UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AVENTIS PHARMA DEUTSCHLAND GMBH and KING PHARMACEUTICALS, INC.,	*	
Plaintiffs,	*	
v.	*	Civil Action No. 03-10492-JLT
COBALT PHARMACEUTICALS, INC.,	*	
Defendant.	*	

MEMORANDUM

February 7, 2005

TAURO, J.

This is an action for patent infringement arising under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act").[1] Plaintiff Aventis Pharma Deutschland GmbH ("Aventis") owns two unexpired patents relating to the ACE inhibitor "ramipril," a drug approved by the FDA to treat hypertension, heart failure, and to reduce the risk of heart attack, stroke, and death from cardiovascular causes. Plaintiff King Pharmaceuticals, Inc. ("King") exclusively sells ramipril in the United States under the trade name "ALTACE." Defendant Cobalt Pharmaceuticals, Inc. ("Cobalt") is seeking FDA approval for the manufacture and sale of a generic version of ramipril. Cobalt contends that Aventis's patents are either invalid or will not be infringed by the proposed generic drug.

[1]Pub. L. No. 98-417, 98 Stat. 1585 (codified at scattered sections of titles 21, 35, and 42 U.S.C.).

Background

Aventis, a German corporation, is the owner of U.S. Patent No. 5,061,722 ("'722 Patent"). The '722 patent claims the angiotensin converting enzyme inhibiting compound ramipril.[2] Ramipril belongs to a family of pharmaceuticals commonly called "ACE inhibitors." Aventis also owns a method-of-use patent, U.S. Patent No. 5,403,856 ("'856 Patent"). The '856 patent claims a method of using ramipril to treat cardiac insufficiency, post-myocardial infarction, *i.e.*, treating heart failure after a heart attack.[3]

The Food and Drug Administration ("FDA") has approved the use of ramipril for three distinct purposes: (1) treating hypertension; (2) treating heart failure; and (3) reducing the risk of heart attack, stroke, and death from cardiovascular causes ("reducing risk").[4] In addition, the FDA-approved dosage recommendations are different for each treatment.[5] It is undisputed that Aventis's '856 patent claims the approved method of treating heart failure, while the approved methods of treating hypertension and reducing risk remain in the public domain.[6]

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[2]Decl. of Benjamin C. Hsing in Supp. of Pls.' Mot. for Summ. J. ("Hsing Decl.") Ex. A.

[3]Decl. of Matthew C. Marlowe in Supp. of Cobalt Pharms., Inc.'s Mot. for Summ. J. as to its Non-Infringement of the '856 Patent ("Marlowe Decl. #1") Ex. A; Pls.' Opp'n to Cobalt Pharms., Inc.'s Mot. for Summ. J. of Non-Infringement of the '856 Patent at 2.

[4]Def. Cobalt Pharms., Inc.'s Supplemental Br. in Supp. of its Mot. for Summ. J. of Non-Infringement of the '856 Patent at 3-4.

[5]Decl. of Matthew C. Marlowe in Supp. of Def. Cobalt Pharms., Inc.'s Supplemental Br. in Supp. of its Mot. for Summ. J. of Non-Infringement of the '856 Patent ("Marlowe Decl. #2") Ex. A at CA2232-233.

[6]Def.'s Statement of Material Facts under Rule 56.1 as to which There Is No Genuine Dispute ¶¶ 6-8. Plaintiffs have never asserted to this court that the '856 patent claims the "reduction of risk" indication, and they have not challenged Cobalt's assertion that the '856 patent does not claim the reduction of risk indication; see also Decl. of Eric C. Stops in Supp. of Pls.'

A. The Hatch-Waxman Act

All pharmaceutical companies must obtain FDA approval before marketing a new drug.[7] The Hatch-Waxman Act permits generic drug companies to use patented pharmaceuticals to develop generic drugs and to seek FDA approval for their manufacture and sale.[8] Filing an Abbreviated New Drug Application ("ANDA") is the initial step in seeking FDA approval for a generic drug.[9] In the ANDA, generic manufacturers must demonstrate that the proposed generic drug is the bioequivalent of a drug previously approved by the FDA.[10] This allows generic drug companies to "'piggyback' on the safety-and-effectiveness information that the brand-name manufacturers submitted" to the FDA.[11]

The ANDA must also address patents that cover the relevant drug. Generic manufacturers must search the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (hereinafter the "Orange Book") in which patent holders list patents relating to their FDA-approved drugs.[12] If the Orange Book lists unexpired patents covering the drug, then the

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Opp'n to Cobalt Pharms., Inc.'s Mot. for Summ. J. of Non-Infringement of the '856 Patent ("Stops Decl.") Ex. E (explaining that "exclusivity" pertaining to the reduction of risk indication has "expired").

[7]21 U.S.C. § 355(a).

[8]35 U.S.C. § 271(e)(1).

[9]21 U.S.C. § 355(j).

[10]21 U.S.C. § 355(j)(4)(F).

[11]Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 879 (D.D.C. 2004) (citing 21 U.S.C. § 355(j)(2)(A) and 21 C.F.R. § 314.94(a)(3)).

[12]See Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1344 (Fed. Cir. 2004); 21 U.S.C. § 355(b)(1).

generic manufacturer must file a "paragraph IV certification" to the FDA indicating either that the patents will not be infringed by the manufacture and sale of the generic drug or that the existing patents are invalid.[13] If a method-of-use patent is listed in the FDA's Orange Book, and the patent *does not claim a use* of the drug for which the ANDA applicant is seeking approval, then the ANDA may simply include a statement to that effect.[14] This is called a "section viii statement." An ANDA containing a section viii statement need not include a paragraph IV certification regarding the method-of-use patent.[15]

When a generic company files an ANDA containing a paragraph IV certification, however, the applicant must notify the patent holder.[16] The patent holder then has forty-five days to bring an infringement suit against the ANDA applicant under 35 U.S.C. § 271(e)(2).[17] Because the ordinary ANDA applicant has not yet infringed the patents in any meaningful sense, § 271(e)(2) deems the filing of an ANDA an artificial act of infringement "sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity."[18] If the patent holder brings suit, the Hatch-Waxman Act suspends FDA approval until the earliest of the following: judicial resolution, the patent has expired, or thirty months from

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[13]21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[14]21 U.S.C. § 355(j)(2)(A)(viii).

[15]See Purepac Pharm. Co., 354 F.3d at 879.

[16]21 U.S.C. § 355(j)(2)(B)(i).

[17]21 U.S.C. § 355(j)(5)(B)(iii).

[18]Glaxo, Inc. v. Novopharm Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997); see also Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1349 (Fed. Cir. 2004) (citing Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990)).

the patent holder's receipt of notice.[19]

Under the Hatch-Waxman Act, the district court must determine whether the generic company's paragraph IV certification is accurate. In other words, the district court must determine "whether the patent in question is 'invalid or *will not be infringed* by the manufacture, use, or sale of the drug for which the [ANDA] is submitted.'"[20] If the court finds that the patents are valid and will be infringed by the generic drug, "then the patent owner is entitled to an order that FDA approval of the ANDA containing the paragraph IV certification not be effective until the patent expires."[21] The court's inquiry is grounded in the ANDA and the accompanying materials submitted in support.[22]

B. Cobalt's ANDA

On November 22, 2002, Defendant Cobalt, a Canadian corporation, submitted an ANDA to the FDA seeking approval to engage in the commercial manufacture, use, and sale of generic ramipril capsules.[23] Cobalt included a paragraph IV certification with respect to the '722 patent owned by Aventis.[24] Cobalt's paragraph IV certification asserted that Aventis's '722 patent is "invalid, unenforceable or will not be infringed" by Cobalt's generic ramipril capsules.[25] Cobalt

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[19]Novopharm, 110 F.3d at 1569.

[20]Id. (emphasis in original) (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)).

[21]Id. (citing 21 U.S.C. § 355(j)(4)(B)(iii)(II) and 35 U.S.C. § 271(e)(4)(A)).

[22]Id.

[23]First Am. Compl. ¶ 13; Marlowe Decl. #1 Ex. C.

[24]Marlowe Decl. #1 Ex. C.

[25]Id.

alleges that the '722 patent is unenforceable because Aventis committed inequitable conduct before the United States Patent and Trademark Office ("PTO").[26] On March 14, 2003, Aventis and King (collectively "Plaintiffs") filed suit under 35 U.S.C. § 271(e)(2) against Cobalt for infringement of the '722 patent.

Cobalt initially did not file a section viii statement regarding Aventis's '856 method-of-use patent because Aventis did not list the '856 patent in the FDA's Orange Book until Plaintiffs filed suit in this court.[27] Upon learning of the '856 patent, Cobalt filed a section viii statement with the FDA declaring that it was not seeking approval for treating heart failure, the method-of-use claimed in the '856 patent.[28] Cobalt also amended its proposed labeling with the FDA and removed the pharmacological information regarding the use of ramipril for treating heart failure.[29] Cobalt intends to market generic ramipril solely for treating hypertension and reducing the risk of heart attack, stroke, and death from cardiovascular causes.[30] Nonetheless, Plaintiffs amended their complaint to allege that "Cobalt will actively induce or contribute to infringement by others" of the '856 patent.[31] Specifically, Plaintiffs argue that Cobalt will indirectly infringe the '856

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[26]First Am. Answer to First Am. Compl. ¶ 33.

[27]Marlowe Decl. #1 Ex. D.

[28]Marlowe Decl. #1 Ex. B.

[29]Mem. in Supp. of Cobalt Pharms., Inc.'s Mot. for Summ. J. as to its Non-Infringement of the '856 Patent at 5-6; Marlowe Decl. #1 Exs. B, H.

[30]See Decl. of Matthew C. Marlowe in Supp. of Cobalt Pharms., Inc.'s Mot. for Leave to File a Supplemental Br. on Non-Infringement of the '856 Patent ("Marlowe Decl. #3") Ex. A at CA2347.

[31]First Am. Compl. ¶ 27.

patent because doctors will prescribe generic ramipril for treating heart failure.

Presently before this court are: (1) Cobalt's Motion for Judgment on the Pleadings with respect to Plaintiffs' Claim of Willful Patent Infringement; (2) Plaintiffs' Motion to Preclude Cobalt from Relying on the Advice of Counsel as a Defense to Plaintiffs' Claim of Willful Infringement; (3) Plaintiffs' Motion for Summary Judgment on Cobalt's Inequitable Conduct Defense; (4) Cobalt's Motion for Summary Judgment with respect to the '856 patent; and (5) King's Motion for Clarification of the Protective Order.

Discussion

A. Willful Patent Infringement

Plaintiffs claim that Cobalt's infringement of the '722 patent "has been, and continues to be, willful and deliberate."[32] Plaintiffs assert that Cobalt willfully infringed the '722 patent by filing an "utterly baseless" paragraph IV certification with the FDA.[33] With respect to this allegation of "willful" patent infringement, Cobalt has moved for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c).[34]

"The standard for evaluating a Rule 12(c) motion for judgment on the pleadings is

[32]First Am. Compl. ¶ 20.

[33]Pls.' Opp'n to Cobalt Pharms., Inc.'s Mot. to Strike Pls.' Claim of Willful Infringement at 7.

[34]Cobalt has moved to strike the allegation of willfulness from the amended complaint pursuant to Fed. R. Civ. P. 12(f). In the alternative, Cobalt has moved for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c). This court will consider Cobalt's alternative request and analyze the issue under the Rule 12(c) standard.

essentially the same as the standard for evaluating a Rule 12(b)(6) motion."[35] "A motion for judgment on the pleadings may be granted only if it appears, beyond doubt, that the plaintiff can prove no facts in support of his claim that entitles him to relief."[36] This court will consider only the information and materials contained in the pleadings, accepting as true all well-pleaded facts in the amended complaint and drawing all reasonable inferences in favor of Plaintiffs.[37]

The Federal Circuit has considered claims of "willful" patent infringement under the Hatch-Waxman Act when reviewing awards of attorney's fees. There are statutorily-defined remedies for a successful patent holder in a suit under the Hatch-Waxman Act. Under 35 U.S.C. § 271(e)(4), the district court may award attorney's fees to the prevailing party only in "exceptional cases."[38] Exceptional cases may involve inequitable conduct before the PTO, litigation misconduct, or willful patent infringement.[39] Recently, the Federal Circuit has limited the types of conduct that may give rise to an award of attorney's fees under the Hatch-Waxman Act.[40] In *Glaxo Group Ltd. v. Apotex, Inc.*, the Federal Circuit held that "the mere fact that a company has filed an ANDA application *or certification* cannot support a finding of willful

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[35]Furtick v. Medford Hous. Auth., 963 F. Supp. 64, 67 (D. Mass. 1997) (citing Nedder v. Rivier Coll., 944 F. Supp. 111, 120 (D.N.H. 1996)).

[36]Petricca v. City of Gardner, 194 F. Supp. 2d 1, 4 (D. Mass. 2002) (citing Conley v. Gibson, 355 U.S. 41, 45-46 (1957)).

[37]See Gulf Coast Bank & Trust Co. v. Reder, 355 F.3d 35, 38 (1st Cir. 2004); Garita Hotel Ltd. P'ship v. Ponce Fed. Bank, F.S.B., 958 F.2d 15, 17 (1st Cir. 1992).

[38]See 35 U.S.C. § 271(e)(4) (incorporating by reference 35 U.S.C. § 285).

[39]Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1350 (Fed. Cir. 2004).

[40]Id.

infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)."[41]

Plaintiffs argue that *Glaxo* does not apply to this case because the generic manufacturer in *Glaxo* did not submit a paragraph IV certification to the FDA. In this respect, *Glaxo* involved factually unusual circumstances.[42] Plaintiffs argue, therefore, that *Glaxo* has very limited applicability, and the act of filing a baseless paragraph IV certification to the FDA may be considered willful patent infringement.[43] This court disagrees.

In *Glaxo*, the district court found that a generic manufacturer's filing of an ANDA "without a reasonable basis for believing that it had a right to market its generic product prior to patent expiration" constituted an act of "willful" patent infringement.[44] In reversing the district court, the Federal Circuit explained that "[t]he act of filing an ANDA constitutes a 'highly artificial' act of infringement."[45] Congress created this artificial act of infringement "to permit patent holders to bring suit against generic companies despite the fact that the generic companies have not yet infringed the patents at issue."[46] The district court was wrong to find "willfulness on

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[41]Id. at 1350-351 (emphasis added).

[42]Glaxo, 376 F.3d at 1344 (explaining that Apotex's ANDA was "atypical" in that it did not include a paragraph IV certification because the patent holder was not required to list the patent in the Orange Book).

[43]Pls.' Opp'n to Cobalt Pharms., Inc.'s Mot. to Strike Pls.' Claim of Willful Infringement at 6-7.

[44]Glaxo Group Ltd. v. Apotex, Inc., 268 F. Supp. 2d 1013, 1035 (N.D. Ill. 2003).

[45]Glaxo, 376 F.3d at 1349 (citing Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990)).

[46]Id. at 1351.

such a special-purpose peg."[47] Accordingly, the Federal Circuit held that "the mere fact that a company has filed an ANDA application *or certification* cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)."[48]

Plaintiffs are correct that *Glaxo* was an "atypical" Hatch-Waxman Act suit insofar as the generic company did not file a paragraph IV certification.[49] But this court cannot read the words "or certification" in the *Glaxo* holding as mere surplusage.[50] In reaching its decision in *Glaxo*, the Federal Circuit clarified their previous ruling in *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc*.[51]

In *Yamanouchi*, the Federal Circuit affirmed an award of attorney's fees under 35 U.S.C. § 271(e)(4) because the generic company engaged in serious and persistent litigation misconduct.[52] This made *Yamanouchi* an exceptional case and justified an award of attorney's fees to the patent holder.[53] The district court, though, awarded attorney's fees under a different rationale. The district court found that the generic company's filing of a baseless paragraph IV

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[47]Id.

[48]Id. at 1350-51 (emphasis added).

[49]Id. at 1344.

[50]Id. at 1350.

[51]Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339 (Fed. Cir. 2000).

[52]Glaxo, 376 F.3d 1350 (quoting Yamanouchi, 231 F.3d at 1347). The Federal Circuit explained that "an award of attorney's fees was permitted because the generic had filed numerous baseless filings supporting its fruitless and meritless arguments, both in its case at trial and in its ANDA certification." Id.

[53]Id. ("Such unjustified litigation and misconduct has always justified a finding of an exceptional case.").

certification constituted willful patent infringement.[54] While affirming the district court's award of attorney's fees based on litigation misconduct, the Federal Circuit "did not agree that the generic company had engaged in willful infringement."[55] Instead, the Federal Circuit "cautioned that the trial court need not have elevated the ANDA *certification* into a finding of willful infringement."[56] The holding in *Glaxo*, "as suggested by *Yamanouchi*," made it clear that the mere act of filing an ANDA or certification with the FDA cannot be considered willful infringement, and an award of attorney's fees must be grounded in some other misconduct.[57]

The only act of infringement alleged in Plaintiffs' amended complaint is Cobalt's filing of an ANDA and a paragraph IV certification with the FDA.[58] Because this artificial act of infringement cannot be considered willful, Plaintiffs have averred no facts that can support a finding of willful patent infringement. For the foregoing reasons, Cobalt's motion for judgment on the pleadings is ALLOWED with respect to Plaintiffs claim of willful infringement. At the appropriate time, however, Plaintiffs may seek to prove additional facts that would support their claim for an award of attorney's fees.[59] Specifically, the prevailing party may seek to prove that this is an exceptional case, like *Yamanouchi*, involving serious and persistent litigation

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[54]Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 21 F. Supp. 2d 366, 377 (S.D.N.Y. 1998).

[55]Glaxo, 376 F.3d at 1350.

[56]Id. (quoting Yamanouchi, 231 F.3d at 1347) (internal quotations omitted) (emphasis added).

[57]Id. at 1350.

[58]First Am. Compl. ¶¶ 16, 25.

[59]See Fed. R. Civ. P. 54(d)(2).

misconduct.[60] This court, though, will deal with allegations of exceptional misconduct only after a disposition of the merits, when there exists a prevailing party.[61]

In response to Plaintiffs' claim of willful patent infringement, Cobalt raised the defense that it reasonably relied on the advice of counsel when preparing the ANDA and paragraph IV certification. Plaintiffs have asked this court to preclude Cobalt from "presenting evidence of its opinion of counsel at trial" because Cobalt has allegedly failed to cooperate with discovery.[62] As a result of this court's decision to allow Cobalt's motion for judgment on the pleadings, Cobalt will not need to raise reliance on the advice of counsel as a defense to willful infringement. Plaintiffs' motion, therefore, is DENIED WITHOUT PREJUDICE to raising the issue in connection with an appropriate motion for an award of attorney's fees.

B. Plaintiffs' Motion for Summary Judgment on Cobalt's Inequitable Conduct Defense

Cobalt has raised the affirmative defense that Aventis's '722 patent, which claims the ramipril compound, is unenforceable due to Aventis's inequitable conduct before the PTO.[63] Specifically, Cobalt alleges that Aventis submitted materially false and misleading statements, in several affidavits, to the PTO during prosecution of the '722 patent.[64] Plaintiffs have moved for

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[60]See Glaxo, 376 F.3d at 1350.

[61]See Larchmont Eng'g, Inc. v. Toggenburg Ski Ctr., Inc., 444 F.2d 490, 491 (2d Cir. 1971) ("The statutory provision for awarding attorney fees in patent cases is normally invoked only at the end of litigation.").

[62]Mem. in Supp. of Pls.' Mot. to Preclude Def. from Relying on the Advice of Counsel as a Defense to Pls.' Claim of Willful Infringement at 8.

[63]First Am. Answer to First Am. Compl. ¶ 33.

[64]Id. ¶¶ 34-71.

summary judgment on Cobalt's affirmative defense of inequitable conduct, arguing that no trier of fact could reasonably find clear and convincing evidence that Aventis's scientists made material misrepresentations to the PTO with the intent to deceive.

A motion for summary judgment is meant "to pierce the boilerplate of the pleadings and assay the parties' proof in order to determine whether trial is actually required."[65] Under Federal Rule of Civil Procedure 56, summary judgment is appropriate only if the record reveals that there is "no genuine issue as to any material fact and . . . the moving party [has demonstrated an] entitle[ment] to a judgment as a matter of law."[66]

It is the responsibility of the "party seeking summary judgment [to] make a preliminary showing that no genuine issue of material fact exists. Once the movant has made this showing, the nonmovant must contradict the showing by pointing to specific facts demonstrating that there is, indeed, a trialworthy issue."[67]

In deciding whether to allow a motion for summary judgment, a court "must view the entire record in the light most hospitable to the party opposing summary judgment, indulging all

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[65]Mullin v. Raytheon Co., 164 F.3d 696, 698 (1st Cir. 1999) (quoting Wynne v. Tufts Univ. Sch. of Med., 976 F.2d 791, 794 (1st Cir. 1992)).

[66]Fed. R. Civ. P. 56(c). "In the lexicon of Rule 56, 'genuine' connotes that the evidence on the point is such that a reasonable jury, drawing favorable inferences, could resolve the fact in the manner urged by the nonmoving party, and 'material' connotes that a contested fact has the potential to alter the outcome of the suit under the governing law if the controversy over it is resolved satisfactorily to the nonmovant." Blackie v. Maine, 75 F.3d 716, 721 (1st Cir. 1996).

[67]Id. (quoting Nat'l Amusements, Inc. v. Town of Dedham, 43 F.3d 731, 735 (1st Cir. 1995)).

reasonable inferences in that party's favor."[68] But, a court "need not credit 'conclusory allegations, improbable inferences, and unsupported speculation.'"[69] In addition, "[e]xpert testimony that offers only a bare conclusion is insufficient to prove the expert's point."[70]

"To hold a patent unenforceable for inequitable conduct, a court must find, by clear and convincing evidence, that the applicant omitted or misrepresented material facts with the intention of misleading or deceiving the patent examiner."[71] To survive Plaintiffs' motion for summary judgment, Cobalt must "introduce evidence from which a trier of fact could find materiality and intent by clear and convincing evidence."[72] For a misrepresentation to be material, it "need not be relied on by the examiner in deciding to allow the patent. The matter misrepresented need only be within a reasonable examiner's realm of consideration."[73] Where inequitable conduct is alleged, the intent to deceive element "need not, and rarely can, be proven by direct evidence."[74] Gross

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[68]Mullin, 164 F.3d at 698 (quoting Griggs-Ryan v. Smith, 904 F.2d 112, 115 (1st Cir. 1990)) (internal quotations omitted).

[69]Bloomfield v. Bernardi Automall Trust, 170 F. Supp. 2d 36, 40 (D. Mass. 2001) (quoting Medina-Munoz v. R.J. Reynolds Tobacco Co., 896 F.2d 5, 8 (1st Cir. 1990)).

[70]SMS Systems Maint. Servs., Inc. v. Digitial Equip. Corp., 188 F.3d 11, 25 (1st Cir. 1999).

[71]Monsanto Co. v. Bayer Bioscience N.V., 363 F.3d 1235, 1239 (Fed. Cir. 2004) (citing Monon Corp. v. Stoughton Trailers, Inc., 239 F.3d 1253, 1261 (Fed. Cir. 2001); Upjohn Co. v. Mova Pharm. Corp., 225 F.3d 1306, 1312 (Fed. Cir. 2000); Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1048 (Fed. Cir. 1995)).

[72]Abbott Labs. v. TorPharm, Inc., 300 F.3d 1367, 1379 (Fed. Cir. 2002) (citing Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 872 (Fed. Cir. 1988)).

[73]Merck & Co., Inc. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1421 (Fed. Cir. 1989).

[74]Id. at 1422.

negligence alone, however, does not "justify an inference of intent to deceive."[75] Instead, an intent to deceive "must generally be inferred from the facts and circumstances surrounding the applicant's overall conduct."[76]

Cobalt has submitted evidence to support the following facts. In 1980, the pharmaceutical company Merck, Sharp & Dome introduced an ACE inhibitor called "enalapril" to the scientific community.[77] Scientists working for Schering Plough Corp. ("Schering") used enalapril as a "lead structure" in developing the ramipril compound.[78] In May of 1982, Schering's European Application No. 0,050,800 (the "Neustadt" patent) claiming the ramipril compound was published.[79] On July 30, 1984, Schering filed a U.S. patent application with respect to the ramipril compound,[80] and on May 6, 1986, Schering obtained U.S. Patent No. 4,587,258 (the "Gold Patent").[81]

In November of 1985, Aventis also filed a U.S. patent application for ramipril.[82] In March of 1986, the PTO initially rejected Aventis's patent application on the grounds that Schering had

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[75]Kingsdown Med. Consultants, 863 F.2d at 876.

[76]Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1190 (Fed. Cir. 1993).

[77]Decl. of Steven A. Maddox in Supp. of Def.'s Opp'n to Pls.' Mot. for Partial Summ. J. ("Maddox Decl.") Ex. A at 31-32.

[78]Maddox Decl. Ex. F at 57-58.

[79]Maddox Decl. Ex. I.

[80]Maddox Decl. Ex. H.

[81]Id.

[82]See Maddox Decl. Ex. J at A006443, A006527.

been the first to develop ramipril.[83] Aventis responded by claiming that the Neustadt patent (Schering's prior art) did not enable a person of ordinary skill in the art to produce ramipril.[84] Aventis submitted several affidavits to the PTO, over a five year period, supporting its claim that the Neustadt patent did not enable synthesis of the ramipril isomer.

In November of 1986, Aventis submitted the declaration of Dr. Hansjörg Urbach to the PTO.[85] Relying on the experiments of Professor Edward C. Taylor and Sir Derek Richard Barton, Urbach claimed that the method of synthesizing ramipril described in the Neustadt patent did not work.[86] Cobalt's expert, Dr. Michael Crimmins, however, claims that Dr. Urbach could not have reasonably relied on the experiments performed by Drs. Taylor and Barton because they failed to apply ordinary chemical synthesis protocols when replicating the Neustadt process.[87] Crimmins also claims that Dr. Urbach's statements were materially false because someone skilled in the relevant art of 1981 only needed to know ramipril's chemical structure to reproduce the compound.[88] In fact, Cobalt claims that Mr. Holger Gaul, an Aventis laboratory assistant, actually produced ramipril relying solely on his knowledge of ramipril's chemical structure.[89]

In January of 1988, in order to determine priority, the PTO declared an interference

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[83]Id. at A006443-06444.

[84]Id. at A006459-06460.

[85]Decl. of Michael T. Crimmins, Ph.D. ("Crimmins Decl.") Ex. C at A000197.

[86]See Maddox Decl. Ex. J at A006477.

[87]Crimmins Decl. ¶¶ 19 & 51.

[88]Id. ¶¶ 65-67.

[89]Crimmins Decl. Ex. L at 65-66.

proceeding between Aventis's application and Schering's Gold patent.[90] Cobalt contends that Aventis conceded priority to Schering and purchased Schering's silence by taking a license, promising to pay Schering a royalty on Aventis's future sales.[91]

Aventis then began asserting new claims to a "superior" and "substantially more effective" version of ramipril–a purer "all S" isomer.[92] To support this new claim, Aventis submitted the declarations of Dr. Reinhard Becker to the PTO.[93] Becker claimed that the purer "all S" isomer was "far superior" to the compounds claimed by Schering's Gold Patent.[94]

Cobalt argues that Dr. Becker's statements were materially false and misleading. Another Cobalt expert, Dr. John Caldwell, claims that Dr. Becker failed to make highly relevant comparisons between this allegedly "superior" ramipril and other ramipril isomers.[95] In addition, Dr. Caldwell claims that Dr. Becker misrepresented the sources of test results and failed to disclose the inaccuracy of his test methods.[96] Moreover, Dr. Caldwell claims that Dr. Becker failed to disclose some test results that undermine his conclusion that the pure "all S" isomer was superior to Schering's prior art.[97]

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[90]Maddox Decl. Ex. J at A006527-06529.

[91]Cobalt Pharms., Inc.'s Mem. in Opp'n to Pls.' Mot. for Partial Summ. J. with Respect to the Defense of Inequitable Conduct at 12-13; Maddox Decl. Ex. M.

[92]Maddox Decl. Ex. N at 7-8.

[93]Decl. of John Caldwell ("Caldwell Decl.") Exs. D & E.

[94]Caldwell Decl. Ex. D at A000245, Ex. E at A000270.

[95]Caldwell Decl. ¶ 8.

[96]Id. ¶¶ 11-25.

[97]Id. ¶ 33, Caldwell Decl. Ex. J. at 54-55.

On January 12, 1989, Aventis filed a patent application for these new claims to the superior ramipril isomer.[98] Aventis again had to confront the prior art. In March of 1989, Aventis submitted the affidavit of Dr. Volker Teetz to the PTO claiming that the Neustadt process, as patented, did not work and only produced small amounts of ramipril when Teetz employed "extraordinary" procedures not revealed by the prior art.[99] Cobalt's expert also claims that these statements were false and misleading and that Dr. Teetz's own laboratory notebooks plainly contradict his conclusions.[100] With respect to Dr. Teetz's experiments, Aventis claims that there are missing private notebooks that allegedly confirm his conclusions.[101] Cobalt claims that there are inexplicable failures to follow the teachings of the Neustadt patent,[102] modifications that made the process more likely to fail,[103] and a failure to disclose material information regarding his experiments to the PTO.[104]

On October 29, 1991, the PTO granted Aventis the '722 patent.[105] Aventis explains that Drs. Urbach, Becker, and Teetz submitted declarations to the PTO attempting to correct some of

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[98]See Crimmins Decl. Ex. K at A000272.

[99]Id. at A000278-281.

[100]Crimmins Decl. ¶¶ 76-99.

[101]Id. ¶ 87.

[102]Id. ¶¶ 85 & 90-91.

[103]Id. ¶ 95.

[104]Id. ¶ 92.

[105]Hsing Decl. Ex. A.

their earlier mistakes and updating the PTO with more accurate data and test results.[106] Cobalt insists that these corrections were either insufficient or misleading. Cobalt argues that neither Dr. Urbach nor Dr. Teetz cured their false testimony regarding Schering's prior art.[107]

Although Plaintiffs argue that Cobalt presents insufficient evidence of intent to deceive, Cobalt has alleged a pattern of false and misleading statements. Given the nature, circumstances, and number of these allegedly false declarations, a fact finder could reasonably infer, by clear and convincing evidence, an intent to deceive. Viewed in a light most favorable to Cobalt, the elements of materiality and intent are reasonably disputed, and the issue is not amenable to summary judgment. For the foregoing reasons, Plaintiffs' Motion for Summary Judgment on Defendant's Inequitable Conduct Defense is DENIED.

C. Cobalt's Motion for Summary Judgment with Respect to the '856 Patent

Cobalt has moved for summary judgment on Plaintiffs' claim that Cobalt will indirectly infringe the '856 patent by encouraging doctors to prescribe Cobalt's generic ramipril for treating heart failure.[108] Reviewing this motion, this court applies the same Rule 56 standard as discussed above, this time drawing all reasonable inferences in favor of Plaintiffs.

Aventis's '856 patent claims, in relevant part, "a method of treating cardiac

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[106]See Mem. of Law in Supp. of Pls.' Mot. for Summ. J. on Def.'s Inequitable Conduct Defense at 10-11, 14.

[107]Cobalt Pharms., Inc.'s Mem. in Opp'n to Pls.' Mot. for Summ. J. with Respect to the Defense of Inequitable Conduct at 15. See Maddox Decl. Ex. L at A006029.

[108]See First Am. Compl. ¶ 27 (asserting claims for active inducement and contributory infringement).

insufficiency."[109] Cobalt seeks to market its generic drug exclusively for treating hypertension and reducing the risk of heart attack, stroke, and death from cardiovascular causes.[110] There is no dispute that the '856 patent does not claim these methods of using ramipril.[111] Cobalt, therefore, will not *directly* infringe the '856 patent by marketing the generic drug solely for treating hypertension and reducing risk. Plaintiffs, however, raise two arguments to support their claim that Cobalt will *indirectly* infringe the '856 patent by actively inducing or encouraging doctors to prescribe generic ramipril for treating heart failure.

1. FDA Rejection of Cobalt's Proposed Labeling

First, Plaintiffs claim that the FDA will inevitably reject Cobalt's amended proposed labeling for not including information regarding the use of ramipril to treat heart failure.[112] As a result, Cobalt will be forced to include pharmacological information about treating heart failure in order to obtain FDA approval. Plaintiffs argue that Cobalt's generic product *will* contain labeling information regarding heart failure, and thereby, actively encourage doctors to prescribe the drug in a manner that infringes the '856 method-of-use patent.

In *Warner-Lambert v. Apotex Corp.*, the Federal Circuit determined that an "ANDA must be judged on its face" considering only "what the generic drug maker is requesting authorization

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[109]Marlowe Decl. #1 Ex. A.

[110]Marlowe Decl. #3 Ex. A at CA2347.

[111]Def.'s Statement of Material Facts under Rule 56.1 as to which There Is No Genuine Dispute ¶¶ 6-8. Plaintiffs do not argue that the '856 patent claims the reduction of risk indication.

[112]Pls.' Opp'n to Cobalt Pharms., Inc.'s Mot. for Summ. J. of Non-Infringement of the '856 Patent at 7-9.

for in the ANDA."[113] The Federal Circuit explained, "Section 271(e)(2) does not encompass 'speculative' claims of infringement."[114] The possibility that "a generic maker may someday induce someone to infringe can only be determined when that act occurs, and § 271(e)(2) was not designed to cover such future acts."[115] Moreover, applying *Warner-Lambert*, a district court recently rejected a brand-name pharmaceutical company's argument that the FDA would likely require the generic companies to modify their labeling in order to approve their ANDAs.[116] The court explained, "[R]egardless of what the future labeling . . . might be, this Section 271(e)(2) suit focuses only on their *current proposed labeling instructions*."[117]

Although Plaintiffs may raise a genuine issue as to whether the FDA is likely to reject or approve Cobalt's proposed labeling *in the future*, the Federal Circuit in *Warner-Lambert* foreclosed precisely this kind of speculation. For this reason, this court will focus only on what Cobalt is requesting authorization for in its current, proposed labeling instructions.[118]

2. Active Inducement Based on Cobalt's Current Proposed Labeling

Plaintiffs argue that Cobalt's proposed labeling, if approved by the FDA in current form,

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[113]Warner-Lambert v. Apotex Corp., 316 F.3d 1348, 1364 (Fed. Cir. 2003).

[114] Id.

[115] Id. at 1365.

[116]ICN Pharms., Inc. v. Geneva Pharms. Tech. Corp., 272 F. Supp. 2d 1028, 1048 (C.D. Cal. 2003).

[117]Id. (emphasis added).

[118]See Marlowe Decl. #3 Ex. A.

will actively induce doctors to prescribe the generic drug for treating heart failure.[119] To prove active inducement, Plaintiffs must show that Cobalt's actions will induce infringing acts and Cobalt "knew or should have known [their] actions would induce actual infringement."[120] The Federal Circuit, however, has stated that "knowledge of the acts alleged to constitute infringement is not enough."[121] Rather, to prove active inducement, a plaintiff must prove "actual intent to cause the acts which constitute the infringement."[122] Intent to cause infringement may be shown by circumstantial evidence.[123] But without evidence that Cobalt has or will "promote or encourage doctors to infringe" the '856 method-of-use patent, there is no genuine issue of material fact.[124]

Plaintiffs argue that "Cobalt knows full well" that physicians will prescribe generic ramipril for treating heart failure because the generic drug is the pharmaceutical equivalent of ALTACE.[125] Indeed, Cobalt "knows" that some state laws require pharmacists to provide the FDA-approved

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[119]Pls.' Opp'n to Cobalt Pharms., Inc.'s Mot. for Summ. J. of Non-Infringement of the '856 Patent at 11-14.

[120]Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1363 (Fed. Cir. 2003) (quoting Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 553 (Fed. Cir. 1990)) (internal quotations omitted).

[121]Id.

[122]Id. (quoting Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990)). In this context, the acts which constitute the infringement are doctors prescribing ramipril to treat heart failure, not the filing of Cobalt's ANDA. See id. at 1365.

[123]Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988).

[124]Warner-Lambert, 316 F.3d at 1364.

[125]Pls.' Opp'n to Cobalt Pharms., Inc.'s Mot. for Summ. J. of Non-Infringement of the '856 Patent at 12.

generic equivalent of brand name drugs.[126] But the Federal Circuit has heard and rejected precisely these arguments. In *Warner-Lambert*, the patent holder argued: (1) it is common knowledge that physicians routinely prescribe approved drugs for purposes other than those listed on the drugs' labels; (2) various publications and databases provide information to the public regarding on- and off-label prescriptions; (3) pharmacists commonly substitute generic drugs for name brand drugs whenever possible, and in many states such substitution is required by statute; (4) the generic company expected to get an "A-B rating" for its drug, which allows physicians and pharmacists to substitute the generic drug for the name brand drug regardless of labeling indications; and (5) the generic company considered the market size and growth potential of the drug in its strategic decision to file an ANDA and enter the market.[127] None of these facts, however, created a genuine issue as to the generic company's specific intent and action to induce infringement.[128]

Stripped of these arguments, Plaintiffs' active inducement claim rests entirely on language in Cobalt's proposed labeling instructions and package insert. Plaintiffs acknowledge that Cobalt has attempted to "carve out" the heart failure indication from their amended proposed labeling.[129] Yet Plaintiffs argue that the "Warnings" and "Precautions" sections of Cobalt's proposed labeling contain information that is intended to encourage doctors to prescribe generic ramipril for treating

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[126]Id. at 12-13.

[127]Warner-Lambert, 316 F.3d at 1364.

[128]See id.

[129]Pls.' Opp'n to Cobalt Pharms., Inc.'s Mot. for Summ. J. of Non-Infringement of the '856 Patent at 11.

heart failure. Specifically, Cobalt's proposed labeling warns, "In patients with severe congestive heart failure . . . treatment with angiotensin converting enzyme inhibitors, including ramipril, may be associated with . . . acute renal failure and/or death."[130] Plaintiffs' expert concludes that a physician reading this warning "would understand that Cobalt's generic ramipril capsules are intended for use in treating congestive heart failure."[131]

On its face, however, Cobalt's labeling appears to *discourage* doctors from prescribing ramipril for persons with congestive heart failure. Some people who might use generic ramipril to lower their blood pressure or to reduce their risk of heart attacks will, unfortunately, suffer from congestive heart failure. Cobalt's labeling simply warns such patients that renal failure and/or death is a possible concern. With all due respect to Plaintiffs' expert, the conclusion that this warning evidences Cobalt's specific intent to market generic ramipril for treating congestive heart failure is counter-intuitive and is not supported by any surveys, literature, or other objective data. Cobalt's proposed labeling certainly does not include instructions regarding the dosage or frequency of administration for treating congestive heart failure. And even if Plaintiffs' expert is correct that some doctors, after reading this grave warning, will be encouraged to prescribe ramipril for treating heart failure, this is not sufficient evidence of *Cobalt's specific intent* to cause such infringement.

In addition, Plaintiffs present evidence suggesting that Cobalt expects to generate some

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[130]Marlowe Decl. #3 Ex. A at CA2350. There is a similar warning about renal insufficiency, hypotension, oliguria, and azotemia. Id. at CA2348.

[131]Expert Report of Dr. Bertram Pitt ¶ 48.

sales revenue associated with the treatment of heart failure.[132] But this only proves Cobalt's knowledge that some physicians will prescribe generic ramipril for treating heart attacks. In a Hatch-Waxman Act suit, the Federal Circuit has deemed this knowledge "legally irrelevant" to an active inducement analysis.[133] For the foregoing reasons, Cobalt's Motion for Summary Judgment as to its Non-Infringement of the '856 Patent (Count II of the First Amended Complaint) is ALLOWED.[134]

D. Clarification of the Protective Order

Plaintiff King has moved for a clarification of the protective order. While the FDA has not approved Cobalt's generic drug or its proposed labeling, King seeks to inform the FDA that Cobalt's proposed labeling for its generic product may render that product unsafe.[135] Specifically, King wants to file a "citizen's petition" with the FDA that references the language of Cobalt's proposed labeling.[136] Cobalt argues that this court's protective order prevents King from disclosing Cobalt's proposed labeling to the FDA.

On December 2, 2003, this court entered a protective order by stipulation of the parties. In the protective order, the parties agreed that "Attorney's Eyes Only" shall mean discovery

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[132]See Pls.' Opp'n to Cobalt Pharms., Inc.'s Mot. for Summ. J. of Non-Infringement of the '856 Patent at 13.

[133]Warner-Lambert, 316 F.3d at 1364.

[134]This disposes of Plaintiffs' claim of contributory infringement. Treating hypertension and reducing risk are substantial non-infringing uses, and there is no evidence of active inducement. See Dynacore Holdings Corp. v. U.S. Philips Corp., 363 F.3d 1263, 1275-76 (Fed. Cir. 2004).

[135]Pl.'s Mot. for Clarification of the Protective Order at 1.

[136]Oral Argument Transcript [#173] at 25:1-7. See 21 C.F.R. § 10.30

material that "contains non-public, confidential or proprietary information . . . the disclosure of which is likely to cause harm to the competitive position of the party making the confidential designation on the Discovery Material."[137] Cobalt argues that its proposed labeling is "confidential" within the meaning of the protective order and can only be disclosed to "qualified persons," which does not include the FDA.[138]

Cobalt insists that King must demonstrate "extraordinary circumstances or compelling need" to justify a modification of the protective order to allow disclosure to the FDA.[139] The cases upon which Cobalt relies, however, involve motions to "modify" protective orders to permit the disclosure of secret information, previously unknown to the government agency.[140] Here, King seeks merely to clarify the existing protective order to determine whether it may discuss information already known to the FDA. The purpose of the protective order, simply put, is to protect the parties against the disclosure of secrets. As far as the FDA is concerned, Cobalt's proposed labeling is no secret. Because the FDA already possesses the labeling information, this court's protective order does not prevent King from discussing the contents of the proposed labeling with King's FDA counsel and the FDA through a citizen's petition.[141]

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[137]Protective Order [#77] at 2.

[138]Def. Cobalt Pharms., Inc.'s Opp'n to Pl.'s Mot. for Clarification of the Protective Order at 3-4.

[139]See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., No. 95 Civ. 8833-RPP, 1999 U.S. Dist. LEXIS 1529, at *7-8 (S.D.N.Y. Feb. 11, 1999).

[140]See id.

[141]This court expresses no opinion as to whether the FDA's own policies or rules prevent it from discussing the contents of a pending ANDA application with third-parties.

AN ORDER WILL ISSUE.

/s/ Joseph L. Tauro
United States District Judge

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