UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GRACEWAY PHARMACEUTICALS, LLC, and 3M INNOVATIVE PROPERTIES CO., **Plaintiffs,** **v.** **PERRIGO COMPANY, PERRIGO ISRAEL PHARMACEUTICALS LTD., and NYCOMED U.S. INC.,** **Defendants.**	**Civil Action Number: 2:10-cv-00937** **OPINION** **HON. WILLIAM J. MARTINI**

OPINION

I. INTRODUCTION

This patent action is brought by Plaintiffs Graceway, LLC ("Graceway") founded in 2006, and Plaintiff 3M Innovative Products Co. ("3M IPC") against Defendant Nycomed U.S. Inc. ("Nycomed") for allegedly infringing Graceway's '672 Patent (Patent No. 7,655,672) which was approved on February 2, 2010. Suit was filed February 23, 2010. Nycomed launched its allegedly infringing product on February 25, 2010, and a temporary restraining order ("TRO") was sought by Plaintiffs on February 28, 2010 based on a limited evidentiary record. On March 8, 2010, this Court denied Plaintiffs' motion for a temporary restraining order.

Plaintiffs have now sought a preliminary injunction after limited discovery. For the reasons elaborated below, the Court will **DENY** the motion for a preliminary injunction.

II. FACTS AND PROCEDURAL POSTURE

As the facts are well known to the parties, the Court refers the reader to the facts as developed in this Court's March 8, 2010 opinion. *See* Doc. No. 40. Since that time Defendants Perrigo Company and Perrigo Israel Pharmaceuticals Ltd. have been dismissed

from this suit; Nycomed has filed a Motion to Dismiss Pursuant to Rule 11, and Graceway has filed the instant motion for a preliminary injunction. The Court will address Nycomed's Rule 11 motion to dismiss in a separate opinion and order, which will follow in short order. This opinion responds to Graceway's motion for a preliminary injunction.

III. LEGAL STANDARD

The legal standard for granting a preliminary injunction is well-settled. *See* Fed. R. Civ. P. 65(a). "The four factors relevant to the district court's decision to grant or deny a preliminary injunction are (1) the likelihood of the patentee's success on the merits; (2) irreparable harm if the injunction is not granted; (3) the balance of hardships between the parties; and (4) the public interest." *Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1200-01 (Fed. Cir. 2007). The adequacy of money damages is a factor to be considered in deciding whether or not harm is irreparable. Furthermore, in reaching a determination under this standard, the Court applies well-established equitable principles and standards. *Cf. eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393 (2006) (precluding, in the permanent injunction context, the use of "expansive principles" to "broad swath[es] of cases" or the use of "general rule[s]... unique to patent disputes," apart from the four-factor test).

IV. ANALYSIS

This opinion discusses the four factor test for granting a preliminary injunction and certain threshold defenses.

A. Threshold Defense: Dilatory Conduct

A legal right against infringement, even where established, does not, without more, establish a right to injunctive relief. Injunctive relief, particularly where a party seeks preliminary relief, based on a limited record, is, as all authorities acknowledge, not a matter of mere legal right, that is, injunctive relief is not a "standard remedy;" rather it is a form of "extraordinary" relief. *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996). Such a remedy will not be granted "whenever the plaintiff has shown a likelihood of success on the merits," *id.*, nor will it be granted in the face of a movant's inequitable conduct, including unjustified delay or dilatory conduct. *See, e.g.*, *Intirtool, Ltd. v. Texar Corp.*, 369 F.3d 1289, 1290 (Fed. Cir. 2004). An otherwise valid infringement claim seeking injunctive relief may not succeed in the face of plaintiff's unjustified, unreasonable, or unexplained delay. *A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1033 (Fed. Cir. 1992) ("Economic prejudice may arise where a defendant and possibly others will suffer the loss of monetary investments or incur damages which *likely* would have been prevented by earlier suit." (emphasis added)).

In 2007, Defendant Nycomed sent Plaintiff Graceway a notice letter in regard to Nycomed's ANDA application for its product, a proposed bioequivalent to Graceway's Aldara. Graceway received this notice letter after Graceway had applied for the '672 Patent. At that time, Graceway took no concrete action putting Nycomed on notice of litigation risk and, again, took no such action, including filing a complaint, in immediate consequence of actual approval of the '672 Patent on February 2, 2010. Instead, Plaintiff filed its complaint on February 23, 2010, and the TRO was filed on February 28, 2010. Plaintiffs' TRO briefing was void of substantial explanation in regard to Plaintiffs' failure to contact Nycomed and in regard to why Plaintiffs' failed to put Nycomed on express notice of its litigation risk prior to February 23, i.e., that Graceway would sue to enjoin exploitation of the '672 Patent, a patent that Graceway does not practice. Nor did the TRO briefing account for the delay in the period between February 2 and February 23. Given the lack of explanation, and the Court's preliminary determination based, on the limited record at the TRO stage, that damages to Nycomed were likely and could have been minimized by earlier suit (or, even by earlier letter communications from Graceway to Nycomed), *A.C. Aukerman Co.*, 960 F.2d at 1033, the Court found Plaintiffs' conduct dilatory.

On further reflection, in view of a better developed record, it is clear that both parties could have acted more diligently. It is also reasonable to conclude that Nycomed knew of the '672 Patent not only prior to its launch, but also prior to Plaintiffs' filing this suit. Each party knew or had substantial knowledge of what the other party was doing in terms of the ANDA filing and the '672 Patent. And although each party could have exercised more caution, by putting the other party on express notice of the concrete litigation risks involved, the parties here are sophisticated and knew or should have known of those risks. The equities here are close and the Court is now unwilling to conclude that Plaintiffs' conduct was dilatory. Moreover, in order to establish laches, a defendant must make a showing in regard to material prejudice. *Intirtool, Ltd. v. Texar Corp.*, 369 F.3d 1289, 1290 (Fed. Cir. 2004) ("The laches defense has two underlying elements: first, the patentee's delay in bringing suit must be unreasonable and inexcusable, and second, the alleged infringer must have suffered material prejudice attributable to the delay." (quotation marks omitted)). At this preliminary injunction stage, Plaintiff now presses the argument that Defendant Nycomed was not substantially prejudiced by Plaintiffs' delay. Nycomed's opposition filings do not meaningfully respond to this argument with substantial supporting evidence (as opposed to mere attorney argument appearing in its brief). Thus, even if this Court were to conclude that Plaintiffs' conduct had been dilatory, this by itself is insufficient to establish a laches defense. Based on the post-discovery expanded record in these proceedings, the fact that Graceway brought suit (although not its TRO motion) prior to Nycomed's launch, and, most importantly, Nycomed's failure to meaningfully respond to Plaintiffs' argument with evidence, the Court determines that Nycomed's argument for laches (and, likewise,

estoppel[1]) fails.

B. Nycomed's License Defense

Nycomed argues that because Plaintiff 3M recently granted (former Defendant) Perrigo a license under the '672 Patent, Graceway no longer holds an exclusive license and therefore lacks standing to sue. Graceway responds that the licensing agreement is between Graceway and Perrigo, with the latter as sublicensee of the former. Graceway therefore holds an exclusive license from 3M and it (Graceway) has sublicensed to Perrigo. This is a factor militating in favor of Graceway as an exclusive licensee, which therefore continues to have standing. *See* *Sicom Sys., Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 977 (Fed. Cir. 2005) ("We are further troubled by the fact that the agreement gives Prima Tek I virtually no control over the ability to sub-license the patents.").

Moreover, the Court notes that neither party has put forward the license agreement at issue. *See* *Sicom Sys.*, 427 F.3d at 976 ("Each license and assignment is unique, therefore this court must ascertain the intention of the parties and examine the substance of what [the licensing agreement] granted to determine if it conveys all of the substantial rights in the patent and is sufficient to grant standing to the licensee."). Because Nycomed has had access to discovery, and it has, nevertheless, failed to put forward the agreement, it appears that Nycomed's defense fails.

C. Nycomed's Remaining Defenses

Nycomed argues that Graceway has taken inconsistent positions in these proceedings and before the FDA in regard to Nycomed's Product. Nycomed's position – apparently akin to judicial estoppel – comes absent any supporting legal authority. Arguments absent substantial development are waived. *See* *Conroy v. Leone*, 316 Fed. Appx. 140, 144 n. 5 (3d Cir. Mar. 9, 2009) ("We find this undeveloped argument has been waived."); *Clay v. Holy Cross Hosp.*, 253 F.3d 1000, 1002 n.1 (7th Cir. 2001).

Likewise, Nycomed argues that Graceway refused to provide it with the procedures Graceway followed to duplicate or test its (Nycomed's) product. But what particular information Nycomed lacked is left unexplained. Nycomed has had access to discovery. If it had an entitlement to such information during these proceedings, there was (and yet

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[1] Nycomed's estoppel argument also fails because Nycomed fails to elucidate any duty to speak that Plaintiff Graceway owed Nycomed – either a duty imposed by law, contract, or connected to the parties' prior course of dealing.

remains) in place a process by which it could seek this information. If Graceway failed to produce such sought after information, Nycomed could move to compel. No such motion has been brought to this Court's attention. If Nycomed has not availed itself of these discovery procedures, it has no cause for complaint.

Finally, Nycomed argues that no injunction should issue to keep new technology off the market facilitating an important public need where the patent holder does not practice the patent. As a mere abstract point of law, there is case law supporting Nycomed's position. However, Nycomed does not put forward any concrete evidence tending to establish that its product fills just such a public need not already filled by Aldara, Graceway's product.

D. The Four Factor Test For Injunctive Relief

1. The Likelihood Of The Patentee's Success On The Merits

Defendant does not actively contest Plaintiffs' claim construction. Likewise, Defendant only makes scattershot arguments in regard to infringement. For example Nycomed makes the argument that: "All of the '672 Patent claims [have a] limitation ... [requiring] "at least about 80% oleic acid by weight as a fatty acid .... Nycomed *intends* to make its product with oleic acid that does not have the claims' requirement of 'at least about 80% oleic acid.'" Opposition Br. 25 (emphasis added). Nycomed's argument comes absent legal authority and comes absent specificity as to what percentage of oleic acid or superrefined oleic acid Nycomed *currently* and *intends* to use in its product. Indeed, Nycomed's use of the future tense leaves unclear what percentage of oleic acid it *currently* uses and if that percentage squarely falls within the ambit of Graceway's claims. Moreover, Graceway has offered persuasive evidence that a cream not using "at least about 80% oleic acid by weight" as a fatty acid would not be stable. Nycomed fails to respond to Plaintiffs' evidence.

The gravamen of Nycomed's defense does not relate to non-infringement; rather, it relates to validity, obviousness, enablement, and the written description requirement.

At trial, the burden is on the alleged infringer to show by clear and convincing evidence that the patent is not valid. *See* *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359-60 (Fed. Cir. 1984). However, this is not the governing standard in regard to validity at the preliminary injunction stage, the stage of interest here. At this stage, the party seeking to oppose injunctive relief "must [only] show a substantial question of invalidity to avoid [the movant's] showing [a] likelihood of success." *Erico Intern. Corp. v. Vutec Corp.*, 516 F.3d 1350, 1354 (Fed. Cir. 2008).

> 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....
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> While the evidentiary burdens at the preliminary injunction stage track the burdens at trial, importantly the ultimate question before the trial court is different. As this court explained in *New England Braiding Co. v. A.W. Chesterton Co.*, the trial court "does not resolve the validity question, but rather must ... make an assessment of the persuasiveness of the challenger's evidence, recognizing that it is doing so without all evidence that may come out at trial." 970 F.2d 878, 882-83 (Fed. Cir. 1992). Instead of the alleged infringer having to persuade the trial court that the patent is invalid, at this stage 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.
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> Thus, 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. We reiterate that the "clear and convincing" standard regarding the challenger's evidence applies only at trial on the merits, not at the preliminary injunction stage. The fact that, at trial on the merits, the proof of invalidity will require clear and convincing evidence is a consideration for the judge to take into account in assessing the challenger's case at the preliminary injunction stage; it is not an evidentiary burden to be met preliminarily by the challenger.

Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1377, 1379-80 (Fed. Cir. 2009) (emphasis added).

As explained in greater detail below, Plaintiffs are not likely to succeed on the merits because Nycomed has shown a substantial question regarding the validity of the '672 Patent due to obviousness. A claimed invention including a combination of elements is not patentable if it differs from the prior art in a manner "such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). Once a patent examiner has concluded that the combination of elements is

obvious, that is, once the patent examiner makes a finding in regard to the prima facie case, the applicant may rebut this presumption with evidence of unexpected results. However, such evidence is only a part of the "totality of the evidence" considered in reaching the ultimate conclusion of obviousness. *See* *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997).

Before issuing the '672 Patent, the United States Patent and Trademark Office ("USPTO") rejected Plaintiffs' application three times[2] as being obvious over the '994 Wick Patent in view of an extant product specification for super refined oleic acid, ("SROA"). *See, e.g.*, Brown Aff. Exs. M at 4 (second office action), & N. In these rejections, the Examiner indicated that it would have been obvious to use SROA to improve the stability of oleic acid and thus the entire formulation of imiquimod and oleic acid presented in the '994 Patent. Despite various arguments by the applicants against the obviousness of the combination, the Examiner maintained that it was obvious.[3] The Examiner never veered from this finding.

The rejection was finally overcome by a showing of unexpected results in the decreased level of imiquimod-related impurities after combining imiquimod with SROA. But the Examiner offered no explanation, reasoned or otherwise, as to why this showing outweighed the obviousness of the combination using the invention described in the '994 Patent and SROA product specification. *See* Brown Aff. Ex. O. Where an examiner does not offer a principled reason for allowance after prior rejections by explaining the balance between the obviousness rejection and the unexpected result described in the allowance, the Court will give less deference to the decision of the USPTO because the Court's ability to understand the examiner's decision is limited to the record and reasoning the examiner provides. Here, no reasoning is offered, and as a result, there is little to which the Court can defer.

Nycomed has offered arguments and affidavits in addition to the Examiner's reasons for initial rejection, to demonstrate the obviousness of the '672 Patent. Nycomed relies primarily on the combination of the Chollet Article, ("Chollet") (Banker Aff. Ex. C) and an extant SROA product specification, (*id*. Ex. D) to arrive at the claimed invention. Chollet

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[2] After a non-final rejection, final rejections were made on May 8, 2009 and August 28, 2009. *See* Brown Aff. Ex. M.

[3] Plaintiffs argued that SROA is susceptible to oxidation, that SROA had no prior pharmaceutical applications and would unlikely be chosen by anyone formulating a topical product, and that no one of skill in the art at the time of the invention could predict the stability of a formulation comprising SROA. Each of these three arguments was rejected by the Examiner through a series of Office actions.

specifically teaches that oleic acid is the *best* solubilizing agent of imiquimod, but oleic acid oxidizes in the air, becomes discolored, and turns rancid when heated. Isostearic acid, however, is not as susceptible to oxidation, color change, and rancidity, and isostearic acid has solubilizing properties similar to those of oleic acid. (Banker Aff. Ex. C 39.) Nycomed asserts that SROA's properties render it an obvious alternative to lessen the disadvantages of regular oleic acid. This is supported by expert testimony tending to establish SROA's improved stability over oleic acid. (Banker Decl. ¶ 33.)

Furthermore, Nycomed has provided testimony that "it is standard practice in the field of pharmaceutical sciences to use the highest grade or purest form of an ingredient when formulating a pharmaceutical product." (Palmieri Decl. ¶ 5(d).) This position seems sensible. While Plaintiffs argue that the Chollet reference teaches away from the use of oleic acid (because of its inferior properties in relation to oxidation, discoloration, and rancidity), it would appear that Chollet actually provides a motivation to test alternatives to improve upon these properties, while still using a better solubilizing agent than isostearic acid.[4] SROA was one such alternative known in the art at the time of this invention. Thus, Nycomed has raised a substantial question as to whether one of ordinary skill in the art at the time of the invention would have had "a reasonable expectation that the substitution of SROA for the oleic acid [described in] the Chollet Article would be successful." (Palmieri Decl. ¶ 5(d).)

In rebuttal to Nycomed's obviousness arguments, Plaintiffs have provided evidence of unexpected results. The specification of the '672 Patent states generally that, with the use of SROA, "[s]urprisingly, the stability of such formulations is substantially greater." *See* Patent No. 7,655,672, col. 7, lines 56-58. Nycomed argues that an increase in the stability of the formulation would be expected, especially since oleic acid constitutes the largest component of the formulation other than water. Plaintiffs have clarified that the unexpected result is not a reduction of impurities in general, but a reduction in impurities specific to imiquimod, as shown in Table 2 of the '672 Patent. Plaintiffs support finding unexpectedness by arguing that the reason for the result is unknown. (Brown I Decl. ¶ 17.)

The parties have had a substantial dispute as to the meaning of Table 2 and whether it is indicative of imiquimod impurities alone or impurities of the formulation in general. The

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[4] *Cf. Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1377 (Fed. Cir. 2006) ("For a chemical compound, a prima facie case of obviousness requires structural similarity between claimed and prior art subject matter ... where the prior art gives reason or motivation to make the claimed compositions. [A] reasonable expectation of success, not absolute predictability supports a conclusion of obviousness." (citations and quotation marks omitted)).

statistical reliability of the results is also contested by Nycomed. The Court does not take a position on these issues. For the purpose of this analysis, the Court assumes Plaintiffs are correct, that is, that the results are unexpected. This assumption is consistent with the findings of the Examiner. Additionally, as the Examiner never veered from the finding that the combination of elements itself, considering the '994 Wick Patent and the SROA product specification, would have been obvious, the Court's finding of obviousness in regard to the combination of elements analysis is also consistent with that of the Examiner.[5] However, as the Examiner provided no reasoning explaining her conclusion in regard to her balancing the obviousness of the combination of elements and the unexpected results, the Court is left to perform its own analysis and balancing in regard to weighing the obviousness of the combination with the unexpected results.

Where there is a strong enough showing of obviousness on the record, expert testimony regarding unexpected results may be insufficient to overcome a prima facie case of obviousness. *Pfizer*, 480 F.3d at 1372 (explaining that a patent initially rejected for obviousness and then allowed on testimony of unexpected results may be invalidated where the showing of unexpected superior properties is insufficient to overcome the prior art's suggestion of the combination, even if the art did not address the expectation of particular benefits discovered by the inventor). In determining the weight of unexpected results against the obviousness of an invention, unexpected results which are not as significant as the expected results of the combination are given less emphasis. *See In re Nolan*, 553 F.2d 1261 (C.C.P.A. 1977) (holding that the unexpected increase in luminosity of a gaseous discharge display and memory device was outweighed in significance by the expected increase in memory margin and lower operating voltage that would be produced by the applicant's obvious combination of gases). Additionally, specific unexpected results in regard to a particular aspect or property of an invention are given less weight, if the specific unexpected result would be encompassed within an expectation of overall improvement in regard to that aspect or property of the combination. *See In re Eli Lilly & Co.*, 902 F.2d 943, 948 (Fed. Cir. 1990) (holding that an unexpected result in increasing the efficiency of feed utilization in ruminant animals was not sufficient when it was expected that the combination would increase weight gain in animals, as the prior art had invited experimentation in this area). However, when the unexpected result involves achieving a different type of improvement along with expected improvements, the unexpected result is given more relative weight. *See In re May*, 574 F.2d 1082 (C.C.P.A. 1978) (explaining that an unexpected result of less

[5] It is Plaintiffs' argument that the combination itself is not obvious that is inconsistent with the findings of the Examiner. The Court's position, by contrast, coheres with the Examiner's position.

addiction potential despite the expected result of pain relief overcame the obviousness of the compound).

As in *In re Eli Lilly*, the prior art here invites experimentation. This is shown in the Chollet article which sought to stabilize imiquimod formulations using solubilizing agents and which also noted that oleic acid was the best solvent discussed. It is highly likely that SROA, as a new, purer product on the market, would have been tested with imiquimod as part of standard industry practice to determine the stability of the formulation. (Palmieri Decl. ¶ 5(d).) As Nycomed has pointed out, one would have expected the use of SROA to increase the overall level of formulation purity.[6] Plaintiffs have not disputed this argument; instead, Plaintiffs rely on the unexpectedness of improvements in regard to imiquimod-related impurities.[7] Thus, Plaintiffs have discovered one specific unexpected property (increased purity of imiquimod) consistent with the more general expected result (increased purity of the formulation as a whole). *See Ex parte Obiaya*, 227 USPQ 58, 60, 1985 WL 71916 (Bd. Pat. App. & Inter. July 23, 1985) (Katz, Examiner-in-Chief), *aff'd*, C.A. No. 86-551, 795 F.2d 1017 (Fed. Cir. May 30, 1986) (NOT PRECEDENTIAL). As in *In re Eli Lilly*, the benefit in regard to a particular aspect of the combination (that is, formulation purity) encompasses the specific unexpected result (that is, improvement in imiquimod-related impurities). It would seem to follow that the unexpected result should be given relatively little weight. This case is unlike *In re May* because the unexpected result here is not an entirely different type of benefit from the expected benefit of the combination of elements.

In this case, as in *Pfizer*, there is a strong showing of obviousness, supported by the Examiner's three rejections in the prosecution history of the '672 Patent and the evidence provided by Nycomed that the prior art invited experimentation in regard to testing for benefits in regard to stability (of the formulation, as explained by Nycomed, and/or of imiquimod, as explained by Plaintiffs, albeit, while denying any conclusion of obviousness). Plaintiffs have not provided evidence tending to show that the combination of elements would not have been obvious, except for the rebuttal evidence in regard to the unexpected

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[6] Not only would one have *expected* an improvement in formulation stability from using SROA, but SROA, in fact, *did* improve formulation stability. *See* Patent No. 7,655,672, Summary, col. 2, line 9 (describing "improved formulation stability"); *id*. Detailed Description, col. 7, lines 56-61.

[7] While the '672 Patent itself states that the increased stability of the overall formulation is unexpected, Plaintiffs have clarified that "the unexpected result of the '672 Patent is not that the impurities in general were reduced, but that *imiquimod* impurities were also reduced." Plaintiffs' Br. 36 (emphasis in original).

result. While Plaintiffs have shown an unexpected result regarding the reduced level of impurities of imiquimod, the Court, as explained, gives this little relative weight and holds that it is insufficient to overcome the abundant evidence of obviousness. After considering the totality of the arguments and evidence, the Court has determined that Nycomed has made a sufficient showing in regards to obviousness and thus has raised a substantial question regarding the validity of the '672 Patent under the governing legal standard. *See Titan Tire Corp*., 566 F.3d at 1379-80. Accordingly, Plaintiffs have not established a likelihood of success on the merits.[8]

Nycomed also challenges validity based on the written description and enablement requirements. Graceway argues that the '672 Patent meets the written description requirement for validity. "To satisfy the written description requirement, the applicant does not have to utilize any particular form of disclosure to describe the subject matter claimed, but the description must clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed. In other words, the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention ... and demonstrate that by disclosure in the specification of the patent." *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc*., 541 F.3d 1115, 1122 (Fed. Cir. 2008). Plaintiffs again make the argument, much as they did in their reply brief at the TRO stage, that the patent is "replete with descriptions of the claimed invention." Based on the more developed record, and the fact that Graceway now buttresses its argument with a declaration by an expert[9] that he, in fact, has made "imiquimod creams ... by following the teachings ... in the patent," Brown 2d Decl. ¶ 22, the Court cannot now conclude that 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." *Titan*, 556 F.3d at 1379-80.

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[8] Because the Court has held that it is unlikely that Plaintiffs will establish infringement (given the obviousness defense), the Court need not address whether a presumption of irreparable harm flows automatically from a finding of infringement.

[9] *See, e.g.*, *Ortho McNeil Pharm., Inc. v. Barr Labs., Inc*., Civil Action No. 03-4678, 2009 WL 2182665, at *4 (D.N.J. July 22, 2009) (explaining that "the decision on [validity] turns on the factual question of wh[at] the [patentee's] patents would have described ... to the person of ordinary skill in the art. At trial, this will be resolved by a battle of the experts. At this [preliminary] juncture, not having heard the experts testify and undergo cross-examination, and not having had the opportunity to weigh their credibility, this Court can find no reason to credit one expert['s] [declaration] over another. Certainly [defendant] gives no [convincing] reason to credit its expert over [plaintiff's]. This Court finds no basis to conclude that it is more likely than not that [defendant] will be able to prove, by clear and convincing evidence, that the [plaintiff's] patents [are invalid] ....").

2. Irreparable Harm To Movant If The Injunction Is Not Granted

Lost Sales and Lost Profits. The Court also notes that in the leading case awarding injunctive relief for injury to a competitive product which is not protected by the patent in suit, the Court awarded relief because the relevant market was characterized by "design wins." *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 702 (Fed. Cir. 2008). In the instant case, unlike *Broadcom*, the market is characterized by unit-by-unit competition. *See* Trans. 65:4-5 (March 3, 2010) (Attorney for Plaintiffs: arguing that damages should be calculated on a unit-by-unit basis – i.e., "every unit of their product that was sold [should be considered] a unit of our product [that was not sold]"). In this situation money damages can be calculated relatively easily and such a calculation undermines the position that harm is irreparable. *See Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1548 (Fed. Cir. 1995) (awarding a patent-holder lost profits for lost sales involving a non-patented product which suffers competitive injury in connection with patent infringement). Finally, "loss of market share and price erosion are economic harms and are compensable by money damages .... [even] in the context of generic competition in the pharmaceutical industry ...." *Novartis Pharms. Corp. v. Teva Pharms. USA, Inc.*, Civil Action No. 05-1887, 2007 WL 2669338, at *14 (D.N.J. Sept. 6, 2007).

Plaintiffs argue that damages associated with unit-by-unit lost sales do not compensate for irreparable harm. Indeed, in terms of lost revenue connected to lost sales, determining damages (should it come to that) can be done with greater ease here than in other patent contexts. In the instant litigation, there are only two competitors. A sale captured by Nycomed is likely to be a sale lost to Graceway. *See Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996) (noting approvingly that "[i]n light of the [two distributor] structure of the cefaclor market, the court found that calculating lost profits would be a relatively simple task") In other contexts, with multiple players, a sale by an alleged infringer might have otherwise gone to the patentee or to some third-party with a non-infringing product. That complexity is not at play here. Plaintiff Graceway also recites loss of exclusive market share, current and future price erosion from an entry of a generic, loss of jobs, loss of good will, and impairment of research and development. Specifically, Graceway states it suffered a loss of 85% of Aldara sales, sales captured by Nycomed, implemented a 60% cut in its employment and development budget, and cut 40% of its work force. Finally, it has hired a restructuring consultant.

Price. Graceway claims current and future price erosion. Opening Br. 25 ("Unless enjoined from further infringement, Nycomed will continue to erode the price of Aldara .... This price erosion would be avoided if Nycomed were enjoined and Graceway would be able to begin moving back to the pre-infringement price point." (emphasis added)). The inference to be drawn from this passage is that Aldara's price dropped in response to competition. In

support of the position stated in its brief, *id.*, Plaintiffs offered the First Moccia Affidavit. But the paragraphs cited in the Moccia Affidavit do not offer any support in regard to Graceway's price erosion claim. *See* Opening Br. 24-25.

Nycomed calls Graceway's representations a "shocking deception" and supplies evidence that Aldara's price increased. Spadea Aff. ¶ 23 & n.32 (noting increase in Aldara price from $568 on February 1, 2010 to $738 on April 1, 2010, where Nycomed entered the market on February 25, 2010). Spadea also suggests that this would account for lost unit sales by Graceway. Graceway's only reply is in a footnote: "Nycomed's argument that Graceway's routine annual price increase is evidence of a 'shocking deception' ... cannot be taken seriously. The precipitous and continued reduction in Aldara *sales* after Nycomed's infringing launch are not attributable to that increase." Reply Br. 13 n.7 (citing Moccia 2d Aff. ¶ 5) (emphasis added). It appears that Graceway is not really contesting Nycomed's point: Graceway's price for Aldara has not declined, that is, neither the brief nor the Second Moccia Affidavit support the position that any decline has taken place. Graceway's unwillingness either to put forward evidence in support of its own position or to correct the record is puzzling. Graceway has failed to establish current price erosion and has made no substantial argument supported by evidence in regard to expected future price erosion caused by Nycomed's product. And, the fact that Aldara's price is now higher, undermines, to some extent, Graceway's position in regard to lost market share.

Market Share. Nycomed makes several unsupportable arguments. It claims that Graceway could not have expected exclusive market share at this time because "the '338 [P]atent [covering imiquimod] and its FDA exclusivity expired on February 25, 2010." But Graceway's position is that Nycomed's rival product making use of the '338 Patent, also infringes on the '672 Patent, thereby wrongfully competing with Aldara (a product based on the '944 Patent). The expiration of the '338 Patent is not relevant unless Nycomed's product does not infringe the other two patents -- owned by Plaintiffs. Nycomed also argues that Graceway had no reasonable expectation of exclusivity because "generic Aldara substitutes will be permitted" in the not so distant future. The '944 Patent protecting Aldara does not expire until February 2011. Graceway is entitled to exclusivity in regard to the '944 Patent until its lawful right to exclude – based on whatever patents it holds – ends. *See Rite-Hite Corp.*, 56 F.3d at 1546-48. Nycomed also argues, as explained in the section discussing price above, that Aldara sales dropped in part because Graceway raised its prices. Although this argument addresses (some) lost sales, it does not address lost market share. Nycomed also argues that Graceway intended to sell authorized generic and Zyclara (a new Graceway product) during the briefing process. Again, this may be true, but it does not impinge on Graceway's statutory right to exclude other parties from the Aldara market if those parties are in violation of Graceway's patents. Graceway is allowed to put its own products on the market without opening the market up to competition from third parties.

In *Automated Merch. Sys. v. Crane Co.*, 357 Fed. Appx. 297 (Fed. Cir. Dec. 16, 2009) (NOT PRECEDENTIAL), the Federal Circuit explained that even when supported by competent evidence, "loss of revenue, loss of market share, and price erosion" do not establish irreparable harm. *Id*. at *3. *Automated* suggests a preliminary injunction should issue for lost market share where "failing to grant [the] preliminary injunction would permit [the alleged infringer] to drop its prices in order to drive [the patentee] out of the market *entirely*." *Id*. at *4 (emphasis added). This is not the situation here. *Automated* also suggests that the loss of third-party distributors to an alleged infringer in the context of lost market share may lead to a finding of irreparable harm. *Id*. at *3. But again, there is no evidence establishing such facts here.

Loss of Jobs. Graceway puts forward an affidavit stating that "approximately 130 people are being let go." Musick Aff. ¶ 4; Reply Br. 4 (noting that "more than 40% of Graceway's 323 employees have been let go"). Musick also indicates that the remaining work force is distracted rather than productive. Nycomed argues: that these changes must have been planned in light of the expiration of Graceway's patents and is supported only by self-serving affidavits. Graceway responds that its business model planned on only lawful entry into the market by competitors until the '944 Patent expired in 2011. These layoffs arise because that plan was compromised. As to self-serving affidavits, it seems nothing else is possible as only Graceway has the most current relevant information. The Court also has considerable discretion in regard to relying on affidavits, self-serving or otherwise, in the context of a preliminary injunction. *See, e.g.*, *Kos Pharms., Inc. v. Andrx Corp.*, 369 F.3d 700, 718-719 (3d Cir. 2004). Nycomed's inference in regard to lost jobs is not without documentary support. A 2009 Moody's publication downgraded Graceway's debt rating in light of the expected launch of generic competition, expected as early as February 2010, which corresponds exactly with what happened here. Moreover, given the limited time prior to expiration of the '944 Patent, when generic competition against Aldara-like copies would be expected, lost market share, sales, revenue, and *jobs* in the intermediate term would have been expected. Given these facts and that Graceway's price for Aldara is now higher than before the alleged infringement, the Court cannot conclude that the loss of these jobs is primarily caused by Nycomed's alleged infringement. The burden of establishing irreparable harm falls on the movant. *World Kitchen (GHC), LLC v. Zyliss Haushaltwaren AG*, 151 Fed. Appx. 970, at *2 (Fed. Cir. Oct. 14, 2005) (noting that "the moving party bears the burden of proving that ... it will suffer irreparable harm").

Adequacy of Money Damages.[10] Nycomed argues that Plaintiffs' structural claims, including lost jobs, price erosion, market share, and business reputation are compensable by money damages and readily calculable as Aldara is a mature product. For the reasons explained above, this Court agrees. Graceway also argues that the premature termination by (allegedly wrongful) generic competition of its right to exclude from the Aldara market interfered with ongoing business plans on which it relied, thereby blocking socially valuable research and development projects. This Court has held in the patent context that research and development cuts connected to lost revenue caused by infringement are irreparable. *See, e.g.*, *Eisai Co. v. Teva Pharms. USA, Inc.*, Civil Action No. 05-5727, 2008 WL 1722098, at *11, 2008 U.S. Dist. LEXIS 33747 (D.N.J. Mar. 28, 2008) (Ackerman, J.) (finding irreparable harm in regard to inability to rely on business plans caused by infringement). But the Federal Circuit has held otherwise.

> Lilly contends that the loss of profits on sales of cefaclor because of competition from the appellees will result in irreparable injury to Lilly's overall pharmaceutical research efforts. As the district court pointed out, however, that claim of injury is not materially different from any claim of injury by a business that is deprived of funds that it could usefully reinvest. If a claim of lost opportunity to conduct research were sufficient to compel a finding of irreparable harm, it is hard to imagine any manufacturer with a research and development program that could not make the same claim and thus be equally entitled to preliminary injunctive relief. Such a rule would convert the "extraordinary" relief of a preliminary injunction into a standard remedy, available whenever the plaintiff has shown a likelihood of success on the merits.

Am. Cyanamid Co., 82 F.3d at 1578.[11]

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[10] The Court notes that Plaintiffs have *not* made any argument suggesting that Nycomed would be judgment proof should Plaintiffs prevail at trial. *See Am. Cyanamid Co.*, 82 F.3d at 1578 (noting that the ability of an alleged infringer to satisfy a potential judgment is part of the irreparable harm analysis).

[11] *See also Ortho Biotech Products, L.P. v. Amgen Inc.*, Civil Action No. 05-4850, 2006 WL 3392939, at *8 (D.N.J. Nov. 21, 2006) ("Any costs associated with the research cuts or with the reinstitution of clinical trials can be remedied with monetary damages."). Interestingly, Judge Ackerman's 2008 decision in *Eisai*, nowhere distinguished *Eisai* from either *Ortho Biotech*, a 2006 decision, or *American Cyanamid*, a 1996 decision.

In sum, the Court does not find that Plaintiffs have made a sufficient showing in regard to irreparable harm.

3. The Balance Of Hardships Between The Parties

The Court again notes it now has a better developed record.

Plaintiffs repeat much of their irreparable harm argument: unit-by-unit competition and sales loss, loss of its exclusive market share, price erosion (now disputed by the parties), loss of jobs, loss of goodwill, and impairment of future projects. For all these reasons, Plaintiffs argue that money damages are inadequate or "incalculable." Graceway argues that Nycomed sales far exceed Graceway's and so Nycomed is better positioned to "absorb temporary loss."

Nycomed will lose its 180 day period of exclusivity should it not be allowed to continue on the market. But Graceway argues that Nycomed moved forward voluntarily and knowingly after Graceway filed its complaint and so the harm to Nycomed is self-inflicted. Moreover, Nycomed had a seventy-five day post-approval grace period in which to move forward and could have begun negotiations (or arbitration, mediation, or, even, litigation) with Graceway prior to moving ahead. (Nycomed suggests in a footnote that exercising the 75 day grace period would not have been prudent -- and may have led to the loss of the 180 exclusivity period -- but no evidence or legal authority for this position is put forward.) Nycomed also argues, as the prior opinion stated, that an injunction now would put at risk its "reputation, its commercial relationships, and, no doubt, on its own employees' moral[e]." Opposition Br. 26. Nycomed claims it invested heavily to ready launch, but does not specify launch costs apart from more general development costs incurred prior to the approval of the '672 Patent. *Id.* It claims it would have to lay off employees, but no number is specified. Nycomed's brief states that its new product is its "biggest generic dermatological product." *Id.* But there does not appear to be any evidentiary support for this claim. Nycomed has not been forthcoming.

Although the record on both sides remains somewhat (and surprisingly) vague on these points – Graceway has the better developed record. On balance, this factor leans to Plaintiff Graceway.

4. The Public Interest

The public interest is enhanced by enforcing valid patents: encouraging the development of new drugs through incentives connected to future profits from limited temporal monopolies. The public interest is also enhanced by competition: encouraging

generic drugs to come onto the market the moment legal patent protection ends. Both interests are at stake here. These two interests are in equipoise. (The parties' conduct is also in equipoise.)

V. CONCLUSION

For the reasons elaborated above, and having weighed the four factors, the Court **DENIES** Plaintiffs' Motion for a preliminary injunction.

s/ William J. Martini

DATE: June 10, 2010 **William J. Martini, U.S.D.J.**