IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PROMETHEUS LABORATORIES INC.,	:	Civil No. 11-230 (FSH)
	:	Civil No. 11-1241 (FSH)
Plaintiff,	:	
	:	
v.	:	**OPINION**
	:	
ROXANE LABORATORIES, INC., et al.,	:	
	:	
Defendants.	:	December 16, 2013
	:	
	:	

HOCHBERG, District Judge:

I. INTRODUCTION

Defendants Roxane Laboratories, Inc. and Cipla Ltd. ("Roxane" and "Cipla," collectively referred to as "Defendants") bring a motion for summary judgment of non-infringement of the '014 patent, and Cipla brings a motion for summary judgment seeking to invalidate the '770 patent under 35 U.S.C. § 305. Plaintiff Prometheus Laboratories, Inc. ("Prometheus" or "Plaintiff") opposes both motions and brings a motion for summary judgment of no invalidity under § 305 for the '770 patent. The Court held a hearing on November 21, 2013 to address the parties' outstanding motions. During the November 21, 2013 hearing, the parties resolved their dispute with respect to the '014 patent. That patent is no longer at issue in this matter.

The parties have also filed the following motions:

- Defendants' Motion *in Limine* No. 1 Regarding Magnet and Rubicon

- Plaintiff's Motions *in Limine* Regarding Dr. Howden's "Single Actor" Testimony, Clinical Studies Evidence, Label Preparation Evidence, and Reexamination Evidence
- Both parties' motions to seal the courtroom during trial

II. BACKGROUND[1]

Prometheus filed the current actions against Defendants alleging that Defendants have or will infringe U.S. Patent No. 6,284,770 ("the '770 patent") under 35 U.S.C. §§ 271(a), 271(b), 271(c), and 271(e)(2)(A) and that Defendants have or will infringe U.S. Patent No. 6,175,014 ("the '014 patent") under 35 U.S.C. §§ 271(b) and 271(g). (Am. Compl., ¶¶ 38, 42-44, 49, 50 [Dkt. No. 67].)[2] Prometheus holds an approved New Drug Application ("NDA") under § 505(a) of the FFDCA, 21 U.S.C. § 355(a), for alosetron hydrochloride tablets (NDA No. 21-107), selling under the brand name LOTRONEX®.[3] (DS ¶ 45; PR ¶ 45.) Prometheus acquired LOTRONEX® and the '770 patent in 2007. (DS ¶ 43; PR ¶ 43.)

Prometheus' claims arise from Roxane's filing of an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to commercially market a generic version of Prometheus' LOTRONEX® drug product prior to the expiration of the '770 patent. (Am. Compl., ¶ 1.) Cipla manufactures the active pharmaceutical ingredient ("API"), *i.e.*, alosetron hydrochloride, used in Roxane's ANDA products. (PCS ¶¶ 2, 3; DRC ¶¶ 2, 3.) Cipla admits

[1] The facts below are taken from the parties' statements of undisputed facts. "DS" refers to the Defendants' Statement of Facts, "PR" refers to the Plaintiff's Response to Defendants' Statement of Facts, "PS" refers to the Plaintiff's Statement of Facts, "DR" refers to Defendants' Response to Plaintiff's Statement of Facts, "PCS" refers to Plaintiff's Counter Statement of Facts, and "DRC" refers to Defendants' response to Plaintiff's Counter Statement of Facts.

[2] All docket numbers refer to docket entries in Civ. No. 11-1241 unless otherwise noted.

[3] Alosetron hydrochloride is the active ingredient in LOTRONEX®.

that it has entered into supply contracts with generic pharmaceutical companies in the United States, and a portion of Cipla's export sales are derived from the United States. (Cipla Answer, ¶ 7 [Dkt. No. 175].)

On September 4, 2001, the USPTO issued the '770 patent titled "Medicaments for the treatment of non-constipated female irritable bowel syndrome." (DS ¶ 36; PR ¶ 36.) In 2007, Prometheus purchased the LOTRONEX® franchise from GSK, which included the '770 patent and the right to market LOTRONEX®. (DS ¶ 43; PR ¶ 43.) Prometheus contends it currently owns the '770 patent. (DS ¶ 44; PR ¶ 44.)

On August 3, 2009, Prometheus filed a request with the USPTO for *ex parte* reexamination of the '770 patent pursuant to 37 C.F.R. § 1.510. (DS ¶ 47; PR ¶ 47.) This request attached and identified "Magnet"[4] and "Rubicon"[5] as non-patent literature documents. (DS ¶ 48; PR ¶ 48.) In the request for reexamination Prometheus argued that "[b]ecause *Magnet* and *Rubicon* were published more than one year before October 5, 1998, they raise a substantial new question of patentability." (DS ¶ 49; PR ¶ 49.) Prometheus' request for reexamination did not cite any prior art references other than Magnet and Rubicon. (DS ¶ 52; PR ¶ 52.) On October 1, 2009, the USPTO mailed an order denying Prometheus' request for reexamination of the '770 patent. (DS ¶ 54; PR ¶ 54.) In their petition for further review of the reexamination, Prometheus stated that Magnet and Rubicon were prior art and should be given weight by a reexaminer as such because they raised a substantial question of patentability. (DS ¶¶ 60, 61; PR

[4] "Magnet" refers to M Magnet – The Magazine for Glaxo Wellcome plc staff. "GLAXO WELLCOME; New Product Makes a Difference; M Magnet – The Magazine for Glaxo Wellcome plc staff; July 1997; pg. 6."

[5] "Rubicon" refers to Rubicon – The International news magazine for Glaxo Wellcome R & D staff. "GLAXO WELLCOME; For Women Only; Rubicon – The International news magazine for Glaxo Wellcome R & D staff; August 1997; pg. 9."

¶¶ 60, 61.) On December 30, 2009, the USPTO granted Prometheus' petition seeking review of the denial of its request for reexamination. (DS ¶ 62; PR ¶ 62.) On February 24, 2010, the USPTO rejected claims 2, 3, 5, 6, and 8-18 under 35 U.S.C. § 103(a) as being unpatentable over Rubicon in view of the Magnet, Bardhan, Hsyu, Drossman, and Saxena[6] references. (DS ¶ 63; PR ¶ 63.) On April 23, 2010, Prometheus filed an amendment to the '770 patent "[i]n response to the Office Action mailed February 24, 2010. . . ." (PCS ¶ 46; DRC ¶ 46.) During the subsequent reexamination, all of the original claims of the '770 patent were either cancelled (claims 1-4 and 7-9) or amended (claims 5-6) in response to the February 24, 2010 office action. (DS ¶ 67; PR ¶ 67; PCS ¶¶ 50, 56; DRC ¶¶ 50, 56.) The reexamination certificate of the '770 patent was issued on October 19, 2010 with amended claims 5-6 and new claims 10-16. (DS ¶ 68; PR ¶ 68.) The '770 patent was subsequently listed in the Orange Book with respect to LOTRONEX®. (DS ¶ 70; PR ¶ 70.)

The parties now agree that Rubicon and Magnet are not prior art. (DS ¶¶ 74-76; PR ¶¶ 74-76.)

III. STANDARD OF REVIEW

Pursuant to Federal Rule of Civil Procedure 56(c), a motion for summary judgment will be granted if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). In other words, "[s]ummary judgment may be granted only if there exists no genuine issue of material fact that would permit a reasonable jury to find for the nonmoving party." *Miller v. Indiana*

[6] Bardhan, Hsyu, Drossman, and Saxena are prior art references cited by the USPTO during the reexamination of the '770 patent.

Hosp., 843 F.2d 139, 143 (3d Cir. 1988). All facts and inferences must be construed in the light most favorable to the non-moving party. *Peters v. Delaware River Port Auth.*, 16 F.3d 1346, 1349 (3d Cir. 1994). The judge's function is not to weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial. *See Anderson*, 477 U.S. at 249. "Consequently, the court must ask whether, on the summary judgment record, reasonable jurors could find facts that demonstrated, by a preponderance of the evidence, that the nonmoving party is entitled to a verdict." *In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829, 860 (3d Cir. 1990).

The party seeking summary judgment always bears the initial burden of production. *Celotex Corp.*, 477 U.S. at 323. This burden requires the moving party to establish either that there is no genuine issue of material fact and that the moving party must prevail as a matter of law, or to demonstrate that the nonmoving party has not shown the requisite facts relating to an essential element of an issue on which it bears the burden. *Id*. at 322-23. Once the party seeking summary judgment has carried this initial burden, the burden shifts to the nonmoving party.

To avoid summary judgment, the nonmoving party must then demonstrate facts supporting each element for which it bears the burden, and it must establish the existence of a "genuine issue of material fact" justifying trial. *Miller*, 843 F.2d at 143; *accord Celotex Corp.*, 477 U.S. at 324. The nonmoving party "must do more than simply show that there is some metaphysical doubt as to material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). "Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no 'genuine issue for trial.'" *Id.* at 587 (quoting *First National Bank of Arizona v. Cities Serv. Co.*, 391 U.S. 253, 289 (1968)). Further, summary

judgment may be granted if the nonmoving party's "evidence is merely colorable or is not significantly probative." *Anderson*, 477 U.S. at 249-50.

IV. DISCUSSION

Prometheus and Cipla have filed dueling motions for summary judgment related to invalidity under § 305 of the Patent Act. Prometheus argues it is entitled to summary judgment of no invalidity under § 305 with respect to the '770 patent for two reasons. First, it argues that whether or not claims were changed in light of prior art should be evaluated based on the record at the time of reexamination using a subjective standard, which it argues is met here. Second, it argues that the latter half of § 305 allows for amendments in response to an adverse action by the USPTO, and there is no dispute that Prometheus amended the '770 patent in response to an adverse action by the USPTO. Cipla argues that it is entitled to summary judgment of invalidity under § 305 regarding the '770 patent because, as the parties now agree, Magnet and Rubicon are not prior art.

a. Legal Background

A party challenging a patent in court "bears the added burden of overcoming the deference that is due to a qualified government agency presumed to have done its job." *PharmaStem Theraputics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1366 (Fed. Cir. 2007). Because of this presumption, invalidity must be proven by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2246 (2011).

"Reexamination proceedings, governed by 35 U.S.C. §§ 301 *et seq.*, are intended to 'permit any party to petition the [PTO] to review the efficacy of a patent, following its issuance, on the basis of new information about preexisting technology that may have escaped review at the time of the initial examination.'" *In re NTP, Inc.*, 654 F.3d 1268, 1275 (Fed. Cir. 2011)

(citing H.R. No. 66–1307, 96th Cong., 2d Sess. (1980), 3-4). "The scope of reexamination proceedings is limited to 'substantial new question[s] of patentability,' 35 U.S.C. § 303(a), which are questions that have not previously been considered by the PTO." *Id.* "These new considerations must be based only on 'prior art consisting of patents or printed publications.'" *Id*. (citing 35 U.S.C. §§ 301, 302). "The function of reexamination is to increase the reliability of patents thought to be of doubtful validity." *In re Freeman*, 30 F.3d 1459, 1468 (Fed. Cir. 1994).

Under 35 U.S.C. § 301(a)(1) any person at any time may cite to the USPTO "prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent." 35 U.S.C. § 302 states that "[a]ny person at any time may file a request for reexamination by the Office of any claim of a patent on the basis of any prior art cited under the provisions of section 301."

Section 305 states:

> . . . In any reexamination proceeding under this chapter, the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, *in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301*, **or** *in response to a decision adverse to the patentability of a claim of a patent*. No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding under this chapter. . . .

35 U.S.C. § 305 (emphases added).[7]

"Under 35 U.S.C. § 305, a patent owner may propose an amendment to its patent to distinguish the claimed invention from the prior art or to respond to an adverse decision as to the patentability of one of the claims. Claim amendments during reexamination are limited to

[7] Defendants do not assert that Prometheus broadened the scope of the '770 patent during reexamination.

'amendment in light of prior art raising a substantial new question of patentability.'" *Sw. Bell Tel. Co. v. Arthur A. Collins, Inc.*, 279 F. App'x 989, 992 (Fed. Cir. 2008) (affirming summary judgment of invalidity based on an improper purpose for reexamination);[8] *see also Cordis Corp. v. Medtronic Ave, Inc.*, 511 F.3d 1157, 1185 (Fed. Cir. 2008), *supplemented sub nom. Cordis Corp. v. Boston Scientific Corp.*, 275 F. App'x 966 (Fed. Cir. 2008). A violation of § 305 results in the invalidity of the amended or added claims. *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1584 (Fed. Cir. 1995).

b. The Parties' Dispute

Cipla[9] argues that the claims of the '770 patent are invalid under 35 U.S.C § 305 because Prometheus amended the claims of the '770 patent during reexamination for an improper purpose—specifically, that Prometheus used non-prior art to initiate a reexamination. Cipla argues that claims amended or added to overcome references that ***are not*** prior art violates the restrictions § 305 places on amendments made during reexamination and therefore invalidates the patent.

Both parties agree that Magnet and Rubicon are not prior art. But Cipla notes that when initiating *ex parte* reexamination, Prometheus' prosecution attorney stated that both Magnet and

[8] In *Southwest Bell*, the district court found that the patent applicant's own reexamination filings with the USPTO showed that it filed the reexamination "to preclude any interpretation of the claims in accordance with [a prior district court's claim construction] opinions." *Sw. Bell Tel., L.P. v. Arthur Collins, Inc.*, 464 F. Supp. 2d 588, 596 (N.D. Tex. 2006).

[9] This Court has found that Roxane failed to act with the proper diligence in moving to amend its invalidity contentions to add failure to comply with 35 U.S.C. § 305 as a defense. (Dkt. No. 120; Dkt. No. 158.) This defense is not available to Roxane under the law of the case.

Rubicon were prior art. Prometheus admits this fact.[10] Given the fact the parties agree Rubicon and Magnet are not prior art, the resolution of the parties' cross motions for summary judgment relating to § 305 turns on what standard must be applied in evaluating "prior art" under § 305 at the time of reexamination.

Prometheus argues that there are no genuine issues as to any material facts that the '770 patent is not invalid under § 305. In support of this position, Prometheus makes two arguments. First, Prometheus argues that its reexamination counsel initiated reexamination under §§ 301-302 and modified the claims of the '770 patent under § 305 with the good-faith belief that Magnet and Rubicon were prior art (whether or not they in fact were objectively prior art), thereby meeting the "prior art" requirements of §§ 301, 302, and 305. Second, Prometheus argues that because it amended and added claims to the '770 patent "in response to a decision adverse to the patentability" of the '770 patent, Prometheus meets the alternative requirement of § 305.

In response to Prometheus' first argument, Cipla asserts that it is the objective status of the claimed prior art that governs whether or not a reexamination procedure was properly initiated, not the subjective beliefs of the party initiating the reexamination. (Def. Reply Br. at 11, 16-17.) In other words, should a reexamination be initiated with the good-faith belief that a document qualifies as prior art and later the document turns out to not qualify as prior art, the reexamined claims are invalid under § 305 because the reexamination statute requires the cited material to be "prior art." Cipla argues that the statute requires "prior art," and, therefore, Prometheus' initiation of the reexamination using what are in hindsight agreed to be non-prior art documents violated the statute, resulting in the invalidity of the '770 patent no matter what

[10] Cipla and Roxane have moved *in limine* to prevent Prometheus from stating Rubicon and Magnet are not prior art at trial. (Dkt. No. 306.) In light of the parties' agreement that Rubicon and Magnet are not prior art, the Court denies Defendants' motion *in limine* on this issue.

occurred after the initiation of the reexamination proceedings. It is, in essence, a strict liability standard as to what is prior art under the reexamination statute.

Cipla also asserts that because the reexamination procedure was initiated using Magnet and Rubicon, any amendments Prometheus made in response to a rejection by the USPTO "are the fruits of the poisonous tree that Prometheus first planted" by using Magnet and Rubicon as prior art. (Def. Opp. Br. at 9.) Cipla also notes that the rejections Prometheus relies on to defend the amendments made during reexamination all include the Magnet and Rubicon references. (Def. Opp. Br. at 11.)

c. Invalidity Under Section 305

Cipla cites no case where a reexamined patent was invalidated for citing documents that later turned out not to be prior art. Similarly, Prometheus cites no case holding that it is the subjective belief of the party during reexamination that governs whether or not a § 305 reexamination is for a proper purpose. The majority of the case law addressing § 305 deals with improper broadening of claims during reexamination. In the few cases addressing reexamination for an improper purpose (other than the broadening of claims), there is usually a clear statement by the patent applicant stating an improper purpose. *See, e.g.*, *Freeman*, 30 F.3d at 1468 (noting, in the context of issue preclusion, that the applicant's disclosed purpose for reexamination was to prevent readers from misconstruing his intent for the claims after an adverse claim construction ruling in district court);[11] *Sw. Bell Tel.*, 464 F. Supp. 2d at 596 (finding that filing a reexamination "to preclude any interpretation of the claims in accordance with [a prior district court's claim construction] opinions" improper); *Total Containment, Inc. v. Environ Products*,

[11] The claims in *Freeman* were rejected by the USPTO under § 305 because they were broadening amendments not because the amendments were made for an improper purpose. *Freeman*, 30 F.3d at 1463.

Inc., 921 F. Supp. 1355, 1383 (E.D. Pa. 1995) (finding a claim invalid under § 305 because the patent applicant admitted it was added to cover prior art rather than distinguish the invention from prior art raising a substantial new question of patentability), *aff'd in part, vacated in part*, 106 F.3d 427 (Fed. Cir. 1997). In the absence of case law, the Court is guided by the language of the statute and its legislative history.

The first half of § 305 permits amendment during reexamination "in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301." 35 U.S.C. § 305. Cipla does not dispute that Prometheus' reexamination counsel ***subjectively*** believed Magnet and Rubicon were prior art at the time of reexamination and that his belief was objectively reasonable. Rather, Cipla asserts that it is the current litigation status of the alleged prior art, viewed with the benefit of hindsight and new discovery, that controls whether a party complied with §§ 301, 302, and 305 in the past, at the time of reexamination. While none of the cases cited by the parties directly address whether Prometheus' subjective belief that Magnet and Rubicon were prior art is enough to meet the requirements of § 305, the plain language of § 301 supports finding that the statute requires only a good-faith subjective belief that is objectively reasonable. Section 301 states that any person may cite to the USPTO "prior art consisting of patents or printed publications ***which that person believes*** to have a bearing on the patentability of any claim of a particular patent. . . ." 35 U.S.C. § 301(a)(1) (emphasis added). The focus of § 301 is on the ***belief*** of the person citing the prior art.[12]

[12] Former Magistrate Judge Shwartz also concluded that § 305 turns on actions of the patentee before the USPTO and not on the actual status of the alleged prior art. (Dkt. No. 131-4 at 15 ("The focus under § 305, therefore, is on the plaintiff's actions before the U.S. PTO and not whether a particular item is or is not, in fact, prior art, and the defendant has cited no law to the contrary.").)

The legislative history of the statute also supports using a standard that requires a good-faith belief that is objectively reasonable as to the status of prior art. According to that history, only submissions that present a substantial question of patentability are allowed; this portion of the statute was designed to reduce spurious applications for reexamination. (Dkt. No. 348-2, Testimony of Hon. Sidney A. Diamond, Commissioner of Patents and Trademarks, from April 1980 ("Each request for reexamination will be carefully screened by a member of our professional staff to assure that it at least raises a ***creditable*** case of invalidity or, in the bill's words, that there be a 'substantial new question of patentability.'" (emphasis added)).) The fact a third-party can initiate these proceedings makes the strict-liability flavor of Cipla's position harsh and inequitable.

Under Cipla's view of the statute, a patent could be invalidated under § 305 if a third-party submitted alleged prior art to the USPTO, the USPTO issued a rejection leading the patentee to amend the patent, and the "prior art" was later ruled to not qualify as prior art.[13] This does not comport with the plain language of the statute or common sense.[14] Essentially this

[13] Cipla also relies on *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 882 F.2d 1556 (Fed. Cir. 1989) for the proposition that § 305 requires strict liability with respect to "prior art." But *Hewlett-Packard* is inapposite. First, *Hewlett-Packard* is a case addressing the reissue statute not the reexamination statute. *Id*. at 1558. Second, *Hewlett-Packard* addressed the statutory requirement that a reissue must be based on an error. In *Hewlett-Packard*, the affidavits submitted to the USPTO claiming error were "blatantly" wrong and "pure fiction." *Id*. at 1561-62. In addition, the patentee failed to establish the second prong for reissue, inadvertent error in conduct—a requirement that is explicitly in the statute. *Id*. at 1565. Given the difference in the statutory language and the facts of the case, *Hewlett-Packard* does not assist Cipla.

[14] "As in all cases involving statutory construction, our starting point must be the language employed by Congress, and we assume that the legislative purpose is expressed by the ordinary meaning of the words used. Thus absent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive." *Am. Tobacco Co. v. Patterson*, 456 U.S. 63, 68 (1982) (internal citations and quotation marks omitted). This "strong presumption that the plain language of the statute expresses congressional intent is rebutted only in rare and

position is that, regardless of a good-faith subjective belief at the time that the references were prior art, and despite the reasonableness of that belief at the time, Cipla argues that later discovered evidence may constitute a basis for invalidating the patent and amendments submitted during reexamination.

In accordance with the plain language of the statute, its legislative history, and case law in the related areas of inequitable conduct and willful infringement,[15,16] the Court finds that § 305 requires that the patent applicant subjectively believes that he or she is submitting prior art to the USPTO[17] and that such belief is objectively reasonable. This same reasonable-belief formulation appears in other areas of the law. *Cf. Gomez v. Toledo*, 446 U.S. 635, 639 (1980) ("And in other contexts we have held, on the basis of [c]ommon-law tradition . . . and strong public-policy reasons that certain categories of executive officers should be allowed qualified

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exceptional circumstances." *United States v. Clintwood Elkhorn Min. Co.*, 553 U.S. 1, 11 (2008) (internal quotation marks omitted).

[15] "[T]o establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent. Once the threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk . . . was either known or so obvious that it should have been known to the accused infringer." *Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc.*, 682 F.3d 1003, 1005 (Fed. Cir. 2012), *cert. denied*, 133 S. Ct. 932 (2013).

[16] Notably, inequitable conduct requires a much higher quantum of proof. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1296 (Fed. Cir. 2011) ("the district court should determine whether there is clear and convincing evidence demonstrating that Sanghera or Pope knew of the [references], knew of their materiality, and made the conscious decision not to disclose them in order to deceive the PTO.") Here, Cipla argues for strict liability. Thus, even if a patentee had a good-faith, objectively reasonable, belief that it was amending due to a piece of prior art, its patent would be invalid if that belief was later proven to be wrong.

[17] This is reinforced by an applicant's duty of candor with the Patent Office. *Avid Identification Sys., Inc. v. Crystal Imp. Corp.*, 603 F.3d 967, 973 (Fed. Cir. 2010) ("PTO Rule 56, codified at 37 C.F.R. § 1.56, imposes on all individuals associated with the filing and prosecution of a patent application a duty of candor and good faith in dealing with the PTO during the period of examination of a patent application.").

immunity from liability for acts done on the basis of an objectively reasonable belief that those acts were lawful." (internal citations and quotation marks omitted)); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071 (Fed. Cir. 1998) (Discussing *Walker Process* fraud and noting that "in order to prove that a suit was within *Noerr's* 'sham' exception to immunity, an antitrust plaintiff must prove that the suit was both objectively baseless and subjectively motivated by a desire to impose collateral, anti-competitive injury rather than to obtain a justifiable legal remedy.").

Because there was a subjective belief that was objectively reasonable at the time of the reexamination request that Magnet and Rubicon were prior art, Prometheus' reexamination complied with § 305. The '770 patent is not invalid under § 305.

d. Amendments Under Section 305

Under the second half of § 305, a party may make changes during reexamination "in response to a decision adverse to the patentability of a claim of a patent." 35 U.S.C. § 305. In this case, there is no dispute that the USPTO issued a rejection citing Magnet, Rubicon, and four other pieces of prior art. It is also undisputed that in response to that rejection Prometheus amended, cancelled, and added claims to the '770 patent. These types of amendments are permitted under § 305. *See Cordis*, 511 F.3d at 1185 (reversing a finding of invalidity under § 305 because the amendments were "'[r]esponsive to' the office action that had rejected all but two of the claims of the [patent-in-suit] in light of prior art references"); *see also Total Containment*, 921 F. Supp. at 1383 ("Although TCI's attorney did not state on the record that these claims were submitted in response to the rejection of claim 9, this fact can be inferred from the timing of their presentation and the fact that they contain all the limitations of claim 9. Therefore, claims 13-18 of the '408 patent do not violate 35 U.S.C. § 305."). Because

Prometheus' modifications during reexamination were in response to a rejection by the USPTO, they were not improper under § 305.

Prometheus' reexamination complied with § 305 as the changes to the '770 patent were made "in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301." The Court grants Prometheus' motion for summary judgment for this separate and independent reason as well.

V. OTHER OUTSTANDING ISSUES

During the hearing on November 21, 2013, the Court ruled on Plaintiff's motions *in limine* regarding Dr. Howden's "single actor" testimony, clinical studies evidence, label preparation evidence, and reexamination evidence [Dkt. No. 309 (Civ. No. 11-1241); Dkt. No. 196 (Civ. No. 11-230)]. The parties should consult the transcript of the hearing for the Court's ruling.

At the hearing, the Court also addressed the parties' motions to seal the courtroom during trial [Dkt. Nos. 323, 324 (Civ. No. 11-1241); Dkt. Nos. 210, 211 (Civ. No. 11-230)]. These motions were denied without prejudice for the reasons stated in the hearing. The parties may re-raise this issue, as appropriate, during trial.

During the hearing, Defendants represented that the FDA has not yet approved their drug but that it may be approved during the first quarter of 2014. The Court requests that the parties keep it apprised of any approval of Defendants' drug by the FDA. The Court also reminds the parties that motions for preliminary injunctions are not automatically granted and require that a plaintiff meet a four-part test. "A plaintiff seeking a preliminary injunction must establish that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the

public interest." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1049 (Fed. Cir. 2010). "A preliminary injunction should not issue if an alleged infringer raises a substantial question regarding either infringement or validity, *i.e.*, the alleged infringer asserts an infringement or invalidity defense that the patentee has not shown lacks substantial merit." *Id.* at 1050. Should a time come when Plaintiff is considering applying for a preliminary injunction, it should carefully consider these requirements.

Finally, the Court asks the parties to file a joint letter within 14 days of this Order indicating whether they believe a settlement conference with the Honorable Michael A. Hammer, U.S.M.J., or another mediator, would be fruitful.

VI. CONCLUSION

For the reasons stated above, the Court denies Cipla's motion for summary judgment of invalidity of the '770 patent under § 305 and grants Prometheus' motion for summary judgment of no invalidity of the '770 patent under § 305. In light of the parties' agreement that Magnet and Rubicon are not prior art, the Court also denies Defendants' motion *in limine* seeking a pretrial ruling that Rubicon and Magnet are prior art. The remaining motions were addressed and ruled on at the hearing, and the parties should consult the transcript for those rulings. An appropriate Order will issue.

/s/ Faith S. Hochberg
Hon. Faith S. Hochberg, U.S.D.J.