UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ROXANE LABORATORIES, INC., Plaintiff, v. CAMBER PHARMACEUTICALS INC. et al., Defendants.	Civil Action No. 14-4042 (SRC) **OPINION & ORDER**

CHESLER, U.S.D.J.

This matter comes before the Court on the motion for a preliminary injunction by Plaintiff Roxane Lanoratories, Inc. ("Roxane") against Defendants Camber Pharmaceuticals Inc. and InvaGen Pharmaceuticals Inc. (collectively, "Defendants"). This Court held oral argument on this motion on July 31, 2014. For the reasons stated below, the motion will be denied.

BACKGROUND

This case arises from a patent infringement dispute involving a pharmaceutical, calcium acetate capsules. Roxane owns U.S. Patent No. 8,563,032 (the "'032 patent"), directed to a pharmaceutical calcium acetate formulation; Roxane markets a generic calcium acetate capsule product. Defendants are pharmaceutical manufacturers who market competing generic calcium acetate capsule products. In March of 2014, Roxane filed a Complaint alleging patent infringement in the United States District Court for the Southern District of Ohio. Defendants moved to dismiss the Complaint or, alternatively, to transfer the case to the District of New Jersey. Roxane opposed the motion and also moved for a preliminary injunction, seeking to

enjoin Defendants from marketing their generic calcium acetate capsule products. The Ohio Court granted the motion to transfer and transferred the case to the District of New Jersey, where the parties completed briefing on the preliminary injunction motion.

APPLICABLE LEGAL STANDARDS

I. Preliminary Injunction

"The grant of a preliminary injunction under 35 U.S.C. § 283 is within the discretion of the district court." Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1378 (Fed. Cir. 2006). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." Winter v. NRDC, Inc., 129 S. Ct. 365, 374 (2008).

As to the requirement that the movant establish that he is likely to succeed on the merits, the Federal Circuit has held:

> [T]he patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent. In assessing whether the patentee is entitled to the injunction, the court views the matter in light of the burdens and presumptions that will inhere at trial. . . .

Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1376 (Fed. Cir. 2009) (citation omitted). "An accused infringer can defeat a showing of likelihood of success on the merits by demonstrating a substantial question of validity or infringement." Trebro Mfg. v. FireFly Equip., LLC, 748 F.3d 1159, 1165 (Fed. Cir. 2014). "A preliminary injunction should not issue if an alleged infringer raises a substantial question regarding either infringement or validity, i.e., the alleged infringer asserts an infringement or invalidity defense that the patentee has not shown

lacks substantial merit." AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1050 (Fed. Cir. 2010).

At trial, the plaintiff bears the burden of proving infringement by a preponderance of the evidence. Tech. Licensing Corp. v. Videotek, Inc., 545 F.3d 1316, 1327 (Fed. Cir. 2008).

ANALYSIS

I. Roxane has not demonstrated that it is likely to succeed on the merits.

Roxane first argues that this Court should preclude Defendants from relying on their noninfringement and invalidity arguments, contending that Defendants failed to disclose them previously, in violation of this district's Local Patent Rules. Roxane has overlooked a key provision in the Local Patent Rules: while these rules do establish a structure for the disclosure of infringement and invalidity contentions by both sides, L. Pat. R. 3.1 specifies that the trigger for these obligations is the initial scheduling conference. No initial scheduling conference has been held in this case, and Defendants have not failed to comply with their disclosure obligations under the Local Patent Rules.

Additionally, to the extent that Roxane contends that Defendants failed to provide appropriate discovery while the case was pending in Ohio, the Court notes that Plaintiff made no request before that court to compel discovery. Indeed, Roxane's motion for expedited discovery remained undecided until this Court decided that it was moot, in light of the current posture of the case. Under these circumstances, the Court declines to impose any sanction sought by Plaintiff.

To obtain a preliminary injunction, Roxane must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent. Roxane has not demonstrated that it will likely prove infringement. In brief, the key obstacle for

Roxane is found in the undisputed facts that claim 1 of the '032 patent requires a "capsule that is size 00 or less," while the accused infringing products are capsules that are size "00el." The parties agree that size 00el capsules have the same diameter as size 00 capsules, but are slightly elongated, so that they are longer and thus have greater volume. Roxane argues two theories of infringement: Defendants' products infringe both literally and under the doctrine of equivalents.

"Determining the likelihood of infringement requires two steps, first claim construction and second a comparison of the properly construed claims to the accused product." Pfizer, Inc. v. Teva Pharms. USA, Inc., 429 F.3d 1364, 1372 (Fed. Cir. 2005). In the context of a motion for a preliminary injunction, the Court's claim construction is preliminary as well: "a conclusion of law such as claim construction is subject to change upon the development of the record after a district court's decision on a motion for preliminary injunction." Id. at 1377.

Roxane's literal infringement theory depends on this proposed claim construction: "capsule that is size 00" means "capsule that is in the size 00 family, which includes size 00el."

> [T]he words of a claim are generally given their ordinary and customary meaning. . . [T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.

Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005). Roxane contends that the ordinary meaning of "size 00" is "in the size 00 family."[1] In support, Roxane begins by pointing to a number of pieces of extrinsic evidence, including a declaration from their expert, Dr. Park,

[1] At the outset, the Court wonders about the use of the "family" metaphor here. Are there really capsule size families that make up the capsule size community?

who asserts that a size 00el capsule is a size 00 capsule that is elongated.[2] Park's second declaration cites a variety of intrinsic and extrinsic evidence in support, but an expert declaration is extrinsic evidence of meaning, and "extrinsic evidence in general [i]s less reliable than the patent and its prosecution history in determining how to read claim terms." Id. at 1318. Roxane also cites other extrinsic evidence: an FDA draft document, reference books, and capsule marketing materials.[3] This is the wrong place to start claim construction: "[c]laim construction analysis begins with the intrinsic evidence." Irdeto Access, Inc. v. Echostar Satellite Corp., 383 F.3d 1295, 1299 (Fed. Cir. 2004).

Roxane's reply brief then turns to the intrinsic evidence and offers a few unpersuasive arguments. Roxane first observes that the claim states "said capsule that is size 00 or less," and not "wherein said capsule is size 00 or less." (Pl.'s Reply Br. 5.) Roxane argues that the use of "that is" instead of "wherein" indicates that "'size 00 or less' is simply an attribute of the antecedent 'pharmaceutically acceptable capsule,' not a further limitation." (Id.) This is an odd and unpersuasive tangent. Whatever "size 00" may mean – not that it seems unclear –, it is definitely a claim limitation. This is followed by another unpersuasive tangent about swallowability.

Roxane next tries to support its proposed construction by parsing some singular forms and plurals in the prosecution history. For example, Roxane points to the use of the plural form

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[2] This is clearly true in that the two have the same diameter and different length, but it does not necessarily have the semantic implications that Roxane contends. The fact that the capsules have the same diameter says nothing about what the term "size 00" means.

[3] Again, the intrinsic evidence carries greater weight, but the Court notes what is absent from Roxane's extrinsic evidence: an independent reference showing a usage of the term "size 00" to refer to a size 00el capsule.

of "capsules" in the applicant's appeal brief submitted to the PTAB.[4] The problem for Roxane is that the appeal brief shows no consistency in whether the singular or plural form of "capsule" is used – there are plenty of examples of each. This does not appear to have any significance, and it does not support Roxane's "size family" argument. As Defendants contend, the intermittent use of the plural form seems to reflect the fact that pharmaceutical doses are typically manufactured in quantity – the calcium acetate is put into more than one capsule, and so the plural is used.

The Court need not come to any conclusion about whether "capsule that is size 00" means "capsule that is in the size 00 family, which includes size 00el." At this juncture, Roxane bears the burden of showing that it will likely prove infringement, and Defendants may defeat that by raising a substantial issue of infringement, which Roxane fails to show lacks substantial merit. Roxane has failed to show that it will likely prove infringement, and Defendants have raised a substantial question of infringement: the claim requires "size 00 or less," and their product is larger than size 00. Roxane has failed to persuade that this question lacks substantial merit, but the key conclusion is that Roxane has failed to make a sufficient demonstration of a likelihood of success in proving infringement.

The Court notes that its initial review of all of the intrinsic evidence does not support Roxane's claim construction position. There is nothing in the patent or in the prosecution history that indicates that the applicants understood "size 00" to refer to more than one specific size of capsule. The first question that the Court asks is whether the specification discusses the issue of capsule size, and there is just one place in the "Detailed Description of the Invention" which does

[4] Roxane argues that the use of the plural form, "capsules," shows that the applicants understood that the invention includes both elongated and non-elongated forms of size 00 capsules.

so:

> According to one embodiment of the invention, the capsule is a size 00 capsule containing 667 mg of calcium acetate. Capsules containing smaller doses of the calcium acetate can be sized accordingly using smaller capsules.

'032 patent, col.3 ll.29-33. Here, the applicant did use the plural form, "capsules," and stated that the size of capsules can vary – but only in the smaller direction, not larger. This is consistent with the clear language of the claim, which limits the capsule to "size 00 or less." There is nothing here to suggest that the applicants understood "size 00" to include the larger size 00el. Nor does anything suggest that the applicant, here, understood the invention to include sizes larger than size 00. Nor does the prosecution history, which will be discussed in more detail later, support Roxane's position.

Roxane also contends that Defendants infringe under the doctrine of equivalents. "One way that a patentee may prove that a particular claim element is met under the doctrine of equivalents is by showing that the accused product performs substantially the same function in substantially the same way with substantially the same result as claimed in the patent." Energy Transp. Group, Inc. v. William Demant Holding A/S, 697 F.3d 1342, 1352 (Fed. Cir. 2012). Defendants do not oppose this theory by challenging the argument that the differences between the patented invention and their product are insubstantial, but rather by arguing that Roxane is barred from succeeding under this theory by prosecution history estoppel.

The Federal Circuit has summarized the basic principles of prosecution history estoppel as follows:

> Prosecution history estoppel prevents a patentee from recapturing through the doctrine of equivalents the subject matter that the applicant surrendered during prosecution. It presumptively applies when the applicant made a narrowing claim

amendment related to patentability.

Integrated Tech. Corp. v. Rudolph Techs., Inc., 734 F.3d 1352, 1356 (Fed. Cir. 2013) (citation omitted). Defendants contend that, during prosecution, the applicants made a narrowing claim amendment related to patentability which surrendered equivalents with capsule sizes larger than size 00. Roxane disagrees, contending that the amendment in question was clarifying, not narrowing.

There is no dispute over the relevant facts about the prosecution history: 1) as originally filed, claim 1 contained no express capsule size limitation; 2) the examiner rejected claim 1 as obvious; 3) the applicants amended claim 1, adding in the "size 00 or less" limitation; and 4) amended claim 1 was allowed after the PTAB reversed the examiner's obviousness rejection.

Roxane fails to persuade that this amendment did not narrow the scope of claim 1 – since the incorporation of an express size limitation clearly narrowed the scope of the claim. Roxane argues that applicants added the phrase "that is size 00 or less" only to clarify something, but it is not clear what. Roxane's reply brief tries to convince that the amendment aimed "to clarify that size 00 is an inherent characteristic of the antecedent 'pharmaceutically acceptable capsule.'" (Pl.'s Reply Br. 8-9.) Roxane argues that the examiner had written a sentence using the phrase "arriving at a capsule," and that the use of this phrase shows that the examiner misunderstood that the claim was directed to a pharmaceutically acceptable capsule, and not merely a capsule. The Court is not persuaded that the sentence at issue written by the examiner in the office action demonstrated any substantial misunderstanding, nor that the amendment was directed toward remedying a misunderstanding. Furthermore, if the applicants believed that the examiner had misunderstood something, would it not have been sufficient to provide clarifying comments in

response to the rejection? As Roxane states in the reply brief, claim 1 prior to the amendment already specified a pharmaceutically acceptable capsule; why is new claim language needed if the problem was that the examiner misunderstood what had already been expressly included in the claim? Furthermore, crucially, this Court does not see how adding in "that is size 00 or less" clarifies that the claim is directed not merely to a capsule, but to a pharmaceutically acceptable capsule.

Rather, the prosecution history shows that the applicants made a narrowing amendment to overcome a rejection. As revised in the prior amendment of November 19, 2008, claim 1 stated:

> A calcium acetate capsule formulation comprising flowable granules comprised of a pharmaceutically acceptable amount of calcium acetate along with other pharmaceutically acceptable adjuvants, wherein said granules are filled into and contained within a pharmaceutically acceptable capsule.

(INVAGEN0003587.) In the office action dated March 20, 2009, the examiner rejected this amended claim 1 as obvious over prior art references Dennett and Nakai. (INVAGEN0003632-33.) In the amendment of August 18, 2009, the applicants added this language at the end of claim 1: "such that 667 mg of said calcium acetate on an anhydrous basis are present in said capsule that is size 00 or less." (INVAGEN0003639.) In the remarks submitted with the amended claims, the applicants distinguished Nakai as follows: "Nakai's process of encapsulation without compression is deficient because its granular material cannot be filled and contained in capsules such that 667 mg of calcium acetate on an anhydrous basis is present in size 00 capsules." (INVAGEN0003644.) The applicants cited and submitted a declaration by applicant Dr. Uraizee which makes a detailed effort to distinguish Nakai. (INVAGEN0003651-54.)

In this declaration, Dr. Uraizee explains that the Nakai patent "describes a wet granulation process to obtain calcium acetate granules." (INVAGEN0003652.) She then describes an experiment she did in which she attempted to use the Nakai process to make calcium acetate granules, and to then fill a size 00 capsule. (Id.) She reported that, using the granules she made with the Nakai process, she was only able to fill the size 00 capsule with approximately 600 mg. (Id.) Dr. Uraizee concluded that it was "impossible" to achieve a fill of 667 mg "and also maintain free flowing status of granules in a pharmaceutically acceptable capsule size (size 00 or less) using Nakai et al.'s process." (INVAGEN0003654.) Dr. Uraizee distinguished the inventive process as capable, unlike Nakai's process, of achieving the desired fill amount in the size 00 capsule. (Id.)

On December 12, 2009, the PTO issued a final rejection. (INVAGEN0003657.) The examiner stated that the declaration submitted was insufficient to overcome the rejection based on Nakai. (INVAGEN0003658.) Claims 1-9 were again rejected as obvious in view of Nakai. (INVAGEN0003660.) The examiner also cited the Torpac reference, stating, "Torpac teaches various capsules and their sizes. It's clear from the metric table that size 00 is about 50% bigger than size 0." (INVAGEN0003663.)

On March 6, 2010, the applicants filed a "Pre-Appeal Brief Request for Review." (INVAGEN0003673-77.) This document repeats the arguments made in the August 18, 2009 submission. (Id.) On July 7, 2010, the PTO issued a decision again rejecting claims 1-9, and instructing the applicants to proceed with the filing of their appeal. (INVAGEN0003685.) On August 9, 2010, the applicants filed a brief for an appeal before the Patent Trial and Appeal Board ("PTAB"). (INVAGEN0003686-707.) The applicants appealed the examiner's rejection

of claims 1-9, repeating the arguments based on Dr. Uraizee's experiment and her declaration. (INVAGEN0003694.) The applicants also argued that "Torpac merely discloses different capsule sizes and does not compensate for the deficiencies of Dennett and Nakai discussed above." (INVAGEN0003699.) The examiner filed an answer, and the applicants filed a reply. In the reply, the applicants stated, "although the Uraizee Declaration only tested size 00 capsules it is commensurate with the claims because since Nakai could not achieve the claimed fill amount in size 00 capsules it could not fill even smaller capsules with the claimed amount . . ." (INVAGEN0003730.)

On March 12, 2013, the PTAB issued its decision reversing all of the rejections. (INVAGEN0003759.) In short, the PTAB was persuaded by the applicants' arguments about Nakai and the Uraizee declaration. (INVAGEN0003757-59.) The PTAB stated: "we find that the Uraizee Declaration provides persuasive evidence to show that Nakai's process does not produce granules of calcium acetate that could provide size 00 capsules containing 667 mg of calcium acetate." (INVAGEN0003759.) The '032 patent issued.

There are two main points to be made from the prosecution history. The first concerns the meaning of the phrase term "size 00." The applicants submitted quite a few documents which discussed size 00 capsules and their fill capacity. Not once did this Court find any suggestion that the applicants understood "size 00" to refer to a family of sizes, or even two sizes. Throughout the prosecution history, the applicants' submissions consistently treat size 00 capsules – whether singular or plural – as capsules of one size only. The applicants' main point was that the Nakai process does not produce granules which will fill a size 00 capsule with 667 mg of calcium acetate. The Uraizee declaration does not suggest that various size 00 capsules

have differing fill capacities.[5]

The second point concerns the surrender of subject matter during prosecution. On this record, it appears to this Court that the applicants filed a narrowing amendment to overcome an obviousness rejection. The applicants amended claim 1 to limit it to capsules that are size 00 or smaller to distinguish Nakai, arguing that the Nakai process cannot produce such capsules. The PTAB was persuaded, reversed the rejection, and the '032 patent issued. Because this Court is not persuaded that the applicants understood "size 00" to refer to a family of sizes which includes capsule size 00el, this Court finds that the applicants surrendered coverage of any capsule larger than size 00. The principle of prosecution history estoppel bars the applicants from recapturing this subject matter through the doctrine of equivalents.

The Court notes that the matter of the size of the capsule was not peripheral to the issues on appeal to the PTAB, but central. The applicants' main point was that claim 1 had a capsule size limitation which distinguished the prior art. The PTAB was persuaded and reversed the rejection. The applicants unambiguously surrendered claim scope involving capsules larger than size 00.

Roxane has failed to persuade that it is reasonably likely to prove that Defendants' product infringes the '032 patent either literally or under the doctrine of equivalents. This Court concludes that Plaintiff has failed to demonstrate a likelihood of success in showing

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[5] It is also worth noting that the Torpac reference, which gives specifications for 15 different capsule sizes, does not mention any size "00el." If the applicants understood "size 00" to be a family of sizes which included size 00el, when they traversed the rejection which cited Torpac, and they argued that the examiner's reference to Torpac did not support his point, why did they not argue that Torpac failed to disclose the full size 00 family of capsule sizes? (See INVAGEN0003670-72.)

infringement. On this basis alone, the motion for a preliminary injunction must be denied.

II. Roxane has not demonstrated irreparable harm.

This Court also finds that Plaintiff has not adequately demonstrated that it is likely to suffer irreparable harm in the absence of preliminary relief. Roxane first argues that the harm is irreparable because Defendants are unable to satisfy a judgment against them for infringement damages. The Court is not satisfied that, given the nature of the market, it is at all clear that Defendants, apparently the wholly-owned subsidiaries of a major corporation, Hetero Drugs Ltd., would be unable to pay damages.

Roxane next contends that it has suffered and will continue to suffer from price erosion due to the alleged infringement, citing to Federal Circuit cases which find price erosion to be a valid ground for finding irreparable harm. The cases cited by Roxane, however, are cases in which the patentee had market exclusivity. See Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359 (Fed. Cir. 2001) (Purdue and OxyContin®); Celsis in Vitro, Inc. v. CellzDirect, Inc., 664 F.3d 922, 924 (Fed. Cir. 2012) (Celsis and hepatocyte-preparation method); Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1343 (Fed. Cir. 2008) (Abbott and Biaxin® XL); and Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368 (Fed. Cir. 2006) (Sanofi and Plavix®). There is no indication in these decisions that the patentees had competition from others marketing an identical product.

As Defendants observe, Roxane is not the only player competing in the calcium acetate market. Roxane entered the marketplace in October of 2008 after the branded calcium acetate pharmaceutical, PhosLo® GelCaps, was on the market.[6] (Peterman Dec. ¶ 3.) In October of

[6] Like Roxane's product, PhosLo® GelCaps contain 667 mg of calcium acetate.

2009, Sandoz entered the market with an authorized generic version of PhosLo®. (Peterman Dec. ¶ 4.) At oral argument, Roxane presented two charts with historical sales data, one showing market share and one showing quarterly average selling prices (also at Peterman Dec. Ex. 2).

The chart showing historical average selling prices provides significant evidence against Roxane's price erosion argument. The chart shows that, in 2009, Roxane sold bottles of its product for an average price of approximately $80 per bottle. After Sandoz entered the market, the average price declined over the next two years to approximately $53 per bottle, but then rose over the following 2 years to approximately $75 per bottle. This shows that the price erosion was *not* irreversible – instead, the price erosion from the entry of a competitor into the market was, in fact, largely reversed. This Court is not persuaded that, under the unusual facts of this case, price erosion is irreversible.

With Invagen's product on the market, there are now at least four players in the marketplace selling 667 mg calcium acetate pharmaceuticals. This is not a case like Sanofi, where Sanofi was the only player in the market for Plavix, and Apotex challenged its position of exclusivity. At the present time, the status quo is a marketplace with four competitors. "The purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." Univ. of Tex. v. Camenisch, 451 U.S. 390, 395 (1981). Roxane seeks not to preserve the status quo pending trial on the merits, but to alter it. The status quo is best preserved by denying, not granting, the application for a preliminary injunction.

This Court finds that Roxane has not sufficiently demonstrated its entitlement to a preliminary injunction. It has not shown that is likely to prove infringement, nor that it is likely to suffer irreparable harm in the absence of preliminary relief. Moreover, since the goal of a

preliminary injunction is the preservation of the status quo, the status quo is best preserved by denying this motion.

For these reasons,

IT IS on this 6th day of August, 2014 hereby

ORDERED that Plaintiff's motion for a preliminary injunction (Docket Entry No. 43) is **DENIED**.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.