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Hearing:
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UNITED STATES PATENT AND TRADEMARK OFFICE

Trademark Trial and Appeal Board

Alfacell Corporation
v.
Anticancer, Inc.

Cancellation No. 92032202

Mark H. Jay for Alfacell Corporation.

Jennifer Lee Taylor of Morrison & Foerster for Anticancer, Inc.

Before Sams, Seeherman and Quinn, Administrative Trademark Judges.

Opinion by Quinn, Administrative Trademark Judge:

Alfacell Corporation has petitioned to cancel a registration owned by Anticancer, Inc. of the mark ONCASE for "therapeutic compositions containing reagents for in vivo anticancer use."[1] As grounds for cancellation under Section 2(d) of the Trademark Act, petitioner alleges that respondent's mark, when used in connection with respondent's goods, so resembles petitioner's previously used and

[1] Registration No. 1,987,445, issued July 16, 1996; Section 8 affidavit filed and accepted.

registered mark ONCONASE for "pharmaceuticals, namely, cancer-treating drugs,"[2] as to be likely to cause confusion.

Respondent, in its answer, has denied the salient allegations of likelihood of confusion. Respondent also has set forth allegations labeled as "Affirmative Defenses," including that the petition is barred by laches.

The record consists of the pleadings; the file of the involved registration; trial testimony, with related exhibits, taken by each party; and excerpts from printed publications and printouts of pages of various websites retrieved from the Internet,[3] all introduced by way of respondent's notices of reliance. The parties filed briefs, and both were represented by counsel at an oral hearing held before the Board.

The Parties

Both parties are involved in the development of cancer-treating drugs. Petitioner's drugs include one that is delivered intravenously to a patient to treat mesothelioma, a cancer caused by exposure to asbestos. According to the

[2] Registration No. 1,651,885, issued July 23, 1991; renewed.
[3] Internet evidence is not proper subject matter for introduction by notice of reliance because the evidence is not self-authenticating. As the Board has stated in the past, the element of self-authentication cannot be presumed to be capable of being satisfied by information obtained and printed out from the Internet. Raccioppi v. Apogee Inc., 47 USPQ2d 1368, 1370 (TTAB 1998). See also TBMP §704.08 (2d ed. rev. 1, March 2004). Because the parties have treated this evidence as if properly made of record, however, we will deem it to be in the record by stipulation of the parties.

testimony of Kuslima Shogen, petitioner's founder and chief executive officer, this drug, marketed under the mark ONCONASE, is petitioner's "flagship" product. The drug is an enzyme derived from the *Rana pipiens* frog. Petitioner's product is in clinical trials being conducted at 33 clinical sites.

Respondent's product marketed under the mark ONCASE is a protein which degrades methionine for treatment of human cancers. Robert Hoffman, respondent's president and chief executive officer, testified that the ONCASE brand drug is currently in pre-clinical trials in the United States, and in clinical trials outside of this country. Respondent's product is administered intravenously in conjunction with chemotherapy; this product, according to Dr. Hoffman's testimony, improves the efficacy of the chemotherapy used in treating a variety of cancers.

As shown by the record, clinical trials of pharmaceuticals, that is, trials in human beings, commence only after an applicant's Investigational New Drug Application ("IND") has been approved by the Food and Drug Administration ("FDA"). Before even beginning the FDA approval process, all drugs must undergo extensive pre-clinical testing. After the pre-clinical testing is complete, the developer of the drug files an IND seeking approval for testing on humans. If the IND is approved, the

drug is tested on humans in three phases of clinical trials. The phases may last for several years. It is only after successful completion of all three phases of clinical trials that the developer of the drug can file a New Drug Application ("NDA") with the FDA seeking approval of the new drug for sales to the public. According to the record in the present case, neither party has filed an NDA for its respective drug herein.

ISSUES

There is no dispute regarding petitioner's priority of use of its mark ONCONASE in connection with its cancer treatment drug. The parties' respective testimony establishes that petitioner's first use of its mark ONCONASE occurred in January, 1991, whereas respondent first used its mark ONCASE in October 1995. Therefore, the only remaining issues in this case are likelihood of confusion and laches. Before turning to the merits of those issues, however, our attention is directed to other subsidiary matters raised by the parties.

The parties filed, earlier in this proceeding, cross motions for partial summary judgment on the pleaded issue of abandonment. The parties were at odds over whether respondent's activities under its mark constituted "use in commerce" as contemplated under the Trademark Act. The Board characterized the issue as follows: Whether, as a

matter of law, respondent's shipments of its pharmaceutical products for purposes of pre-clinical trials within the United States, and for purposes of clinical trials in foreign countries constitute "use in commerce." In an order dated September 24, 2002, the Board ruled in respondent's favor, entering partial summary judgment on the issue of abandonment. The Board found that Congress intended the term "use in commerce" to encompass shipments of pharmaceuticals for pre-clinical trials in this country and for clinical trials abroad prior to receiving FDA approval as a reflection of common industry practice; that the "use in commerce" Congress can regulate is the actual shipment of the pharmaceuticals overseas; and that it is not necessary that Congress be able to regulate the clinical testing. In that interlocutory order, the Board indicated that "this case will proceed solely on the issues of likelihood of confusion and priority of use."

In its brief on the case, petitioner raises for the first time a claim that respondent's use of its mark was unlawful. Petitioner makes reference to this unpleaded "subsidiary" issue as follows: "Whether the Board should draw an adverse inference against [respondent] for the improper refusal of its President to answer questions posed during his trial testimony, and to consequently hold the ONCASE registration invalid as having been improperly issued

on the basis of unlawful commerce." (Brief, p. 5). Petitioner contends that respondent "stonewalled highly relevant cross-examination during its trial testimony and the Board should draw a dispositive adverse inference against it." (Brief, p. 19).

In connection with its motion for summary judgment, respondent submitted the declaration of Dr. Hoffman wherein he indicated that respondent's pharmaceutical marketed under the mark ONCASE was shipped in commerce to Mexico for clinical trials. The declaration was introduced later at trial as an exhibit during Dr. Hoffman's testimony deposition. Petitioner now claims that respondent's use was unlawful because the FDA had not authorized shipment of respondent's drug for use in clinical trials. Petitioner contends that it was entitled to cross examine Dr. Hoffman about the legality of that alleged unauthorized exportation. In view of Mr. Hoffman's refusal to answer questions regarding these shipments, petitioner urges that "the Board should infer that the exportation of ONCASE from the United States to Mexico preceded, and therefore took place in the absence of, any authorization by the FDA to use the drug in a clinical trial." Petitioner concludes that the adverse inference to be drawn from Dr. Hoffman's refusal to answer questions on these shipments is that respondent committed a

per se violation of 21 CFR §312.110.[4] Petitioner asserts that an IND has never been issued for the ONCASE brand drug, and that respondent's exportation of the drug for clinical trials in Mexico occurred before the FDA had authorized respondent to export the drug.

Respondent has objected to consideration of this issue, maintaining that the issue was not added by petitioner in any amended pleading, and that there has been no trial of this issue. Respondent goes on to assert that, in any event, the only evidence on this issue is the relevant regulation itself, and that this evidence standing alone falls far short of establishing that respondent's use was unlawful.

We find that petitioner's claim of unlawful use is untimely and, thus, we decline to consider it. Petitioner knew of this possible claim for relief at least as early as when respondent filed its motion for summary judgment which was supported by the same affidavit of Dr. Hoffman upon which petitioner now relies as a basis for its newly raised claim. Yet petitioner did not raise this claim until its brief on the case. Hilson Research Inc. v. Society for

[4] The regulation provides, in relevant part, that an investigational new drug intended for export from the United States must comply with FDA regulations if an IND is in effect for the drug, or if an IND is not in effect, then the FDA must authorize shipment of the drug for use in any clinical investigation.

Human Resource Management, 27 USPQ2d 1423, 1439-40 (TTAB 1993); and Chicago Corp. v. North American Chicago Corp., 20 USPQ2d 1715, 1717 n. 5 (TTAB 1991). Petitioner simply failed to promptly amend the petition for cancellation after it learned of facts which, petitioner contends, establish this additional claim. To allow petitioner to raise the claim at this late juncture would be an unfair surprise to respondent.

Further, given respondent's clear and repeated objections to the questions relating to the purported unlawful use, there was neither an implied nor an explicit trial of this issue. Fed. R. Civ. P. 15(b). The objections were well taken inasmuch as the issue of unlawful use was not pleaded and the Board, in its decision on the motion for summary judgment, had explicitly stated that the only issues for trial were priority and likelihood of confusion. Therefore, the questions being posed went beyond the scope of the issues in this case. Given that respondent's objections were well taken, we have not drawn an adverse inference from Dr. Hoffman's refusal to answer the questions pertaining to respondent's exportation of its drug to Mexico. TBMP §707.03(d) (2d ed. rev. 1, March 2004). Cf.: Levi Strauss & Co. v. R. Josephs Sportswear Inc., 28 USPQ2d 1464, 1467 (TTAB 1993).

Accordingly, we have given no consideration on the merits to petitioner's claim that respondent's use was unlawful.

LIKELIHOOD OF CONFUSION

Our determination under Section 2(d) is based on an analysis of all of the facts in evidence that are relevant to the factors bearing on the likelihood of confusion issue. In re E. I. du Pont de Nemours & Co., 476 F.2d 1357, 177 USPQ 563 (CCPA 1973).

In any likelihood of confusion analysis, two key considerations are the similarities or dissimilarities between the marks and the similarities or dissimilarities between the goods. Federated Foods, Inc. v. Fort Howard Paper Co., 544 F.2d 1098, 192 USPQ 24 (CCPA 1976). These, and other du Pont factors deemed pertinent in the proceeding now before us, are discussed below.

THE PARTIES' GOODS

Petitioner's goods, in its pleaded registration, are identified as "pharmaceuticals, namely, cancer-treating drugs" while respondent's goods, in the registration sought to be cancelled, are identified as "therapeutic compositions containing reagents for in vivo anti-cancer use." As often stated, Board proceedings are concerned with registrability and not use of a mark and, thus, the identification of goods in the respective registrations herein frames the issue.

Cunningham v. Laser Golf Corp., 222 F.3d 943, 55 USPQ2d 1842 (Fed. Cir. 2000); and Canadian Imperial Bank of Commerce v. Wells Fargo Bank, N.A., 811 F.2d 1490, 1 USPQ2d 1813 (Fed. Cir. 1987). Both products here are pharmaceuticals used in treating cancer patients. As identified in the respective registrations, we find that the goods are legally identical for purposes of our likelihood of confusion determination.

Respondent contends that the goods "look dramatically different from one another and are used in distinct treatment regimes." More specifically, respondent states that because both products are administered intravenously, the medical professionals administering the products will see that "[a] bag of clear liquid [petitioner's product] is highly distinguishable from a bag of brilliant yellow liquid [respondent's product]." (Brief, p. 18). Simply put, these distinctions are of little moment in our likelihood of confusion analysis which, to reiterate, is based on a comparison of the goods as identified in the involved registrations. Moreover, the question is whether the relevant classes of purchasers are likely to confuse the source of the goods, not the goods themselves.

THE PARTIES'S MARKS

Insofar as the marks are concerned, we initially note that when marks are applied to legally identical goods, as is the case here, "the degree of similarity [between the

marks] necessary to support a conclusion of likely confusion declines." Century 21 Real Estate Corp. v. Century Life of America, 970 F.2d 874, 23 USPQ2d 1698, 1700 (Fed. Cir. 1992).

The marks are similar in sound and appearance. Both marks begin with ONC and end in ASE (the scientific names of petitioner's and respondent's drugs are, respectively, "ranpirnase" and "recombinant methioninase"). Although petitioner's mark includes an additional syllable, it is the middle portion of the mark. As seen and spoken, this middle portion may be missed by many of the relevant purchasers. As to meaning, we find that the first portion of the respective marks, "ONC-", connotes that each product has something to do with oncology. Thus, while each mark is suggestive, the marks convey, at least superficially, the same basic idea. Notwithstanding this suggestiveness, Dr. Costanzi, a board certified physician in medical oncology, testified that he was not aware of any other "ONC-" marks in the field. The record is otherwise devoid of any probative evidence showing third-party uses or registrations of similar marks in the oncology field.

In sum, we find that the similarities between the marks outweigh the differences.

TRADE CHANNELS

There are certain other duPont factors that are relevant in the present case. The first relates to channels of trade.

Respondent concedes that the goods presently move in overlapping channels of trade, but goes on to assert that these channels consist of tightly controlled pre-clinical and clinical trials. Respondent contends that clinical trials are designed so that confusion cannot occur; according to respondent, confusion is all but impossible due to careful labeling and security procedures that are followed to ensure the accuracy of the test results.

Respondent's argument to restrict the trade channels factor to these trials, and to not consider the general pharmaceutical market, is misplaced. Neither of the identifications of goods includes a restriction to pre-clinical or clinical trials. We must assume, therefore, that the respective drugs will both gain FDA approval and subsequently travel in the future in the same general pharmaceutical trade channels.[5]

[5] Respondent also contends that petitioner's product is unlikely to pass the clinical stage and, accordingly, the drug will never make its way to the pharmaceutical market for sale. Suffice it to say that the likelihood that the FDA will or will not approve petitioner's drug for market use, or that the efficacy of respondent's drug is greater than that of petitioner's drug, is entirely irrelevant to the issue of likelihood of confusion before us.

Inasmuch as the identifications of goods do not include any limitations, it is assumed that the goods move through the same trade channels, namely all trade channels normal for goods of this type in the healthcare field. These would in the future include hospitals and other healthcare facilities. However, the goods, *as identified*, are not limited to hospital use, and it is reasonable to assume that, at some point in the future, the drugs may be dispensed outside of the hospital setting, perhaps even as medications which can be taken by the patient at home. Dr. Costanzi touched on this point when he testified about the coming days of "brown bag" pharmaceuticals. (Dep., pp. 14-16). Thus, the precautionary controls over cancer-treating drugs that generally exist within the hospital may be lost when prescriptions for such drugs might be filled at the local drug store or pharmacy.

CONDITIONS OF SALE

In considering the conditions of sale of the respective products, we note that the drugs would be prescribed by physicians, dispensed by pharmacists and normally administered by healthcare professionals such as doctors and nurses. We acknowledge that such persons are sophisticated and are not prone to carelessness. Nonetheless, we find that confusion is likely, even among these healthcare professionals, where these similar goods are marketed under

the similar marks involved herein; there is no reason to believe that medical expertise as to pharmaceuticals will ensure that there will be no likelihood of confusion as to source or affiliation. See: In re Merck & Co., Inc., 189 USPQ 355 (TTAB 1975). See also: KOS Pharmaceuticals Inc. v. Andrx Corp., ___F.3d___ (3d Cir., No. 03-3977, May 24, 2004). As Dr. John Costanzi testified, contrary to the gist of Dr. Hoffman's remarks on this point, mistakes have been made where cancer patients were given the wrong drug, as a result of name or trademark confusion, with dire consequences (pointing to a reported death due to confusion between Taxol and Taxotere). (Dep. pp. 13-19; and exhibit no. 16 which is an article captioned "Lethal Confusion" retrieved from Forbes.com). See generally: J.T. McCarthy, McCarthy on Trademarks and Unfair Competition, §19:149 (4th ed. 2004).

Moreover, as noted above, the parties' drugs, *as identified*, also could be dispensed outside of the hospital setting, such that the ultimate users will have direct contact with them. As stated in KOS Pharmaceuticals Inc., id., citing Checkpoint Sys., Inc. v. Check Point Software Techs., Inc., 269 F.3d 270, 285 (3d Cir. 2001), "[w]here both professionals and the general public are relevant consumers, 'the standard of care to be exercised....will be equal to that of the least sophisticated consumer in the

class.'" Thus, we must be sensitive to the fact that patients from the general public will not exercise the degree of care exhibited by medical professionals. As also stated by the Third Circuit in KOS Pharmaceuticals Inc., id.: "While doctors and pharmacists play a gate-keeping role between patients and prescription drugs, they are not the ultimate consumers. Patients are. Courts have noted that drugs are increasingly marketed directly to potential patients through, for example, 'ask-your-doctor-about-Brand-X' style advertising." [citations omitted].

ACTUAL CONFUSION

The absence of evidence of actual confusion does not compel a different result. The tight controls over drugs during clinical testing may have prevented any meaningful opportunity for confusion to occur between the marks. Further, respondent has shipped only seven vials of the drug in connection with pre-clinical testing in this country, and it would appear that any opportunity for confusion has been virtually nonexistent. Cunningham v. Laser Golf Corp., supra at 1847 [In order for lack of actual confusion to be a meaningful factor, there must be evidence showing that there has been an opportunity for incidents of actual confusion to occur.] In any event, the test here is likelihood of confusion, and actual confusion need not be found in order to conclude that there is a likelihood of confusion between

the marks. Weiss Associates Inc. v. HRL Associates Inc., 902 F.2d 1546, 14 USPQ2d 1840 (Fed. Cir. 1990).

CONCLUSION

We conclude, based on a preponderance of the evidence, that there is a likelihood of confusion when the marks ONCONASE and ONCASE are contemporaneously used on the parties' respective cancer-treating drugs.

As a final point, prior decisions state that, where the marks are used on pharmaceuticals and confusion as to source can lead to serious consequences, it is extremely important to avoid that which will cause confusion. This further supports our conclusion herein. See: Glenwood Laboratories, Inc. v. American Home Products Corp., 455 F.2d 1384, 173 USPQ 19 (CCPA 1972); Blansett Pharmacal Co. Inc. v. Carmrick Laboratories Inc., 25 USPQ2d 1473 (TTAB 1992); Schering Corp. v. Alza Corp., 207 USPQ 504 (TTAB 1980); and American Home Products Corp. v. USV Pharmaceutical Corp., 190 USPQ 357 (TTAB 1976). See also: KOS Pharmaceuticals Inc. v. Andrx Corp., supra. See generally: McCarthy on Trademarks and Unfair Competition, supra, §23:32.

LACHES

The last issue for us to consider is respondent's affirmative defense of laches. Respondent contends that petitioner's undue and unreasonable delay in asserting its rights requires dismissal of the petition for cancellation.

In the present case, respondent specifically asserts that petitioner knew or should have known that it had a cause of action as early as July 5, 1994, when respondent's mark ONCASE was published for opposition; that the resulting registration of the mark in 1996 put petitioner on constructive notice of respondent's ownership and use of the mark; and that rather than taking timely action, petitioner waited until three days prior to the fifth anniversary date of the registration to file the present petition for cancellation. Respondent contends that it has been prejudiced by petitioner's delay in that it has built up and promoted its mark ONCASE in reliance on its registration thereof and petitioner's silence. Respondent maintains that its product has been extensively promoted through trade shows, conferences and presentations, and that if respondent's registration is cancelled, it will lose the value of its extensive investment through its promotion of the mark.

Petitioner responds by characterizing the defense as "makeweight" and asserting that respondent's investment in the mark ONCASE has been only minimal.

Respondent, as the party raising the affirmative defense of laches, bears the burden of proof. To prevail on laches, respondent is required to establish that there was undue or unreasonable delay by petitioner in asserting its

rights, and prejudice to respondent resulting from the delay. Bridgestone/Firestone Research Inc. v. Automobile Club de l'Ouest de la France, 245 F.3d 1359, 58 USPQ2d 1460 (Fed. Cir. 2001). See also: National Cable Television Association, Inc. v. American Cinema Editors, Inc., 937 F.2d 1572, 19 USPQ2d 1424 (Fed. Cir. 1991) [laches runs from the time from which action could be taken against the trademark rights inhering upon registration].

In the present case, respondent's mark was published for opposition on July 5, 1994;[6] issuance of respondent's registration on the Principal Register occurred on July 16, 1996; and the petition for cancellation was filed on July 13, 2001. Thus, the delay comprises a little over seven years. Petitioner has been completely silent as to the reason for its delay, and we consider the unexplained delay of over seven years to be substantial.

As petitioner points out, however, mere delay in asserting a trademark-related right does not necessarily result in changed conditions sufficient to support the defense of laches. There must also have been some detriment to the defendant due to the delay. Bridgestone/Firestone Research Inc. v. Automobile Club de l'Ouest de la France, supra at 1463. Prejudice is generally shown by the fact

[6] Respondent was not aware of petitioner's registered mark when it filed the underlying application. (Hoffman dep., p. 183).

that in reliance on petitioner's silence, respondent built up a valuable business and good will around the mark during the time petitioner never objected. Turner v. Hops Grill and Bar Inc., 52 USPQ2d 1310 (TTAB 1999). See generally: J.T. McCarthy, McCarthy on Trademarks and Unfair Competition, §20:76 (4th ed. 2004).

Economic prejudice arises when a defendant suffers the loss of monetary investments or incurs damage that likely would have been prevented by an earlier suit. A.C. Aukerman Co. v. R. L. Chaides Construction Co., 960 F.2d 1020, 22 USPQ2d 1321 (Fed. Cir. 1992). A nexus must be shown between the delay in filing suit and the expenditures; the alleged infringer must change his position because of and as a result of the plaintiff's delay. The essential inquiry is to determine if there was a change in the economic position of the alleged infringer during the period of delay. State Contracting & Engineering Corp. v. Condotte America, Inc., 346 F.3d 1057, 68 USPQ2d 1481 (Fed. Cir. 2003).

Respondent has provided insufficient specifics about the detriment it alleges to have suffered. Respondent has failed to provide any dollar amounts regarding the costs of development and promotion of its product marketed under the mark ONCASE. Respondent has shipped only *seven* vials of product for testing. In addition to these shipments,

according to Dr. Hoffman, respondent has promoted its product at conferences and trade shows by way of posters and distribution of informational handouts. More specifically, respondent promoted its product, in the period July 1994 to 2003, by way of 21 presentations, 12 meetings and 45 trade shows. According to Dr. Hoffman, he presents papers, hands out printed material, and engages in discussions with potential customers and partners at the trade shows. In its brief (p. 9), respondent highlights its promotional efforts at two of the most widely attended events, namely the American Association of Cancer Research annual meeting and the American Society of Clinical Oncology annual meeting, drawing 10,000 and 15,000 attendees, respectively. At each recent meeting, respondent distributed about 200 copies of a bibliography of articles about the ONCASE brand drug. Dr. Hoffman further testified that scientific information, technical bulletins and posters were available at respondent's booths. Respondent also has promoted its drug at other meetings and conferences, giving presentations to oncologists and/or scientists in the field of cancer research. Dr. Hoffman testified that the presentations generally attract 50-100 attendees. Dr. Hoffman also testified that respondent's website counted more than 13,000 visits in a recent one-year period.

Although respondent contends that its investment in the ONCASE brand product has been extensive, it is difficult to gauge, in the absence of dollar amounts or other specific information relative to its promotional efforts, the degree to which there has been any detriment. We also lack any testimony or other evidence which would shed light on the effect and success of respondent's promotional efforts. Further, respondent's testimony regarding its appearances at conferences, trade shows and presentations is diminished by the fact that it was promoting other drugs at the same time. For example, exhibit no. 11 to Dr. Hoffman's depostion is a photograph of one of respondent's booths at a trade show; no fewer than four of respondent's other drugs are being promoted under different marks. Thus, in all likelihood, respondent's expenditures in connection with the promotion of its ONCASE brand drug would appear to be little more than what it was spending in any event to promote its other drugs. That is to say, respondent might very well have attended the various trade shows and conferences to promote its other drugs even if its ONCASE brand drug had not been developed. Again, in the absence of details relating to the specific economic prejudice suffered, we are unable to say that respondent has established a meritorious laches defense.

Further, while Dr. Hoffman has authored scientific papers concerning respondent's drug, the drug is hardly ever referred to by its trademark ONCASE; instead, it is called by its scientific name (recombinant methioninase).

In sum, respondent has failed to put forward sufficient evidence of material prejudice to support a finding of laches. Accordingly, we find that respondent's laches defense fails for lack of proof.

Decision: The petition for cancellation grounded on likelihood of confusion is granted. Registration No. 1,987,445 will be cancelled in due course.