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Filing date: **11/12/2015**

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

Proceeding	77787804
Applicant	Interface Biologics Inc.
Applied for Mark	EPIDEL
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Submission	Request for Remand and Applicant's Brief
Attachments	Ex A - Workshops & Conferences (Medical Devices) _ Public Workshop - ASTM-FDA Workshop on Absorbable Medical Devices_ Lessons Learned from Correlations of Bench Testing and Clinical Performance, November 28, 2012.pdf(62425 bytes) Ex B - Interface Biologics - COMBINATION DRUG DELIVERY DEVICES.pdf(143997 bytes) Ex B - biomedical polymer is proving to be a powerful infection fighter that protects patients.pdf(119749 bytes) EPIDEL Request for Remand and Appeal Brief.pdf(77346 bytes) Ex C - Ciprofloxacinreleasing bioabsorbable polymer.pdf(20939 bytes)
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U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

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Public Workshop - ASTM-FDA Workshop on Absorbable Medical Devices: Lessons Learned from Correlations of Bench Testing and Clinical Performance, November 28, 2012

The Food and Drug Administration (FDA) is announcing a public Workshop entitled "ASTM-FDA Workshop on Absorbable Medical Devices: Lessons Learned from Correlations of Bench Testing and Clinical Performance." FDA is co-sponsoring the workshop together with ASTM International, an organization responsible for the development and delivery of international voluntary consensus standards.

The purpose of the workshop is to provide a forum for industry, academia, FDA to discuss test methods for establishing correlations between in vitro and in vivo degradation of absorbable implant devices, and the interaction of mechanical loading and mechanical performance with degradation. While there will be an emphasis on cardiovascular indications as part of a panel session, characterization techniques and experiences from both cardiovascular as well as non-cardiovascular devices will be discussed and are encouraged.

- [Date, Time and Location](#)
- [Federal Register Notice \(http://www.gpo.gov/fdsys/pkg/FR-2012-08-20/html/2012-20322.htm\)](http://www.gpo.gov/fdsys/pkg/FR-2012-08-20/html/2012-20322.htm)
- [Background and Discussion Topics](#)
- [Agenda](#)
- [Transcript](#)
- [Program and Booklet](#)
- [Contact Us](#)

Date, Time and Location

This workshop was held November 28, 2012, beginning at 8:15AM at the following location:

FDA White Oak Campus
10903 New Hampshire Avenue
Building 31 Conference Center (Great Room, Room 1503)
Silver Spring, MD 20993

Background and Discussion Topics

Recent studies have identified promising results for the use of absorbable materials in implantable devices for endovascular therapies such as fully absorbable cardiovascular stents, where the stent platform degrades, as well as absorbable coatings. The use of these materials for cardiovascular indications poses new risks due to the critical fatigue and mechanical loading demands that the implant must withstand and perform. However, the optimal preclinical/bench testing paradigm to predict clinical performance of fully absorbable cardiovascular devices is not yet defined. This workshop will discuss the use of absorbable materials (including synthetic polymers as well as erodible metals) in medical devices across a broad range of indications with the aim of defining successful and unsuccessful methods to predict clinical performance, and will subsequently apply these methods to unique challenges for cardiovascular indications. Therefore, we invite presenters to share their experience from cardiovascular and non-cardiovascular medical devices, as well as devices that are fully absorbable, and devices with only a component or coating that is absorbable. This workshop will bring together the expertise of academia and industry professionals to define test methods as well as to educate and inform their colleagues in industry, academia, and device regulation on the performance and predictability of absorbable medical device degradation. Workshop participants will seek to define the critical factors for preclinical/bench testing and clinical predictability. They will then apply lessons learned from marketed devices for non-cardiovascular indications to the emerging uses of absorbable devices to treat cardiovascular disease.

Topics to be discussed at the workshop include:

- Correlations of in vitro and in vivo absorption
- Quantitative characterization of absorption kinetics
- Test methods to identify interactions of absorption with mechanical loading and
- Test methods to assess mechanical performance of the absorbable product

The lessons learned from both early cardiovascular and well-established non-cardiovascular device experiences will be presented. These lessons will be discussed in the context of emerging cardiovascular uses of absorbable materials as part of a panel session at the end of the workshop.

Agenda

Time	Subject
7:30-8:15	Registration

8:15-8:30	<u>Opening Remarks (downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM331541.pdf)</u>
8:30-9:30	Plenary Presentation <ul style="list-style-type: none"> • <u>John Middleton, “Tailoring of Poly(lactide-co-glycolide) to Control Properties” (downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM335606.pdf)</u>
9:30-10:30	Session I: Considerations for Modeling Degradation in Vitro Moderator : Hany Demian <ul style="list-style-type: none"> • <u>Karen Burg, “Processing Considerations for Degradable Materials: The many profiles of ‘polylactide’” (downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM331547.pdf)</u> • Elizabeth M. Perepezko, “Establishing Accelerated In Vitro Aging Methods for Evaluating Resorbable Polymeric Implants” • Jeremy Schaffer, “Corrosion and fracture behavior of bioabsorbable wires in Bio-simulated fluid”
10:30-10:45	Break
10:45-11:45	Session II: In Vitro-In Vivo Correlation (IVIVC) & Predicting Corrosion in Degradable Metals Moderator : Erica Takai <ul style="list-style-type: none"> • <u>Frank Witte, “Current Opinion of the Science Community on Guidelines and Testings of Biodegradable Metals” (downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM331548.pdf)</u> • Yeohung Yun, “Testing Corrosion for Biodegradable Mg alloys: Science, Current Methods, and Limitation” • John Disegi, “In Vitro Mechanical Property Degradation of 2.0 mm Dynamic Compression Plates Fabricated from Absorbable Fe-28Mn Alloy”
11:45-13:00	Lunch on your own Food for purchase will be available
13:00-14:45	Session III: In Vivo Performance and In Vitro-In Vivo Correlation (IVIVC) of Polymer Systems Moderator : Ji Guo <ul style="list-style-type: none"> • <u>Kathryn Uhrich, “Polymorphine: a biodegradable drug delivery system for extended analgesia” (downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM331543.ppt)</u> • <u>Meng Deng, “In Vitro and In Vivo Degradation of Absorbable Polymeric Biomaterials: Experiences and Learning” (downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM331545.pdf)</u> • Nathan Lockwood, “Characterization of Novel Degradable Polymers for Drug Delivery Applications” • Renu Virmani, “Histopathologic results of bioabsorbable stent (BVS) in the porcine model” • Yen-Lane Chen et al., “Characterization of the In Vivo and In Vitro Degradation of Poly(DL-lactic-co-glycolic acid) on a Drug-Eluting Stent”

14:45-15:00	Break
15:00-16:20	Session IV:Mechanical Interactions & Product Development Considerations Moderator : Scott Anderson <ul style="list-style-type: none"> • /downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM335604.pdf “<i>Mechanical Evaluation of Biodegradable Magnesium and Magnesium Alloys: Identifying the Necessary Testing, Challenges, and Pitfalls for Biomaterial Characterization</i> (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM335604.pdf)” • /downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM335605.pdf <i>“Defining a Material Model for a Bioresorbable Stent Fiber”</i> (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM335605.pdf) • Julia Fox et al., “<i>Relationship between Mechanical Loading and Chemical Degradation in Polymeric Bioresorbable Vascular Scaffolds</i>” • /downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM331546.pdf <i>“Standards Development in Absorbable Medical Devices”</i> (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM331546.pdf)
16:20-16:30	Break
16:30-17:30	Panel Discussion Moderator : Maureen Dreher (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM331551.pdf)

Transcript

- [Transcript for November 28 \(/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM335036.pdf\)](/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM335036.pdf)

Program and Booklet

- [Workshop Program and Booklet \(/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM329321.pdf\)](/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM329321.pdf) (PDF)

Contact Us

For questions regarding workshop content please contact:

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[\(/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm\)](#)

[2015 Medical Device Meetings and Workshops \(/MedicalDevices/NewsEvents/WorkshopsConferences/ucm430331.htm\)](#)

[2014 Medical Device Meetings and Workshops \(/MedicalDevices/NewsEvents/WorkshopsConferences/ucm404511.htm\)](#)

[Medical Device Webinars and Stakeholder Calls \(/MedicalDevices/NewsEvents/WorkshopsConferences/ucm411063.htm\)](#)

[HOME](#)[TECHNOLOGY](#)[ABOUT US](#)[INVESTORS](#)[PUBLICATIONS](#)[NEWS](#)[PARTNERS](#)[CAREERS](#)[Technology](#) [Combination Drug Delivery Devices](#)[Anti-thrombogenic Devices](#)**Combination Drug Delivery Devices**

COMBINATION DRUG DELIVERY DEVICES

Ineffective drug delivery is caused by problems with systemic drug delivery, lack of sustained release capabilities, poor drug transfer, and downstream complications. In the context of drug delivery, the need for efficient systems remains a challenge. There is as yet no perfect drug delivery platform.

In recent years there has been significant renaissance in the polymer drug delivery field. The ideal parameters for these platforms are dictated by the specific clinical consideration and drug physio/chemical properties.

Interface Biologics' biomedical polymer enabled drug delivery devices include Epidel™ anti-infective polymers and Kinesyx™ bioactive oligomers. Based on the repertoire of unprecedented properties offered by Epidel and Kinesyx technologies, it is expected that these materials will play a significant role in the development of new combination products and strategies in drug delivery.

Epidel™

Implantable medical devices inherently increase the risk of infection either through the implant procedure itself or as an access point to external microorganisms. Chronic infections place a major burden on the healthcare system with some estimates as high as \$12 billion per year for the U.S. alone. This is caused by patients spending more time in the hospital, requiring more doctor and nurse time and the use of expensive systemic antibiotics as more aggressive treatment options are explored.

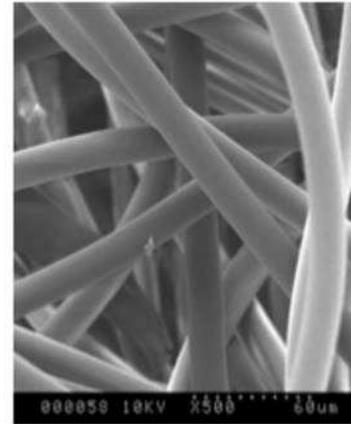
Infection caused by implantable medical devices is often a result of biofilm development on the device surfaces. Microorganisms adhere to the surface of the device, anchoring themselves and facilitating the attachment of other microbes, which leads to further colonization and formation of a polymicrobial environment with increased pathogenic effect. Once the biofilm is developed, it is increasingly difficult to eliminate and the cells become more antibiotic resistant. Biofilm infections have been

estimated to be 1,000 times more resistant to antibiotics than conventional infections.

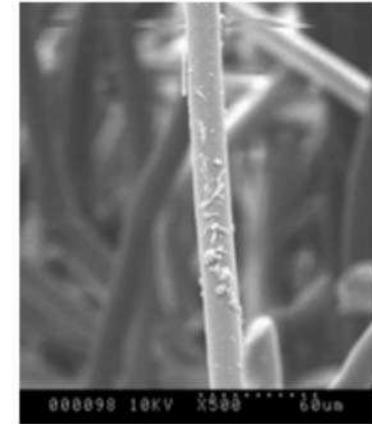
The current state of the art in infection control devices employ mainly silver based technologies. The challenge is that while effective in the short term, silver coatings have limited duration and may not last long enough to prevent infections in devices that are implanted for more than 7 days. Silver is also non-selective and kills healthy cells as well as the targeted microbes.

Interface Biologics' EpiDel™ anti-infective polymers allows for pharmaceuticals to be integrated directly into the medical device providing for long term anti-microbial effectiveness, release of the drugs directly from the device to prevent biofilm development and maintenance of tissue in-growth properties for porous matrices. The EpiDel™ technology is flexible, providing solutions for a myriad of medical devices with different surface characteristics (e.g. mesh, polymeric, metallic), manufacturing processes (e.g. coating, extrusion, heat press) and a broad range of compatible drugs.

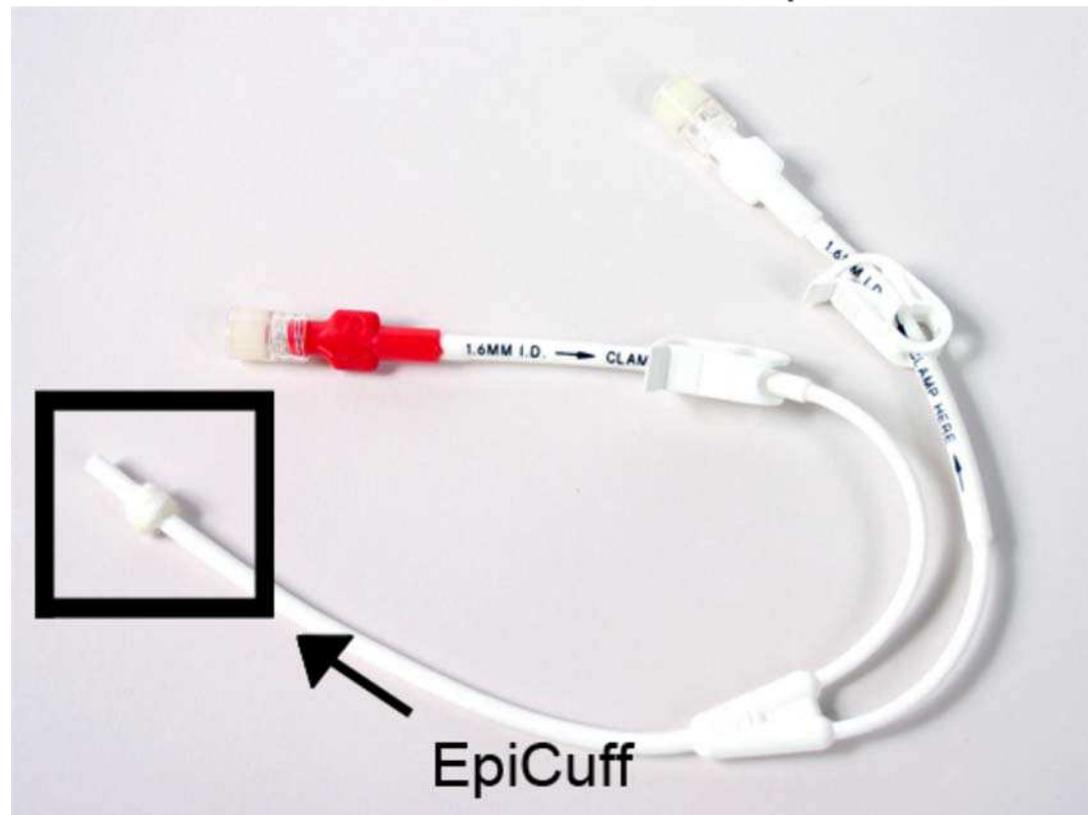
The current product focus for the EpiDel™ technology is called EpiCuff – a percutaneous infection control device that can be used as a cuff with devices such as dialysis catheters, peritoneal dialysis catheters and LVAD leads in order to provide long term anti-microbial effect while supporting the tissue in-growth properties required to effectively seal the entry wound. The company is currently evaluating various product prototypes in animal models.



EpiDel™



Drug Alone



Product extensions of the EpiCuff technology include: hernia mesh, incontinence slings, sutures and bandages.

Kinesyx™

Interface Biologics' Kinesyx™ technology is an extension of the Endexo™ platform. Kinesyx™ molecules are polyurethane oligomers with fluorinated segments, and can be designed to work with a number of different pharmaceuticals and biologics with specific release requirements. It is a versatile technology platform with a broad range of formulations. A sustained or transient release profile can be achieved depending on the formulation selection as well as clinical consideration. Kinesyx™ bioactive surface pacifying oligomers provide an ideal platform for drug delivery due to the benefits of the fluorine chemistry, the flexible small molecular structure, the bio-elimination properties, and the ability to tailor both pharmaceutical release and polymer residency.



Interface Biologics is currently evaluating the Kinesyx™ technology in a drug coated angioplasty balloon for peripheral vascular disease (PVD). PVD afflicts an estimated 20 million people in the US and Europe and the lack of effective current solutions results in over 250,000 amputations per year. Balloon angioplasty is often used to treat restricted vessels due to PVD but suffers from a 40% re-occlusion rate because of the accelerated smooth muscle cell growth caused by the procedure itself. Stents are largely ineffective in the periphery because of the mechanical challenges associated with normal flexing of the leg and other pressures as a result of daily activities. Angioplasty balloons which are coated with cytotoxic or cytostatic drugs would appear to be an ideal solution because of the ability both to remodel the vessels and prevent the immediate smooth muscle cell reaction, but the products on the market in Europe today suffer from a number of challenges that will make US approval difficult.

IBI's Kinesyx™ technology provides a unique solution to the existing problems. Due to its unique structure, the Kinesyx™ coating can be consistently applied to the device (either in wrapped or unwrapped states) and has minimal particulate development – significantly below the USP limits for particles >10 and >25 microns.



Commercially available DCB



Kinesyx™ DCB

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THIS IS BIOTECH

BEYOND MOOSE AND MOUNTAINS: BUILDING CANADA'S BIO-BASED ECONOMY.



Biomedical Polymer Is Proving to be a Powerful Infection Fighter that Protects Patients

Interface Biologics, Toronto, Ontario

Just about everyone on the planet will get a sliver of something in a finger at one time or another. Whether it is wood, metal, plastic or glass, if you don't get it out, it soon becomes a painful mess of infection. Your body is just not meant to have foreign things and bad bacteria inside it. Period.

But what if your life depends on having foreign materials inserted or implanted in your body? Medical devices like urinary catheters, hernia patches and even sutures are critical components to many treatments, yet these essential devices can become ground zero to many infections. Getting through the protective barrier of a human body, especially with devices intended to remain in the body for days at a time, increases the risk of infection complications in patients that are already sick.

To combat this source of infection, a Toronto-based company, Interface Biologics, has developed an ingenious method of coating medical devices with infection-fighting medicine that kicks in when the body's own immune system signals that it needs help to fight off bad bacteria.

Called Epidel, it is actually a "biological polymer". With Epidel, the anti-infective drugs are incorporated into the backbone of the polymer, which can then either be spun into fibers – ideal for bandages or hernia patches – or coated onto the area of catheters that penetrate the body. Traditionally, these products, although sterile when inserted, can be the gathering spot for bacteria. It is this bacterial playground called a biofilm, which begins a vicious cycle of infection.

Epidel is unique because the medicine is "embedded in the product itself and it kills the biofilm before it can create a surface that allows other bugs to grow," says Tom Reeves, Interface's president and CEO.

While infections from catheters and hernia patches may only occur in five or six percent of hospital patients, when it does happen it is costly both in terms of pain and finances. It is estimated that patients who acquire infections while in the hospital have to stay in for an extra six days, which could easily add up to another \$30,000 in costs. In Canada, the cost of hospital-acquired infections like those from catheters, reaches almost \$1 billion annually. If the infection is severe enough, patients may have to undergo more surgery to replace the device, which is never good news, says Reeves.



Unlike traditional silver coating, which is a short duration anti-infective agent, Epidel coated devices are capable of delivering infection-fighting medicine for up to 90-days, which makes it unique as well as advantageous to the patient.

The cleverness of Epidel, which will be ready for market in 2011, is that it doesn't just deliver the anti-infective medicine indiscriminately. If there is no infection, the bioresponsive polymer doesn't react, but if the body's immune system recognizes the presence of bad bacteria and releases certain enzymes, the Epidel device immediately begins delivering anti-infective medicine, killing the unwanted biofilm. No biofilm means there is no chance of infection setting in. And that means no nurse is going to be pulling out that catheter any time soon to replace it with a new one.

Interface Biologics also develops biomedical polymers that help prevent thrombosis (blood clots) from developing on or in implantable devices (Endexo), which it will commercialize in 2010. The company also has biomedical polymers that can be used as drug delivery devices (Kinesyx), which are still in early stage development but show great promise with targeted drug delivery or sustained drug release.

TRADEMARK

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:)	
)	T.M. Law Office: 115
Interface Biologics Inc.)	
)	Examining Attorney: Nicholas A. Coleman
Serial No.: 77/787,804)	
)	
Filing Date: July 23, 2009)	
)	
Mark: EPIDEL)	
)	
Atty. File No.: 2240IBI-2-1)	

Commissioner for Trademarks
P.O. Box 1451
Alexandria, VA 22313-1451

**APPLICANT'S BRIEF IN SUPPORT OF ITS REQUEST FOR REMAND,
AND IN THE ALTERNATIVE, IN SUPPORT OF ITS
APPEAL OF THE REFUSAL OF REGISTRATION**

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Applicant, by and through its undersigned attorneys, respectfully submits this brief in support of its request that the Trademark Trial and Appeal Board (the “Board”) suspend this Appeal and remand Application Serial No. 77/787,804 for “EPIDEL” to the Examining Attorney for further examination, in accordance with 37 C.F.R § 2.142(d) and Trademark Trial and Appeal Board Manual of Procedure (“TBMP”) § 1207.02. In the alternative, if Applicant’s Request for Remand is denied, Applicant submits this brief in support of its appeal from the Examining Attorney’s final refusal to register “EPIDEL” in International Classes 1 and 5 under Trademark Act Sections 1 and 45, 15 U.S.C. §§1051(a)(1) and 1127. The Examining Attorney refused registration on the ground that the Specimen of Use Applicant submitted with its Statement of Use does not show use of Applicant’s mark in commerce in connection with the applied-for goods. Applicant respectfully disagrees, as set forth herein, and requests that the Examining Attorney’s refusal to register the mark be reversed.

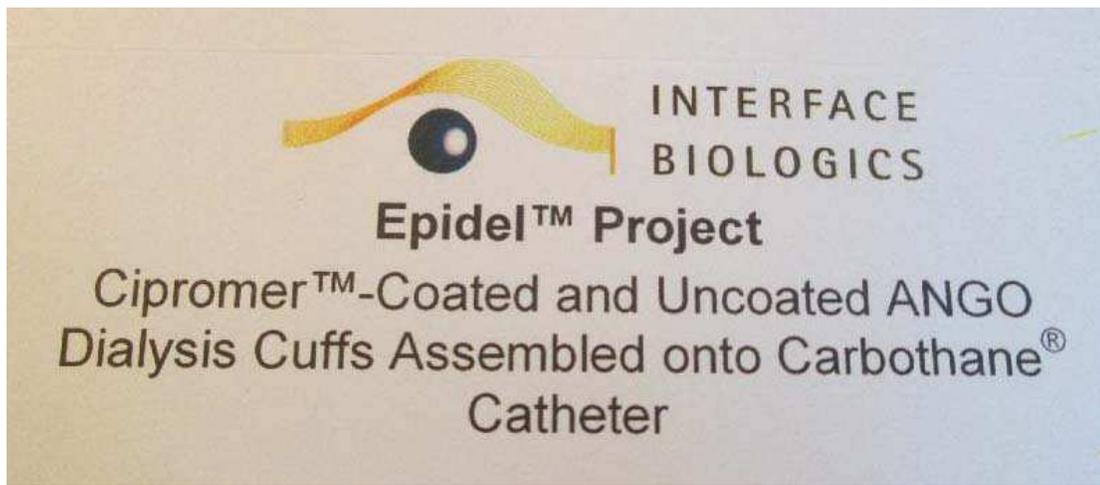
SUMMARY OF PROCEEDINGS BELOW

Applicant filed Application Serial No. 77/787,804 for the mark “EPIDEL” covering International Classes 1, 5 and 10 on an intent-to-use basis on July 23, 2009 (the “Application”). A Notice of Allowance was issued for the mark on March 8, 2011. Applicant was thereafter granted five extensions of time to file a Statement of Use. On March 7, 2014, Applicant filed a Statement of Use for the following Class 1 and 5 goods, deleting some of the goods originally identified in Classes 1 and 5 and deleting Class 10 from the Application in its entirety:

International Class 001: Bioresponsive resorbable polymers for use in the manufacture of drug delivery systems; and

International Class 005: Bioresponsive resorbable polymers containing pharmaceuticals and sold as a component of devices used in cardiovascular, urological, neurological and musculoskeletal applications, namely, orthopedic, ear, nose, throat, dental, faciomaxillary, neurosurgical, soft tissue replacement, intra-abdominal, thoracic, and ophthalmic surgical implants made from living tissue, implants made from living tissue for repairing muscular or other tissue, or for augmenting, strengthening, or aiding muscular or other tissue in performing a function, surgical implants made from living tissue for bone, joint, and cartilage repair, connective tissue implants made from living tissue; coatings sold as an integral component of the above listed implants.

Applicant submitted the below image of packaging for its goods as a specimen of use:



On March 28, 2014, the Examining Attorney issued an Office Action refusing registration under Trademark Act Section 1(a), 15 U.S.C. §§1051, stating that the mark on the

drawing did not match the mark shown on Applicant's specimen because the specimen shows use of the mark as EPIDEL™ followed by the word PROJECT, rather than "EPIDEL" alone. On May 20, 2014, Applicant responded to this refusal and on June 16, 2014, the Examining Attorney issued a Final Office Action maintaining the specimen refusal based on the assertion that the specimen shows use of the mark EPIDEL™ followed by the word PROJECT. Applicant filed a Request for Reconsideration after Final Action and Notice of Appeal with respect to this refusal on December 15, 2014, further arguing that the specimen shows use of the mark "EPIDEL".

On January 14, 2015, the Examining Attorney issued a new Office Action that did not address the prior refusal but asserted two new substantive grounds for refusal of Applicant's Specimen of Use under Trademark Act Sections 1 and 45. In this Office Action, the Examining Attorney 1) argued that because Applicant's goods were still in testing, they had not yet been sold to consumers, and thus the mark was not in use in commerce and 2) for the first time, argued that the specimen does not show use of the mark on the goods identified in the Application, stating that "[t]hese systems consisting of a dialysis cuff and catheter reference neither a resorbable polymer or a surgical implant."

On July 7, 2015, Applicant responded to the Examining Attorney's new substantive refusals, 1) arguing that Applicant's use of the mark in connection with interstate (and international) shipping for clinical testing constitutes bona fide use of the mark in commerce in Applicant's industry and 2) confirming that, despite the Examining Attorney's interpretation of the specimen, the label for the EPIDEL product pictured in Applicant's specimen of use the

does show use of the mark on the applied-for goods. On August 11, 2014, the Examining Attorney issued a new Final Office Action. Although the Examining Attorney withdrew the refusal based on his allegation that the mark was not in use in commerce, he maintained the refusal based on the contention that Applicant's specimen of use does not show use of the mark in connection with the applied-for goods under Trademark Act Sections 1 and 45.

The August 11, 2014 Final Office Action indicated that Applicant had six months to either submit argument against the refusal or file an appeal. A month later, Applicant received a notice from the Board with a Mailing Date of September 12, 2015, informing it that the Examining Attorney's statement that Applicant would have six months to respond to the Final Office action was in error, and that instead, Applicant had 60 days from the mailing date of the order to file an Appeal brief.

ARGUMENT

I. Applicant Requests that this Matter be Remanded to the Examining Attorney for Further Consideration

Pursuant to 37 CFR 2.142(d) and TBMP Section 1207.02, Applicant requests that this matter be remanded to the Examining Attorney for consideration of the further evidence attached hereto as Exhibits A-C. The reason for Applicant's Request for Remand is twofold.

First, as set forth in the Summary of Proceedings above, the Examining Attorney has refused Applicant's specimen of use in this matter under several different bases since its filing in March of 2014. When Applicant first filed its Notice of Appeal on December 15, 2014, the appeal related to an earlier, different basis for refusing its specimen. After Applicant overcame that refusal via its Request for Reconsideration, the Examining Attorney then issued a new

refusal on January 14, 2015, asserting two entirely different bases for refusing the same specimen, one of which is the subject of this appeal. The new basis for the refusal that is at issue in this appeal, that the specimen does not show use of the mark for the goods identified in the Application, did not arise as a result of new information Applicant presented in response to the prior refusals. Rather, it was a refusal that could have been issued almost a year earlier, when the first Office Action issued on March 7, 2014.¹

Due to the unique procedural posture of this matter, Applicant was under the impression at the time it submitted its response to the January 14, 2015 Office Action that if the Examining Attorney rejected its arguments, Applicant would have an opportunity to submit a response to a Final Office Action issued with respect to this newly raised issue. The Examining Attorney himself was apparently under the same impression, as demonstrated by the fact that when he did issue the Final Office Action on August 11, 2015, it included the usual six month timeline for Applicant to submit substantive argument and/or file a Notice of Appeal. It was only a month later, when the Board issued an order reinstating this Appeal that Applicant was informed that it would only have one chance to address this refusal before the Examining Attorney.

Second, because Applicant's goods are medical in nature, they must go through years of testing and government review before being finally approved for market and sold directly to

¹ Applicant notes that TMEP § 706 states that when an examining attorney raises a new ground for refusal after a first action, such new refusal should only be raised "when the failure to do so would result in clear error." Further, that section explains that "[s]ince it is unusual to make a new refusal or requirement that could have been raised in the first action, an examining attorney who does make a new refusal or requirement must clearly explain why the refusal or requirement is necessary, and apologize for the delay in raising the issue, if appropriate." This procedure was not followed in this matter and Applicant submits that the "clear error" standard was not met with respect to the new refusals.

consumers. Therefore, use of the mark has continued to evolve and develop since Applicant first submitted its statement of use and some of the new evidence attached as Exhibits A-C, about the nature of Applicant's goods, was not previously available. Applicant believes this new evidence will assist the Examining Attorney in understanding how the Specimen of Use shows use of the "EPIDEL" mark in connection with Applicant's goods.

Applicant makes this Request for Remand at an early stage in this Appeal, before the Board has received or considered any argument on the substantive refusal. Applicant submits that the factual circumstances described above constitute good cause for the remand to the Examining Attorney, in accordance with TBMP § 1207.02

II. If the Request for Remand is Denied, in the Alternative Applicant Requests that the Refusal to Register the Mark EPIDEL be Reversed

The Examining Attorney has maintained the refusal of the instant application under Trademark Act Sections 1 and 45, 15 U.S.C. §§1051 and 1127, on the basis that Applicant's specimen of use does not show use of the mark in connection with the applied for goods. Applicant respectfully disagrees with the Examining Attorney's refusal, and submits the following.

To register a trademark under Section 1(a) of the Trademark Act, an Applicant must submit "one specimen for each class, showing use of the mark in commerce on or in connection with the goods." TMEP § 904; 15 U.S.C. §1051(a)(1). A trademark is used in commerce when "it is placed in any manner on the goods or their containers or the displays associated therewith or on the tags or labels affixed thereto." 15 U.S.C. § 1127. *See also* TMEP § 904.03(a). "The terminology 'applied to the containers for the goods' means applied to any type of commercial

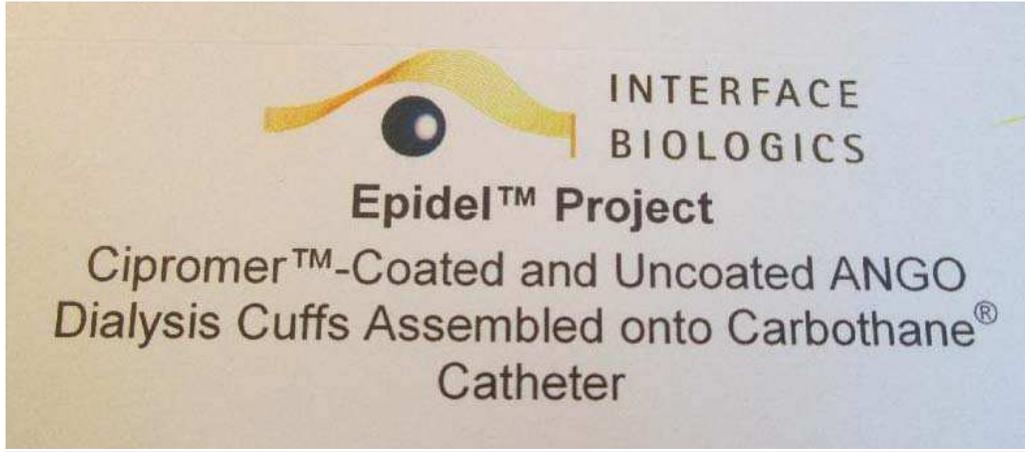
packaging that is normal for the particular goods as they move in trade. Thus, a showing of the trademark on the normal commercial package for the particular goods is an acceptable specimen.” TMEP § 904.03(c).

Applicant’s Statement of Use covers the following goods:

International Class 001: Bioresponsive resorbable polymers for use in the manufacture of drug delivery systems; and

International Class 005: Bioresponsive resorbable polymers containing pharmaceuticals and sold as a component of devices used in cardiovascular, urological, neurological and musculoskeletal applications, namely, orthopedic, ear, nose, throat, dental, faciomaxillary, neurosurgical, soft tissue replacement, intra-abdominal, thoracic, and ophthalmic surgical implants made from living tissue, implants made from living tissue for repairing muscular or other tissue, or for augmenting, strengthening, or aiding muscular or other tissue in performing a function, surgical implants made from living tissue for bone, joint, and cartilage repair, connective tissue implants made from living tissue; coatings sold as an integral component of the above listed implants.

Applicant’s Specimen of Use consists of an image of the following label for a dialysis cuff that is coated with an antibiotic drug called Cipromer and assembled onto a catheter made of a material called Carbothane. Applicant’s bioresponsive polymer “EPIDEL” is embedded within this product and is an integral part thereof:



The Examining Attorney’s refusal focuses largely on the fact that the label does not directly list the goods identified in the Application, noting that “[t]he specimen makes no reference to the provision of a ‘resorbable polymer.’ There is no reference to a polymer at all.” Applicant notes that due to the medical nature of its “EPIDEL” product, years of testing and government review are required before the product can be sold to end-consumers.² See Exhibit A for information regarding the FDA approval process for absorbable medical devices. Thus, its packaging reflects the fact that the product is not being shipped to an individual consumer, but rather to various medical laboratories, where sophisticated medical staff is the intended audience. As a result, the exact description of the product is not spelled out on the packaging in layman’s terms. There is no requirement that the name of the goods be included on the label for the goods to be a proper specimen. Rather, the specimen should be the normal commercial packaging. Moreover, as will be discussed below, the goods descriptions indicate that the polymers are

² As set forth in the Summary of Proceedings, the Examining Attorney argued in a previous refusal that shipping of medical products for testing purposes did not constitute use in commerce under the Trademark Act. Applicant responded to, and overcame that refusal, noting that TMEP § 901.02 specifically contemplates this scenario, and states that “ongoing shipments . . . to clinical investigators by a company awaiting FDA approval” can constitute use in commerce.

associated with the drug delivery device through this language: “for use in the manufacture of drug delivery systems” in Class 1 and “sold as a component of devices” in Class 5. In fact, the description of goods even includes the language “containing pharmaceuticals”, so it should not be a surprise that other products are mentioned on the label.

This type of packaging is normal commercial packaging for medical goods that are still undergoing testing and clinical trials and is thus an acceptable Specimen of Use. *See* TMEP § 904.03(c) (“a showing of the trademark on the normal commercial package for the particular goods is an acceptable specimen. For example, gasoline pumps are normal containers of “packaging” for gasoline”). Furthermore, that this is not the packaging that may be used for the ultimate consumer facing version of this product is not relevant. The TMEP makes it clear that “nothing prohibits the registration of a mark in an application that contains only “temporary” specimens, provided that the specimens were actually used in commerce.” TMEP § 904.03(a).

The Examining Attorney also argues that “to the extent the proposed mark indicates the source of any product, it is the finished cuff and catheter, and not the polymer coating” and notes that “[e]ven if the indication “Cipromer” identifies a bioresponsive resorbable polymer, the proposed mark is not “Cipromer,” but rather “EPIDEL.” Applicant submits the documentation attached as Exhibit B to further explain how its “EPIDEL” products works. As these materials explain, “EPIDEL” is a bioresponsive resorbable polymer that is infused with infection fighting drugs and coated onto surgical implants. When the device coated with “EPIDEL” is subcutaneously implanted into a patient, the “EPIDEL” breaks down, absorbs or degrades, allowing the drug to be delivered to the patient, preventing infection at the insertion point.

Thus, “EPIDEL” is an integrated and inseparable component of drug delivery devices, as also clearly reflected in Applicant’s description of goods. Applicant’s class 1 description specifies that the product is: “Bioresponsive resorbable polymers *for use in the manufacture of drug delivery systems*” (emphasis added). Similarly, the Class 5 description states “Bioresponsive resorbable polymers *containing pharmaceuticals and sold as a component of devices . . . namely . . . surgical implants; coatings sold as *an integral component of the above listed implants**” (emphasis added).

As Applicant explained in an earlier response, the dialysis cuff pictured in its Specimen of Use is coated with “EPIDEL” and is the “delivery mechanism for the [EPIDEL] polymer” in this specific product. The Examining Attorney’s suggest that the name “Cipromer” identifies the polymer rather than “EPIDEL” is not correct. Rather, “Cipromer” is an antibiotic drug, derived from Ciprofloxacin, that is used in connection with the “EPIDEL” polymer in this device to prevent infection. See Exhibit C.

In effect, the Examining Attorney argues that Applicant’s specimen shows a label not for the “EPIDEL” resorbable polymer itself, but for the delivery mechanism for the “EPIDEL” polymer, or, the cuff. However, it is impractical for Applicant to apply a label directly to its polymer coating, and indeed, this is not how the mark is used in commerce. Rather, the mark is used on the packaging for the product on which Applicant’s goods are applied, the surgical implant or drug delivery system itself. The USPTO has recognized that “in rare circumstances it may be impracticable to place the mark on the goods or packaging for the goods.” TMEP § 904.03(k) (giving as examples scenarios where the goods are natural gas, grain that is sold in

bulk, or chemicals that are transported only in tanker cars).” Here, the resorbable polymer is applied to the delivery device and the description of goods indicates as much. The fact that the other components of the delivery device are mentioned on the label should not make the specimen unacceptable.

In sum, the photograph of the product label Applicant submitted shows the “EPIDEL” mark as it is used in the normal course of commerce for the goods listed in the Application and is sufficient to support Applicant’s Statement of Use.

CONCLUSION

In accordance with the foregoing, Applicant respectfully requests that this Appeal be suspended and that its Application be remanded to the Examining Attorney for further consideration. If this request is denied, in the alternative, Application requests that the Examining Attorney’s refusal to register Application Serial No. 77/787,804 for “EPIDEL” in International Classes 1 and 5 be reversed.

Respectfully Submitted,

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Ciprofloxacin-releasing bioabsorbable polymer is superior to titanium in preventing Staphylococcus epidermidis attachment and biofilm formation in vitro.

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Abstract

Antibiotic coating systems have been successfully used to prevent bacterial attachment and biofilm formation. Our purpose was to evaluate whether bioabsorbable polylactide-co-glycolide (PLGA) 80/20 on its own, and PLGA together with ciprofloxacin (PLGA+C) have any advantages over titanium in preventing Staphylococcus epidermidis attachment and biofilm formation in vitro. Cylindrical specimens of titanium, PLGA, and PLGA+C in triplicate were examined for S. epidermidis ATCC 35989 attachment and biofilm formation after incubation with a bacterial suspension of about 10(5) cfu/mL for 1, 3, 7, 14, and 21 days, using scanning electron microscopy. Growth inhibition properties of PLGA and PLGA+C cylinders were tested on agar plates. On days 1, 3, and 21, no bacterial attachment was seen in 19.5, 9.2, and 41.4% of the titanium specimens; in 18.4, 28.7, and 34.5% of the PLGA specimens; and in 57.5, 62.1, and 57.5% of the PLGA+C specimens, respectively. During the whole study period, no biofilm was observed on 74-93% of the titanium specimens, 58-78% of the PLGA specimens, and 93-100% of the PLGA+C specimens. PLGA+C showed clear bacterial growth inhibition on agar plates, while PLGA and titanium did not show any inhibition. PLGA+C bioabsorbable material was superior to titanium in preventing bacterial attachment and biofilm formation and may have clinical applicability, for example, in prevention of infection in trauma surgery or in the treatment of chronic osteomyelitis.

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