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. FACTS AND PROCEDURAL POSTURE

This patent infringement action is brought by Plaintiff Graceway, LLC (Graceway) founded in 2006, and Plaintiff 3M Innovative Products Co. ("3M IPC") against several defendants, all of whom have since been dismissed, except for Defendant Nycomed.

Three distinct patents are involved in this lawsuit. First, the '338 Patent (Patent No. 4,698,338) covers imiquimod, the active pharmacological ingredient in Aldara, a product originally approved by the Food and Drug Administration ("FDA") in 1997. Aldara is Graceway's core product, a mature product which it acquired in 2006 from 3M IPC. The '338 Patent expired on August 25, 2009, with a period of exclusivity which ran to February 25, 2010.

Second, Graceway also holds the '944 Patent (Patent No. 5,238,944) or a license thereunder, a formulation of imiquimod with isostearic acid. This patent was approved on August 24, 1993, and will expire on August 24, 2010, with a period of exclusivity running to February 24, 2011. The '944 Patent covers Aldara.

Third, Plaintiff 3M IPC is the owner of the '672 Patent (Patent No. 7,655,672) filed December 17, 2004, with Graceway (originally) holding an exclusive license (although its exclusivity is now disputed). This patent was issued on February 2, 2010. It protects a formulation of imiquimod and a refined grade of oleic acid, i.e., Super Refined Oleic Acid ("SROA"). Graceway markets no product in the United States covered by the '672 Patent.

On January 10, 2007, Nycomed informed Graceway by letter that it had filed an Abbreviated New Drug Application ("ANDA") to produce a bioequivalent generic version of Aldara. Graceway understood this to mean that Nycomed would manufacture, use, offer for sale, etc., its product after Nycomed received FDA approval for its ANDA and after the '338 Patent on imiquimod had expired on February 25, 2010. On February 25, 2010, the FDA approved Defendant Nycomed's ANDA application seeking to produce a generic of Aldara, albeit one with a different formulation from Aldara. Nycomed's bioequivalent of Aldara, i.e., "Nycomed's Product," has been determined by the FDA to be a bioequivalent of Aldara, with both products functioning as creams for application to dermal or mucosal surfaces for delivery of imiquimod. (Plaintiffs' opening brief stated that approval occurred on February 23, 2010 at 8:59 a.m. – but the docket item cited says February 25, 2010 at 8:59 a.m.) Once approved, Nycomed immediately began advertising, selling, and distributing its product domestically. It is not disputed that Nycomed's Product does *not* infringe either the '338 Patent (which is now expired) or the '944 Patent (covering a formulation using isostearic acid). Nycomed's Product, like the formulation described in the '672 Patent, makes use of a formulation of imiquimod and oleic acid (or super-refined oleic acid).

In a Complaint filed on February 23, 2010, Plaintiffs allege that Nycomed's Product infringes the '672 Patent and seek damages and (preliminary and permanent) injunctive relief for the injury Graceway has and will sustain in consequence of lost profits and sales of Aldara. Before the Court is Defendant Nycomed's Rule 11 Motion seeking dismissal of the Plaintiffs' infringement suit because, allegedly, Graceway failed to do a pre-filing investigation to determine if Nycomed's product infringed Graceway's '672 Patent. For the reasons elaborated below, the Court will **DENY** Nycomed's motion.

II. POSITIONS OF THE PARTIES

As explained, Nycomed alleges that Graceway failed to conduct a pre-filing investigation. In other words, the '672 Patent applies to creams that are "at least about 80% oleic acid by weight as a fatty acid," a specific oleic acid component with specific peroxide and impurity values under certain testing conditions. Nycomed claims that Graceway had no good faith basis to believe that Nycomed's product infringed the '672 Patent because Graceway failed to "investigate[], analyze[], test[], obtain[] or even request a sample of

Nycomed's product prior to before filing suit" on February 23, 2010. Nycomed argues that Graceway did not (and perhaps even now does not) know the source of Nycomed's oleic acid and has not tested Nycomed's product in regard to whether it actually infringes the claims of the '672 Patent. Nycomed further explains that Plaintiff Graceway failed to request a sample of Nycomed's product either after January 10, 2007 (when the ANDA was filed) or after February 2, 2010 (when Graceway's '672 Patent was issued), but nevertheless brought suit on February 23, 2010.

Plaintiffs respond that *after* filing suit, but before the parties incurred significant litigation costs, Graceway requested information about Nycomed's product, but Nycomed refused to turn over basic information about its formulation on the grounds that it is a trade secret. Graceway argues that the likelihood that Nycomed would have turned over actual samples for testing prior to its filing suit was "zero." Graceway argues that although it did not test Nycomed's actual product, its counsel "performed [an] independent claim construction analysis" before filing the instant litigation. Graceway argued in the Nordsiek Declaration that it had a basis for filing this action. At the time of filing, Graceway understood the properties of oleic acid as such that any oleic acid used had to be refined to at least the extent that it would meet the requirement of the '672 Patent or else it would not be stable in imiquimod cream. In fact, Graceway argues that it engaged in its testing "long" before it filed this suit.[1]

In Nycomed's reply, it argues that the Nordsiek Declaration is insufficient as a matter of law to meet the pre-suit filing requirement because the Declaration was created five days after suit was filed and the declarant is not an attorney. "Rule 11, we think, must be interpreted to require the *law firm* to, at a bare minimum, apply the claims of each and every

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[1] The Court notes that any such testing made by Graceway must have been based on public information (or Nycomed's 2007 notice letter to Graceway) and on the Graceway's '672 Patent application. At this time, Graceway "could not know whether Nycomed's proposed product would ever be approved by the FDA; could not know whether the formulation described in Nycomed's Paragraph IV letter would be changed prior to approval; had only limited knowledge about Nycomed's proposed product; could not know whether the patent application which ultimately resulted in the '672 Patent would ever issue; and could not know whether the claims in its pending patent application would change ... before the patent issued." Memorandum of Law in Support of Plaintiffs' Motion for Preliminary Injunction 8-9. Notwithstanding all these unknowns, Plaintiffs allegedly actively compared Nycomed's product with the claims of the '672 Patent. Although Graceway was willing to engage in its presuit investigation notwithstanding these unknowns, it was unwilling to file suit on February 3, 2010, a time by which many of these unknowns had been resolved.

patent that is being brought into the lawsuit to an accused device ...." *View Eng., Inc. v. Robotic Vision Sys., Inc*., 208 F.3d 981, 986 (Fed. Cir. 2000). Finally, Nycomed argues that it would have turned over a sample had it been asked and that Graceway's failure to ask and to engage in reverse engineering based is fatal to Graceway's position.

After the Reply was filed, the parties filed a number of letter responses. Graceway asked to file a proposed sur-reply and an affidavit. The affidavit of Barbara Moore states that the infringement analysis described in Graceway's opposition brief was conducted before suit was filed and it was merely memorialized in the Nordsiek Declaration, not that the Nordsiek Declaration was the actual analysis. The Nordsiek Declaration was "not offered as [direct] evidence of [a pre-filing] investigation, but rather to explain how Graceway knew Nycomed infringed at the time it filed suit." In the proposed sur-reply brief, Graceway argues that "Graceway and its counsel did conduct a rigorous investigation prior to filing suit." But the affidavit offered in support does not specify that *counsel* conducted an investigation. It only states that an infringement analysis was conducted "before suit was filed." As to Graceway's requesting a sample of Nycomed's product, Graceway argues that Nycomed's position, that Nycomed would have provided a sample if it had it been asked, was self-serving and undermined by the fact that since February 23, 2010 (when suit was filed), Graceway has asked Nycomed for samples, and has been to date refused.[2] In a responsive letter, Nycomed argued that the Graceway's letter is unsupported attorney rhetoric, which fails to specify what pre-filing infringement analysis was done by an attorney using actual product or reverse engineered product, and further argues that the Graceway's letter amounts to waiver of attorney-client privilege and work-product protection in regard to pre-filing investigations. Graceway argues that there was no waiver because the contents of its investigation was not revealed, rather it only revealed the time the investigation was conducted: prior to filing suit. Nycomed argues that the content was revealed, in part, when Graceway claimed that its counsel conducted a "rigorous" review. Nycomed argues that having made the assertion that its lawyer conducted a rigorous review, Graceway cannot deny Nycomed access to the underlying documents supporting that assertion.

III. STANDARD OF REVIEW

Rule 11 Legal Standard. Federal Rule of Civil Procedure 11(b) states: "Representations to the Court. By presenting to the court a pleading, written motion, or other paper – whether by signing, filing, submitting, or later advocating it – an attorney or

[2] Of course, for Graceway to *prove* this, it would have to point to some discovery request it made to Nycomed, and then, where refused, it would have to point to some motion to compel it filed, and if not granted by Magistrate Judge Falk, it should have appealed any such order to this Court. No such showing has been made.

unrepresented party certifies that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances ... the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery ...." *See also Garr v. U.S. Healthcare*, 22 F.3d 1274, 1279 (3d Cir. 1994) ("[A] signer making an inadequate inquiry into the sufficiency of the facts and law underlying a document will not be saved from a Rule 11 sanction by the stroke of luck that the document happened to be justified."); *Centillion Data Sys., LLC v. Convergys Corp.*, Civil Action No. No. 104-0073, 2006 WL 20777, at *1 (S.D. Ind. Jan. 4, 2006) ("Because the issue of Rule 11 sanction is a procedural issue that is not unique to patent law, the [c]ourt applies the law of the [circuit in which it was heard]."). Patent claims must be both "well-founded" and may only be asserted after "reasonable inquiry" by a would-be plaintiff. *Cf. View Eng.*, 208 F.3d at 984 n.4 ("We hold today that the application of Rule 11 sanctions in this instance was justified, since Robotic's counterclaims were *neither* well-founded *nor* the subject of a reasonable inquiry." – suggesting a two prong inquiry (emphasis added)); *S. Bravo Sys., Inc. v. Containment Techs. Corp.*, 96 F.3d 1372, 1375 (Fed. Cir. 1996) ("A 'frivolous' argument or claim is one that is both baseless and made without a reasonable and competent inquiry." (quotation marks omitted)); *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, Civil Action No. 04-00689, 2007 WL 6137003, at *3 (C.D. Cal. April 16, 2007) ("[Rule] 11 permits sanctions for filings, such as pleadings, motions or other 'paper[s],' where: 1) such papers are legally or factually baseless from an objective perspective; *and* 2) the asserting party cannot show that it conducted a reasonable and competent inquiry before signing and filing the document." (emphasis added)).

Furthermore, in the patent context, "[b]efore filing []claims of patent infringement, Rule 11 ... [is] interpreted to require the *law firm* to, at a bare minimum, apply the claims of each and every patent that is being brought into the lawsuit to an accused device and conclude that there is a reasonable basis for a finding of infringement of at least one claim of each patent so asserted. The presence of an infringement analysis plays the key role in determining the reasonableness of the pre-filing inquiry made in a patent infringement case under Rule 11." *View Eng.*, 208 F.3d at 986 As the Federal Circuit has explained:

> [Rule 11] requires that the inquiry be undertaken before the suit is filed, not after. Defendants have no choice when served with a complaint if they wish to avoid a default. They must undertake a defense, and that necessarily involves costs. Rule 11 prohibits imposing those costs upon a defendant absent a basis, well-grounded in fact, for bringing the suit. In this case, prior to the filing of the suit, neither [the party asserting patent infringement] or his counsel had made a reasonable effort to ascertain whether the accused devices satisfied the two key claim limitations, either literally or under the doctrine of equivalents. No adequate explanation was offered for why they failed to

> obtain, or attempted to obtain, a sample of the accused device from the Postal Service or a vendor so that its actual design and functioning could be compared with the claims of the patent.

Judin v. United States, 110 F.3d 780, 784 (Fed. Cir. 1997); *Centillion Data Sys., LLC*, Civil Action No. No. 104-0073, 2006 WL 20777, at *4 ("[T]he Court finds that [the patentee's] factual inquiry was objectively unreasonable because [the patentee], nor its lawyers, never actually tested the allegedly infringing products to see if they met each of the … patent's limitations.").

The touchstone of a pre-suit investigation would appear to be reasonable inquiry in the circumstances, not necessarily testing the actual alleged infringing product. As a policy matter, adopting Nycomed's position – that product must be tested – would preclude suit where a defendant fails to turn over a sample, although otherwise obligated to do so. *Morda v. Klein*, 865 F.2d 782, 785-86 (6th Cir. 1989) ("It would be particularly difficult to fault plaintiffs for a lack of pre-filing inquiry when, as here, defendants have refused plaintiffs access to material information that would bear on certain allegations made in the complaint.").

IV. ANALYSIS

Plaintiffs have the better argument. Rule 11 and Federal Circuit case law require plaintiffs to engage in a meaningful investigation (including claim interpretation and an infringement analysis) in regard to alleged patent infringement prior to filing suit. *Judin v. United States*, 110 F.3d 780, 784 (Fed. Cir. 1997).[3] This may include an analysis of the alleged infringer's actual product or, for example, reverse engineering the product based on public information.

> However, *Judin* did not create a blanket rule that a patentee must obtain and thoroughly deconstruct a sample of a defendant's product to avoid violating Rule 11. Rather, in *Judin*, the patentee could have easily obtained a sample of the accused device (a bar code scanner) for a nominal price from the post office. In this case, the technology presented the patentee with

[3] Federal Circuit law on Rule 11 legal standards is persuasive, not controlling, because Rule 11 is not unique to patent law. *See Digeo, Inc. v. Audible, Inc*., 505 F.3d 1362, 1366-67 (Fed. Cir. 2007) (" We apply Federal Circuit caselaw to the § 285 analysis, as it is unique to patent law.... Motions under Rule 11 and § 285 are different. We apply the law of the regional circuit ... to Rule 11 cases ... whereas we apply the law of our circuit to § 285 cases." (citations omitted)).

> unreasonable obstacles to any effort to obtain a sample of Magnetar's amusement ride brake system, let alone the difficulty of opening the casing.
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> In lieu of cutting open the casing, Intamin might have tested a Magnetar device for magnetic polarities. In *Q-Pharma*, however, this court did not impose on a patentee a Rule 11 obligation to perform a simple chemical test on a sample to determine its composition. Instead, this court found that the patentee satisfied its Rule 11 obligations with other reasonable pre-filing inquiries. Here, the district court determined: "In light of the other information [Intamin] had at the time of filing ... [its] pre-filing inquiry was reasonable." In particular, the district court noted that Intamin "evaluated the patent portfolio, analyzed the patent's validity, determined the scope of the patent's claims, and performed an infringement analysis." The district court further determined that Intamin "reviewed publicly available documents on [Magnetar's] brakes, inspected [Magnetar's] brakes as installed on a roller coaster, took photos of the brakes, and reviewed the brakes with experts." Thus the district court determined that Intamin's pre-filing inquiry was reasonable under the circumstances. This court discerns no abuse of discretion in the district court's determination.

Intamin, Ltd. v. Magnetar Techs., Corp., 483 F.3d 1328, 1338 (Fed. Cir. 2007) (citations omitted). In the instant litigation, Graceway did not make any effort to obtain a sample of product from Nycomed before filing suit. Graceway argues that such an attempt would have been fruitless; this fact is contested. But even so, Graceway – according to its brief – engaged in other presuit investigation. Plaintiffs tested imiquimod formulations nearly identical to the formulation described in Nycomed's notice letter to Graceway. On that basis, Graceway reasonably concluded that Nycomed's product was substantially the same as that protected by the '672 Patent.

Nycomed would argue that the Nordsiek Declaration was generated after suit was filed and the Moore affidavit is self-serving, and as such there is no evidence of any presuit investigation by Graceway.

Nycomed's position appears to be incorrect. Nycomed may only positively assert that there was no presuit investigation if it, Nycomed, had first made a discovery request (including admissions, documents, interrogatories, etc.) and on that basis determined that Graceway failed to comply with Rule 11. Apparently, Defendant made no concrete efforts to seek discovery to support its motion: none is cited in Nycomed's brief. No motion to compel was filed in front of Magistrate Judge Falk, and no party has appealed any discovery order made by Judge Falk to this Court. To date, the only discovery sought in this case has related to the separate preliminary injunction motion. Certainly Nycomed puts forward no evidence; rather, it argues that the Nordsiek declaration, created and filed after suit was

launched, is insufficient. That declaration *is* insufficient, but that insufficiency does not establish that Graceway's actions did not otherwise comply with Rule 11. If anything it suggests the opposite. Moore Aff. ¶ 2 (April 15, 2010) ("The infringement analysis described in Graceway's Opposition to Nycomed's Rule 11 Motion was conducted before suit was filed and memorialized in the Declaration of Michael Nordseik after suit was filed."). The evidentiary burden is on Nycomed to show that Graceway failed to comply with Rule 11. *See, e.g.*, *Rich Art Sign Co., Inc. v. Ring*, 122 F.R.D. 472, 474 (E.D. Pa. 1988) ("The burden of proof on Rule 11 falls here on the defendants. We find they failed to prove that the plaintiff did not have a legitimate claim when he filed his complaint. Therefore, we will deny defendants' motion for Rule 11 sanctions.").[4]

In regard to any purported waiver of privilege, such issues should be directed, in the first instance, to Judge Falk, to whom matters relating to discovery have been referred in this case, and the Court adds that privilege issues may only be adjudicated in the context of *concrete* discovery disputes, as opposed to any request for an adjudication of an abstract privilege issue apart from a concrete (and refused) request for sought-after discovery materials.

V. CONCLUSION

For the reasons elaborated above, the Court **DENIES** Defendant Nycomed's Rule 11 motion.

s/ William J. Martini

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

[4] *View Eng., Inc. v. Robotic Vision Sys., Inc.*, 208 F.3d 981 (Fed. Cir. 2000), is distinguishable from the instant litigation. In *View Engineering*, the Court imposed sanctions based on a determination that "[the law firm which filed the patent claim] performed *no* independent claim construction analysis, nor did it do any formal written infringement analysis before filing the counterclaims." *Id*. at 985 (emphasis added). On the record before it, this Court cannot make any such finding. *See* Moore Aff. ¶ 2 (April 15, 2010). Also in *View Engineering*, the party filing the patent claim, a counter-claimant, had access to discovery *prior* to bringing its infringement claim. In the instant litigation, Plaintiff Graceway only had access to discovery after it brought suit. Its ability to conduct a presuit investigation was, therefore, more limited than the claimant in *View Engineering*. The Court adds that nothing herein prevents Nycomed from clarifying this issue through discovery requests.