

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CELGENE CORPORATION, NOVARTIS
PHARMACEUTICALS CORPORATION,
and NOVARTIS PHARMA AG,

Plaintiffs,

v.

KV PHARMACEUTICAL COMPANY,

Defendant.

Civil Action No. 07-4819 (SDW)

OPINION

WIGENTON, U.S.D.J.

Before the Court is the motion for sanctions, pursuant to FED. R. CIV. P. 11, by Defendant KV Pharmaceutical Company (“KV”) (Docket Entry No. 46). KV has submitted its moving brief. Before the Court is also the application by Plaintiffs Celgene Corporation, Novartis Pharmaceutical Corporation, and Novartis AG (collectively, “Plaintiffs”), asking this Court to deny the motion for sanctions without further briefing. For the reasons stated below, Plaintiffs’ application will be **GRANTED** and the motion for sanctions will be **DENIED** with prejudice.

I. BACKGROUND

In brief, the background to this motion is as follows. This case involves a Hatch-Waxman patent dispute between Plaintiffs, assignees of two patents related to treatment using methylphenidate in an extended release form, and KV, who seeks to market generic methylphenidate extended release capsules. After KV submitted Abbreviated New Drug Application (“ANDA”) No. 79-004 for methylphenidate in an extended release form to the FDA,

which included paragraph IV certifications regarding Plaintiffs' patents, Plaintiffs sued KV for patent infringement. Plaintiffs filed the Complaint on October 4, 2007.

The Complaint states that Celgene is the assignee of U.S. Patent Nos. 5,837,284 and 6,635,284, and alleges that the filing of ANDA 79-004 constitutes an act of patent infringement. On August 21, 2007, KV sent Celgene a letter (the "Notice Letter") stating that KV had submitted ANDA 79-004 to the FDA. (Green Dec. Ex. A.) The Notice Letter states that ANDA 79-004 includes a paragraph IV certification referencing U.S. Patent Nos. 5,837,284 and 6,635,284. Id. The parties do not dispute that the Notice Letter was sent, as the Complaint alleges, nor that the paragraph IV certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), references Celgene's patents. The parties have engaged in limited written and document discovery.

KV asks the Court to dismiss Plaintiffs' Complaint and award fees as a sanction, pursuant to FED. R. CIV. P. 11, because Plaintiffs failed to make a reasonable inquiry into their infringement claims before filing suit. KV contends that Plaintiffs should be sanctioned because they did not conduct a factual investigation into whether KV's methylphenidate actually infringes Celgene's patents prior to filing the Complaint. KV argues that, at the time that Plaintiffs filed their Complaint, the only information that they had was that contained in the Notice Letter. KV contends that, under Rule 11, Plaintiff's attorneys failed to conduct a reasonable and competent pre-filing inquiry. Plaintiffs have asked this Court to deny KV's motion without prejudice because it is premature and involves factual determinations that require further discovery.

II. DISCUSSION

FED. R. CIV. P. 11(b) states, in pertinent part:

By presenting to the court a pleading, written motion, or other paper – whether by signing, filing, submitting, or later advocating it – an attorney or unrepresented party certifies that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances: . . .

(3) 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 . . .

Rule 11(c) authorizes the Court to “impose an appropriate sanction” on an attorney or party who violates Rule 11(b). “A sanction imposed under this rule must be limited to what suffices to deter repetition of the conduct or comparable conduct by others similarly situated.” FED. R. CIV. P. 11(c)(4). “It is well-settled that the test for determining whether Rule 11 sanctions should be imposed is one of reasonableness under the circumstances, the determination of which falls within the sound discretion of the District Court.” Brubaker Kitchens, Inc. v. Brown, 2008 U.S. App. LEXIS 11046, *27 (3d Cir. 2008).

KV contends that Celgene’s attorneys failed to meet their Rule 11 obligations under Federal Circuit law. In Q-Pharma, Inc. v. Andrew Jergens Co., 360 F.3d 1295, 1300 (Fed. Cir. 2004), the Federal Circuit stated:

Rule 11(b) requires an attorney to conduct a reasonable inquiry into the law and facts before filing a pleading in a court and to certify that the claims contained therein are not frivolous, legally unreasonable, without factual foundation, or asserted for an improper purpose. Rule 11(c) then permits a district court to impose sanctions on a party and its attorneys for violation of subdivision (b). In the context of patent infringement actions, we have interpreted Rule 11 to require, at a minimum, that an attorney interpret the asserted patent claims and compare the accused device with those claims before filing a claim alleging infringement.

Federal Circuit law also contains a procedural mechanism which shifts the burden of proof:

“Once a litigant moves based upon non-frivolous allegations for a Rule 11 sanction, the burden of proof shifts to the non-movant to show it made a reasonable pre-suit inquiry into its claim.”

Digeo, Inc. v. Audible, Inc., 505 F.3d 1362, 1368 (Fed. Cir. 2007).

KV fails to persuade this Court that the holding of Q-Pharma, requiring a pre-filing infringement analysis, applies to a Hatch-Waxman ANDA case. The Drug Price Competition and Patent Term Restoration Act of 1984, often referred to as the Hatch-Waxman Act (the “Act”), specifically authorizes an owner of a patent to file an action for patent infringement against an ANDA applicant who has made a paragraph IV certification referencing its patents. The act of filing an ANDA, with a paragraph IV certification, is itself an act of infringement of the referenced patents:

It shall be an act of infringement to submit--

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 355(j)] or described in section 505(b)(2) of such Act [21 USCS § 355(b)(2)] for a drug claimed in a patent or the use of which is claimed in a patent.

35 U.S.C. § 271(e)(2). The referenced section, 21 U.S.C. 355(j), provides for “Abbreviated New Drug Applications.”

The pre-filing requirements stated in Q-Pharma make sense only in the context of a typical patent infringement case, and not in the context of a Hatch-Waxman ANDA case. In Q-Pharma, Q-Pharma held the patent for a method of treating damaged human tissue. 360 F.3d at 1297. Jergens sold Curel® lotion. Id. Q-Pharma sued Jergens for patent infringement. Id. Jergens subsequently moved for Rule 11 sanctions on the ground that, prior to instituting suit, Q-Pharma had not made a sufficient pre-filing inquiry to determine whether the accused product infringed. Id. at 1298. The district court denied the motion for sanctions and the Federal Circuit

reviewed the decision, applying the standard quoted above, and affirmed it. Id. at 1303.

In Q-Pharma, the act of infringement alleged in the complaint was the sale of the infringing product. The Federal Circuit held that Q-Pharma, as plaintiff, was obligated under Rule 11 to make a sufficient pre-filing infringement analysis to determine whether the accused product infringed. Here, in contrast, the act of infringement alleged in the complaint is the filing of an ANDA – **not** the manufacture or sale of the product. Because the Act has made the act of submitting an ANDA itself an act of infringement, in a Hatch-Waxman ANDA case, the attorney can conduct a reasonable and competent inquiry into the act of infringement by investigating whether a relevant ANDA has been filed. In the instant case, the Notice Letter provided sufficient basis for an attorney to reasonably believe that a relevant ANDA had been filed, and thus that an actionable act of infringement had occurred. Because submitting the ANDA itself is an act of infringement, and is therefore actionable, and because Celgene's Complaint predicates both of its two counts on that act of infringement, Celgene and its attorneys had no pre-filing obligation to investigate whether KV's methylphenidate drug actually infringed Celgene's patents. Because there is no dispute that KV submitted an ANDA which constitutes an act of infringement, and because KV states that, prior to filing suit, Celgene had received the Notice Letter which gave notice of the ANDA submission, this Court concludes that Celgene's pre-filing infringement investigation was reasonable under the circumstances.

This Court cannot conclude that KV has based its motion on non-frivolous allegations. Thus, pursuant to Digeo, the burden of proof does not shift to the non-movant to show it made a reasonable pre-suit inquiry into its claim.

Moreover, KV's position makes no sense when viewed in the context of the larger Hatch-

Waxman scheme. The Federal Circuit has stated:

The act of infringement that gives rise to a case or controversy under section 271(e)(2) has been stated to be ‘artificial,’ in the sense that a specific infringing composition has not yet been made, used, or sold, and is thus not necessarily available for a court to compare to the claims.

Glaxo Inc. v. Novopharm Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997) (citation omitted). Because the infringing composition might not be in existence at the time the ANDA is filed, and might not come into existence in the following 45 days, if this Court were to agree with KV, it would require that patent holders perform an infringement analysis on a possibly nonexistent product prior to filing. Such an interpretation of the Act is absurd and cannot be correct.

Moreover, KV’s motion is premised on a proposition which would upend Hatch-Waxman law, were this Court to accept it. KV seeks to impose on pharmaceutical patent owners who have received a paragraph IV notification an obligation to perform a Q-Pharma infringement analysis in the limited time period that the Act allows for filing suit. The Act sets a time limit on instituting suit that – even if the product actually exists at that time – makes it quite difficult for a patent owner to perform the kind of analysis that KV contends is necessary:

If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification.

21 U.S.C. § 355(j)(5)(B)(iii). Thus, unless a patent owner acts within 45 days, the FDA may approve the application. It is apparent that Congress intended that owners of pharmaceutical patents would bring suit promptly after receiving notice of the filing of an ANDA with a paragraph IV certification referencing one of their patents.

If this Court were to grant KV's motion, it would put pharmaceutical patent owners in an untenable position. After receipt of notification of an ANDA application for a generic pharmaceutical, the patent owner would need to conduct what is likely to be a highly technical infringement analysis, make the decision to file suit, and then do so, all within 45 days, or face dismissal as a sanction under Rule 11. This would be difficult for patent owners to accomplish and would have the effect of frustrating the purpose of the Hatch-Waxman scheme.

The Supreme Court has explained the role of the paragraph IV certification in the ANDA process as follows:

If the applicant makes the fourth certification, however, the effective date must depend on the outcome of further events triggered by the Act. An applicant who makes the fourth certification is required to give notice to the holder of the patent alleged to be invalid or not infringed, stating that an application has been filed seeking approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent, and setting forth a detailed statement of the factual and legal basis for the applicant's opinion that the patent is not valid or will not be infringed. See 21 U.S.C. §§ 355(b)(3)(B), 355(j)(2)(B)(ii). Approval of an ANDA or paper NDA containing the fourth certification may become effective immediately only if the patent owner has not initiated a lawsuit for infringement within 45 days of receiving notice of the certification. If the owner brings such a suit, then approval may not be made effective until the court rules that the patent is not infringed or until the expiration of (in general) 30 months, whichever first occurs. See 21 U.S.C. §§ 355(c)(3)(C), 355(j)(4)(B)(iii).

This scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement.

Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 677-678 (1990). Were this Court to grant KV's motion, it would have the effect of interfering with the ability of pioneer drug patent holders to establish infringement in court.

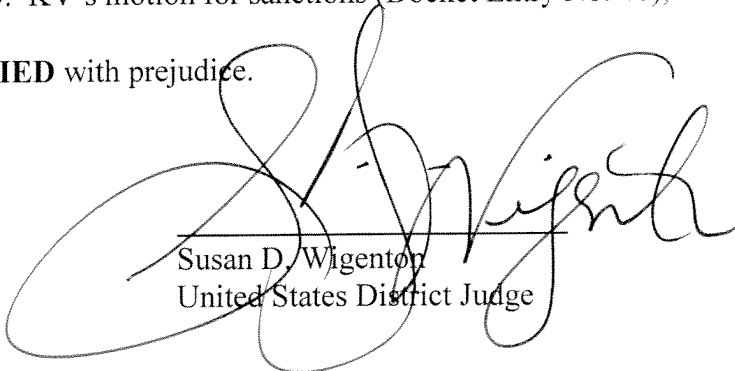
KV makes several arguments that go to the merits of Celgene's patent infringement case

and involve questions of pharmaceutical chemistry. These are complex technical issues that will surely be the subject of expert discovery and motion practice, perhaps trial. This Court will not rule on the merits of the patent infringement case on a Rule 11 motion made at the beginning of litigation.

Because KV's motion is premised on an erroneous application of Federal Circuit law, and because this Court finds the record before it sufficient to determine that Celgene's pre-filing investigation of the allegation that KV infringed Celgene's patents by filing ANDA No. 79-004 was reasonable under the circumstances, it is appropriate not only to deny this motion prior to full briefing, but to deny it with prejudice.

III. CONCLUSION

For the reasons set forth above, this Court is satisfied from the record as it currently stands, before Celgene has submitted its opposition brief, that KV's motion for sanctions has no merit and cannot succeed. Because of this, Celgene's request that the Court decide this motion without further briefing is **GRANTED**. KV's motion for sanctions (Docket Entry No. 46), pursuant to FED. R. CIV. P. 11, is **DENIED** with prejudice.



Susan D. Wigenton
United States District Judge

Dated: July 17, 2008

cc: Hon. Madeline Cox Arleo, U.S.M.J.
Clerk of the Court
Parties