAL-5 and 6.

Are you familiar with this document, sir?

A. Yes, I am.

Q. And it bears your signature on the second page?

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A. Yes, it is.

Q. By your signature, you accepted and agreed to the terms of this Letter of Intent; isn't that correct?

A. As a Letter of Intent, yes.

Q. And if you look at the top of page 2, let me read the first paragraph on that page to you. "All trademarks associated with the drug delivery system; the proposed intellectual property; products deriving therefrom and products marketed and to be marketed by Collagenex or any commercial partner of Collagenex anywhere in the world shall be applied for and registered in the name of Collagenex and be the exclusive property of Collagenex."

Did I read that properly, sir?

A. Yes.

Q. And that indicates all trademarks were to be the exclusive property of Collagenex, correct?

A. Yes, it does.

Q. And you'll see that it refers to all trademarks associated with the drug delivery system, and then next it says the proposed

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intellectual property. That's your concept, right, what you've called your technology, right, the intellectual property?

A. What I refer to what is part of the asset is the patents, the trademarks and know-how and documents that is related to Restoraderm technology. And even though it says trademarks, as you say here, that is exactly what they also told me how they wanted the patents.

So any patents, any trademarks ~~trademark~~ I would have and had used would be put in their name and used as long as they fulfilled their obligations according to any kind of agreement that we would have.

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Q. I'm referring to Galderma Exhibit B. That indicates that all trademarks shall be the exclusive property of Collagenex, correct?

A. That is correct. That's what it says.

Q. Just a couple more questions about the samples or as you called them experimental samples that were prepared in late 2001 and early 2002. Those were only sent to Collagenex, correct?

A. Those were only sent to Collagenex except for the samples I brought with me for a

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meeting in January 2002.

Q. That was the meeting in Puerto Rico?

A. That was the meeting in Puerto Rico, yes.

Q. And you provided those to Jeff Day at that conference?

A. I think we played around with them with numerous people, including doctors.

Q. Those samples couldn't be used by an individual, could they, sir? They weren't authorized for use, were they?

A. No. What you would say? For technical purposes.

Q. In fact, those samples from that time period had issues around separation and infection; did they not?

A. No. Where would you have gotten that from?

(Galderma Exhibit C was marked.)

BY MR. ROCHFORD:

Q. Do you recall a time in early 2002 where you provided Rob Ashley with an experimental example sample?

A. No, but it probably happened several

times.

Q. I'm going to show you what's been marked as Galderma Exhibit C. It had previously been produced as Skold document 1850 and 1851. Take your time to read the whole thing if you would like, but I'm focusing --

A. Both pages?

Q. I'm focusing my questions on the email on the top of the first page from Mr. Ashley to you. But you're welcome to read the whole thing if you wish.

(Witness reviewed the exhibit.)

BY MR. ROCHFORD:

Q. Directing your attention to the top of the first page of Galderma Exhibit C, it's an email from Rob Ashley to Thomas Skold dated May 1, 2002. You'll see there in the text of that email, the third line down Mr. Ashley writes, "Any interim stability data? I noticed the little bottle of cream I brought home separated, then got infected. I'm growing an interesting bacteria colony on my desk at the moment."

Did I read that correctly?

A. Yes, you did.

SKOLD

Q. That's referring to an experimental example sample you provided to Mr. Ashley?

A. I don't know. If I did, I don't know when he received it.

Q. Some time prior to May 2002; isn't that correct?

A. It could be in early October 2001. I don't know.

Q. Do you recall Mr. Ashley visiting you in Sweden in early 2002?

A. No, I don't. That doesn't mean it didn't happen.

Q. Was Mr. Ashley at the Puerto Rico meeting in January?

A. Yes, he was.

Q. Did you give him a bottle of cream at that time?

A. No.

Q. Are you sure?

A. Yes.

Q. All those bottles went to Mr. Day?

A. No. I brought only aerosol containers with me. So I'm not sure because the early items was only aerosol containers. It could be that

they wanted me or someone else to play around with a cream instead of a foam, but I don't recall who was doing it, who we got it from and when. Sorry.

Q. Now, these experimental example samples that you prepared in late 2001, early 2002, you weren't paid for those, were you, sir? You didn't charge Collagenex for those?

A. No, I did not.

Q. And you don't have any evidence of any labels that were placed on any of those experimental example samples, do you, sir?

A. I don't think anyone would have, not even Collagenex, which would be the one that should have them. But it's a long time ago.

Q. And it's your belief that they did bear some form of label though; is that correct?

A. Oh, yes, they did.

Q. Was that a home-made label that you drew up or what form of label was that?

A. That was printed labels, but the kind of printed labels that you would be able to do in your own computer.

Q. And you don't have any computer records of what those labels might be?

SKOLD

A. No.

Q. You didn't keep that in any of your business records, did you, sir?

A. No, I did not.

Q. Is it your recollection that you prepared and printed the labels?

A. I don't know.

Q. And you don't recall --

A. I would imagine that I -- it makes sense at least that I made them in 2001 and that we had someone else doing it for us in Sweden in 2002.

Q. You don't recall what those labels said, do you, sir, of your personal knowledge?

A. I believe that everything early days -- and when I'm saying early, it's 2001 -- had LipoDerm and Restoraderm on them, and the closer we got to February 2002, it was only Restoraderm. And again, Collagenex wasn't interested in anything else but the Restoraderm. LipoDerm they didn't think was a good name. So I think LipoDerm faded away, and the only thing that was on it was Restoraderm.

Q. Because Collagenex chose Restoraderm, correct?

SKOLD

A. They wanted to use that as the name of the vehicle.

Q. Based that direction from Collagenex, you placed that name on the experimental samples; isn't that correct?

A. That is correct. I gave them two examples, LipoDerm or Restoraderm. They chose Restoraderm.

Q. You gave them other choices, Lipoid; isn't that correct?

A. I think I never gave them that opportunity, not officially at least. But I mean, as I recall it, the main -- maybe Collagenex remembers it better, but as I remember it, it was Lipoderm and Restoraderm that was there at the end at least.

MR. ROCHFORD: We've been going here for a bit. Why don't we take a brief recess, like ten minutes. Then we'll plow ahead.

(There was a recess in the proceedings.)

BY MR. ROCHFORD:

Q. Mr. Skold, we're back on the record.

A. Yes.

Q. I want to next direct your attention to

SKOLD

T2, a document that's been marked for identification as T2.

A. Page 2?

Q. It's the Cooperation Development and Licensing Agreement. Do you have that in front of you, sir?

A. Right.

Q. It's a multipage document produced by Galderma at Galderma 15 through 28 and it's been marked for identification by Petitioner as T2.

Now, this Cooperation, Development and Licensing Agreement was entered into between yourself and Collagenex on February 11, 2002; isn't that correct?

A. That is correct.

Q. And your signature appears on the last page of this exhibit; is that correct?

A. Yes, that is correct.

Q. I'd like to direct your attention to page or paragraph 4. I believe it's page 7 of the document.

A. Paragraph 4, I have that.

Q. Paragraph 4 relates to intellectual property, correct, sir?

SKOLD

A. Yes. I have that on page 10.

Q. Under paragraph 4, there's a paragraph 4.2 which reads first Trademarks, correct, sir?

MR. JACKSON: We're going to object. The document speaks for itself.

A. That's correct.

BY MR. ROCHFORD:

Q. Do you see Section 4.2.1? I'm going to read it. It says, "All trademarks applied for or registered (including Restoraderm) shall be in the sole name of Collagenex and be the exclusive property of Collagenex during the term and thereafter (the trademarks)."

Did I read that correctly, sir?

A. You did.

Q. So in this agreement it's indicated that Collagenex holds the trademarks including Restoraderm as its exclusive property, correct, sir?

MR. JACKSON: Objection, calls for a legal conclusion. But go ahead.

A. No. I'm probably not the legal person to ask that question to. But it's -- from what I'm reading, it's supposed to be registered under

SKOLD

the name of Collagenex as should the patents ~~patent~~.

BY MR. ROCHFORD:

Q. Right. It says that it will be applied for and registered and it also says it will be the exclusive property of Collagenex, doesn't it, sir?

A. Yes.

Q. Indeed Collagenex applied for and registered the trademark Restoraderm in many jurisdictions including the United States, correct?

A. Yes, they did.

Q. And that section -- if you remember earlier we were looking at the Letter of Intent.

A. Correlates with the Letter of Intent, correct.

Q. It does correlate. Both of them indicate the trademarks will be the exclusive property of Collagenex, correct?

A. Correct, as well as the patents.

Q. I'm just asking about the trademarks, sir. Correct?

A. It's difficult for me to answer on just the trademarks issue separately.

Q. Well, they're addressed separately in

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each agreement, aren't they?

A. Under the same paragraph, yes.

Q. Now, you filed a provisional patent application in March of 2003; isn't that correct?

A. That's correct.

(Galderma Exhibit D was marked.)

BY MR. ROCHFORD:

Q. I'm only going to ask you about a couple of aspects of this. You're welcome to read it in its entirety.

A. You don't know where it's originated from?

Q. That's what I'm going to indicate on the record, that Galderma Exhibit D is a provisional patent application entitled Water-Based Topical Delivery System, and it bears running vertically on the first page the No. 60365059.031302, which is the filing number and the filing date in the United States Patent Office for this particular filing.

A. Which was March 13.

Q. ~~2010~~ 2002.

A. Okay. I think I'm with you.

Q. It's an 11-page document. You're

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familiar with this, Mr. Skold?

A. I, of course, I need to say yes even though it's an extremely long time since I saw this.

Q. Let me direct your attention to page 4 of the document, Exhibit D.

A. Starts with in one embodiment.

Q. Correct. I'll direct you to line 10 and that paragraph that begins, "Without the intention to limit the scope of the invention, a possible theory explaining the herein mechanical properties of the topical delivery system," and then it goes on.

Do you see that language there in that paragraph? You can just read it to yourself.

A. No. It's mine.

Q. Is that similar to the language that was in your document, the November 5, 2001 document that's been marked for identification as T8?

A. It may be a little bit improved, but yes.

Q. So as of March 13, 2002, the vehicle that you were working on was still viewed by you as theoretical as a concept; is that correct?

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A. Would you please repeat the question?

Q. Sure. As of March 13, 2002, you were still describing your work as a possible theory; isn't that correct?

A. No, I wouldn't say that. I would probably more say that the provisional patent that we filed in March 2002 was supposed to be as broad as possible for us to narrow it down for the following year when we filed the nonprovisional patent.

Q. And in the application, as we've just looked at on page 4, it describes your possible theory surrounding your concept, correct?

A. Yes, it does.

Q. And indeed you did file a PCT patent application within a year after Galderma Exhibit D, correct, sir?

A. I can't answer that. I have to throw out a question. ~~Is~~ Isn't that normal that you would have to do that within 12 months?

Q. Let me spare Mr. Jackson from having to comment.

A. Basically my answer is I really can't -- I can't say.

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Q. Let me make it easier. We'll get out the '810 patent.

A. 8,029,810 beginning at page 424.

Q. If you can take a look at what's been marked T30.

MR. JACKSON: T130.

BY MR. ROCHFORD:

Q. T130 for identification.

A. What page?

MR. JACKSON: Page 424.

A. Yes.

BY MR. ROCHFORD:

Q. So you recognize this as the '810 patent issued to Skold on October ~~11, 2004~~ 4, 2011?

A. Yes.

Q. If you look at the first page of that, you'll see it at line 63 a reference to related application data which indicates the filing of your application in March 2003, and then at line 60 it refers to the provisional application we were just looking at filed on March 13, 2002.

Do you see that, sir?

A. Yes, I do.

Q. And, in fact, the '810 patent contains a

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lot of information that was added after the application you filed in March of 2003; isn't that correct?

A. That's correct.

Q. You submitted a number of examples after 2003 that were -- that had not previously been part of the application; isn't that correct?

A. I believe that we submitted new things as late as 2010 even. That is at least what I believe.

Q. And that included amending the claims of the patent as of 2010, correct?

A. When we got the patent application portfolio back from Galderma early 2010, I know that we had to do a lot of rework. So yes, I do believe there are amendments to it.

Q. In particular examples -- take a look at column 17. Do you see at line 40 of column 17 of Exhibit T130, it refers to Example 5, in vivo model and skin penetration results?

A. Yes.

Q. And that work that's indicated under Example 5 was added after 2003, correct?

A. I don't know because I don't know when

SKOLD

we did this. But -- I don't know.

Q. Do you recall when the in vivo work was done, sir?

A. I was part of publishing this data. When did we do that? 2003, 2004; 2003, 2004 I think.

Q. Certainly that work was done no earlier than 2003, was it, sir, the in vivo work?

A. Well, it could have been 2003, but it wasn't before 2003, if that was your question.

Q. That's my question. There was no in vivo work done before 2003 on your concept?

A. Yes, there were, but nothing that we used.

Q. Looking again at column 17, Example 6 at column 55 refers to the addition of nonionic adjuvants into the formulation of Example 2. That material was added after 2003 to your patent application, correct?

A. That's correct.

Q. It was at that time you learned of the benefits of using nonionic adjuvants?

A. No. This is actually -- I had -- how should I say -- one of my hobbies is to sponsor ~~pH~~ Ph.D. TJ

PUBLIC

SKOLD

students and I set up different ~~things~~ tasks for them to do and then I pay for everything, and this is actually part of that. It doesn't have anything to do with specifics of the technology. So this is work conducted by youngsters.

Q. It was conducted after 2003?

A. Oh, yes, or -- I would say it was not in 2002.

Q. It was after that?

A. It was after that, but I can't say exactly when. I could find out though. That's published data.

Q. Okay. Directing your attention to column 20 at line 50 of document T130, that refers to Example 7, a skin penetration model; is that correct, sir?

A. That is correct.

Q. And the text describes using pig skin to investigate skin penetration, correct?

A. That is correct.

Q. And the work that's cited in that example occurred after 2002; isn't that correct?

A. This is also part of the youngster's work that was published.

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Q. Wasn't this part of the work of Ruby?

A. No. Ruby brought in a few items, a few simple things that she did to add on to the publication. And this work is, first of all, for these young people to get published and, secondly, the results. That's basically how it works.

Q. Then the work, as you've described it by the youngsters and by Ruby, occurred after 2002 relating to the Example 7?

A. You are correct.

Q. Likewise, with Example 8 in column 22, line 15?

A. Would you please repeat that.

Q. Yes. Take a look at column 22, line 15.

A. Yes.

Q. That work described in Example 8, skin penetration results of the formulation of Example 7 also occurred ~~in~~ after 2002; is that correct?

A. That's correct.

Q. Example 9 on column 23, at line 45, that represents work that was done after 2002 as well, correct?

A. Yes, and also part of the published data.

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SKOLD

Q. And that data was published in 2004?

A. Yeah, that's probably right, yeah.

Q. Not earlier than that?

A. No. I would say 2004. We probably did the work a year earlier, and then published it a little bit later, yep. These all refer to -- I can also add -- to transdermal delivery and what you would have to do to be able to get APIs, active ingredients, through the skin, I mean, to the ~~body system~~ systemic body. So it doesn't refer to normal topical products. And it's never been practiced since then, if I could add.

Q. After T2, that Cooperation, Development and Licensing Agreement was signed in February of 2002, you provided some of the first base formulations to Collagenex pursuant to that agreement, correct?

A. Before and after.

Q. Those formulations were then subject to three-month stability testing; isn't that correct?

A. I don't think that we started that until about the time when we filed the provisional patent which would have been in mid March.

Q. Right.

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SKOLD

A. For specific products.

Q. So the results on the three-month stability testing were not expected until June of 2002?

A. If we were to be looking for three month accelerated data, that would be mid June, yeah.

Q. And then additional tests were run on the base formulation after in time, correct?

A. There are testing every day up until April 2007. After that there wasn't that much testing. Up until that time we probably had something on some kind of a test all the time.

The ~~Lightra~~ Lytra product was, I believe, ready by the summer of 2002. So yeah, that's correct ~~Lightra~~ Lytra was Lidocaine products, surface anesthetical products.

(Galderma Exhibit E was marked.)

BY MR. ROCHFORD:

Q. What's been marked as Galderma E is the Asset Purchase and Product Development Agreement by and between Collagenex Pharmaceuticals, Inc. and Thomas Skold dated as of August 19, 2004. It's a 20-plus-page document, and it bears on the second to last page ~~a~~ signatures of Mr. Skold and

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SKOLD

Colin Stewart on behalf of Collagenex.

You're familiar with this document, aren't you, Mr. Skold?

A. Absolutely.

Q. And I believe you were asked some questions earlier about a provision on page 5, Section 1.20.

A. Yes.

Q. And that defines for purposes of this agreement Restoraderm intellectual property, correct?

A. Yes.

Q. And that includes A, patent rights, B, know-how and C, rights to sue, correct?

A. Correct.

(Galderma Exhibit F was marked.)

BY MR. ROCHFORD:

Q. Mr. Skold, I know you're familiar with this document, what's been marked as Galderma Exhibit F, because it was produced as Skold, bearing Bates Nos. 241 through 273. And this is a draft of the Asset Purchase Agreement that's undated and bears some what's called red lining, some things that were added there or to be

considered.

A. Do you know when this was produced?

Q. It bears your production number. I'm not sure exactly the date of this. My belief, it was around August 13 or so of 2004. I don't know if your counsel indicated when you produced it what the date of this one might be. Anyway, it's a prior version of what ultimately was finalized as Galderma Exhibit E.

What I'd like to direct your attention to is page 5 of Exhibit F and particularly the provision 1.20. Do you have that, sir?

A. Yes.

Q. And do you see that in this draft, Exhibit F, Restoraderm intellectual property included A, patent rights, B, trademarks, C, know-how and D, rights to sue, correct?

A. That is correct.

Q. And it also at paragraph 1.24 had a defined term Restoraderm trademarks; is that correct?

A. Would you please say that again.

Q. Yes. On the same page you'll see -- look down from 1.20 -- there's a 1.24. It's a

SKOLD

defined term for Restoraderm trademarks, correct?

A. Yes.

Q. Now, I believe you were shown an email message this morning.

MR. ROCHFORD: And, counsel, I'll need your help just so we can identify it for him to look at again.

MR. JACKSON: It's the first one in the book, page 1, Exhibit T1.

A. David Glazer.

MR. JACKSON: David Glazer.

BY MR. ROCHFORD:

Q. Now, if I can direct your attention to T1, Mr. Skold.

A. Yes.

Q. So this is Mr. Glazer's email. Mr. Glazer was at the Morgan Lewis firm, correct?

A. Yes.

Q. Morgan Lewis was your counsel for purposes of the Asset Purchase and Product Development Agreement?

A. It was someone that Collagenex hired to do the job.

Q. But they were acting on your behalf,

SKOLD

correct?

A. No.

Q. Morgan Lewis was not?

A. No.

Q. Did you have your own attorney in this matter?

A. Yes.

Q. Who was that?

A. ~~Stefan Zelo~~. Staffan Willow

Q. Where is Mr. ~~Zelo~~? Willow

A. Stockholm, Sweden.

Q. Now, you'll see here that in Mr. Glazer's email to you, as we talked about this morning, he cites, "Also, Collagenex has informed me that it already owns the Restoraderm trademark. Accordingly, are there any other trademarks that you own that should be assigned to Collagenex relating to this technology? If there's not, we can delete these trademark provisions from the agreement."

Now, in fact, that's what happened; isn't that correct, sir? The trademark provisions that we just looked at in Exhibit F in Section 1.20 and 1.24 were removed, were deleted or removed from

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SKOLD

the draft; isn't that correct?

A. I don't know when, but it's apparent that it is not in the signed version, and I imagine that it ~~that~~ is due to that I didn't have any other names that they were interested in to be part of the asset.

Q. Okay.

A. So your conclusion is probably right.

Q. Okay.

(The record was read back.)

A. Maybe if I can just continue and finish. I would still like to draw your attention to what I mentioned earlier today, that based on the confirmation from David that it was part of the asset and my approval from my attorney, that was when I responded then we are in agreement.

Q. So your attorney approved Exhibit E prior to signing it; is that correct?

A. Yes.

Q. We were talking about Mr. Day earlier. When is the last time you saw him?

A. Oh, I believe I saw him in Stockholm before this summer, but before that, it was at the previous Caribbean Derm meeting in January 2013,

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but I only saw him briefly when he was in town for business.

Q. What is Mr. Day doing now?

A. To my knowledge, he is the CEO of a company called Quinnova.

Q. Do you know what Quinnova does?

A. Dermatology.

Q. Do you have any ongoing business dealings with Mr. Day?

A. No, I don't.

Q. So you haven't approached him about coming back into the marketplace with your concept?

A. For various reasons, I have not.

Q. And you haven't seen him within the past week?

A. No.

Q. Have you spoken with him?

A. Yes. I spoke to him today, and before that I don't know. He is an extremely occupied guy at the moment. So it was probably quite some time ago. However, I do get some updates from emails from him and stuff, but I haven't talked to him.

SKOLD

Q. Have you discussed this case with him?

A. Yes, I have on the context that he -- I believe he and I talked in May about it, April or May.

Q. Was that in preparation for these trial depositions when they were originally scheduled?

A. I don't think it was preparation because I haven't been that much part of it. That's Art's work. I think it's more a worried guy that just wants to be more comfortable giving a ~~phone call~~ deposition. TS

Q. Now, Professor Marks is also a close friend of yours, correct?

A. Well, coming back to the term ~~friends~~ friend, I do have some friends in the community, yes. TS

Q. And he's one of them?

A. And he's one of them.

Q. And you've socialized with he and his wife?

A. We usually do when we are at meetings. Some of the meetings, they are part of the faculty and we are usually invited to some of them.

Q. So you see him basically every year?

A. At least once a year.

Q. And stayed with him at his house in

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SKOLD

Hershey?

A. Yes, I have.

Q. With his wife and your wife?

A. With his wife, with other dermatologists from advisory board, but we've been, a couple of doctors and myself, there for parties.

Q. You've asked for him to vouch for you as a person recently?

A. I don't know when it was, but when it came up for -- for me it's all obvious, and, of course, it's not because we're sitting here. But I was told I probably needed someone that could talk about what I was doing in those early days.

Q. And he's indicated he'll do whatever he can to help you; isn't that correct?

A. What do you mean by anything?

Q. He'll help you any way he can.

A. In any way he's able to.

Q. Did you make it on that Italian cruise with Professor Marks in 2007?

A. No, I did not.

Q. Have you taken other trips with him?

A. They were supposed to come with us for a Finland cruise ~~another thing~~, but that in the end was other people. That

PUBLIC

was Joe Fowler and Vince Deleo from New York. No. We have -- we've stayed with them in one of their places in the Caribbean for a few days attached to one of the Caribbean Derm meetings.

Q. When is the last time you spoke with Professor Marks?

A. When you say spoke, you're meaning like this (indicating) or by the phone?

Q. Either, either by phone or in person.

A. January 2013.

MR. ROCHFORD: Let's take a brief recess.

(There was a recess in the proceedings.)

(Galderma Exhibit G was marked.)

BY MR. ROCHFORD:

Q. Mr. Skold, I'm showing you Galderma Exhibit G. It was produced as Skold 2042. This is my only copy of it. Let me identify it and give it to you. It's from jday60@comcast.net to you, re: Possible Development Deal (Restoraderm).

MR. JACKSON: It's going to be marked what? G?

MR. ROCHFORD: G.

(Witness reviewed the exhibit.)

SKOLD

A. Yep, I see it.

BY MR. ROCHFORD:

Q. Do you recall that document?

A. Yep.

Q. Does that refresh your recollection that Mr. Day has been engaged in development opportunities on your behalf?

A. No. I think this was more ... not on my behalf. This is again -- I get these from various derm people I know probably on a weekly basis. And for various reasons I ~~decline~~ declined kindly because I know and knew at the time that that would have been conflict of interest with the agreement I signed this summer that I've been working on for 18 months.

Q. So you didn't pursue this opportunity that Mr. Day was talking about --

A. No.

Q. -- in Exhibit G?

A. No. I don't remember exactly, but I believe -- you can ask him. I imagine it was a friend of his that was interested in doing something.

Q. And you hadn't asked Mr. Day to

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SKOLD

undertake these activities?

A. No.

Q. He was doing this on his own initially?

A. Absolutely.

Q. [redacted]

A. No. As a fact, I kept it from him and felt obligated to shoot him an email, I believe, in August or something like that just to explain what I've done so he doesn't have to be thinking in those perspectives.

Q. Nothing further at this time. Thank you, sir.

MR. JACKSON: I would like to do some redirect. Give me about ten minutes, and we'll do some redirect.

MR. ROCHFORD: Okay.

(There was a recess in the proceedings.)

A. If I'm just thinking of something I might have said that is not a hundred percent accurate, should I --

REDIRECT EXAMINATION

SKOLD

BY MR. JACKSON:

Q. Is there anything you said during this testimony, Mr. Skold, that you feel needs a correction?

A. Well, even though it's not -- doesn't matter that much, I think I said that the J & J meeting was supposed to be a full day meeting. I think it was not. It was half a day. I was supposed to have a late lunch at the World Trade district that day. But that was it.

Q. There's been much discussion about whether you could prove your theory about why your product would help deliver substances to the skin. If you look at Exhibit -- Plaintiff's Exhibit T143, which is a poster by J.F. Fowler -- this is on page 469 of the second book -- which is a poster by J.F. Fowler and J.H. Perryman of the University of Louisville entitled a "Comparator Study of an Adjunctive Dermal Lipid Replacement Foam (Restoraderm) in the Management of Refractory Hand Contact Dermatitis."

In looking at that exhibit, is there evidence there that, irrespective in theory of how it works, that your formulation helps deliver

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substances to the skin?

MR. ROCHFORD: Object to form, relevance, hearsay.

A. This study, I believe this was -- got public knowledge in 2004. The formulation which should be out there somewhere to verify is very much identical to the ones that was delivered in the end of 2001, beginning of 2002 and became within Collagenex known under the brand ~~Cetaphil-based~~ Restoraderm technology.

MR. ROCHFORD: Move to strike as nonresponsive and lack of foundation, relevance and hearsay.

A. It's a good study.

BY MR. JACKSON:

Q. Let's move on.

Were there other studies that were published in the 2004, 2005 timeframe that showed in one fashion or another that your formulation helped to cause the formulation chemicals to penetrate the skin?

MR. ROCHFORD: Object to form, relevance, hearsay, foundation.

A. The ones that comes to mind would be the

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Ruby Ghadially studies we went through from the patent, and there was several surface anesthetical studies also performed I think by Joe Fowler or maybe someone else that proved superiority against what one was comparing itself with.

BY MR. JACKSON:

Q. With what, comparing with what?

A. The biggest brand on the market in the U.S.

Q. Which is?

A. In that case with Lidocaine it was ~~LMX~~ EleMax.

MR. ROCHFORD: Same objections, form, foundation, hearsay.

MR. JACKSON: Sounds good. Not agreeing to the objections, you understand.

BY MR. JACKSON:

Q. In your testimony, you did lose confidence in whether or not you had delivered to Medicis the copies of Trial Exhibits T8 and T9. But do you have confidence that you relayed the substance of those exhibits to Medicis in the September 2001 timeframe?

MR. ROCHFORD: Object to form, foundation, hearsay.

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SKOLD

A. We spent at least 30 minutes on the phone reviewing the matter which should be enough.

BY MR. JACKSON:

Q. And by that you mean that you should have relayed all of those concepts?

A. Of course.

Q. Did you relay the name of your technology Restoraderm?

A. I did.

MR. ROCHFORD: Object to form, foundation, hearsay.

BY MR. JACKSON:

Q. If we look at what we've labeled Exhibit T2, which is the ~~Cooperative~~ Co-Operation, Development and Licensing Agreement of 2002, and you look at Section -- it's in the exhibit book, page 6, Section 2.1(b), if you would read from the first sentence of 2.1(b)?

A. Upon payment?

Q. Yes.

A. "Upon payment by Collagenex to Skold pursuant to Section 31(d), Skold shall automatically," and I have actually irrevocably underneath crossed out, "assign to Collagenex

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PUBLIC

without any further action then (sic) signing this agreement, the rights granted to Collagenex pursuant to Section 21(a)."

Q. Section 2.1(a).

MR. ROCHFORD: Just my objection on relevance grounds, the document speaks for itself, on this line of questions.

BY MR. JACKSON:

Q. Could you note what you assigned in 2.1(a)? You might see that under little (i), 2.1(a)(i).

A. Subject to terms?

Q. Let's just read the full first sentence until we get to little (i).

MR. ROCHFORD: Same objection.

BY MR. JACKSON:

Q. Just read.

A. It says, "Subject to the terms and conditions of this agreement, Skold hereby grants to Collagenex an exclusive sublicensable, transferable license, including as to Skold (other than for Skold to perform Skold's obligations under this agreement) in the technology, including intellectual property thereto, which is specified

SKOLD

in," whatever it says there, "attached hereto and incorporated by reference..."

Q. That's sufficient.

Were you paid the payment specified under 3.1(d)?

MR. ROCHFORD: Same objection.

A. Yes.

BY MR. JACKSON:

Q. Did you receive back from in this case Galderma the patents that are thereby said to be irrevocably assigned?

A. Yes, I did.

MR. ROCHFORD: Object to the question, move to strike the testimony as the agreements in question -- and there's two that were compressed into one -- in the question speak for themselves, relevance, foundation, competence, calls for a legal conclusion.

BY MR. JACKSON:

Q. You testified that you weren't paid such in invoicing monies when you delivered Restoraderm sample in November, December to Collagenex and in January -- November, December 2001 and in January 2002 to Collagenex at the Caribbean Derm

SKOLD

meeting.

However, you earlier testified, did you not, that you did not believe that you would have been paid the monies that came to you pursuant to the 2002 and 2004 agreements that's Exhibits T3 and T4 had you not sent those samples; is that correct?

MR. ROCHFORD: Objection, lack of foundation, relevance, form of question.

A. Answer?

MR. ROCHFORD: Competence.

BY MR. JACKSON:

Q. Yes, sir.

A. I believe so, and I also believe that if I would have asked for payments for these, I would probably have received them, but I decided to show good faith. And even after the agreement was signed, I probably spent $500,000 on their accounts at the time to move things forward, from my own pocket.

MR. ROCHFORD: Move to strike the response as nonresponsive, speculation.

BY MR. JACKSON:

Q. When we discussed Exhibit T130, your patent in this technology, and some of what may

SKOLD

have been additions, such as examples 7 and particularly Example 6 --

A. Where are you?

Q. Page 441, the smaller book.

A. Okay. Please repeat.

Q. When you discussed Examples 6, 7, 8 and 9, you mentioned that was the work of youngsters. I'm going to particularly focus on the elements that speak of nonionic adjuvants.

Did any recitations of nonionic adjuvants end up in the claims?

A. No. I could add also the girl in question, her name is ~~Lorisa Rinkstad~~ Lovisa Ringstad.

Q. You were saying something about your colleague, and I lost track.

A. Lorisa Rinkstad, I wanted to mention most of this work, if not all of her work, was a subject for her Ph.D.

Q. That closes the record, I believe.

MR. ROCHFORD: I have nothing further at this time.

(Whereupon, at 3:22 p.m., the taking of the instant deposition ceased.)

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STATE OF N/A)
) :ss
COUNTY OF N/A)

I, THOMAS SKOLD, the witness herein, having read the foregoing testimony of the pages of this deposition, do hereby certify it to be a true and correct transcript, subject to the corrections~~, if any, shown on the attached page~~. clearly marked above the original testimony set forth in the above pages and, for each insertion or substitution, initialed ("TS") by me TS TS

THOMAS SKOLD

Sworn and subscribed to before me, this 13th day of December 2013, 2013.

Notary Public
Ann-Kristin Eklöf

NOTARIUS PUBLICUS SWEDEN

PUBLIC

1

2 COMMONWEALTH OF PENNSYLVANIA)

3 COUNTY OF DAUPHIN) SS:

4 C E R T I F I C A T E

5 I, Ann Medis, Registered Professional

6 Reporter, Certified Livenote Reporter and Notary

7 Public within and for the Commonwealth of

8 Pennsylvania, do hereby certify:

9 That THOMAS SKOLD, the witness whose

10 deposition is hereinbefore set forth, was duly

11 sworn by me and that such deposition is a true

12 record of the testimony given by such witness.

13 I further certify the inspection,

14 reading and signing of said deposition were not

15 waived by counsel for the respective parties and

16 by the witness.

17 I further certify that I am not related

18 to any of the parties to this action by blood or

19 marriage and that I am in no way interested in the

20 outcome of this matter.

21 IN WITNESS WHEREOF, I have hereunto set

22 my hand this 21st day of November, 2013.

23

24 _____

25 Notary Public

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the Matter of Registration Nos. 2985751; and 3394514

Dated: August 16, 2005 & March 11, 2008, Respectively

Thomas Sköld, Petitioner v. Galderma Laboratories, Inc., Registrant	)	Cancellation No. 92052897

NOTICE OF FILING SKÖLD DEPOSITION EXHIBITS

Pursuant to 37 CFR 1.123(h), Petitioner herewith files true copies of the exhibits introduced in the Deposition of Thomas Sköld, taken 13 November 2013. The exhibits filed herewith are those checked in the tables below. Given the varying designations of the documents, it is anticipated that a number of electronic filings will be necessary.

TRADE SECRET/COMMERCIALLY SENSITIVE EXHIBITS[1]

G	☐	T132	☐	T145	☐
T126	☐	T133	☐		

CONFIDENTIAL EXHIBITS[1]

E	☐	T146	☐
F	☐		
T2	☐		
T3	☐		
T6	☐		
T11	☐		
T12	☐		
T61	☐		
T74	☐		

[1] Sent to Registrant's counsel by mail under separate cover.

PUBLIC DOCUMENTS EXHIBITS[2]

A	☒	T12	☒	T126	☒
B	☒	T15	☒	T130	☒
C	☒	T27	☒	T132	☒
D	☒	T58	☒	T133	☒
E	☒	T59	☒	T143	☒
F	☒	T61	☒	T145	☒
G	☒	T69	☒	T146	☒
T1	☒	T70	☒	T147	☒
T2	☒	T71	☒		
T3	☒	T73	☒		
T6	☒	T74	☒		
T7	☒	T125	☒		

Respectfully submitted,

Date: July 2, 2014

By: /Arthur E. Jackson/

Arthur E. Jackson, Esq.
New Jersey Bar No. 00288-1995
ajackson@mtiplaw.com
MOSER TABOADA
1030 Broad Street, Suite 203
Shrewsbury, NJ 07702
(732) 935-7100
(732) 935-7122
Attorney for Petitioner

[2] Sent to Registrant's counsel by e-mail.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Thomas Sköld,	)	
Petitioner,	)	
	)	
v.	)	
	)	Cancellation No. 92052897
Galderma Laboratories, Inc.,	)	
Registrant	)	
	)	

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Notice of Filing Sköld Deposition Exhibits and the documents referred to therein were sent by email or U.S. Mail (as referenced above) on this 2nd day of July, 2014 to:

Jeff Becker, Esq.
Haynes and Boone, LLP
2323 Victory Avenue - Suite 700
Dallas, TX 75219
jeff.becker@haynesboone.com

/Arthur E. Jackson/
Arthur E. Jackson

~~TRADE SECRET/COMMERCIALLY SENSITIVE~~

From: Willis, Joe [NEUUS] [mailto:JWillis8@NEUUS.JNJ.com]
Sent: den 13 januari 2008 03:41
To: Thomas Sköld
Subject: RE: Derm delivery system

Public

Dear Thomas,

No need to come to San Antonio just for me. How about the next dermatology meeting you plan to attend? You mentioned the Caribbean derm, but I am guessing you do not live in the US. Where are you located? With that understanding, we may be able to meet at a time that is more compatible for the both of us.

Thanks,
Joe

-----Original Message-----
From: Thomas Sköld [mailto:thomas-skold@telia.com]
Sent: Saturday, January 12, 2008 3:33 AM
To: Willis, Joe [NEUUS]
Cc: 'Physicians Skin Care'
Subject: SV: Derm delivery system

Dear Joe,

I didn't plan on going but if there is a sincere interest in discussing with me, I will be there for sure. In regards to Peter's IP there are similarities but no conflict. The ratio between the lipids and the fact that you don't need a surfactant in my system makes them different. However the major difference is that my system includes solid lipid particles surrounded by a monolayer (phopholipids, ceramides and cholesterol), vesicles with a bilayer (phopholipids, ceramides, fatty acid and cholesterol) and finally gas spheres with a monolayer (phopholipids, ceramides, fatty acid and cholesterol). These three structures diffuse them self through the stratum corneum differently. With a better understanding of that fact one can tailor make the final product in a way that so far has been impossible.
I was fortune enough to be working with Professor Bo Forslind (Karolinska Institute) for a number of years before he deceased. Bo pioneered in the early 1970 conducting research on the stratum corneum lipids. Later on Peter did some work with Bo and thereafter stayed in this field of research.

What is kind of interesting is that on September 11th 2001 I was scheduled to present my early findings of my development efforts for your people in your New Jersey office. On my way in to your office the first aircraft hit one of the towers and the presentation got cancelled (even though I stayed watching it all on TV in your cafeteria for the entire day). Since I was stuck in the US for about a week I spent time with a friend of mine that became the VP of Dermatology for Collagenex and that is why it ended up with them and not Ortho (at that time at least)!
In terms of Rx developments there are some 8 formulations that have past 6 months accelerated stability. Due to, among other things, lack of resources no NDA has been filed to date which for me have been extremely frustrating. I would argue that some of these could potentially be very interesting products but there are also other opportunities out there that should be looked at as well.

If possible I would like us to have a more confidential discussion in San Antonio, so that you get all the important information you need to enable you to understand if this is something that Ortho would benefit from, which I'm fairly confident that you would. Let me know what you need to take us to this level of interest.

With kind regards,
Thomas

Från: Willis, Joe [NEUUS] [mailto:JWillis8@NEUUS.JNJ.com]
Skickat: den 11 januari 2008 18:30
Till: Thomas Sköld

EXHIBIT
Cancellation
92052897
Skold v Galderma
PENGAD 800-631-6989

EXHIBIT
A
Galderma
PENGAD 800-631-6989

Kopia: Physicians Skin Care
Ämne: RE: Derm delivery system

TRADE SECRET/COMMERCIALLY SENSITI

Public

Dear Thomas,

Thanks for the introduction and information. Perhaps we can meet at the American Academy of Dermatology and have a non-confidential conversation? I appreciate what you have shared, one point of confusion – I am under the impression that Peter Elias, holds IP as it relates to the composition you describe, is there a conflict? Separately, I would like to get a better understanding of the plans for development from an Rx perspective.

Would you be attending the AAD in San Antonio and have availability?

Best,
Joe

-----Original Message-----
From: Thomas Sköld [mailto:thomas-skold@telia.com]
Sent: Tuesday, January 08, 2008 8:44 AM
To: Willis, Joe [NEUUS]
Cc: 'Physicians Skin Care'
Subject: Derm delivery system

Dear Joe,

Let me briefly introduce my self. My name is Thomas Sköld from Stockholm Sweden and I have been working on lipid drug delivery systems since 1994. The first 6 years as the CEO of a small (20 people) drug delivery company. We were pioneers in the foam delivery business and our company got sold some years ago. In 2002 I filed a provisional patent application on a new invention of mine based on phospholipids, ceramides, cholesterol and fatty acid in a three structure matrix system. The system can hold both water soluble actives as well as fat soluble actives and can be formulated as a lotion, cream, ointment or foam product. Very flexible and very delivery efficient! In 2002 I out licensed the technology to a US Company where one of my friends was the VP of dermatology. In 2004/2005 they had a management shift and our relationship started to fall apart due to, among other things, lack of effort in the clinical arena from the new management. I'm now re-claiming the technology after some 15 formulations in total. None of the Rx products however have been in clinical trails which is why I had to make this decision. The IP should get issued some time later on this year if everything goes as planed and I feel therefore that it is important that I find a new holder of the technology as quickly as possible.
The last two years I have been focusing on transmucosal delivery looking mostly at intra nasal delivery (together with people from Suny Stony Brook on Long Island) but I see now that I have go back in to dermatology. At least for a while until this situation is fully resolved (I never really left).
I'm right now on my way to St Thomas where the Carib Derm meeting will be held next week. During the time I will be in the Caribbean I'm reachable through both e-mails and cell phone (+46 70 6600040).

Let me know if you would be interested to understand more about this opportunity.

With kind regards,
Thomas Skold

Från: Physicians Skin Care [mailto:wedoderm@bellsouth.net]
Skickat: den 8 januari 2008 16:23
Till: joe willis; Thomas Sköld
Ämne: Re:

Joe and Thomas

I discussed with both of you and with your permission ,I am sending this email to both of you as an introduction

Good Luck

Leon
-----Original Message-----

~~TRADE SECRET/COMMERCIALLY SENSITIVI~~

Public

Thanks Leon

Från: Physicians Skin Care [mailto:wedoderm@bellsouth.net]
Skickat: den 8 januari 2008 01:24
Till: Thomas Sköld
Ämne: Re:

His name is Joe Willis and he is the VP of Orth Neutogena which is a J&J company I did not give any information except that there is a vehicle for sale that is it so I will send another e mail to both of you for introductions

leon

----- Original Message -----
From: Thomas Sköld
To: 'Physicians Skin Care'
Sent: Monday, January 07, 2008 5:20 PM
Subject: SV:

And happy New Year to you too!

I would love to talk to them and e-mail is a good start. I would appreciate if you could give me some feed back on the person in question and what kind of info you have given them. Anne and I have started packing for St Thomas and we are leaving already on Saturday (I will of course bring my computer) for St Martin.

All the best,
Thomas

Från: Physicians Skin Care [mailto:wedoderm@bellsouth.net]
Skickat: den 7 januari 2008 20:03
Till: Thomas Sköld
Ämne:

Happy New Year

I found sombody at J&j Ortho Neutrogena that may be interested
do you want to communicate with him via email

leon

COLLAGENEX
pharmaceuticals

12th December 2001

Thomas Skold,
Bjørnogård,
S – 761 41 Norrtalge,
Sweden.

Dear Mr. Skold,

LETTER OF INTENT

Further to various discussions and meetings between yourself; Robert Ashley and Jeffrey Day of CollaGenex Pharmaceuticals, Inc. and David Pettit of CollaGenex International Limited (collectively "CollaGenex"), the purpose of this Letter of Intent, which is Subject to Contract and, where applicable, to Due Diligence on planned intellectual property, is to set out the initial understanding of both sides for a future agreement or agreements between you and CollaGenex and/or a company owned and controlled by CollaGenex.

BACKGROUND

CollaGenex has established a dermatology products franchise in the USA which is being expanded internationally and CollaGenex has expressed an interest in the acquisition and development of new drug delivery technologies and products for this franchise. You have invented and are developing a new topical drug delivery system which is capable of being patented in major jurisdictions (USA, Europe and Japan) without infringing the patent rights of third parties and you are prepared to assign the patent applications to CollaGenex and to undertake the formulation and stability work required to develop a base delivery vehicle capable of being marketed in its own right and to be further developed to provide stable formulations containing active substances for the treatment of dermatological conditions. These active substances are to be determined by CollaGenex.

INTELLECTUAL PROPERTY

Whilst no formal applications for patents have been made and your patent attorneys are still undertaking the necessary searches, you anticipate that patent applications will be made, in your name, by the end of February 2002 and you agree that once an agreement or agreements have been reached between you and CollaGenex that those patent applications, which will be subject to Due Diligence by CollaGenex's own patent attorneys, will be assigned to CollaGenex. It is also agreed that in the event of the Due Diligence establishing irresolvable deficiencies in the patent applications; or an opinion that patents would be unlikely to issue or that the patents applied for would appear to infringe the patent rights of third parties not associated with you or CollaGenex; that any agreement between you and CollaGenex, whether or not then executed, would become null and void and that no further claims as to development or any other costs could be made by you or any third party upon CollaGenex.

CollaGenex Pharmaceuticals, Inc., 41 University Drive, Suite 200, Newtown, PA 18940 USA
215-579-7388 voice 215-579-8577 fax

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PENGAD 800-631-6989 EXHIBIT B Galderma

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All trade marks associated with the drug delivery system; the proposed intellectual property; products deriving therefrom and products marketed or to be marketed by CollaGenex and/or any commercial partner of CollaGenex anywhere in the world shall be applied for and registered in the name of CollaGenex and be the exclusive property of CollaGenex.

CONSULTING AGREEMENT

CollaGenex has agreed with you that concurrent but independent of any agreement(s) associated with the drug delivery technology and the resulting intellectual property, it will wish to enter into a consulting agreement with you. Such an agreement is likely to reflect a potential "roving ambassador" role and is likely to be direct with the CollaGenex in the USA and not with a European based CollaGenex company.

DRUG DELIVERY TECHNOLOGY – FORMULATION & DEVELOPMENT

It is agreed between us that the development of a stable formulation of the drug technology is key to both sides going forward and that such formulation should be cosmetically acceptable; capable of gaining intellectual property protection both itself and in combination with active substances that do not infringe the intellectual property rights of others and capable of achieving stable formulations with active substances that will then be subject to ensuing intellectual property. This base product or "vehicle" should be developed and placed on stability between December 2001 and February 2002 and its formulation will form the basis of the patent applications which are likely to be filed in February 2002. The "vehicle " will be subjected to three months accelerated stability always bearing in mind that real time stability time points will be required for regulatory purposes in the future.

REGULATORY APPLICATIONS

Regulatory applications for marketing authorisations for the vehicle and products containing an active substance will be applied for by, and held in the name of, CollaGenex.

This letter of intent is subject to the execution of appropriate agreements between you and CollaGenex and is provided to set out the initial understandings of both sides. It would be appreciated if you could countersign the enclosed duplicate copy of this letter as your acceptance of its terms.

Yours sincerely,

ROBERT A. ASHLEY
Senior Vice President

ACCEPTED AND AGREED

Signed.....(Thomas Skold)

Date.....10-12-2001

~~CONFIDENTIAL~~

Public

Arthur Jackson

210

From: Rob Ashley [rashley@collagenex.com]
Sent: Wednesday, May 01, 2002 9:48 AM
To: Thomas Sköld
Subject: RE: Visit to ATS

Thomas,
Its not Atrix its ATS! I think they will go for an OTC "skin rejuvenation" type claim in the first instance. All we provide is the more elegant vehicle. As with Melanotan, maybe the liposomal formulations will be more attractive.
Any interim stability data? I notice hte little bottle of cream I brought home separated then got infected. I'm growing an interesting bacterial colony on my desk at the moment!!
Rob

-----Original Message-----
From: Thomas Sköld [mailto:thomas-skold@swipnet.se]
Sent: Wednesday, May 01, 2002 9:32 AM
To: 'Robert A. Ashley'
Subject: RE: Visit to ATS

Hi again,
Sounds good! So they are interested after all. Do we know what specific product (indication) would Atrix be interested in?
So you know, we hope to get more Restoraderm chemicals in the end of next week. We will then start with the neutral version and go on to the lidocain formulations. Everything is done on paper we just need to verify it in the lab. Mats Silvander is up to date with the Melanotan substance. I will have a meeting with Mats early next week.

Hope to see you in Sweden soon.

Regards,
Thomas

-----Original Message-----
From: Robert A. Ashley [mailto:rashley@collagenex.com]
Sent: Wednesday, May 01, 2002 2:49 AM
To: 'Don Rindell'
Cc: 'Brian Gallagher'; 'Michael Romanowicz'; thomas-skold@swipnet.se
Subject: RE: Visit to ATS

Dear Don,
My apologies for not following up diligently on these issues.
With respect to Atrix, I will drop an e-mail to Dr Steve Garrett at Atrix and introduce the concept.
With respect to Restoraderm the stability testing of the base formulations is progressing well. We have 4 different formulations on stability. Meanwhile we are building the intellectual infrastructure around the world to develop the technology into products. 3 months stability will be up in mid June at which time we can be confident that the formulations are marketable. In the meantime we can send you samples of the final formulations if this will help you determine their acceptability or otherwise. We need a Material Transfer Agreement in place to be able to do this. I'll get something going tomorrow on that front.
Finally with respect to Dermagraft, we are currently focusing our efforts on Periostat and our forays into dermatology. Given that, I don't think that we would be able to devote the significant selling effort to Dermagraft which would be required to be successful. If the situation changes, we would be happy to reconsider.
Best regards,
Rob Ashley

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-----Original Message-----
From: Don Rindell [mailto:Don.Rindell@advancedtissue.com]
Sent: Tuesday, April 30, 2002 10:36 AM
To: 'Rob Ashley'
Cc: 'Brian Gallagher'; 'Mike Romanowicz'; Mark Gergen
Subject: RE: Visit to ATS

PENGAD 800-631-6989 EXHIBIT C Galdeima

Dear Rob:

There were a few action items coming out of our San Diego meeting, and I would appreciate your response as to how you would like to proceed.

- Setting up a meeting a between Atrix and ATS to introduce NouriCel (Conditioned Medica) as a potential new combination product
- ATS interest in testing NouriCel with Collagenex's new delivery platform
- Continued communication regarding the future marketing of Dermagraft to the Periodontal market segment

I look forward to hearing from you.

Best regards
Don

-----Original Message-----
From: Don Rindell
Sent: Thursday, March 21, 2002 2:54 PM
To: 'Rob Ashley'
Cc: Brian Gallagher; Mike Romanowicz
Subject: RE: Visit to ATS

Dear Rob

Just a quick note to thank you and Brian for taking the time to visit ATS during your recent stay in San Diego. We were impressed with the progress Collagenex has made in securing a solid position in the dental and periodontal market place. We were also intrigued with the multiple areas of potential collaboration between our companies and look forward to future discussions.

As a follow-up to our meeting, we agreed that a good next step would be to meet with Atrix Labs exploring the development of an ATRISORB / NouriCel product. Please let me know how we can best proceed in setting up that meeting.

Best regards
Don

WATER-BASED TOPICAL DELIVERY SYSTEM

Field of the Invention

The present invention relates to a novel topical delivery system for drugs or any other active substance, formulated for good penetration without disturbing the skin barrier function, as is the case with prior art formulations. With most active substances, the delivery system of the invention will even enhance the skin barrier restoration in the stratum corneum.

Background of the invention

The main demand on the human skin is to prevent loss of water and in addition to prevent water and other matter from the environment from entering the body indiscriminatedly. The human skin thus forms a selectively permissible physical barrier between the human body and its surroundings.

The barrier function has been shown to reside in the stratum corneum, which is the topmost layer of the skin, and is built of corneocytes, cells that contain extensively cross-linked proteins, surrounded by a highly resistant cell envelope. The corneocytes are embedded in a bed of specific lipid structures, long chain lipids, which are organised as bilamellar structures stacked on top of each other and filling the intercellular spaces between the corneocytes.

To account for such barrier properties, and for the selective hydrophilic and hydrophobic pathways that exist through it, the skin has been described as a mosaic barrier model. This model envisages the barrier lipids to exist predominantly in crystalline (gel) form, and therefore to be water impermeable domains surrounded by so called grain borders of lipids in a liquid crystalline state. This arrangement provides an effective, water tight barrier that still allows a minute but controlled loss of water through the liquid crystalline interdomains. This controlled water loss is enough to keep the keratin of the stratum corneum hydrated. The liquid character of the interdomain grain borders will allow passage of hydrophilic and hydrophobic molecules on down-hill gradients. It is in these interdomain regions that permeation enhancers may induce

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structural transformations of the bilamellar structure and thus promote transdermal delivery of e.g. pharmacological substances.

Typical dermal delivery systems have an alcohol or petroleum base, with little consideration given to the biological properties of the vehicle itself. For example, emulsified fatty acids can inherit certain detergent properties if their structure is significantly altered from those in the normal skin. The detergent properties can lead to disruption of the normal barrier function, which is counteractive to the potential benefit of the vehicle technology. The result is often that the stratum corneum loses its natural potential to function properly as a barrier and the skin gets either too dry or too permeable for environmental substances.

Other conventional delivery systems that are also thought to protect the skin from harmful substances are barrier ointments. The purpose of these is to provide a film and thereby create a layer which is impermeable to environmental substances. Due to the impermeability, though, they will both increase the body temperature of the treated body part, as well as prevent perspiration, and thus render a most uncomfortable sensation.

U.S. Patent No.: 5,993,830 describes a skin preparation comprising both lipophilic (stearic acid) as well as hydrophilic components characterised by being capable of creating a semipermeable membrane in the skin, and which can be used as a carrier for various substances.

However, none of the preparations described above is able to provide a topical delivery system that is formulated to sufficiently deliver a substance to, or through, the human skin without permanently disrupting the stratum corneum's natural barrier function.

Summary

A water-based topical delivery system for an active substance, characterised by enhancing skin barrier restoration in the stratum corneum comprising: water, a fatty acid, cholesterol, a ceramide, and skin lipid precursors is provided.

Detailed Description of Invention

The present invention provides a new and improved topical delivery system, formulated to deliver a substance to, or through, the human skin without permanently disrupting the stratum corneum's natural barrier function and additionally to provide unique skin barrier restoration properties.

All percentages given in the present application are indicated in percent by weight. All numbers are approximate.

The topical delivery system of the present invention is a water-based formulation. The delivery system comprises lipids similar to those which make up the normal stratum corneum, such as fatty acids, cholesterol and ceramides. The fatty acids are preferably C16-24, e.g. palmitic acid.

The topical system of the present invention is further characterised by comprising skin lipid precursors. The preferred lipid precursors are mevalonic acid which promotes *in situ* cholesterol synthesis, and 25 hydroxycholecalciferol which promotes *in situ* ceramide synthesis in the skin. By said promotion of *in situ* cholesterol and ceramide synthesis in the skin, the overall content of lipid in the system can be maintained in a range as low as 2-20%. Therefore, the water content can be as high as 80-98%. The high water content enables the skin to "breathe" normally, and enhances its ability to restore its normal barrier function rapidly.

Other lipid precursors used in the present invention include, for example:

deoxyacetein cimifugoside, adapalene, adenosine, aloe derived lectins, 3-aminopropyl dihydrogen phosphate, anise extracts, ascorbic acid and derivatives thereof, ascorbyl palmitate, Asiatic acid, benzoic acid derivatives, biotin, butanoyl betulinic acid, cathecholamines, coenzyme Q10, dehydrocholesterol, dehydroascorbic acid and derivatives thereof, estrogen and derivatives, eythrobic acid, genistein, lipoic acid, 4-methoxy salicylic acid, N-acetyl cysteine, panthetine, pregnenolone and derivatives, retinal, retinoates, retinal, retinyl acetate, retinyl glucuronate, retinyl linoleate, retinyl palmitate, retinyl proprionate, phytosphingosine, sphingosine, and others.

In one embodiment, along with the lipid precursors, interleukin can be added.

In a preferred embodiment, the formulation does not contain any irritating ingredients, i.e. ethanol. Preferably, the formulation contains less than 10% of ethanol, more preferably less than 5% of ethanol, most preferably less than 1% of ethanol, and optimally no ethanol.

The topical delivery system of the present invention is designed, in its choice and composition of lipids, to resemble the normal lipid organisation of the stratum corneum, as much as possible. Thus the administered formulation will easily penetrate the lipid bilayer of the skin and in doing so carry with it the active substances to be administered.

Without the intention to limit the scope of the invention, a possible theory explaining the herein mechanical properties of the topical delivery system is that the administered formulation will easily penetrate the lipid bilayer of the skin and in doing so create a temporary and reversible state of enhanced atrophy among the lipid components of the bilayer. The enhanced atrophy in itself should then give rise to either a) enhanced energy levels, wherein said energy could promote active transport of the to-be-carried substances into the skin, and/or b) create naturally and reversibly occurring holes and disorganised patches in the lipid bilayer, through which the active substances could then pass more easily. It is very well feasible that the temporary disarray in the lipid bilayer will temporarily break up the organised structure of the bilayer and create micelles of lipids with areas between them/surrounding them through which lipophobic/hydrophilic substances and/or compositions can enter through the stratum corneum. As the lipid composition of the formulation resembles the natural lipid composition of the skin, the so introduced new lipids will after a short time of creative chaos easily blend in with the natural lipid building stones of the lipid bilayer and thus not permanently damage the barrier function of the skin.

In one embodiment, the topical delivery system of the present invention is designed to enhance the penetration of active substances into and/or through the stratum corneum. Whereas in prior art formulations the penetration arises due to disruption of the natural barrier which concomitantly leads to physiological consequences, the formulation

of the present invention is designed to enhance penetration while leaving the normal barrier of the stratum corneum intact and/or even functionally enhanced. This effect is achieved by careful selection of the lipids of the vehicle, which blend with the lipids naturally present in the horny layer and the enhancing effect of the added skin lipid precursor on cholesterol synthesis. Thus administration of the presently described skin delivery system will result in a temporary and reversible disruption of the stratum corneum and enhanced penetration, followed by a rapid return to normal barrier function of the skin.

In a preferred embodiment of the present invention, the skin delivery system of the present invention is designed, in its choice and composition of lipids, to resemble the normal lipid organisation of the stratum corneum, as much as possible. Thus the administered formulation will easily penetrate the lipid bilayer of the skin and in doing so carry with it an active substance to be administered. Temporarily, a reversible state of enhanced atrophy is herein believed to be created among the lipid components of the bilayer, which promotes the active transport of the to-be-carried substances into the skin.

In another possible, not limiting explanation, reversibly occurring holes and disorganised patches are created in the lipid bilayer by administering the formulation related to in the present invention, through which the active substances can pass more easily. The temporary disarray in the lipid bilayer will herein temporarily break up the organised structure of the bilayer and create micelles of lipids with areas between them/surrounding them through which lipophobic/hydrophilic substances and/or compositions can enter through the stratum corneum. As the lipid composition of the formulation resembles the natural lipid composition of the skin, the so introduced new lipids will blend in with the natural lipid building stones of the lipid bilayer and thus not permanently damage the barrier function of the skin.

The present invention relates to a water-based dermal delivery system for topical administration of an active substance, characterised by enhancing skin barrier restoration in the stratum corneum. Said delivery system is characterised by comprising a fatty acid, cholesterol, a ceramide, and skin lipid precursors. The preferred amounts of these

components are as follows: Fatty Acid: 0.5-10%; cholesterol: 0.5-10%; lipid precursors: 0.000001-10%; and ceramide: 0.005-20%. Up to 15% of ceramide can be replaced with phospholipids.

In a preferred embodiment, the fatty acids comprise fourteen, sixteen, eighteen, twenty, twenty-two or twenty-four carbon atoms, or any mixtures thereof.

In a preferred embodiment, the delivery system of the present invention comprises a water content exceeding 50%, such as more than 55%, 60%, 65%, 70%, 75%, 76%, 77%, 78%, 79% or 80%. Most preferably, the water content will be between 60-80%, such as between 70-80%.

In another preferred embodiment, the delivery system will comprise a combined content of a fatty acid, cholesterol, a ceramide, and skin lipid precursors between about 2-20%, such as between about 5-20%, 5-15%, or 6-13%. In a first aspect thereof, the present invention relates to a skin delivery system prepared from lipophilic as well as hydrophilic components. In one preferred embodiment, the lipophilic components are chosen among fatty acids with fourteen, sixteen, eighteen, twenty, twenty-two and twenty-four carbon atoms or any mixtures thereof.

In another preferred embodiment, the skin preparation according to the present invention is prepared from a mixture of fatty acids of the following composition: at most about 2% of a component comprising a chain of fourteen carbon atoms, between about 47 and about 52% of a component comprising a chain of 16 carbon atoms, between about 43 and about 48% of a component comprising a chain of 18 carbon atoms and at most about 1% of a component comprising a chain of twenty carbon atoms.

In one alternative embodiment, said fatty acid comprising a chain of fourteen to twenty carbon atoms, or said mixture of such fatty acids, may be of any other composition, for example containing an essential portion of myristic acid, such as about 90% myristic acid or an essential portion of palmitic acid, such as about 90% palmitic acid. Thus, in the present context "a fatty acid comprising a chain of fourteen to twenty carbon atoms, or a mixture of such fatty acids", refers to any suitable mixture of higher

fatty acids. However, a predominant portion of a fatty acid comprising a chain of 18 carbon atoms is most preferred.

The most preferred embodiment of the skin preparation according to the present invention is prepared from a ratio between a fatty acid mixture, having the above defined preferred composition, and triethanolamine which is higher than about 2:1, preferably higher than about 3:1. Other advantageous embodiments of the skin preparation according to the present invention are prepared from the same ratio between any equivalent lipophilic component and triethanolamine.

It has been shown to be advantageous to adapt the ratio between the primary lipophilic components, i.e. the fatty acid comprising a chain of 14 to 20 carbon atoms or the mixture of such fatty acids, preferably of the above defined composition, and triethanolamine to enable a certain portion of the acid in the final skin preparation to form a salt with the triethanolamine, while another portion exists as free fatty acid.

Preferably, alkali compounds are included in the formulation to adjust the pH and viscosity. Examples of such alkali compounds include sodium hydroxide and sodium chloride. Preferably, sodium hydroxide is used to adjust the pH, and sodium chloride is used to adjust the viscosity.

The preferred ratio between the lipids is 2:1:1 (e.g., phospholipids/ceramide, cholesterol and fatty acid).

A delivery system according to the present invention preferably comprises a combination of:

Fatty Acid (C16-24)	0.5-10 wt%
Phospholipid	0.5-10 wt%
Cholesterol	0.5-7 wt%
Lipid precursor: Mevalonic acid 25-Hydroxycholecalciferol	0.000001-10 wt%

Ceramide	0.005% -7 wt%

Another preferred embodiment of the delivery system comprises:

Fatty Acid (C16-24)	0.5-10 wt%
Phospholipid	0.5-10 wt%
Cholesterol	0.5-7 wt%
Lipid precursor: Mevalonic acid 25-Hydroxycholecalciferol	0.000001-10 wt%
Ceramide	0.005% -7 wt%
Glycerine	0-5 wt%
Propylene glycol	0-48 wt%
PVP (M weight 40,000)	0-5 wt%
TEA	0-3 wt%

An even more preferred embodiment of the delivery system comprises:

Fatty Acid (C16-24)	2 wt%
Phospholipid	4.5 wt%
Cholesterol	2 wt%
Lipid precursor: Mevalonic acid 25-Hydroxycholecalciferol	0.000001-10 wt% 1% 0.015%
Ceramide 3	0.015 wt%
Glycerine	3 wt%
Propylene glycol	4 wt%
PVP (M weight 40.000)	2 wt%
TEA	0.5 wt%

An even more preferred embodiment of the delivery system comprises :

Fatty Acid (C16-24)	2 wt%
Phospholipid	4.5 wt%

Cholesterol	2 wt%
Lipid precursor: Mevalonic acid 25-Hydroxycholecalciferol	0.000001-10 wt% 1% 0.015%
Ceramide 3	0.015 wt%
Glycerine	3 wt%
Propylene glycol	4 wt%
PVP (M weight 40.000)	2 wt%
TEA	0.5 wt%
Ceramide 1	0.025%

The ceramide component comprised in the present delivery system is selected from the group comprising ceramides, pseudo ceramides, and neo ceramides, such as ceramide 1-7, and/or mixtures thereof. Further ceramide precursors, such as palmitoyl CoA, and serine which together are converted to 3-ketosphinganane are also comprised.

Some examples of ceramides include:

Ceramide 1 , ceramide 4, ceramide 5, ceramide 6A, cerebrosides or ceramide 6B.

Some examples of pseudoceramides include:

N-(2-hydroxyoctadecyl)-N-(2-hydroxyethyl)hexadecanamide

N-(2-hydroxyoctadecyl)-N-(2-hydroxyethyl)propanamide

N-(2-hydroxyhexadecyl)-N-(2-hydroxyethyl)butanamide

N-(2-hydroxyhexadecyl)-N-(2-hydroxyethyl)heptanamide

N-(2-hydroxyoctadecyl)-N-(2-hydroxyethyl)ethanamide

N-(2-hydroxyoctadecyl)-N-(2-O-glucopyranosyl)ethylpentanamide

N-(2-hydroxydodecyl)-N-(2-hydroxyethyl)hexanamide

N-(2-hydroxydodecyl)-N-(2-hydroxyethyl)-2butylhexanamide

N-(2-hydroxyhexadecyl)-N-(2-hydroxyethyl)ethanamide

N-(2-hydroxydodecyl)-N-(2-hydroxyethyl)-2-hydroxyhexanamide

N-(2-hydroxytetraadecyl)-N-(2-hydroxyethyl)propanamide

N-(2-hydroxyhexadecyl)-N-(2-sulfoethyl)hexadecanamide

N-(2-hydroxyoctadecyl)-N-(2-phosphoethyl)butanamide

N-(2-hydroxyoctadecyl)-N-(2-hydroxyethyl)-2-hydroxypropanamide

N-(2-hydroxy-3-octadecyloxypropyl)-N-(2-hydroxyethyl)hexadecanamide

N-(2-hydroxy-3-nonanyloxypropyl)-N-(2-hydroxyethyl)propanamide

N-(2-hydroxyoctadecyl)-N-(2-hydroxyethyl)-2-hydroxypropanamide

N-(2-hydroxy-3-hexadecyloxypropyl)-N-(2-hydroxyethyl)hexadecanamide

N-(2-hydroxy-3-octadecyloxypropyl)-N-(2-hydroxyethyl)butanamide

N-(2-hydroxy-3-hexadecyloxypropyl)-N-(2-hydroxyethyl)ethanamide

N-(2-hydroxy-3-dodecyloxypropyl)-N-(2-sulfohydroxyethyl)decanamide

N-(2-hydroxy-3-decyloxypropyl)-N-(2-hydroxyethyl)hexanamide

N-(2-hydroxy-3-octadecyloxypropyl)-N-(2-hydroxyethyl)hexadecanamide

N-(2-hydroxy-3-dodecyloxypropyl)-N-(2-hydroxyethyl)butanamide

N-(2-hydroxy-3-octadecyloxypropyl)-N-(2-hydroxyethyl)co-o-linoleoyldocosanamide

N-(2-hydroxy-3-dodecyloxypropyl)-N-(2-hydroxyethyl)propanamide

N-(2-hydroxy-3-hexadecyloxypropyl)-N-(2-hydroxyethyl)-2-methylpropanamide

N-(2-hydroxy-3-tetraadecyloxypropyl)-N-(2-hydroxyethyl)ethanamide

N-(2-hydroxy-3-dodecyloxypropyl)-N-(2-hydroxyethyl)heptanamide

N-(2-hydroxy-3-hexadecyloxypropyl)-N-(2-phosphoethyl)hexadecanamide

N-(2-hydroxy-3-dodecyloxypropyl)-N-(2-hydroxyethyl)propanamide

N-(2-hydroxy-3-octadecyloxypropyl)-N-(2-)-glucopyranosyl)ethyl-2-hydroxypropanamide

N-(2-hydroxy-3-octyloxypropyl)-N-(2-hydroxyethyl)pentanamide

Some examples of neoceramides include:

N-(2, 3-dihydroxypropyl)-N-(hexadecyl)butanamide

N-(2, 3-dihydroxypropyl)-N-(tetradecyl)ethanamide

N-(2, 3-dihydroxypropyl)-N-(hexadecyl)-2-hydroxypropanamide

N-(2, 3-dihydroxypropyl)-N-(octadecyl)butanamide

N-(2, 3-dihydroxypropyl)-N-(2-ethylhexadecyl)hexanamide

N-(2, 3-dihydroxypropyl)-N-(hexadecyl)-2-hydroxyoctanamide

N-(2,3-dihydroxypropyl)-N-(3-methylhexadecyl)ethanamide

N-(2,3-dihydroxypropyl)-N-(dodecyl)butanamide

N-(2, 3-dihydroxypropyl)-N-(hexadecyl)-2-hydroxyhexanamide

N-(2-hydroxy-3-O-glucopyranosylpropyl)-N-(hexadecyl)octanamide

N-(2-hydroxy-3-phosphopropyl)-N-(octadecyl)ethanamide

N-(2-hydroxy-3-sulfopropyl)-N-(hexadecyl)butanamide

N-(2-hydroxy-3-O-glucopyranosylpropyl)-N-(hexadecyl)decanamide

N-(2, 3-dihydroxypropyl)-N-(heptadecyl)ethanamide

N-(2, 3-dihydroxypropyl)-N-(3-methylhexadecyl)ethanamide

N-(2,3-dihydroxypropyl)-N-(heptadecyl)butanamide

N-(2,3-dihydroxypropyl)-N-(6-dodecenyl)hexadecan-amide

N-(2,3-dihydroxypropyl)-N-(2-methylhexadecyl)-2-hydroxy-ethanamide

N-(2,3-dihydroxypropyl)-N-(octadecyl)2-hydroxypropan-amide

N-(2-hydroxy-3-O-glucopyranosylpropyl)-N-(heptadecyl)-ethanamide

N-(2-hydroxy-3-sulfopropyl)-N-(dodecyl)heptanamide

N-(2,3-dihydroxypropyl)-N-(tetradecyl)-4-hydroxybutan-amide

N-(2,3-dihydroxypropyl)-N-(octadecyl)-(t)-O-linoleoyl-docosanamide

N-(2,3-dihydroxypropyl)-N-(linoleyl)ethanamide

N-(2,3-dihydroxypropyl)-N-(oleyl)-2-hydroxy-heptan-amide

N-(2,3-dihydroxypropyl)-N-iyiodecyl)-(t)-O-linoleoyldocosanamide

N-(2,3-dihydroxypropyl)-N-(octadecyl)-3-hyrdoxybutanamide

N-(2-phospho-3hydroxypropyl)-N-(heptadecyl)butanamide

N-(2, 3-dihydroxypropyl)-N-(2-methylheptadecyl)propanamide

N-(2, 3-dihydroxypropyl)-N-(3-ethylheptadecyl)butanamide

N-(2-sulfo-3-hydroxypropyl)-N-(1-octadecyl)ethanamide

N-(2,3-dihydroxypropyl)-N-(octadecyl)propanamide

N-(2, 3-dihydroxypropyl)-N-(dodecyl)decanamide

N-(2,3-dihydroxypropyl)-N-(3-ethyldodecyl)butanamide

N-(2-O-glucopyranosyl-3-hydroxy propyl)-N-(heptadecyl)butanamide

N-(2,3-dihydroxypropyl)-N-(oleyl)-2-hydroxypropanamide

N-(2, 3-dihydroxypropyl)-N-(linoleyl)-2-hydroxyheptanamide

N-(2, 3-dihydroxypropyl)-N-(dodecyl)-2-hydroxyoctanamide

N-(2, 3-dihydroxypropyl)-N(hexadecyl)-2-methylheptanamide

N-(2, 3-dihydroxypropyl)-N-(octadecyl)-2-hydroxypentanamide

N-(2,3-dihydroxypropyl)-N-(2-methylhexadecyl)-2-hydroxyheptanamide

N-(2,3-dihydroxypropyl)-N-(lioleyl)-2-hydroxypropanamide

N-(2; 3-dihydroxypropyl)-N-(tetreadecyl)ethanamide

Preferably the phospholipid component in the present delivery system is DSPC 18. Other examples of phospholipids include phosphatidic acid, lysophosphotidic acid, inositol phosphate, phosphatidylglycerol, phosphatidylinositol, phosphatidylserine, and phosphatidylethanolamine. Mixtures of different types of phospholipids can also be used. These lipid molecules are involved in transduction of signals for growth and differentiation in keratinocytes. They play an important role in mediating the actions of cytokines and other growth factors within the skin cells. These molecules will potentially stimulate the turnover rate of the skin resulting in a younger looking skin.

The present invention relates to a delivery system, wherein the cornea stratum skin barrier restoration is enhanced by *in situ* promotion of cholesterol synthesis in the stratum corneum, by *in situ* promotion of ceramide synthesis in the stratum corneum and/or by *in situ* promotion of sphingolipid synthesis in the stratum corneum.

The topical delivery system according to the present invention further comprises

one or more cosmetically and/or therapeutically active substances. Active substances are defined as agents other than emollients and other than ingredients that merely improve the physical characteristics of the formulation.

Although not limited to this category, general examples of active substances include sunscreens, tanning agents, skin anti-wrinkling agents, anti-dandruff agents, anti-acne agents and hair growth stimulants. Therapeutically active substances include, but are not limited to, substances which treat conditions such as eczema, dry skin, itchy skin, fungal, acne, skin cancer, hair loss, louse, psoriasis, and wounds. Therapeutically active substances also include substances for transdermal delivery i.e. hormones, vaccines, nicotine, interferon, and pain killers.

Active substances also include, for example, steroid hormones. Steroid hormones inhibit inflammation and hyperproliferation of the epidermis thus resulting in normalization of hypersensitive skin conditions. Examples of steroid hormones include, but are not limited to, glucocorticoids, androgens and estrogens.

Examples of sunscreens include those materials commonly employed to block ultraviolet light. Illustrative compounds are the derivatives of PABA, cinnamate and salicylate. For example, octyl methoxycinnamate and 2-hydroxy-4-methoxy benzophenone (also known as oxybenzone) can be used. Octyl methoxycinnamate and 2-hydroxy-4-methoxy benzophenone are commercially available under the trademarks, Parsol MCX and Benzophenone-3, respectively. The exact amount of sunscreen employed in the systems can vary depending upon the degree of protection desired from the sun's UV radiation.

Additionally, vitamins may also be included in the formulations of the present invention. Especially preferred is vitamin A palmitate (retinyl palmitate) and vitamin E linoleate (tocopheryl linoleate). Other esters of vitamins A and E may also be utilized.

Preservatives may also be included in the formulations of the present invention. Suitable preservatives include alkyl esters of p-hydroxybenzoic acid, hydantoin derivatives, propionate salts, and a variety of quaternary ammonium compounds. Particularly preferred preservatives of this invention are methyl paraben, propyl paraben,

imidazolidinyl urea, sodium dehydroxyacetate and benzyl alcohol. Preservatives can be used in amounts up to about 2% by weight of the formulation.

Powders may be incorporated into a cosmetic formulation of the invention. These powders include chalk, talc, Fullers earth, kaolin, starch, smectites clays, chemically modified magnesium aluminum silicate, organically modified montmorillonite clay, hydrated aluminum silicate, fumed silica, aluminum starch octenyl succinate and mixtures thereof.

Other adjunct minor components may also be incorporated into the formulations of the present invention. These components may include thickeners coloring agents, opacifiers and perfumes. Amounts of these components may range anywhere from 0.001 up to 20% by weight of the composition.

Essential fatty acids (EFA) are essential for the plasma membrane formation of all cells. In keratinocytes, EFA deficiency makes cells hyperproliferative. Supplementation of EFA reverses the hyperproliferation. EFAs also enhance lipid biosynthesis of epidermis and provide lipids for the barrier formation of the epidermis. The essential fatty acids are preferably chosen from linoleic acid, γ-linolenic acid, homo-γ-linolenic aid, columbinic acid, eicosa- (n-6,9,13)-trienoic acid, arachidonic acid , γ-linolenic acid, timnodonic acid, hexaenoic acid, and mixtures thereof.

A most preferred embodiment of the present invention comprises a delivery system, wherein the lipids of said system blend with the lipids present in the cornea stratum, resulting in a temporary and reversible atrophy in the lipid bilayer, thereby enhancing the possibility for penetration of therapeutical substances delivered by the system.

Experiments

Measurement of Skin Barrier Restoration:

In the present context enhancing skin barrier restoration can be measured by the following method. Tape and/or acetone striping of stratum corneum skin lipid content

before, during and after a treatment period with the present invention and other systems is performed. Then HPLC analysis of skin lipid content of stratum corneum is conducted.

Example of a Method of Making:

The phospholipid, cholesterol, palmitic acid and ceramide components are put together with water, and agitated at a temperature of 70-80° C. Next, mevalonic acid lactone and 25-hydroxycholecalciferol are added. Next, propylene glycol, glycerine, PVP and TEA added along with water. Next, sodium hydroxide and sodium chloride are added to get a desired viscosity and stable formulation. Next, water is added, and the formulation is agitated well. Next, the formulation is slowly cooled down.

An active substance can be dissolved in both the lipid phase and/or the water phase, depending on the solubility and concentration of the active substance.

Claims:

1. A water-based topical delivery system for an active substance, characterised by enhancing skin barrier restoration in the stratum corneum comprising: water, a fatty acid, cholesterol, a ceramide, and skin lipid precursors.

2. A delivery system according to Claim 1 wherein the fatty acid is between 0.5-10wt%; the cholesterol is between 0.5-10wt%; the lipid precursors are between 0.000001-10%; and ceramide is between 0.005-20%.

3. A delivery system according to Claim 1 wherein the fatty acid comprises fourteen to twenty-four carbons.

4. A delivery system according to Claim 3 wherein the fatty acid comprises sixteen to eighteen carbons.

5. A delivery system according to Claim 1 wherein the lipid precursor comprises mevalonic acid.

6. A delivery system according to Claim 1, wherein the water content exceeds 50%.

7. A delivery system according to Claim 1, wherein the water content exceeds 75%.

8. A delivery system according to Claim 1, wherein the water content exceeds 79%.

9. A delivery system according to Claim 1, wherein the combined content of a fatty acid, cholesterol, a ceramide, and a skin lipid precursor in said system is between about 2-20%.

10. A delivery system according to Claim 1, wherein the combined content of a fatty acid, cholesterol, a ceramide, and a skin lipid precursor in said system is between about 5-20%.

11. A delivery system according to Claim 1, wherein the combined content of a fatty acid, cholesterol, a ceramide, and a skin lipid precursor in said system is between about 5-15%.

12. A delivery system according to Claim 1, wherein the combined content of a fatty acid, cholesterol, a ceramide, and a skin lipid precursor in said system is between about 6-13%.

13. A delivery system according to Claim 1, comprising a combination of:

Fatty Acid	0.5-10 wt%
Phospholipid	0.5-10 wt%
Cholesterol	0.5-7 wt%
Lipid precursor	0.000001-10 wt%
Ceramide	0.005% - 7 wt%

14. A delivery system according to Claim 13 wherein the lipid precursor is mevalonic acid.

15. A delivery system according to Claim 13, further comprising

Glycerine	0-5 wt%
Propylene glycol	0-48 wt%
PVP (M weight 40.000)	0-5 wt%
TEA	0-3 wt%

16. A delivery system according to Claim 13, further comprising

25 Hydroxycholecalciferol	0,015%
Acylceramides	0,025%

17. A delivery system according to Claim 1, wherein said fatty acid is selected from a group consisting of palmitic acid, myristic acid, stearic acid, and/or unsaturated derivatives thereof, as well as mixtures thereof.

18. A delivery system according to Claim 1, wherein said ceramide is selected from the group consisting of ceramides, pseudo ceramides, and neo ceramides, such as ceramide 1-7, and/or mixtures thereof, and precursors thereof.

19. A delivery system according to Claim 1, wherein said phospholipid is selected from a group consisting of DSPC 18, phosphatidic acid, lysophosphotidic acid, inositol phosphate, phosphatidylglycerol, phosphatidylinositol, phosphatidylserine, and phosphatidylethanolamine, as well as mixtures thereof.

20. A delivery system according to Claim 1, wherein said skin barrier restoration is enhanced by *in situ* promotion of cholesterol synthesis in the stratum corneum.

21. A delivery system according to Claim 1, wherein said skin barrier restoration is enhanced by *in situ* promotion of ceramide synthesis in the stratum corneum.

22. A delivery system according to Claim 1, wherein said skin barrier restoration is enhanced by *in situ* promotion of sphingolipid synthesis in the stratum corneum.

23. A delivery system according to Claim 1, wherein said system further comprises one or more therapeutically active substances selected from the group consisting of: sunscreens, tanning agents, skin anti-wrinkling agents, anti-dandruff agents, anti-acne agents, hair growth stimulants, hormones, vaccines, nicotine, interferon, pain killers, vitamins; and substances which treat conditions such as eczema, dry skin, itchy skin, fungal infections, acne, skin cancer, hair loss, louse, psoriasis, and wounds.

24. A delivery system according to Claim 1, wherein the lipids of said system blend with the lipids present in the cornea stratum, resulting in a temporary and reversible atrophy in the lipid bilayer, thereby enhancing possibility for penetration of therapeutic substances delivered by the system

ASSET PURCHASE AND PRODUCT DEVELOPMENT AGREEMENT

by and between

COLLAGENEX PHARMACEUTICALS INC.

and

THOMAS SKOLD

Dated as of August 19, 2004

1-PR/1256533.9

PENGAD 800-631-6989
EXHIBIT
Cancellation
92052897
Skold v Galderma

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ASSET PURCHASE AND PRODUCT DEVELOPMENT AGREEMENT

This ASSET PURCHASE AND PRODUCT DEVELOPMENT AGREEMENT (the "Agreement"), dated as of August 19, 2004 (the "Effective Date"), is made by and between CollaGenex Pharmaceuticals Inc., a Delaware corporation having its principal office at 41 University Drive, Newtown, Pennsylvania, United States of America 18940 ("CollaGenex"), and Thomas Skold, a citizen and resident of Sweden of Bjorno Gard, S-761 41 Norrtalje, Sweden ("Skold"). CollaGenex and Skold are each sometimes referred to individually as a "Party" and together as the "Parties."

RECITALS

WHEREAS, the Parties entered into that certain Co-operation, Development and Licensing Agreement dated February 12, 2002 (the "Original Agreement");

WHEREAS, the Parties desire to modify the terms of their relationship by terminating the Original Agreement and, simultaneously therewith, entering into this Agreement; and

WHEREAS, in connection with such modification of terms, CollaGenex desires to acquire from Skold the topical technology that Skold has developed, as more specifically described herein, and Skold desires to transfer to CollaGenex, such topical delivery technology.

NOW, THEREFORE, in consideration of the foregoing premises and the representations, covenants and agreements contained herein, CollaGenex and Skold, intending to be legally bound, hereby agree as follows:

ARTICLE 1
DEFINITIONS

When used in this Agreement, whether in the singular or plural, each of the following capitalized terms shall have the meanings set forth in this Article 1.

1.1 "Affiliate" means a Person that, directly or indirectly, through one or more intermediates, controls, is controlled by, or is under common control with, the Person specified. For the purposes of this definition, control shall mean the direct or indirect ownership of (i) in the case of corporate entities, securities authorized to cast more than fifty percent (50%) of the votes in any election for directors, (ii) in the case of non-corporate entities, more than fifty percent (50%) ownership interest with the power to direct the management and policies of such non-corporate entity, or (iii) such lesser percentage as may be the maximum percentage allowed to be owned by a foreign corporation under the applicable laws or regulations of a particular jurisdiction outside of the United States) of the equity having the power to vote in the election of directors or to direct the management and policies of another entity. Notwithstanding the foregoing, the term "Affiliate" shall not include subsidiaries in which a Person or its Affiliates owns a majority of the ordinary voting power to elect a majority of the board of directors, but is restricted from electing such majority by contract or otherwise, until such time as such restriction is no longer in effect.

1.2 "Books and Records" [redacted] Affiliates related to the Restoraderm [redacted]

1.3 "Additional Records" means any and all records or documentation in whatever [redacted] materials.

1.4 "Business Day" means any day except Saturday and Sunday, on which commercial banking institutions in New York are open for business. Any reference in this Agreement to "day", whether or not capitalized, shall refer to a calendar day, not a Business Day.

[redacted]

1.6 "Confidential Information" means all secret, confidential or proprietary [redacted] Notwithstanding the foregoing sentences, Confidential Information shall not include any information or materials that:

(a) were already known to the Receiving Party (other than under an obligation of confidentiality) at the time of disclosure by the Disclosing Party to the extent such Receiving Party has documentary evidence to that effect;

(b) were generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure or development, as the case may be, and other than through any act or omission of a Party in breach of such Party's confidentiality obligations under this Agreement; or

(d) were subsequently lawfully disclosed to the Receiving Party by a Third Party who had no obligation to the Disclosing Party not to disclose such information or materials to others.

1.7 "Control," "Controls," "Controller" or "Controlled" means with respect to [redacted]

1.8 "FDA" means the United States Food and Drug Administration, or any successor agency thereof.

1.9 [redacted]

1.10 "Force Majeure" means any occurrence beyond the reasonable control of a Party [redacted]

1.11 [redacted]

1.12 [redacted]

1.13 [redacted]

1.14 "Net Sales" mean [redacted]

(a) [redacted]

(b)
such Products) and

(c)
in the invoice price
the ordinary course

(d)

(e)

(f)

(g)
one or more ingredi

(h)
GAAP consistently

1.15

1.16 "Person" means any individual, firm, corporation, partnership, limited liability company, trust, unincorporated organization or other entity or a government agency or political subdivision thereto, and shall include any successor (by merger or otherwise) of such Person.

1.17 "Product"

1.18

1.19 "Regulatory Authority" means any national (e.g., the FDA), supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity involved in the granting of Regulatory Approval in any country.

1.20

1.21 by Skold or its

1.22

1.23

1.24

1.25 "Third Party(ies)" means any Person other than Skold, CollaGenex and their respective Affiliates.

1.26 "Trademark" or "Trademarks" means all trademarks, service marks, trade names, domain names, and registrations and applications for registration of the foregoing.

1.27

ARTICLE 2

PURCHASE AND SALE; [redacted]

2.1 Purchase and Sale of Purchased Assets. Upon the terms and subject to the [redacted]

(a) [redacted]

(b) [redacted]

(c) [redacted]

(d) [redacted]

[redacted]

(a) books and records that Skold or its Affiliates are required to retain pursuant to any applicable law or regulations, other than the Books and Records; and

(b) general books of account and books of original entry that comprise Skold's or its Affiliates' permanent accounting or tax records.

[redacted]

2.4 Further Assurances. Skold shall execute and deliver (and shall [redacted]

2.5 [redacted]

[redacted]

[redacted]

3.2 Selection of and Responsibility for Development of Products.

[redacted]

[redacted]

ARTICLE 4
FINANCIAL PROVISIONS

4.1

(a)

(b)

(c)

4.2

[redacted]

4.3 [redacted]

4.4 [redacted]

4.5 Statements and Payment. [redacted]

4.6 Taxes [redacted]

4.7 Payment Currency; Currency Exchange. All payments made by CollaGenex to Skold hereunder shall be in United States dollars. With respect to Net Sales invoiced or expenses incurred in U.S. dollars, the Net Sales or expense amounts and the amounts due to Skold hereunder shall be expressed in U.S. dollars. With respect to Net Sales invoiced or expenses incurred in a currency other than U.S. dollars, the Net Sales or expense shall be expressed in the domestic currency of the entity making the sale or incurring the expense, together with the U.S. dollar equivalent, calculated using the arithmetic average of the spot rates on the last Business Day of each month of the calendar quarter in which the Net Sales were made or the expense was incurred. The "closing mid-point rates" found in the "Dollar spot forward

against the Dollar" table published by *The Financial Times*, or any other publication as agreed to by the Parties, shall be used as the source of spot rates to calculate the average as defined in the preceding sentence. All payments shall be made by wire transfer in U.S. dollars to the credit of such bank account as shall be designated at least five (5) Business Days in advance by Skold in writing to CollaGenex.

4.8 Maintenance of Records; Audit. [redacted]

such audit.

ARTICLE 5
REPRESENTATIONS, WARRANTIES AND COVENANTS

5.1 Mutual Representations, Warranties and Covenants. Each of Skold and CollaGenex hereby represents, warrants and covenants to the other Party as follows:

(a) It is duly organized and validly existing, or is a citizen and resident, as applicable, and in good standing under the laws of such Party's respective jurisdiction. It has the requisite legal power and authority to conduct its business as presently being conducted and as proposed to be conducted by it and is duly qualified to do business in those jurisdictions where its ownership of property or the conduct of its business requires;

[redacted]

5.2 Additional Representations, Warranties and Covenants of Skold. Skold hereby further represents, warrants and covenants to CollaGenex that:

[redacted]

[redacted]

ARTICLE 6
CONFIDENTIALITY, PUBLICATION AND PUBLIC ANNOUNCEMENTS

[redacted]

[redacted]

6.2 [redacted]

6.3 [redacted]

6.4 Unauthorized Use. If either Party becomes aware or has knowledge of any unauthorized use or disclosure of the other Party's Confidential Information, it shall promptly notify the disclosing Party of such unauthorized use or disclosure.

6.5 [redacted]

ARTICLE 7
INDEMNIFICATION

[redacted]

[redacted]

[redacted]

ARTICLE 8
TERM AND TERMINATION

[redacted]

8.5 Effect of Termination.

[redacted]

[redacted]

ARTICLE 9
MISCELLANEOUS

[redacted]

9.2 Assignment. Thi

9.3 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

9.4 Force Majeure

9.5 Notices. Notices to Skold shall be addressed to:

Thomas Skold
Bjorno Gard
S-761 41 Norrtalje
Sweden
Facsimile No.: (0046) 176 22 4420

Notices to CollaGenex shall be addressed to:

CollaGenex Pharmaceuticals, Inc.
41 University Drive, Suite 200
Newtown, Pennsylvania 18940
United States of America
Attention: Chief Executive Officer
Facsimile No.: (001) 215 579 8577

9.6 Amendment. No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

9.7 Waiver. No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

9.8 Counterparts; Facsimile Signatures. This Agreement may be executed in counterparts and such counterparts taken together shall constitute one and the same agreement. This Agreement may be executed by facsimile signatures, which signatures shall have the same force and effect as original signatures.

9.9 Descriptive Headings. The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

9.10 Governing Law.

9.11 Severability. If any provision hereof should be held invalid, illegal or

9.12 Entire Agreement of the Parties. This Agreement hereby, together with the

9.13 Independent Contractors. The relationship between the Parties created by this Agreement is one of independent contractors and neither Party shall have the power or authority to bind or obligate the other except as expressly set forth in this Agreement.

9.14 Expenses. Unless otherwise provided herein, all costs and expenses incurred in

[redacted]

9.15 No Third Party Beneficiaries. No person or entity other than the Parties hereto and their respective Affiliates, successors and permitted assigns shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

9.16 No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party.

[Signature Page Immediately Follows]

IN WITNESS WHEREOF, duly authorized representatives of the Parties have duly executed this Agreement as of the Effective Date.

THOMAS SKOLD

By: _____
Name: Thomas Skold

COLLAGENEX PHARMACEUTICALS INC.

By: _____
Name: Colin Stewart
Title: Chief Executive Officer and President

SCHEDULE 1.22

Patent Rights

The following Patent Rights have been previously assigned by Skold to CollaGenex. Skold's representations, warranties, covenants and obligations set forth herein shall also apply to such previously assigned Patent Rights, including those obligations set forth in Sections 2.5 and 5.2 of the Agreement.

- Provisional application filed on March 13, 2002 (Application Serial No. 60/365,059)
- U.S. Application Serial No. 10/388,371 filed on March 13, 2003
- International application Serial No. PCT/US03/07752 filed on March 13, 2003

ASSET PURCHASE AND PRODUCT DEVELOPMENT AGREEMENT

by and between

COLLAGENEX PHARMACEUTICALS INC.

and

THOMAS SKOLD

Dated as of _____ __, 2004

1-PR/1256533.9

EXHIBIT
Cancellation
92052897
Skold v Galderma
PENGAD 800-631-6989

EXHIBIT
F
Galderma
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9.16	No Strict Construction	23

ASSET PURCHASE AND PRODUCT DEVELOPMENT AGREEMENT

This ASSET PURCHASE AND PRODUCT DEVELOPMENT AGREEMENT (the "Agreement"), dated as of _____ __, 2004 (the "Effective Date"), is made by and between CollaGenex Pharmaceuticals Inc., a Delaware corporation having its principal office at 41 University Drive, Newtown, Pennsylvania, United States of America 18940 ("CollaGenex"), and Thomas Skold, a citizen and resident of Sweden of Bjorno Gard, S-761 41 Norrtalje, Sweden ("Skold"). CollaGenex and Skold are each sometimes referred to individually as a "Party" and together as the "Parties."

RECITALS

WHEREAS, the Parties entered into that certain Co-operation, Development and Licensing Agreement dated _____ (the "Original Agreement");

WHEREAS, the Parties desire to modify the terms of their relationship by terminating the Original Agreement and, simultaneously therewith, entering into this Agreement; and

WHEREAS, in connection with such modification of terms, CollaGenex desires to acquire from Skold the topical technology that Skold has developed, as more specifically described herein, and Skold desires to transfer to CollaGenex, such topical delivery technology.

NOW, THEREFORE, in consideration of the foregoing premises and the representations, covenants and agreements contained herein, CollaGenex and Skold, intending to be legally bound, hereby agree as follows:

ARTICLE 1
DEFINITIONS

When used in this Agreement, whether in the singular or plural, each of the following capitalized terms shall have the meanings set forth in this Article 1.

1.1 "Affiliate" means a Person that, directly or indirectly, through one or more intermediates, controls, is controlled by, or is under common control with, the Person specified. For the purposes of this definition, control shall mean the direct or indirect ownership of (i) in the case of corporate entities, securities authorized to cast more than fifty percent (50%) of the votes in any election for directors, (ii) in the case of non-corporate entities, more than fifty percent (50%) ownership interest with the power to direct the management and policies of such non-corporate entity, or (iii) such lesser percentage as may be the maximum percentage allowed to be owned by a foreign corporation under the applicable laws or regulations of a particular jurisdiction outside of the United States) of the equity having the power to vote in the election of directors or to direct the management and policies of another entity. Notwithstanding the foregoing, the term "Affiliate" shall not include subsidiaries in which a Person or its Affiliates owns a majority of the ordinary voting power to elect a majority of the board of directors, but is restricted from electing such majority by contract or otherwise, until such time as such restriction is no longer in effect.

1.2 "Books and Records" [redacted] Affiliates related to the Restoraderm [redacted]

1.3 "Additional Records" means any and all records or documentation in whatever [redacted]

1.4 "Business Day" means any day except Saturday and Sunday, on which commercial banking institutions in New York are open for business. Any reference in this Agreement to "day", whether or not capitalized, shall refer to a calendar day, not a Business Day.

1.5 [redacted]

1.6 "Confidential Information" means all secret, confidential or proprietary [redacted] Notwithstanding the foregoing sentences, Confidential Information shall not include any information or materials that:

(a) were already known to the Receiving Party (other than under an obligation of confidentiality) at the time of disclosure by the Disclosing Party to the extent such Receiving Party has documentary evidence to that effect;

(b) were generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure or development, as the case may be, and other than through any act or omission of a Party in breach of such Party's confidentiality obligations under this Agreement; or

(d) were subsequently lawfully disclosed to the Receiving Party by a Third Party who had no obligation to the Disclosing Party not to disclose such information or materials to others.

SKOLD-000246

1.7 "Control," "Controls," "Controller" or "Controlled" means with respect to [redacted] is granted.

1.8 "FDA" means the United States Food and Drug Administration, or any successor agency thereof.

1.9 [redacted] sublicensees [redacted] Regulatory [redacted]

1.10 "Force Majeure" means any occurrence beyond the reasonable control of a Party [redacted]

1.11 [redacted]

1.12 [redacted]

1.13 [redacted]

1.14 "Net Sales" [redacted]

(a) [redacted] are not already reflec[redacted]

(b)
such Products) and c

(c)
in the invoice price a
the ordinary course o

(d)

(e)

(f)

(g)
one or more ingredie

(h)
GAAP consistently a

1.15 "Pate

1.16 "Person" means any individual, firm, corporation, partnership, limited liability company, trust, unincorporated organization or other entity or a government agency or political subdivision thereto, and shall include any successor (by merger or otherwise) of such Person.

1.17 "Product"

1.18

1.19

1.20

1.21
by Skold or its

1.22

1.23

1.24

1.25

1.26 "Third Party(ies)" means any Person other than Skold, CollaGenex and their respective Affiliates.

1.27 "Trademark" or "Trademarks" means all trademarks, service marks, trade names, domain names, and registrations and applications for registration of the foregoing.

1.28

[redacted]

ARTICLE 2
PURCHASE AND SALE; [redacted]

2.1 Purchase and Sale of Purchased Assets. Upon the terms and subject to the [redacted]

(a) [redacted]

(b) [redacted]

(c) [redacted] Purch [redacted]

(d) [redacted]

2.2 Excluded Assets. Notwithstanding anything to the contrary contained herein, [redacted]

(a) books and records that Skold or its Affiliates are required to retain pursuant to any applicable law or regulations, other than the Books and Records; and

(b) general books of account and books of original entry that comprise Skold's or its Affiliates' permanent accounting or tax records.

2.3 Purchase Price. The purchase price payable to Skold (the "Purchase Price") for [redacted]

2.4 Deliveries by Seller. On the Effective Date, Skold shall deliver, or cause its Affiliates to deliver, to CollaGenex:

(a) a duly executed patent assignment agreement substantially in the form attached hereto as Exhibit A; and

(b) a duly executed trademark assignment agreement substantially in the form attached hereto as Exhibit B.

2.5 Further Assurances. Skold shall execute and deliver (and shall cause its Affiliates

2.6

ARTICLE 3

[redacted]

SKOLD-000252

3.2 Selection of and Responsibility for Development of Products

[redacted]

[redacted]

ARTICLE 4
FINANCIAL PROVISIONS

4.1 [redacted]
shall pay the [redacted]
calendar days [redacted]

(a) [redacted]

(b) [redacted]

(c) [redacted]

[redacted]

4.2 [redacted]

4.3 [redacted]

4.4 [redacted]

4.5 Statements and Payment. [redacted]

4.6 Taxe[redacted]

[redacted]

4.7 Payment Currency; Currency Exchange. All payments made by CollaGenex to Skold hereunder shall be in United States dollars. With respect to Net Sales invoiced or expenses incurred in U.S. dollars, the Net Sales or expense amounts and the amounts due to Skold hereunder shall be expressed in U.S. dollars. With respect to Net Sales invoiced or expenses incurred in a currency other than U.S. dollars, the Net Sales or expense shall be expressed in the domestic currency of the entity making the sale or incurring the expense, together with the U.S. dollar equivalent, calculated using the arithmetic average of the spot rates on the last Business Day of each month of the calendar quarter in which the Net Sales were made or the expense was incurred. The "closing mid-point rates" found in the "Dollar spot forward against the Dollar" table published by *The Financial Times*, or any other publication as agreed to by the Parties, shall be used as the source of spot rates to calculate the average as defined in the preceding sentence. All payments shall be made by wire transfer in U.S. dollars to the credit of such bank account as shall be designated at least five (5) Business Days in advance by Skold in writing to CollaGenex.

4.8 Maintenance of Records; Audit. [redacted]

[redacted]

ARTICLE 5
REPRESENTATIONS, WARRANTIES AND COVENANTS

5.1 Mutual Representations, Warranties and Covenants. Each of Skold and CollaGenex hereby represents, warrants and covenants to the other Party as follows:

(a) It is duly organized and validly existing, or is a citizen and resident, as applicable, and in good standing under the laws of such Party's respective jurisdiction. It has the requisite legal power and authority to conduct its business as presently being conducted and as proposed to be conducted by it and is duly qualified to do business in those jurisdictions where its ownership of property or the conduct of its business requires;

[redacted]

SKOLD-000257

[redacted]

5.2 Additional Representations, Warranties and Covenants of Skold. Skold hereby further represents, warrants and covenants to CollaGenex that:

[redacted]

ARTICLE 6
CONFIDENTIALITY, PUBLICATION AND PUBLIC ANNOUNCEMENTS

[redacted]

6.2 Authorized Disclosure. Notwithstanding the foregoing, each of CollaGenex and [redacted]

6.3 Return of Confidential Information. Upon termination of this Agreement, the [redacted]

6.4 Unauthorized Use. If either Party becomes aware or has knowledge of any unauthorized use or disclosure of the other Party's Confidential Information, it shall promptly notify the disclosing Party of such unauthorized use or disclosure.

6.5 Public Announcements. Except as set forth in press releases published by [redacted]

[redacted]

ARTICLE 7

[redacted]

SKOLD-000260

[redacted]

[redacted]

ARTICLE 8
TERM AND TERMINATION

[redacted]

[redacted]

[redacted]

ARTICLE 9
MISCELLANEOUS

[redacted]

SKOLD-000264

9.2 Assignment. [redacted]

9.3 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

9.4 Force Majeure [redacted]

SKOLD-000265

9.5 Notices. Notices to Skold shall be addressed to:

Thomas Skold
Bjorno Gard
S-761 41 Norrtalje
Sweden
Facsimile No.: (0046) 176 22 4420

Notices to CollaGenex shall be addressed to:

CollaGenex Pharmaceuticals, Inc.
41 University Drive, Suite 200
Newtown, Pennsylvania 18940
United States of America
Attention: Senior Vice President
Facsimile No.: (001) 215 579 8577

[redacted]

9.6 Amendment. No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

9.7 Waiver. No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

9.8 Counterparts; Facsimile Signatures. This Agreement may be executed in counterparts and such counterparts taken together shall constitute one and the same agreement. This Agreement may be executed by facsimile signatures, which signatures shall have the same force and effect as original signatures.

9.9 Descriptive Headings. The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

9.10 Governing Law. [redacted]

objection on the grounds of lack of jurisdiction (including, without limitation, venue) to the exercise of such jurisdiction over it by any such courts.

9.11 Severability. If any provision hereof should be held invalid, illegal or

[redacted]

9.12 Entire Agreement of the Parties. This Agreement hereby, together with the

[redacted]

9.13 Independent Contractors. The relationship between the Parties created by this Agreement is one of independent contractors and neither Party shall have the power or authority to bind or obligate the other except as expressly set forth in this Agreement.

9.14 Expenses. Unless otherwise provided herein, all costs and expenses incurred in

[redacted]

9.15 No Third Party Beneficiaries. No person or entity other than the Parties hereto and their respective Affiliates, successors and permitted assigns shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

9.16 No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party.

[Signature Page Immediately Follows]

SKOLD-000267

IN WITNESS WHEREOF, duly authorized representatives of the Parties have duly executed this Agreement as of the Effective Date.

THOMAS SKOLD

By: _____
Name: Thomas Skold

COLLAGENEX PHARMACEUTICALS INC.

By: _____
Name:
Title:

SCHEDULE 1.22

~~Restoraderm~~ Patent Rights

A. Restoraderm Patent Rights

- [TO BE INSERTED.]

Formatted: Bullets and Numbering

B. The following Patent Rights have been previously assigned by Skold to CollaGenex. Skold's representations, warranties, covenants and obligations set forth herein shall also apply to such previously assigned Patent Rights, including those obligations set forth in Sections 2.5 and 5.2 of the Agreement.

- Provisional application filed on March 13, 2002 (Application Serial No. 60/365,059)
- U.S. Application Serial No. 10/388,371 filed on March 13, 2003 ~~[NOTE: To be confirmed whether this has already been assigned to CollaGenex.]~~
- International application Serial No. PCT/US03/07752 filed on March 13, 2003 ~~[NOTE: To be confirmed whether this has already been assigned to CollaGenex.]~~

EXHIBIT A

Patent Assignment

WHEREAS, _____, an _____ corporation, whose address is _____, ("Assignor") is the owner of the patents and applications for patent listed on the attached Appendix A; and

WHEREAS, _____, an _____ corporation, whose address is _____, ("Assignee") desires to acquire Assignor's entire right, title and interest in, to and under said patents and applications, and in and to the inventions covered thereby,

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, Assignor does hereby sell, assign, and transfer to Assignee, its entire right, title and interest in and to, including without limitation the exclusive right to make, use and sell, the inventions disclosed in the patents and applications listed in Appendix A hereto for the territory of the United States and its possessions and territories and all foreign countries, including all rights of priority created by said applications and patents and any provisional, non-provisional, divisional, continuation or continuation-in-part applications that may be filed based on or related to any such applications; any patents issuing on any of the foregoing applications, and any reissues, renewals, certificates of reexamination or extensions of any of the foregoing patents, all of the foregoing referred to herein as Patents, the same to be held and enjoyed by Assignee, for its own use and enjoyment, and for the use and enjoyment of its successors, assigns, to the end of the term or terms for which said patents are or may be granted, together with the right to take action for past, present and future infringements and to retain any damages obtained as a result of such action.

Assignor shall at the reasonable request of Assignee and at the expense of Assignor, prepare and execute or have executed all documents, papers, forms or authorizations, necessary or useful to vest full title in and to the Patents and inventions disclosed in the Patents, to Assignee.

[ASSIGNOR]
By:
Name:_____
Title:_____

Appendix A

I. Issued and Granted Patents

Patent No. Country

II. Pending Applications

Patent Application No. Country

EXHIBIT B

Trademark Assignment

WHEREAS, _____, an _____ corporation, whose address is _____, ("Assignor") is the owner of the trademarks listed on the attached Appendix A (the "Marks") and the registrations and applications for registration pertaining thereto; and

WHEREAS, _____, an _____ corporation, whose address is _____, ("Assignee") desires to acquire Assignor's entire right, title and interest in, to and under said Marks and the registrations and applications for registration pertaining thereto.

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, Assignor hereby irrevocably assigns, transfers, and conveys unto Assignee all of its rights, title and interest in and to the Marks, whether statutory or at common law, including all registrations thereof and applications for registration pertaining thereto, together with the goodwill of the business symbolized by the Marks, and the right to take action for past, present and future infringements of rights in the Marks and to retain any damages obtained as a result of such action.

Assignor shall at the reasonable request of Assignee, and at the expense of Assignor, prepare and execute or have executed all further documents, papers, forms or authorizations necessary or useful to vest full title in and to the Marks and the goodwill of the business in which the Marks have been used by the Assignor to Assignee

[ASSIGNOR]
By:
Name:_____
Title:_____

1-PR/1256533.9

APPENDIX A

Mark	App. No.	Reg. No.	Filing Date	Reg. Date	Country	Class

From: dglazer@morganlewis.com
Sent: Tuesday, August 17, 2004 2:27 PM
To: thomas-skold@telia.com
Cc: nbroadbent@collagenex.com; kleisten@morganlewis.com
Subject: Asset Purchase Agreement

Dear Thomas,

Schedule A should contain a list of any patent, patent applications, cips, divisionals, etc. that you own that are to be transferred to CollaGenex. Please confirm whether there are any patents, etc. in addition to the ones already listed on the schedule that need to be added. Also, CollaGenex has informed me that it already owns the Restoraderm trademark. Accordingly, are there any other trademarks that you own that should be assigned to CollaGenex relating to this technology. If there is not, we can delete these trademark provisions from the agreement. Could you please forward this email to Staffan as I don't have his email address and work with him in finalizing these schedules.

Should you have any questions, do not hesitate to contact me.

Thank you for your attention to this matter. It has been a pleasure working with you and Staffan.

David G. Glazer, Esq.
Morgan, Lewis & Bockius LLP
502 Carnegie Center
Princeton, NJ 08540
Phone: 609.919.6624
Fax: 609.919.6701
E-Fax: 877.4FAXMLB
E-Mail: dglazer@morganlewis.com

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Arthur Jackson SKOLD-001891

From: [redacted]
Sent: Friday, February 01, 2013 11:37 AM
To: Thomas Sköld
Subject: Possible Development Deal (Restoraderm)

TRADE SECI **SITIVE**

Public

Thomas,
I am following up on the meeting I had last week with the prospective company; utilizing Restoraderm to develop a line of [redacted] products. I have sent them the Fowler study and a few items on the technology. They did ask for the Patent #, but I dont have it. Can you send me the Patent number so they can review?

Keep you posted.
[redacted]

EXHIBIT
Cancellation
92052897
Sköld v Galderma
PENGAD 800-631-6989

EXHIBIT
G
Galderma
PENGAD 800-631-6989

SKOLD v. Galderma, Cancellation No. 92052897, Exhibit Book p. 1
TS-000001

rthur Jackson

'om: dglazer@morganlewis.com
ent: Wednesday, August 18, 2004 4:19 PM
o: Thomas Sköld
c: kleisten@morganlewis.com; nbroadbent@collagenex.com
ubject: RE: Asset Purchase Agreement

homas,

ould you please confirm that there are no other patents, patent applications, etc. that need to be listed on the Schedule. Thanks.

David G. Glazer, Esq.
Morgan, Lewis & Bockius LLP
502 Carnegie Center
Princeton, NJ 08540
Phone: 609.919.6624
Fax: 609.919.6701
E-Fax: 877.4FAXMLB
E-Mail: dglazer@morganlewis.com

"Thomas Sköld" <thomas-skold@telia.com>
08/18/2004 04:16 PM

To: dglazer@morganlewis.com
cc: nbroadbent@collagenex.com, kleisten@morganlewis.com
Subject: RE: Asset Purchase Agreement

Dear David,

I can finally confirm that we are in an agreement.
Staffan has been away in business but gave me a cal tonight after reviewing it all.

In the consultant agreement's attachment we should though mention Ponsus Pharma AB, which is the company where I hold approximately 20% of the shares (for the moment).

I look forward receiving two signed copies and if possible also through fax and I will return one signed also by me.

Regards,
Thomas

-----Original Message-----
From: dglazer@morganlewis.com [mailto:dglazer@morganlewis.com]
Sent: Tuesday, August 17, 2004 4:27 PM
To: thomas-skold@telia.com

Public

Exhibit 1
Skold v Galderma
Cal

CONFIDENTIAL

Cc: nbroadbent@collagenex.com; kleisten@morganlewis.com
Subject: Asset Purchase Agreement

Dear Thomas,

Schedule A should contain a list of any patent, patent applications, cips, divisionals, etc. that you own that are to be transferred to CollaGenex.
Please confirm whether there are any patents, etc. in addition to the ones already listed on the schedule that need to be added. Also, CollaGenex has informed me that it already owns the Restoraderm trademark.
Accordingly,
are there any other trademarks that you own that should be assigned to CollaGenex relating to this technology. If there is not, we can delete these trademark provisions from the agreement. Could you please forward this email to Staffan as I don't have his email address and work with him in finalizing these schedules.

Should you have any questions, do not hesitate to contact me.

Thank you for your attention to this matter. It has been a pleasure working with you and Staffan.

David G. Glazer, Esq.
Morgan, Lewis & Bockius LLP
502 Carnegie Center
Princeton, NJ 08540
Phone: 609.919.6624
Fax: 609.919.6701
E-Fax: 877.4FAXMLB
E-Mail: dglazer@morganlewis.com

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#302

Exhibit T 2
Skold v. Galderma
Cancellation No. 92052897

Exhil
(2002 Ag

~~CONFIDENTIAL~~

Public

Sköld v. Galderma
Cancellation No. __
Re Registration Nos. 2985751 and 3394514

CO-OPERATION, DEVELOPMENT AND LICENSING AGREEMENT

THIS AGREEMENT ("the Agreement") is made and effective the 11th day of February, 2002 by and between:-

1. COLLAGENEX PHARMACEUTICALS INC., a company organised and existing under the laws of the State of Delaware, United States of America and having its principal place of business at 41 University Drive, Newtown, Pennsylvania 18940, United States of America (hereinafter "CollaGenex");

   and

2. THOMAS SKOLD, a citizen and resident of Sweden of Bjorno Gard, S-761 41 Norrtalje, Sweden (hereinafter "Skold").

(A) WHEREAS Skold is developing, will continue to develop and has rights to the Technology (as defined hereafter) and the potential Products (as defined hereafter) resulting there from and desires to develop said technology in conjunction with CollaGenex in accordance with the terms and conditions hereof; and

(B) WHEREAS CollaGenex is desirous to participate in and control the development of the technology as defined herein and to obtain all rights thereto in accordance with the terms and conditions hereof;

NOW, THEREFORE, in consideration of the premises and mutual covenants and agreements hereinafter contained, the parties hereto, intending to be legally bound, hereby undertake and agree as follows:-

1. DEFINITIONS

1.1. The term "Affiliate" shall mean any entity in which the party has a direct or indirect equity interest or income interest ownership of at least fifty per cent (50%) or more, or any entity which, directly or indirectly, through one or more intermediaries, controls or is controlled by, or is under common control with the party.

1.2. The term "Confidential Information" shall mean any and all information or any portion thereof howsoever disclosed to or otherwise acquired or observed by either party or its employees, agents or Affiliates (each individually referred to as a "Recipient") either directly or indirectly from the other party, including, but not limited to, the technology and/or the products resulting there from as defined herein, enhancements, modifications, discoveries, claims, formulae, processes, apparatuses, research, development, patents, Confidential Information, Know-how as defined herein, trade secrets, knowledge, [redacted] designs, specifications, drawings, concepts, data, reports, methods, documentation, methodology, pricing, marketing and sales plans, customer lists, collaborators, salaries or business affairs and any other information or knowledge owned or developed or controlled by either party except for information which the Recipient can demonstrate:-

   (a) was at the time of disclosure to such Recipient part of the public domain or thereafter becomes part of the public domain through no act or omission by such Recipient; or

   (b) was lawfully in such Recipient's possession as evidenced by written records prior to disclosure by the disclosing party and without any obligation of confidentiality; or

(c) was lawfully received by such Recipient after disclosure from a third party without obligation of confidentiality and without violation by said third party of any obligation of confidentiality to another party; or

(d) was required to be disclosed by law or court order; or

(e) was independently developed by the Recipient without reference to or reliance on any of the Confidential Information.

1.3. The term [redacted]

1.4. The term [redacted] defined h[redacted] Affiliates. [redacted]

1.5. The term [redacted]

1.6. The term [redacted]

1.7. The term "Net Sales" shall mean [redacted]

1.8. The term [redacted]

1.9. The term [redacted]

1.10. The term [redacted]

1.11. The term "the Term" shall mean the term of this Agreement and any extension thereto as defined herein.

1.12. The term "the Territory" shall mean [redacted]

2. GRANT OF RIGHTS

2.1. (a) [redacted]

(b) [redacted]

2.2. [redacted]

2.3. [redacted]

records, ledgers, books and laboratory to verify Skold's compliance with the terms of this Agreement.

2.4. [redacted]

2.5. [redacted]

3. PAYMENTS FOR RIGHTS

3.1. [redacted]

a) [redacted]

i. [redacted]

ii. [redacted]

iii. [redacted]

[redacted]

c) [redacted]

d) [redacted]

e) [redacted]

f) [redacted]

g) [redacted]

h) [redacted]

i) [redacted]

3.2. [redacted]

3.3. [redacted]

(a) [redacted]

(b) [redacted]

(c) all payments by CollaGenex to Skold will be in United States dollars.

(d) [redacted]

(e) [redacted]

3.4. [redacted]

(a) [redacted]

(b) [redacted]

(i) [redacted]

(i) [redacted]

(ii) [redacted]

(iii)

(c) [redacted]

4. INTELLECTUAL PROPERTY

4.1. Patents

4.1.1. [redacted]

4.1.2. [redacted]

4.1.3. [redacted]

4.1.4. [redacted]

(a) [redacted]

(b)

(c)

[redacted]

4.2. Trade Marks

4.2.1. [redacted]

4.2.2.

4.2.3.

5. REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE PARTIES

5.1. CollaGenex represents and warrants to Skold that:-

(a) CollaGenex Pharmaceuticals, Inc. is a corporation duly organised, validly existing and in good standing under the laws of the State of Delaware, United States of America and that it has full corporate power and authority to conduct the business in which it is now engaged and as contemplated by this Agreement; and

(b) [redacted]

(c) [redacted]

(d) [redacted]

[redacted]

5.2. Skold hereby warrants and represents to CollaGenex that:-

(a) he is a citizen and resident of Sweden and in good standing in that country; and

(b) [redacted]

(c)

(d)

(e)

(f)

(g)

6. [redacted] INSURANCE

[redacted]

[redacted]

7. MARKETING AUTHORISATIONS

[redacted]

8. CONFIDENTIALITY

8.1. [redacted]

8.2. [redacted]

(a) [redacted]

(b)

8.3. The parties acknowledge and agree that the financial terms contained in this Agreement shall be considered as Confidential Information hereunder.

8.4. [redacted]

9. TERM AND TERMINATION AND REVERSION OF RIGHTS

9.1. [redacted]

9.2.

9.3.

(a)

(b)

9.4. [redacted]

9.5.

9.6. [redacted]

10. FORCE MAJEURE

10.1. [redacted]

10.2.

10.3.

10.4.

10.5.

11. OTHER PROVISIONS

11.1. [redacted]

11.2.

Any notice shall be deemed to have been given on day of delivery or receipt. Notices shall be delivered to the parties at the following addresses until a different address has been designated, by notice, to the other party:-

If to CollaGenex	CollaGenex Pharmaceuticals, Inc., 41 University Drive, Suite 200, Newtown, Pennsylvania 18940, United States of America. Telefax : (001) 215 579 8577 Attention : Senior Vice President
If to Skold	Thomas Skold, Bjorno Gard, S-761 41 Norrtalje, Sweden. Telefax : (0046) 176 22 4420

11.3. This Agreement is executed in two counterparts each one of which is deemed an original and which taken together shall constitute one and the same instrument.

11.4. [redacted]

11.5.

11.6.

11.7.

11.8.

11.9.

11.10.

11.11. Except where the context otherwise permits or requires, words denoting the singular include the plural and vice versa; wording denoting one gender include all genders; words denoting persons include firms and corporations and vice versa.

11.12. [redacted]

11.13. [redacted]

IN WITNESS WHEREOF, THE PARTIES HAVE CAUSED THIS AGREEMENT TO BE SIGNED BY THEIR DULY AUTHORISED REPRESENTATIVES THE DAY AND YEAR FIRST ABOVE WRITTEN :

COLLAGENEX PHARMACEUTICALS, INC.

by.....
Brian M. Gallagher Ph.D.,
Chairman, President & Chief Executive Officer

THOMAS SKOLD

.....

Exhibit
(2004 Agreer

Exhibit T 3
Skold v. Galderma
Cancellation No. 92052897

CONFIDENTIAL

Public

Sköld v. Galderma
Cancellation No. __
Re Registration Nos. 2985751 and 3394514

ASSET PURCHASE AND PRODUCT DEVELOPMENT AGREEMENT

by and between

COLLAGENEX PHARMACEUTICALS INC.

and

THOMAS SKOLD

Dated as of August 19, 2004

1-PR/1256533.9

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ASSET PURCHASE AND PRODUCT DEVELOPMENT AGREEMENT

This ASSET PURCHASE AND PRODUCT DEVELOPMENT AGREEMENT (the "Agreement"), dated as of August 19, 2004 (the "Effective Date"), is made by and between CollaGenex Pharmaceuticals Inc., a Delaware corporation having its principal office at 41 University Drive, Newtown, Pennsylvania, United States of America 18940 ("CollaGenex"), and Thomas Skold, a citizen and resident of Sweden of Bjorno Gard, S-761 41 Norrtalje, Sweden ("Skold"). CollaGenex and Skold are each sometimes referred to individually as a "Party" and together as the "Parties."

RECITALS

WHEREAS, the Parties entered into that certain Co-operation, Development and Licensing Agreement dated February 12, 2002 (the "Original Agreement");

WHEREAS, the Parties desire to modify the terms of their relationship by terminating the Original Agreement and, simultaneously therewith, entering into this Agreement; and

WHEREAS, in connection with such modification of terms, CollaGenex desires to acquire from Skold the topical technology that Skold has developed, as more specifically described herein, and Skold desires to transfer to CollaGenex, such topical delivery technology.

NOW, THEREFORE, in consideration of the foregoing premises and the representations, covenants and agreements contained herein, CollaGenex and Skold, intending to be legally bound, hereby agree as follows:

ARTICLE 1
DEFINITIONS

When used in this Agreement, whether in the singular or plural, each of the following capitalized terms shall have the meanings set forth in this Article 1.

1.1 "Affiliate" means a Person that, directly or indirectly, through one or more intermediates, controls, is controlled by, or is under common control with, the Person specified. For the purposes of this definition, control shall mean the direct or indirect ownership of (i) in the case of corporate entities, securities authorized to cast more than fifty percent (50%) of the votes in any election for directors, (ii) in the case of non-corporate entities, more than fifty percent (50%) ownership interest with the power to direct the management and policies of such non-corporate entity, or (iii) such lesser percentage as may be the maximum percentage allowed to be owned by a foreign corporation under the applicable laws or regulations of a particular jurisdiction outside of the United States) of the equity having the power to vote in the election of directors or to direct the management and policies of another entity. Notwithstanding the foregoing, the term "Affiliate" shall not include subsidiaries in which a Person or its Affiliates owns a majority of the ordinary voting power to elect a majority of the board of directors, but is restricted from electing such majority by contract or otherwise, until such time as such restriction is no longer in effect.

1.2 "Books and Records" [redacted] Affiliates related to the Restoraderm [redacted]

1.3 "Additional Records" means any and all records or documentation in whatever [redacted]

1.4 "Business Day" means any day except Saturday and Sunday, on which commercial banking institutions in New York are open for business. Any reference in this Agreement to "day", whether or not capitalized, shall refer to a calendar day, not a Business Day.

1.5 [redacted]

1.6 "Confidential Information" means all secret, confidential or proprietary [redacted] Notwithstanding the foregoing sentences, Confidential Information shall not include any information or materials that:

(a) were already known to the Receiving Party (other than under an obligation of confidentiality) at the time of disclosure by the Disclosing Party to the extent such Receiving Party has documentary evidence to that effect;

(b) were generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure or development, as the case may be, and other than through any act or omission of a Party in breach of such Party's confidentiality obligations under this Agreement; or

(d) were subsequently lawfully disclosed to the Receiving Party by a Third Party who had no obligation to the Disclosing Party not to disclose such information or materials to others.

1.7 "Control," "Controls," "Controller" or "Controlled" [redacted]

1.8 "FDA" means the United States Food and Drug Administration, or any successor agency thereof.

1.9 [redacted]

1.10 "Force Majeure" means any occurrence beyond the reasonable control of a Party [redacted]

1.11 [redacted]

1.12 [redacted]

1.13 [redacted]

1.14 "Net Sales" means [redacted]

(a) [redacted]

(b) [redacted]
such Products) and [redacted]

(c) [redacted]
in the invoice price [redacted]
the ordinary course [redacted]

(d) [redacted]

(e) [redacted]

(f) [redacted]

(g) [redacted]
one or more ingredi [redacted]

(h) [redacted]
GAAP consistently [redacted]

1.15 [redacted]

1.16 "Person" means any individual, firm, corporation, partnership, limited liability company, trust, unincorporated organization or other entity or a government agency or political subdivision thereto, and shall include any successor (by merger or otherwise) of such Person.

1.17 "Product" [redacted]

1.18 [redacted]

[redacted]

1.19 [redacted]

1.20 [redacted]

1.21 [redacted]
by Skold or

1.22 [redacted]

1.23 [redacted]

1.24 [redacted]

1.25 "Third Party(ies)" means any Person other than Skold, CollaGenex and their respective Affiliates.

1.26 "Trademark" or "Trademarks" means all trademarks, service marks, trade names, domain names, and registrations and applications for registration of the foregoing.

1.27 [redacted]

ARTICLE 2
PURCHASE AND SALE; [redacted]

2.1 Purchase and Sale of Purchased Assets. Upon the terms and subject to the [redacted]

(a) [redacted]

(b) [redacted]

(c) [redacted]

(d) [redacted]

2.2 Excluded Assets. Notwithstanding anything to the contrary contained herein, [redacted]

(a) books and records that Skold or its Affiliates are required to retain pursuant to any applicable law or regulations, other than the Books and Records; and

(b) general books of account and books of original entry that comprise Skold's or its Affiliates' permanent accounting or tax records.

2.3 Purchase Price. The purchase price payable to Skold (the "Purchase Price") for [redacted]

[redacted]

2.4 Further Assurances. Skold shall execute and deliver (and shall cause its Affiliates [redacted]

2.5 [redacted]

[redacted]

[redacted]

3.2 Selection of and Responsibility for Development of Products.

[redacted]

[redacted]

[redacted]

ARTICLE 4
FINANCIAL PROVISIONS

4.1 [redacted]

(a) [redacted]

(b) [redacted]

(c) [redacted]

[redacted]

4.2 [redacted]

[redacted]

4.3 [redacted]

4.4 [redacted]

4.5 Statements and Payment. [redacted]

4.6 Taxes [redacted]

4.7 Payment Currency; Currency Exchange. All payments made by CollaGenex to Skold hereunder shall be in United States dollars. With respect to Net Sales invoiced or expenses incurred in U.S. dollars, the Net Sales or expense amounts and the amounts due to Skold hereunder shall be expressed in U.S. dollars. With respect to Net Sales invoiced or expenses incurred in a currency other than U.S. dollars, the Net Sales or expense shall be expressed in the domestic currency of the entity making the sale or incurring the expense, together with the U.S. dollar equivalent, calculated using the arithmetic average of the spot rates on the last Business Day of each month of the calendar quarter in which the Net Sales were made or the expense was incurred. The "closing mid-point rates" found in the "Dollar spot forward

against the Dollar" table published by *The Financial Times*, or any other publication as agreed to by the Parties, shall be used as the source of spot rates to calculate the average as defined in the preceding sentence. All payments shall be made by wire transfer in U.S. dollars to the credit of such bank account as shall be designated at least five (5) Business Days in advance by Skold in writing to CollaGenex.

4.8 Maintenance of Records; Audit. [redacted]

ARTICLE 5
REPRESENTATIONS, WARRANTIES AND COVENANTS

5.1 Mutual Representations, Warranties and Covenants. Each of Skold and CollaGenex hereby represents, warrants and covenants to the other Party as follows:

(a) It is duly organized and validly existing, or is a citizen and resident, as applicable, and in good standing under the laws of such Party's respective jurisdiction. It has the requisite legal power and authority to conduct its business as presently being conducted and as proposed to be conducted by it and is duly qualified to do business in those jurisdictions where its ownership of property or the conduct of its business requires;

[redacted]

5.2 Additional Representations, Warranties and Covenants of Skold. Skold hereby further represents, warrants and covenants to CollaGenex that:

[redacted]

[redacted]

ARTICLE 6
CONFIDENTIALITY, PUBLICATION AND PUBLIC ANNOUNCEMENTS

[redacted]

[redacted]

6.2 Authorized Disclosure. Notwithstanding the foregoing, each of CollaGenex and [redacted]

6.3 Return of Confidential Information. Upon termination of this Agreement, the [redacted]

6.4 Unauthorized Use. If either Party becomes aware or has knowledge of any unauthorized use or disclosure of the other Party's Confidential Information, it shall promptly notify the disclosing Party of such unauthorized use or disclosure.

6.5 Public Announcements. Except as set forth in press releases published by [redacted]

ARTICLE 7

[redacted]

[redacted]

[redacted]

ARTICLE 8
TERM AND TERMINATION

8.1 Term. Unless earlier terminated by mutual [redacted]

8.5 Effect of Termination.

[redacted]

[redacted]

ARTICLE 9
MISCELLANEOUS

[redacted]

[redacted]

9.2 Assignment. [redacted]

9.3 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

9.4 Force Majeure. [redacted]

9.5 Notices. Notices to Skold shall be addressed to:

Thomas Skold
Bjorno Gard
S-761 41 Norrtalje
Sweden
Facsimile No.: (0046) 176 22 4420

Notices to CollaGenex shall be addressed to:

CollaGenex Pharmaceuticals, Inc.
41 University Drive, Suite 200
Newtown, Pennsylvania 18940
United States of America
Attention: Chief Executive Officer
Facsimile No.: (001) 215 579 8577

[redacted]

[redacted]

9.6 Amendment. No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

9.7 Waiver. No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

9.8 Counterparts; Facsimile Signatures. This Agreement may be executed in counterparts and such counterparts taken together shall constitute one and the same agreement. This Agreement may be executed by facsimile signatures, which signatures shall have the same force and effect as original signatures.

9.9 Descriptive Headings. The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

9.10 Governing Law. [redacted]

9.11 Severability. If any provision hereof should be held invalid, illegal or [redacted]

9.12 Entire Agreement of the Parties. This Agreement hereby, together with the [redacted]

9.13 Independent Contractors. The relationship between the Parties created by this Agreement is one of independent contractors and neither Party shall have the power or authority to bind or obligate the other except as expressly set forth in this Agreement.

9.14 Expenses. Unless otherwise provided herein, all costs and expenses incurred in [redacted]

9.15 No Third Party Beneficiaries. No person or entity other than the Parties hereto and their respective Affiliates, successors and permitted assigns shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

9.16 No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party.

[Signature Page Immediately Follows]

Exhibit T 6
Skold v. Galderma
Cancellation No. 92052897

Exhibit 10

(Consulting Agreement)

CONFIDENTIAL

Sköld v. Galderma
Cancellation No. 92052897
Re Registration Nos. 2985751 and 3394514

CONSULTING AGREEMENT

THIS CONSULTING SERVICES AGREEMENT (the "Agreement"), is entered into as of August 1, 2004 by and between CollaGenex, Inc. (the "Company"), and Thomas Skold, an individual ("Consultant").

BACKGROUND

The Company wishes to obtain the services of Consultant for certain purposes, and Consultant wishes to provide such services, all subject to the terms and condition of this Agreement.

[redacted]

NOW, THEREFORE, in consideration of the mutual promises hereinafter set forth, and intending to be legally bound hereby, the Company and Consultant hereby agree as follows:

[redacted]

3. **Compensation** [redacted]

[redacted]

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(b) Further Assurances. Upon the request and at the expense of the

[redacted]

(c) Survival. The obligations of Consultant that by their nature should survive shall survive termination or expiration of this Agreement including the provisions of this paragraph 6.

7. **Termination**. Notwithstanding the provisions of paragraph 2, Company may

[redacted]

8. **No Conflicting Agreements** [redacted]

[redacted]

14. **Notices**. All notices and other communications required or permitted hereunder or necessary or convenient in connection herewith shall be in writing and shall be deemed to have been given when hand delivered, sent by facsimile or mailed by registered or certified mail, as follows (provided that notice of change of address shall be deemed given only when received):

If to the Company, to:

CollaGenex Pharmaceuticals, Inc.
41 University Drive, Suite 200
Newtown, Pennsylvania 18940
United States of America
Attention: Chief Executive Officer
Facsimile No.: (001) 215 579 8577

If to Consultant, to:

Thomas Skold
Bjorno Gard
S-761 41 Norrtalje
Sweden
Facsimile No.: (0046) 176 22 4420

or to such other names or addresses as the Company or Consultant, as the case may be, shall designate by notice to each other person entitled to receive notices in the manner specified in this paragraph.

15. **Counterparts**. This Agreement shall become binding when any one or more counterparts hereof, individually or taken together, shall bear the signatures of Consultant and the Company. This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original as against any party whose signature appears thereon, but both of which together shall constitute but one and the same instrument.

16. **Severability**. If any provision of this Agreement or application thereof to anyone or under any circumstances is adjudicated to be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect any other provision or application of this Agreement which can be given effect without the invalid or unenforceable provision or application and shall not invalidate or render unenforceable such provision or application in any other jurisdiction.

[Signature Page Immediately Follows]

IN WITNESS WHEREOF, the undersigned, intending to be legally bound, have duly executed this Agreement as of the date first above written.

COLLAGENEX PHARMACEUTICALS INC.:

By: _____
Name: Colin Stewart
Title: Chief Executive Officer and President

THOMAS SKOLD:

By: _____
Name:

CONFIDENTIAL

Public

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Från: fowlerjoe [mailto:fowlerjoe@msn.com]
Skickat: den 4 september 2001 04:00
Till: Thomas Sköld
Ämne: Re: Some info

Exhibit T7
Skold v. Galderma
Cancellation No. 92052897

Hi Thomas,

Good luck with the meetings in the US. Have a safe and pleasant trip. Someday we will get you back in Arizona to see the Grand Canyon.

We will call you when we get to Stockholm, either Thursday evening the 20th at home or Friday morning at the office. If your schedule is open we will plan to see you in the afternoon Friday then dinner Friday evening. Is there anything we can bring you from the states??

Your plan for the Caribbean looks excellent. Let me know if you need any help making travel arrangements.

Best Regards,

Joe

----- Original Message -----
From: Thomas Sköld
To: fowlerjoe
Sent: Monday, September 03, 2001 7:28 AM
Subject: RE: Some info

Hi Joe,

I am supposed to see a potential investor on the east coast Monday 10th and Tuesday we have a meeting with Neutrogena (who has merge with Ortho McNiel). Wednesday we will see Medicis and Thursday Allerga. I do know that we are competing with Connetics but I feel that we have a good chance.

Give us a call when you get in to Stockholm. On Friday we will be at our office from 9,15 a.m. and my direct line is 514 818 01. If there would something before that our home number is 0176-22 44 00 and mobile; 070-660 00 40

Regarding Caribbean, we have not received any confirmation yet but the schedule right now is as follows; arrival Puerto Rico 15th, leave for Tortola Jan 20, arrival in Anguilla Jan 22, departure for St. Barts Jan 24th. We will then try to stay on St. Barts for approximately one week before going back to Stockholm.
Would this work for you?

Have a great journey to Finland and say hi to every one. The US trip is very important, otherwise we would have taken the trip to Finland as well.

All the best and we look forward seeing you soon.

Regards,
Thomas

-----Original Message-----
From: fowlerjoe [mailto:fowlerjoe@msn.com]
Sent: Tuesday, August 28, 2001 8:08 PM
To: Thomas Sköld
Subject: Re: Some info

Hi Thomas,

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Good luck with your visit to the states. We do not really have any contacts with these companies, although we are oing some clinical studies for Allergan. Do not actually know any high level people.

Regarding the Caribbean-- This sounds like a good plan. We would love to see you for a couple days. Your schedule looks OK, but it may be a bit difficult getting around to all those places in a short time. You can easily fly to and from Puerto Rico to any of the islands, but it is tougher to go from the smaller islands to another. You can go directly from Anguilla to St. Barts (15 minute flight), but I am not sure you can go directly to or from Tortola from either Anguilla or St. Barts. You might have to go back through PR, which makes it at least 3-5 hours travel usually. The alternative would be to get a charter flight on a small plane or maybe even a boat. Not sure about the cost, though. If you do want to hit all 3 places it would probably easier to go first to Tortola from PR. Then get to Anguilla, then go from Anguilla to St. Barts.
I would recommend 3 places to stay in Anguilla. We stay at Carimar Beach Club, which is more of a condo than a hotel(not as much service). Less than 300 meters away is the Malihouhana Hotel which is the best on the island. They have about 60 rooms and a great restaurant and bar that we walk over to sometimes. About 1km the other way is the Frangipani Beach Club, which is a small hotel. All are right on the beach and it is easy to walk from one to the other. Any of these would be great. We will have a car so you can explore the island with or without us as you wish. Carimar has a web site, I think is www.carimar.com . Also you can easily find other links to Anguilla on the web with info about other hotels, etc. If you get a tentative itinerary I will be glad to review it and make suggestions if you want.

Let's plan on getting together with you in the afternoon and then for dinner in Stockholm on Friday Sept. 21. Could see your office then. Dinner at our hotel or whatever you would like.

We look forward to seeing you then.

Joe

----- Original Message -----

From: Thomas Sköld

To: fowlerjoe

Sent: Monday, August 27, 2001 9:47 AM

Subject: RE: Some info

Hello again,

Even though you are finally back you did not get the chance to stay home that long this time either. We are extremely happy to see that you are visiting our town again. We do need to arrange something and at least for Friday night but I would also like you to see our new office with al people in it of course. You definitely have chosen a good Hotel and their French restaurant is one of our absolute best once in the country.

Caribbean, Ann and I were thinking maybe to visit Anguilla for two days, Tortuolla two days and end our trip with a week at St. Bartha. That is our ultimate goal but has not been getting any confirmation from the travel agency yet. Please advice on hotel and I think maybe that we would start with Anguilla. Then you will have 8 days only to your selves.

I hope to hear something from Vince during September. By the way, Thursday, September 13 I have a meeting with Neutrogena in Californian but that week is also the week we will see both Allergan and Medicis. Have you been working with any one of those companies? I am coming back to Sweden Saturday the 15th. You are already in our agendas. Perhaps we could see each other Friday lunch or afternoon and then have dinner that evening. Maybe at your hotel. If there is anything we can do for you during your visit here please do not hesitate to ask us.

All the best to you and Lynn and we will see each other in only three weeks.

Regards

Public

Exhibit T8
Skold v. Galderma
Cancellation No. 92052897

A theory of the "mode of action" concerning this new technology

5 November, 2001

The vehicle is designed in its choice of and share of lipids to resemble the normal lipid organisation of the stratum corneum. Thus the administered vehicle will easily penetrate the lipid bilayer of the skin and in doing so create a temporary and reversible state of enhanced atrophy among the bilayer.

The enhanced atrophy in itself should then give rise to a) enhanced energy levels, said energy could promote active transport of the to-be-carried substances into the skin, and/or b) naturally and reversibly occurring holes and disorganised patches in the lipid bilayer, through which the active substances could then pass more easily.

It is very well feasible that the temporary disarray in the lipid bilayer will temporarily break up the organised structure of the bilayer and create micelles of lipids with areas between them/ surrounding them through which lipophobic/hydrophilic substances and compositions can enter the stratum corneum.

As the content of the vehicle resembles the natural lipid build-up of the skin, the so introduced new lipids will after a short span of creative chaos easily blend in with the natural lipid building stones of the lipid bilayer and thus not permanently damage the skin.

Thomas Sköld

LipoDerm Lipoid Restoraderm Technology

Public

CONFIDENTIAL

Exhibit T9
Skold v. Galderma
Cancellation No. 92052897

LipoDerm Restoraderm a vehicle technology for topical use

This technology is a water based lipid product aimed to deliver, to the human body and skin, different active ingredients with a therapeutic value. The lipids that are used are very similar or the same as what is natural existing in the stratum corneum (skin barrier) with an exception of triglycerides, namely palmitin acid, cholesterol and ceramide 3. To this lipids also mevalonic acid is added, a substance that contributes to the lipid biosynthesis. It takes a very small portion of mevalonic acid, in time, to reach the same cholesterol level as if cholesterol is delivered direct to the skin. The lipid content in this technology is only 6-13% and the water content 70-80%, which allows the skin to breath (evaporate) normally. Some active ingredient needs to be dissolved in for example propylene glycol or ethanol and in those cases that amount should be taken out from the water content.

Vehicles has until recently not been given to much credit and products has been developed on either an alcohol or petrolatum base depending on the solubility on the active ingredient. In the treatment of a skin disorder the vehicle can act both positive and negative to the skin. This technology is developed to act as a part of the treatment regime, which means that at the same time as it is delivering the active ingredient it is also restoring the skin barrier function. It is doing that through delivering natural lipids but also, with the lipid biosynthesis, in time help the skin to produce some of them it self.

It is important not to change, too much, the structure and functioning of these lipids. An emulsified fatty acid for an example will not keep its lipid abilities. On the contrary it will act as a detergent instead, which means ability to disrupt the barrier. When formulating, this fact needs to be considered.

For an active ingredient to penetrate the stratum corneum it some time needs help by a "penetration enhancer", which is a substance that will breake the natural lipid pattern and resistance. With chronic use of such a substance one will disrupt the barrier function and the "transepidermal water loss" (TEWL) will increase, which will result in a sensitive skin followed by a skin disorder.
The theory behind this technology is, when the vehicles lipids blends with the lipids of the stratum corneum a very temporarily disorder will occur and the active ingredient can during that time more easily penetrate. This can be explained in more technical terms but future studies can give a more thoroughly explanation/description of what is happening.

Studies that should be done in the nearest 8-12 month are;

1, Lipid study tape stripping human skin measuring lipid contents after applications

2, Blanching study measuring potency of a hydrocortisone in different vehicles

3, Dual action study the effect of the vehicles in chronic hand dermatitis

4 Surface anastatical study a comparesant study with other formulations

Public

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Exhibit T9
Skold v. Galderma
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It is important not to change, too much, the structure and functioning of these lipids. An emulsified fatty acid for an example will not keep its lipid abilities. On the contrary it will act as a detergent instead, which means ability to disrupt the barrier. When formulating, this fact needs to be considered.

For an active ingredient to penetrate the stratum corneum it some time needs help by a "penetration enhancer", which is a substance that will breake the natural lipid pattern and resistance. With chronic use of such a substance one will disrupt the barrier function and the "transepidermal water loss" (TEWL) will increase, which will result in a sensitive skin followed by a skin disorder.
The theory behind this technology is, when the vehicles lipids blends with the lipids of the stratum corneum a very temporarily disorder will occur and the active ingredient can during that time more easily penetrate. This can be explained in more technical terms but future studies can give a more thoroughly explanation/description of what is happening.

Studies that should be done in the nearest 8-12 month are;

1, Lipid study tape stripping human skin measuring lipid contents after applications

2, Blanching study measuring potency of a hydrocortisone in different vehicles

3, Dual action study the effect of the vehicles in chronic hand dermatitis

4 Surface anastatical study a comparesant study with other formulations

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Final
Date 9 May 2003

Exhibit T 11
Skold v. Galderma
Cancellation No. 92052897

Licence & Feasibility Study Agreement

EPITAN LIMITED (**EpiTan**)
COLLAGENEX PHARMACEUTICALS INCORPORATED (**CollaGenex**)
THOMAS SKÖLD (**Sköld**)

MinterEllison
LAWYERS

RIALTO TOWERS 525 COLLINS STREET, MELBOURNE VIC 3000 DX 204 MELBOURNE
TEL +61 3 9608 2000 FAX +61 3 9608 1000

Details CONFIDENTIAL

Date

29 May 2003

Parties

Name	**EPITAN LIMITED** ACN 089 644 119
Short form name	**EpiTan**
Notice details	Level 10, 52 Collins Street, Melbourne, 3000 Australia

Name	**COLLAGENEX PHARMACEUTICALS INCORPORATED**
Short form name	**CollaGenex**
Notice details	41 University Drive, Suite 200, Newtown, Pennsylvania, 18940 United States of America

Name	**THOMAS SKÖLD**
Short form name	**Sköld**
Notice details	Björnö Gård, 761 41 Norrtälje, Sweden

Background

A EpiTan has been involved in the development of, and has exclusive rights to, Melanotan (as defined in this agreement), being a synthetic hormone that mimics the action of α-MSH, or alpha melanocyte stimulating hormone.

B Sköld has know how and experience in the development of pharmaceutical products, especially formulations relating to the transport of pharmaceutically active ingredients (small molecules, peptides and proteins) across the skin.

C On 12 February 2002, Sköld and CollaGenex, a specialty pharmaceutical company, entered into a Co-Operation, Development and Licensing agreement (the Sköld Licence Agreement, as defined in this agreement) under which, amongst other things, Sköld agreed to grant an exclusive worldwide license to CollaGenex for certain Restoraderm™ (as defined in this agreement).

D To add value to a Melanotan Product, EpiTan and Sköld wish to conduct a feasibility study on a drug delivery mechanism for Melanotan in accordance with the Proposal (as defined in this agreement) using the Restoraderm.

E In order for EpiTan to conduct the Feasibility Study, CollaGenex has agreed to grant, and EpiTan has agreed to accept, a non-exclusive licence to the use of the Restoraderm for the purpose of conducting the Feasibility Study on the terms and conditions set out in this agreement.

F Sköld and EpiTan have agreed to conduct the Feasibility Study (as defined in this agreement) on the terms and conditions set out in this agreement.

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NOW, THEREFORE, in consideration of the foregoing premises and the promises and covenants set forth in this agreement, intending to be legally bound, EpiTan, CollaGenex and Sköld hereby agree as follows:

1. Defined terms & interpretation

1.1 Defined terms

In this document:

Affiliate means, when used with reference to a party, any individual or entity directly or indirectly controlling, controlled by or under common control with such party. For purposes of this Agreement, "control" (including correlative meanings "controlling," "controlled by," or "under common control with") means: (a) the direct or indirect ownership, in the aggregate, of more than 50% of the outstanding voting securities of an entity; or (b) the right or power, directly or indirectly, to direct or cause the direction of the policy decisions of an entity, whether by ownership of voting securities, contract or otherwise.

Approved Travel means return economy airfare (ex-Sweden), accommodation and meals and other reasonable expenses for one person.

Business Day means:

(a) in the case of time periods applicable to EpiTan, a day on which banks (as defined in the Australian *Banking Act 1959* (Cth)) are open for general banking business in Melbourne, Victoria, Australia;

(b) in the case of time periods applicable to CollaGenex, a day on which the Federal Reserve Bank of Pennsylvania is open for general banking business in Philadelphia, Pennsylvania, United States of America; or

(c) in the case of time periods applicable to Sköld, a day on which the Sveriges Riksbank (Swedish Central Bank) is open for general banking business in Stockholm, Sweden,

in all cases excluding Saturdays and Sundays

[redacted]

Confidential Information means any information or data, whether or not in a material form, disclosed by or on behalf of a party to another party, and including information acquired, collected or developed as part of or for the purpose of the Feasibility Study or obtained during the Term, except such information or data of the disclosing party as is shown by written evidence (i) created by the recipient party independently of this agreement; (ii) already in or otherwise enters the public domain (otherwise than as a result of a breach of this agreement by the recipient party); (iii) received in good faith from a third party and such third party does not place obligations of

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non-disclosure and non-use of the recipient party, or by already known by the recipient party at the time of disclosure.

Effective Date means the date first set forth above.

[redacted]

Intellectual Property or **IP** includes without limitation:

(a) any invention or discovery, manner, method or process of manufacture, method or principle of construction, plan, drawing or design, or scientific, technical or engineering information or document;

(b) any improvement, modification or development of any intellectual property referred to in paragraph (a);

(c) any patent, patent application, or similar rights for or in respect of any intellectual property referred to in paragraphs (a) or (b);

(d) any confidential information (including trade secrets and know-how) or right of confidentiality in respect of any information or document or other intellectual property referred to in paragraphs (a) or (b);

(e) any copyright or other rights in the nature of copyright subsisting in any works or other subject matter referred to in paragraphs (a) or (b);

in each case throughout the world and for the duration of the rights whether present or future, and without regard to the patentability or registrability of such rights.

Invention means any and all inventions, trade secrets, discoveries, developments, know-how, methods, techniques, formulae, processes and compositions of matter, whether or not patentable, resulting from or derived from or directly relating to CollaGenex's and / or EpiTan's and / or Sköld's performance under this agreement.

[redacted]

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as the case may be, pursuant to **clause 7.8**.

Joint Management Team or **JMT** has the meaning in **clause 4**.

[redacted]

Term means the period starting on the Effective Date and ending on the date of termination of this agreement.

Territory means all regions throughout the world.

1.2 Interpretation

In this agreement, unless the contrary intention appears:

(a) headings are for ease of reference only and do not affect the meaning of this agreement;

(b) the singular includes the plural and vice versa and words importing a gender include other genders;

(c) other grammatical forms of defined words or expressions have corresponding meanings;

(d) a reference to a clause, paragraph, schedule or annexure is a reference to a clause or paragraph of or schedule or annexure to this agreement and a reference to this agreement includes any schedules and annexures;

(e) a reference to a document or agreement, including this agreement, includes a reference to that document or agreement as novated, altered or replaced from time to time;

(f) a reference to 'US$', '$US', 'dollar' or '$' is a reference to currency of the United States of America;

(g) a reference to a party includes its permitted successors and assigns; and

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(h) Words and expressions importing natural persons include partnerships, bodies corporate, limited liability companies, associations, governments and governmental and local authorities and agencies.

2. Conduct of Feasibility Study

2.1 Sköld's obligations

[redacted]

2.2 EpiTan's obligations

[redacted]

2.3 Precedence of Sköld Licensing Agreement

(a) EpiTan acknowledges that CollaGenex and Sköld have entered into the Sköld Licensing Agreement. Any project(s) under the Sköld Licensing Agreement shall take precedence over the Feasibility Study and CollaGenex, at its sole discretion, may require Sköld to perform such project(s) prior to the Feasibility Study.

(b) If any resources provided by CollaGenex to Sköld pursuant to the Sköld Licensing Agreement ('**CollaGenex Resources**') are used in the performance or conduct of the Feasibility Study, CollaGenex shall, subject to written consent from the JMT (after the JMT is provided with details of the CollaGenex Resources and the terms of their use in the Feasibility Study), govern the Feasibility Study, but only in relation to, and the extent of the use of, the CollaGenex Resources. For the avoidance of doubt, the CollaGenex Resources expressly exclude Dr Thomas Sköld and Dr Mats Silvander.

2.4 Consent from CollaGenex to the conduct of the Feasibility Study

CollaGenex consents to Sköld undertaking the Feasibility Study with EpiTan in accordance with this agreement.

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3. Costs of Feasibility Study

3.1 Limitation on costs

[redacted]

3.2 EpiTan's obligations to pay Sköld

[redacted]

3.3 No costs payable by CollaGenex

Subject to **clause 3.1**, EpiTan is responsible for all costs incurred in respect of the Feasibility Study and, except where agreed otherwise in writing by all parties, there are no costs payable to Sköld or EpiTan by CollaGenex in relation to the Feasibility Study.

4. Joint Management Team

4.1 Establishment of JMT

[redacted]

4.2 Meetings of JMT

[redacted]

4.3 Responsibilities of JMT

The JMT is responsible for:

(a) overseeing the conduct of the Feasibility Study;

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(b) subject to approval in writing by the Sköld and EpiTan agreeing on any changes to the Proposal;

(c) serve as the first forum, on a 'without prejudice' basis, for attempted settlement of disputes or disagreements between Sköld and EpiTan regarding the Feasibility Study; and

(d) perform such other functions as Sköld and EpiTan agree in writing from time to time.

4.4 Decision making

[redacted]

5. Proposal

[redacted]

6. Licences

6.1 CollaGenex Licence

[redacted]

6.2 EpiTan Licence

[redacted]

7. Ownership of Intellectual Property

7.1 General ownership

(a) EpiTan retains all right, title and interest in and to the EpiTan IP.

[redacted]

7.2 Notification of Inventions

[redacted]

7.3 Determination of inventorship and ownership of Inventions

[redacted]

7.4 EpiTan IP

[redacted]

7.5 CollaGenex IP

[redacted]

[redacted]

7.6 Sköld IP

(a) It is the express intent of [redacted]

[redacted]

7.7 Inventions owned jointly by Sköld and CollaGenex

Where:

[redacted]

7.8 Joint Inventions other than Excluded Inventions

[redacted]

7.9 Use of Joint Inventions

[redacted]

[redacted]

7.6 Sköld IP

[redacted]

7.7 Inventions owned jointly by Sköld and CollaGenex

Where:

[redacted]

7.8 Joint Inventions other than Excluded Inventions

[redacted]

7.9 Use of Joint Inventions

[redacted]

[redacted]

8.4 Decision on protection of Joint IP by patent or not

[redacted]

8.5 Procedure for where protection for Joint IP to be by patent law

[redacted]

8.6 Decision not to continue with protection

[redacted]

9. Product Commercialisation

9.1 **Notice to CollaGenex**

[redacted]

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9.2 Reasonable commercial terms

[redacted]

9.3 No deemed licence

[redacted]

10. Reports

(a) Sköld will furnish EpiTan timely progress updates by fax and/or e-mail summarising the data and results of the Feasibility Study. These updates will contain technical information (including, but not limited to, a summary of all Inventions and data) generated in the course of the Feasibility Study.

(b) Sköld will furnish EpiTan a final summary report at the end of the Feasibility Study within 20 Business Days after completion or early termination of the Feasibility Study.

(c) Sköld will use diligent efforts to provide reports or other information to EpiTan under this agreement that are true, accurate, complete and not misleading in any material respect.

11. Records and Information

11.1 Duties to keep records of Feasibility Study

Sköld must at all times ensure that its directors, officers, employees, contractors and agents and all students working in association with Sköld keep complete and accurate records of the work conducted during the Feasibility Study using standard laboratory procedures including the recording of experimental data and results in bound, dedicated, signed laboratory notebooks.

11.2 Permission to examine records

Sköld must at all times during usual business hours and otherwise on reasonable notice:

(a) permit EpiTan and its representatives to examine and copy Sköld's technical records and documents relating to the Feasibility Study for the purposes of EpiTan:

(i) monitoring the Feasibility Study;

(ii) ensuring that Sköld has complied and is complying with all the obligations imposed on it under this agreement; and

(iii) assessing the viability and prospects of any Product arising out of the Feasibility Study for commercialisation.

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(b) otherwise, co-operate fully with EpiTan and its representatives to enable EpiTan to exercise its rights under **paragraph (a)**.

12. Provision of samples

Sköld must provide EpiTan with samples of the Product for evaluation as they become available, in accordance with the Proposal. In addition to the samples, Sköld will provide sufficient information to enable EpiTan to evaluate the Product.

13. Termination

13.1 Early Termination

[redacted]

13.2 Termination by mutual agreement

The parties may terminate this agreement at any time with immediate effect by mutual written agreement and on such terms as the parties see fit.

13.3 Termination for cause

[redacted]

13.4 Termination not to affect accrued rights

[redacted]

13.5 Effect of Early Termination of Feasibility Study

[redacted]

[redacted]

13.6 Effect of termination of the Feasibility Study for cause by EpiTan against Sköld

[redacted]

14. After Termination

[redacted]

15. Termination of Sköld Licensing Agreement

If the exclusive licence granted to CollaGenex by Sköld under the Sköld Licensing Agreement is terminated, for whatever reason, Sköld agrees to grant to EpiTan a licence to the Restoraderm for the purpose of EpiTan continuing the Feasibility Study and developing a Product.

16. Warranties

Each party represents and warrants to each other party that:

(a) it has the power and authority to enter into and perform its obligations under this agreement;

(b) the execution, delivery and performance of this agreement by the party will constitute legal, valid and binding obligations of that party, enforceable in accordance with the terms of this agreement;

(c) if the party:

(i) is a corporation, it is not under any external or insolvency or bankruptcy administration;

(ii) is a partnership or any body (other than a body corporate or a body politic), none of the members of the partnership or other entity (as the case may be) is under any form of external or insolvency or bankruptcy administration.

(d) the execution, delivery and performance of this agreement will not violate, breach or constitute a default under:

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(i) any legislation or rule of law or regulation, authorisation, consent or any order, governmental or other public authority, institution or body;

(ii) the party's constitution, charter, bylaws or any legislation, rules or other document constituting that party or governing the party's activities; or

(iii) any written or oral undertaking, or any instrument (including any contract of employment, consultancy agreement or other arrangement, whether in written form or not) of a similar nature, to which it is a party or which is binding on it.

16.2 Sköld's warranty

Sköld warrants to EpiTan that Sköld will use its diligent efforts to conduct the Feasibility Study diligently and competently, in accordance with the Proposal (including any timeframes set out in the Proposal) and in accordance with generally accepted professional, scientific, ethical, business and financial principles and standards.

17. Indemnities

17.1 Provision of indemnity

[redacted]

17.2 Notice of claim and assistance by other party(s)

Each party shall provide prompt notice to the other party(s) of any actual or threatened demand, claim, suit or action or claim for which it may seek indemnification; provided that the failure to provide prompt notice shall reduce the Indemnifying Party's obligations under **clause 17.1** only to the extend that the Indemnifying Party was prejudiced by such failure. In the event of any such actual or threatened demand, claim, suit or action or claim or claim therefor, each party shall provide the other party(s) such information and assistance as the other party(s) shall reasonably request for purposes of defence and each party shall receive from the other party(s) all necessary and reasonably cooperation in such defence, including, but not limited to, the services of employees of the other party(s) who are familiar with the transactions or occurrences out of which any such demand, claim, suit or action or claim may have arisen. The Indemnified Party(s) shall have the right to participate in and with respect to the defence of any demand, claim, suit or action or claim with counsel of its choosing whose fees shall be borne by the Indemnified Party(s). The Indemnifying Party shall not settle any claim or agree to the entry of any judgment or other relief without the prior consent of the Indemnified Party(s), which consent shall not be withheld unreasonably or delayed.

18. Limitation of Liability

[redacted]

[redacted]

19. Confidential Information

19.1 Duties of confidentiality

Each party:

(a) must keep all Confidential Information of any other party confidential;

(b) subject to **clause 19.2**, may disclose Confidential Information of any other party if required to do so by law;

(c) may disclose Confidential Information of any other party only to those of its employees, contractors, directors, officers, agents or representatives who require the Confidential Information of any other party in order for that party to perform its obligations or enjoy its rights under this agreement and who agree to be bound by this **clause 19**; and

(d) must use Confidential Information of any other party only for the purposes of performing its obligations or enjoying its rights under this agreement.

19.2 Disclosure

If any party (or any of its respective officers or employees) is required by law to disclose any Confidential Information of any other party to a third person (including, but not limited to, government) that party must:

(a) immediately notify the other party whose Confidential Information is required by law to be disclosed;

(b) (if possible), not disclose the Confidential Information of the other party until the other party has had a reasonable opportunity to take any steps that the other party considers necessary to protect the confidentiality of that information;

(c) in any case notify the third party that the information is confidential information belonging to the other party; and

(d) only disclose as much Confidential Information as is required by law and no more.

19.3 Limitations on disclosure

No party may disclose Confidential Information of any other party to any person other than those persons referred to in **clause 19.1(c)** without the prior written consent of the other relevant party for a period of ten (10) years following termination of this agreement.

19.4 Effect of termination on Confidential Information

On termination of this agreement, upon written request, each party must deliver up to the other relevant party, or at that party's election, destroy all Confidential Information in its possession or control except one copy to be retained for its files.

19.5 Damages for breach of confidentiality obligations

The parties agree that any breach or threatened breach of this **clause 19** will result in irreparable harm which cannot be remedied by money damages. Consequently, each party shall be entitled to enforce this **clause 19** through an order of specific performance or other equitable or injunctive relief.

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20. Publicity

Subject to **clause 21**, the parties agree to jointly discuss and agree on any press releases or statements to the public regarding this agreement or any aspect of this agreement subject in each case to disclosure otherwise required by law or regulation as determined reasonably and in good faith by each party. Where a party is required by law or regulation to make a press release or statement to the public, it will provide the other parties with reasonable notice of and an opportunity to comment on such disclosure.

21. Publication of Results or Trials

21.1 No publication without agreement

Save for any information required to be disclosed by law, each party agrees that it will not publish or present publicly the results of studies or trials carried out pursuant to this agreement unless the other parties:

(a) consent (which consent may be withheld in the other parties' sole and absolute discretion) in writing to such publication or disclosure, and

(b) has had a reasonable opportunity to review and comment on such information before it is published or presented.

21.2 Necessity of clause 21.1

The parties acknowledge that **clause 21.1** is necessary to protect each party's legitimate intellectual property rights and commercial interests.

22. Further action and good faith

Each party must use its best efforts to do all things necessary or desirable to give full effect to this agreement.

23. Notice

23.1 Form of notice

A notice by a party to another party under this agreement must be:

(a) in writing;

(b) directed to the recipient's address specified in this **clause 23** as varied by written notice; and

(c) sent by internationally recognised overnight courier or facsimile to that address,

and will be deemed to be duly given:

(d) in the case of internationally recognised overnight courier, on the day of delivery; or

(e) if sent by facsimile, when the answer back or message confirmation is received,

in each case if a Business Day, otherwise at 9.00am on the next Business Day.

23.2 Addresses

The parties' addresses and facsimile numbers are:

EpiTan:

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Attention: Mr. Michael Fleming
Pharmaceutical Development Manager
New Business Development Manager
Address: EpiTan Limited
Level 10, 52 Collins Street
Melbourne VIC Australia 3000
Facsimile No +61 3 9662 4788

CollaGenex:
Attention: Mr. Robert Ashley
Senior Vice President
Commercial Development
Address: CollaGenex Pharmaceuticals, Inc.
41 University Drive, Suite 200,
Newtown, Pennsylvania 18940
United States of America
Facsimile No: +1 215 579 8577

Sköld:
Attention: Mr Thomas Sköld
Address: Björnö Gård
761 41 Norrtälje
Sweden
Facsimile No: +46 176 22 4420

24. Resolution of Disputes

24.1 No court proceedings without compliance with dispute resolution clause

No party is entitled to commence court proceedings (except proceedings seeking equitable or injunctive relief which may be commenced by a party at any time in any court of competent jurisdiction) in respect of a dispute arising out of or related to this agreement (**'Dispute'**) unless it has complied with this **clause 24**.

24.2 Notice required

A party claiming that a Dispute has arisen must notify the other party(s) to the Dispute giving details of the Dispute.

24.3 Reasonable efforts to resolve

During the 20 Business Day period after a notice is given under **clause 24.2** (or longer period agreed in writing by the parties to the Dispute) (**'Initial Period'**) each party to the Dispute (**'Disputant'**) must use its reasonable efforts to resolve the Dispute by referring the matter:

(a) for any Dispute between Sköld and EpiTan, to the JMT;

(b) for all other Disputes, to the Chief Executive Officers, or their designated representatives, of each party for resolution.

24.4 Referral to mediation

If the Chief Executive Officers or the JMT (as the case may be) are unable to resolve the Dispute within the Initial Period, each Disputant agrees that the Dispute must be referred for mediation at the request of either or any Disputant. Such mediation shall be conducted under the auspices of the American Arbitration Association (the 'AAA') in accordance with its then current Commercial Mediation Rules. Such mediation shall take place at a mutually agreeable location within the United States of America.

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24.5 Role of mediator

The role of any mediator is to assist in negotiating a resolution of the Dispute. A mediator may not make a decision that is binding on a Disputant unless that Disputant has so agreed in writing.

24.6 Use of information or documents

Any information or documents disclosed by a Disputant in a mediation conducted under this clause may not be used by the recipient of that information except to attempt to resolve the Dispute as part of the mediation.

24.7 Costs

Each Disputant must bear its own costs of complying with this clause and the Disputants must bear equally the costs of any mediator engaged.

24.8 Termination of dispute resolution process

Twenty (20) Business Days after the appointment of the mediator by the AAA, a Disputant that has otherwise complied with **clauses 24.1** to **24.7** may terminate the dispute resolution process by giving notice to any other Disputant and seek redress through any court of competent jurisdiction.

24.9 Non-compliance with process

If in relation to a Dispute a Disputant breaches any provision of **clauses 24.1** to **24.7** then the other Disputants need not comply with **clauses 24.1** to **24.7** in relation to that Dispute.

25. Miscellaneous

25.1 Survival

Clauses 1, 3.2, 7, 8, 13.5, 13.6, 14, 16 to **21, 23** to **25** survive termination of this agreement.

25.2 Costs

Each of the parties to this agreement is responsible for its own costs and expenses of and in connection with the negotiation, preparation, execution, stamping, registration and completion of this agreement and of any document contemplated by this agreement.

25.3 Governing law and jurisdiction

This Agreement will be governed and construed in accordance with the laws of the United States of America and the laws of the State of New York without reference to the conflict of law principles or jurisprudence of any jurisdiction. The parties consent to the jurisdiction of the state and federal courts of the State of New York and hereby waive any objection that they may have to such courts asserting personal jurisdiction over the parties.

25.4 No waiver

The failure of a party at any time to require performance of any obligation under this agreement is not a waiver of that party's right:

(a) to insist on performance of, or claim damages for breach of, that obligation unless that party acknowledges in writing that the failure is a waiver; and

(b) at any other time to require performance of that or any other obligation under this agreement.

25.5 Relationship between the parties

No party:

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(a) is in any way an agent of another party for any purpose or has any right to hold itself out as such; and

(b) may make any promise, warranty or representation or execute any contract or otherwise deal on behalf of another party.

25.6 Assignment

A party must not assign this agreement or any right under this agreement unless that party:

(a) is not in breach of this agreement;

(b) obtains the prior written consent of each other party;

(c) ensures that the assignee agrees to be bound by all of that party's obligations under this agreement; and

(d) acknowledges that it remains bound by this agreement.

25.7 Severability

All or part of any provision of this agreement that is illegal or unenforceable may be severed from the agreement and the remaining provisions of this agreement will continue in force.

25.8 Alteration

This agreement may be altered only in writing signed by each party.

25.9 Entire Agreement

This agreement, including the schedules and annexures:

(a) constitutes the entire agreement between the parties as to its subject matter; and

(b) in relation to that subject matter, supersedes any prior understanding or agreement between the parties and any prior condition, warranty, indemnity or representation imposed, given or made by a party.

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Signing page

IN WITNESS WHEREOF, EpiTan, CollaGenex and Sköld have caused their authorised representatives to execute this Agreement on the date first written above.

Signed for **EPITAN LIMITED** by an authorised officer in the presence of

Signature of officer

Signature of witness

Dr Wayne Millen

Name of officer (print)

Name of witness (print)

CEO - Director

Office held

Signed for **COLLAGENEX PHARMACEUTICALS INCORPORATED** by an authorised officer in the presence of

Signature of officer

Signature of witness

RAASHLEY

Name of officer (print)

Name of witness (print)

Senior V.P.

Office held

Signed by **THOMAS SKÖLD** in the presence of

Signature of witness

THOMAS SKÖLD

Name of witness (print)

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-----Original Message-----
From: Robert Ashley
Sent: Tuesday, December [illegible], 2009 [illegible]:05 PM
To: Frank Ruffo; Nancy Broadbent; Jeff Day; Paul Lubetkin; Colin Stewart
Subject: Minor Amendments

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Public

Gentlemen,
Appended is the Skold agreement with a couple of additional minor amendments. Paul and Colin, Skold is the inventor and developer of Restoraderm. This is the agreement that controls the relationship between CGPI and Skold. All payments up to and including the third [redacted]00 have been made. The next payment due is the first product-related payment of [redacted] when the first Rx product hits the market.
What you see here are fairly substantial amendments to the original structure of the agreement which we have been negotiating with Skold for some time (really our fault for dropping the ball). In particular, the first product payment is significantly delayed because originally it related to the first product, not the first Rx product. Obviously this was a significant barrier to us introducing lower value OTC products (eg Lytra or Ceracel) so we have been trying to negotiate a deferment of payment to the higher value Rx product. Unfortunately for Skold this delays his first significant payment by at least a year (and maybe more – we are controlling the rate of development). He has been trying to link payments to transfer of technology – eg instead of a licensing agreement changing this to a sale of technology to us, on payment of a fee (obviously sooner). The problem with this approach is that the fee is not necessarily amortizable over the life of the technology, whereas a fee to deliver a product is amortizable over the life of the product.
The e-mail correspondence which follows allows you to follow this discussion as it has developed.
Obviously we need to make some decisions about the future of this technology, and, if we are serious about pursuing it, we should reach a fair and equitable compromise with Skold who has been funding a lot of the development work out of his own pocket in the expectation that CGPI would pay our contractually agreed milestones. Skold is extremely reasonable, has so far been patient and has basically delivered on his side of the bargain.
One side issue relates to insurance, and Frank is looking in to this.
Rob

Exhibit T 12
Skold v. Galderma
Cancellation No. 92052897

Arthur Jackson ~~CONFIDENTIAL~~ 109

From: Jeff Day [jday@collagenex.com]
Sent: Monday, July 19, 2004 8:00 AM
To: Thomas Sköld
Subject: Ph Level

Public

Thomas,
What is the PH Level range for Restoraderm? I think Ponsus vehicle is 6.5-8?
This is for Berlex?

Jeff Day

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Exhibit T 15
Skold v. Galderma
Cancellation No. 92052897

CONFIDENTIAL

From: CASSADY Quintin [mailto:quintin.cassady@galderma.com]
Sent: den 15 juli 2009 15:54
To: Thomas Sköld
Subject: RE: Restoraderm and october

Exhibit T 27
Skold v. Galderma
Cancellation No. 92052897

Thomas:

Per our agreement, Galderma has the rights to Restoraderm Intellectual Property, which is comprised of, among other things, (1) all Restoraderm Patent Rights and (2) all Restoraderm know-how related to the Restoraderm Technology. The Restoraderm Patent Rights include all patent rights related to the Restoraderm Technology, as defined in section 1.23. As stated therein, oral, nasal, and intravenous are not considered to be part of the topical drug delivery technology.

As such, you are free to explore opportunities that are exclusively related to oral, nasal, or intravenous use.

Best regards,

Quintin

Public

Quintin Cassady
Vice President and General Counsel
Galderma Laboratories L.P.
14501 North Freeway
Fort Worth, TX 76177
(817) 961-5003 (office)
(817) 905-5272 (cell)
(817) 961-0034 (fax)
quintin.cassady@galderma.com
www.galdermausa.com

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From: Thomas Sköld [mailto:thomas-skold@telia.com]
Sent: Monday, July 13, 2009 10:55 AM
To: CASSADY Quintin
Subject: SV: Restoraderm and october

Thanks Quintin,

I believe I have a favour to ask you.

Public

CONFIDENTIAL

As you know I'm working on an intra nasal project with some friends, which is based on a separate patent application but with the similar lipids in smaller quantities plus pegulated lipids. We are just in the phase to put our NSAID in to humans for the first time and preparations have recently started. So for the first time significant resources need to be invested and due to that, questions have been raised over Restoraderm and my existing agreement with Collagenex/Galderma. In paragraph 1.23 I carved out oral, nasal and intravenous administration for obvious reasons. I don't want to share our agreement with them nor our patent applications so what I'm asking for is if you can, in a few words, confirm to me Galderma's rights and that they are limited to skin preparations/dermatology. I only need a few words from you that I can share with my friends. That would make my life a bit easier. At the same time it is of interest also to Galderma to get confirmation and understand that LiPoint doesn't have any rights to anything within dermatology (even if there would have been a intra nasal potential there).

If Art hasn't told you my friends are Rob Ashley former Collagenex, Mike Sember former Elan and the Mario family former Alza).

Thanks in advance and have a very pleasant summer,
Thomas

Från: CASSADY Quintin [mailto:quintin.cassady@galderma.com]
Skickat: den 10 juli 2009 21:32
Till: Thomas Sköld
Ämne: RE: Restoraderm and october

Thomas:

Thank you for your mail. I hope you had success in your sailing race.

I will confer with Art and Pierre as to the dates you suggest below and we will try to get something scheduled. I do agree that we need to have a productive meeting if we are going to do so.

In the interim, all the best to you during your time off.

Best regards,

Quintin

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the author hereof in any way from its use. If you have received this communication in error, please immediately notify us by return E-mail.

CONFIDENTIAL

From: Thomas Sköld [mailto:thomas-skold@telia.com]
Sent: Thursday, July 09, 2009 9:01 AM
To: CASSADY Quintin
Subject: Restoraderm and october

Dear Quintin,

I never got the time to thank you for our conference call on June 24th. At the time we had the 2nd World Psoriasis convention here in Sweden and Prof. Chuck Ellis with wife as our guests and as soon as they left for Michigan I went on an 8 days ocean sailing race. I'm now about to take some time off and wanted to get back to you before that.

A brief summarize on what we discussed and please correct me if you think I'm wrong; Galderma are in the middle of doing your homework in understanding the technology better including technical feasibility studies together with a human study on the vehicle it self. The results from the human study won't be written down until some time in September. Therefore we will continue our discussion in October in regards to how to go forward. At the same time we need to have a "joint steering committee" meeting in October as well and perhaps we could combine these items for one and the same meeting. We also need to put people on board of the committee which is something for you to think about. Chuck Ellis recommended Thomas Hultsch that recently has joined Galderma but this is of course up to you.
On Sept 27th I'll be in Los Angeles together with some dermatologists and on Sept 30th the Coastal Derm meeting starts in San Diego (www.coastalderm.org). The Coastal meeting ends on Oct 3rd. So to be cost effective an option would be to either have our meeting in San Diego during the meeting which would be nice or have it in Texas on Monday Oct 5th which is right after the meeting. France and or Sweden are of course also options we could pursue. What ever we decide I would like us to schedule the day(s) as soon as possible for everyone's convenience.

I would urge you to start thinking about terms you think is fair for us to work under as soon as some of the results starts to reveal them selves to you so that our meeting in October will be productive.

All the best,
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Till: Thomas Sköld
Ämne: RE: Restoraderm and october

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All the best,
Thomas

Public

Exhibit
Skold v. Galderma
Cancellation No. 92052897

Från: CASSADY Quintin [mailto:quintin.cassady@galderma.com]
Skickat: den 2 juni 2009 18:04
Till: thomas-skold@telia.com
Kopia: CLAPP Art
Ämne: RESTORADERM update

Thomas:

Good day to you. I hope you are doing well.

I regret that I was unable to spend much time with you when you visited Fort Worth late last year. However going forward, I am going to try to be more involved in the RESTORADERM project in terms of being a resource for you on the status of the project. I am certain you know my reference, but by "RESTORADERM project", I am referring to the topical dermal technology known as RESTORADERM as now owned by Galderma under the terms of the Asset Purchase and Product Development Agreement with you dated August 19, 2004.

In that regard, I have received the following information this week:

1. **Galderma is currently conducting the following studies using its own protocols:**

- technical manufacturing feasibility study;
- stability studies; and
- skin barrier recovery tests.

A study on volunteers will be performed in July 2009. The results of the study should be available in October 2009 and the results will help to guide our plans for RESTORADERM going forward.

2. Patent proceedings:

Below is a status on the pending applications relating to the delivery system compositions.

European Procedure:

European Patent application EP 03728242.3

- Patent application is under examination
- Last action dated 05/02/2009: answer to the examination report is enclosed as well as the pending set of claims.

We have amended the "delivery system" appellation to "skin preparation", as "skin preparation" seems a better definition of the invention.

Furthermore, you will note that we focused on the three –phases process to obtain the composition, process that leads to the specific structure of the composition with these three phases :
- the dispersed phase (also called foam phase in the patent) comprising lipid particles and optionally gas sphere.
- The ultrafine dispersed phase (also called vesicle phase in the patent) comprising vesicles
- The hydrophilic phase comprising the other components of the composition.

We have amended the claims to this precise three-phase-composition and the process to obtain it.

US procedure:

US2004/0009213 : Appl. N° 10/957 320 (the " '320 patent") :

As you may remember, regarding the analysis made by the examiner and patent attorneys, mainly due to the prior art consisting of the previous publication of the 371'patent, the "320'patent" was considered not patentable. As such, '320 patent application was abandoned in favour of the '371 patent.

US 2005/0129722 : Appl. N° 10/388 371 (the" '371 patent") :

The '371 patent application was subsequently abandoned in favour of the '406 patent due to prosecution issues and strategy.

US2009/081139 : Appl.N° 12/082,406 (the" '406 patent") :

Patent application is pending and not yet under examination. The Published application is enclosed. But please note that in answer to the future Office actions, we will amend the US claims in accordance with the European ones.

Please find also herewith enclosed a summary of the main relevant prior art cited during patent examination:

• "Elias "patent (WO 94/00127 - priority date : June 18, 1992, publication date : January 6; 1994) discloses :

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~~CONFIDENTIAL - Initial Disclosure~~

Arthur Jackson

To: Thomas Sköld
Subject: RE: Restoraderm

Från: CASSADY Quintin [mailto:quintin.cassady@galderma.com]
Skickat: den 17 juni 2009 15:35
Till: Thomas Sköld
Ämne: RE: Restoraderm

Exhibit T 59
Skold v. Galderma
Cancellation No. 92052897

Thomas:

I have forwarded your questions to our R&D personnel requesting that they provide me with answers. Upon receipt, I will forward them to you.

Regarding the other matters raised in your mail below, I would be curious to know the details about what you heard at the AAD in March regarding Restoraderm. Without the details, it is difficult for me to look into it and comment.

On your agreement, I don't believe Galderma ever agreed to do a new agreement with you or otherwise modify the existing one. We did agree to listen to your requests and review what CollaGenex was talking with you about in this regard and we did so. However, as stated in my prior e-mail to you, Galderma simply does not believe that there is a need to replace or modify our existing agreement at this time. It continues to govern our relationship and sets forth certain terms for royalties in the event a product incorporating a Restoraderm patent goes to market.

If you would like to arrange a call with me so we can avoid further trading of e-mails on this matter, please let me know. I am traveling the rest of this week and also the latter part of next week, but sometime in the morning (Texas time) on Tuesday or Wednesday next week would generally be good for me.

Best regards,

Quintin

Quintin Cassady
Vice President and General Counsel
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From: Thomas Sköld [mailto:thomas-skold@telia.com]
Sent: Tuesday, June 16, 2009 11:01 AM
To: CASSADY Quintin
Subject: Restoraderm

~~CONFIDENTIAL - Initial Disclosure~~

Dear Quintin,

I have a few follow up questions for you in regards to the update but also last week's statement.

Could you please be more specific when it comes to;
1, technical manufacturing feasibility study – what kind of study are we talking about?
2, stability studies – what active compounds are you working with?
3 skin barrier recovery tests – what parameters will you be looking at and where will the study be conducted? If you have not, I recommend you to study similar studies conducted earlier with Restoraderm by Dr Ruby Gadhially in San Francisco where she, among other things, concluded that since Restoraderm is not occluding the skin after application a treatment for 5 – 7 days should be advised before measuring for example TEWL.
4, the human study that will be conducted in July 2009 – what kind of study is it (end points) and where will it be conducted.

During the AAD meeting in the beginning of March this year it came to my attention that Galderma revealed to third parties that Galderma were only interested in the name Restoraderm and not the technology it self. When I on March 16th received an e-mail from Galderma stating that the R&D team was meeting with your legal folks to draft an agreement for my review I was positively surprised. Since a new agreement would for sure benefit a long term committed Galderma I am sincerely confused by your recent statement. For me to better understand your position is it possible for you to communicate some of the arguments behind your point of view. Or is it merely temporarily until results are available in October?

Best regards,
Thomas

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~~CONFIDENTIAL - Initial Disclosure~~

Exhibit T 61
Skold v. Galderma
Cancellation No. 92052897

Thomas Sköld / Restoraderm Technology

Per section 8.5, Galderma is to return the following;

Note. Due to very little information on hand and especially from Jan 2006 – Nov 2009 there might and or should be more documents that Galderma should return.

A, Patents and related documents including signed transfer document

1, U.S Patents

US2004/0009213 (Appl. No. 10/388,371)
Continuation Application US2009/0081139

US2005/0129722 (Appl. No. 10/957,320, CIP of 10/388,371
Continuation Application US2009/0226491

Including listed Foreign Equivalent Patents

2, European Patent

EUR Patent (Appl. No. 03728242.3)

3, Rest of the World Patent Applications if any

B, Development Documents and Materials

Technology & Development Materials (CD and Hard Copy)
1, Studies and tests conducted during 2002-2004
Ruby Ghadially; hydration studies, fluorescence penetration study, comparison Restoraderm Clobetasol with Olux (hydration/dehydration study)
Joe Fowler; Lidocain studies, comparing Restoraderm vehicle with Cetaphil and several other moisturizers (also as a poster)
YKI; Skold sponsored flux study (published) Lovisa Ringstad et all
YKI; Manufacturing and process studies
(YKI is The Institute if surface Chemistry a division of the Royal School of Technology Stockholm Sweden)

Studies 2005 - 2009
I am not aware of any relevant studies conducted during 2005 - 2008 but if something ever took place that should be part of the returned information. Of interest is also any relevant or irrelevant tests and or clinical study performed/conducted by Galderma.

2. Stability data on:

[redacted]

3, Process and Batch Records
Of each and everyone of the above (used at these studies)

4, Manufacturing information

[redacted]

Lipid structures stability tests
Communications between Collagenex, Avanti and Degussa in regards to filing an excipient DMF on Ceramide III. DMF on Ceramide 6 from Avanti.
Any purchase orders and or quotations in regards to Restoraderm excipients

5, Formulations/products
Except for your listed ones there should be canisters from Sciarra and their stability studies.

6, Marketing Research, Business Plans, Development Plans, Clinical Plans
Anything that can be related to Restoraderm and our contract including JSC minutes.

7, Trademarks and layouts
Any trademark and layouts in regards to developments, studies and published data that also can be related to our contract.

Best regards,

Thomas Sköld
Björnö Gård
761 41 Norrtälje
Sweden

Phone; +46 70 660 00 40
Fax; +46 176 22 44 20
E-mail; thomas-skold@telia.com

~~CONFIDENTIAL~~

Public

Arthur Jackson

201

From: Thomas Sköld [skold@ponsus.se]
Sent: Wednesday, September 05, 2001 3:43 AM
To: Jeff Day
Subject: RE: Products for Medicis

Exhibit T 69
Skold v. Galderma
Cancellation No. 92052897

Thank you!

Talk to you later and keep your fingers cross today when Ralph is seeing David Kohn.

Regards,
Thomas

-----Original Message-----
From: Jeff Day [mailto:jday@myexcel.com]
Sent: Wednesday, September 05, 2001 2:01 AM
To: Thomas Sköld
Subject: Re: Products for Medicis

Medicis:
Loprox (ciclopirox olamine 1%) Cream / Solution
Lidex (fluocinonide 0.05%) Cream/Oint/Solution/Gel

Neutrogena / Ortho Dermatology:
Spectazole Cream (econazole nitrate 1%)
Sunscreen
Note: We will be meeting with the following people, primarily to discuss Spectazole. They seem to be interested in teh sunscreen, but the marketing director for OTC's is located in LA. We may have to move on this at a later date, and concentrate on Spectazole to start. I am trying to set up a meeting on Wed PM or early Thursday with this guy.
-Tom Carey - VP Bus Development
-Yossi Camu - Director Bus Development
-R & D group

I am waiting to hear back from Allergan, as soon as I hear I will alert you! You will need to arrive in on Monday, and depart on Friday. I will take care of arrangements from Newark/Philly.

Jeff Day

----- Original Message -----
From: Thomas Sköld

To: Jeff Day

Sent: Monday, September 03, 2001 4:05 AM

Subject: RE: Products for Medicis

Morning Jeff,

I know you have a day off today and I hope you will enjoy it.

I did not get in contact with Ralph again but I think we are going to have a conference call tomorrow with David Kohn and Ralph.
About next week, I do need to know as soon as possible if we are going to see Allergan also. Reason being that we need to plan Prof. Stefan Arvers trip so he will be useful the whole time. Remember that this trip will be on me personally and not the company at this time. If we succeed I will be able to transfer the costs to Ponsus.
Please let me know what Neutrogena expects from us on Tuesday? Are they ready to make a decision? Are we talking both on the sunscreen range and Spectazole?

Give me also as much info on Medicis as possible. Stefan needs this info to prepare him self. Please give us the info on Loprox as well.

Could you possible buy and send us the "book with all registered pharmaceuticals" in the US? I don't remember the name of it.

We should also talk tomorrow. Suggest a time for that call.

All the best,
Thomas

> -----Original Message-----
> **From:** Jeff Day [mailto:jday@myexcel.com]
> **Sent:** Friday, August 31, 2001 6:30 PM
> **To:** Thomas Sköld
> **Subject:** Products for Medicis
>
> Thomas,
> The second product we are discussing at Medicis as as follows:
> Lidex
> Fluocinide .01%
>
> You have already recieved the information on Loprox, is this correct?
> Jeff Day

~~CONFIDENTIAL~~

Public

Arthur Jackson

202

From: Thomas Sköld [skold@ponsus.se]
Sent: Monday, September 03, 2001 6:06 AM
To: Ralph Soldo
Subject: Conference call

Exhibit T 70
Skold v. Galderma
Cancellation No. 92052897

Good morning Ralph,

I hope your long weekend was pleasant.

I am writing you just to find out about our conference call with David Kohn on Tuesday. Were you able to agree with David, before the weekend, about a certain time on Tuesday? If not, please respond on this E-mail as soon as you can so I know when I need to be on my home phone.
I really hope we can do this on Tuesday. That would give you some time to send us something in writing that I can use internally. Then as you know I will be on the east coast Monday and Tuesday next week. I will be arriving at Newark Monday 2 p.m. We have a meeting with Ortho McNiel and Neutrogen on Tuesday afternoon so we could meet to finalize this either Monday afternoon or before and during lunch on Tuesday.

Please advice.

All the best,
Regards

Thomas

CONFIDENTIAL

Public

Arthur Jackson

203

From: Jeff Day [jday@myexcel.com]
Sent: Wednesday, September 05, 2001 8:06 AM
To: Thomas Sköld
Subject: Re: Schedule

Exhibit T 71
Skold v. Galderma
Cancellation No. 92052897

I am working out the details as we speak!
Jeff Day

----- Original Message -----
From: Thomas Sköld
To: Jeff Day
Sent: Wednesday, September 05, 2001 3:40 AM
Subject: RE: Schedule

We might have to squeeze in Ralph either on Monday or Tuesday.

Could you arrange this for me?

If there will be no meeting with Allergan I might take the Thursday flight home instead of Friday.

Regards,
Thomas

-----Original Message-----
From: Jeff Day [mailto:jday@myexcel.com]
Sent: Tuesday, September 04, 2001 10:10 PM
To: Thomas Sköld
Subject: Schedule

I have confirmed several meetings:

Monday: Arrival into Newark
Meeting with CollaGenex
Tuesday: AM meeting with Neutrogena / Ortho Derm
PM - Depart for Phoenix
Wednesday: 9:00 AM - 11:30 Medicis

I am still waiting for Allergan to confirm, and if we go there we will also meet with OMP (Direct to Physcian sales organization), located outside of Los Angeles.

Jeff Day

CONFIDENTIAL

Public

Arthur Jackson

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T 73

Exhibit _____
Skold v. Galderma
Cancellation No. 92052897

From: Thomas Sköld [skold@ponsus.se]
Sent: Thursday, September 06, 2001 3:58 AM
To: Jeff Day
Subject: FW: USA biljetter som budas nu.

Good morning Jeff,

Unfortunately I did not hear anything from Ralph yesterday.

I have arranged tickets for us but from Newark. $ 590 for each of us. This is the price you get if you are coming from Europe and they do not have to know that you were not on that flight.

I hope you arrange all hotels for us. Which means two night at Newark and one in Phoenix.

Regards,
Thomas

-----Original Message-----
From: svante.isberg@nymans.se [mailto:svante.isberg@nymans.se]On Behalf Of platinum.travel@nymans.se
Sent: Thursday, September 06, 2001 9:32 AM
To: SKOLD@PONSUS.SE
Subject: USA biljetter som budas nu.

Hej,
Här kommer tidtabellerna med priser.
Allt ska vara under kontroll, jag bjuder på budkostnaden men då det finns en risk för uppdebitering av Jeff Bay´s biljett ber jag dig att maila mig ett svar att du godkänner en uppdebitering om det mot förmodan skulle ske.

Trevlig resa!

Svante Isberg
AMERICAN EXPRESS RESEBYRA
106 82 STOCKHOLM
SWEDEN
EML:Y

DATUM 06SEPTEMBER01
BOKNINGSREF ZIW9IM

SKOLD/THOMAS MR

SERVICE	FRAN	TILL	AVRESA	ANKOMST
AIRLINES - SK 903				SCANDINAVIAN
MAN 10SEP	STOCKHOLM SE	NEWARK NJ	1040	1310
	ARLANDA	NEWARK INTL		
	UTRU BOEING 767-200/300			
	PLATS 02H BEKRAEFTAD			
	RESERVATION BEKRAEFTAD - D BUSINESS			
AMERICA WEST AIRLINES - HP 687				
TIS 11SEP	NEWARK NJ	PHOENIX AZ	1800	2041
	NEWARK INTL	SKY HARBOR INTL		
	UTRU AIRBUS INDUSTRIE A319			
	PLATS 18F BEKRAEFTAD			
	RESERVATION BEKRAEFTAD - H ECONOMY			
AMERICA WEST AIRLINES - HP 684				
ONS 12SEP	PHOENIX AZ	NEWARK NJ	1504	2242
	SKY HARBOR INTL	NEWARK INTL		
	UTRU AIRBUS INDUSTRIE A320-100/200			
	PLATS 19B BEKRAEFTAD			

RESERVATION BEKRAEFTAD - H ECONOMY

SCANDINAVIAN AIRLINES - SK 904
FRE 14SEP NEWARK NJ STOCKHOLM SE 1745 0740
NEWARK INTL ARLANDA 15SEP
UTRU BOEING 767-200/300
PLATS 03G BEKRAEFTAD
RESERVATION BEKRAEFTAD - D BUSINESS

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VI RESERVERAR OSS FÖR PRISHÖJNINGAR UTANFÖR VÅR KONTROLL.
>

AMERICAN EXPRESS RESEBYRA DATUM 06SEPTEMBER01
BOKNINGSREF ZRNSHO

106 82 STOCKHOLM
SWEDEN BAY/JEFF MR
EML:Y

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VI RESERVERAR OSS FÖR PRISHÖJNINGAR UTANFÖR VÅR KONTROLL.
>
Pris Atlantsträckan 20862 sek
Pris Inrikes USA 5909 sek

~~CONFIDENTIAL~~

Public

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FLOW CHART WITH TRIGGER EVENTS
LipoDerm/RestoDerm/EpiLip Technology

Exhibit T 74
Skold v. Galderma
Cancellation No. 92052897

November 2001 – February 2002

1, Practical formulation work (base product = vehicle)

2, Patent formulation and registration

3, Start formulation work on one or two more products (OTC)

Total cost, $ [redacted]

February 2002 – June 2002

1, 3 month stability study on base formulation

2, Start stability work on the other potentially two products

Total cost includes in the above cost

March 2002 – June 2002

1, Lipid study (tape stripping human skin measuring lipid content after appl.)

2, Tewl study (trans epidermal water loss study)

Total cost approx. $ [redacted]

May 2002 – October 2002

1, Chronic hand dermatitis study with the vehicle

2, Study on the second OTC product

3, Study on the third OTC product

Total cost, $ [redacted]

[redacted]

1

September 2002 – December 2002

At this point I anticipate that the purchase of the rights is done and taken care of, which means that CollaGenex will now pay for actual costs for technical feasibility studies. Since most of the groundwork by this time is conducted, costs might be a bit lower that the $ 70.000 per technical feasibility study previous paid by CollaGenex.

I also anticipate that we will start at least one Rx technical feasibility study and perhaps one or two products for other companies. Potential partners and products could be Allergan with a lies product and Fujisawa with an immune modulator (instead of a steroid but with the same indication, namely Tacrolimus). Could also be with Taisho, or how the spell their name, and that would be one or more steroid products.

Total costs except for the work between Sept and Dec will be approx. $ 340.000 except for the $ [redacted]0 as a cash down payment for the technology.

Pretend that we will launch only two products during 2002, which will at least do 100.000 units each just to fill a tiny pipeline in a few chains. [redacted]0 [redacted] a price of $ [redacted] per unit and a marginal of approximately 70% in the beginning would create revenue of around $ [redacted] and a profit of $ [redacted]. So launching only two products in late 2002 will pay for the full cash investment during that same year.

Once again I would like to mention that I think that we should have our eyes open for the progress within Ponsus and potentially be ready to act if the opportunity occurs. If it would, I guess that it would not occur before March next year. My suggestion, if that would be a reality, would be that CollaGenex puts in $ [redacted] same time as I arrange, from some of the other owners, agreements to convert their shares with CollaGenex. CollaGenex would then become a majority owner of Ponsus. The benefits would be to gain access to a skilled organisation, four major partners and something to put on NASDAQ with a good profit after taking advantages of what fits CollaGenex at the time.

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Public

Companies Promoted to During the Collagenex-Skold, Galderma-Skold collaboration (Collagenex-Tied Promotions)

Exhibit T 125
Skold v. Galderma
Cancellation No. 92052897

Proctor & Gamble	X
Optime (Liposomal, John Kinzell)	X
ATS (Advanced Tissue), Atrix	X
Antares	X
Epitan	X
Fujisawa	X
Ortho	X
Watson	X
Pathfinder	X
Skin Medica (Diane Goostree)	X
Cardinal	X
Novartis (Katrin Kriwet)	X
Galderma (Art Clapp)	X
Therapeutics, Inc. or DUSA (Dan Paquadio)	X
TexasDerm (Abramovits)	X
Ranbaxy (Deborah McRonald)	X
InyX-Pharma (Uli Bartke)	X
Pfizer	X
Johnson & Johnson	X
Connetics	X

Confidential

Public

Company Correlation	Party Correlation	Company Headquarters
[redacted]	[redacted]	US headquartered
		US headquartered
		US headquartered
		Swedish headquarters
		US headquartered
		Swiss headquarters
		Canadian headquarters
		US headquartered
		Danish headquarters
		US headquartered
		US headquartered
		US headquartered
		German headquarters
		~~UK~~ US headquarters
		US headquartered
		US headquartered, acquired by PreCision Dermatology
		US headquartered, German parent
		US headquartered
		Re Physician Dispence
		US headquartered
		German headquarters
		US headquartered
		Swedish headquarters

Exhibit T 126
Skold v. Galderma
Cancellation No. 92052897

US008029810B2

(12) **United States Patent**
Skold

(10) **Patent No.: US 8,029,810 B2**
(45) **Date of Patent: Oct. 4, 2011**

(54) **WATER-BASED DELIVERY SYSTEMS**

(75) Inventor: **Thomas Skold**, Norrtalje (SE)

(73) Assignee: **Thomas Skold**, Norrtalje (SE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 297 days.

(21) Appl. No.: **12/290,455**

(22) Filed: **Oct. 30, 2008**

(65) **Prior Publication Data**

US 2009/0226491 A1 Sep. 10, 2009

Related U.S. Application Data

(63) Continuation of application No. 10/957,320, filed on Sep. 30, 2004, now abandoned, which is a continuation-in-part of application No. PCT/US03/07752, filed on Mar. 13, 2003, and a continuation-in-part of application No. 10/388,371, filed on Mar. 13, 2003, now abandoned.

(60) Provisional application No. 60/365,059, filed on Mar. 13, 2002.

(51) **Int. Cl.**

A61K 9/00	(2006.01)
A61K 31/74	(2006.01)
A61K 47/00	(2006.01)

(52) **U.S. Cl.** **424/400**; 424/78.02; 514/784

(58) **Field of Classification Search** 424/400, 424/78.02; 514/784

See application file for complete search history.

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Primary Examiner — Blessing Fubara

(74) *Attorney, Agent, or Firm* — Moser Taboada

(57) **ABSTRACT**

The invention relates to a water-based delivery system for an active substance, characterized by enhancing skin barrier restoration in the stratum corneum comprising water, a fatty acid, cholesterol, a ceramide and at least one skin lipid precursor.

73 Claims, 7 Drawing Sheets

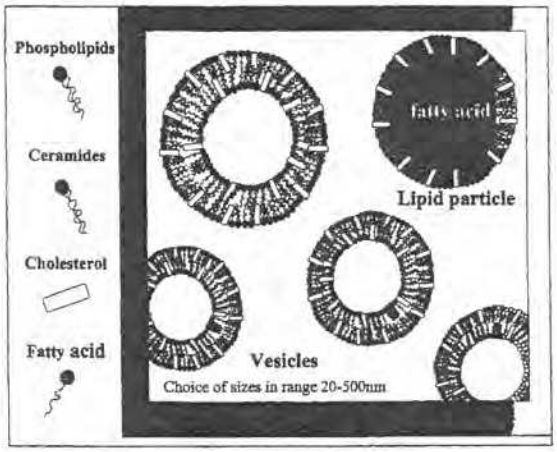

Exhibit T 130
Skold v. Galderma
Cancellation No. 92052897

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Igarashi, et al. (Advanced Drug Delivery Reviews 20, p. 147-154, 1996).

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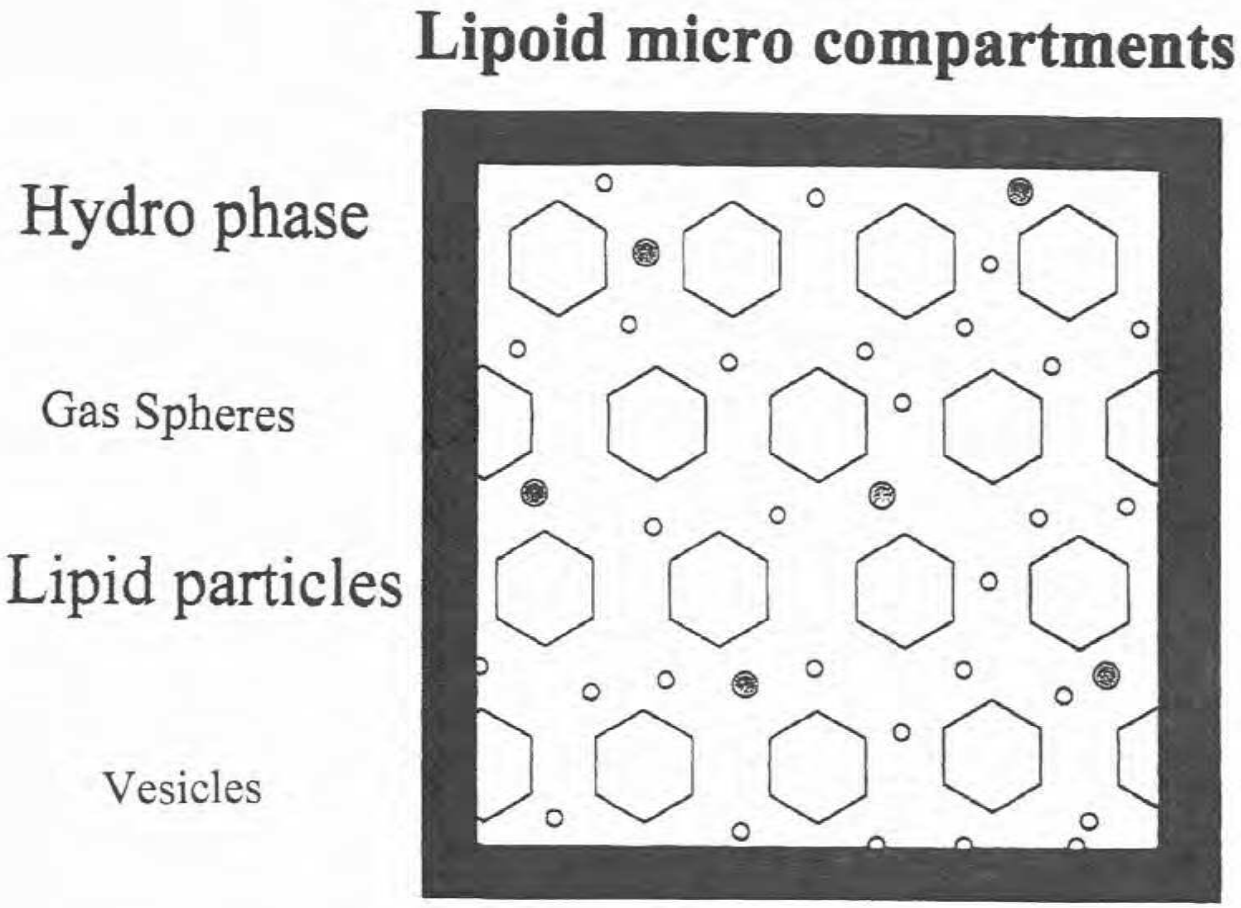

Lipoid micro compartments
Hydro phase
Gas Spheres
Lipid particles
Vesicles

FIGURE 1

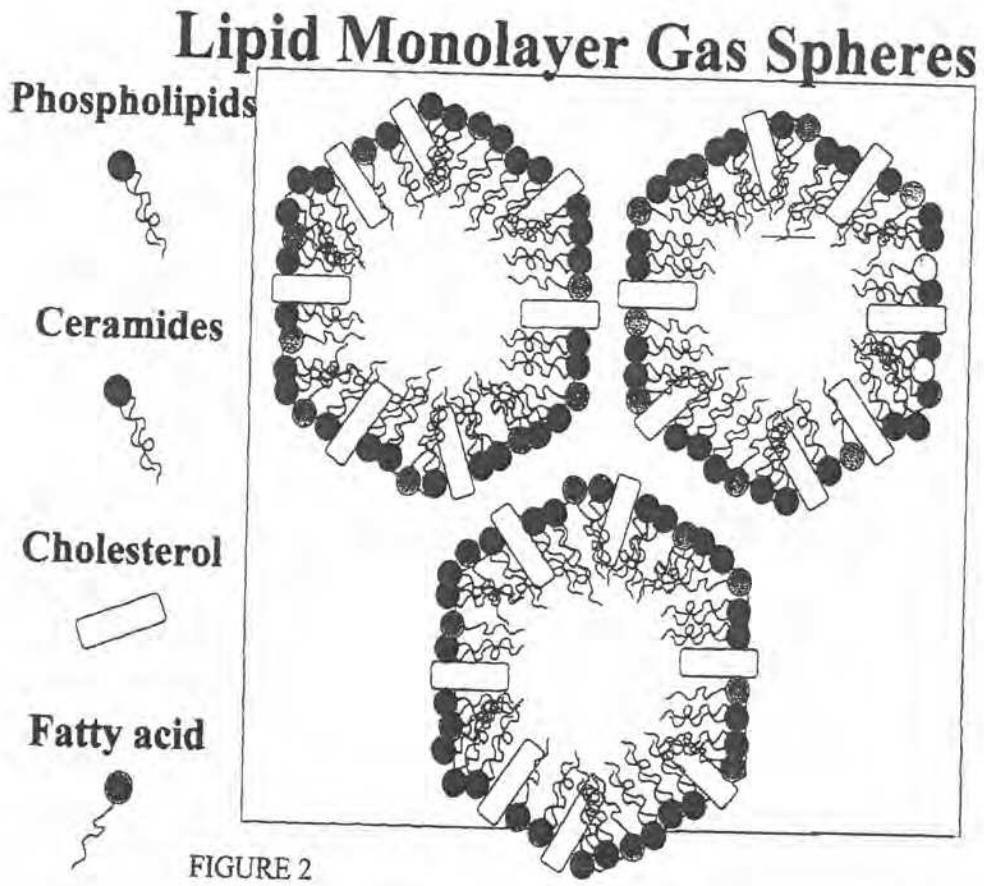

Lipid Monolayer Gas Spheres
Phospholipids
Ceramides
Cholesterol
Fatty acid

FIGURE 2

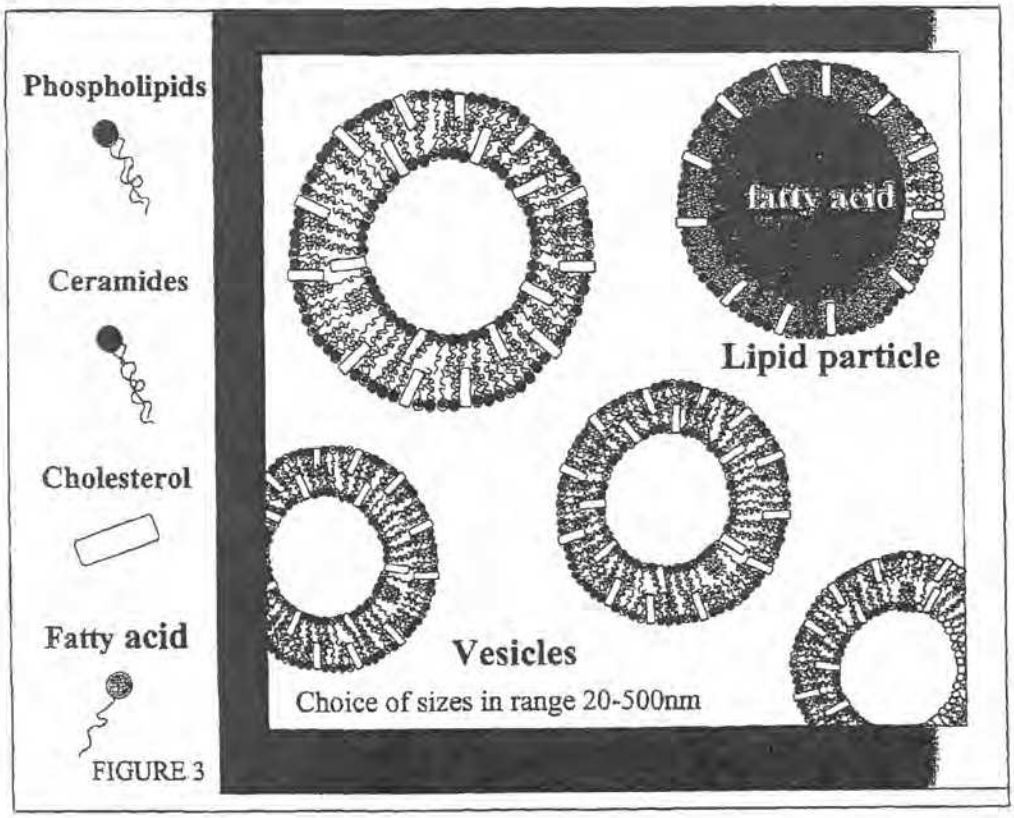

Phospholipids
Ceramides
Cholesterol
Fatty acid
fatty acid
Lipid particle
Vesicles
Choice of sizes in range 20-500nm

FIGURE 3

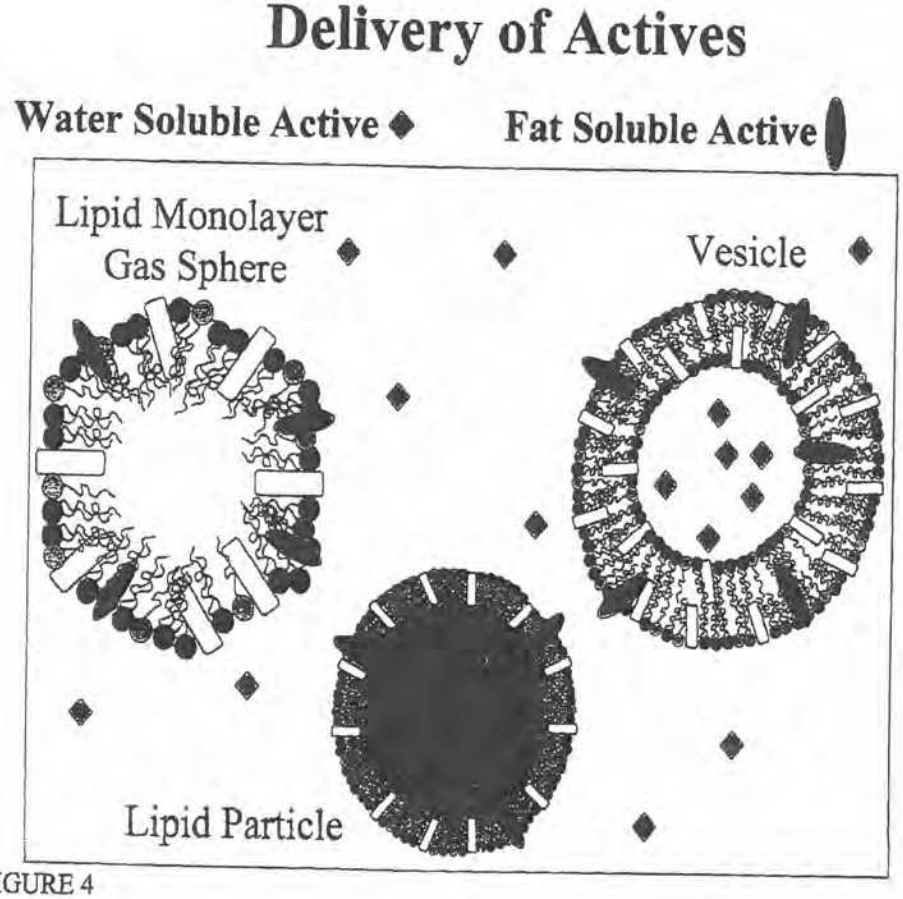

Delivery of Actives
Water Soluble Active
Fat Soluble Active
Lipid Monolayer
Gas Sphere
Vesicle
Lipid Particle

FIGURE 4

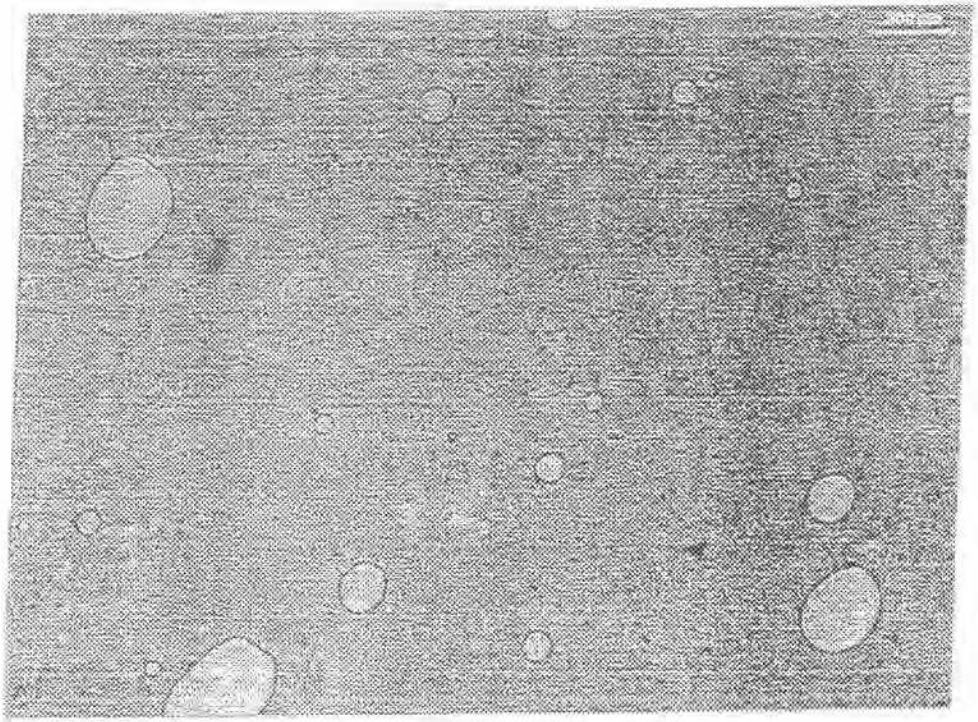


FIGURE 5 - A microscope image of the foam phase.

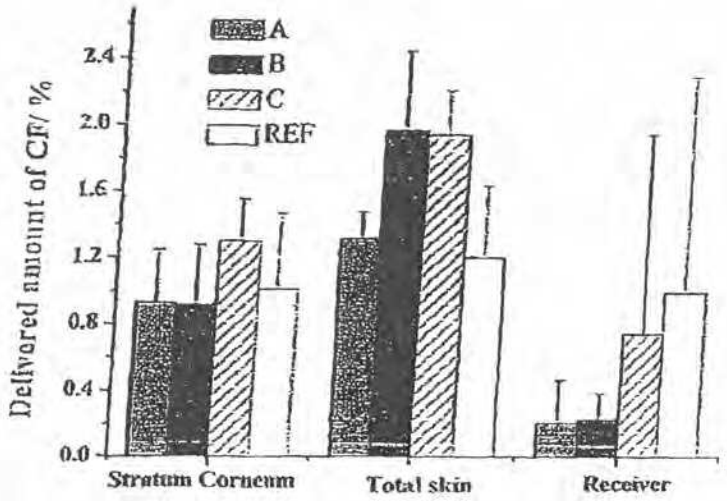


FIGURE 6 - Amount of CF detected in stratum corneum, total skin and the receiver compartment.

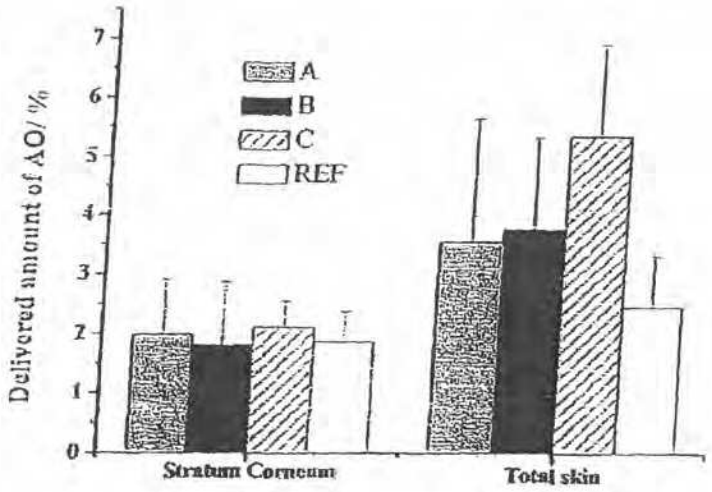


FIGURE 7 - Amount of AO detected in stratum corneum and total skin.

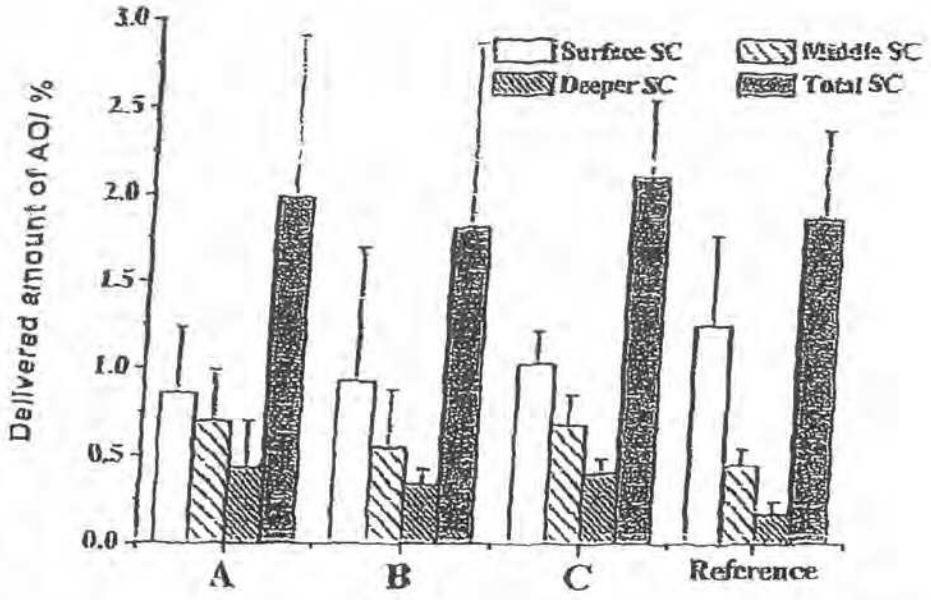


FIGURE 8 - Amount of AO detected at different depth of stratum corneum.

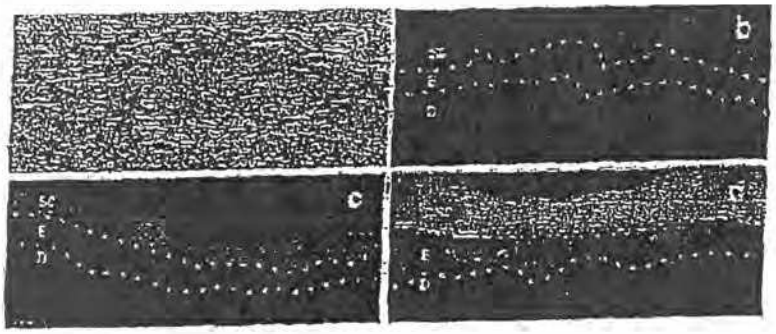


FIGURE 9 - Fluorescence microscopy images.

WATER-BASED DELIVERY SYSTEMS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. patent application Ser. No. 10/388,371, filed Mar. 13, 2003; and U.S. Provisional Application No. 60/365,059, filed Mar. 13, 2002, both of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to a novel topical and mucosal delivery systems for drugs or any other active substance.

BACKGROUND OF THE INVENTION

The main demands on human skin are to prevent loss of water, and to prevent water and other matter of the environment from entering the body indiscriminately. The human skin thus forms a selectively permissible physical barrier between the human body and its surroundings.

The barrier function has been shown to reside in the stratum corneum. The stratum corneum is the topmost layer of the skin, and is built of corneocytes. Corneocytes are cells that contain extensively cross-linked proteins, surrounded by a highly resistant cell envelope. The corneocytes are embedded in a bed of specific lipid structures of long chain lipids. These long chain lipids are organized as bilamellar structures stacked on top of each other. The bilamellar structures fill the intercellular spaces between the corneocytes.

To account for the skin's barrier properties, and for its selective hydrophilic and hydrophobic pathways, the skin has been described as a mosaic barrier model. This model envisages barrier lipids to exist predominantly in crystalline (gel) form. Such a form provides water impermeable domains, which are surrounded by so-called grain borders of lipids in a liquid crystalline state. This arrangement provides an effective, water tight barrier that still allows a minute but controlled loss of water through the liquid crystalline interdomains. This controlled water loss is enough to keep the keratin of the stratum corneum hydrated. The liquid character of the interdomain grain borders allows passage of hydrophilic and hydrophobic molecules on down-hill gradients, i.e. passage by passive diffusion.

Dermal delivery systems are compositions which deliver active substances to, or through, the skin. These compositions typically contain skin permeation enhancers. Permeation enhancers may induce structural transformations of the bilamellar structure in the liquid crystalline interdomain regions, and thus promote transdermal delivery of, for example, pharmacological substances.

Typical dermal delivery systems have an alcohol or petroleum base, with little consideration given to the biological properties of the vehicle itself. For example, emulsified fatty acids can inherit certain detergent properties if their structure is significantly altered from those in the normal skin. The detergent properties can lead to disruption of the normal barrier function, which is counteractive to the potential benefit of the delivery system. Disruption of the normal barrier function often causes the stratum corneum to lose its natural potential to function properly as a barrier. As a result, the skin becomes either too dry or too permeable to environmental substances.

Other conventional delivery systems that are thought to protect the skin from harmful substances are barrier ointments. The purpose of barrier ointments is to provide a film, and thereby create a layer which is impermeable to environmental substances. Due to the impermeability, though, these ointments both increase the body temperature of the treated body part, as well as prevent perspiration, and thus render an uncomfortable sensation.

The dermal delivery systems described above are not formulated to deliver a substance to, or through, the human skin without permanently disrupting the stratum corneum's natural barrier function.

SUMMARY OF THE INVENTION

In one embodiment, the invention relates to a water-based delivery system for an active substance, characterized by enhancing skin barrier restoration in the stratum corneum comprising water, a fatty acid, cholesterol, and a ceramide. In another embodiment, the delivery system also comprises at least one skin lipid precursor.

In an additional embodiment, the invention relates to delivery system for an active substance comprising water and lipophilic components, wherein the lipophilic components comprise fatty acids, cholesterol, and a ceramide/phospholipid portion, and wherein the lipophilic components are in the form of lipid particles, and gas spheres or vesicles. This delivery system can also comprise at least one skin lipid precursor.

BRIEF DESCRIPTION OF DRAWINGS

FIG. **1** is a diagram showing the gas spheres, lipid particles, vesicles and hydrophilic phase of the delivery systems.

FIG. **2** is a diagram showing the components of the gas spheres of the delivery systems.

FIG. **3** is a diagram showing the components of the lipid particles and of the vesicles of the delivery systems.

FIG. **4** is a diagram showing the location of active substances within the various microcompartments of the delivery systems.

FIG. **5** is a microscopic image of the foam phase.

FIG. **6** is a graph showing the amount of 5(6)-carboxyfluorescein (CF) detected in the stratum corneum, total skin and the receiver compartment for four different formulations, CF-A, CF-B, CF-C and the reference.

FIG. **7** is a graph showing the amount of acridine orange 10-nonyl bromide (AO) detected in the stratum corneum, total skin and the receiver compartment for four different formulations, AO-A, AO-B, AO-C and the reference.

FIG. **8** is a graph showing the amount of AO detected at different depths of the stratum corneum.

FIG. **9** are fluorescent microscope images showing in vivo results for the penetration of active ingredients into the skin using the delivery systems: a) frozen section of normal skin stained with hematoxylin viewed by light microscopy, b) auto fluorescence of untreated epidermis, c) auto fluorescence of petrolatum with penetration only into stratum corneum, d) auto fluorescence of the total lipid formulation (variation A) with penetration into the viable epidermis and dermis.

DETAILED DESCRIPTION OF INVENTION

The present invention provides an improved topical delivery system (skin preparation) formulated to deliver a substance to, or through, the human skin without permanently disrupting the stratum corneum's natural barrier function. Additionally, the topical delivery system of the present invention provides unique skin barrier restoration properties.

All percentages given below are indicated in percent by weight. All numbers are approximate.

The topical delivery system of the present invention is a water-based formulation comprising hydrophilic and lipophilic components. In a preferred embodiment, the delivery system comprises a water content exceeding 50%, such as more than 55%, 60%, 65%, 70%, 75%, 76%, 77%, 78%, 79%, 80%, 85%, 87%, 90%, 94%, 95% and 98%. Preferably, the water content is between 60-80%, more preferably, between 70 and 80%.

The topical delivery system is preferably designed, in its choice and composition of lipids, to resemble the normal lipid organization of the stratum corneum (horny layer), as much as possible. Upon administration, the system (formulation) blends with the lipids naturally present in the stratum corneum, and easily penetrates the lipid bilayer of the skin. In doing so, the system carries along with it one or more active substances to be administered. The system enhances penetration of active substances into and/or through the stratum corneum, while the normal barrier properties of the stratum corneum are left intact, and/or are even functionally enhanced.

The lipophilic component (i.e. lipids) of the system comprises fatty acids, cholesterol and a ceramide/phospholipid portion. The lipids are similar to those which make up the normal stratum corneum. The preferred ratio of the ceramide/phospholipid portion:cholesterol:fatty acid is in the range of approximately 2:1:1.5 to approximately 2.95:0.5:0.5. Preferably, for example, the ratio is approximately 2:1:1; more preferably the ratio is approximately 2.35:1:1.

The fatty acids of the present invention can be any fatty acid, mixtures of fatty acids, salts of fatty acids, or mixtures of fatty acids and salts of fatty acids. The fatty acids can be saturated or unsaturated. Additionally, the fatty acids can comprise precursors of fatty acids. In a preferred embodiment, the fatty acids comprise ten, twelve, fourteen, sixteen, eighteen, twenty, twenty-two, or twenty-four carbon atoms, or any mixture of such fatty acids. A fatty acid mixture with a predominant portion of fatty acids which comprise a chain of sixteen or eighteen carbon atoms is most preferred.

For example, the delivery system can be prepared from a mixture of fatty acids of the following composition: at most about 2% of a component comprising a chain of fourteen carbon atoms, between about 47 and about 52% of a component comprising a chain of sixteen carbon atoms, between about 43 and about 48% of a component comprising a chain of eighteen carbon atoms, and at most about 1% of a component comprising a chain of twenty carbon atoms.

Examples of suitable saturated fatty acids for use in the delivery system include lauric acid, myristic acid, palmitic acid, stearic acid, arachidic acid, behenic acid, and lignoceric acid. Examples of suitable unsaturated fatty acids include oleic acid, palmitoleic acid, linoleic acid, linolenic acid, and arachidonic acid. Preferably, the delivery system contains an essential portion, such as about 90%, of such fatty acids.

The preferred fatty acids are the essential fatty acids (EFAs). EFAs are essential for the plasma membrane formation of all cells. In keratinocytes, EFA deficiency makes cells hyperproliferative. Supplementation of EFAs reverses the hyperproliferation. EFAs also enhance lipid biosynthesis of the epidermis and provide lipids for the barrier formation of the epidermis. The essential fatty acids are preferably chosen from linoleic acid, γ-linolenic acid, homo-γ-linolenic acid, columbinic acid, eicosa-n-6,9,13)-trienoic acid, arachidonic acid, timnodonic acid, hexaenoic acid, and mixtures thereof.

The delivery system also comprises cholesterol, or derivatives of cholesterol such as, for example, lipid esters of cholesterol.

The ceramide/phospholipid portion can comprise 100% ceramide, 100% phospholipids, or any other percent combination of ceramide and phospholipids. For example, the ceramide/phospholipid portion can comprise 95% ceramide and 5% phospholipids, 90% ceramide and 10% phospholipids, 85% ceramide and 15% phospholipids, or 80% ceramide and 20% phospholipids.

Since the system preferably resembles the lipid composition of the skin as much as possible, it is desirable to use 100% ceramide in the ceramide/phospholipid portion. However, from an economic point of view, the addition of phospholipid to the ceramide/phospholipid portion may be a more suitable choice.

The ceramide component of the delivery system can be any ceramide or any mixture of ceramides. In this specification, ceramides include pseudoceramides and neoceramides.

For example, the ceramide may be any of ceramide 1-7; and/or mixtures thereof. Some specific examples of ceramides include ceramide 1, ceramide 3, ceramide 4, ceramide 5, ceramide 6A, cerebrosides and ceramide 6B. Preferably, the ceramides used in the systems are ceramides 1, 3 and 6. An example of a formulation that comprises these ceramides is SK-Influx® (Cosmoferm).

Some examples of pseudoceramides include:

N-(2-hydroxyoctadecyl)-N-(2-hydroxyethyl)hexadecanamide
N-(2-hydroxyoctadecyl)-N-(2-hydroxyethyl)propanamide
N-(2-hydroxyhexadecyl)-N-(2-hydroxyethyl)butanamide
N-(2-hydroxyhexadecyl)-N-(2-hydroxyethyl)heptanamide
N-(2-hydroxyoctadecyl)-N-(2-hydroxyethyl)ethanamide
N-(2-hydroxyoctadecyl)-N-2-O-glucopyranosyl)ethylpentanamide
N-(2-hydroxydodecyl)-N-(2-hydroxyethyl)hexanamide
N-(2-hydroxydodecyl)-N-(2-hydroxyethyl)-2butylhexanamide
N-(2-hydroxyhexadecyl)-N-(2-hydroxyethyl)ethanamide
N-(2-hydroxydodecyl)-N-(2-hydroxyethyl)-2-hydroxyhexanamide
N-(2-hydroxytetraadecyl)-N-(2-hydroxyethyl)propanamide
N-(2-hydroxyhexadecyl)-N-(2-sulfoethyl)hexadecanamide
N-(2-hydroxyoctadecyl)-N-(2-phosphoethyl)butanamide
N-(2-hydroxyoctadecyl)-N-(2-hydroxyethyl)-2-hydroxypropanamide
N-(2-hydroxy-3-octadecyloxypropyl)-N-(2-hydroxyethyl) hexadecanamide
N-(2-hydroxy-3-nonanyloxypropyl)-N-(2-hydroxyethyl) propanamide
N-(2-hydroxyoctadecyl)-N-(2-hydroxyethyl)-2-hydroxypropanamide
N-(2-hydroxy-3-hexadecyloxypropyl)-N-(2-hydroxyethyl) hexadecanamide
N-(2-hydroxy-3-octadecyloxypropyl)-N-(2-hydroxyethyl) butanamide
N-(2-hydroxy-3-hexadecyloxypropyl)-N-(2-hydroxyethyl) ethanamide
N-(2-hydroxy-3-dodecyloxypropyl)-N-(2-sulfohydroxyethyl)decanamide
N-(2-hydroxy-3-decyloxypropyl)-N-(2-hydroxyethyl)hexanamide
N-(2-hydroxy-3-octadecyloxypropyl)-N-(2-hydroxyethyl) hexadecanamide
N-(2-hydroxy-3-dodecyloxypropyl)-N-(2-hydroxyethyl)butanamide

N-(2-hydroxy-3-octadecyloxypropyl)-N-(2-hydroxyethyl) co-o-linoleoyldocosanamide
N-(2-hydroxy-3-dodecyloxypropyl)-N-(2-hydroxyethyl) propanamide
N-(2-hydroxy-3-hexadecyloxypropyl)-N-(2-hydroxyethyl)-2-methylpropanamide
N-(2-hydroxy-3-tetradecyloxypropyl)-N-(2-hydroxyethyl) ethanamide
N-(2-hydroxy-3-dodecyloxypropyl)-N-(2-hydroxyethyl) heptanamide
N-(2-hydroxy-3-hexadecyloxypropyl)-N-(2-phosphoethyl) hexadecanamide
N-(2-hydroxy-3-dodecyloxypropyl)-N-(2-hydroxyethyl) propanamide
N-(2-hydroxy-3-octadecyloxypropyl)-N-(2-)-glucopyranosyl)ethyl-2-hydroxy pro-panamide
N-(2-hydroxy-3-octyloxypropyl)-N-(2-hydroxyethyl)pentanamide

Some examples of neoceramides include:

N-(2,3-dihydroxypropyl)-N-(hexadecyl)butanamide
N-(2,3-dihydroxypropyl)-N-(tetradecyl)ethanamide
N-(2,3-dihydroxypropyl)-N-(hexadecyl)-2-hydroxypropanamide
N-(2,3-dihydroxypropyl)-N-(octadecyl)butamide
N-(2,3-dihydroxypropyl)-N-(2-ethylhexadecyl)hexanamide
N-(2,3-dihydroxypropyl)-N-(hexadecyl)-2-hydroxyoctanamide
N-(2,3-dihydroxypropyl)-N-(3-methylhexadecyl)ethanamide
N-(2,3-dihydroxypropyl)-N-(dodecyl)butanamide
N-(2,3-dihydroxypropyl)-N-(hexadecyl)-2-hydroxyhexanamide
N-(2-hydroxy-3-O-glucopyranosylpropyl)-N-(hexadecyl) octanamide
N-(2-hydroxy-3-phosphopropyl)-N-(octadecyl)ethanamide
N-(2-hydroxy-3-sulfopropyl)-N-(hexadecyl)butanamide
N-(2-hydroxy-3-O-glucopyranosylpropyl)-N-(hexadecyl) decanamide
N-(2,3-dihydroxypropyl)-N-(heptadecyl)ethanamide
N-(2,3-dihydroxypropyl)-N-(3-methylhexadecyl)ethanamide
N-(2,3-dihydroxypropyl)-N-(heptadecyl)butanamide
N-(2,3-dihydroxypropyl)-N-(6-dodecenyl)hexadecanamide
N-(2,3-dihydroxypropyl)-N-(2-methylhexadecyl)-2-hydroxy-ethanamide
N-(2,3-dihydroxypropyl)-N-(octadecyl)-2-hydroxypropanamide
N-(2-hydroxy-3-O-glucopyranosylpropyl)-N-(heptadecyl)-ethanamide
N-(2-hydroxy-3-sulfopropyl)-N-(dodecyl)heptanamide
N-(2,3-dihydroxypropyl)-N-(tetradecyl)-4-hydroxybutanamide
N-(2,3-dihydroxypropyl)-N-octadecyl)-(t)-O-linoleoyl-docosanamide
N-(2,3-dihydroxypropyl)-N-(linoleyl)ethanamide
N-(2,3-dihydroxypropyl)-N-(oleyl)-2-hydroxy-heptanamide
N-(2,3-dihydroxypropyl)-N-iyiodecyl)-(t)-O-linoleoyl-docosanamide
N-(2,3-dihydroxypropyl)-N-(octadecyl)-3-hydroxybutanamide
N-(2-phospho-3hydroxypropyl)-N-(heptadecyl)butanamide
N-(2,3-dihydroxypropyl)-N-(2-methylheptadecyl)propanamide
N-(2,3-dihydroxypropyl)-N-(3-ethylheptadecyl)butanamide
N-(2-sulfo-3-hydroxypropyl)-N-(1-octadecyl)ethanamide
N-(2,3-dihydroxypropyl)-N-octadecyl)propanamide
N-(2,3-dihydroxypropyl)-N-(dodecyl)decanamide
N-(2,3-dihydroxypropyl)-N-(3-ethyldodecyl)butanamide
N-(2-O-glucopyranosyl-3-hydroxy propyl)-N-(heptadecyl) butanamide
N-(2,3-dihydroxypropyl)-N-(oleyl)-2-hydroxypropanamide
N-(2,3-dihydroxypropyl)-N-(linoleyl)-2-hydroxyheptanamide
N-(2,3-dihydroxypropyl)-N-(dodecyl)-2-hydroxyoctanamide
N-(2,3-dihydroxypropyl)-N(hexadecyl)-2-methylheptanamide
N-(2,3-dihydroxypropyl)-N-(octadecyl)-2-hydroxypentanamide
N-(2,3-dihydroxypropyl)-N-(2-methylhexadecyl)-2-hydroxyheptanamide
N-(2,3-dihydroxypropyl)-N-(linoleyl)-2-hydroxypropanamide
N-(2:3-dihydroxypropyl)-N-(tetradecyl)ethanamide.

The phospholipid component may contain any phospholipid or mixtures of phospholipids. Preferably the phospholipid component comprises phosphatidylcholine (PC). Other examples of phospholipids include distearoylphosphatidylcholine (DSPC 18), phosphatidic acid, inositol phosphate, phosphatidylglycerol, phosphatidylinositol, phosphatidylserine, and phosphatidylethanolamine.

Additionally, the phospholipid component can comprise one or more lysophospholipids. Lysophospholipids are single chain phospholipids. Examples of lysophospholipids include lysophosphatidylcholines, such as monopalmitoylphosphatidylcholine (MPPC); lysophosphatidylglycerols; lysophosphatidylethanolamines; lysophosphatidylinositols; lysophosphatidylserines; and lysophosphatidic acid. Mixtures of different types of phospholipids and/or lysophospholipids can also be used.

Examples of phospholipid components include formulations which are sold by Degussa BioActives under the following names: Epikuron 200SH, Epikuron 200 and Epikuron 170. All these formulations comprise phospholipids, e.g., soya phosphatidylcholines (PC), and fatty acids. These formulations differ in the saturation and chain length of their constituent phospholipids and fatty acids.

EPIKURON® 200 SH comprises about 95% PC and 1.2% lysophosphatidylcholine. The phospholipids used in this formulation are saturated, long-chain phospholipids. Saturated phospholipids prevent leakage of active substances through the vesicular bilayer to a greater extent than unsaturated phospholipids do. Also, saturated phospholipids are more stable, both mechanically and chemically. The fatty acids in EPIKURON® 200 SH are all saturated fatty acids, and are mainly stearic fatty acid.

EPIKURON® 200 comprises about 95% PC and 3% lysophosphatidylcholine. The phospholipids used in this formulation are mainly unsaturated. Also, about 85% of the fatty acids are unsaturated. The fatty acids are mainly linoleic acid. This formulation provides enhanced penetration.

EPIKURON® 170 comprises PC and other phospholipids such as phosphatidylethanolamine (PE). The phase behaviour of PE is different from PC because of the smaller head group area in PE. In particular, PE forms reversed hexagonal phases instead of lamellar phases in excess water and at high temperatures. Also, about 85% of the fatty acids in EPIKURON® 170 are unsaturated. The fatty acids are mainly linoleic acid.

The chain melting temperature for phospholipids is the temperature at which the transition from solid phase to liquid crystalline phase of the lipid bilayers occurs. The chain melting temperature decreases with increasing unsaturation and decreasing chain length of the phospholipid. In the case of

saturated long-chained phospholipids, the addition of cholesterol lowers this temperature. In the case of highly unsaturated phospholipids, the addition of cholesterol has the opposite effect than for saturated phospholipids.

If there is a need to change the properties of the formulation, the choice of phospholipid is an important component to consider, since different phospholipids give rise to varying characteristics of the formulation.

In a preferred embodiment, the present system also comprises skin lipid precursors. The lipid precursors include any compound that promotes in situ cholesterol, ceramide or sphingolipid synthesis. The preferred lipid precursors are mevalonic acid, which promotes in situ cholesterol synthesis; and 25-hydroxycholecalciferol, which promotes in situ ceramide synthesis in the skin. Other preferred precursors are palmitoyl CoA and serine, which together are converted to 3-ketosphinganine, which promotes in situ ceramide synthesis in the skin.

By the promotion of in situ cholesterol and ceramide synthesis in the skin, the overall content of lipid in the system can be maintained in a range as low as approximately 2-20%. Therefore, the water content of the delivery system can be as high as 80-98%. The high water content enables the skin to "breathe" normally, and enhances its ability to restore its normal barrier function rapidly.

Other lipid precursors useful in the present invention include, for example: acylceramides; deoxyacetein cimifugoside, adapalene, adenosine, aloe derived lectins, 3-aminopropyl dihydrogen phosphate, anise extracts, ascorbic acid and derivatives thereof, ascorbyl palmitate, asiatic acid, benzoic acid derivatives, biotin, butanoyl betulinic acid, cathecholamines, coenzyme Q10, dehydrocholesterol, dehydroascorbic acid and derivatives thereof, estrogen and derivatives, eythrobic acid, genistein, lipoic acid, 4-methoxysalicylic acid, N-acetylcysteine, panthetine, pregnenolone and derivatives, retinal, retinoates, retinal, retinyl acetate, retinyl glucuronate, retinyl linoleate, retinyl palmitate, retinyl proprionate, phytosphingosine, sphingosine, and others.

Preferably, an alkaline compound, or buffer system, is included in the formulation to adjust the pH. Examples of alkaline compounds include triethanolamine (TEA), sodium hydroxide, sodium acetate, and sodium bicarbonate. Examples of buffer systems include carbonic acid/potassium carbonate, phosphoric acid/potassium phosphate, and acetic acid/sodium acetate.

The fatty acids of the final delivery system can be in a free state or can form a salt. The portion of fatty acids which is in a free state is partially dependent on the pH of the formulation. In general, the level of free fatty acid increases as the pH of the formulation decreases. Depending upon the particular use of the formulation, the pH of the formulation can vary. Preferably, the pH of the formulation is about 6.5 to 7.8.

In a preferred embodiment, the delivery system comprises triethanolamine (TEA). It is preferred to adapt the molar ratio between the fatty acids and triethanolamine to enable a certain portion of the fatty acids in the final delivery system to form a triethanolaminium salt, while another portion of the acid exists as free fatty acid. Preferably, the delivery system is prepared from fatty acids and triethanolamine in which the molar ratio of the fatty acids to the triethanolamine is higher than about 2:1, preferably higher than about 3:1.

In a preferred embodiment, the delivery system comprises a combined content of a fatty acid, cholesterol, a ceramide/phospholipid portion, and skin lipid precursors between about 2-20%. A preferred low end of this range is about 2%, 3%, 4%, 5%, 6%, 7% or 8%. A preferred high end of this range is about 13%, 14%, 15%, 16%, 17%, 18%, 19% and 20%.

In another preferred embodiment, the amounts of the components of the delivery system are as follows: fatty acid: 0.5-10%; cholesterol: 0.5-10%; a ceramide/phospholipid portion: 0.005-20%; and lipid precursors: 0.000001-10%.

In a preferred embodiment, the formulation does not contain any irritating ingredients. Examples of irritating ingredients include alcohols, such as isopropanol and ethanol; short chain fatty acids; and detergents. Preferably, the formulation contains less than 10% alcohol, more preferably less than 5% alcohol, most preferably less than 1% alcohol, and optimally no alcohol.

Without the intention to limit the scope of the invention, a possible theory explaining the mechanical properties of the delivery system follows. The administered formulation easily penetrates the lipid bilayer of the skin. In doing so, the system creates a temporary and reversible state of enhanced atrophy among the lipid components of the bilayer. The enhanced atrophy in itself then gives rise to either a) enhanced energy levels, wherein the energy could promote active transport of the to-be-carried substances into the skin, and/or b) creates naturally and reversibly occurring holes and disorganized patches in the lipid bilayer through which the active substances could then pass more easily. It is very well feasible that the temporary disarray in the lipid bilayer will temporarily break up the organized structure of the bilayer and create micelles of lipids with areas between them, or surrounding them, through which lipophobic/hydrophilic substances and/or compositions can enter through the stratum corneum. As the lipid composition of the formulation resembles the natural lipid composition of the skin, the so introduced new lipids will after a short time of creative chaos easily blend in with the natural lipid building stones of the lipid bilayer, and thus not permanently damage the barrier function of the skin.

Following the temporary disarray in the lipid bilayer, the normal barrier function of the cornea stratum rapidly returns. (That is, the skin barrier restoration is rapid.) The rapid return may be enhanced by the lipid precursors of the formulation. For example, the in situ promotion of cholesterol synthesis in the stratum corneum, the in situ promotion of ceramide synthesis in the stratum corneum, and/or the in situ promotion of sphingolipid synthesis in the stratum corneum may allow for the rapid skin barrier restoration.

A delivery system according to the present invention preferably comprises a combination of:

Fatty Acid (C16-24)	0.5-10%
Phospholipid	0.5-10%
Cholesterol	0.5-7%
Lipid precursor:	0.000001-10%
Mevalonic acid and/or	
25-Hydroxycholecalciferol	
Ceramide	0.005%-7%

(Not all components are present are 0%.)

Another preferred embodiment of the delivery system comprises:

Fatty Acid (C16-24)	0.5-10%
Phospholipid	0.5-10%
Cholesterol	0.5-7%

-continued

Lipid precursor:	0.000001-10%
Mevalonic acid and/or	
25-Hydroxycholecalciferol	
Ceramide	0.005%-7%
Glycerine	0-5%
Propylene glycol	0-48%
PVP (e.g., M weight 40,000)	0-5%
TEA	0-3%

(Not all components are present are 0%.)

An even more preferred embodiment of the delivery system comprises:

Fatty Acid (C16-24)	2%
Phospholipid	4.5%
Cholesterol	2%
Lipid precursor:	0.000001-10%
Mevalonic acid and/or	1% or 0.01%
25-Hydroxycholecalciferol	0.015% or 0.0015%
Ceramide 3	0.015%
Glycerine	3%
Propylene glycol	4%
PVP (M weight 40,000)	2%
TEA	0.5%

An even more preferred embodiment of the delivery system comprises:

Fatty Acid (C16-24)	2%
Phospholipid	4.5%
Cholesterol	2%
Lipid precursor:	0.000001-10%
Mevalonic acid and/or	1% or 0.01%
25-Hydroxycholecalciferol	0.015% or 0.0015%
Ceramide 3	0.015%
Glycerine	3%
Propylene glycol	4%
PVP (M weight 40,000)	2%
TEA	0.5%
Ceramide 1	0.025%

For delivery systems formulated for dry skin conditions, such as, for example, eczema, psoriasis and shingles, the amount of the lipid precursors are preferably increased by a factor of about three to about six, more preferably by a factor of about four to five, vis-à-vis systems not formulated for dry skin conditions. For example, a system for a dry skin condition can comprise about four to five times as much mevalonic acid and/or 25-hydroxycholecalciferol as a system not made for a dry skin condition. For example, a dry skin system can comprise about 0.01% mevalonic acid and about 0.0015% 25-hydroxycholecalciferol vis-à-vis about 0.002% mevalonic acid and about 0.0003% 25-hydroxycholecalciferol in other type of systems.

The topical delivery system according to the present invention further comprises one or more cosmetically and/or therapeutically active substances. Active substances are defined as agents other than emollients and other than ingredients that merely improve the physical characteristics of the formulation.

Some general examples of active substances include sunscreens, tanning agents, skin anti-wrinkling agents, anti-dandruff agents, anti-acne agents, hair growth stimulants and vitamins. Therapeutically active substances include, but are not limited to, substances which treat conditions such as eczema, dry skin, itchy skin, fungal infection, acne, skin cancer, hair loss, louse infection, psoriasis, and skin lesions (i.e. wounds). Therapeutically active substances also include substances for transdermal delivery, for example, interleukin, hormones, vaccines, nicotine, interferon, pain killers, peptides, proteins and vitamins.

Active substances also include steroid hormones. Steroid hormones inhibit inflammation and hyperproliferation of the epidermis thus resulting in normalization of hypersensitive skin conditions. Examples of steroid hormones include, but are not limited to, glucocorticoids, androgens and estrogens.

Examples of sunscreens include those materials commonly employed to block ultraviolet light. Illustrative compounds are derivatives of PABA, cinnamate and salicylate. For example, octyl methoxycinnamate and 2-hydroxy-4-methoxybenzophenone (also known as oxybenzone) can be used. Octyl methoxycinnamate and 2-hydroxy-4-methoxybenzophenone are commercially available under the trademarks, Parsol MCX and Benzophenone-3, respectively. The exact amount of sunscreen employed in the systems can vary depending upon the degree of protection desired from the sun's UV radiation.

Examples of vitamins include vitamin A and vitamin E, preferably in the form of an ester of a fatty acid, such as vitamin A palmitate (retinyl palmitate) and vitamin E linoleate (tocopheryl linoleate). Other esters of vitamins A and E may also be utilized, such as any of the fatty acids mentioned above and below.

Preservatives may also be included in the formulations of the present invention. Suitable preservatives include alkyl esters of p-hydroxybenzoic acid, hydantoin derivatives, propionate salts, and a variety of quaternary ammonium compounds. Particularly preferred preservatives of this invention are methyl paraben, propyl paraben, imidazolidinyl urea, sodium dehydroxyacetate and benzyl alcohol. Preservatives are typically used in amounts up to about 2% by weight of the formulation. An example of a preservative is Phenonip®.

Other adjunct minor components may also be incorporated into the formulations of the present invention. These components may include thickeners, coloring agents, opacifiers and perfumes. For example, any thickening agent can be included in the formulation to adjust the viscosity of the formulation. Examples of suitable thickening agents include glycerol and xanthan gum. Some additional adjunct minor components include chalk, talc, Fullers earth, kaolin, starch, smectites clays, chemically modified magnesium aluminium silicate, organically modified montmorillonite clay, hydrated aluminium silicate, fumed silica, aluminium starch octenyl succinate and mixtures thereof. Amounts of these adjunct minor components may range anywhere from 0.001 up to 20% by weight of the formulation (i.e. composition). Additionally, to adjust the pH, bases can be included in the systems, e.g., sodium hydroxide and triethanolamine.

The delivery system can be in any form, such as a cream, a lotion, a gel, and an aerosol foam. The amount of certain adjunct minor components used in a particular formulation varies depending on the desired form of the delivery system, as would be known by a skilled artisan. For example, the amount of thickening agent used to prepare an aerosol foam formulation is about 10 to 20% of the amount used to prepare a cream formulation. Additionally, emulsifiers are added to an aerosol foam formulation, such as, for example, laureth 4.

In another embodiment, the present invention provides a mucosal delivery system formulated to deliver a substance to, or through, a human mucous membrane without permanently disturbing the integrity of the mucous membrane. The mucous membrane is the moist tissue that lines some organs and body cavities (such as nose, mouth, lungs, rectum, stom-

ach and vagina) and secretes mucous. The mucosal delivery system comprises the lipophilic and hydrophilic components, as described above. The particular formulations of the mucosal delivery systems are varied to accommodate the particular environment of the mucosa, as would be known by a skilled artisan.

In a preferred embodiment, the lipophilic components of the topical or mucosal delivery system form three types of particles: gas spheres, vesicles, and lipid particles. These three types of particles are within a hydrophilic phase (i.e. aqueous medium). See FIG. **1**.

The gas spheres are lipid monolayers that enclose air bubbles. These monolayers are formed from the lipophilic components. Negatively charged carboxylate groups stud the outer surfaces of these gas spheres. See FIG. **2**. Preferably, these gas spheres are approximately 1 μm to approximately 500 μm in diameter.

The vesicles are lipid bilayers enclosing a hydrophilic core. These bilayers are formed from the lipophilic components. Negatively charged carboxylate groups stud the inner and outer surfaces of the vesicles. See FIG. **3**. The vesicles can range from approximately 0.02 μm to approximately 0.5 μm in diameter, or from approximately 0.5 μm to approximately 2 μm in diameter, or from approximately 1 μm to approximately 2.5 μm in diameter. The diameter of a vesicle increases as the amount of an active ingredient incorporated into the vesicle increases.

The lipid particles are lipid monolayers enclosing fatty acids. These monolayers are formed from the lipophilic components. See FIG. **3**. The lipid particles are less than approximately 1 to approximately 150 μm in diameter. The lipid particles may be in the form of individual lipid particles, or the lipid particles may aggregate to form crystals.

The various particles of the delivery system provide microcompartments with different properties. Due to these different microcompartments, the delivery system can be used to deliver both hydrophilic and lipophilic active substances. For example, a water soluble active substance can be located in the hydrophilic core of the vesicles, or can be located in the hydrophilic phase of the system. A lipid soluble active substance can be located within the monolayer of the gas spheres, within the bilayer of the vesicles, or within the monolayer or within the core of the lipid particles. See FIG. **4**.

Preferably, the delivery systems comprise three phases, i.e. a foam phase, a vesicle phase and a hydrophilic phase. The foam phase comprises the gas spheres and the lipid particles. The vesicle phase comprises the vesicles and the lipid particles. The hydrophilic phase comprises water and hydrophilic components.

In a preferred embodiment, the delivery system is produced from three portions (i.e. fractions), in particular a hydrophilic portion and two lipophilic portions. The two lipophilic portions comprise the lipophilic components as defined above. Both lipophilic portions are immersed in aqueous media. One portion is made into the foam phase. The other portion is made into the vesicle phase. The foam phase portion and the vesicle phase portion can be in a ratio from about 1:7 to about 7:1. Preferably, the foam phase portion and the vesicle phase portion are approximately equal in amount.

Preferably, the foam phase is formed by mixing the foam phase portion at about 65 to 85° C. The pH is set to the range of about 5.5 to 8.2. The mixing is performed under conditions so as to allow gas spheres to form. Mixing can be performed by using an mixing apparatus, such as, for example, an Ultra Turrax® (Ultra Turrax T 25, Janke & Kunkel IKA-Labortechnik). The time and speed of mixing can vary. For example, Ultra-turraxing can be performed for one minute at a speed of 9500 rpm.

Preferably, the vesicle phase is formed by gently mixing the vesicle phase portion at about 65 to 85° C. More preferably, the vesicle phase is formed by homogenizing or sonicating the vesicle phase portion at about 65 to 85° C. The pH is set to the range of about 5.5 to 8.2. Preferably, the vesicle phase is produced under conditions which do not allow any gas to enter the formulation, such as in a vacuum.

Homogenization can be accomplished with, for example, a high pressure homogenizer or a sonicator. An example of a homogenizer is a Rannie homogenizer from APV. The pressure of the homogenizer can be set, for example, from about 10,000 to 40,000 psi. An example of a sonicator is Soniprep 150, manufactured by Sanyo Gallencamp Plc. Ultrasound radiation is transmitted by high frequency vibrations via a titanium alloy probe from a transducer that converts electrical energy to mechanical energy. The diameter of the probe tip can vary. An example of a diameter of a probe tip is about 9.5 mm. The amplitude at which the sonication can be performed can vary. An example of an amplitude is 10 microns for 30 minutes.

The lipid particles, and/or lipid particle crystals, form as a by-product of the formation of the foam phase and vesicle phase. In either the foam phase or vesicle phase, up to 30% of the lipophilic components can be in the form of lipid particles and/or lipid particle crystals.

The hydrophilic phase is formed by mixing together water soluble components with water (i.e. hydrophilic portion). Examples of water soluble components include propylene glycol, glycerol, polyvinylpyrrolidone, and thickeners, e.g., xanthan gum.

The foam phase, vesicle phase and hydrophilic phases are mixed together. Preferably, an equal amount of each phase is used in the formulation.

The foam phase, vesicle phase and hydrophilic phases can be mixed together in any order. For example, the foam phase and the vesicle phase can be first mixed together, and then the resulting mixture can be mixed with the hydrophilic phase. As another example, the foam phase can be first mixed with the hydrophilic phase, and then the vesicle phase can be added.

One or more active substances can be added to the foam phase portion, the vesicle phase portion, the hydrophilic portion, or a combination of these portions.

The specific components of a formulation, and the formulation process, can be varied to obtain delivery systems which allow for different rates of the release, and degrees of penetration, of active substance(s). For example, the phase of the system in which an active substance is placed affects release and penetration rates. For instance, to enhance penetration rates of either a hydrophilic or lipophilic active substance, a major portion of the active substance is placed within the vesicle phase portion.

Another factor which affects release and penetration rates is the size of the micro-compartments. The size of the vesicles can be controlled via the formulation process. For example, during processing, as the homogenizing pressure and duration increases, the vesicle size decreases.

An additional factor which affects release and penetration rates is the type of phospholipids used in the formulation. For example, penetration can be enhanced by including a greater portion of unsaturated phospholipids within the formulation. Preferably, greater than about 90%, greater than about 95%, or greater than about 99% of the phospholipids used in the formulation are unsaturated phospholipids.

Also, phospholipids which include elevated levels of surface active single chain agents enhance penetration. Surface active single chain agents at about a level of 2% to 10% of the phospholipids are considered to be at an elevated level. Examples of surface active agents are lysophospholipids.

Examples of phospholipid formulations that enhance penetration include EPIKURON® 200SH and EPIKURON® 200, and are described above.

The concentration of free fatty acid is also an important parameter affecting penetration rates. A relatively high level of free fatty acid enhances penetration of hydrophilic active substances.

Penetration rates can also be enhanced by the addition of certain adjuvants. For example, an anionic surfactant can be added to the foam phase portion. Also, incorporation of glyceryldilaurate into the vesicle bilayers creates more flexible vesicles which can enhance penetration.

Penetration rates can also be enhanced by the addition of non-ionic adjuvants. In a preferred embodiment, the delivery systems of the present invention further comprise non-ionic adjuvants.

Unlike ionic surfactants, non-ionic adjuvants do not carry a charged species. Instead non-ionic adjuvants comprise a hydrophilic group (e.g. a short, water-soluble polymer chain). The polymers used in non-ionic adjuvants are preferably 10 to 100 units long. These adjuvants are mild on the skin even at high loadings and long-term exposure.

Non-ionic adjuvants are known in the art. Examples of non-ionic adjuvants can be found, for instance, in "Non-ionic Surfactants: Organic Chemistry," edited by Nico M. van Os, published by Marcel Dekker (1998), and "Non-ionic Surfactants: Chemical Analysis (Surfactant Science Series, Vol 19)" by John Cross, published by Marcel Dekker (Oct. 1, 1986). Some non-ionic adjuvants can be divided into classes depending on the type of hydrophilic group appearing in the adjuvant.

Two classes of non-ionic adjuvants that comprise poly (ethylene oxide) groups as their hydrophilic groups are alcohol ethoxylates and the alkylphenol ethoxylates. Examples of non-ionic adjuvants of these classes include tetraethylene glycol monododecyl ether; polyoxyethylene 23 glycol monododecyl ether, polyethylenoxide-polypropylenoxide (PEO-PPO) block-copolymers (such as the commercially available PEO-PPO-PEO triblockcopolymers, called Synperonics F108 and F127), polyoxyethylene alkylphenols; polyoxyethylene alcohols; polyoxyethylene esters of fatty acids; polyoxyethylene mercaptans; and polyoxyethylene alkylamines.

Another class of non-ionic adjuvants is the alkyl polyglycosides. In these molecules, the hydrophilic group is a sugar molecule, such as a polysaccharide, disaccharide, trisaccharide, maltose, etc. Preferably, the polyglycosides have one or two sugar groups in their chains. Examples of non-ionic adjuvants of this class include alkyl glucoside and a glucose ester.

Another class of non-ionic adjuvants is sorbitan ester surfactants. Examples of non-ionic adjuvants of this class include polysorbate 20 (i.e. polyoxyethylene (20) sorbitan monolaurate, sold as Tween 20™); polysorbate 60 (i.e. polyoxyethylene (60) sorbitan monostearate); polysorbate 80 (i.e. polyoxyethylene (20) sorbitan monooleate); and polysorbate 65 (i.e. polyoxyethylene (20) sorbitan tristearate).

The delivery systems of the invention can comprise one non-ionic adjuvant or a combination of non-ionic adjuvants.

Preferably, approximately 0.1% to approximately 15% of a delivery system of the present invention is comprised of a non-ionic adjuvant. Preferred lower boundaries of this range include approximately 0.1%, 0.2%, 0.3%, 0.4%, 0.5%, 1% and 2%. Preferred upper boundaries of this range include approximately 0.3%, 0.4%, 0.5%, 1%, 2%, 3%, 4%, 5%, 6%, 7%, 8%, 9%, 10%, 11%, 12%, 13%, 14%, and 15% of the delivery systems. Each lower boundary can be combined with each upper boundary to define a range. The lower and upper boundaries should each be taken as a separate element.

The non-ionic adjuvant can be added to the hydrophilic portion, either lipophilic portion, or combinations of these portions. Preferably the non-ionic adjuvant is added to all the portions. During the production of the hydrophilic portion or either lipophilic portion, the non-ionic adjuvant is preferably added before the mixing step.

In addition to increasing the rates of penetration of active ingredients, the inclusion of non-ionic adjuvants in the delivery systems also increases the diameter of the vesicles vis-à-vis the delivery systems without these adjuvants (while keeping the amount of active ingredient constant). The vesicle can range from approximately 0.02 μm to approximately 2.5 μm in diameter with the addition of the adjuvants. The size of the other particles are not significantly affected by the addition of the non-ionic adjuvants.

Additional factors which affect release and penetration rates include: the ratio between the different lipid components; the ratio between the foam phase, the vesicle phase and the hydrophilic phase; and the ratio between the amounts of active substances within each phase.

In one embodiment of the present invention, the lipophilic components of the delivery system form only two of the above-defined particles. That is, the formulation comprises only the gas spheres and lipid particles; or the formulation comprises only the vesicles and lipid particles.

In this embodiment, the delivery system is produced from a hydrophilic portion and a lipophilic portion. The lipophilic portion is made either into the foam phase or the vesicle phase, as described above. Preferably, the vesicle phase is produced under conditions which do not allow any gas to enter the formulation, such as in a vacuum. The foam phase or vesicle phase is mixed with the hydrophilic phase. Preferably, an equal amount of either the foam phase or vesicle phase, and the hydrophilic phase is used in the formulation.

Thus, while there have been described what are presently believed to be the preferred embodiments of the present invention, other and further embodiments, modifications, and improvements will be known to those skilled in the art, and it is intended to include all such further embodiments, modifications, and improvements and come within the true scope of the claims as set forth below.

EXAMPLES

Example 1

A General Method of Making

The phospholipid, cholesterol, palmitic acid and ceramide components are mixed together with water, and agitated at a temperature of 70-80° C. The following additional components are added: mevalonic acid lactone, 25-hydroxycholecalciferol, propylene glycol, glycerine, PVP, TEA added along with water, and sodium hydroxide. Sodium hydroxide is added to adjust viscosity and stabilize the formulation. Water is then added, and the formulation is agitated well. The formulation is then cooled down.

An active substance can be dissolved in both the lipid phase and/or the water phase, depending on the solubility and concentration of the active substance.

Example 2

Formulation of a Preferred Embodiment of the Topical Delivery System

(An active ingredient is excluded from this formulation.)

Component	Total amount
Water	79.5% of formulation
Epikuron 200SH	3.5% of formulation
Palmitic acid	1.5% of formulation
Cholesterol	1.5% of formulation
Mevalonic acid	0.01% of formulation or 0.1% of formulation
Triethanolamine	0.5% of formulation
Phenonip ®	0.4% of formulation
Xanthan gum	2.0% of formulation
Skinflux	2.0% of formulation
25-hydroxycholecalciferol	0.0015% of formulation or 0.015% of formulation
Propylene glycol	4.0% of formulation
Glycerol	3.0% of formulation
Polyvinylpyrrolidone	2.0% of formulation

Epikuron 200SH are hydrogenated lecithins, i.e. phosphatidylcholine (PC).

"Skinflux" is a blend product obtainable from Degussa Goldschmidt which contains: Ceramide 1, 3, 6II; Phytosphingosine; Cholesterol; Sodium Lauroyl Lactylate; Carbomer; and Xanthan Gum.

Mevalonic acid lactone is a lipid precursor for cholesterol/fatty acids.

25-Hydroxycholecalciferol is a lipid precursor for ceramides.

Xanthan Gum is a thickener (polysaccharide).

PHENONIP ® is a preservative and a blend of parabens.

Three fractions, a vesicle fraction, a foam fraction and a hydrophilic fraction, are first prepared separately, as described below. Each fraction weighs 3.3 kg. Then the three fractions are mixed together. The following tables show the percent amount of each component contributed by each fraction to the final formulation. Thus, for each component, the sum of the percent amounts of all the fractions is 100%.

1: Vesicle Fraction

Component	Percent Amount in Final Formulation
Water	33% of total water
Hydrogenated lecithins	50% of total amount
Palmitic acid	50% of total amount
Cholesterol	50% of total amount
Mevalonic acid	50% of total amount
Triethanolamine	50% of total amount
Preservative (e.g., Paraben mixture)	50% of total amount
Xanthan gum	15% of total amount
Skinflux	33% of total amount
25-hydroxycholecalciferol	50% of total amount
5M sodium hydroxide	1.3 ml per 1000 grams of water

The "Percent Amount in Final Formulation" indicates the percentage of each component which is contributed by the vesicle fraction to the final formulation.

In forming the vesicle fraction, the components are mixed and heated to the temperature range of 65 to 85° C. while gently stirring. The pH is set to the range of 5.5 to 8.2 by the use of sodium hydroxide. The resulting mixture is then homogenized. Homogenization can be accomplished by, for example, a homogenizer set at a high pressure (e.g. 10,000 to 40,000 psi); or by a sonicator. The size of the vesicles is partially dependent upon how long the resulting mixture is agitated. For example, to obtain an average vesicle size of 0.140 μm, the resulting mixture is agitated for 60 minutes at about 70° C. The mixture is then allowed to cool to below 40° C.

2: Foam Fraction

Component	Percent Amount in Final Formulation
Water	33% of total water
Hydrogenated lecithins	50% of total amount
Palmitic acid	50% of total amount
Cholesterol	50% of total amount
Mevalonic acid	50% of total amount
Triethanol amine	50% of total amount
Preservative (e.g. a paraben mixture)	50% of total amount
Xanthan gum	7.5% of total amount
SK-inflix ®	33% of total amount
25-hydroxycholecalciferol	50% of total amount
5M sodium hydroxide	1.3 ml per 1000 g of water

The "Percent Amount in Final Formulation" indicates the percentage of each component which is contributed by the foam fraction to the final formulation.

In forming the foam fraction, the components are mixed and heated to the temperature range of 65 to 85° C. while stirring. The pH is set to the range of 5.5 to 8.2 by the use of sodium hydroxide. The composition is mixed vigorously for 1 minute. Mixing can be done with ULTRATURRAX® from IKA Werke, Janke & Kunkel GmbH & Co KG (Staufen, Germany). The composition is then allowed to cool to below 40° C.

3: Hydrophilic Fraction

Component	Percent Amount in Final Formulation
Water	34% of total water
Propylene glycol	100% of total amount
Glycerol	100% of total amount
Polyvinylpyrrolidone	100% of total amount
Xanthan gum	77.5% of total amount
Skinflux	34% of total amount
5M sodium hydroxide	3.0 ml per 1000 g of water

The "Percent Amount in Final Formulation" indicates the percentage of each component which is contributed by the hydrophilic fraction to the final formulation.

In forming the hydrophilic fraction, the components are mixed and heated to the temperature range of 65 to 85° C. while stirring. The pH is set to the range of 5.5 to 8.2 by use of sodium hydroxide. Once homogeneous, the composition is then allowed to cool to below 40° C.

In forming the final formulation, after all the fractions are cooled down (below 40° C.), the three fractions are mixed together in any order. For example, the foam fraction is added to the vesicle fraction and gently mixed. Then the hydrophilic fraction is added. The resulting mixture is gently blended for several minutes to obtain a homogeneous solution.

The delivery system of this example is in the form of a cream. In order to produce a delivery system in an aerosol foam form, the total amount of xanthan gum in the final formulation is reduced from 2% to about 0.3%. Additionally, an emulsifier is added, such as laureth 4. Preferably, the emulsifier makes up about 0.7% of the final formulation.

Example 3

Formulation of Example 2 with Lidocaine as an Active Ingredient

An example of a 48 kg batch of a formulation of the delivery system follows. The three fractions used to prepare this formulation each contain 16 kg.

INCI Name	Trade Name	Supplier	CAS	Amount
Hydrogenated Lecithines	Epikuron 200SH	Degussa Goldschmidt		1.7 kg
Cholesterol		Vendico	57-88-5	0.8 kg
Palmitic acid		Karlshamn	57-10-3	0.8 kg
Ceramide 1, 3, 6II, Phytosphingosine, Cholesterol, Sodium Lauroyl Lactylate, Carbomer, Xanthan Gum,	Skin Flux	Degussa Goldschmidt		1.0 kg
Mevalonic acid lactone		Sigma Aldrich	674-26-0	4.8 g
25-Hydroxy-cholecalciferol		Solvay	19356-17-3	0.72 kg
Propylene glycol		MB-Sveda	57-55-6	2.0 kg
Glycerin, 99.5%		Vendico	56-81-5	1.5 kg
Polyvinylpyrrolidone		Apoteket	9003-39-8	1.0 kg
Xanthan gum		Sigma Aldrich	11138-66-2	1.0 kg
Triethanolamine, 85%		MB-Sveda	102-71-6	0.3 kg
Phenonip 30		Vendico Chemical		0.2 kg
Lidocain	USP-grade	Apoteket		2.4 kg
Purified Water				Up to 48 kg

Example 4

Measurement of Skin Barrier Restoration

In the present context enhancing skin barrier restoration can be measured by tape and/or acetone striping of stratum corneum skin lipid content before, during and after a treatment period with the present invention and other systems. Then HPLC analysis of skin lipid content of stratum corneum is conducted.

Example 5

In Vivo Model and Skin Penetration Results

Tracer amounts of the fluorescent dye NBD C6-ceramide were added to the formulation of Example 2 and to a reference (Vaseline®). The formulation and the reference were each applied to hairless mice epidermis. Skin biopsies from three mice in each experimental group were taken two hours after application for fluorescence microscopy (Zeiss Axioplan 2).

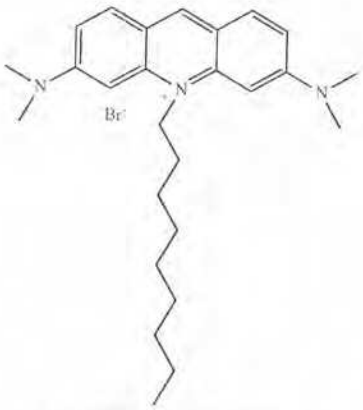
FIG. **9** is a fluorescent microscope image. This image clearly shows that the uptake of the fluorescent probe is more enhanced for the formulation of Example 2 than for the reference. Remarkably, the effect was seen as soon as two hours after application.

Example 6

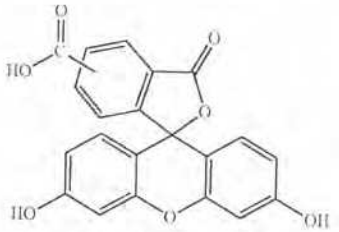
Addition of Non-Ionic Adjuvants into the Formulation of Example 2

This example demonstrates how the addition of non-ionic adjuvants to the formulations of the present invention, in particular the formulation in Example 2, affects the characteristics of the formulation. This example also demonstrates a preferred distribution of active ingredients in the vesicle and foam phases.

Two different model active ingredients (model actives) were used in this example, i.e. a hydrophilic and a lipophilic model active. The lipophilic model active is acridine orange 10-nonyl bromide (AO). The hydrophilic model active is 5(6)-carboxyfluorescein (CF). The penetration of these model actives correspond to the penetration that would be obtained for typical hydrophilic and lipophilic drugs. The structures of these model actives are shown below.



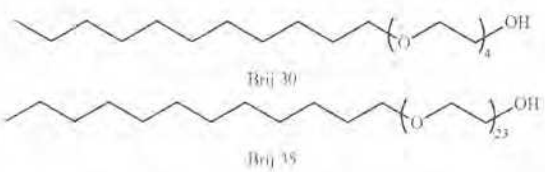
Acridine orange 10-nonyl bromide



5(6)-Carboxyfluorescein

The non-ionic adjuvants used were tetraethylene glycol monododecyl ether (Brij® 30) and polyoxyethylene 23 dode-

cyl ether (Brij® 35), and were obtained from Sigma-Aldrich (St. Louis, Mo.). Their structures are shown below.



Three different variations of the formulations were studied for each model active. These formulation variations are defined as Formulation A, B and C as follows:

A) Formulation with 50% of the model active in the vesicle phase and 50% in the foam phase;

B) Formulation with all of the model active in vesicle phase; and

C) Formulation containing Brij® 30 and Brij® 35, with 50% of the model active in vesicle phase and 50% in the foam phase. The non-ionic adjuvants were added to the vesicle fraction and the foam fraction, and constituted 1.0 wt % of the total formulation.

Of the model actives, 0.028 wt % ($5.9\cdot10^{-4}$M) of AO was used; and 0.011 wt % ($3.0\cdot10^{-4}$M) of CF was used.

Characterization of Vesicle Phase

A comparison of the particle size, polydispersity index and zeta potential of the vesicles of Formulations A, B and C was conducted.

An autosizer (Malvern Zetasizer 1000HS, Malvern Instruments Ltd, Malvern, UK) was used to measure the size distribution of the vesicles. A zetasizer (Malvern Zetasizer 2000, Malvern Instruments Ltd, Malvern, UK) was used to measure the zeta potential. The zeta-potential is defined as the potential across the diffuse layer of ions surrounding the vesicles. The zeta-potential is related to the stability of the vesicles in such a way that a high magnitude of the zeta-potential implies vesicles with a higher surface charge. This higher surface charge in turn increases the repulsion between the vesicles and accordingly the stability of the formulation.

Preferably, the samples were diluted before measurements were taken. For example, before measuring the size distribution, water was used to dilute the sample. Before measuring the zeta-potential, 10 mM NaCl was used to dilute the sample.

A comparison of Formulations A, B and C with respect to the parameters of particle size, polydispersity index and zeta potential are shown in Table 1.

TABLE 1

Parameters of the Vesicle Phase for Formulations A, B and C

	CF			AO		
Formulation	A	B	C	A	B	C
Particle diameter (nm)	276	494	975	345	1730	1395
Polydispersity index	0.4	0.7	0.9	0.5	1.0	1.0
Zeta-potential (mV)	−39	−41	−33	−36	−35	−30
pH	7.5	7.4	7.4	7.3	7.3	7.3

As described above, the A and C formulations (CF-A, AO-A, CF-C and AO-C) have 50% of the model active in the vesicle phase and 50% in the foam phase. Only the C formulations (CF-C and AO-C) include the non-ionic adjuvants. A comparison of the A and C formulations shows that the presence of the non-ionic adjuvants significantly increase vesicle size and decreases the magnitude of zeta-potential. See Table 2.

The inclusion of the non-ionic adjuvants into the vesicle membrane results in ethylene oxide coils reaching out from the vesicle surfaces. Without wanting to be bound to a theory, it is believed that a reason for the increase in vesicle size is that a lateral pressure between ethylene oxide coils in the membrane counteracts the creation of very small vesicles. It is also believed that these coils bind water thereby increasing the mass of the vesicles and reducing their mobility which results in a decrease in the zeta-potential (Silvander et al. *Langmuir* 16:3696-3702 (2000)).

As described above, the A formulations (CF-A and AO-A) have 50% of the model active in the vesicle phase and 50% in the foam phase. The B formulations (CF-B and AO-B) have 100% of the model active in the vesicle phase. A comparison of the A and B formulations shows that the vesicle size increases when all the active is added to the vesicle phase. See Table 1.

This increase in vesicle size is much more dramatic for the formulations containing AO than those containing CF. Without wanting to be bound to a theory, it is believed that this increase results from the interaction of the lipophilic active with the membranes of the vesicles in destabilizing manner. Even though there is a small increase in the vesicle size when all the CF is added to the vesicle phase (Formulation CF-B), it is not believed that CF interacts with the membranes to any large extent. Instead, the difference is likely due to a normal variance in the preparation process.

Characterization of the Foam Phase

The foam phase was investigated by means of light microscopy. As can be seen in FIG. **5**, the distribution of the gas spheres of the foam phase is broad. No differences in the parameters of particle size, polydispersity index and zeta potential were found between Formulations A, B and C for each model active. The phase volume of air directly after production was estimated to 7% directly after production (Master size measurements) and was the same after five days storage at room temperature.

Stability of the Formulations

A change in color of the formulations would indicate oxidation of phospholipids or physical separation. No color change was observed even after 12 months storage both at about 25° C. and at about 40° C. It is believed that the physical stability is ensured due to the negative potential of the small particles together with the gel-like character of the total formulation.

Example 7

Skin Penetration Model

Diffusion Cell

Pig skin was chosen to investigate skin penetration since its stratum corneum structure resembles human stratum corneum more than does mouse skin (Bouwstra et al. *J. Lipid Res.* 36(4): 685-95 (1995)).

Ears of seven to eight month old pigham pigs were obtained from Swedish Meat (Uppsala, Sweden) approximately two hours after slaughter and used the same day. Patches of ear skin were removed with a scalpel. The appropriate thickness (640 μm) was obtained by use of a manual dermatome (Padgett Dermatome, Padgett Instruments Inc., Kansas City). The skin was mounted on diffusion cells of a skin permeation system (Laboratory Glass Apparatus Inc., CA, USA). The receiver capacity of the system was 3 ml. The

skin was mounted with the stratum corneum facing upwards. The surface area of the skin patches was 0.67 cm^2.

An amount of 100 μl of each formulation being tested was applied to the skin and carefully spread to cover the entire surface area. The formulations tested were Formulations AO-A, AO-B, AO-C, CF-A, CF-B, CF-C from Example 6, and two reference formulations. For the AO formulations, Vaseline® containing 0.028 wt % AO was used as a reference. For the CF formulations, xanthan gum gel containing 0.011 wt % CF was used as a reference. Because of the high viscosity of the formulations, the exact amount was determined by weighing after application. For each formulation, three experiments were performed using skin patches from different pigs. The receiver compartment was continuously rinsed with 25 mM HEPES buffer containing 133 mM NaCl (isotonic conditions). The pH of the buffer was set to 7.4 by addition of 1 M NaOH. Before use, the buffer was placed in an ultrasound bath for a few minutes to remove air bubbles. When connecting the buffer solution to the receiver compartment, care was exercised to ensure that no air bubbles appeared on the dermal side of the skin or elsewhere in the receiver compartment. The receiver solution was continuously stirred using a small magnet and the temperature was maintained at 37° C. throughout the experiment by coupling a water bath (HETO, Denmark) to the cells. The experiments were carried out for 24 hours under non-occluded conditions and fractions were collected from the receiver. The flow rate of the receiver solution was set to 1-2 ml/h and fractions were collected every 90 minutes throughout the experiment. After 24 hours, the flow through the receiver compartment was stopped and the donor compartment was rinsed. The first rinsing was performed with 10 ml HEPES buffer followed by two rinses of 10 ml methanol. In cases where the formulation contained 10-nonyl bromide acridine orange, the first rinsing step was excluded since the probe is not soluble in HEPES buffer.

Tape Stripping Procedure

The skin patches were placed on a board. The remaining dried formulations were removed and placed in HEPES buffer. Then the skin patches were stripped. The stripping was carried out using adhesive tape (Scotch magic tape, 3M) by covering the area of the skin that had been in contact with the formulation with a piece of tape, 1.9 cm wide and 4 cm long. Fifteen strippings were performed to ensure that the stratum corneum was removed (Plessis et al. Int. J. Pharm. 103:R1-R5 (1994)). The first two tape strips (Strips 1 and 2) were used to get rid of excess formulation on the skin. Strips 1 and 2 were used to get rid of excess formulation on the skin. Strips 3-5 represent the upper stratum corneum. Strips 6-10 represent the middle stratum corneum. Strips 11-15 represent the lower stratum corneum. The strips were placed into 5 ml HEPES buffer or ml methanol depending on the solubility of the probe. The remaining skin was placed in HEPES buffer for at least 48 hours and after that in methanol for at least 24 hours. These solutions are referred to as the extraction fractions. In cases where the formulation contained acridine orange 10-nonyl bromide, the skin was only placed in methanol for at least 24 hours.

In summary, after stopping the flow though the receiver compartment, the skin was rinsed and tape stripped giving rise to the following fractions:

1. 10 ml HEPES buffer
2. 10 ml methanol
3. 10 ml methanol
4. Remaining dried formulation
5. Tape strips 1-2, excess formulation
6. Tape strips 3-5, surface stratum corneum
7. Tape strips 6-10, middle stratum corneum
8. Tape strips 11-15, deeper stratum corneum
9. Extraction fractions

Fraction Analysis

The collected fractions were analysed by use of a spectrofluorimeter (FluoroMax-2, Instruments S. A., Inc.). The wave lengths found were 490 nm (excitation) and 513 nm (emission) for CF in HEPES, and 490 nm (excitation) and 517 nm (emission) for AO in methanol. Special care was taken in order for the fractions containing CF to be in a linear concentration to intensity region (Weinstein et al. Liposome Technology Gregoriadis, G., ed. Vol. 3, pp. 183, CRC Press, Boca Raton).

Example 8

Skin Penetration Results of the Formulations of Example 7

This example shows the performance results of the penetration of Formulations AO-A, AO-B, AO-C, CF-A, CF-B, CF-C, and the references Vaseline® and xanthan gum gel, as tested by the model described in Example 7. These results demonstrate that the non-ionic adjuvants work well both for hydrophilic and lipophilic actives.

Results for the CF Formulations

The penetration behaviours of the hydrophilic active for the different CF formulations (CF-A, CF-B, CF-C), and for the reference xanthan gum gel formulation, are shown in FIG. **6**.

The amount detected in stratum corneum was similar for CF-A, CF-B and the reference xanthan gum gel. A larger amount of CF was found in the stratum corneum for the CF-C formulation, thus demonstrating that the adjuvants increase penetration.

Concerning the total amount detected in skin, both the CF-B and CF-C formulations penetrate better than does the reference xanthan gum gel. These results show that it is beneficial to distribute more of a hydrophilic active in the vesicle phase when a larger uptake is desired; and that it is beneficial to add non-ionic adjuvants to a formulation when a larger uptake is desired.

These results also show that in addition to the size of the vesicles influencing penetration, there is an effect of the vesicle carrier per se. That is, although the vesicles are smaller in the CF-B formulation vis-à-vis the CF-C formulation, the total amount of the active ingredient detected in the skin is similar. Without wanting to be bound by a mechanism, it is believed that the effect is probably due to an ability of small vesicles to function as carriers down to a lower depth of the skin.

The largest amount of actives found in the receiver was for the reference xanthan gum gel formulation. That is, an active in the gel is more easily transferred to the receiver than is an active incorporated into the lipid matrices of the formulations of the present invention. Thus an active incorporated into the xanthan gum gel is not retained. Without wanting to be bound by a mechanism, it is believed that this occurs because the amount of free water in the xanthan gum is larger than in the other formulations. Water is known to work as a penetration enhancer (Willams et al, *Crit. Rev. Ther. Drug Carrier Syst.* 9(3-4):305-53 (1992)). Moreover, the conditions with a large amount of free water in a gel layer of non-negligible height is close to occluded conditions. Such conditions have been reported beneficial for uptake of drugs (Honeywell et al. *J Controlled Release* 90:243-55 (2003), Bodde et al. *Crit. Rev. Ther. Drug Carrier Syst* 61:87-115). However, the slow

release from the formulations of the present invention to the receiver indicate a slow release mechanism that is beneficial for many topical treatments since systemic toxicity is more easily avoided.

Results for the AO Formulations

The penetration behaviours of the lipophilic active for the different AO formulations (AO-A, AO-B, AO-C) and the reference Vaseline®, are shown in Table 2 and FIG. **7**.

The amount of AO in the total skin is highest for the formulation containing the non-ionic adjuvants, i.e. AO-C. The incorporation of all of the AO into the vesicle phase (AO-B) did not have any beneficial effect on the total skin penetration. Without wanting to be bound to a mechanism, it is believed that this is due in part to that the homogenization was less efficient with all of the AO placed into the vesicle phase. This mechanism is supported by the observation that the vesicle size distribution was large. (See Table 2).

The deeper layers of the stratum corneum contain much less AO when Vaseline® is used than when the other formulations are used. See Table 2 and FIG. **8**. Notably, the formulation containing the adjuvants (AO-C) delivered more than twice the total amount of AO to the deeper layer of the stratum corneum than that delivered by the reference. This is a dramatic improvement. Also, when evaluating the deeper parts of the skin (i.e. below SC), delivery is increased by over four times.

TABLE 2

Penetration of AO and Vaseline into the Stratum Corneum

	AO-A	AO-B	AO-C	Vaseline®
Surface SC	0.56	0.93	1.03	1.25
Middle SC	0.70	0.55	0.68	0.45
Deeper SC	0.44	0.34	0.40	0.17
Total SC	1.70	1.82	2.11	1.87

Note that no amount of AO could be detected in the receiver since its water solubility is low.

Example 9

Variation of the Vesicle Fraction of the Formulation

The object of this example was to evaluate how the physical properties of the vesicle fraction change when its formulation is varied. The vesicle fraction of the formulation of Example 2 was varied with respect to pH, amount of cholesterol, type of phospholipids and addition of surface active agents. The parameters which were varied are presented in Table 3. In particular, fraction L1 is the standard formulation of Example 2. Fraction L3 is the same as fraction L1 except that the Epikuron 200SH phospholipid mixture is replaced with Epikuron 170. Fraction L7 is the same as fraction L1 except that Epikuron 200SH is replaced with Epikuron 200. Fractions L8, L9 and L10 are the same as fraction L7 except that the amount of cholesterol is varied. Fraction L11 is the same as fraction L1 except that surface active agents are included (i.e. Brij 30 and Brij 35). Fractions L2, L5 and L6 are the same as fraction L1 except that the pH is varied. Fraction L4 is the same as fraction L1 except that the amount of cholesterol is reduced.

All fractions were prepared as described in Example 2 except for the varied characteristic. Additionally, unlike in Example 2, the sonication time was prolonged up to 120 minutes in order to study the effect of this on the vesicle properties. Samples were collected after 30, 60 and 120 minutes of sonication for most of the fractions.

TABLE 3

Variation of the composition of the vesicle fraction.

Fraction Name	Varied Characteristic
L1	Example 2 Formulation (i.e. no variation)
L2	2.0 ml 5M NaOH per 1000 g water
L3	Epikuron 170
L4	17% cholesterol (of total amount)
L5	4.0 ml 5M NaOH per 1000 g water
L6	7.0 ml 5M NaOH per 1000 g water
L7	Epikuron 200, 50% cholesterol
L8	Epikuron 200, 20% cholesterol
L9	Epikuron 200, without cholesterol
L10	Epikuron 200, 10% cholesterol
L11	Addition of 0.5% Brij 30 and 0.5% Brij 35

The particle sizes in the vesicle fractions after different sonication times are summarized in Table 4. The diameter given is the Z-average that has been calculated directly from Stoke-Einsteins equation. PI is the polydispersity index. For L3-L6, the particle size was only studied after 30 and 120 minutes sonication.

TABLE 4

Vesicle size and polydispersity index (PI) after 30, 60 and 120 min sonication.

		30 min		60 min		120 min	
Fraction	Zeta Potential (mv)	Diameter (nm)	PI	Diameter (nm)	PI	Diameter (nm)	PI
L1	−44 ± 1.6	130	0.43	130	0.42	131	0.42
L2	−50 ± 0.9	140	0.34	130	0.36	140	0.36
L3	−47 ± 2.9	200	0.27	—	—	370	0.51
L4	−41 ± 0.8	1100	1.00			2300	1.00
L5	−50 ± 3.6	170	0.23	—		190	0.23
L6	−38 ± 1.2	210	0.27	—	—	190	0.24
L7	−51 ± 2.9	860	1.00	—	1.00	130	0.45
L8	−29 ± 3.6	530	0.66	170	0.28	180	0.39
L9	−31 ± 4.7	150	0.50	—	1.00	130	0.78
L10	−32 ± 3.8	160	0.62	170	0.56	220	0.58
L11	−30 ± 6.4	780	1.00	1600	1.00	1500	1.00

The choice of phospholipid is shown to be important for the properties of the vesicle fraction. Epikuron 200SH, 200 and 170 all are mixtures of phospholipids but differ in the saturation and chain length of the phospholipids and also in their amounts of soya phosphatidylcholines (PC).

From the results presented in Table 4, it is clear that use of Epikuron 170 (fraction L3) gives rise to larger vesicles vis-à-vis Epikuron 200SH (fraction L1). The phospholipids of Epikuron 170 are less saturated than the phospholipids in Epikuron 200SH.

The phospholipids in Epikuron 200 (fraction L7) are also less saturated than Epikuron 200SH. However, the difference in vesicle size between fraction L1 (Epikuron 200SH) and fraction L7 (Epikuron 200) is small after 120 minutes sonication.

Thus, after 120 minutes of sonication, when compared to the standard formulation containing Epikuron 200SH, Epikuron 170 yields larger vesicles while Epikuron 200 does not. Without wanting to be bound by a mechanism, it is believed that this result is because Epikuron 170 contains approximately 8% phosphatidylethanolamine (PE), while Epikuron

200 does not. PE has much smaller head groups than PC and so forms inverted structures that can make the formation of membranes more difficult.

The amount of cholesterol also influences the vesicle size, and particle stability. For example, when the amount of cholesterol in the formulation is lowered to 17% (fraction L4) vis-à-vis the standard formulation wherein cholesterol is 50% (fraction L1), the vesicle size is dramatically increased, and the zeta potential is decreased.

Additionally, comparison between fractions L7, L8, L9 and L10 also indicates that the amount of cholesterol affects the stability of the vesicles in such a way that a higher amounts of cholesterol give rise to more stable vesicles (higher magnitude of the zeta potential). Fractions L7, L8, L9 and L10 contain 50%, 20%, 0% and 10% cholesterol, respectively. Fractions L8, L9 and L10 have much lower zeta potentials than L7, additionally, the level of cholesterol is also seen to affect the stability of vesicles more when saturated phospholipids are used vis-à-vis when unsaturated phospholipids are used.

For fractions L7 and L8, the sonication time is of importance to obtain vesicles of the desirable size and size distribution. There is a distinct decrease in vesicle size between 30 and 120 minutes of sonication for these fractions. However, for the other fractions sonication for more than 30 minutes seem to be unnecessary since there is no particular change in vesicle size with increased time of sonication. In some cases, for example fraction L4, it even appears that the particle size is increased with increased sonication time. Without wanting to be bound by a mechanism, a possible explanation for this increase is that oxidation occurs in the sample during the sonication.

The addition of the surfactants Brij 30 and Brij 35 (fraction 11) increases the vesicle size considerably. Without wanting to be bound by a mechanism, an explanation for this is that the addition of surfactants increases the fluidity of the vesicle membranes. It is also possible that additional surface active agents decrease the stability of the vesicles by increasing the steric repulsions between the head groups on the inside of the vesicles. What is usually an advantage for the outer part of the membrane has in general a negative effect on the inside of the vesicles.

I claim:

1. A method of delivering an active substance through the stratum corneum, the method comprising applying to skin a delivery composition comprising:

an aqueous carrier, wherein water comprises 65% or more of the delivery composition by weight;

a lipid component suspended in the aqueous carrier comprising lipids consisting essentially of

(a) fatty acid, which comprises 0.5-10% by weight of the delivery composition, which fatty acid is fatty acid of 10 to 24 carbons,

(b) cholesterol, which comprises 0.5-7% by weight of the delivery composition, and

(c) phospholipid and/or ceramide which component is 0.5-20% by weight of the delivery composition, wherein the phospholipid and/or ceramide component comprises 5% or more by weight phospholipid, and wherein the weight ratio of phospholipid/ceramide to cholesterol is 2:1 to 5.9:1, and

(d) optionally, skin lipid precursors, wherein a combination of said lipids comprises 2 to 20% by weight of the delivery composition;

said lipid component comprises:

(i) a lipid particle component comprising particles formed from said lipids, said particles being surrounded by a lipid monolayer, the particles ranging from approximately 1 μm to approximately 150 μm in diameter, and

(ii) a vesicle component comprising vesicles of formed from said lipids enclosed by a lipid bilayer, the vessicles ranging from approximately 0.02 μm to approximately 0.5 μm in diameter; and

a bioactive agent suitable for delivery to or through skin.

2. The method of claim **1**, wherein the phospholipid and/or ceramide component comprises 10% or more by weight phospholipid.

3. The method of claim **1**, wherein the phospholipid and/or ceramide component comprises 15% or more by weight phospholipid.

4. The method of claim **1**, wherein the phospholipid and/or ceramide component comprises 20% or more by weight phospholipid.

5. The method of claim **1**, wherein a predominant portion of the fatty acid component is C16 or C18 fatty acid.

6. The method of claim **1**, wherein the weight ratio of phospholipid/ceramide to fatty acid is 2:1.5 to 2.95:0.5.

7. The method of claim **6**, wherein phospholipid and/or ceramide component comprises 20% or more by weight phospholipid.

8. The method of claim **6**, wherein the combination of said lipids comprises 3 to 18% by weight of the delivery composition.

9. The method of claim **6**, wherein the combination of said lipids comprises 4 to 16% by weight of the delivery composition.

10. The method of claim **6**, wherein the combination of said lipids comprises 5 to 13% by weight of the delivery composition.

11. The method of claim **6**, wherein a predominant portion of the fatty acid component is C16 or C18 fatty acid.

12. The method of claim **6**, wherein the bioactive agent is a peptide, protein, sunscreen, tanning agent, skin anti-wrinkling agent, anti-dandruff agent, anti-acne agent, hair growth stimulant, hormone, nicotine, interferon, pain killer, vitamin, antifungal, anti-acne, anti-louse agent, anti-skin cancer agent or a substance to treat eczema, dry skin, itchy skin, hair loss, psoriasis or skin lesions.

13. The method of claim **6**, wherein the bioactive agent is a steroid hormone.

14. The method of claim **6**, wherein the lipid component comprises 25-hydroxycholecalciferol, mevalonic acid, mevalonic acid lactone or mixtures thereof as skin lipid precursor.

15. The method of claim **1**, wherein the combination of said lipids comprises 3 to 18% by weight of the delivery composition.

16. The method of claim **1**, wherein the combination of said lipids comprises 4 to 16% by weight of the delivery composition.

17. The method of claim **1**, wherein the combination of said lipids comprises 5 to 13% by weight of the delivery composition.

18. The method of claim **1**, wherein the bioactive agent is a peptide, protein, sunscreen, tanning agent, skin anti-wrinkling agent, anti-dandruff agent, anti-acne agent, hair growth stimulant, hormone, nicotine, interferon, pain killer, vitamin, antifungal, anti-acne, anti-louse agent, anti-skin cancer agent or a substance to treat eczema, dry skin, itchy skin, hair loss, psoriasis or skin lesions.

19. The method of claim **1**, wherein the bioactive agent is a steroid hormone.

20. The method of claim 1, wherein the lipid component comprises 25-hydroxycholecalciferol, mevalonic acid, mevalonic acid lactone or mixtures thereof as skin lipid precursor.

21. The method of claim 1, wherein water comprises 70% or more of the delivery composition by weight.

22. The method of claim 21, wherein the phospholipid and/or ceramide component comprises 10% or more by weight phospholipid.

23. The method of claim 21, wherein the phospholipid and/or ceramide component comprises 15% or more by weight phospholipid.

24. The method of claim 21, wherein the phospholipid and/or ceramide component comprises 20% or more by weight phospholipid.

25. The method of claim 21, wherein a predominant portion of the fatty acid component is C16 or C18 fatty acid.

26. The method of claim 21, wherein the weight ratio of phospholipid/ceramide to fatty acid is 2:1.5 to 2.95:0.5.

27. The method of claim 26, wherein the phospholipid and/or ceramide component comprises 10% or more by weight phospholipid.

28. The method of claim 26, wherein the phospholipid and/or ceramide component comprises 15% or more by weight phospholipid.

29. The method of claim 26, wherein the phospholipid and/or ceramide component comprises 20% or more by weight phospholipid.

30. The method of claim 26, wherein the combination of said lipids comprises 3 to 18% by weight of the delivery composition.

31. The method of claim 26, wherein the combination of said lipids comprises 4 to 16% by weight of the delivery composition.

32. The method of claim 26, wherein the combination of said lipids comprises 5 to 13% by weight of the delivery composition.

33. The method of claim 26, wherein a predominant portion of the fatty acid component is C16 or C18 fatty acid.

34. The method of claim 26, wherein the bioactive agent is a peptide, protein, sunscreen, tanning agent, skin anti-wrinkling agent, anti-dandruff agent, anti-acne agent, hair growth stimulant, hormone, nicotine, interferon, pain killer, vitamin, antifungal, anti-acne, anti-louse agent, anti-skin cancer agent or a substance to treat eczema, dry skin, itchy skin, hair loss, psoriasis or skin lesions.

35. The method of claim 26, wherein the bioactive agent is a steroid hormone.

36. The method of claim 26, wherein the lipid component comprises 25-hydroxycholecalciferol, mevalonic acid, mevalonic acid lactone or mixtures thereof as skin lipid precursor.

37. The method of claim 21, wherein the combination of said lipids comprises 3 to 18% by weight of the delivery composition.

38. The method of claim 21, wherein the combination of said lipids comprises 4 to 16% by weight of the delivery composition.

39. The method of claim 21, wherein the combination of said lipids comprises 5 to 13% by weight of the delivery composition.

40. The method of claim 21, wherein the bioactive agent is a peptide, protein, sunscreen, tanning agent, skin anti-wrinkling agent, anti-dandruff agent, anti-acne agent, hair growth stimulant, hormone, nicotine, interferon, pain killer, vitamin, antifungal, anti-acne, anti-louse agent, anti-skin cancer agent or a substance to treat eczema, dry skin, itchy skin, hair loss, psoriasis or skin lesions.

41. The method of claim 21, wherein the bioactive agent is a steroid hormone.

42. The method of claim 21, wherein the lipid component comprises 25-hydroxycholecalciferol, mevalonic acid, mevalonic acid lactone or mixtures thereof as skin lipid precursor.

43. The method of claim 1, wherein the composition is delivered to the skin as a foam and water comprises 75% or more of the delivery composition by weight.

44. The method of claim 43, wherein the phospholipid and/or ceramide component comprises 10% or more by weight phospholipid.

45. The method of claim 43, wherein the phospholipid and/or ceramide component comprises 15% or more by weight phospholipid.

46. The method of claim 43, wherein the phospholipid and/or ceramide component comprises 20% or more by weight phospholipid.

47. The method of claim 43, wherein a predominant portion of the fatty acid component is C16 or C18 fatty acid.

48. The method of claim 43, wherein the weight ratio of phospholipid/ceramide to fatty acid is 2:1.5 to 2.95:0.5.

49. The method of claim 48, wherein the phospholipid and/or ceramide component comprises 10% or more by weight phospholipid.

50. The method of claim 48, wherein the phospholipid and/or ceramide component comprises 15% or more by weight phospholipid.

51. The method of claim 48, wherein the phospholipid and/or ceramide component comprises 20% or more by weight phospholipid.

52. The method of claim 48, wherein the combination of said lipids comprises 3 to 18% by weight of the delivery composition.

53. The method of claim 48, wherein the combination of said lipids comprises 4 to 16% by weight of the delivery composition.

54. The method of claim 48, wherein the combination of said lipids comprises 5 to 13% by weight of the delivery composition.

55. The method of claim 48, wherein a predominant portion of the fatty acid component is C16 or C18 fatty acid.

56. The method of claim 48, wherein the bioactive agent is a peptide, protein, sunscreen, tanning agent, skin anti-wrinkling agent, anti-dandruff agent, anti-acne agent, hair growth stimulant, hormone, nicotine, interferon, pain killer, vitamin, antifungal, anti-acne, anti-louse agent, anti-skin cancer agent or a substance to treat eczema, dry skin, itchy skin, hair loss, psoriasis or skin lesions.

57. The method of claim 48, wherein the bioactive agent is a steroid hormone.

58. The method of claim 48, wherein the lipid component comprises 25-hydroxycholecalciferol, mevalonic acid, mevalonic acid lactone or mixtures thereof as skin lipid precursor.

59. The method of claim 43, wherein the combination of said lipids comprises 3 to 18% by weight of the delivery composition.

60. The method of claim 43, wherein the combination of said lipids comprises 4 to 16% by weight of the delivery composition.

61. The method of claim 43, wherein the combination of said lipids comprises 5 to 13% by weight of the delivery composition.

62. The method of claim 43, wherein the bioactive agent is a peptide, protein, sunscreen, tanning agent, skin anti-wrinkling agent, anti-dandruff agent, anti-acne agent, hair growth stimulant, hormones, nicotine, interferon, pain killer, vita-

min, antifungal, anti-acne, anti-louse agent, anti-skin cancer agent or a substance to treat eczema, dry skin, itchy skin, hair loss, psoriasis or skin lesions.

63. The method of claim **43**, wherein the bioactive agent is a steroid hormone.

64. The method of claim **43**, wherein the lipid component comprises 25-hydroxycholecalciferol, mevalonic acid, mevalonic acid lactone or mixtures thereof as skin lipid precursor.

65. The method according to claim **1**, wherein the delivery composition comprises: fatty acid at between 0.5-10%; the cholesterol at between 0.5-10%; the lipid precursors at between 0.000001-10%; and the ceramide/phospholipid portion at between 0.005-20%.

66. The method according to claim **1**, wherein the delivery composition comprises: fatty acid comprising ten to twenty-four carbon atoms.

67. The method according to claim **1**, wherein the water content in the delivery composition exceeds 79%.

68. The method according to claim **1**, wherein the water content in the delivery composition exceeds 90%.

69. The method according to claim **1**, wherein the delivery composition comprises a combination of:

Fatty Acid 0.5-10%
Phospholipid 0.5-10%
Cholesterol 0.5-7%
Lipid precursor 0.000001-10%
Ceramide 0.005%-7%.

70. The method according to claim **69**, wherein the lipid precursor in the delivery composition is mevalonic acid.

71. The method according to claim **69**, wherein the delivery composition further comprises

Glycerine 0-5%
Propylene glycol 0-48%
PVP (M weight 40.000) 0-5%
triethanolamine (TEA) 0-3%.

72. The method according to claim **69**, wherein the delivery composition further comprises

25-Hydroxycholecalciferol 0.015%
Acylceramides 0.025%.

73. The method according to claim **69**, wherein the lipid precursor comprises 0.01% of Mevalonic acid, 0.0015% 25-Hydroxycholecalciferol, or a combination of Mevalonic acid, and 25-Hydroxycholecalciferol.

* * * * *

Recollections of Promotional Meetings

Public

Date	Meeting/ Company Involved (if relevant)	Point Person Organizing for Company
0010911	Johnson & Johnson	Tom Carey
20010911	Collagenex in Newtown PA	Rob Ashley
20010911	Neutragena/Ortho McNeil -Scheduled/Canceled in part	Jeff Day
20010912	Medicis -Scheduled/Canceled in person, but with teleconference	Biku Patel
20010913	Allergan -Scheduled/Canceled	Jeff Day
20020115	Carib. Derm meeting	
20020300	AAD meeting in New Orleans	
20030100	Carib Derm in Puerto Rico	
20030301	**EpiTan**	Michael Kleinig
20030721	**Skin Medica** and Chicago	Diane Goostree
20030800	AAD Chicago	
20040100	Carib Derm in Puerto Rico	
20040801	AAD meeting Washington DC (also presentation to Scientifc board)	
20040929	Presentation to Dr W Abromovitz in Dallas	
20040929	Presentation to Art Clapp Galderma in Dallas	Art Clapp
20041104	**Ranbaxy** US visiting Skold's Lab in Sweden	Beborah McRonald
20050100	Carib Derm in Auruba	
20050200	AAD in New Orleans with Posters at the contact derm meeting	
20050900	Coastal Derm Meeting in Napa	
20060100	Carib Derm in Aruba	
20060300	AAD in San Francisco	
20070100	Carib Derm on Grand Cayman	
20070200	AAD in Washington DC	
20070700	AAD in New York	
20070700	[redacted]	
20070731		
20070801		
20080100		
20080128		
20080218		
20090927		
20090930		
20100000		
20100100		
20100100		
20100100		
20100100		
20100200		
20100300		
20100507		
20110100		
20110900		
20111000		
20111000		
20111100		
20120100		
20120100		
20120100		

* A date designation of yyyymm00 represents that the meeting occurred during the month specified.
** One or more company labeled by pseudonym (e.g., "Company A" or the like) may be the same as a company openly named in pre-2007 time frame, or an affiliate thereof.

Exhibit T 132
Skold v. Galderma
Cancellation No. 92052897

~~TRADE SECRET/COMMERCIALLY SENSITIVE~~

Trade Secret/Commercially Sensitive

RESTORADERM Technology Projects and Products Worked on by Sköld Since 2001

Products Developed in Collaboration with Collagenex	Stability comments
[redacted]	satisfactory
	satisfactory
	satisfactory
	satisfactory
	satisfactory
	satisfactory
	(failed in stability)

not product

Products Developed Independently of Collagenex	
[redacted]	satisfactory
	satisfactory
	satisfactory
	satisfactory
	satisfactory
	satisfactory
	satisfactory
	needs more formulation work
	satisfactory
	needs more formulation work

Product Developed Independently by Sköld	
[redacted]	on its way into stability testing
	satisfactory but will undergo a new
	on its way into stability testing

Launchable products
[redacted]

Pre NDA meeting with FDA
[redacted]

Exhibit T 133
Skold v. Galderma
Cancellation No. 92052897

SKOLD v. Galderma, Cancellation No. 92052897, Exhibit Book p. 469

A Comparator Study of an Adjunctive Dermal Lipid Replacement Foam (Restoraderm™) in the Management of Refractory Hand Contact Dermatitis

Fowler JF, Perryman JH; University of Louisville, Louisville, Kentucky

ABSTRACT

Background: Dermatitis (irritant, allergic, or both) is the most common occupational skin disease. Although many "barrier creams" with high concentrations of petrolatum are sold, none have shown consistent effectiveness.

Restoraderm is composed of an exclusive non-alcohol, water-based formulation of lipids that mimics the body's own natural skin barrier system. It contains ceramides, cholesterol, palmitic acid and two biologic precursors, mevalonic acid and hydroxycholecalciferol. It does not contain petrolatum, and is a non-greasy formulation. Many occupational hand dermatitis patients find it difficult to work when using a product with petrolatum as its greasy residue can negatively affect grip and impair the protection of latex gloves.

Objective: To measure the effectiveness of Restoraderm in reducing or eliminating chronic hand contact dermatitis. The primary endpoints were mean percent change from baseline in the Clinician's Global Assessment Score and mean change in frequency of topical steroid use.

Methods: Thirty-one patients were randomized to receive either Restoraderm or a comparator (ointment or lotion) at the baseline visit. Each patient received Restoraderm for a 3 week period followed by comparator or vice versa. There was a two-week washout between study phases.

Results: Restoraderm proved to be effective in reducing or eliminating chronic hand contact dermatitis caused by occupational exposures. It was preferred by patients over the comparators. The non-greasy foam formulation of Restoraderm may contribute to compliance, ease of use, and patient satisfaction in patients with chronic hand dermatitis.

INTRODUCTION

Dermatologic conditions account for the majority of reported occupational illness in the United States. Dermatitis (irritant, allergic, or both) is the most common occupational skin disease. Although many "barrier creams" are sold none have shown consistent effectiveness in preventing occupational hand dermatitis. Some occupational hand dermatitis patients, such as beauticians, nurses, mechanics, and culinary workers, are not able to work when using a product with a high concentration of petrolatum to treat the condition. Petrolatum leaves a greasy residue which can negatively effect grip and render latex gloves ineffective in bacterial protection.

Restoraderm (CollaGenex Pharmaceuticals) is a dermal lipid replacement foam composed of an exclusive non-alcohol, water-based formulation of lipids that mimics the body's own natural skin barrier system. Restoraderm does not contain petrolatum. Restoraderm is a non-greasy formulation.

OBJECTIVE

The objective of this study is to measure the effectiveness of Restoraderm in reducing or eliminating irritant and/or allergic contact dermatitis of the hands in patients with chronic hand dermatitis caused by occupational exposures. The primary endpoints were mean percent change from baseline in the Clinician's Global Assessment Score and mean change in frequency of topical steroid use from baseline.

METHODS

Study Design: Prospectively randomized, cross-over design

Inclusion Criteria: Normal healthy males or females with chronic hand dermatitis verified by a score of 3 to 8 on the Clinician's Global Assessment Scale (Table 1).

Table 1. Clinician's Global Assessment Scale

0	Clear
1	Almost Clear: Minimal scattered erythema and/or scaling (<10% involved)
2	Minimal Dermatitis: Minimal scattered scaling and/or erythema (<50% involved)
3	Mild Dermatitis: Mild scattered scaling with mild to minimal erythema (<50%)
4	Mild to Moderate Dermatitis: Same as #3 but more extensive, ± a few papules or vesicles
5	Moderate Dermatitis: Moderate scaling with moderate erythema, some papules, vesicles, and/or early fissures (<50%)
6	Moderate Dermatitis: Same as #5 but more extensive
7	Moderate to Severe Dermatitis: Scaling and deeper fissures and/or confluent papules, vesicles and moderate to severe erythema (<50%)
8	Moderate to Severe Dermatitis: Same as #7 but more extensive
9	Severe Dermatitis: Severe scaling and fissures, papules, and/or vesicles with erythema (<50%)
10	Severe Dermatitis: Severe scaling and fissures and/or vesicles and crusting with erythema, covering most of the hand surface

Week 0: Thirty-one patients randomized to receive Restoraderm Foam or a comparator (Aquaphor Ointment or Lubriderm Lotion) for a 3-week period

Week 3 - Week 5: Washout period

Week 5: Patients on Restoraderm receive either of the two comparators and individuals on comparator receive Restoraderm for an additional 3-week period

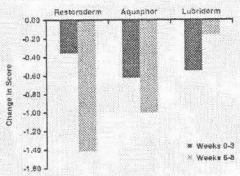
Week 8: Last observation

Investigator Evaluation: Occurred at weeks 0, 3, 5, and 8. Parameters evaluated on a scale of 0-5: erythema, scaling, cracking and fissuring, vesicles. Nail changes indicted as either present or absent. Location of activity noted. Global evaluation on a scale of 0-10 recorded.

RESULTS

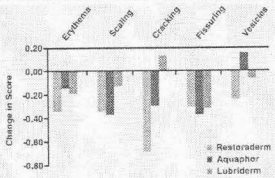
- Patients who received Restoraderm during the second treatment period exhibited a significant improvement in Global Assessment Score vs comparator groups (Figure 1).

Figure 1. Investigator Global Assessment Score – Change From Baseline



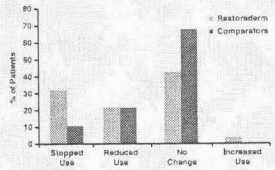
- Patients who received Restoraderm exhibited consistent improvement in all five categories and significant improvement in erythema and cracking vs comparator groups (Figure 2).

Figure 2. Skin Irritancy Scores – Cumulative Change From Baseline Following Both Treatment Periods



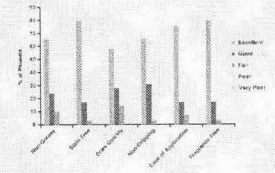
- Patients who received Restoraderm were 3-fold more likely to stop concomitant use of steroids vs comparator groups (Figure 3).

Figure 3. Steroid Usage – Cumulative Change From Baseline Following Both Treatment Periods



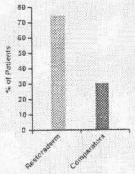
- Restoraderm received an excellent rating from at least 60% of patients in all characteristics (Figure 4).

Figure 4. Rating the Cosmetic Characteristics of Restoraderm



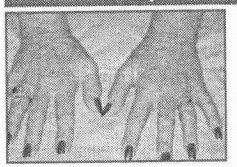
- Restoraderm was preferred by 71% of patients vs 29% for comparators (Figure 5).

Figure 5. Overall Patient Preference For Restoraderm and Comparators

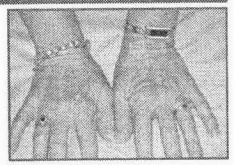


- Photos of one patient in the study are displayed in Figure 6.

Figure 6. Overall Patient Preference For Restoraderm and Comparators



Baseline



After 3 weeks of treatment with Restoraderm foam

CONCLUSIONS

- Restoraderm proved to be effective in reducing or eliminating chronic hand contact dermatitis caused by occupational exposures.
- Restoraderm users exhibited an overall improvement in Skin Irritancy & Global Assessment Scores.
- Restoraderm users were more likely to stop steroid usage than those receiving comparators.
- Restoraderm received excellent ratings in 5 major cosmetic categories from the majority of patients.
- The non-greasy foam formulation of Restoraderm may contribute to compliance, ease of use, and satisfaction in patients with chronic hand dermatitis.
- Restoraderm was preferred by patients by a margin greater than 2:1 vs comparators.

Disclosure or Support: Dr. Fowler has received consulting fees from CollaGenex Pharmaceuticals. This study was supported by an unrestricted grant from CollaGenex Pharmaceuticals, Inc.

Exhibit
T 143
Skold v. Galderma
Cancellation No. 92052897

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the Matter of Registration Nos. 2985751; and 3394514

Dated: August 16, 2005 & March 11, 2008, Respectively

Public

Thomas Sköld, Petitioner v. Galderma Laboratories, Inc., Registrant	)	Cancellation No. 92052897

~~TRADE SECRET/ COMMERCIALLY SENSITIVE~~

SKÖLD TRIAL EXHIBIT T 145 – DOCUMENT AUTHENTICATION

At his deposition, **Thomas Sköld will be asked to confirm that he has reviewed the booklet labeled Skold Deposition Exhibit Workbook (which has an index identifying the documents tabulated below), and each document therein**. The Skold Deposition Exhibit Workbook identifies the documents in the Deposition Workbook by Bates Number (either SKD-xxxxxx or TS-xxxxxx), Trial exhibit number, and page number in the Deposition Workbook.

In the table below
Collagenex Pharmaceuticals, Inc. is abbreviated "CGX",
Galderma Laboratories, Inc. is abbreviated "GDM",
Thomas Sköld is abbreviated "TS",
Jeff Day is abbreviated "JD",
Greg Ford is abbreviated "GF",
Art Clapp is abbreviated "AC",
Quintin Cassady is abbreviated "QC",
Rob Ashley is abbreviated "RA", and
Brad Zerler is abbreviated "BZ".
Parties identified with a following parenthetical reference to CGX or GDM were at the time of the document affiliated with that company.

From the review of the Skold Deposition Exhibit Workbook, Skold will be asked to affirm as to each of the following **Group A** documents (which should be available to Registrant from its corporate files) and **Group B** documents that:

A) it is a true copy of the document, as found in Skold's physical files; and
B) Skold stored the document in the ordinary course of business, as Skold does with comparable important business documents.

Of the **Group C** documents, **Skold will be asked to affirm** that each is a recordation of Skold's recollections on the subject matter thereof.

The **Group D** documents comprise official records or publications. Of these, **Skold will be asked to affirm** that the SEC 10-K statement and the press releases match Skold's recollections

In the listings below, a previous reference number is listed below the trial exhibit number, for convenience to the litigants.

TRADE SECRET/ COMMERCIALLY SENSITIVE

Group A

Bates No.	Ex. No.	Pg No.	Identifier, Notes
TS-000001	T1 (302)	1	Aug. 17-18, 2004 Emails between D. Glazer and TS concerning 2004 Agreement.
TS-000002-17	T2 (Ex2)	2	2002 Agreement between CGX and Sköld. Page 3 of the agreement is provided twice, with the second copy showing the text "Exhibit A" which is visible in the original.
TS-000018-45	T3 (Ex3)	18	2004 Agreement between CGX and Sköld.
TS-000046-47	T4 (Ex5)	46	Nov. 27, 2009 notification of termination from GDM to TS.
TS-000048-49	T5 (Ex6)	48	Feb. 22, 2010 Assignment of patent estate from GDM to TS.
TS-000050-56	T6 (Ex10)	50	Aug. 1, 2004 Consulting Agreement between CGX and TS.
SKOLD-000013	T10 (104)	61	Oct. 22, 2002 Email from S. Kennedy (CGX) to TS concerning promotional activity.
SKOLD-000014-35	T11 (105)	62	Epitan Agreement dated 9 May 2003. The complete document includes SKOLD-001950, found at p. 416.
SKOLD-000036	T12 (106)	84	Dec. 9, 2003 Email from R. Ashley (CGX) to other CGX personnel on draft changes to agremment.
SKOLD-000037-50	T13 (107)	85	Draft amendments to agreement attached to SKOLD-000036.
SKOLD-000051-52	T14 (108)	99	July 10-12, 2004 Emails btwn JD (CGX) and TS on promotion to Therapeutics, Inc.
SKOLD-000053	T15 (109)	101	July 19, 2004 Email JD (CGX) to TS on technology consultation.

Bates No.	Ex. No.	Pg No.	Identifier, Notes
SKOLD-000054-57	T16 (110)	102	Oct. 4, 2004 Emails btwn CGX and TS on use of "Restoraderm."
SKOLD-000055	T17 (111)	103	Dec. 15, 2005 G. Ford (CGX) to TS about promotions.
SKOLD-000058-60	T18 (111.1)	104	Feb. 27, 2006 B. Zerler (CGX) to TS on formulation stability (with attached data).
SKOLD-000061-63	T19 (112)	107	Jul. 7, 2006 Wiggin&Dana (TS attorneys) ltr to CGX.
SKOLD-000064-66	T20 (113)	110	Jun. 27 – Jul. 27, 2006 Emails btwn GF (CGX) and formulator, copying TS.
SKOLD-000067-68	T21 (116)	113	Jul. 27 – Aug. 1, 2007 Emails btwn GF (CGX) and TS on promotion activity at American Academy of Dermatology (AAD) meeting.
SKOLD-000069-70	T22 (125)	115	Jan. 29, 2008 Wiggin&Dana (TS attorneys) ltr to CGX asserting voluntary termination by CGX of 2004 Agreement.
SKOLD-000071-74	T23 (126)	117	Sep. 1, 2008 Emails btwn S Samira (GDM) and TS, attaching memo on technology consultation meeting ("Restoraderm technical Meeting").
SKOLD-000075	T24 (127)	121	Sep. 3, 2008 Emails btwn S Samira (GDM) and TS concerning technology.
SKOLD-000076-78	T25 (128)	122	Sep. 1 – Sep. 4, 2008 Emails btwn S Samira (GDM), L Fredon (GDM) and TS concerning technology.
SKOLD-000079-82	T26 (129)	125	Sep. 8, 2008 Email btwn S Samira (GDM) and TS, attaching revised memo on technology consultation meeting ("Restoraderm technical Meeting").
SKOLD-000083-85	T27 (130)	129	Jul. 9 – Jul. 15, 2009 Emails btwn QC (GDM) and TS on status of relationship and marketing Restoraderm outside dermal.
SKOLD-000086	T28 (131)	132	Dec. 1, 2009 Email TS to C de Bruyne (GDM) on post-breakup marketing of Restoraderm.
SKOLD-000087-88	T29 (132)	133	Jan. 27 – Feb. 8, 2010 Emails btwn J Wallace (GDM) and TS on material returns.
SKOLD-000606	T45 (Ex11)	240	Nov. 29, 2007 Emails btwn GF (CGX) and TS on CGX deciding to divest Restoraderm.
SKOLD-000658-63	T46 (Ex4)	241	Feb. 12, 2008 CGX response ltr to Wiggin&Dana on TS's notice of termination.
SKOLD-000872-90	T47 (14)	247	PowerPoint presentation on Restoraderm with CGX logo. The presentation was attached to the Email of SKOLD-001790-91 (below).
SKOLD-001023	T48 (1)	266	Feb. 14, 2002, JD (CGX) Email to TS seeking technical advice re promotion to P&G.
SKOLD-001751	T50 (3)	269	Jan. 26, 2004 Email JD (CGX) to TS on technical help with Sci. Advisory Bd.
SKOLD-001766-67	T51 (8)	270	Statement from CGX of agreed term sheet for 2004 Agreement, speaking of Restoraderm Technology.

Bates No.	Ex. No.	Pg No.	Identifier, Notes
SKOLD-001788	T52 (11)	272	Jul. 15, 2004, Email JD (CGX) to TS on promoting to Abramovitz.
SKOLD-001790-91	T53 (12)	273	Sep. 3 – 8, 2004, Emails btwn Ranbaxy, TS and CGX on promotional teleconference.
SKOLD-001792	T54 (13)	275	Meeting agenda attached to SKOLD-001790.
SKOLD-001803	T55 (15)	276	Oct. 26, 2004 Email GF (CGX) to TS on promotion to GDM.
SKOLD-001804-08	T56 (16)	277	Nov. 3 – 18, 2004 Emails btwn CGX parties and TS on seeking additional Restoraderm samples from TS
SKOLD-001809	T57 (17)	282	Mar. 10 –16, 2009 Email btwn AC (GDM) and TS on a proposed new relationship.
SKOLD-001810-03	T58 (18)	283	Jun. 2, 2009 Email from QC (GDM) to TS on "topical dermal technology know as RESTORADERM".
SKOLD-001814-16	T59 (19)	287	Jun. 16 – 17, 2009 Emails btwn QC (GDM) and TS on no new agreement, and declining to comment on rumor that GDM would take the trademark, divorced from the technology.
SKOLD-001817	T60 (20)	290	Jun. 22, 2009 QC (GDM) to TS on arranging a teleconference.
SKOLD-001818-19	T61 (21)	291	TS list, sent to GDM, of items to be returned per Section 8.5 of the 2004 Agreement.
SKOLD-001820-21	T62 (24)	293	May 31 – Jul. 14, 2010 Emails btwn C de Bruyne (GDM) to TS on no further agreement with TS.
SKOLD-001848-49	T75 (209)	315	Feb. 17 – 18, 2002 Emails btwn JD (CGX) and TS on promotional activity (Connectics)
SKOLD-001850-51	T76 (210)	317	Mar. 21 – May 1, 2009 Emails btwn CGX and potential partner, and to TS on promotion
SKOLD-001852	T77 (211)	319	Apr. 29 – May 3, 2002 Emails btwn RA (CGX) and TS on promotions.
SKOLD-001853	T78 (212)	320	May 7, 2002 Email JD (CGX) to TS on input on promotions for presentation to Board
SKOLD-001854-55	T79 (213)	321	Apr. 12 – Jun. 26, 2002 Emails btwn RA (CGX), Epitan and TS on a formulation collaboration.
SKOLD-001858-59	T81 (215)	325	Oct. 4 – 9, 2002 Emails btwn JF (CGX), Fujisawa and TS on collaboration.
SKOLD-001860-61	T82 (216)	327	Mar. 7 – 10, 2003 Emails btwn JD (CGX) and TS on product development and promotions.
SKOLD-001862-65	T83 (217)	329	Mar. 13 – 14 Emails btwn JD (CGX), TS and others on planning promotional activity at AAD meeting, with attached agenda.
SKOLD-001866-68	T84 (218)	333	May 12 – 16, 2003 Emails btwn JD (CGX), TS and R Ghadially on product testing, product development.
SKOLD-001869-70	T85 (219)	336	Jul.21, 2003 JD (CGX) to D. Goostree of Skin Medica, Inc.

Bates No.	Ex. No.	Pg No.	Identifier, Notes
SKOLD-001871-72	T86 (220)	338	Oct. 2 – 3, 2003 Emails btwn JD (CGX), TS and R Ghadially on product testing data.
SKOLD-001873-74	T87 (221)	340	Oct. 23 – 24, 2003 Emails btwn JD (CGX) and TS on promotions.
SKOLD-001875-76	T88 (222)	342	Oct 25 – Nov. 7, 2003 Emails btwn JD (CGX) and TS on promotions.
SKOLD-001877-79	T89 (223)	344	Jun. 30 – Jul. 8, 2004 Emails btwn JD (CGX), TS and others on product development.
SKOLD-001880-82	T90 (224)	347	Feb. 27 – Sep 27, 2004 Emails btwn JD (CGX), GDM and TS on promotion to GDM.
SKOLD-001883-84	T91 (225)	350	Jul. 10 – 12, 2004 Emails btwn JD (CGX) and TS on promotion to Therapeutics, Inc./Product Development Co..
SKOLD-001885-88	T92 (226)	352	Feb. 20 – Aug. 9, 2004 Emails btwn JD (CGX), TS and others on promotion to TexasDerm.
SKOLD-001889	T93 (227)	356	Aug. 16 – 17, 2004 Emails btwn JD (CGX), TS, others on promotion to Ranbaxy.
SKOLD-001890-91	T94 (228)	357	Sep. 10, 2004 Email BZ (CGX) to TS on forming a project plan for Ranbaxy, attaching an initial outline.
SKOLD-001892-93	T95 (229)	359	Mar. 2 – Mar. 4, 2005 Emails btwn GF (CGX), TS, others on formulation development.
SKOLD-001894-96	T96 (230)	361	Sept. 28, 2004 Email InyX-Pharma to GF (CGX), TS, others on summary of promotional meeting.
SKOLD-001897	T97 (231)	364	Jun. 14, 2005 Email GF (CGX) to TS seeking technical presentation for promotions.
SKOLD-001898	T98 (232)	365	Jan. 22, 2007 Email GF (CGX) to TS on promotions to Pfizer and J&J.
SKOLD-001946-47	T121 (256)	412	May 6 – 10, 2006 Emails btwn GF (CGX) and TS on status of the licensing relationship.
SKOLD-001948	T122 (257)	414	May 11, 2006 Emails btwn GF (CGX) and TS on status of the licensing relationship.
SKOLD-001949	T123 (258)	415	Feb. 6, 2008 Email A Powell to TS on status of the licensing relationship, TS's seeking to terminate, divestiture of the Restoraderm asset.
SKOLD-001950	T124 (259)	416	Page from Epitan Agreement. This is the page missing from SKOLD-000014-35.
SKOLD- 001846	T134 (207)	451	Feb. 14, 2002 Email JD to TS regarding P&G
SKOLD-001847	T135 (208)	452	Feb. 18, 2002 Emails btwn JD and TS regarding promotion (Optime).
SKOLD-001850-1	T136 (210)	453	Mar. 21 – May 1, 2002 Emails btwn CGX and TS on promotion [ATS (Advanced Tissue) and Atrix (Steve Garrett)].
SKOLD-001852	T137 (211)	455	Apr. 29 – May 3, 2002 Emails btwn CGX and TS on promotion [Antares Pharma (Dario Carraras)].

Bates No.	Ex. No.	Pg No.	Identifier, Notes
SKOLD-001858-9	T138 (215)	456	Oct. 4 – 9, 2002 Emails btwn CGX and TS on promotion [Fujisawa (Hean Rumsfield), Ortho, Watson].
SKOLD-001860-1	T139 (216)	458	Mar. 7 – 10, 2003 Emails btwn CGX and TS on promotion (Ortho).
SKOLD-001862-5	T140 (217)	460	Mar. 13 – 14, 2003 Emails btwn CGX and TS on promotion (Ortho (Tom Carey), Pathfinder).
SKOLD-001871-2	T141 (220)	464	Oct. 2 – 4, 2003 Emails btwn CGX and TS on promotion (Cardinal).
SKOLD-001873-4	T142 (221)	466	Sep. 18 – Oct 24, 2003 Emails btwn CGX and TS on promotion [Novartis (Katrin Kriwet)].
	T143 (Ex 9)	469	Fowler et al., a published scientific poster presented at a American Contact Dermatitis Society, 16th Annual Meeting, February 17, 2005 (New Orleans, LA).

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Group B

Bates No.	Ex. No.	Page No.	Identifier, Notes
SKOLD-000009-10	T7 (101)	57	Aug. 28 – Sep. 4, 2001 Emails btwn TS and J Fowler discussing promotional activity with Neutrogena (J&J), Medicis and Allerga.
SKOLD-000011	T8 (102)	59	Mode of Action document
SKOLD-000012	T9 (103)	60	A description of the Restoraderm Technology.
SKOLD-000096-99	T30 (114)	135	[redacted]
SKOLD-000100	T31 (115)	139	[redacted]
SKOLD-000101	T32 (117)	140	[redacted]
SKOLD-000102-3	T33 (118)	141	[redacted]
SKOLD-000104-16	T34 (119)	143	[redacted]
SKOLD-000117-18	T35 (120)	156	[redacted] block provided by Impasse with CGX.
SKOLD-000119-62	T36 (121)	158	Business plan on a mucosal form of the Restoraderm technology. Attached to Email of SKOLD-000117-18.

Bates No.	Ex. No.	Page No.	Identifier, Notes
SKOLD-000163	**T37 (122)**	202	Spreadsheet attached to Email of SKOLD-000117-18.
SKOLD-000164-66	**T38 (123)**	203	[redacted]
SKOLD-000167-69	**T39 (124)**	206	[redacted]
SKOLD-000170-94	**T40 (133)**	209	[redacted]
SKOLD-000195-96	**T41 (134)**	234	[redacted]
SKOLD-000197	**T42 (136)**	236	[redacted]
SKOLD-000198-99	**T43 (136.1)**	237	[redacted]
SKOLD-000200	**T44 (138)**	239	[redacted]
SKOLD-001694-95	**T49 (301)**	267	[redacted]
SKOLD-001828-29	**T64 (22)**	297	[redacted]
SKOLD-001830	**T65 (23)**	299	[redacted]
SKOLD-001831-32	**T66 (26)**	300	[redacted]
SKOLD-001833-35	**T67 (27)**	302	[redacted]
SKOLD-001836	**T68 (28)**	305	[redacted]
SKOLD-001837-38	**T69 (201)**	306	Aug. 31 – Sep. 5, 2001 Emails btwn TS and JD on promotion.
SKOLD-001839	**T70 (202)**	308	Sep. 3, 2001 Email TS to BiCoastal Pharma (Ralph Soldo) re teleconference (promotion)(email mentions Ortho McNeil/Neutrogena).
SKOLD-001840	**T71 (203)**	309	Sep. 4 – 5, 2001 Emails btwn TS and JD on promotional planning (Allergan).
SKOLD-001841	**T72 (204)**	310	Sep. 4, 2001 Email JD to TS on meeting Collagenex, Neutrogena/Ortho, Medicis and Allergan (promotion).
SKOLD-001842-43	**T73 (205)**	311	Sep. 6, 2001 Email TS to JD on travel planning to meet with Medicis in Pheonix (promotion).
SKOLD-001844-45	**T74 (206)**	313	A business plan prepared by TS using the mark Restoraderm.
SKOLD-001856-57	**T80 (214)**	323	May 27 (Sweden) – May 26 (AU), 2005 Emails btwn TS and Epitan (promotion, consulting).

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Bates No.	Ex. No.	Page No.	Identifier, Notes
SKOLD-001899-902	**T99 (233)**	366	[redacted]
SKOLD-001902-04	**T100 (234)**	369	[redacted]
SKOLD-001906	**T101 (235)**	373	[redacted]
SKOLD-001907	**T102 (236)**	374	[redacted]
SKOLD-001908-09	**T103 (237)**	375	[redacted]
SKOLD-001910	**T104 (238)**	377	[redacted]
SKOLD-001911-12	**T105 (239)**	378	[redacted]
SKOLD-001913	**T106 (240)**	380	[redacted]
SKOLD-001914-16	**T107 (241)**	381	[redacted]
SKOLD-001917-19	**T108 (242)**	384	[redacted]
SKOLD-001920-21	**T109 (243)**	387	[redacted]
SKOLD-001922	**T110 (244)**	389	[redacted]
SKOLD-001923	**T111 (245)**	390	[redacted]
SKOLD-001924-26	**T112 (246)**	391	[redacted]
SKOLD-001927-31	**T113 (247)**	394	[redacted]
SKOLD-001932-35	**T114 (248)**	399	[redacted]
SKOLD-001937	**T115 (250)**	403	[redacted]
SKOLD-001938-39	**T116 (251)**	404	[redacted]
SKOLD-001940	**T117 (252)**	406	[redacted]
SKOLD-001941-42	**T118 (253)**	407	[redacted]
SKOLD-001943-44	**T119 (254)**	409	[redacted]

Bates No.	Ex. No.	Page No.	Identifier, Notes
SKOLD-001945	**T120 (255)**	411	[redacted]
SKOLD-001953-54	**T127 (262)**	419	[redacted]
SKOLD-001955-56	**T128 (263)**	421	[redacted]

~~TRADE SECRET/ COMMERCIALLY SENSITIVE~~

Group C

Bates No.	Ex. No.	Page No.	Identifier, Notes
None	**T125**	417	**Notes:** These are Skold recollections of companies to whom Skold assisted in promoting the Restoraderm technology during the term of Skold's collaborative relationship with CGX. In parentheses, are listed some of the people with whom Skold interacted. For companies marked with an "X", corroborating emails can be found as listed above. All of Skold's discussions with these companies involved personnel of CGX.
None	**T126**	418	N [redacted]
Nome	**T132**	449	**Notes:** This is a listing of Skold's recollections of meetings Skold undertook to promote Restoraderm technology. For the companies listed in **bold**, corroborating emails to/from the company or principles thereof can be found as listed above.
TS-000057	**T133**	**450**	**Notes:** This is a listing of drugs for which Skold recollects having supervised the formulation in Restoraderm technology, with an indication of stability for many.

Group D

Bates No.	Ex. No.	Page No.	Identifier, Notes
SKOLD-001822-23	**T63 (25)**	295	Sep. 14, 2010 Press Release from GDM on Cetaphil Restoraderm.
SKOLD—001957	**T129 (264)**	423	Collagenex Form 10-K for the fiscal year ended December 31, 2001.
SKOLD-001958-81	**T130 (265)**	424	U.S. Patent 8,029,810, resulting from the patent Skold filed in collaboration with CGX to cover Restoraderm technology.
SKOLD-001982	**T131 (266)**	448	Feb. 12, 2002 Press Release from CGX on "Restoraderm drug delivery technology" as published by Business Wire.
None	**T144**	470	pp. 1-3, 5-6 and 10 of the meeting program of the American Contact Dermatitis Society, 16th Annual Meeting, February 17, 2005 (New Orleans, LA).

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TRADE SECRET/
COMMERCIALLY SENSITIVE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the Matter of Registration Nos. 2985751; and 3394514

Dated: August 16, 2005 & March 11, 2008, Respectively

Exhibit T 146
Skold v. Galderma
Cancellation No. 92052897

Thomas Sköld, Petitioner, v. Galderma Laboratories, Inc., Registrant	))))))))	Cancellation No. 92052897

DECLARATION OF THOMAS SKÖLD

I, Thomas Sköld, declare as follows:

1. I am the Petitioner in this Cancellation proceeding.
2. I am over the age of eighteen (18) and am competent to make this declaration.
3. I have personal knowledge of the matters which are the subject of this declaration.
4. I first met with Collagenex Pharmaceuticals, Inc., Registrant's predecessor in interest, at its Newton, Pennsylvania location on 12 September 2001, the day after the memorable day of 11 September 2001. In the meeting, I presented the Restoraderm technology, my services in developing specific formulations thereof, and my availability to provide specific formulations within the technology, for example formulations carrying specific drugs. At the meeting, I showed Collagenex a document substantially the same as, if not identical to, that attached hereto as Sköld Decl. Exhibit E. That document shown to shown to Collagenex included the recitation of "Restoraderm" Technology found in Sköld Decl. Exhibit E. Thereafter I

PUBLIC

Ex E = Skold
Trial Ex T8

worked collaboratively with Collagenex to develop a product that was termed "Restoraderm" until at least November 2007.

5. The 12 September 2001 meeting came about because an 11 September 2001 meeting with Johnson & Johnson/Neutrogena/Ortho Derm (related companies, treated here as one) to sell Restoraderm technology was cancelled mid-meeting, due to the tragic events of that day. I also had later September 2001 meetings scheduled with Medicis (scheduled 12 September 2001 in Arizona) and Allergan (California) to sell the technology. Because of the post 11 September 2001 travel restrictions and because I was soon in intense negotiations with Collagenex, the Medicis meeting converted to a conference call and the Allergan meeting was cancelled. Johnson & Johnson/Neutrogena/Ortho Derm and Medicis all received for their scheduled September 2001 meetings with Sköld a copy of a document substantially the same as, if not identical to, that attached hereto as Sköld Decl. Exhibit E. In September, 2001 I used, with Allergan, the mark "Restoraderm" in connection with the technology.

6. In November and December of 2001 I transported samples of a skin-care formulation labeled "Restoraderm" to Collagenex from Sweden. Multiple shipments reflected improvement in the formulation as manufactured in Sweden. Some of the samples were transported from Sweden by myself, and some I had mailed to Jeffrey S. Day. I further hand delivered such samples to Collagenex at the Caribbean Derm. meeting in Puerto Rico, which meeting occurred on or about 18 January 2002. All

the samples from 2001 and 2002 were formulated in Sweden, under my direction, by myself and my assistant, Mats Silvander.

7. Primary participants of the 12 September 2001 meeting were myself, the Brian M. Gallagher, president of Collagenex, Robert A. Ashley, senior vice president, Commercial Development, of Collagenix, and Jeffrey S. Day (soon to be vice president, dermatology, of Collagenix). These officers remained together at Collagenex through at least about mid-2004. Jeffrey S. Day officially began at Collagenex soon after the 12 September 2001 meeting, but was in attendance at that meeting.

8. Prior to the 12 September 2001 meeting, I had been the CEO of Ponsus AB, a Swedish dermatology products company, from approximately 1995 to August, 2001. Ponsus is a dermatology company that developed, and developed during my tenure as CEO, new dermatology products. Accordingly, I am familiar with the norms of the dermatology industry, and the dermatology product development industry.

9. The services and product I was selling at the 12 September 2001 meeting were for formulation of new dermatology products in the new vehicle I invented, which vehicle is now the subject U.S. Pat. No. 8,029,810. This type of service is to be sold on an exclusive or a well-defined exclusive field-of-use basis, or would be without substantial value. Accordingly, it is normal in the industry that selling of the services is to a limited number of entities. It is normal that limited samples are provided (if at all) in selling presentations.

10. The presentations made to Collagenex in connection with Restoraderm beginning 12 September 2001 and prior to 28 February 2012 were sufficient to generate, prior to early 2007, [redacted]0 [redacted] consulting fees from Collagenex to me, and in this same period, $[redacted]0 (USD) in milestone or milestone-like payments from Collagenex to me. Thus, these efforts obtained $[redacted]0 in payments from Collagenex to me, indicating that my selling efforts were not token, nor made merely to reserve the mark. The agreements that flowed from these presentations contemplated further payments in excess of [redacted] U.S., which payments were never realized.

11. From the context of my discussions with Collagenex in late 2001 and early 2002, it is clear to me that I would not have gained the 2002 contract with Collagenex if I had not, as I did, send samples to Collagenex in November and December 2001.

12. After execution of the 11 February 2002 Agreement, and before 28 February 2001, I and an assistant, Mats Silvander, manufactured Restoraderm formulation on behalf of Collagenex in Sweden.

13. In the late 2001, early 2002 time frame, the number of financially credible dermatology development companies in the United States was limited. My recollection, refreshed by reviewing the January 2002 Caribbean Derm Meeting program, is that the following were the significant players:

1, Johnson &Johnson, Neutrogena, Ortho Derm (related, treated as one);
2, Novartis Pharmaceuticals;
3, Medicis;
4, Allergan;
5, Galderma;
6, Fujisawa;
7. Ferndale Laboratories;

8, Stiefel; and
9. Connetics;

14. At the time, Collagenex was just emerging into the group of significantly credible dermatology development companies. At the outside, if I have forgotten any players, or if I was unaware of a few companies that I might have wished to have been aware of, the number of significantly credible dermatology development companies in the United States cannot have exceeded 15 in late 2001 or early 2002.

Ex D = Skold
Trial Ex T12

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15. Collagenex's motive for changing of the 2002 Agreement to create the 2004 Agreement were represented to me to be those financial motives outlined in the Sköld Decl. Exhibit D, with one caveat. Later in negotiations, Collagenex's General Counsel, Nancy Broadbent, represented to me that styling the agreement as an acquisition would allow Collagenex to treat its expenses as capital expenses, and not a mere expense. In other words, Collagenex was seeking a more favorable accounting treatment. As represented to me by Collagenex, the substance of the agreement, other tshan the timing of payments, was intended to remain the same.

16. As a private individual, I am the custodian of physical and electronic document copies for my Restoraderm enterprise. As to the documents indicated below, and attached hereto, I testify as follows:

- Sköld Decl. Exhibit A: 11 February 2012 Cooperation, Development and Licensing Agreement ("2002 Agreement"): This is a true copy of the agreement, as found in my physical files. I received this document from Collagenex soon after its execution by Collagenex and myself. I stored the

document in the ordinary course of business, as I do comparable important business documents.

- Sköld Decl. Exhibit B: Epitan Agreement dated 9 May 2003, SKOLD-000014-35 and SKOLD-001950: This is a true copy of the agreement, as found in my physical files. I received this document from Collagenex soon after its execution by Collagenex and myself. I stored the document in the ordinary course of business, as I do comparable important business documents.
- Sköld Decl. Exhibit C: Collagenex General Counsel's Letter of 12 February 2008, SKOLD-000658-63: This is a true copy of the letter, as found in my my computers as an attachment from my attorneys at Wiggin and Dana. I received this document soon after its receipt by Wiggin and Dana. I stored the document in the ordinary course of business, as I do comparable important business documents.
- Sköld Decl. Exhibit D: Ashley Email dated 9 December 2003, SKOLD-000036: This is a true copy of the email, as found in my computers. I received this document from Collagenex. I stored the document in the ordinary course of business, as I do comparable important business documents.
- Sköld Decl. Exhibit E: SKOLD-000011 (Mode of Action): This is a true copy of the Mode of Action document, as found in my physical files. I personally prepared this document. I stored the document in the ordinary course of business, as I do comparable important business documents.

17. At I declare, under penalty of perjury under the laws of the United States of America and 28 U.S.C. § 1746, that the foregoing is true and correct, and that this declaration was executed this 14th day of May 2013 in New York, New York, United States of America.

Respectfully submitted,

Date: MAY 14TH 2013

By: _____
Thomas Sköld

Exhibit T147
Skold v. Galderma
Cancellation No. 92052897

Sweden, March 3rd 2010.

Galderma Laboratories L.P.
Attn. Nora Anderson
14501 North Freeway
Ft. Worth, TX 76177
USA

Dear Nora,

Enclosed please find a signed version of our assignments of patents.

I hope with this that all matter related to IP is settled.

Thank you so much.

With kind regards,

Thomas Sköld

Björnö gård
761 41 Norrtälje
Sweden

Thomas-skold@telia.com

ASSIGNMENT OF PATENTS.

WHEREAS, Galderma Laboratories, Inc., ("Assignor"), a corporation, having its main office and place of business at 14501 North Freeway, Fort Worth, Texas 76177 U.S.A. is the owner of the entire right, title and interest in and to the following United States patent application(s) and all corresponding non-US patent applications including those listed below:

Country	Application Number	Filing Date	Title
US	10/388,371	03/13/2003	Water-Based Topical Delivery System
US	10/957,320	09/30/2004	Water-Based Delivery Systems
US	12/082,406	04/09/2008	Water-Based Delivery Systems
US	12/290,455	10/30/2008	Water-Based Delivery Systems
US	60/365,059	03/13/2002	Water-Based Topical Delivery System
US-PCT	WO2003US07752	03/13/2003	Water-Based Delivery Systems
US-PCT	WO2005US35531	09/30/2005	Water-Based Delivery Systems

Country	Application Number	Country	Application Number
AU-Australia	2003233396	JP-Japan	2003-575915
AU-Australia	2007211879	KR-Korea (South)	2004-7014070
CA-Canada	2,476,859	NZ-New Zealand	534377
EP-European Pat. Org	03728242.3		

AND WHEREAS, Thomas Sköld ("Assignee"), an individual residing at Björnö Gård, S-71 41, Norrtälje, Sweden, is desirous of acquiring said right, title and interest;

NOW THEREFORE, for good and valuable consideration, receipt of which is hereby acknowledged, Assignor does hereby assign and transfer to Assignee and its successors and assigns, the entire right, title and interest in and to the above-identified patents applications, including all reissues, divisions, continuations, continuation-in-part, and extensions and foreign counterparts thereof, to be held and enjoyed by Assignee as fully and entirely as it would have been held and enjoyed by Assignor if this assignment had not been made, including all claims, demands and right recovery that Assignor has or may have in profits and damages for past and future infringements, if any, and all rights to compromise, sue for, and collect such profits and damages.

In the event of any inconsistency between this Assignment and Article 8 of the August 19, 2004 Asset Purchase and Product Development Agreement between Thomas Sköld and CollaGenex Pharmaceuticals, Inc. (to which company Galderma Laboratories, Inc. is the successor in interest), Article 8 shall be controlling.

This Agreement may be executed in any number of counterparts and each such counterpart shall be deemed to be an original.

For Galderma Laboratories, Inc.

Name: Quintin Cassady
Title: Vice President

For Thomas Sköld

Name: Thomas Sköld

Dated: February 22, 2010

STATE OF TEXAS :
: ss.
COUNTY OF DENTON :

On this 22nd day of February, 2010 before me appeared Quintin Cassady, the person who signed this instrument and acknowledged that he signed it as a free act on behalf of Galderma Laboratories, Inc.

Notary Public

(Seal) NORA ANDERSON MY COMMISSION EXPIRES July 20, 2013

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