IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK; NEW YORK UNIVERSITY; GALDERMA LABORATORIES INC.; AND GALDERMA LABORATORIES, L.P.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 09-184-GMS-LPS
MYLAN PHARMACEUTICALS INC.,	:	PUBLIC VERSION
Defendant.	:	

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MEMORANDUM OPINION

June 28, 2010
Wilmington, Delaware.

Stark, Magistrate Judge

In this patent infringement action, Plaintiffs – The Research Foundation of State University of New York ("SUNY"), New York University ("NYU"), Galderma Laboratories, Inc. ("Galderma"), and Galderma Laboratories L.P. ("GLLP") (collectively, "Plaintiffs") – seek to preliminarily enjoin Defendant, Mylan Pharmaceuticals, Inc. ("Mylan"), from bringing to market Mylan's generic version of Plaintiffs' 40 mg Oracea® capsules.[1] (D.I. 87) Plaintiffs hold a New Drug Application on Oracea® as well as all rights in U.S. Patent Nos. 7,211,267 ("the '267 patent") and 7,232,572 ("the '572 patent"), two of the four patents-in-suit (hereinafter, the "Ashley patents").[2] Oracea® is approved for treatment of the dermatological condition acne rosacea.

Mylan has filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval for the commercial use, manufacture, and sale of a generic version of Oracea® capsules prior to the expiration of the patents-in-suit.

The Court held a preliminary injunction hearing on May 24, 2010. Defendants thereafter voluntarily agreed to refrain from launching their proposed generic product until at least July 1, 2010. (D.I. 146 at 3; *see also* D.I. 152.) For the reasons that follow, the Court will **GRANT** Plaintiffs' motion for a preliminary injunction.

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[1]The parties have consented to the jurisdiction of the undersigned magistrate judge to rule on Plaintiffs' preliminary injunction motion. (D.I. 93)

[2]The '267 and '572 patents are found in the record at D.I. 88 Exs. A & B, respectively.

BACKGROUND[3]

Plaintiffs' Branded Product: Oracea®

Acne rosacea, also known as rosacea, is a chronic inflammatory skin disorder that affects approximately 14 million Americans. (Webster Decl. (D.I. 91) ¶ 11) Rosacea is not an infection but, instead, a chronic inflammatory disorder. (*Id.* ¶ 15) Therefore, treatment by antibiotics – i.e., drugs that kill bacteria – is not required. (*Id.*) Also, given rosacea's chronic nature, long-term treatment is necessary. (*Id.*) Because long-term treatment with antibiotics can have significant side effects – such as dizziness and gastrointestinal disturbances for the patient and the development of antibiotic-resistant organisms for society – it is preferable not to treat rosacea with an antibiotic. (*Id.* ¶¶ 16-17)

Robert A. Ashley, the inventor of the patents-in-suit that are the subject of the preliminary injunction motion, claims to have discovered that administration of compounds of the antibiotic tetracycline in amounts too small to have antibiotic effect could effectively and safely treat rosacea without the unwanted side effects of antibiotics. (*See* D.I. 88 Exs. A & B at Example 38.) On May 26, 2006, Oracea® became the first – and remains the sole – oral therapy approved by the FDA for the treatment of rosacea. (D.I. 88 at 3) Plaintiffs insist Oracea® has no antimicrobial effect but, instead, acts only as an anti-inflammatory drug. (Webster Decl. (D.I. 91) ¶ 19)

Plaintiffs' Patents-in-Suit

The Ashley patents are directed to methods of treating acne and rosacea with tetracycline

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[3]This opinion constitutes the Court's findings of fact and conclusions of law pursuant to Fed. R. Civ. Proc. 52(a).

compounds. The other patents-in-suit, referred to as the "Amin patents," are U.S. Patent Nos. 5,789,395 ("the '395 patent") and 5,919,775 ("the '775 patent").[4] The Amin patents are directed to methods of using tetracycline compounds to inhibit production of nitric oxide ("NO"), a mediator of rosacea.

All four of the patents-in-suit are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for Oracea®. Plaintiffs' preliminary injunction motion is based only on the Ashley patents (i.e., the '267 and '572 patents). (D.I. 88 at 5 n.4) The '572 patent is a continuation of the '267 patent. (D.I. 88 at 16)

Mylan's ANDA and the Instant Litigation

Mylan has submitted ANDA No. 90-855 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j). (D.I. 88 Ex. X) As required by statute, on February 4, 2009 Mylan notified Plaintiffs of its ANDA filing and certified to the FDA its belief that the Ashley patents are invalid and/or would not be infringed by the commercial manufacture, use, or sale of Mylan's proposed generic product. (*Id.*)

On March 19, 2009, Plaintiffs filed their complaint, alleging that Mylan's generic version of Oracea® would infringe the patents-in-suit. (D.I. 1) On April 16, 2009, Mylan filed its answer and counterclaims, asserting counterclaims seeking declaratory judgments of invalidity and non-infringement with respect to both Ashley patents. (D.I. 14) On April 9, 2010 Mylan filed a motion for leave to amend its answer and counterclaims to add a counterclaim seeking a declaratory judgment that the Ashley patents are unenforceable due to inequitable conduct before the U.S. Patent and Trademark Office ("PTO"). (D.I. 96)

[4]The Amin patents are found at D.I. 1 Exs. C & D.

Trial is scheduled for December 7, 2010. (D.I. 26)

Claim Construction

The Court held a *Markman* hearing to consider the parties' claim construction disputes on March 23, 2010. *See* March 23, 2010 Hearing Transcript (D.I. 133) (hereinafter "*Markman* Tr."). The undersigned magistrate judge issued a Report & Recommendation as to the proper resolution of these disputes on May 12, 2010. (D.I. 134) No objections were filed. On June 24, 2010, Chief Judge Gregory M. Sleet adopted the Report and Recommendation. (D.I. 166)

Plaintiffs' Preliminary Injunction Motion

At the conclusion of the *Markman* hearing, the parties advised the Court that Mylan was contemplating an "at-risk launch" of its proposed generic product in the event that Mylan were to receive FDA approval for it. (*Markman* Tr. at 118-26) Thereafter, Mylan agreed voluntarily to refrain from launching its generic product until May 31, 2010. (D.I. 77 at 2) On April 2, 2010, Plaintiffs filed their motion for a preliminary injunction to enjoin Mylan's launch until after conclusion of this litigation. (D.I. 87; D.I. 88) The parties filed additional pre-hearing submissions on April 30 and May 14, 2010. (D.I. 105; D.I. 138) Among the parties' filings were declarations from Brian Johnson, Galderma's Vice President of Prescription Marketing (D.I. 89); Professor Jerry A. Hausman, Plaintiffs' damages expert (D.I. 90; D.I. 140); Dr. Guy F. Webster, Plaintiffs' infringement and validity expert (D.I. 91; D.I. 139); Dr. Harry F. Chambers, Mylan's infringement expert (D.I. 106); Dr. Ronald N. Jones, Mylan's expert in the area of microbiology (D.I. 107); Jason Harper, Mylan's Executive Director of Product Portfolio Management (D.I. 108); Dr. Philip B. Nelson, Mylan's damages expert (D.I. 111); and Dr. Barbara A. Gilchrist, Mylan's invalidity expert (D.I. 112; D.I. 113; D.I. 114).

On May 24, 2010, the Court held an evidentiary hearing on the preliminary injunction motion. *See* May 24, 2010 Hearing Transcript (D.I. 169) (hereinafter "Tr."). In addition to legal argument, the Court heard testimony from the following witnesses called by Plaintiffs: Dr. Webster (Tr. at 107-79), Mr. Johnson (Tr. at 180-204), and Professor Hausman (Tr. at 208-44). Defendants chose not to call any witnesses.

At the direction of the Court, the parties filed post-hearing letter briefs on May 25, 2010 (D.I. 146; D.I. 147) and May 26, 2010 (D.I. 149; D.I. 150). In its letter of May 25, Mylan advised the Court that it would agree not to launch a product pursuant to the ANDA at issue in this litigation before July 1, 2010. (D.I. 146 at 3)

On June 16, 2010, Plaintiffs wrote to the Court pursuant to D. Del. LR 7.1.2(b) to bring new case law and facts to the Court's attention. (D.I. 160) Specifically, Plaintiffs provided the Court with copies of a recent opinion in the District of New Jersey preliminarily enjoining the launch of a generic drug. (D.I. 160 Ex. 1) They also provided the Court with excerpts of the post-hearing deposition of Mr. Ashley, including his testimony regarding disclosures to the PTO. (D.I. 160 Ex. 2) Mylan responded to Plaintiffs' letter on June 18, 2010. (D.I. 161)

LEGAL STANDARDS

Federal Circuit law provides the standard for granting an application for a preliminary injunction of patent infringement. *See Hybridtech, Inc. v. Abbott Labs*, 849 F.2d 1446, 1451 n.12 (Fed. Cir. 1988). A preliminary injunction is "extraordinary relief." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1375 (Fed. Cir. 2009). A "patentee's entitlement to such an injunction is a matter largely within the discretion of the trial court." *Id.*

"'[A] plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest.'" *Id.* at 1375-76 (quoting *Winter v. Natural Res. Def. Council, Inc.*, ___ U.S. ___, 129 S. Ct. 365, 374 (2008)).

"[A]ll findings of fact and conclusions of law at the preliminary injunction stage are subject to change upon the ultimate trial on the merits." *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001).

DISCUSSION

As set forth below, the Court finds that Plaintiffs have established a strong likelihood of success on the merits of their claims. The Court further finds that Plaintiffs have met their burden to show they will suffer irreparable harm in the absence of preliminary relief, that this harm outweighs the harm that will be suffered by Mylan in the event that the preliminary injunction turns out to have been improvidently granted, and that the competing public interests at stake favor Plaintiffs. Although these latter three factors weigh only slightly in favor of Plaintiffs, on the whole the factors the Court must consider in exercise of its discretion justify granting Plaintiffs the extraordinary relief they seek. *See generally FMC Corp. v. U.S.*, 3 F.3d 424, 427 (Fed. Cir. 1993) ("If a preliminary injunction is granted by the trial court, the weakness of the showing regarding one factor may be overborne by the strength of the others."); *Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683-84 (Fed. Cir. 1990) (suggesting that not all preliminary injunction factors need be weighed equally).

I. Plaintiffs Have Established A Likelihood Of Success On The Merits

"With regard to the first factor – establishing a likelihood of success on the merits – the 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." *Titan Tire*, 566 F.3d at 1376. "[T]he ultimate question regarding the first preliminary injunction factor remains that of the patentee's likelihood of success on the merits. . . . That test places the burden on the plaintiff to prove likelihood of success." *Id.* at 1380.

A. Infringement

Assessing whether Plaintiffs are likely to prove that Mylan's generic product will infringe the Ashley patents requires a two-step analysis. First, the Court must determine "the meaning and scope of the patent claims asserted to be infringed." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). Second, the Court must compare the properly construed claims to the accused device. *Id.*

1. Claim construction

The Court held a *Markman* hearing and construed the claims. (D.I. 134; D.I. 166) The Court will apply the constructions already provided for purposes of evaluating the preliminary injunction motion.

2. Application of claim terms to Defendant's generic product

In support of their motion for a preliminary injunction, Plaintiffs assert that Mylan infringes claims 1, 22, 24, and 26 of the '267 patent and claims 1, 12, and 14 of the '572 patent. (D.I. 88 at 7, 9) Plaintiffs may satisfy their burden on likelihood of success on the merits by demonstrating they are likely to prove infringement on any single claim. *See Erico Intern. Corp.*

v. Vutec Corp., 516 F.3d 1350, 1354 (Fed. Cir. 2008) (stating that to support preliminary injunction a patentee must show likelihood that alleged infringer "infringes *a valid claim*" of a patent) (emphasis added). Much of the parties' argument has focused on Plaintiffs' allegations of infringement of claims 1 of both the '267 and '572 patents. The Court will limit its analysis to these two claims.

For purposes of the instant motion, Mylan admits that it infringes all but one limitation in each of these two claims: that Mylan's generic product does not involve administration of a "sub-antibacterial amount" ('267 patent, claim 1) and that Mylan's generic product does not involve administration of "an amount that . . . has substantially no antibiotic activity" ('572 patent, claim 1). (D.I. 105 at 5) These claim limitations are related; indeed, the Court has construed them in an essentially identical manner. Specifically, "sub-antibacterial amount" as used in claim 1 of the '267 patent is construed as "*an amount that does not significantly inhibit the growth of microorganisms, e.g., bacteria*," and "an amount that . . . has substantially no antibiotic activity" as used in claim 1 of the '572 patent is construed as "*an amount that* is effective to treat the papules and pustules of rosacea but *does not significantly inhibit the growth of microorganisms, e.g., bacteria.*" (D.I. 166; D.I. 134 at 17) (emphasis added) Mylan argues that its generic product does not infringe because it "contains an amount of doxycycline that **does** significantly inhibit the growth of bacteria." (D.I. 105 at 6) (citing Chambers Decl. (D.I. 106) at ¶¶ 28-29)

The Court does not agree. As explained by Plaintiffs, the label that Mylan has proposed to the FDA to accompany its generic product expressly states that [redacted]

[redacted]

(emphasis omitted)

Mylan argues that it is not proper for the Court to rely on its proposed label, because, by law, Mylan is required to copy the label Plaintiffs use for Oracea®. (D.I. 105 at 11; Tr. at 49) However, the law also requires that Mylan's proposed label must be truthful and accurate; the proposed label is submitted to the FDA under penalty of perjury. Here, Mylan's counsel has confirmed that "everything we say in the label is true." (Tr. at 316-17) Under the circumstances, it is entirely proper to rely on the statements in Mylan's label, which here provide substantial evidence that Mylan's generic product will not significantly inhibit the growth of bacteria. *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000) ("[A]n ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry.").[5]

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[5]Mylan points to other portions of its proposed label to support its non-infringement position. For example, the label states: [redacted] These statements do not mean that Oracea® or Mylan's proposed generic version of it significantly inhibit microbial growth.

Mylan further insists that the statements in both parties' labels are inaccurate, because the amount of doxycycline administered daily – 40 mg of Oracea® or of Mylan's proposed generic – does significantly inhibit the growth of microorganisms. Therefore, according to Mylan, neither Oracea® nor its proposed generic version of it contains a "sub-antibacterial amount" or "an amount that . . . has substantially no antibiotic activity." (*See* D.I. 105 at 1 ("Because administering 40 mg of doxycycline significantly inhibits the growth of bacteria **and** has substantial antibiotic effects, neither Mylan's accused product (40 mg doxycycline) nor Oracea® (same) is covered by the asserted claims and, therefore, Mylan cannot be found to infringe.").) In contending that Oracea® and Mylan's proposed generic version are administered in antibiotic amounts, Mylan relies on evidence consisting of *in vitro*, not *in vivo*, results. "*In vitro*" measurements are taken in laboratories, measuring the effects of (for instance) doxycycline on bacteria in solution in a test-tube or petri dish. "*In vivo*" measurements, by contrast, are taken in the human body, measuring the effects of (for instance) doxycycline on bacteria found in human blood or tissue.

Mylan has introduced evidence that seven-day administration of 40 mg of Oracea® or Mylan's generic product results in a mean peak doxycycline serum concentration of 0.6 μg/mL, which is substantially greater than the minimum inhibitory concentration that inhibits visible growth of many common infection-causing bacteria. (D.I. 105 at 4-6; Chambers Decl. (D.I. 106) ¶¶ 23-29)

The problem with Mylan's argument is that the serum concentration levels and minimum inhibitory concentrations that it reports are based solely on *in vitro* studies. That is, Mylan is relying on laboratory measurements to show that 40 mg of doxycycline has a significant

antibiotic effect. The invention disclosed and claimed in the Ashley patents, however, requires administration in a human. Thus, what matters for purposes of the infringement analysis is whether Mylan's proposed generic product will significantly inhibit the growth of bacteria in a human, that is *in vivo*. As Dr. Webster opines, Mylan's *in vitro* data does not measure the antibacterial effect of a drug as administered to humans and, therefore, is not relevant to the question of infringement presented here. (D.I. 139 ¶¶ 43-45)

Dr. Webster testified credibly that there is no one-to-one correlation between an *in vitro* antibiotic effect at a particular amount or concentration of doxycycline and the corresponding effect *in vivo* of the same amount or concentration. (Tr. at 121-22; *see also* D.I. 139 ¶¶ 43-58.) According to Dr. Webster, "The MIC [minimum inhibitory concentration[6]] values from *in vitro* testing are not subject to direct quantitative comparison to the complex *in vivo* environment. . . . There are numerous differences between the simplified, artificial *in vitro* environment used for MIC testing and the complex, variable environment of the human body that make it difficult, if not impossible, to reliably extrapolate from the results of *in vitro* MIC testing to the likelihood of *in vivo* effects." (D.I. 139 ¶¶ 50, 52) Hence, the record is devoid of any evidence that Mylan's generic product will significantly inhibit the growth of bacteria in a human. Mylan's *in vitro* evidence simply does not rebut Plaintiffs' evidence of infringement based on Mylan's proposed label.

Relatedly, Mylan's other primary argument against infringement turns on the Court's

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[6]Defendants' expert Dr. Chambers explained: "The most commonly used measure of antibacterial activity *in vitro* is the Minimum Inhibitory Concentration (MIC). The MIC is the lowest concentration of an antibiotic that will inhibit visible growth of bacteria after incubation . . . . MICs are used to predict the likelihood that a given antibiotic will inhibit bacterial growth *in vivo* and to guide therapy for bacterial infections." (D.I. 106 ¶¶ 24-25)

construction of the term "minimum antibiotic serum concentration," also referred to as "MASC."[7] Mylan argues: "[T]he Court's ruling that 'minimum antibiotic serum concentration' in claim 12 [of the '267 patent] is an *in vitro* value and not an *in vivo* value . . . compels the conclusion that 'sub-antibacterial amount' in claim 1 (from which claim 12 depends) necessarily includes, but is not limited to, *in vitro* values." (D.I. 149 at 1-2) Citing 35 U.S.C. § 112, ¶ 4, Mylan insists that "claim 12 includes all of the limitations of independent claim 1." (D.I. 146 at 1)

Mylan's position is wrong for several reasons, including that it is based on a selective reading of the Report and Recommendation and is inconsistent with how Mylan approached claim construction. As an initial matter, Mylan did not at any point during the claim construction process state or suggest that the terms on which its argument relies – "sub-antibacterial amount" and "an amount that . . . has substantially no antibiotic activity" – were limited to *in vitro* amounts. Although the parties initially disputed the proper construction of these terms, their dispute did not involve whether, as Mylan now contends, the "amounts" claimed could not have significant antibiotic effect *in vitro*, even if they lack such antibiotic effect *in vivo*. At the *Markman* hearing, Plaintiffs – unaware of Mylan's undisclosed belief that these "amounts" should be construed as "*in vitro* amounts" – agreed to Mylan's proposed construction of these terms. The undersigned magistrate judge then recommended that the parties' agreed-upon

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[7]*See* Tr. at 311 (Mylan's counsel arguing, "Our positions rely entirely on Your Honor's claim construction and . . . analysis of the claims which is a legal issue. There is no dispute about the underlying facts. It's only whether or not our position about how the claims ought to be interpreted is correct because if it is, then the underlying facts prove that there is no infringement."); *id.* at 316 ("[I]t didn't matter what he said, what Webster said because it's a matter of claim construction.").

constructions be accepted, and the Court adopted this recommendation. As Plaintiffs contend, "if Mylan wanted 'sub-antibacterial amount' construed to mean 'an amount that does not substantially inhibit the growth of microorganisms ***in vitro***,' it should have requested that construction during the *Markman* proceedings. But it did not." (D.I. 150 at 1)

Even if Mylan had disclosed its intended construction of the "amount" terms, Mylan's position would have been rejected. This is because the Ashley patents are directed to treatment of humans, from which it follows that the "amounts" claimed are *in vivo* amounts. This is reflected in the specification's numerous statements to the effect that "[t]he present invention provides a method of treating acne in a human in need thereof" and doing so by "administering . . . to the human a tetracycline compound in an amount that is effective to treat acne but has substantially no antibiotic activity." ('267 patent, col. 3 lines 45-49)[8] The whole point of these inventions is to give humans an amount of tetracycline that effectively reduces the inflammation associated with acne rosacea without killing bacteria in the same human patients. Necessarily, the invention's references to amounts (at least in the claims now at issue) are references to *in vivo* amounts.

Moreover, the portion of the Report and Recommendation on which Mylan relies does

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[8]*See also, e.g.*, '267 patent, col. 3 lines 56-62 ("These methods comprise administering systemically to the human a tetracycline compound in an amount that is effective for its purpose, e.g., to reduce the number of comedones, to inhibit oxidation of melanin, and/or to inhibit lipid-associated follicular differentiation, but has substantially no antibiotic activity."); *id.* col. 4 lines 56-60 ("The method comprises the administration of a tetracycline compound to a human in an amount which is effective for its purpose e.g., the treatment of acne, including reducing the number of comedones, but which has substantially no antibiotic activity."); *id.* col. 5 lines 32-38 ("The minimal amount of the tetracycline compound administered to a human is the lowest amount capable of providing effective treatment of acne. Effective treatment is a reduction or inhibition of the blemishes and lesions associated with acne. The amount of the tetracycline compound is such that it does not significantly prevent the growth of microbes, e.g. bacteria.").

not concern claim 1 of either the '267 or '572 patents. Instead, the disputed term "MASC" was construed as it is used in claim 12 of the '267 patent and claim 4 of the '572 patent. (D.I. 134 at 4, 15) Neither of these claims is asserted as a basis for preliminary injunctive relief. The recommended construction – "The term 'minimum antibiotic serum concentration,' as used in claim 12 of the Ashley '267 patent and claim 4 of the Ashley '572 patent, be construed as 'the lowest concentration known to exert a significant antibiotic effect'" – does not itself state whether MASC is limited to *in vitro* values or may also refer to *in vivo* values. (D.I. 134 at 15) It is true that the Report and Recommendation agreed with Mylan that MASC is "the lowest concentration of a given compound known to exert a significant antibiotic effect. . . . [It] is not a measure of the serum antibiotic level (i.e., the antibiotic level in the blood), but is instead a characteristic of the tetracycline compound. It is a constant; and it is measured in a laboratory, not in a patient's body." (*Id.* at 13) But it does not follow from this statement that every reference to a "serum concentration" or "amount" in the Ashley patents' claims must be construed to be limited to "serum concentrations" or "amounts" that do not have antibiotic effect *in vitro*. This issue was simply not before the Court.[9]

To draw the conclusion that Mylan does from the Report and Recommendation requires ignoring other portions of the analysis therein, including that the disputed claim term "the

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[9]Indeed, both parties advised the Court that very little separated their proposed constructions of MASC. *Compare Markman* Tr. at 93 (Plaintiffs' counsel introducing MASC dispute by stating, "The parties aren't too far apart here."); *id.* at 97 (Plaintiffs' counsel: "I think there's a slight difference between the two" proposals) *with id.* at 101 (Mylan's counsel: "Counsel is right. We're very close."). Plaintiffs' counsel also repeatedly stated that he did not view this claim dispute as having much impact. *See id.* at 95-96 ("Is it the most critical claim term we're arguing today? No, Your Honor, it's not."); *id.* at 97-98 ("Again I don't think this is the most critical claim we're arguing today, Your Honor.").

tetracycline compound has substantially no anti-microbial activity" refers to "a functional limitation of the tetracycline compound ***as it is administered to a mammal***, rather than a physical characteristic of the compound itself." (D.I. 134 at 11) (emphasis added) Mylan's interpretation of the recommended claim construction is also in tension with statements Mylan itself made during the claim construction process. For instance, during the *Markman* hearing, counsel for Mylan all but acknowledged that the "amounts" claimed in the patent are *in vivo* amounts, not *in vitro* amounts. Counsel stated: "[I]f you read the patent – if the Court reads the patent, ***I think it's pretty clear what 'antibacterial effective amount' means*** . . . . It's an amount that has an antibiotic effect. You're trying to kill bugs. ***It's the dosage that you give to someone*** when they have an infection." (*Markman* Tr. at 107) (emphasis added) Likewise, in its claim construction briefing, Mylan wrote as if it agreed that the "amount" terms would be measured *in vivo*, not *in vitro*: "Mylan submits that 'the antibacterial effective amount' and 'the antibiotic amount' are the ***amounts commonly recommended for treatment of microbial or bacterial infections***, examples of which are provided in the Ashley patents, cited prior art, and contemporaneous reference materials." (D.I. 55 at 19 n.6) (original emphasis omitted; emphasis added) Mylan also argued that its proposals for the "sub-antibiotic/no antibiotic activity" terms were derived from the express definitions the inventor had given these terms during prosecution. (D.I. 55 at 22) It follows that Mylan's argument is that Mr. Ashley, the inventor, expressly defined key claim terms in a manner that had the consequence of excluding from the scope of his patent the very embodiment of his invention that his employer intended to practice. There is no support in the record for this highly improbable contention. *See Dow Chem. Co. v. Sumitomo Chem. Co., Ltd.*, 257 F.3d 1364, 1378 (Fed. Cir. 2001) ("[I]t is . . . well established that a claim construction that

excluded a preferred embodiment is rarely, if ever, correct. This is because it is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way.") (internal quotation marks and emphasis omitted).

Furthermore, even assuming, *arguendo*, that Mylan is correct that the principle of dependency dictates that the subject matter covered by the narrower dependent claim 12 of the '267 patent is also covered by the broader independent claim 1, it does not follow that claim 1 is limited to amounts that are less than the MASC as measured *in vitro*. This is because Mylan's comparisons between MIC (minimum inhibitory concentration) values and MASC values are inappropriate. Even Mylan's expert, Dr. Chambers, admitted that at least 82-90% of the doxycycline found *in vivo* in serum is protein bound, and that protein binding of drugs may mean that a serum concentration 20 times the *in vitro* MIC value is necessary to have a comparable effect *in vivo*. (Webster Suppl. Decl. (D.I. 139 ¶¶ 52-53) (citing Chambers Decl. (D.I. 106) ¶ 32)) As Dr. Webster testified, MASC values, measured *in vitro*, have no necessary relationship to concentrations founds *in vivo* upon administering the same dose to a human.[10]

Therefore, Plaintiffs have shown a likelihood of success on the merits of establishing that use of Mylan's generic doxycycline product will infringe at least claim 1 of the '267 patent as

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[10]Mylan's related contention – "the term '10-80% of the minimum antibiotic serum concentration,' recited in claim 12 of the '267 patent, is a further narrowing – *i.e.*, a species or instance – of 'sub-antibacterial amount' recited in claim 1 of the '267 patent, from which claim 12 depends, as opposed to an unrelated limitation as plaintiffs assert. Moreover, because 'minimum antibiotic serum concentration' in claim 12 is an '*in vitro*' value (D.I. 134 at 13 ("it is measured in a laboratory, not in a patient's body")), the term 'sub-antibacterial amount' in claim 1 **must** include (but not be limited to) *in vitro* amounts" (D.I. 146 at 1) (citing *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1334 (Fed. Cir. 2010); *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003)) – is rejected for the same reasons given above.

well as claim 1 of the '572 patent.

B. Invalidity

"If . . . the alleged infringer responds to the preliminary injunction motion by launching an attack on the validity of the patent, the burden is on the challenger to come forward with evidence of invalidity, just as it would be at trial. The patentee, to avoid a conclusion that it is unable to show a likelihood of success, then has the burden of responding with contrary evidence, which of course may include analysis and argument." *Titan Tire*, 566 F.3d at 1377. That is, "[o]nce the challenger presents initially persuasive evidence of invalidity, the burden of going forward shifts to the patentee to present contrary evidence and argument." *Id.* at 1376-77. While "the patent enjoys the same presumption of validity during preliminary injunction proceedings as at other stages of litigation," nonetheless "it is the patentee, the movant, who must persuade the court that, despite the challenge presented to validity, the patentee nevertheless is likely to succeed at trial on the validity issue." *Id.* at 1377. Ultimately, "when analyzing the likelihood of success factor, the trial court, after considering all the evidence available at this early stage of the litigation, must determine whether it is more likely than not that the challenger will be able to prove at trial, by clear and convincing evidence, that the patent is invalid." *Id.* at 1379.

Here, Mylan asserts multiple bases for invalidating claim 1 of the '267 patent and claim 1 of the '572 patent. These are: (i) at least nine prior art references, not considered by the Examiner, anticipate the exemplary claims of the '267 patent; (ii) claim 1 of the '267 patent is also anticipated by U.S. Patent No. 6,455,583 ("Pflugfelder"); (iii) claim 1 of the '572 patent is anticipated by Sneddon; (iv) claim 1 of the '572 patent is rendered obvious by four prior art

references (including Sneddon); and (v) claim 1 of the '572 patent is obvious in light of Pflugfelder in combination with either Marmion or Sneddon. (D.I. 105 at 14-22)[11] While Mylan has come forward with evidence of invalidity, the Court finds that, nonetheless, Plaintiffs are likely to prevail on the issue of validity at trial.[12]

None of Mylan's nine prior art references that were not considered by the Examiner disclose that the tetracycline compound be administered in an amount that is sub-antibacterial; that is, that the amount be one that does not significantly inhibit the growth of bacteria in humans. (Tr. at 144-45; Webster Suppl. Decl. (D.I. 139) ¶¶ 76-157) Also, none of the nine prior art references disclose that the beneficial effects of the low dose tetracycline are anti-inflammatory, rather than antibiotic. (Webster Suppl. Decl. (D.I. 139) ¶¶ 76-157) Nor do any of the nine prior art references disclose doxycycline as the specific tetracycline compound to be used. (Tr. at 145, 156; Webster Suppl. Decl. (D.I. 139) ¶ 146) Pflugfelder, which was considered by the Examiner in connection with the '572 patent application, concerns a method for treating meibomian gland disease using tetracycline compounds, not treating acne rosacea. (Webster Suppl. Decl. (D.I. 139) ¶¶ 158, 160, 165) The Examiner understood the distinctions between these two diseases and concluded that Pflugfelder did not teach the methods of the '572 patent. (D.I. 88 Ex. W at 3) ("The closest prior art, Pflugfelder, teaches a method for treating

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[11]The complete citations to the prior art references cited by Mylan are found in D.I. 105 at 15 nn.11-12. Copies of each of the references are in the record as exhibits to the report of Mylan's invalidity expert, Dr. Gilchrist. (D.I. 114 at Exs. 9-17, 19)

[12]As with its position on infringement, Mylan insists that its position on invalidity is based solely on claim construction, and not on disputed facts. *See* Tr. at 318 ("[O]n invalidity there is no dispute that the prior art shows those percentage amounts that we went through earlier today that fall within ten to 80, it comes down to claim construction.").

meibomian gland disease associated with rosacea. Pflugfelder, however, does not explicitly teach a method for treating papules and pustules of rosacea by orally administering an antibiotic tetracycline compound in an amount of 10-80% of the antibiotic effective amount, which results in no reduction of skin microflora in long term treatment without administering a bisphosphonate compound."); *see also* Webster Decl. (D.I. 91) ¶¶ 61-63; Webster Suppl. Decl. (D.I. 139) ¶¶ 158-68.) For these reasons, none of Mylan's prior art references, either singly or in combination, anticipates nor renders obvious the claims of the Ashley patents.

Additionally, with respect to obviousness, there is strong evidence of secondary indicia of non-obviousness. This includes evidence of the commercial success of Oracea®, the long-felt need for an oral treatment for rosacea without the side effects caused by antibiotic doses of tetracycline, and industry praise for and acceptance of Oracea®. (D.I. 88 at 19-22) (citing evidence) Another objective indicator of non-obviousness is that at the same time Oracea® was introduced, Medicis Pharmaceutical Corporation launched Solodyn, a new full-dose antibiotic tetracycline treatment for acne. (Webster Decl. (D.I. 91) ¶ 90) As Plaintiffs argue, "[h]ad the prior art shown that acne could be treated with a sub-antibacterial dose of tetracycline, one would have expected the developers of new acne products such as Solodyn to have attempted to avoid the known disadvantages of administering an antibacterial dose." (D.I. 88 at 20) There is also the fact that at least three generic drug manufacturers, including Mylan, are attempting to copy Oracea®.

Two other Mylan arguments for invalidity are also unpersuasive. First, with reference to claim 1 of the '267 patent, Mylan contends that "[t]he recitation of '**said amount** being 10-80% of the antibacterial effective amount' requires that the '**said amount**' (i.e., 'sub-antibacterial

amount') is '10-80% of the antibacterial effective amount.'" (D.I. 146 at 2) However, as Plaintiffs respond, Mylan is attempting by this argument to redefine "sub-antibacterial amount," which the Court defined as a functional limitation (an amount that does not significantly inhibit the growth of microorganisms) to mean 10-80% of the antibacterial effective amount. (D.I. 150 at 2) But "Mylan did not ask the Court to construe 'sub-antibacterial amount' to mean '10-80% of the antibiotic amount.'" (D.I. 150 at 2) Furthermore, as Plaintiffs explain:

> The patents . . . do not claim every amount that is 'sub-antibacterial' but only those sub-antibacterial amounts that are also 10-80% of the antibiotic amount. . . . An amount that does not significantly inhibit the growth of microorganisms and is 85% of the antibiotic amount is still 'sub-antibacterial' but is not claimed by the patent because it is not ***also*** 10-80% of the antibiotic amount. Similarly, an amount that is 10-80% of the antibacterial amount, but significantly inhibits the growth of microorganisms, is not a sub-antibacterial amount and, therefore, is not within the scope of the claims.

(D.I. 150 at 2-3)

Second, Mylan contends, with respect to claim 1 of the '572 patent, that Plaintiffs cannot distinguish the prior art based on the prior art's failure to disclose that the administered amount "results in no reduction of skin microflora during a six month treatment" because this language appears in a "wherein" clause and merely expresses the intended result of the process step of the claim. (D.I. 146 at 3) However, as the authorities relied on by Mylan demonstrate, determining whether a "wherein" or "whereby" clause is a limitation or instead a recitation of an inherent property of the claimed method requires a fact specific inquiry. *See Griffin v. Bertina*, 285 F.3d 1029, 1034 (Fed. Cir. 2002); *see also* D.I. 146 at 7-9 (excerpt from Manual of Patent Examining Procedure, stating "[t]he determination of whether each of these clauses is a limitation in a claim depends on the specific facts of the case" and citing *Hoffer v. Microsoft Corp.*, 405 F.3d 1329,

1329 (Fed. Cir. 2005)) Here, Mylan has failed to show that the allegedly inherent properties "add nothing to the count beyond the other recited limitations and are not material to the patentability of the invention." *Griffin*, 285 F.3d at 1034. As Plaintiffs show, the Examiner added the "wherein" element to the independent claim to overcome prior art references cited, including Pflugfelder. (D.I. 147 at 3) (citing D.I. 88 Ex. H at 4 (claim 86) and D.I. 88 Ex. W at 2 (Notice of Allowability))

C. **Enforceability**

By separate order issued this same day, the Court has granted Mylan's motion for leave to file an amended answer and counterclaim to assert an affirmative defense and counterclaim that the Ashley patents are unenforceable due to inequitable conduct, by Ashley and a patent attorney, during prosecution of the Ashley patent applications. Thus, the Court must preliminarily evaluate the merits of Mylan's inequitable conduct contentions.

Inequitable conduct occurs when a patent applicant violates his or her "duty of candor and good faith . . . which includes a duty to disclose to the Office all information known to that individual to be material to patentability." 37 C.F.R. § 1.56(a) (2007). A court will hold a patent unenforceable due to inequitable conduct if there is clear and convincing evidence that the applicant, while prosecuting the patent at issue, (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the U.S. Patent and Trademark Office. *See Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1374 (Fed. Cir. 2006).

To demonstrate a failure to disclose material information, the party asserting inequitable conduct must show: "(1) prior art that was material; (2) knowledge chargeable to an applicant of

that prior art and of its materiality; and (3) failure of the applicant to disclose the art resulting from an intent to mislead the PTO." *Elk Corp. v. GAF Bldg. Materials Corp.*, 168 F.3d 28, 30 (Fed. Cir. 1999). The patentee may then rebut such proof of inequitable conduct by "a showing that (a) the prior art was not material, (b) if the prior art was material, a showing that the applicant did not know of that art; (c) if the applicant did know of the art, a showing that the applicant did not know of its materiality; or (d) a showing that the applicant's failure to disclose the art did not result from an intent to mislead the PTO." *Id.* "[A]n otherwise material reference need not be disclosed if it is merely cumulative of or less material than other references already disclosed." *Id.* at 31.

Information is considered material if there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the patent. *See Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314-16 (Fed. Cir. 2006).[13] Even where material, withheld information must also be of importance to an Examiner to be the basis for a finding of inequitable conduct. *See Abbott Labs. v. Sandoz, Inc.*, 500 F. Supp. 2d 807, 822 (N.D. Ill. 2007) (finding expert declaration to be immaterial, notwithstanding that it satisfied definition of "material" in § 1.56(b), as "[t]here still must be a showing of a substantial likelihood that a reasonable examiner would consider the statement important in deciding whether to allow the application to issue as a patent"), *aff'd*, 544 F.3d 1341 (Fed. Cir. 2008). Materiality is

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[13] *See also* 37 C.F.R. § 1.56(b) (stating information is material when "it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with a position the applicant takes in: (I) Opposing an argument of unpatentability relied on by the Office, or (II) Asserting an argument of patentability").

determined from the point of view of the reasonable examiner, not the subjective view of the patentee. *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1238 (Fed. Cir. 2003).

Mylan contends that Mr. Ashley committed inequitable conduct by failing to disclose to the PTO Examiner a 2003 FDA Memo regarding Periostat®. (D.I. 110 Ex. 28) The specification explicitly disclosed Periostat® – which it described as "doxycycline hyclate . . . administered at a 20 milligram dose twice daily . . . for the treatment of periodontal disease" – as "an especially preferred embodiment." ('267 patent, col. 5 lines 63-67) In the course of litigation between CollaGenex, which then held the patent on Periostat, and the FDA, the FDA concluded that Periostat is an "antibiotic drug" as that term is defined under the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 321(jj). To Mylan, the FDA Memo is material to the patentability of the Ashley patents: "the 2003 FDA Report concludes that Periostat does **not** result in **sub**-MIC levels of doxycycline. Rather, it reports that Periostat results in a concentration dramatically **above** the MICs of numerous pathogens, and concludes that Periostat (Ashley's preferred embodiment) 'has the capacity to inhibit or destroy strains of bacteria.' No similar information was before the Patent Office." (D.I. 146 at 2)

The Court does not agree that the FDA Memo was material. As has already been noted, the PTO already knew that doxycycline – like all tetracyclines – is an antibiotic in the sense that it has the capacity, at certain amounts or concentrations, to significantly inhibit bacteria. This basic fact is disclosed in the specification. *See, e.g.*, '267 patent, col. 3 lines 17-24 ("Clearly, the state-of-the-art teaching is that the clinical efficacy of systemically-administered tetracyclines in the treatment of acne is due, at least in significant part, to ***the antibiotic effects of the***

tetracyclines.") (emphasis added). Thus, as Dr. Webster testified, the FDA Memo was cumulative of information already disclosed by Mr. Ashley to the PTO. (Tr. at 142-43) Therefore, the FDA Memo was not material. *See Upjohn Co. v. MOVA Pharm. Corp.*, 225 F.3d 1306, 1312 (Fed. Cir. 2000) ("[A] reference need not be provided to the examiner if it is merely cumulative to or less material than other references before the examiner.").

Moreover, as explained by Dr. Webster, the FDA Memo "only describes the effect that doxycycline may have on certain bacterial strains *in vitro*. . . . [T]he *in vitro* MIC testing results disclosed in the 2003 FDA Memorandum cannot reliably be extrapolated to determine the dosage at which doxycycline inhibits the growth of bacteria *in vivo*." (Webster Suppl. Decl. (D.I. 139) ¶¶ 59-60) Thus, the FDA Memo would not have been important to the Examiner's decision. (*Id.* ¶¶ 171-72)

Even if Mylan could adduce clear and convincing evidence that the FDA Memo is material, there is simply no evidence that Mr. Ashley intended to deceive the Examiner by not disclosing it. "Materiality is not evidence of intent, which must be established as a separate factual element of a discretionary ruling of inequitable conduct." *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1356 (Fed. Cir. 2008). Mylan's contention that if Mr. Ashley had disclosed the FDA Memo then many of the positions he took before the Examiner would have been unavailable to him is incorrect. (*See* Tr. at 65; D.I. 144 at 2-3.) Mr. Ashley could have made the same statements to the FDA because his statements were based on the view that what is relevant in terms of validity are *in vivo* measurements, not *in vitro* values. Mr. Ashley surely would have explained this to the PTO.

Mylan's insistence that the record is devoid of an explanation for the non-disclosure (Tr.

at 69) is also wrong – and now outdated. By agreement of the parties (and due to a family illness), Mr. Ashley's deposition was taken following the May 24, 2010 hearing, on June 11, 2010. (Tr. at 102-03) Plaintiffs submitted excerpts of Mr. Ashley's deposition transcript to the Court along with a letter on June 16, 2010. (D.I. 160 Ex. 2) Mylan responded, including by submitting additional excerpts from the Ashley deposition, on June 18, 2010. (D.I. 161 Ex. C) In pertinent part, Mr. Ashley testified that (i) he did not think there was any prior art that showed that Periostat was a sub-antibiotic dose in humans; (ii) "in vitro data on susceptibility, or whatever, of microorganisms is utterly irrelevant in the context of the invention, and of the use in humans of sub-antimicrobial-dose doxycycline. In my opinion." (iii) he did not consider submitting the FDA Memo to the PTO; and (iv) he had no intent to deceive the PTO with respect to any aspect of his invention. (D.I. 160 Ex. 2 at 166, 168, 290, 292-93) Mr. Ashley also explicitly agreed with the proposition that "in vitro data would not be interesting or not be relevant as relates to the inhibition of microorganisms by systemic delivery of doxycycline." (D.I. 161 Ex. C at 187) Mr. Ashley further explained that "doxycycline . . . the substance is an antibiotic, yes. There was never any attempt to withhold that. Clearly, it's discussed at great length in all of the documents." (D.I. 161 Ex. C at 293) Although Mylan argues this denial is incomplete – asserting that "Ashley did ***not*** testify that (1) he held this belief during prosecution of his applications, or (2) this belief was the reason that he withheld the FDA Memo from the Patent Office" (D.I. 161 at 3) – what Mr. Ashley did testify to is sufficient to demonstrate, along with the other evidence already cited, that there is no substantial question of enforceability on the

current record.[14] At trial, the burden will be on Mylan to prove that the intent to deceive is "the single most reasonable inference able to be drawn from the evidence." *Sea Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008). On the present record, it appears to the Court that Mylan will not be able to meet this high burden.[15]

It would have been better practice for Mr. Ashley to have disclosed the FDA Memo to the Examiner. Patent applicants are expected to err on the side of disclosure. *See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997) ("It is axiomatic that [c]lose cases should be resolved by disclosure, not unilaterally by applicant.") (internal quotation marks omitted). It appears likely that Mylan will be able to prove by clear and convincing evidence that Mr. Ashley knew of the FDA Memo at the time he was prosecuting the

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[14]Mr. Ashley also testified that he did not specifically recall if he saw the FDA Memo at the time he was prosecuting the patents. (D.I. 161 Ex. C at 221-22) When pressed, Mr. Ashley eventually acknowledged with respect to the FDA Memo (and other documents he did not recall seeing at the time of prosecution), "I don't recall intentionally withholding any of these documents." (D.I. 161 Ex. C at 298-99) Even if this testimony is unhelpful to Plaintiffs, plainly it is also unhelpful to Mylan, which would have the burden at trial of proving intent to deceive by clear and convincing evidence.

[15]Mylan relies on *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006), and its three-part test: "summary judgment is appropriate on the issue of intent if there has been a failure to supply highly material information and if the summary judgment record establishes that (1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding." Even applying this test, Plaintiffs have articulated a credible explanation for not disclosing the FDA Memo: that the patent applicant viewed the FDA Memo as irrelevant and, therefore, immaterial. Moreover, even Mylan concedes that *Ferring* (to the extent it applies) only permits, but does not mandate, a finding of an intent to deceive based on circumstantial evidence when its three factors are present. (D.I. 149 at 2; Tr. at 322 ("[Y]ou can infer intent when those three prongs of the test [are] met."))

Ashley patents.[16] His knowledge and non-disclosure, however, do not themselves constitute inequitable conduct rendering his patents unenforceable.

This conclusion is bolstered by the findings of the district court in litigation between the FDA and CollaGenex about the FDA's decision to treat Periostat as an antibiotic drug, which is the subject of the undislcosed FDA Memo. The district court described the FDA Memo as providing two reasons for the FDA's decision to classify Periostat as an antibiotic drug. *Collagenex Pharms., Inc. v. Thompson*, 2005 WL 256561, at *6 (D.D.C. Jan. 19, 2005). The court wrote:

> The 2003 Decision concurred that Periostat is properly classified as an antibiotic drug for two reasons; *first*, that the amount of doxycycline hyclate in a daily dose of Periostat of 40 mg (two 20-mg capsules) "inhibit some micro-organisms as determined by *in vitro* susceptibility testing;" and *second*, that the most reasonable interpretation of the statutory language is that "any drug intended for human use containing *any quantity* of an antibiotic substance is considered to be an antibiotic drug.

Id. The first of these reasons is arguably material to the PTO, but was cumulative. The second was irrelevant to the PTO.

Moreover, under the statute involved in the litigation, 21 U.S.C. § 321(jj), an antibiotic drug is defined (in pertinent part) as "any . . . drug intended for human use containing *any quantity* of any chemical substance which is produced by a micro-organism and which *has the capacity to inhibit or destroy micro-organisms in dilute solution.*" (Emphasis added) Hence, the

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[16]Mr. Ashley is not only the named inventor on the '267 and '572 patents; he also served as Senior Vice President of Commercial Development at CollaGenex Pharmaceuticals, Inc. and, in that capacity, was responsible for overseeing the efforts of CollaGenex to obtain FDA approval of Periostat. (D.I. 109 Ex. 16 ¶ 1)

issue considered by the FDA, and the district court, was whether a 40 mg dose of doxycycline has "the capacity to inhibit or destroy micro-organisms" *in vitro*. The PTO knew that doxycycline has this capacity, an issue that was never in dispute during prosecution of the Ashley patents or in the instant litigation. As the district court observed, "[t]here is really no dispute that doxycycline is an antibiotic drug that was subject to pre-FDAMA approval by FDA." *CollaGenex*, 2005 WL 256561, at *10.

Finally, the district court expressly "decline[d] to rely on the *in vitro* tests as these results directly contradict testing performed by CollaGenex and accepted in 1998 by the FDA . . . and because the record is unclear as to the reliability of *in vitro* tests." *Id.* at *6 n.14 (internal citations omitted). For the same reasons, again, the FDA Memo would not have been important to the Examiner's analysis of the Ashley patent applications, as these applications deal with *in vivo* administration of sub-antibiotic amounts of doxycycline.

II. Plaintiffs Have Demonstrated Irreparable Harm

Plaintiffs identify numerous irreparable harms they contend they will suffer in the absence of preliminary relief. These harms are loss of market share (Tr. at 196, 213-22), price erosion (Tr. at 214), loss of research opportunities and community education opportunities (Tr. at 195-96, 202-03), and loss of brand recognition (Tr. at 198).[17] Plaintiffs also contend "there is a substantial possibility of significant downsizing or elimination of the rosacea sales force and dedicated marketing personnel." (D.I. 88 at 25) To Plaintiffs, these harms are irreparable

[17]Plaintiffs also contend that, having met their burden on likelihood of success on the merits, they enjoy a presumption of irreparable harm. (D.I. 88 at 22-25; Tr. at 295) However, as many courts have recognized, "irreparable harm can no longer be presumed." *Albany Molecular Research, Inc. v. Dr. Reddy's Labs., Ltd.*, 2010 WL 2516465, at *10 (D.N.J. June 14, 2010); *see also Winter*, 129 S. Ct. at 375-76; *eBay Inc. v. MercExchange L.L.C.*, 547 U.S. 388, 393 (2006).

because they will be difficult if not impossible to quantify and will not be fully compensable by payment of money damages.

In support of its contentions, Plaintiffs have placed in the record declarations and testimony of Brian Johnson, Galderma's Vice President of Prescription Marketing, and Dr. Jerry Hausman, Professor of Economics at the Massachusetts Institute of Technology. In particular, Dr. Hausman testified that, typically, branded drugs lose 50-75% of their market share within six months of market entry by a generic competitor. (Tr. at 220-21; *see also* D.I. 90 ¶ 6.) Dr. Hausman anticipates that something similar will occur upon Mylan's introduction of its generic version of Oracea®. (Tr. at 222) He adds that the impact of Mylan's generic would outlast this litigation, even if Plaintiffs ultimately prevail at trial, in part due to "inventory overhang" and the fact that third-party payers for pharmaceutical products will resist paying the current price for Oracea® once they experience paying a much lower price for Mylan's generic version of it. (Tr. at 222-23)

Mylan responds to Plaintiffs' evidence by providing declarations from Jason Harper, Mylan's Executive Director of Product Portfolio Management, and Dr. Philip B. Nelson, Mylan's damages expert. Mylan contends that the evidence supports the view that "[l]ost sales of Oracea are easily calculable and compensable and, thus, not irreparable." (D.I. 105 at 2) Mylan cites to earlier examples of generic competition with branded pharmaceuticals (Plavix, Solodyn, and OxyContin) as "conclusively demonstrat[ing] that there is no irreparable harm from an interim launch" of a generic that is subsequently removed from the market after trial. (D.I. 105 at 2) Further, "[h]istory demonstrates that the market is likely to return to the *status quo ante* upon withdrawal of the generic product." (D.I. 105 at 25)

Depending on circumstances, evidence of price erosion, loss of market share, loss of profits, loss of research opportunities, and possible layoffs may constitute irreparable harm. *See Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1010 (Fed. Cir. 2009); *Purdue Pharma*, 237 F.3d at 1368 (holding that evidence of likelihood of price erosion and loss of market position caused by generic's entry to market may support a finding of irreparable harm); *Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 342 (S.D.N.Y. 2006), *aff'd* 470 F.3d 1368, 1382-83 (Fed. Cir. 2006) (granting preliminary injunction based on "independent evidence of irreparable harm, namely, evidence that this Court credits that [branded manufacturer] will suffer irreversible price erosion, loss of good will, and will be forced to lay off personnel and discontinue research devoted to developing other medical uses for Plavix"). This is due in part to the fact that "[t]he structure of the pharmaceutical market makes it difficult to determine the effect of generic competitor market entry." *Abbott Labs*, 500 F. Supp. 2d at 844 (describing three-level pricing tier system).[18] Still, in any particular case, the type of evidence and harms

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[18] *Abbott*, 500 F. Supp.2d at 844, explains this well:

> The structure of the pharmaceutical market makes it difficult to determine the effect of generic competitor market entry. Most prescription drug purchases in the United States are paid for, at least in part, by employer-sponsored health insurance plans or by government programs like Medicaid. When a pharmaceutical enters the market, insurance companies, managed care organizations, and Medicaid plans decide whether to place the drug on their pharmaceutical formularies. The formulary is a list of approved medications for which the plan will pay some part of the cost. These formularies are, in many instances, divided into three tiers. The first tier comprises low cost generic products. The second tier comprises "preferred branded" products. The third tier comprises "non-preferred branded" products. Patients must pay more out-of-pocket for drugs listed on a higher tier than for a drug of the same price listed on a lower tier. The managed care provider

cited by Plaintiffs may be either accepted or rejected by a court.[19]

The Federal Circuit has also stated: "The patent statute provides injunctive relief to preserve the legal interests of the parties against future infringement which *may have* market

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> typically pays more for drugs listed on a lower tier (e.g., Tier 1) than for a drug of the same price listed on a higher tier (e.g., Tier 3). The Medicaid formulary does not have tiers; either a drug is listed on the formulary (also known as the preferred drug list) or it is not. If the drug is not on the Medicaid formulary, the program will not cover any portion of its cost. If a doctor prescribes a non-formulary drug to a Medicaid patient, the patient must pay the entire cost out-of-pocket.
>
> When a generic version of a branded product enters the market, managed care providers generally add the generic to their formulary on Tier 1. They will then move the branded product to a higher position (e.g., from Tier 2 to Tier 3). Some plans will remove the branded drug from their formulary altogether. If the generic product is AB rated, meaning that the FDA considers it therapeutically equivalent to the branded product, many pharmacies will substitute the generic product for the branded product unless the physician specifies on the prescription form "Dispense as Written." Medicaid programs typically remove branded products from their formularies altogether once a generic has entered the market.

[19]*Compare, e.g.*, *Albany Molecular Research*, 2010 WL 2516465, at *11 (decision of Chief Judge Brown, cited by Plaintiffs, preliminarily enjoining launch of generic drug due to, *inter alia*, loss of market share, price erosion, loss of research opportunities, and loss of brand recognition); *id.* ("Though many of the damages alleged will 'boil down to money,' the calculation of these damages will be very difficult.") *with King Pharms., Inc. v. Sandoz, Inc.*, 2010 WL 1957640, at *5 (D.N.J. May 17, 2010) (decision of Chief Judge Brown denying preliminary injunction, rejecting testimony of Dr. Hausman that two months of damages resulting from generic entry would be "extremely difficult to estimate," and noting Hausman "gives no reason why these damages are more difficult to estimate or calculate than in any other patent case") (internal quotation marks omitted); *id.* ("[C]ourts have routinely decided that market share and price erosion do not amount to irreparable harm.") *and Novartis Pharms. Corp. v. Teva Pharms. USA. Inc.*, 2007 WL 2669338, at *14 (D.N.J. Sept. 6, 2007) ("[I]n the context of generic competition in the pharmaceutical industry, courts have held that loss of market share is a compensable injury.") (citing cases).

effects never fully compensable in money." *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1557 (Fed. Cir. 1994) (emphasis added). Additionally, "[b]ecause the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole." *Hybritech*, 849 F.2d at 1456-57.

Here, the Court is persuaded, although just barely, by the evidence of irreparable harm offered by Plaintiffs. It is more likely than not that Plaintiffs would suffer some irreparable harm if Mylan launches its generic version of Oracea® and, thereafter, Plaintiffs prevail on the merits at trial. There is no doubt that Plaintiffs would lose market share; they would also almost certainly experience lost profits and price erosion. While the Court does not believe that measuring these harms would be impossible, it would be very difficult (largely because the market is dominated by third-party payers), and the Court is convinced that not all of the harm would be fully compensable by a monetary payment from Mylan to Plaintiffs.[20]

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[20]Despite the testimony of Galderma's Johnson (Tr. at 188-89, 202-03), the Court does not find credible Plaintiffs' insistence that, almost immediately after a judicial decision to deny a preliminary injunction, they would terminate essentially the entirety of their Oracea® sales force and eliminate at least 90% of their promotional expenditures for Oracea®. As Professor Hausman testified, in the somewhat analogous situation of the introduction of a generic competitor to Plavix, marketing expenditures declined by about 25% – not 100%. (Tr. at 240-41) Professor Hausman's view appears to be that the economically rational course for Galderma in the absence of a preliminary injunction would be to reduce, but not eliminate, promotional expenditures for Oracea®. *See* D.I. 140 ¶ 3 ("Even if Galderma knew with certainty that it would prevail at trial, it would be economically irrational for Galderma to continue promoting Oracea® *at the same level* during the period of generic entry as before generic entry because of the 'free riding' concern . . . .") (emphasis added); *id.* ("Because generic entry reduces the marginal benefit of promotion, it would be economically irrational for Galderma not *to reduce* promotion.") (emphasis added); Tr. at 243 (Professor Hausman testifying he would expect Galderma to *reduce* promotional expenditures "a lot more" than Plavix did). Mylan's expert, Dr. Nelson, notes some of the reasons it would be economically rational for Galderma to continue promotional efforts on behalf of Oracea® even without a preliminary injunction, if Galderma

III. Plaintiffs Have Demonstrated That The Irreparable Harm To Themselves Outweighs Any Harm Defendants Might Suffer From A Preliminary Injunction

The Court next considers the harm Mylan would suffer if it is preliminarily enjoined but then, after trial, the Court concludes that the preliminary injunction should not have been granted. Mylan contends that it would be hurt by a preliminary injunction in three ways: from the delay in entering the market, from loss of some portion of its period of exclusivity, and from the possibility that the injunction would give Plaintiffs additional time to pursue strategies to diminish the success Mylan could otherwise expect to enjoy when it introduces its generic product. The Court will consider each of these asserted harms in turn.

Mylan, as the first filer of an ANDA relating to Oracea®, is entitled (under the circumstances presented here) to a 180-day period of exclusivity, during which time the FDA is precluded from approving any additional generic version of Oracea®. Hence, although there are two other ANDA filers (Impax and Lupin), it is undisputed that a preliminary injunction would not change Mylan's position relative to Impax and Lupin; that is, Mylan would still have an exclusivity period of 180 days. (D.I. 138 at 10; D.I. 88 at 28; Tr. at 281) (Mylan's counsel admitting there is "no doubt" Mylan will have at least 180 days of exclusivity as non-authorized generic product even if preliminary injunction is granted) Whether Mylan enjoys these 180 days

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believes it will prevail at trial. (D.I. 111 ¶¶ 6, 37) ("It would be economically irrational for Galderma to significantly cut promotions if it is confident in the merits of its patent case, given the strong recent growth of the Oracea® brand, the likelihood that promotions have a continuing effect beyond the period of promotion, and the use of a sales force that promotes multiple dermatological brands. . . . Continued promotion is rational during the interim period because evidence shows that Galderma should expect to convert new Mylan generic prescriptions into continuing Oracea® prescriptions assuming Galderma prevails.") Given this record, as well as the fact that trial is scheduled to take place in less than six months, and that Plaintiffs insist it would take a year to rebuild their Oracea® sales force, the Court is not persuaded that Plaintiffs would immediately take the drastic cutback measures they forecast if their motion is denied.

of exclusivity from July to December 2010, in the absence of a preliminary injunction, or sometime in 2011, following trial and a final judgment for Mylan, is neither a substantial nor irreparable harm.[21] Instead, it is merely "time-shifting" of revenues. *See Glaxo Group Ltd. v. Apotex, Inc.*, 64 Fed. Appx. 751, 756 (Fed. Cir. 2003) (affirming grant of preliminary injunction where "without the preliminary injunction, [patentee] would lose the value of its patent while [generic manufacturer] would only lose the ability to go on the market and begin earning profits earlier"); *Albany Molecular Research,* 2010 WL 2516465, at *11 ("Any sales that [the generic manufacturer] would lose if this injunction is improvidently granted would be time-shifted, and lost sales will not be destroyed.").

Mylan's second asserted harm is also related to exclusivity. Mylan contends that if it were permitted to begin marketing its generic version of Oracea® on July 1, 2010, Mylan would actually enjoy more than 180 days of exclusivity. In fact, Mylan might have up to 17 months of exclusivity, instead of the typical six months. This is because, due to a statutory amendment, Mylan believes it is not subject to an automatic 30-month stay of FDA approval of its ANDA. (*See* Tr. at 279-80; D.I. 111 ¶ 68.) Plaintiffs appear to agree. (D.I. 137 at 6) By contrast, the other ANDA filers are subject to such a stay and, evidently, cannot obtain FDA approval of their generic versions of Oracea® until at least December 2011. (Tr. at 280; D.I. 111 ¶ 68) Hence, in Mylan's view, in the absence of a preliminary injunction, Mylan might have the exclusive (unauthorized) generic version of Oracea® on the market from July 2010 to December 2011.

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[21]This is all the more so because there is no indication that Mylan has yet to receive FDA approval, which is a prerequisite to launch of its generic product, whether or not the Court enters a preliminary injunction. *See* Tr. at 325 (Mylan acknowledging it had not received FDA approval as of date of hearing).

(D.I. 161 at 2) ("An injunction will destroy the exclusivity advantage Mylan obtained by not being subject to a 30-month stay, unlike other generic competitors. . . . Mylan will irrevocably lose periods of exclusivity (well beyond 180 days) to which it is otherwise entitled.")

Assuming Mylan is correct, and assuming Mylan obtains FDA approval imminently, the "loss" of up to 11 extra months of exclusivity is not a legally cognizable harm for purposes of a preliminary injunction motion. The careful statutory framework enacted by Congress, balancing the important competing interests of branded pharmaceutical companies and generic pharmaceutical companies, relies on the incentives created by a 180-day period of exclusivity to the first ANDA filer. The additional 11 months Mylan might enjoy in the unusual circumstances presented here are not something to which Mylan has a statutory, or equitable, entitlement. The Court does not accord this harm great weight.

The third harm cited by Mylan is that insulating Oracea® from generic competition for another six to nine months or more, until after trial and judgment, will permit Plaintiffs to implement strategies to thwart the impact of impending generic competition. These strategies include Plaintiffs launching an authorized generic product or modifying Oracea® (e.g., introducing a tablet to compete with Mylan's generic capsule) in a way that might shift consumer demand to "new Oracea®" rather than to Mylan's generic version of "old Oracea®." (D.I. 161 at 2) (citing Tr. at 195, 285-87) Plaintiffs are not yet ready to implement either of these "line extension" strategies. (Tr. at 195, 200-01) However, Galderma has done so in the past with respect to other products faced with losing market exclusivity. (D.I. 111 ¶ 72)

Mylan is correct that a preliminary injunction will provide Plaintiffs additional time to pursue such strategies, if Plaintiffs choose to do so. However, Mylan's assertion that "a

Galderma line extension would likely render Mylan's ANDA valueless" is not convincing. (D.I. 108 ¶ 3) Plaintiffs have always had the right to pursue such strategies and could have done so over the 15 months this case has been pending. The possibility that Plaintiffs would implement such a strategy has been known to Mylan from the time it chose to prepare its ANDA. If it is as easy as Mylan suggests to render an ANDA utterly devoid of value, it is difficult to fathom how Mylan can have accomplished the success its own witness reports. (*See* D.I. 108 ¶ 5 (Mylan's Mr. Harper declaring: "Mylan currently offers over 200 generic products in the United States and generated $2.18 billion in revenue from generic drug sales in the North American market. Mylan invested $275 million in 2009 in research and development bringing more affordable drugs to market. Mylan has approximately $10.8 billion in assets and $380 million in cash and equivalents on hand going into 2010.").)

Two other factors are relevant to assessing the harms to Mylan and weighing them against the potential harms to Plaintiffs. First is the fact that the Court will, in connection with granting the preliminary injunction, impose upon Plaintiffs the obligation that they post a sizeable bond. Mylan will have the opportunity to ask the Court to allow it to draw on the value of the bond if it turns out that the preliminary injunction has been improvidently granted. In this way, the bond mitigates the harms that Mylan will suffer. *See Glaxo Group*, 64 Fed. Appx. at 756 (holding enjoined generic manufacturer's "loss of profit is secured by the issuance of the bond if the ultimate ruling is non-infringement or patent invalidity"). Second, the harms Mylan will suffer are quantifiable, moreso and more easily than the harms Plaintiffs would suffer in the absence of a preliminary injunction. (Hausman Suppl. Decl. (D.I. 140) ¶ 32 ("[T]he only harm to Mylan from a preliminary injunction is lost profits during the pre-trial period. At the time of trial, sales

of Oracea® during this period will be known, and hence it will be possible to estimate Mylan's lost profits by estimating what Mylan's sales would have been had a preliminary injunction not issued.")) The Court agrees with Plaintiffs that "Mylan's hardship, if the injunction were granted and Mylan ultimately prevailed at trial, would be 'reasonably quantifiable and capable of being protected against by a bond if need be.'" (D.I. 88 at 27) (quoting *Sandoz*, 500 F. Supp. 2d at 844-45)

Thus, on the whole, the balance of harms favors Plaintiffs.

IV. The Public Interest Is Served By A Preliminary Injunction

As other courts have recognized in similar cases, "there are competing – and substantial – public interests at stake on both sides of this litigation." *Sanofi-Synthelabo*, 488 F. Supp. 2d at 321. In particular, "the public interest in lower-priced drugs is balanced by a significant public interest in encouraging the massive investment in research and development that is required before a new drug can be developed and brought to market." *Id.* at 345. In an ANDA case, the Federal Circuit noted: "[T]he public interest includes consideration of whether, by shifting market benefits to the infringer while litigation is pending for patents that are likely to withstand the attack, the incentive for discovery and development of new products is adversely affected. The statutory period of exclusivity reflects the congressional balance of interests, and warrants weight in considering the public interest." *Abbott Labs.*, 544 F.3d at 1362; *see also Pfizer Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005) ("[W]hile the statutory framework under which [defendant] filed its ANDA does seek to make low cost generic drugs available to the public, it does not do so by entirely eliminating the exclusionary rights conveyed by pharmaceutical patents. Nor does the statutory framework encourage or excuse infringement

of valid pharmaceutical patents.").

Here, the Court concludes that the public interest favors Plaintiffs, who hold a patent that the Court has found will likely be proven to be valid, enforceable, and infringed by Mylan's proposed generic product. In the present circumstances – and particularly given that trial is only six months away – the public interest in recognizing Plaintiffs' patent rights, and more generally promoting continued, large-scale investment in research and development of new pharmaceuticals, outweighs the public's interest in promoting generic, low-cost alternatives to branded pharmaceuticals. *See Smith Int'l, Inc. v. Hughes Tools Co.*, 718 F.2d 1573, 1581 (Fed. Cir. 1983) ("[P]ublic policy favors the protection of the rights secured by . . . valid patents."); *King Pharms.*, 2010 WL 1957640, at *6 ("The Court concludes that the public interest in protecting patent rights outweighs the public interest in low cost generic drugs, and thus this factor favors King [the patentee-branded manufacturer]."); *Sanofi-Synthelabo*, 488 F. Supp. 2d at 321 ("[T]he balance of those competing public interests slightly favors Sanofi [the branded patentee]."); *Impax Labs. v. Aventis Pharms., Inc.*, 235 F. Supp. 2d 390, 397 (D. Del. 2002) ("[T]here is a strong public interest in protecting valid patents by preventing the premature entry of generic drugs into the marketplace."); Hausman Suppl. Decl. (D.I. 140) ¶ 33 ("A failure to grant a preliminary injunction would reduce the incentives for innovation in new drugs, and thereby cause a substantial reduction in consumer welfare.").

V. Relief

Given that Plaintiffs have satisfied their burden, the Court will enter a preliminary injunction, enjoining Mylan from bringing its generic version of Oracea® to market until after the Court enters a judgment on the merits following trial. Pursuant to Federal Rule of Civil

Procedure 65(c), the Court will also require Plaintiffs to give security "in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined." *See also Zambelli Fireworks Mfg. Co. v. Wood*, 592 F.3d 412, 425 (3d Cir. 2003); *Frank's GMC Truck Center, Inc. v. General Motors Corp.*, 847 F.2d 100, 103 (3d Cir. 1988).

A party injured by the issuance of an injunction later determined to be erroneous has no action for damages stemming from the injunction in the absence of such a bond. *See W.R. Grace v. Local 759, Int'l Union of the United Rubber, Cork, Linoleum & Plastic Workers*, 461 U.S. 757, 770 (1983). However, an improvidently enjoined party may collect damages up to the value of the bond, in the discretion of the district court. *See Sprint Commc'ns Co. v. Cat Commc'ns Int'l, Inc.*, 335 F.3d 235, 240 (3d Cir. 2003); *Hupp v. Siroflex, Inc.*, 122 F.3d 1456, 1467-68 (Fed. Cir. 1997); *Virginia Plastics Co. v. Biostim, Inc.*, 820 F.2d 76, 80-81 n.6 (3d Cir. 1987). The amount of the bond is determined according to the law of the district court's regional circuit. *See Int'l Game Tech. v. WMS Gaming Inc.*, 1999 WL 717801, at *1 n.1 (Fed. Cir. Sept. 3, 1999); *see also Sanofi-Synthelabo*, 488 F. Supp. 2d at 349 ("[T]his Court has found no authority from the Federal Circuit governing the parameters for the amount of the bond – and the parties have supplied none . . . .").

Plaintiffs propose to post a bond in a "reasonable" amount, (D.I. 138 at 10 n.9), which they suggest is $4 million (D.I. 147 at 1). This amount is approximately 40% of Plaintiffs' profit on Oracea® for three months. (D.I. 147 at 1) Plaintiffs propose to post this bond within 10 days of receipt of notice from Mylan that it has received FDA approval. (*Id.*) Mylan, on the other hand, requests a bond of at least [redacted] (D.I. 149 at 3) According to Mylan, this is what

Mylan's gross margin would be on sales of its generic product between June 2010 and February 2011. (*Id.*; *see also* D.I. 108 ¶ 3.)

The Court will require Plaintiffs to post a bond in the amount of $26 million. Between July 2010, just after entry of the preliminary injunction, and February 2011, which Mylan identifies as a reasonable estimation of the date judgment will be entered, Plaintiffs expect to make profits of approximately $26 million on sales of Oracea®.[22] Although Mylan contends it will lose approximately [redacted] in this time frame [redacted] the Court does not believe the circumstances here warrant requiring Plaintiffs to post a bond that exceeds ***Plaintiffs'*** expected profits during the anticipated length of the injunction. The Court will require Plaintiffs to post the bond within 10 days of receipt of notice from Mylan of FDA approval of Mylan's ANDA.[23]

CONCLUSION

For the reasons provided above, Plaintiffs' motion for a preliminary injunction is **GRANTED**. An appropriate Order will be entered.

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[22]The Court arrives at this estimate based on Plaintiffs' representation that 40% of profits on three months of sales is $4 million, which implies that 100% of profits on three months of sales is $10 million, which translates into monthly profits of approximately $3.3 million. Hence, eight months of profits (July to February) is approximately $26.4 million ($3.3 million x 8 months).

[23]The Court rejects Mylan's request that, if a preliminary injunction is granted, Plaintiffs be precluded from launching an authorized generic or taking other life-cycle actions to thwart the impact of an eventual generic launch by Mylan. (D.I. 105 at 30) Mylan has already received "credit" for the potentially adverse impact of such actions by Plaintiffs in the Court's analysis of the balance of harms and in setting the amount of the bond.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK; NEW YORK UNIVERSITY; GALDERMA LABORATORIES INC.; AND GALDERMA LABORATORIES, L.P.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 09-184-GMS-LPS
MYLAN PHARMACEUTICALS INC.,	:	
Defendant.	:	

ORDER GRANTING MOTION FOR PRELIMINARY INJUNCTION

At Wilmington, this 28th day of June 2010, for the reasons discussed in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that:

1. Plaintiffs' motion for a preliminary injunction (D.I. 87) is **GRANTED**.

2. The parties shall submit, within three (3) days of this Order, a proposed form of Order consistent with and giving effect to the rulings set forth in the Memorandum Opinion issued this date.

UNITED STATES MAGISTRATE JUDGE