IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: ROSUVASTATIN CALCIUM PATENT LITIGATION,	:	MDL No. 08-1949-JJF
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., AND SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. MYLAN PHARMACEUTICALS INC., Defendant.	:	Civil Action No. 07-805-JJF-LPS
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., AND SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES LTD., Defendant.	:	Civil Action No. 07-806-JJF-LPS
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., AND SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. SANDOZ INC., Defendant.	:	Civil Action No. 07-807-JJF-LPS

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., AND SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. PAR PHARMACEUTICALS INC., Defendant.	:	Civil Action No. 07-808-JJF-LPS
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., AND SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. APOTEX CORP., Defendants.	:	Civil Action No. 07-809-JJF-LPS
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., AND SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. AUROBINDO PHARMA LTD. AND AUROBINDO PHARMA USA INC., Defendants.	:	Civil Action No. 07-810-JJF-LPS

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., AND SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. COBALT PHARMACEUTICALS INC. AND COBALT LABORATORIES INC., Defendants.	:	Civil Action No. 07-811-JJF-LPS
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., AND SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. AUROBINDO PHARMA LTD. AND AUROBINDO PHARMA USA INC., Defendants.	:	Civil Action No. 08-359-JJF-LPS
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., AND SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. TEVA PHARMACEUTICALS USA, Defendant.	:	Civil Action No. 08-426-JJF-LPS

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MEMORANDUM OPINION

June 29, 2010
Wilmington, Delaware

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Farnan, District Judge.

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc. and Shionogi Seiyaku Kabushiki Kaisha (collectively, "Plaintiffs") brought this action against several different genereric drug manufacturers, Mylan Pharmaceuticals Inc., Sun Pharmaceutical Industries, Ltd., Par Pharmaceutical, Inc., Apotex Corp., Aurobindo Pharma Ltd., Cobalt Pharmaceuticals Inc., Cobalt Laboratories Inc., Teva Pharmaceuticals USA, Inc. (collectively, "Defendants")[1] alleging infringement of U.S. Patent No. RE 37,314 (the "'314 patent"), covering rosuvastatin and its salts, based on Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use, or sale in the United States of rosuvastatin calcium tablets. With the exception of Apotex Corp., Defendants admit that they have infringed claims 6 and 8 of the '314 patent by submitting its ANDA under 35 U.S.C. § 271(e)(2)(A). However, Defendants contend that claims 6 and 8 of the '314 patent are

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[1] Unless otherwise noted, all docket item ("D.I.") references are to MDL. 08-1949. An action was also brought against Apotex, Inc., Aurobindo Pharma USA Inc., and Sandoz Inc. The action against Apotex, Inc. was transferred by the Court to the Southern Disrict of Florida (D.I. 456.) The action against Aurobindo Pharma USA Inc. was dismissed by stipulation of the parties. (D.I. 359 in Civ. Act. No. 07-810; D.I. 218 in Civ. Act. No. 08-359.) The action against Sandoz, Inc. has been stayed, and the parties have agreed to be bound by the Court's decision in this litigation. (D.I. 217, 218 in Civ. Act. No. 07-807.)

invalid and unenforceable. In addition, Defendants have challenged the standing of Plaintiff AstraZeneca Pharmaceuticals LP to sue for infringement and have filed motions to dismiss based on this issue. As for Defendant Apotex Corp., Apotex Corp. contends that it did not engage in an infringing act in the first instance, because it did not "submit" the ANDA within the meaning of Section 271(e)(2)(A).

With the exception of Defendant Apotex Corp., no Defendant contests that the Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338, as arising under the patent laws of the United States, Title 35 of the United States Code and the Abbreviated New Drug Application provisions of the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j). Personal jurisdiction and venue are also uncontested.

The Court held a Bench Trial on the issues of invalidity and unenforceability from February 22, 2010, through March 3, 2010, and reserved decision on the standing issue for resolution post-trial. Briefing on the various post-trial issues was not completed until June 4, 2010.[2] This Memorandum Opinion

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[2] Following Defendants' final post-trial submission, Plaintiffs filed a Motion For Leave To File A Sur-Reply. (D.I. 546.) Plaintiffs contend that they are entitled to a sur-reply to address issues raised for the first time in Defendants' final submission, specifically the Japanese testimony of Mr. Masamichi Watanabe, the case Schering Corp. v. Glenmark Pharms. Inc. USA, 07-1334(JLL), 2010 U.S. Dist. LEXIS 38382 (D.N.J. Apr. 19, 2010),

constitutes the Court's findings of fact and conclusions of law on the issues of standing, invalidity and unenforceability.

BACKGROUND

I. The Parties

Plaintiff AstraZeneca Pharmaceuticals LP is a Delaware corporation with its principal place of business in Wilmington, Delaware. Plaintiff AstraZeneca UK Limited is a corporation existing under the laws of the United Kingdom with its principal place of business in London, England. Plaintiff IPR Pharmaceuticals Inc. is a wholly owned subsidiary of AstraZeneca UK, existing under the laws of the Commonwealth of Puerto Rico with a principal place of business in Canovanas, Puerto Rico. Plaintiff Shionogi Seiyaku Kabushiki Kaisha is a Japanese corporation with a principal place of business in Osaka Japan. Plaintiffs are engaged in the business of research, development, manufacturing and/or selling pharmaceutical products world-wide.

Defendant Aptoex Corp. is a Delaware corporation with its principal place of business in Weston, Florida. Defendant Aurobindo Pharma Limited is a corporation existing under the laws of India with its principal place of business in Andhra Pradesh, India. Defendant Cobalt Pharmaceuticals Inc. is a Canadian

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and alleged misstatements made by Defendants. Defendants oppose the Motion. (D.I. 550.) In the Court's view, much of the disputed material is newly raised, and Plaintiffs did not have an opportunity to address it. Accordingly, the Court will grant Plaintiffs' Motion and the Sur-Reply will be deemed filed.

corporation with its principal place of business in Ontario, Canada. Defendant Cobalt Laboratories Inc. is a Delaware corporation with its principal place of business in Bonita Springs, Florida. Defendant Mylan Pharmaceuticals Inc. is a West Virginia corporation with its principal place of business in Morgantown, West Virginia. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business in Woodcliff Lake, New Jersey. Defendant Sun Pharmaceutical Industries Ltd. is a corporation existing under the laws of India with its principal place of business in Maharashtra, India. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Defendants are engaged in the business of making, selling and/or distributing generic drugs in the United States.

II. The Patent Generally

The '314 patent is a reissue of U.S. Patent No. 5,260,440 (the "'440 patent"), which pertains to rosuvastatin and its salts, which are compounds useful in the treatment of hypercholesterolemia, hyperlipoproteinemia and atherosclerosis. (PTX-682 at 1:26-28; PTX-1054 at 1:32-34.) The invention secured in the '440 patent was made by co-inventors Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe. Plaintiff Shionogi Seiyaku Kabushiki Kaisha is the owner of the '440 patent, and after consummation of a license agreement with the

AstraZeneca-affiliated Plaintiffs, an application was made to reissue the '440 patent. The drug covered by the reissued '314 patent is known as rosuvastatin calcium and marketed and sold by the AstraZeneca-affiliated Plaintiffs under the name CRESTOR® as a result of a licensing agreement between Shionogi and the AstraZeneca-affiliated Plaintiffs.

Claims 6 and 8 of the '314 patent are at issue in this litigation. Claim 6 is an independent claim directed to

> the compound 7-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methyl-N-methylsulfonylamino)pyrimidin-5-yl)-(3R,5S)-dihydroxy-(E)-6-heptenoic acid (rosuvastatin) in the form of a non-toxic pharmaceutically acceptable salt thereof.

(PTX-1054 at 16:30-33.) Claim 8 is a dependent claim directed to the compound of claim 6 in the form of a calcium salt, which is rosuvastatin calcium, the active ingredient in CRESTOR®. (PTX-1054 at 16:35.)

The claims at issue were construed by Magistrate Judge Stark, and his recommendations concerning claim construction were adopted by the Court. (D.I. 348 in 08-md-1949.) Claim 6 is construed as "[a] non-toxic pharmaceutically acceptable salt of the compound 7-(4-(4-fluorophenyl)-6-isopropyl-2-(n-methyl-N-methylsulfonylamino)pyrimidin-5-yl)-(3R,5S)-dihydroxy-(E)-6-heptenoic acid." (Id.) Claim 8 is construed so as to encompass the monocalcium bis salt, reading the claim as "[t]he compound of Claim 6 in the form of a calcium salt." (Id.)

By this action, Plaintiffs seek an order prohibiting the FDA from approving Defendants' ANDAs prior to the expiration of the '314 patent on February 12, 2011, and enjoining Defendants from the commercial manufacture, use, offer to sell, sale or importation of their rosuvastatin calcium tablets prior to the expiration of Plaintiff's exclusivity. Defendants contend that claims 6 and 8 are invalid as obvious under 35 U.S.C. § 103 and as improperly reissued claims under 35 U.S.C. § 251. Defendants also contend that the '314 patent is unenforceable based upon the allegation that the original '440 patent was procured through inequitable conduct. Defendants also seek an order that Plaintiff AstraZeneca Pharmaceutical LP lacks standing to sue. The Court will address the issues raised by the parties in turn.

DISCUSSION

I. Infringement

A. The Parties' Contentions

Infringement is only at issue in this case with respect to Defendant Apotex Corp. ("Apotex"), and only concerns the question of whether Apotex "submitted" ANDA No. 79-145, such that it may be liable for infringement under Section 271(e)(2)(A). Plaintiffs contend that this Court, both in this action and others, as well as numerous other courts, have recognized that an agent for a foreign ANDA applicant who signs the ANDA application and intends to benefit directly if the ANDA is approved may be

liable for infringement under Section 271(e)(2)(A). (D.I. 499 at 4-6.) Plaintiffs contend that under this standard, Apotex is liable for infringement, because it signed the ANDA, as the U.S. agent of its related company, Apotex, Inc., and further that Apotex intends to directly benefit if the FDA approves the application. (Id. at 6-8.) Thus, Plaintiffs contend that Apotex is properly considered to be an entity that submitted the ANDA.

In response, Apotex contends that it did not "submit" the ANDA within the meaning of Section 271(e)(2)(A). According to Apotex, the FDA regulations make it clear that only the "applicant" submits an ANDA. (D.I. 521 at 3-6.) Apotex contends that it has not sought approval to commercially manufacture, use, or sell the claimed invention and that every certification made in the ANDA was made by Apotex Inc., not Apotex. (Id. at 7-8.) Thus, Apotex contends that it is not the applicant of the ANDA. Although Apotex acknowledges that it acted as the authorized U.S. agent for the ANDA on behalf of Apotex, Inc., Apotex maintains that authorized U.S. agents cannot be liable for infringement under Section 271(e)(2), even though they have signed an ANDA application. Apotex contends that the act of signing the ANDA is a ministerial act that is insufficient to create "submitter" liability. According to Apotex, the cases relied upon by Plaintiffs for a contrary position are inconsistent with the statutory and regulatory framework governing ANDA submissions,

including 21 U.S.C. § 355(j), 21 C.F.R. § 314.3(b), 21 C.F.R. §§ 314, 94(a)(1), and FDA Form 356h, and are distinguishable both procedurally and factually from this action. (Id. at 8-14.) Apotex further contends that Section 271(e)(2)(A) does not require an inquiry into whether one intends to benefit from ANDA approval, and that such an inquiry is speculative and does not meet the specified acts of seeking approval to make, use, or sell the claimed invention as required by Section 271(e)(2)(A).

Alternatively, Apotex contends that Plaintiffs have not demonstrated by a preponderance of the evidence that Apotex Corp intends to directly benefit if the FDA approves ANDA No. 79-145. In this regard, Apotex contends that it is a distinct company from Apotex Inc., and that the decisions of Apotex, Inc. should not be imputed to Apotex. Apotex further contends that it selects which Apotex products it will market, and that it does not market every generic manufactured by Apotex, Inc. (Id. at 14-15.) Thus, Apotex contends that the evidence does not support a finding that Apotex intends to directly benefit from the FDA's approval of ANDA No. 79-145.

B. Whether Apotex Corp. May Be Liable For Infringement As The "Submitter" Of An ANDA

In previous decisions issued by the Court, the Court has held that

> a wholly-owned subsidiary of a foreign ANDA applicant, which signs an ANDA as the agent of its parent-applicant, and which intends to

> benefit directly if the ANDA is approved -- by participating in the manufacture, importation, distribution and/or sale of the generic drug -- [is] subject to suit under § 271(e) as one who has "submitted" an ANDA.

In re Rosuvastatin Calcium Patent Litig., 2008 WL 5046424, at *10 (D. Del. Nov. 24, 2008) (Stark, J.) ("Rosuvastatin I"), adopted by AstraZeneca Pharms. LP v. Aurobindo Pharma Ltd., 2009 WL 483131 at *3 (D. Del. Feb. 25, 2009) (Farnan, J.) ("Rosuvastatin II"). Regardless of whether this standard may be considered the law of the case as Plaintiffs contend, the Court is not persuaded that this recitation of the legal standard for determining who may be liable for submission of an ANDA application is erroneous such that it should be reconsidered by the Court as urged by Apotex. The Court's conclusion that liability for infringement may extend to an agent of the applicant who signs the ANDA and intends to benefit directly if the ANDA is approved is consistent with the decision of other courts considering this issue. Wyeth v. Lupin Ltd., 505 F. Supp. 2d 303, 306-307 (D. Md. 2007); Aventis Pharma Deutschland GmbH v. Lupin Ltd., 403 F. Supp. 2d 484, 492-494 (E.D. Va. 2005). Recent decisions of this Court are also consistent. See Cephalon, Inc. v. Watson Pharmaceuticals, Inc., 629 F. Supp. 2d 338, 349 (D. Del. 2009) (Robinson, J.); see also In re Cyclobenzprine Hydrochloride Extended-Release Capsule Patent Litigation, MDL, No. 09-2118, 2010 WL 902552 at * 6 (D. Del. Mar. 12, 2010) (Robinson, J.). As Judge Robinson explained

in Cephalon, "[p]arties 'actively involved' in preparing the ANDA are deemed to have 'submitted' the ANDA, regardless of whether they are the named applicant; this is especially true where the parties involved are in the same corporate family. 'Active involvement' includes 'marketing and distributing the approved generic drugs in the United States.'" 629 F. Supp. 2d at 349 (citations omitted).

Apotex contends that the aforementioned cases are distinguishable on their facts in that the companies involved had a different corporate relationship and/or were more involved in the ANDA preparation than Apotex was in this case. While the Court acknowledges differences among the cases, the Court is not persuaded that these differences justify a different result insofar as the appropriate legal standard for a "submitter" of an ANDA application is considered. In the Court's view, the FDA regulations cited by Apotex do not construe Section 271(e)(2)(A), and do not preclude an authorized agent who signs an applicant from being considered a "submitter" of the ANDA. See 21 C.F.R. § 314.3(b) (describing the "applicant" as any person who "submits" an ANDA). In addition, the Court finds nothing in the text of Section 271(e)(2)(A) to limit the submitter of the ANDA to one who signs the Paragraph IV certification. Moreover, the Court is persuaded that this interpretation of Section 271(e)(2)(A) is consistent with Congressional intent as explained by Magistrate

Judge Stark in Rosuvastatin I, 2008 WL 5046424 at *10-11, and subsequently adopted by the Court.

Applying this legal standard to the facts of this case, the Court concludes that Apotex submitted the ANDA application such that it may be liable for infringement of the '314 patent. Apotex is identified in the ANDA and its amendment as the authorized U.S. agent for Apotex, Inc., and these documents were signed by Mr. Kiran Krishnan, Manager of Regulatory Affairs for Apotex, using the address and phone number of Apotex. (PTX-1343; PTX-1410 at 2; Tao Dep. 73:13-19.) Although Apotex is not a wholly owned subsidiary of Apotex, Inc., the two companies are closely related. Apotex is a wholly-owned subsidiary of Aposherm, Inc., which in turn, is a wholly-owned subsidiary of Apotex Holdings Inc. (PTX-1255.) Apotex Inc. is a wholly-owned subsidiary of Apotex Pharmaceutical Holdings Inc., which in turn, is 94 percent-owned by Apotex Holdings Inc. (Id.) Aposherm, Inc., Apotex Pharmaceutical Holdings, Inc., and Apotex Holdings, Inc., are shell-companies that exist on paper, but have no formal meetings. (Sherman Dep. 9:22-12:11.) Apotex Inc. and Apotex hold themselves out publically and internally as part of the Apotex Group of companies. (PTX-1624; PTX-1625; PTX-1630; Fahner Dep. 14:21-15:6; McIntire Dep. 134:16-139:8; 140:5-11.)

In addition, the Court is persuaded that Apotex actively participated in activities related to the ANDA submission. The

FDA directed inquiries to Apotex regarding the ANDA application (PTX-1779 at AC461; PTX-1780 at AC473), and Mr. Krishnan stayed at the headquarters of Apotex Inc. in Canada to assist in the preparation of the ANDA and answer questions while the Director of Regulatory Affairs for Apotex Inc., Ms. Bernice Atao, was out of the office. (Krishnan Dep. 64:2-65:5; Tao Dep. 60:1-13, 83:5-19, 98:7-99:4.) Mr. Krishnan reviewed the draft ANDA prior to submission to the FDA and consulted with and answered substantive questions posed by the regulatory staff of Apotex Inc., in connection with the submission. (PTX-1315; PTX-1329; PTX-1337; PTX-1340; PTX-1342; PTX-1357; PTX-1358; PTX-1360; Krishnan Dep. 56:20-57:18, 59:12-60:14, 61:16-62:14, 64:2-66:5, 67:11-69:20, 70:1-20, 76:1-78:8, 85:13-86:10, 86:21-91:15; Tao Dep. 83:13-19, 86:21-91:15, 107:10-108:15, 123:6-22.)

In addition to the foregoing, the Court is also persuaded that Plaintiffs have established by a preponderance of the evidence that Apotex intends to directly benefit from the approval of the ANDA. Apotex is the marketing arm of Apotex Inc. Ms. Tammy McIntire, the President of Apotex, testified that Apotex Inc. made the decision "to develop [r]osuvastatin calcium as a generic product for the United States, for Apotex Corp. to sell in the United States. . . ." (McIntire Dep. 204:5-9.) Apotex's intention to market and sell Apotex Inc.'s generic rosuvastatin calcium products in the United States, coupled with

its actions in connection with the ANDA submission and its designation as the U.S. agent for Apotex Inc., satisfy the legal standard for liability as an ANDA "submitter" under Section 271(e)(2)(A). Accordingly, the Court concludes that Apotex may be held liable for infringement of claims 6 and 8 of the '314 patent under Section 271(e)(2)(A) as a submitter of an ANDA.

II. STANDING

A. The Parties' Contentions

Defendants have also moved to dismiss Plaintiff AstraZeneca Pharmaceuticals LP ("AstraZeneca) from this litigation for lack of standing. (D.I. 422.) Defendants contend that AstraZeneca LP does not own the '314 patent, does not possess an exclusive license to the '314 patent, and is not an exclusive marketer of CRESTOR®. Defendants further point out that Plaintiffs never specifically pled that each party had standing, but generally averred that all Plaintiffs held substantial rights in the '314 patent. Because AstraZeneca LP lacks any proprietary rights to the patent in suit, Defendants contend that it has no standing to pursue a claim of infringement under the Hatch-Waxman Act.

In response, AstraZeneca LP contends that it has standing because (1) it serves as the exclusive agent of Plaintiff, IPR Pharmaceuticals Inc. ("IPR"), who is the owner of the New Drug Application ("NDA") for CRESTOR®; (2) it submitted IPR's NDA to the FDA; and (3) it is IPR's licensed marketer of CRESTOR® in the

United States. (D.I. 443.) AstraZeneca LP acknowledges that in a typical patent case, it would not have standing, but contends that a different conclusion is warranted here because the text, structure, and legislative history of the Hatch-Waxman Act supports standing for an NDA holder in the first instance and for the agent of an NDA holder under agency principles. (Id. at 4-13.)

B. Legal Principles Related To Standing

The party bringing an action for patent infringement bears the burden of establishing that it has standing. Sitcom Sys., Ltd. v. Agilent Techs., Inc., 427 F.3d 971, 976 (Fed. Cir. 2005). For purposes of demonstrating standing under Article III of the Constitution, the plaintiff must show (1) an injury in fact, (2) with a fairly traceable connection to the challenged action, and (3) the requested relief will redress the alleged injury. Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 103 (1998). Courts also recognize three prudential principles that must be considered in the standing analysis: (1) a party generally must litigate its own rights and not the rights of a third party; (2) the question must not be an abstract, generalized grievance; and (3) the harm must be in the zone of interests protected by the statute or constitutional provision at issue. Valley Forge Christian College v. Americans United for Separation of Church & State, 454 U.S. 464, 474-475 (1982).

The Federal Circuit has recognized three potential categories of plaintiffs for purposes of considering the question of standing: "those that can sue in their own name alone; those that can sue as long as the patent owner is joined in the suit; and those who cannot even participate as a party to an infringement suit." Morrow v. Microsoft Corp., 499 F.3d 1332, 1339 (Fed. Cir. 2007). The first category of plaintiffs hold all legal rights to the patent as the patentee or assignee of all patent rights. Id. at 1339-1340. The second category includes plaintiffs who hold exclusionary rights and interests, but not all substantial rights to the patent such as exclusive licensees. Id. at 1340. The third category of plaintiffs are those who hold less than all substantial rights to the patent, and lack exclusionary rights such as non-exclusive licensees. Id. at 1340-1341. Plaintiffs in the third category lack standing and cannot bring suit. Id.

C. Whether AstraZeneca LP Lacks Standing To Bring This Action

In this case, AstraZeneca LP urges the Court to expand the second category of recognized plaintiffs to include NDA holders and their authorized agents. However, the Court is not persuaded that a valid legal basis exists for this expansion. Plaintiffs arguments and citations notwithstanding, the Court does not understand the Hatch-Waxman Act or its amendments to have expanded the traditional categories of recognized standing in

patent infringement actions, except to create a case or controversy by a defined act of infringement. See e.g. Glaxo, Inc. v. Novopharm Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997). Indeed, this Court has previously utilized the traditional standing analysis in evaluating standing questions under the Hatch-Waxman Act. See Purdue Pharma Prods. L.P. v. Par Pharms, Inc., 2008 U.S. Dist. LEXIS 98178 at *6-7 (D. Del. Dec. 3, 2008) (stating that "'only a patent owner or an exclusive licensee can have constitutional standing to bring an infringement suit; a non-exclusive licensee does not'"). Although AstraZeneca LP premises its argument on IPR's status as the NDA holder, IPR is actually the exclusive sub-licensee of the patent, allowing IPR to fall into one of the already recognized categories of plaintiffs with standing. AstraZeneca LP is not an exclusive licensee of the patent, Ortho Pharm. Corp. v. Genetics Inst., 52 F.3d 1026, 1031 (Fed Cir. 1995), and IPR's presence in this action cannot cure AstraZeneca LP's standing deficiency. Fairchild Semiconductor Corp. v. Power Integrations, Inc., 630 F. Supp. 2d 365, 370 (D. Del. 2007). Moreover, AstraZeneca LP is even further removed from IPR's status, because even if IPR's status as an NDA holder is considered relevant, AstraZeneca LP is only the authorized agent for IPR. AstraZeneca makes much of the fact that, as authorized agent for IPR, it received the Hatch-Waxman Act Notice Letters from Defendants. However, the mailing

of Notice Letters is a requirement of the Hatch-Waxman Act and is not an action that in and of itself creates standing, absent a cognizable constitutional or statutory basis.

In sum, AstraZeneca Pharmaceuticals LP holds no interest in and does not have any exclusionary rights in the '314 patent, and therefore, the Court concludes that AstraZeneca LP has no standing to bring or join in this infringement action. Accordingly, the Court will grant Defendants' Motion and dismiss AstraZeneca LP from this action based upon lack of standing.

III. INEQUITABLE CONDUCT

A. The Parties' Contentions

Defendants contend that the '314 patent is unenforceable as a result of inequitable conduct in the prosecution of the original '440 patent from which the '314 patent was reissued. (D.I. 501.) Specifically, Defendants contend that three members of the Patent Department at Plaintiff Shionogi Seiyaku Kabushiki Kaisha ("Shionogi"), Ms. Kitamura[3], Mr. Shibata and Mr. Tamaki, failed to disclose to the PTO two highly material prior art patent applications by Bayer and Sandoz, as well as a European Search Report. Defendants have no direct evidence of an intent to deceive the PTO, but urge the Court to infer such intent based

[3] Ms. Kitamura is also referred to in the record by her married name, Ms. Ozawa. However, for ease of understanding and consistency, she is referred to as Ms. Kitamura for both the purposes of discussion and for purposes of citation to the transcripts.

on various actions taken by each of the aforementioned individuals during their tenure at Shionogi and their work in prosecuting the '440 patent.

In response, Plaintiffs contend that Defendants cannot establish intent to deceive by clear and convincing evidence, because there are other reasonable inferences that can be drawn from the actions of Ms. Kitamura, Mr. Shibata and Mr. Tamaki. (D.I. 540.) In particular, Plaintiffs contend that Ms. Kitamura left Shionogi before any Information Disclosure Statement ("IDS") was due, and in any event, did not recognize a patentability problem that would prompt her to make a disclosure prior to her departure. (Id. at 13-16.) Plaintiffs also contend that neither Mr. Shibata nor Mr. Tamaki were substantively involved in the patent application at issue, and that to the extent they were involved, neither realized that the prior art had not been disclosed because the Shionogi Patent Department was in a state of confusion and chaos due to the departure of certain employees and a significantly increased workload on the remaining employees. (Id. at 22-38.)

B. Legal Principles Related To Inequitable Conduct

Individuals associated with the filing and prosecution of a patent application, including inventors named in the application, attorneys or agents prosecuting the application, and those involved in the preparation or prosecution of the application who

are associated with the inventor, have a duty of candor, good faith and honesty in their dealings with the PTO. 37 C.F.R. § 1.56(a), (c). The duty of candor, good faith and honesty includes the duty to submit truthful information to the PTO, as well as information which is material to the examination of the patent application. Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 30 (Fed. Cir. 1999).

"Inequitable conduct occurs when a patentee breaches his or her duty to the PTO of 'candor, good faith, and honesty.'" Warner-Lambert Co. v. Teva Pharms. USA, Inc., 418 F.3d 1326, 1342 (Fed. Cir. 2005). A patent procured as a result of inequitable conduct is unenforceable, and if inequitable conduct occurred in relation to one patent claim, the entire patent is rendered unenforceable. Kingsdown Medical Consultants v. Hollister Incorporated, 863 F.2d 867, 877 (Fed. Cir. 1988).

To establish inequitable conduct due to the failure to disclose material information or the submission of false information, the party raising the issue must prove by clear and convincing evidence that (1) the information is material; (2) the knowledge of this information and its materiality is chargeable to the patent applicant; and (3) the applicant's submission of false information or its failure to disclose this information resulted from an intent to mislead the PTO. Warner-Lambert, 418 F.3d at 1342-1343 (citations omitted). "Information is

considered material when there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent." TAP Pharm. Prods. v. OWL Pharm., L.L.C., 419 F.3d 1346, 1351 (Fed. Cir. 2005). However, a reference that is material need not be disclosed if it is cumulative to or less material than other references that have already been disclosed. Elk Corp., 168 F.3d at 31. A reference is cumulative if it "teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO." Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1575 (Fed. Cir. 1997).

In addition to materiality, the party seeking to establish inequitable conduct must demonstrate that the patent applicant acted with the intent to deceive the PTO. Intent to deceive the PTO may be established by direct evidence or inferred from the facts and circumstances surrounding the applicant's overall conduct. Impax Labs. v. Aventis Pharms., 468 F.3d 1366, 1375 (Fed. Cir. 2006); Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 (Fed. Cir. 1995). In determining whether the applicant's overall conduct evidences an intent to deceive the PTO, the Federal Circuit has emphasized that the challenged "conduct must be sufficient to require a finding of deceitful intent in the light of all the circumstances." Kingsdown Medical Consultants, 863

F.2d at 873. "'In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a *deliberate decision* to withhold a *known* material reference.'" Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357 (Fed. Cir. 2008) (quoting Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181 (Fed. Cir. 1995) (emphasis in original)). Intent to deceive may not be inferred from the materiality of the undisclosed reference alone, but an inference of intent to deceive is generally appropriate where there is (1) a high degree of materiality of the reference; (2) evidence that the applicant knew or should have known of its materiality, and (3) the applicant has not provided a credible explanation for withholding the reference. Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1368 (Fed. Cir. 2007); Cancer Research Tech. v. Barr Labs., Inc., 2010 WL 286639, *18 (D. Del. Jan. 26, 2010) (Robinson, J.) (quoting Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1314 (Fed. Cir. 2008) (internal quotations and citations omitted). Generally, the more material the omission, the less the degree of intent that must be shown to reach a conclusion of inequitable conduct. Digital Control Inc. v. Charles Machine Works, 437 F.3d 1309, 1313 (Fed. Cir. 2006) (discussing the balancing of materiality and intent and stating that "a greater showing of one factor allow[s] a lesser showing of the other"); Elk Corp., 168 F.3d at 32. In addition, an inference of intent to deceive must

be "*the single most reasonable inference able to be drawn from the evidence* to meet the clear and convincing standard," and a court errs when it overlooks one reasonable inference in favor of an equally plausible inference where the evidence is susceptible to multiple reasonable inferences. Id. (citing Scanner Techs. Corp. v. ICOS Vision Sys. Corp., 528 F.3d 1365, 1376 (Fed. Cir. 2008) (emphasis added)).

Once materiality and intent have been established, the court must conduct a balancing test to determine "whether the scales tilt to a conclusion that 'inequitable conduct' occurred." Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997). The question of whether inequitable conduct occurred is equitable in nature, and thus, is committed to the sound discretion of the trial court. Elk Corp., 168 F.3d at 30-31; Kingsdown Medical Consultants, 863 F.2d at 876.

Reissue proceedings cannot cure a patent held to be unenforceable due to inequitable conduct. Aventis Pharma S.A. v. Amphastar Pharms., Inc., 525 F.3d 1334, 1341 n.6 (Fed. Cir. 2008) (citing Hoffman-LaRoche Inc. v. Lemmon Co., 906 F.2d 684 (Fed. Cir. 1990)). As the Federal Circuit has explained, "[i]t is well settled that, in the reverse case of inequitable conduct during prosecution of the original application, reissue is not available to obtain new claims and thereby rehabilitate the patent."

Hewlett-Packard Co. v. Bausch & Lomb, Inc., 882 F.2d 1556, 1563 n.7 (Fed. Cir. 1989).

C. Whether The '440 Patent Was Procured Through Inequitable Conduct

After reviewing the evidence adduced by the parties at trial, the Court concludes that Defendants have not established that the '440 patent was procured through inequitable conduct. Plaintiffs have not challenged the materiality of the Sandoz reference, but have challenged the materiality of the European Search Report and the Bayer reference. Based on the evidence submitted by the parties, the Court cannot conclude that these references are immaterial; however, the Court is not inclined to find them to be highly material such that the degree of materiality of these references should permit Defendants to make a lesser evidentiary showing on the intent element. Rather, the Court views the evidence of intent in this case on its own strength and concludes that Defendants have not established, by clear and convincing evidence, that Ms. Kitamura, Mr. Shibata and Mr. Tamaki intended to deceive the PTO by failing to disclose these reference. Although the Court certainly understands how the circumstances raised by Defendants could be suggestive of nefarious conduct on the part of the aforementioned individuals in the Shionogi Patent Department, the Court cannot conclude that these circumstances taken individually or collectively rise to

the level of clear and convincing evidence of inequitable conduct.

In reaching this conclusion, the Court is simply not persuaded that the single most reasonable inference to be drawn from these circumstances is deceptive intent. For example, Defendants make much of the fact that Mr. Shibata held on to the European Search Report for forty days before sending it for filing, calling this an "unprecedented period of study" compared with Mr. Shibata's treatment of other correspondence during this time frame. (D.I. 501 at 14.) However, there is no evidence that Mr. Shibata was "studying" or otherwise even evaluating this document. Rather, the evidence produced by Plaintiffs collectively suggests a time of confusion, personnel change, and overwork in the Shionogi Patent Department such that it would not be unreasonable to infer from this 40 day period that the document had merely been caught in a stack of papers. (DTX-508-T at 79; Shibata Tr. 682:1-19.) Indeed, Mr. Shibata had no recollection of having reviewed this report, which required no response, and Mr. Shibata testified that he did not make any connections between the European Search Report that he sent unreviewed to the file and the correspondence that he checked for Ms. Shimizu concerning the timing of a response to the U.S. rejection of the pending application and matters of form associated with the U.S. claims. (Shibata Tr. 682:1-19; 798:15-

801:14, 803:19-804:16.) As Mr. Shibata candidly explained, "I think I was in a very near sighted myopic state of mind" because

> there was very much a limitation in time and much workload. And that meant that the amount of time that could be spent for individual matters had been reduced dramatically. And I think the result of it is that the care that could be allocated to each assignment, each task and the manner in which the job was being done just was not up to par.

(Shibata Tr. 800:6-15.)

Defendants also point to the splitting of the '440 application between Ms. Shimizu and Mr. Tamaki contending that "Mr. Shibata violated the longstanding Shionogi rule requiring that the same person be responsible for handling all corresponding applications" so that he could manipulate and prevent the disclosure of the European Search report and the Sandoz reference. (D.I. 501 at 16.) However, the countervailing evidence produced by Plaintiffs and viewed as a whole, paints a more innocent explanation of Mr. Shibata as a new and inexperienced manager attempting to handle an understaffed and overworked Patent Department. (Shibata Tr. 798:15-801:14, 803:4-804:16.) Mr. Shibata admitted as much on the witness stand testifying, that:

> [B]ack then, I was - I was doing the best I could do, and I thought I was doing what I had to do and ought to do. But through this lawsuit, I have been shown various documents and I have come to be ashamed as to my management. I think the management was very

> poor. And on that score, I do regret and I've done a lot of self retrospection.

(Shibata Tr. 803:10-16.)

In addition, Defendants emphasize Mr. Shibata's role in comparative testing of the compound claimed in the S-4522 application with the compounds from the Bayer, Nissan and Sandoz references to suggest that he was attempting to conceal these references. However, an equally plausible inference is that this comparative testing could have been used to confront the prior art and overcome challenges to patentability, particularly given Mr. Shibata's testimony, which the Court finds credible, that he had likely thought, at the relevant time, that the Bayer and Sandoz references had already been disclosed. (Shibata Tr. 751:12-752:18; DTX-68-T at 1.)

Defendants point to several actions by Mr. Tamaki to suggest that he intended to conceal material prior art from the PTO; however, Mr. Tamaki's conduct is also explained by the at least equally plausible explanation of the work load and confusion at the Shionogi Patent Department. (Tamaki Tr. 566:20-568:21; PTX-624-SUM.) Moreover, the evidence indicates that Mr. Tamaki's work on the '440 patent was much less extensive than what has been suggested by Defendants. (Tamaki Tr. 420:11-20, 431:22-432:4, 523:6-525:5; DTX-500-T at 159.) Although Mr. Shibata intended to assign the U.S. application to Mr. Tamaki, that intention was ultimately not carried out because of Mr. Tamaki's

already strained workload. (Shibata 686:12-687:4, 709:7-18, 802:5-803:3; DTX-500-T at 138.)

Defendants also attempt to undermine Mr. Tamaki's credibility by pointing to his conduct with the AstraZeneca-affiliated Plaintiffs during licensing negotiations. In the Court's view, however, this evidence has limited relevance because it pertains to a period of time occurring well-after the issuance of the '440 patent. Star Scientific, 537 F.3d at 1370, n.10. Further, it is equally reasonable for this evidence to be construed as indicative of Mr. Tamaki's good faith and credibility in that he conceded that Shionogi knew about the Sandoz and Bayer references, but provided reasonable explanations to the AstraZeneca-affiliated Plaintiffs for why the references were not disclosed. (Tamaki Tr. 482:22-484:9, 486:6-20, 542:12-545:3, 549:23-550:22; DTX-32-T; DTX-33 at 2-3; DTX22-T at 5-6; DTX-36 at 1.)

Defendants make much of Ms. Kitamura's testimony during trial that she knew of the duty of disclosure in connection with U.S. patent applications, but that she did not disclose the Bayer application, even though she knew that it "encompassed" at least some of the compounds being claimed in the application that issued as the '440 patent. As Plaintiffs point out, however, the duty to disclose does not pertain to prior art that "encompasses" the invention, but only to prior art that establishes a prima

facie case of unpatentability. See e.g. In re Baird, 16 F.3d 380, 382 (Fed. Cir. 1994) ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious.") (citations omitted). Indeed, the fact that a later invention may infringe an earlier patent does not affect the patentability of the later invention, and it is not unreasonable to view the June 1991 search report with respect to the Bayer application as raising a potential infringement problem, but not an invalidity or patentability problem. Ms. Kitamura testified that she did not perceive a patentability problem based on the Bayer application prior to her departure from Shionogi, and that she did not substantively consider what prior art, beyond that cited already in the specification, should be cited to the PTO in the IDS. (Kitamura Tr. 1533:13-23, 1535:6-14; PTX-1676-T; DTX-500 at 131.) Mr. Kitamura's testimony is not implausible as Defendants contend, given that Ms. Kitamura had given notice around the time the U.S. application was filed, that she would be leaving Shionogi at the end of July 1992. (Kitamura Tr. 1536:3-9.) Indeed, at the time Ms. Kitamura left Shionogi, the IDS was not due, and her testimony regarding the lack of a patentability issue is not inconsistent with the documentary evidence which judged the compounds to be novel. (PTX-1676-T at SH95938; DTX-500 at 131; DTX-508 at 79-82; DTX-22-T at 5-6; Kitamura Tr. 1459:10-13; Tamaki Tr. 544:16-545:3.)

Defendants also point to a July 20, 1992 memorandum by Mr. Yasumi suggesting a potential patentability problem under Japanese law based on the Bayer reference to suggest that Ms. Kitamura was aware of a patentability problem. However, the memo is dated two days before Ms. Kitamura's departure, and therefore, it is not unreasonable to believe that Ms. Kitamura would not have been informed of this memorandum. (DTX-57-T; PTX-1676-T at SH95938.) Indeed, Ms. Kitamura had no recollection of receiving this memorandum, and there is no evidence in the record to the contrary. (Kitamura Tr. 1450:11-1451:1, 1536:3-9.)

In sum, the Court is not persuaded that the evidence presented by Defendants rises to the level of the clear and convincing evidence required to establish inequitable conduct. In reaching this conclusion, the Court credits the testimony of Ms. Kitamura, Mr. Shibata and Mr. Tamaki and finds the rationale concerning the inexperience, increased workload, and resulting confusion in the Shionogi Patent Department to be an equally plausible explanation for the failure of Shionogi to cite the European Search Report, the Bayer reference and the Sandoz reference to the USPTO during the application process that led to the issuance of the '440 patent. Indeed, none of the aforementioned individuals was a Japanese patent attorney or agent, and in fact, the Shionogi Patent Department as a whole employed no one with legal experience in the field of patents.

While in hindsight it may be attractive to construct a deliberate scheme of deceptive intent from the actions of these individuals given the success of CRESTOR® in the marketplace, it is at least equally plausible from their testimony and the contemporaneous documentary evidence, that a scheme to defraud was the furthest thing from the minds of these individuals at the relevant time and that their vision was limited to the overwhelming demands they faced daily in their severely understaffed department. Viewed in this context, which the Court is persuaded is the appropriate context given the testimony and evidence, actions suggestive of malfeasance become no more than a string of mishaps, mistakes, misapprehensions and misjudgments on the part of inexperienced and overworked individuals. Accordingly, the Court will enter judgment in favor of Plaintiffs and against Defendants' on the issue of inequitable conduct.

IV. OBVIOUSNESS

A. The Parties' Contentions

Defendants contend that the asserted claims of the '314 patent would have been obvious as of July 1, 1991, the date of the claimed invention, and thus, are invalid. (D.I. 501 at 35.) In presenting this argument, Defendants contend that the testimony and evidence at trial creates a prima facie showing of obviousness based on the prior art and that the secondary

considerations related to obviousness are insufficient to overcome the patent's invalidity.

Defendant's argument is first premised on the contention that a person of ordinary skill in the art would likely have started the process of developing rosuvastatin with Compound 1b. (Id. at 42.) Defendants note that Compound 1b is the closest prior art reference to the claimed invention and is derived from the Sandoz reference. (Id. at 37 (citing D.I. 517 at DFF 422).) Defendants further contend that Compound 1b was a particularly obvious choice from which to initiate development of rosuvastatin, because it was notably important within the Sandoz reference as highlighted by Sandoz's preferential treatment of Compound 1b in the reference. (Id. at 47.) According to Defendants, Compound 1b does not need to be shown to be the only possible starting point or the "lead compound" in the development of rosuvastatin, but rather, that Compound 1b would have been an obvious and suitable starting point from which to begin the development of rosuvastatin. (Id. at 37-42.)

From this starting point, Defendants further contend that the development of rosuvastatin would have been obvious because the pyrimidine core structures within rosuvastatin would also have been an obvious development at the time rosuvastatin was created, based upon contemporaneous experimentation with and publications concerning such structures. (Id. at 45.)

Defendants also contend that a person of ordinary skill in the art would have been motivated to develop a more hydrophilic statin, such as rosuvastatin, so as to position a new product in the marketplace. (Id. at 49.) Lastly, Defendants contend that the differences between rosuvastatin and the prior art would have been obvious to a person of skill in the art, both concerning the method of modifying the prior art and in the expected results of rosuvastatin. (Id. at 52-59.)

In addition to Defendants' direct arguments on obviousness, Defendants contend that the secondary considerations relevant to obviousness do not overcome invalidity. (Id. at 59.) Specifically, Defendants contend that: (1) Plaintiff's clinical expert, Dr. Jones, was not credible and should not be considered (id. at 60-61); (2) rosuvastatin is not a commercial success (id. at 61); (3) rosuvastatin did not satisfy any long felt, but unmet need (id. at 61-62); (4) rosuvastatin's properties were not unexpected (id. at 62-63); (5) Plaintiffs did not establish that others tried and failed to develop a statin comparable to rosuvastatin (id. at 64); (6) there was no skepticism concerning rosuvastatin (id. at 65); and (7) the evidence of copying rosuvastatin is limited to Defendants' attempts to produce a generic version which is not evidence of non-obviousness. (Id. at 65-66.)

In response, Plaintiffs contend that Defendants have not established by clear and convincing evidence that the '314 patent is obvious. (D.I. 540 at 53.) Specifically, Plaintiffs contend that the scope and content of the relevant prior art does not provide evidence of obviousness, because several entities abandoned their research efforts related to pyrimidine core statins based upon the prevailing belief that pyrimidine cores were inferior to then existing technology. (Id. at 61-62.) Additionally, Plaintiffs contend that the claims of the '314 patent that are specific to rosuvastatin present unique and inseparable features and properties that were discovered and developed by the inventors of the patent-in-suit. (Id. at 63-64.)

According to Plaintiffs, Defendants' assumptions and assertions about the development of rosuvastatin are based on a hindsight analysis of a successful product and ignore the judgments, decisions, and experimentation that was required to reach the end product. (Id. at 65-66.) In this regard, Plaintiffs contend that Defendants have not shown any reason why it would have been obvious to start with Compound 1b as opposed to one of the many other suitable starting points. (Id. at 67.) However, even if a person skilled in the art happened to start with Compound 1b, Plaintiffs contend that there was no obvious

motivation to make the modifications to Compound 1b that ultimately led to the creation of rosuvastatin. (Id. at 68.)

In addition, Plaintiffs contend that the secondary considerations demonstrate that the invention claimed in the '314 patent was not obvious. Specifically, Plaintiffs contend that (1) rosuvastatin had unexpected properties; (2) others were skeptical of the safety of rosuvastatin; (3) rosuvastatin met a long-felt, but unmet need; and (4) other companies failed to develop a pyrimidine based statin at the time of the invention of rosuvastatin and Defendants now seek to copy the product that Plaintiffs succeeded in bringing to the market. (Id. at 72-76.)

B. Legal Principles Related To Obviousness

In pertinent part, 35 U.S.C. § 103 provides that a patent may not be obtained "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art." 35 U.S.C. § 103. Obviousness is a question of law that is predicated upon several factual inquiries. See Richardson-Vicks v. Upjohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997). Specifically, the trier of fact must consider four issues: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) secondary considerations of non-obviousness, such as commercial

success, long felt but unsolved need, failure of others, acquiescence of others in the industry that the patent is valid, and unexpected results. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966) (the "Graham factors"). In KSR Intern. Co. v. Teleflex Inc., the Supreme Court reaffirmed that the Graham factors "continue to define the inquiry that controls" an obviousness analysis. 550 U.S. 398, 407 (2007).

Because an issued patent is presumed valid, the party-seeking to challenge the validity of a patent based on obviousness must demonstrate by clear and convincing evidence that the invention described in the patent would have been obvious to a person of ordinary skill in the art at the time the invention was made. Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1359-60 (Fed. Cir. 2007). Clear and convincing evidence is evidence that places in the fact finder "an abiding conviction that the truth of [the] factual contentions are 'highly probable.'" Colorado v. New Mexico, 467 U.S. 310, 316 (1984).

C. Whether The '314 Patent Is Invalid As Obvious

After evaluating the extensive arguments of the parties and the evidence adduced at trial, the Court concludes that Defendants have not demonstrated by clear and convincing evidence that the '314 patent is invalid as obvious. In the Court's view, Defendants' arguments are driven by hindsight and based on numerous assumptions, the validity of which were countered by

Plaintiffs' equally compelling evidence that significant work was needed to develop rosuvastatin. (See Heathcock Tr. 263:2-270:21; Roush Tr. 1743:24-1745:2, 1769:20-1773:15.) In addition, the Court is persuaded that the first and third Graham factors, concerning the scope and content of the prior art and the differences between the prior art and the claimed subject matter, respectively, weigh in favor of a conclusion that the claimed invention was not obvious. For example, while Compound 1b was relevant prior art to the '314 patent, the Court is not convinced that it would have been obvious to a person skilled in the art that rosuvastatin was merely several, obvious modifications away from Compound 1b. That rosuvastatin was not obvious from the scope and content of the prior art is demonstrated by the fact that other pharmaceutical entities working on pyrimidine core statins did not create a statin comparable to rosuvastatin and, in fact, abandoned their efforts. Furthermore, multiple modifications to the basic pyrimidine core structure were required to create rosuvastatin, and the Court is not persuaded that these modifications would have been obvious to one skilled in the art.

Additionally, the Court concludes that the secondary factors of non-obviousness weigh in favor of a conclusion that the '314 patent is not obvious. The evidence demonstrates that there was much skepticism in the industry concerning the safety of

rosuvastatin (Pears Tr. 1307:12-1310:22), and the Court finds it telling that no other pharmaceutical companies attempted to create a comparable product despite research in the area and the economic incentives of entering an additional player in the statin market. (Heathcock Tr. 290:6-18; Roush Tr. 1728:13-1729:19.) Accordingly, based on the foregoing, the Court concludes that Defendants have not shown by clear and convincing evidence that the '314 patent is invalid as obvious, and therefore, judgment will be entered in favor of Plaintiffs and against Defendants on the issue of invalidity due to obviousness.

V. REISSUE

A. The Parties' Contentions

Defendants contend that Plaintiffs cannot establish infringement of the '314 patent because it is invalid as improperly reissued. (D.I. 501 at 66.) According to Defendants, there were no errors in the original '440 patent that warranted reissue under the governing statute. (Id.) Defendants contend that Shionogi deliberately chose not to claim rosuvastatin in the '440 patent as part of a company decision to conceal the development of the product from competitors. (Id. at 78-80.) Defendants also contend that Shionogi deliberately crafted a broad claim in the '440 patent that overlapped the Sandoz reference in an attempt to garner extensive protection, despite timely knowledge of the Sandoz reference. (Id. at 80-83.)

Defendants maintain that Shionogi took full advantage of the breadth of the claimed invention and only sought to narrow the patent to claim rosuvastatin specifically, when it became advantageous to license the compound. (Id. at 83.)

In response, Plaintiffs contend that the reissue of the '440 patent was entirely proper and based upon valid grounds for reissue. (D.I. 540 at 42.) Specifically, Plaintiffs contend that the deliberate presentation of claims that are later recognized to be too broad is a correctable error justifying reissue. According to Plaintiffs, the over breadth of the '440 patent and the failure to claim rosuvastatin specifically was not based on an intent to deceive, but on the misunderstandings and misapprehensions of individuals who were not well-trained and sufficiently experienced. (See Id. generally.) Plaintiffs further contend that there is no legal support for Defendants' contention that equitable principles demand a conclusion that the reissue was improper. (Id. at 50.)

B. Legal Principles Related To The Reissue of Patents

A patent may be reissued to correct an error under 35 U.S.C. § 251, which, in pertinent part states:

> Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the

> invention disclosed in the original patent, and in accordance with a new amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

35 U.S.C. § 251. Under this section, reissue is permitted to correct the following types of defects: (1) an error in the specification, (2) a defective drawing, (3) the original claim was too broad, and (4) the original claim was too narrow. Forest Labs., Inc. v. Ivax Pharms., Inc., 438 F. Supp. 2d 479, 497 (D. Del. 2006). "[T]he purpose of the reissue statute is to avoid forfeiture of substantive rights due to error made without intent to deceive." Id. (citations omitted). The statute is remedial in nature and based upon fundamental principles of equity and fairness, and thus, should be liberally construed so as to permit reissue. See In re Wilder, 736 F.2d 1516, 1519 (Fed Cir. 1984).

Not every event or circumstance that might be labeled an "error" is correctable by reissue proceedings. In re Weiler, 790 F.2d 1576, 1579 (Fed. Cir. 1986)(citation omitted); see also MBO Labs. Inc. v. Becton, Dickinson & Co., 602 F.3d 1306, 1313 (Fed. Cir. 2010) (confirming standard). Generally, those errors that are correctable by reissue are errors of "inadvertence, accident, or mistake." Weiler, 790 F.2d at 1582. A "deliberate action of an inventor or attorney during prosecution generally fails to qualify as correctable error," where the reissue would contravene the operation of applicable statutes or USPTO rules. In re

Serenkin, 479 F.3d 1359, 1362, 1364 (Fed. Cir. 2007). Thus, the mere fact that an action was taken in "full consciousness" does not necessarily preclude the finding of a correctable error, where the action was not taken with deceptive intent, and the reissue would not contravene the law. In re Wadlinger, 496 F.2d 1200, 1207 (C.C.P.A. 1974).

When a party challenges a patent's validity based on reissue, the presumption that the patent is valid remains. Thus, the party challenging the appropriateness of the reissue must prove the invalidity of the reissue by clear and convincing evidence. See Kaufman Co. v. Lantech, Inc., 807 F.2d 970, 973-74 (Fed. Cir. 1986).

C. Whether the '314 Patent Is Invalid As Improperly Reissued

After reviewing the parties' arguments in light of the evidence adduced at trial, the Court concludes that Defendants have not established, by clear and convincing evidence, that the '314 patent is invalid as an improper reissue of the '440 patent. While the troubles in the Shionogi Patent Department raise the specter of malfeasance in hindsight, the Court is ultimately not convinced that the claims of the '440 patent that overlapped with the Sandoz reference were the result of some planned strategy or sinister motivation as opposed to mere mistake or oversight by overworked individuals with limited training and expertise. To reach a contrary conclusion in this case would require the Court

to credit a number of inferences, which the Court finds unsupported by the requisite clear and convincing standard. Rather, the totality of the evidence demonstrates to the Court that it was equally plausible that this error was driven by chaos, confusion, and inexperience rather than any deliberate plan of action. The lack of legal training within the Shionogi Patent Department, the changing and limited personnel within that department, and the ongoing confusion level indicate that confusion is at least as likely a cause of the overlap with Sandoz, as any cause that would have made reissue improper. (See Shibata 799:9-800:19, 803:4-804:16; Kitamura 1536:3-9; DTX-500 at 214; Takayama Dep. 231:3-25.) As Ms. Kitamura credibly testified, the internal Shionogi search report of which she was aware, did not raise a patentability problem with respect to Sandoz, and a full copy of the Sandoz reference was not sent to her. (Kitamura Tr. 1414:14-1422:3, 1423:20-1424:4, 1481:3-14, 1458:17-22; DTX-33; DTX-22-T.) Thus, Ms. Kitamura did not appreciate any overlap with the Sandoz reference prior to her departure from Shionogi, and those who prosecuted the '440 patent after her departure were likewise unaware of the Sandoz reference due to the unintentional miscommunications that ensued during the various transitions at Shionogi. (Kitamura 1504:10-1505:14; DTX-515-T at 22-23; DTX-5.)

Defendants also suggest that the overbreadth of the claims was a deliberate intent to conceal Shionogi's development of rosuvastatain from its competitors, and that this deceitful intent precludes reissue. Although Defendants provided some evidence that the Shionogi patent application process may have been driven by strategic decisions to delay competitiors from learning of their development of rosuvastatin, the Court is ultimately not persuaded that Defendants have established, by clear and convincing evidence, that the reissue was improper. As a threshold matter, the Court finds no evidence that Shionogi deliberately and deceptively decided to forgo narrowly claiming rosuvastatin. Rather, the '440 patent both covered and described rosuvastatin in the examples listed within the specification and in the breadth of the original claims. (PTX-495 at SH89082-86; SH89090; PTX-590 at C57140-44, C57149-50; PTX-609 at SH88362, SH88369-71, SH88374; Tamaki 459:7-460:-13.) The application also presented data showing that rosuvastatin had activity 4.5 times higher than mevinolin, and therefore, rosuvastatin clearly had the best activity of any of the compounds disclosed in the patent application. (PTX-495 at SH89092; PTX-590 at C57150; PTX-609 at SH88375.) Thus, Shionogi's interest in rosuvastatin would have been evident from the application, and the Court is not persuaded that the failure to specifically claim rosuvastatin was the result of any deceptive intent by Shionogi or any purposeful

desire to avoid such a narrow claim. Based on this disclosure, it is the Court's view, that the error in the '440 patent was not in failing to claim rosuvastatin but in unknowingly claiming subject matter broader than rosuvastatin that overlapped with the Sandoz reference, an error which the Court concludes is properly remedied by reissue. See In re Harita, 847 F.2d 801, 804-805 (Fed. Cir. 1988); Wilder, 736 F.2d at 1519.

In addition, the Court finds the circumstances here to be distinguishable from cases like In re Serenkin, 479 F.3d 1359, 1363 (Fed. Cir. 2007). In Serenkin, reissue was denied for lack of error because the attorney prosecuting the patent knowingly surrendered a priority date for the patent in order to achieve a specific and defined gain in the form of being able to submit new drawings and other materials that had been missing in the earlier application. In contrast, the evidence adduced in this case shows no such deliberate choices and no violations of rules or statutes that would render the reissue of the '440 patent improper. Accordingly, the Court concludes that Defendants have not established by clear and convincing evidence that the reissued '314 patent, with its rosuvastatin specific claims, is invalid, and therefore, the Court will grant judgment in favor of Plaintiffs and against Defendants on the issue of improper reissue.

CONCLUSION

For the reasons discussed, the Court concludes that Apotex may be held liable for infringement of claims 6 and 8 of the '314 patent under Section 271(e)(2)(A) as a submitter of an ANDA. In addition, the Court will grant Defendants' Motion To Dismiss AstraZeneca Pharmaceuticals LP For Lack of Standing. Judgment will be entered in favor of Plaintiffs and against Defendants on the issues of invalidity and unenforceability of the '314 patent. Plaintiffs shall submit, with notice to Defendants a proposed Final Judgment Order, outlining the Court's rulings on infringement, invalidity and unenforceability contained herein.

An appropriate Order will be entered.