NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC., Plaintiff, v. APOTEX INC. and APOTEX CORP., Defendants.	Civil Action No. 07-4417 (SRC) (MAS) Civil Action No. 08-3065 (SRC) (MAS) Civil Action No. 08-4053 (SRC) (MAS) (consolidated with 07-4417 for all purposes) **OPINION**
HOFFMANN-LA ROCHE INC., Plaintiff, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. 07-4516 (SRC) (MAS) Civil Action No. 08-3607 (SRC) (MAS) Civil Action No. 08-4055 (SRC) (MAS) (consolidated with 07-4516 for all purposes)
HOFFMANN-LA ROCHE INC., Plaintiff, v. COBALT PHARMACEUTICALS INC., and COBALT LABORATORIES, INC., Defendants.	Civil Action No. 07-4539 (SRC) (MAS) Civil Action No. 07-4540 (SRC) (MAS) Civil Action No. 08-4054 (SRC) (MAS) (consolidated with 07-4539 for all purposes)

HOFFMANN-LA ROCHE INC., Plaintiff, v. ORCHID CHEMICALS & PHARMACEUTICALS LTD., ORCHID HEALTHCARE, ORCHID PHARMACEUTICALS INC., and ORGENUS PHARMA INC., Defendants.	Civil Action No. 07-4582 (SRC) (MAS) Civil Action No. 08-4051 (SRC) (MAS) (consolidated with 07-4582 for all purposes)
HOFFMANN-LA ROCHE INC., Plaintiff, v. GENPHARM INC. and GENPHARM, L.P., Defendants.	Civil Action No. 07-4661 (SRC) (MAS) Civil Action No. 08-4052 (SRC) (MAS) (consolidated with 07-4661 for all purposes)

CHESLER, U.S.D.J.

This matter comes before the Court on four motions for summary judgment, pursuant to Federal Rule of Civil Procedure 56: 1) the motion for summary judgment that Defendants infringe the '957 patent by Plaintiff Hoffman-La Roche Inc. ("Roche"), against Defendants Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc. (collectively, "Cobalt"), Apotex Inc. and Apotex Corp. (collectively, "Apotex"), Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL"), Orchid Chemicals & Pharmaceuticals Ltd., Orchid Healthcare, Orchid Pharmaceuticals Inc., and Orgenus Pharma Inc. (collectively, "Orchid"), and

Genpharm Inc. and Genpharm, L.P. (collectively, "Genpharm"); 2) the cross-motion for summary judgment of non-infringement of the '957 patent by Defendant DRL; 3) the cross-motion for summary judgment of non-infringement of the '957 patent by Defendant Genpharm; and 4) the motion for summary judgment of non-infringement of the '957 patent by Defendant Orchid. For the reasons stated below, Roche's motion will be granted, the cross-motions will be denied, and Orchid's motion for summary judgment will be granted in part and denied in part.

BACKGROUND

This matter involves several Hatch-Waxman actions for patent infringement. The cases have been consolidated for pretrial purposes and arise from the following facts. Briefly, Roche owns the U.S. Patent No. 7,410,957 (the "'957 patent"), which is directed to methods of treating osteoporosis with a salt of ibandronic acid, the active ingredient in Roche's osteoporosis drug Boniva®. Defendants are generic pharmaceutical manufacturers who have filed Abbreviated New Drug Applications seeking FDA approval to engage in the manufacture and sale of generic versions of Boniva® prior to the expiration of the Roche patents.

ANALYSIS

I. Relevant legal standards

A. Motions for summary judgment

Summary judgment is appropriate under FED. R. CIV. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of

the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255).

"When the moving party has the burden of proof at trial, that party must show affirmatively the absence of a genuine issue of material fact: it must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." In re Bressman, 327 F.3d 229, 238 (3d Cir. 2003) (quoting United States v. Four Parcels of Real Property, 941 F.2d 1428, 1438 (11th Cir. 1991)). "[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by 'showing' – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party's case." Celotex, 477 U.S. at 325.

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. Jersey Cent. Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. Anderson, 477 U.S. at 248; Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). "[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990); see also FED. R. CIV. P. 56(e) (requiring

nonmoving party to "set out specific facts showing a genuine issue for trial"). "A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial." Gleason v. Norwest Mortg., Inc., 243 F.3d 130, 138 (3d Cir. 2001).

If the nonmoving party has failed "to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial, . . . there can be 'no genuine issue of material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Katz v. Aetna Cas. & Sur. Co., 972 F.2d 53, 55 (3d Cir. 1992) (quoting Celotex, 477 U.S. at 322-23).

B. Inducing infringement

Pursuant to 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." "Inducement requires a showing that the alleged inducer knew of the patent, knowingly induced the infringing acts, and possessed a specific intent to encourage another's infringement of the patent." Vita-Mix Corp. v. Basic Holding, Inc., 581 F.3d 1317, 1328 (Fed. Cir. 2009). "[I]nducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities." DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1306 (Fed. Cir. 2006).

II. Roche's motion for summary judgment

Roche's motion concerns claims 1 and 6 of the '957 patent:

> 1. A method for treating osteoporosis comprising commencing treatment by orally administering to a subject in need of such treatment, on a single day, a first dose in the form of a tablet, wherein said tablet comprises an amount of a

pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid and continuing said treatment by orally administering, once monthly on a single day, a tablet comprising an amount of a pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid.

6. A method for treating osteoporosis consisting of orally administering to a subject in need of such treatment, once monthly on a single day, a tablet comprising an amount of a pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid.

Roche contends that it is entitled to summary judgment of infringement because the product labeling specified in each Defendant's ANDA instructs patients to practice every element of both these claims.

There is no dispute that Defendants' proposed product labels are virtually identical to Roche's product label. And there is no genuine dispute that the proposed product labels direct patients to take actions which constitute infringement of claims 1 and 6 of the '957 patent. For example, the proposed "FDA-Approved Patient Labeling" for the Apotex product instructs patients as follows: "Take one ibandronate sodium 150 mg tablet once a month. Choose one date of the month (your ibandronate sodium tablets day) that you will remember and that best fits your schedule to take your ibandronate sodium 150 mg tablet."[1] (Dede Decl. Ex. G1 at 20.) "To establish literal infringement, all of the elements of the claim, as correctly construed, must be present in the accused system." TechSearch L.L.C. v. Intel Corp., 286 F.3d 1360, 1371 (Fed. Cir. 2002). This Court finds that Defendants' product labels instruct patients to practice every element of claims 1 and 6.[2]

[1] The proposed labels for the products of the different Defendants do not materially differ.

[2] Defendants do raise arguments against the conclusion that the product labels instruct patients to practice every element of the claims at issue, but these arguments are all meritless.

Other than the various insubstantial arguments which fail to persuade this Court that the proposed product labels do not instruct patients to practice every element of the claims at issue, Defendants principally attempt to defeat Roche's motion for summary judgment with arguments related to the substantial non-infringing uses of their products. Representative of this is DRL's two-step argument:[3] 1) the scope of the treatment method stated by the label is much broader than the scope of the treatment method stated by the claims at issue, which means that there are substantial non-infringing uses; 2) when there are substantial non-infringing uses, there can be no intent to induce infringement.

The heart of Defendants' opposition is the argument that the substantial non-infringing uses for their products negate finding the requisite specific intent to induce infringement. Although Defendants filed separate opposition briefs, all cite the Federal Circuit's decision in Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1365 (Fed. Cir. 2003), which states: "Especially where a product has substantial non-infringing uses, intent to induce infringement

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For example, Cobalt argues that the claim language "administering to a subject" requires two people, but its product label implicates only one person. The argument that the product label does not instruct patients to engage in "commencing treatment" is only very slightly more worthy. Since this Court has construed "commencing treatment" as signaling a time frame of reference of a treatment episode, there is no way that a patient could take Defendants' tablets for the first time without simultaneously commencing a treatment episode. Similarly, DRL argues that the proposed label does not include the "commencing treatment" and "consisting of" limitations: "The absence of any language in Dr. Reddy's label corresponding to those claim limitations of the '957 patent takes this case outside the realm of active inducement of infringement." (DRL Opp. Br. 16.) This is unpersuasive. Federal Circuit law requires that defendant induce acts of infringement of every element of a claim. There is no requirement that the language used to induce infringement mirror the language of the claim.

[3] DRL and other Defendants also argue that a party cannot induce infringement of a patent that does not yet exist, and that, when they originally submitted their ANDA with the proposed label to the FDA in 2007, the '957 patent did not exist. Fine. The patent exists now.

cannot be inferred even when the defendant has actual knowledge that some users of its product may be infringing the patent."

Taken out of context, this statement from Warner-Lambert does appear to support Defendants' position. Warner-Lambert is, however, distinguishable from the present case on the facts. In Warner-Lambert, the treatment method patent was directed to an off-label use, the treatment of neurodegenerative disease. Id. at 1363. Furthermore, the Federal Circuit observed that there was substantial off-label use of gabapentin as a treatment for neurodegenerative disease. Id. at 1363-1364. The Federal Circuit was thus examining an entirely different issue, the inference of specific intent to induce infringement when the label does not direct the patient to engage in the infringing use.[4]

In the instant case, in contrast, Defendants' labels direct patients to engage in the infringing use. Under such circumstances, the approach of the Warner-Lambert Court to the analysis of specific intent to induce infringement is inapplicable.[5] Defendants do not cite any Federal Circuit case in which the product label directed patients to perform an infringing method, and the existence of substantial non-infringing uses raised a genuine factual issue as to specific intent to induce infringement.

In reply, Roche argues, in short, that the inducement of non-infringing uses is a red

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[4] The Federal Circuit summarized its analysis as follows: "Here, the request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of infringement (induced or otherwise) with respect to a patent on an unapproved use, as the ANDA does not induce anyone to perform the unapproved acts required to infringe." Id. at 1364-1365. A drug labeled for an infringing, approved use – as in the instant case – is an entirely different situation, since the label does induce patients to perform the acts required to infringe.

[5] Similarly, Defendants' citation of Organon Inc. v. Teva Pharms., Inc., 244 F. Supp. 2d 370 (D.N.J. 2002), another case in which the patent covered an off-label use only, is inapposite.

herring, as it is the inducement of infringement that subjects Defendants to liability. In view of the discussion above, this Court agrees. The proposed product labels direct patients to practice the patented method. Defendants are expressly instructing others to perform a method which infringes a method patent. The fact that they may, in addition, be instructing others to do things which do not infringe has no bearing on the inference of specific intent to induce infringement. While this may constitute evidence about some additional intent on the part of Defendants, evidence of an additional intent to induce non-infringing acts does not raise a genuine factual issue about the specific intent to induce infringing acts.

Defendants argue as well that Roche has failed to present any evidence that they have induced actual infringement, that any patients have actually practiced the infringing method. As Roche notes, this argument overlooks the fact that this is Hatch-Waxman litigation. On this issue, Warner-Lambert is on point:

> [T]he ANDA must be judged on its face for what an accused infringer seeks the FDA's approval to do. Section 271(e)(2) does not encompass "speculative" claims of infringement. The statute explicitly defines the act of infringement as the filing of the ANDA. The infringement case is therefore limited to an analysis of whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed. . . .
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> As we explained in *Glaxo*, 35 U.S.C. § 271(e)(2)(A) simply provides an "artificial" act of infringement that creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product. Once jurisdiction is established, however, the substantive determination whether actual infringement or inducement will take place is determined by traditional patent infringement analysis, just the same as it is in other infringement suits, including those in a non-ANDA context, the only difference being that the inquiries now are hypothetical because the allegedly infringing product has not yet been marketed. The plain language of [35 U.S.C. § 271(e)(2)(A)] does not alter a patentee's burden of proving infringement. The proper inquiry under § 271(e)(2)(A) is whether, if a particular drug were put on the market, it would infringe the relevant

patent.

Id. at 1364, 1365-1366 (citations omitted). As the Federal Circuit has explained in this quote, the inducement analysis in a Hatch-Waxman case is necessarily hypothetical. The law does not require a plaintiff to show that infringement has actually occurred, but only that, if a particular drug were put on the market, it would induce infringement of the relevant patent. Plaintiff has met this requirement.

Defendants also contend that the fact that the FDA required them to use the particular product labels they have proposed negates any finding of specific intent. This is unpersuasive. A thief who assaults a man because it was the only possible way to get his wallet from him does not lack specific intent to assault because, under the circumstances, it was a necessary means to accomplish his ultimate goal of robbery. The argument that the thief was just doing what the circumstances required him to do to achieve other ultimate ends does not effectively negate finding specific intent to assault.

"Evidence of active steps taken to encourage direct infringement, such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe, and a showing that infringement was encouraged overcomes the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use." MGM Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 936 (2005). Roche has presented evidence that Defendants have taken such active steps: providing instructions to others to engage in an infringing use. Roche has satisfied the Grokster requirement that it show "purposeful, culpable expression and conduct" by Defendants. Id. at 937. The evidence unequivocally demonstrates that Defendants intend that their purchasers follow the package

insert instructions, and therefore have the requisite specific intent to induce infringement. Defendants have failed to raise any genuine factual disputes that might preclude a grant of summary judgment. Roche's motion for summary judgment will be granted.

III. The cross-motions for summary judgment of non-infringement of the '957 patent

DRL and Genpharm have filed cross-motions for summary judgment of non-infringement of the '957 patent. Genpharm's brief relies on the arguments made by DRL. Although DRL refers to theories of direct and contributory infringement, this Court will only entertain DRL's cross-motion on the issue of inducing infringement, as that is the subject of Roche's original motion. See L. Civ. R. 7.1(h). At the time that these cross-motions were filed, Roche moved to strike them, objecting to them as improper because they were not related to the subject matter of the original motion. This Court denied Roche's motion but, having examined the cross-motions more closely, now agrees that, even as they relate to inducing infringement, the cross-motions are not sufficiently related to the original motions: the cross-motions address claims 5 and 10, while the original motions address claims 1 and 6. More importantly, they appear to turn on the question of whether the DRL product is in the monohydrate form, which is totally unrelated to the issues raised by Roche's original motion. The cross-motions will be denied without prejudice.

IV. Orchid's motion for summary judgment of non-infringement of the '957 patent

Orchid moves for summary judgment of non-infringement based on both contributory infringement and inducing infringement. As to inducing infringement, the motion for summary judgment is denied, based on the analysis already explained above.

Orchid moves for summary judgment of non-infringement based on contributory

infringement, pursuant to 35 U.S.C. § 271(c):

> Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

Orchid argues that it cannot be liable under § 271(c) because its product is a commodity of commerce suitable for substantial non-infringing use. Procedurally, Orchid is the movant who does not bear the burden of proof of contributory infringement at trial, and unsuitability for substantial non-infringing use is an element of contributory infringement. See DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1303 (Fed. Cir. 2006) ("Thus, to prevail on contributory infringement, DSU must have shown that ITL made and sold the Platypus, that the Platypus has no substantial non-infringing uses in its closed-shell configuration. . ."[6]) Thus, at summary judgment, Orchid satisfies its initial burden by pointing to the absence of evidence to support Roche's case, and the summary judgment burden then shifts to Roche. At this juncture, to defeat the motion for summary judgment, Roche must offer evidence that Orchid's product is not suitable for substantial non-infringing use.

In its opposition brief, Roche misapprehends the law and fails to recognize, no less meet, its legal burden to defeat the motion for summary judgment. Roche contends that Orchid "bears the burden of proving substantial non-infringing uses." (Pl.'s Opp. Br. 13.) This is incorrect, and seems to be based on viewing substantial non-infringing use as an affirmative defense to contributory infringement. DSU makes clear that such is not the case: unsuitability for

[6] Note: DSU was the patentee, and ITL the alleged contributory infringer.

substantial non-infringing use is not an affirmative defense but an element of contributory infringement.

This Court asked the parties to provide supplementary briefing on the issue of who bears the burden of proof as to unsuitability for substantial non-infringing use. In its supplementary brief, Roche modified its position, contending that the Federal Circuit applies a burden-shifting approach in which the patentee bears the initial burden of making out a prima facie case that the accused product was not suitable for non-infringing use; the burden then shifts to the defendant. This Court need not reach the question of what quantum of evidence of unsuitability for non-infringing use Roche must initially produce to satisfy its burden at summary judgment, because Roche has not produced any such evidence,[7] since it took the incorrect position that it was Orchid's burden to prove substantial non-infringing uses.

Despite Roche's missteps in opposing Orchid's motion for summary judgment of no contributory infringement, this Court will not grant Orchid's motion. Orchid has, nonetheless, failed to persuade this Court that it is entitled to judgment as a matter of law, as Rule 56 requires.

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[7] Roche appears to concede that it has not produced such evidence. In its supplementary brief, Roche stated:

> Here, Roche has introduced evidence that Orchid will market an ANDA product that is specifically adapted for infringing use with specific instructions for infringing Roche's patent (Roche Opp. Br. at 19-20) and that Orchid's proposed ANDA product is not a staple article of commerce (Roche Opp. Br. at 35, fn 62). Therefore, Roche respectfully submits that it has made a prima facie showing of contributory infringement and the burden of production should shift to Orchid to produce evidence that its product is a staple article of commerce adapted to other lawful noninfringing uses.

Thus, Roche claims no more than having offered evidence that Orchid will market a product adapted for infringing use. Roche must show, however, that the product is not suitable for substantial non-infringing use – a distinctly different matter.

To start with, Roche has offered evidence from which a finder of fact could reasonably conclude that each Defendant's product is not a staple article. (See Roche's Opp. Br. 35 n.62.) Should this be sufficient to raise a material factual issue? The answer to this question requires an analysis of the statutory language ("and not a staple article or commodity of commerce") that neither party has even started, no less done persuasively. It may well be that Roche cannot prove contributory infringement but, on this briefing, this Court does not find that the elements of this cause of action have been sufficiently analyzed to allow this Court to conclude, as a matter of law, that Roche cannot prevail. The parties have not adequately briefed, legally and factually, whether or not the proposed products are or are not staple articles or commodities of commerce. As to the issue of contributory infringement, the motion for summary judgment of non-infringement will be denied.

CONCLUSION

For the reasons stated above, as to Roche's motion for summary judgment on inducing infringement, Roche has shown that it is entitled to judgment as a matter of law. Roche's motion for summary judgment on inducing infringement is granted. The cross-motions for summary judgment of non-infringement by DRL and Genpharm are denied. Orchid's motion for summary judgment of non-infringement is denied.

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

Dated: September 2, 2010