IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

ALEMBIC PHARMACEUTICALS LIMITED,	)	
Plaintiff,	)	
v.	)	
NOVARTIS AG	)	Civil Action No. 1:17-cv-292 (AJT/MSN)
and	)	
MITSUBISHI TANABE PHARMA CORPORATION	)	
Defendants.	)	

COMPLAINT FOR DECLARATORY JUDGMENT OF
PATENT INVALIDITY AND NON-INFRINGEMENT

Plaintiff Alembic Pharmaceuticals Limited ("Alembic") hereby brings this action against Defendants Novartis AG and Mitsubishi Tanabe Pharma Corporation (collectively "Defendants") seeking a declaration that Alembic has not infringed, does not infringe, and will not infringe any valid claim of U.S. Patent No. 8,324,283 ("the '283 patent"). Alembic brings this suit to obtain patent certainty under 21 U.S.C. § 355(j)(5)(C)(i)(I), and to obtain final FDA approval to market its low-cost, generic fingolimod[1] drug product at the earliest possible date pursuant to 21 U.S.C. §355(j)(5)(D)(i)(I). Alembic seeks a declaratory judgment of non-infringement and/or invalidity of the '283 patent that would free the FDA to approve Alembic's generic drug application at the earliest possible date, thereby allowing Alembic to market its low-cost, generic fingolimod drug product.

[1] Fingolimod is used to treat multiple sclerosis ("MS") by preventing autoimmune reactions that cause relapse and disability in patients with relapsing-remitting MS.

I. NATURE AND SUMMARY OF THIS ACTION

1. This action arises under the patent laws of the United States and Amendments to the Federal Food, Drug, and Cosmetics Act (the "Hatch-Waxman Act"),[2] which govern the U.S. Food and Drug Administration's ("FDA") approval of both new and generic drugs. *See* 21 U.S.C. § 355 *et seq.*; 35 U.S.C. §§ 156, 217(e). Alembic seeks FDA approval for the commercial manufacture, use, importation, offer for sale, and sale of a generic version of Gilenya (fingolimod) capsules as described in Alembic's Abbreviated New Drug Application ("ANDA") No. 207974 ("Alembic's ANDA"). Alembic's ANDA contains a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that U.S. Patent No. 8,324,283 is invalid or will not be infringed by the manufacture, use, or sale of the Alembic's fingolimod product.

2. In accordance with 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Alembic sent notice to the respective Defendants of Alembic's '283 patent certification in Alembic's ANDA and provided an Offer of Confidential Access to its ANDA No. 207974. Defendants chose not bring a suit for patent infringement, even though they had a right to bring such suit. *See* 21 U.S.C. § 355(j)(5)(C).

3. The Hatch-Waxman Act provides for a "civil action to obtain patent certainty" when a generic applicant makes such certifications. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc). This declaratory judgment provision in the Hatch-Waxman Act aims to encourage early resolution of patent disputes, and prevent brand-name drug companies from using tactics that forestall the competing generic drug makers from entering the market. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008).

[2] Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355(j) (1984).

4. The Medicare Modernization Act of 2003 ("MMA") sets forth certain provisions by which first ANDA applicants would forfeit their exclusivity. For example, the entry of a final judgment of non-infringement or invalidity with respect to the patents against which the first ANDA applicant filed paragraph IV certifications, regardless of whether or not those patents are asserted against subsequent ANDA filers, will cause the first ANDA filer to forfeit its exclusivity. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

5. Alembic's complaint seeks a judgment to obtain patent certainty that Alembic's fingolimod product does not infringe any valid and enforceable claim of the '283 patent. Such judgment would trigger forfeiture of the first ANDA applicant's 180-days exclusivity, and enable Alembic to bring its fingolimod products to market at the earliest possible date allowed under applicable statutory and FDA regulatory provisions.

II. THE PARTIES

6. Alembic is a company organized and existing under the laws of India having a principal place of business at Alembic Road, Vadodara, 390 003, Gujarat, India.

7. Based on publicly available information, Novartis AG is a Swiss Corporation having a principal place of business at Lichtstrasse 35, Basel, Switzerland 4056.

8. Based on publicly available information, Mitsubishi Tanabe Pharma Corporation is a Japanese Corporation having a principal place of business at 2-6-18 Kitahama, Chuo-Ku, Osaka, Japan 541-0046.

9. Based on publicly available information, Novartis AG and Mitsubishi Tanabe Pharma Corporation are the assignees of record with the United States Patent and Trademark Office ("USPTO") of the '283 patent. Exhibit 2.

III. JURISDICTION AND VENUE

10. This is a Complaint for declaratory judgment that the claims of the ’283 patent are invalid and that Alembic has not, does not, and will not infringe the claims of the ’283 patent, which arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, the Hatch-Waxman Act, 21 U.S.C. §§ 355(j) *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action involves substantial claims arising under the United States Patent Act (35 U.S.C. §§ 1 *et seq.*), the Declaratory Judgment Act (28 U.S.C. §§ 2201-2202), 21 U.S.C. § 355(j)(5)(C), and 35 U.S.C. § 271(e)(5).

12. This Court has personal jurisdiction over Defendants under 35 U.S.C. § 293, which provides that in cases involving a patentee not residing in the United States, the United States District Court for the Eastern District of Virginia “shall have the same jurisdiction to take any action respecting the patent or rights thereunder that it would have if the patentee were personally within the jurisdiction of the court,” assuming that “no person” has been designated “within the Patent and Trademark Office … on whom may be served process or notice of proceedings affecting the patent or rights thereunder.” Defendants do not reside in the United States and have not designated an agent to accept service of process as provided by 35 U.S.C. § 293.

13. Further, this Court has personal jurisdiction over Defendants because they are foreign corporations and under Rule 4(k)(2) of the Federal Rules of Civil Procedure, commonly referred to as the federal long-arm statute, which provides that for claims arising under federal law, such as patent claims, an entity can sue a foreign entity in any U.S. District Court if the

defendant is not subject to the jurisdiction of the courts of any one state but its contacts with the United States as a whole are sufficient to meet the requirements of due process under U.S. law.

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(c), 1400(b), and/or 21 U.S.C. § 355.

IV. HATCH-WAXMAN ACT OVERVIEW

15. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. *See* 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271(e). The Hatch-Waxman Act was intended to encourage generic-drug competition while leaving intact incentives for research and development of new drugs by pioneering, *i.e.*, "branded," drug companies. *See* H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984), *reprinted in* U.S.C.C.A.N. 2647, 2648.

16. To accomplish this goal, the Hatch-Waxman Act established a framework with five elements that are pertinent here.

17. First, a company seeking FDA approval of a new drug must submit a New Drug Application ("NDA") to the FDA. *See* 21 U.S.C. § 355. A brand-name drug sponsor must also inform the FDA of every patent that claims the "drug" or "method of using [the] drug" for which a claim of patent infringement could reasonably be asserted against unlicensed manufacture, use, or sale of that drug product. *See* 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(c)(2); 21 C.F.R. § 314.53(b), (c)(2). Upon approval of the NDA, the FDA publishes a listing of patent information for the approved drug in a document referred to as the Orange Book. *See* 21 U.S.C. § 355(b)(1). The new FDA-approved drug is known as the "reference-listed drug."

18. Second, the Hatch-Waxman Act provides a streamlined process for approving generic drugs. Before marketing a generic version of an FDA-approved drug, a generic-drug manufacturer must submit an ANDA to the FDA. An ANDA is "abbreviated" because applicants

are generally not required to include the extensive preclinical and clinical data that must be included in an NDA for a brand-name drug. Instead, the ANDA applicants can rely on the NDA's preclinical and clinical data if the proposed generic product is "bioequivalent" to the corresponding reference-listed drug. *See* 21 U.S.C. § 355(j)(4)(F).

19. An ANDA must also contain one of four certifications for each patent listed in the Orange Book: (i) that there are no patents listed in the Orange Book; (ii) that any listed patent has expired; (iii) that the patent will expire before the generic manufacturer is seeking to market its generic product; or (iv) that the patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV); 21 C.F.R. § 314.94(a)(12). The last of these is commonly referred to as a "paragraph IV certification."

20. An applicant submitting an ANDA containing a paragraph IV certification must provide formal written notice (*i.e.*, "a notice letter") informing both the patent holder and the NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

21. Third, the Hatch-Waxman Act encourages prompt resolution of patent disputes by authorizing a patent owner to sue an ANDA applicant for patent infringement if a paragraph IV certification has been made. *See* 35 U.S.C. § 271(e)(2). By statute, if the patent owner brings suit within 45-days of receiving notice of the paragraph IV certification, the suit will trigger an automatic statutory 30-month stay of approval by the FDA of the ANDA to allow parties time to adjudicate the merits of the infringement action before the generic company launches its product. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

22. Fourth, to encourage prompt generic-market entry, the Hatch-Waxman Act grants the first generic applicant to file a substantially complete ANDA containing a paragraph IV

certification ("first-filer") to an Orange-Book-listed patent a 180-day period of marketing exclusivity that begins on the earliest of (1) the date it begins commercial marketing of its generic-drug product or (2) the date of a court decision finding the listed patent invalid, unenforceable, or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv); *see also* 21 C.F.R. § 314.107(c)(1).

23. If the first-filer does not commercially market the generic drug and none of the MMA forfeiture provisions are triggered (including the entry of a final judgment of non-infringement or invalidity), the first-filer's 180-day exclusivity period will be delayed indefinitely, ultimately blocking final FDA approval of all subsequent ANDAs. This block is known as "bottlenecking" or the "statutory block" of a subsequent ANDA.

24. Fifth, to alleviate the potential for bottlenecking and to avoid gamesmanship by the NDA holder or patent owner, the Hatch-Waxman Act allows ANDA applicants to bring declaratory-judgment actions against an NDA holder or an owner of an Orange-Book-listed patent if (1) neither the patent owner nor the NDA holder brought an action for infringement of the patent within the 45-day period; and (2) the ANDA applicant's notice of paragraph IV certification included an offer of confidential access to the ANDA. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc).

25. By authorizing declaratory-judgment actions under these circumstances, Congress intended that full generic competition would not be delayed indefinitely, or blocked, by the first-filer's 180-day exclusivity. A declaratory-judgment action by a subsequent ANDA applicant could result in a court decision that triggers forfeiture of the first-filer's 180-day exclusivity under 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA), thereby clearing the way for approval of the subsequent-filers' bottlenecked ANDAs.

26. Congress explained the need for civil actions to obtain patent certainty:

> [W]hen generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could … force the first generic to market. In … these … circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug.

Caraco, 527 F.3d at 1285 (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of U.S. Senate Committee on Health, Education, Labor, and Pensions)).

27. By specifically allowing declaratory-judgment actions under these circumstances, Congress intended that full generic competition would not be delayed or blocked, by the first-filer's 180-day exclusivity, to the detriment of the public.

V. DEFENDANTS BLOCK ALEMBIC'S GENERIC ENTRY

1. The FDA's Orange Book Lists the '283 Patent

28. In connection with the Gilenya NDA, the '283 patent is listed in the Orange Book as a patent to which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" product containing 0.5 mg of fingolimod in capsule form. 21 U.S.C. § 355(b)(1), (c)(2).

29. Upon information and belief, Novartis Pharmaceuticals Corporation, a subsidiary of Novartis AG, is the holder of the approved Gilenya NDA No. 022527. Upon information and belief, as joint patentees, Defendants caused or authorized the '283 patent to be listed in the Orange Book in conjunction with Gilenya.

30. The '283 patent entitled "Solid Pharmaceutical Compositions Comprising a S1P Receptor Agonist and a Sugar Alcohol" was issued by the USPTO on December 4, 2012 to Defendants. On information and belief, that '283 patent will expire on March 29, 2026. A copy of the '283 patent is attached as Exhibit 1.

31. Relevant here, the Orange Book also lists U.S. Patent No. 5,604,229 ("the '229 patent") which expires on February 18, 2019.

2. The First Paragraph IV Certification for Gilenya

32. The FDA maintains the identity of the first-filer(s) as confidential. However, the FDA publishes the date of submission of the first substantially complete ANDA containing a paragraph IV certification for each drug. For Gilenya, the FDA identifies the date of submission of the first-filer(s) as September 22, 2014. Exhibit 6, p. 19.

33. As of September 22, 2014, the Orange Book listed the '283 patent in connection with Gilenya. Exhibit 7.

34. Upon information and belief, at least one of the various parties in the pending action in the District of Delaware filed the first substantially complete ANDA that included a paragraph IV certification with respect to the '283 and '229 patents and, thus, holds eligibility for 180-day market exclusivity for fingolimod. *Novartis AG et al. v. Actavis, Inc. et al.*, 14-cv-01487 (filed Dec. 16, 2014).

35. Defendants maintain an infringement action against the first-filer(s) on the '229 patent, but not the '283 patent, in the District of Delaware. *Novartis AG et al. v. Actavis, Inc. et al.*, 14-cv-01487 (D. Del. filed Dec. 16, 2014). However, absent a judgment by this Court on the '283 patent, the first-filer(s) will retain eligibility for 180-days of marketing exclusivity upon expiration of the '229 patent on February 18, 2019, thereby artificially blocking Alembic's market entry.

3. Alembic Applies for FDA Approval of its Generic Fingolimod Products

36. Alembic submitted ANDA No. 207974 to the FDA seeking approval for the commercial manufacture, use, importation, offer for sale, and sale of a generic version of Gilenya fingolimod capsules. Alembic's ANDA contains a paragraph IV certification that the

’283 patent is invalid and/or will not be infringed by the manufacture, use, or sale of the Alembic’s fingolimod product. Alembic submitted its ANDA *after* September 22, 2014, and therefore is considered a “subsequent filer.” As a subsequent filer, Alembic is blocked from marketing its fingolimod product by the first-filer(s) exclusivity.

37. On August 19, 2016, Alembic sent notice to Defendants of Alembic’s paragraph IV certification regarding the ’283 patent in Alembic’s ANDA and provided an Offer of Confidential Access to its ANDA No. 207974 pursuant to 21 U.S.C. § 355(j)(2)(B)(i) (“notice letter”).

38. Upon information and belief, Defendants received Alembic’s notice letter on August 22, 2016.

39. In its notice letter, Alembic provided to Defendants a detailed factual and legal basis for Alembic’s paragraph IV certification that the ’283 patent is invalid and will not be infringed by Alembic’s proposed fingolimod product. As such, the relevant statute provided Defendants with a right to bring suit against Alembic for infringement of the ’283 patent, but Defendants chose not to sue Alembic. 21 U.S.C. § 355(j)(5)(B)(iii). Having failed to sue Alembic within a 45-day period following receipt of Alembic’s notice letter, the relevant statute provides Alembic with a statutory right to bring the present declaratory judgment action for patent certainty. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc).

4. Alembic’s Approval is Blocked

40. Alembic is prepared to begin commercial marketing of its fingolimod product on February 18, 2019, upon expiration of the ’229 patent. Alembic, however, will be blocked from receiving final approval and prevented from actually entering the market until the end of the first-filer’s exclusivity, because the ’283 patent will be listed in the Orange Book.

41. As such, absent a court declaration that the ’283 patent is invalid and/or not infringed, Alembic will be unable to sell its fingolimod product until 180 days after the first-filer(s) enters the market, thereby injuring Alembic by depriving it of sales revenue that it could earn for that period of time.

42. Were Alembic free to market its generic fingolimod product at the earliest possible date, it would earn substantial profits.

43. Upon information and belief, no court has signed a “settlement order or consent decree” identified in 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB).

44. On September 24, 2015, the Patent Trial and Appeal Board (“PTAB”) issued a Final Written Decision holding all the claims of the ’283 patent as being unpatentable after an *inter partes* review (“the ’283 IPR”). Exhibit 3; *Torrent Pharms. Ltd. et al. v. Novartis AG and Mitsubishi Pharma Corp.*, IPR2014-00784, IPR2015-00518, Final Written Decision (P.T.A.B. Sept. 24, 2015). Defendants appealed this decision, and the United States Court of Appeals for the Federal Circuit has not issued an opinion. *Novartis AG v. Torrent Pharmaceuticals*, Appeal No. 2016-1352 (Fed. Cir. Dec. 21, 2015).

45. To trigger the first-filer’s exclusivity, a court must enter a final decision in an infringement or declaratory judgment action. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA). Judgments from the ’283 IPR and its appeal are not infringement actions, and are thus not a “final decision” as required by the Hatch-Waxman act. Neither the ’283 IPR final decision, nor any affirmance on appeal, will trigger the first-filer’s exclusivity. Only a final judgment from this Court can accomplish that.

VI. AN ARTICLE III CASE OR CONTROVERSY EXISTS

46. There is an actual and ongoing controversy between Alembic and Defendants with respect to infringement and validity of the ’283 patent that can be resolved by a declaratory

judgment from this Court. A judgment of non-infringement or invalidity from this Court will trigger forfeiture of the first-filer's exclusivity, thereby allowing Alembic to bring its generic fingolimod products to market at the earliest possible date, and enhancing generic competition as Congress intended.

47. Even if the outcome of the '283 IPR and appeal render the claims of the '283 patent invalid, the '283 patent will continue to harm Alembic in its business by its continued listing in the FDA's Orange Book and resulting block of approval of Alembic's ANDA, and will serve only to unfairly continue to benefit Defendants in their business by limiting the number of generic manufacturers against whom Defendants must compete. Only a judgment from this Court can alleviate that harm to Alembic and the public.

48. The present dispute between Alembic and Defendants satisfies the three-part framework for determining whether an action presents a justiciable Article III controversy: (1) the plaintiffs have standing; (2) the issues are ripe for adjudication; and (3) the case is not rendered moot. *Caraco*, 527 F.3d at 1278.

49. Standing requires three elements: (1) an alleged injury in fact—"a harm suffered by the plaintiff that is 'concrete' and actual or imminent, not 'conjectural' or 'hypothetical'"; (2) causation—"a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant"; and (3) redressability—"a likelihood that the requested relief will redress the alleged injury." *Caraco*, 527 F.3d at 1291.

50. Alembic is being injured in fact by the ongoing listing of Defendant's '283 patent in FDA's Orange Book. The '283 patent confers 180-day exclusivity eligibility for the first-filer, which serves to preclude Alembic from marketing its non-infringing generic fingolimod product at the earliest possible date. Alembic's injury is unique in the Hatch–Waxman context as

compared to ordinary infringement action: "Ordinarily, a potential competitor in other fields is legally free to market its product in the fact of an adversely-held patent. In contrast, under the Hatch-Waxman Act, an ANDA filer is not legally free to enter the market without FDA approval." *Id.* Defendants' continued listing of the '283 patent in the Orange Book creates the bottleneck to Alembic's ANDA causing injury-in-fact to Alembic. *Id.*

51. Alembic's injury is directly traceable to the Defendant's actions, not the Hatch-Waxman Act or the FDA regulations. For example, the following facts, each traceable to Defendants, are the reasons for Alembic's injury: (1) Defendants chose not to sue Alembic after receiving a notice of Alembic's paragraph IV certification, so as to avoid an adverse judgment on the '283 patent; (2) Defendants did not bring suit on the '283 patent against the first-filers in the '229 patent litigation to avoid an adverse judgment; (3) when a first-filer countersued Defendants on the '283 patent, the parties agreed to dismiss the '283 patent from the lawsuit, knowing that the judgment would increase competition in the fingolimod market. *Novartis AG et al. v. HEC Pharm Co., Ltd. et al.*, 15-cv-00151, Order (Nov. 10, 2016). Defendants' actions are precisely the sort of "gaming" the system that the civil action to obtain patent certainty is designed to prevent. *Id.* at 1285.

52. But for Defendants' attempts to avoid litigating the validity and infringement of the '283 patent, final approval of Alembic's ANDA would not be independently and artificially delayed. But for Defendants' actions, the FDA could grant final approval of Alembic's ANDA upon expiration of the '229 patent on February 18, 2019, or upon a final decision against Defendants in the ongoing '229 patent infringement action, not including any other exclusivity which prevents Alembic from obtaining final FDA approval.

53. Alembic's injury is redressable: judgment of non-infringement or invalidity of the '283 patent from this Court will activate forfeiture of the first-filer's exclusivity period, allowing Alembic to enter the market at the earliest possible date and obtain patent certainty.

54. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between Alembic and Defendants over which this Court can and should exercise jurisdiction and declare the rights of the parties. *Id.* at 1278.

55. Whether an action is "ripe" requires an evaluation of "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Id.* at 1294. Alembic satisfies both prongs for ripeness. First, additional factual development would not advance the district court's ability to decide Alembic's action because Alembic's ANDA has all the necessary information to determine if Alembic's fingolimod product would infringe the '283 patent. Further, no additional facts are required to determine the '283 patent claims are unenforceable because Defendants were given a full and fair opportunity to litigate the issue of validity in the '283 IPR, and lost. Second, Alembic will not be able to obtain patent certainty to market their fingolimod product to enter the market at the earliest possible date without a declaratory judgment: a hardship that creates the potential for substantial lost profits.

56. The mootness doctrine requires that the parties must maintain a requisite personal stake to have standing throughout all stages of the action. The '283 IPR and appeal does not render Alembic's declaratory judgment action moot. Notwithstanding the '283 IPR final decision and potential affirmance on appeal, Alembic's fingolimod product will still be blocked from the market, preventing Alembic from selling its low-cost fingolimod products. Only a judgment from this Court can alleviate the harm Defendants cause to Alembic and the public.

VII. NON-INFRINGEMENT AND INVALIDITY OF THE ’283 PATENT

57. Infringement of a patent under 35 U.S.C. §271(e)(2) requires a comparison between the patent claims and the ANDA applicant’s proposed generic drug. If any claim limitation is absent from the ANDA applicant’s proposed generic drug, there is no infringement as a matter of law. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247-48 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). Under the doctrine of equivalents, an equivalent of a missing claim limitation is found only if “‘insubstantial differences’ distinguish the missing claim element from the corresponding aspects of the accused [product].” *Abbott Labs. v. Novopharm Ltd.*, 323 F.3d 1324, 1329 (Fed. Cir. 2003)(quoting *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1423 (Fed. Cir. 1997)). Further, the doctrine of prosecution history estoppel precludes a patent owner from utilizing the doctrine of equivalents to expand the scope of his claims to recapture claim scope that he has surrendered by amendment or by argument that limited the interpretation of language used therein. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 733 (2002).

58. The claims of the ’283 patent require a solid pharmaceutical composition suitable for oral administration comprising the limitation of a sugar alcohol or mannitol, which is a type of sugar alcohol. *See* Exhibit 1, col. 17-18.

59. Alembic’s fingolimod ANDA products do not and cannot infringe the claims of the ’283 patent, either literally or under the doctrine of equivalents, because Alembic’s fingolimod ANDA products do not contain any sugar alcohols, and specifically does not contain mannitol.

60. Further, Defendants cannot expand the scope of the ’283 patent claims to encompass Alembic’s fingolimod ANDA products. In a response to an examiner rejection during the prosecution of the ’283 patent, Defendants submitted a declaration allegedly demonstrating

"unexpectedly superior compatibility" of fingolimod in a composition containing fingolimod and mannitol, as compared to other combinations containing microcrystalline cellulose, lactose, and starch. Exhibit 8. As such, Defendants are estopped from reclaiming certain fingolimod products under the doctrine of equivalents.

61. The claims of the '283 patent are invalid because they fail to meet the conditions of patentability and/or otherwise comply with one or more of the requirements set forth in 35 U.S.C. §§1 *et seq.* In particular, the claims of the '283 patent are invalid for at least the reasons set forth in the PTAB's final written decision in the aforementioned IPR, which is expressly incorporated herein. Exhibit 3.

62. Specifically, the PTAB found that all of the claims of the '283 patent are unpatentable as obvious under 35 U.S.C. § 103 over the combination of U.S. Patent No. 6,004,565 and PHARMACEUTICS: THE SCIENCE OF DOSAGE FORM DESIGN, 223-321 (Michael E. Aulton ed., 1988). Exhibits 3-5.

63. For at least the same reasons and with the same prior art, this Court can find, by clear and convincing evidence, that the claims of the '283 patent are invalid as obvious under 35 U.S.C. § 103.

VIII. FIRST CLAIM FOR RELIEF

(Declaratory Judgment of Non-infringement of the '283 patent)

64. Alembic realleges paragraphs 1 to 63 above as if fully set forth herein.

65. There is an actual, substantial, and continuing justiciable case or controversy between Defendants and Alembic regarding infringement of the '283 patent.

66. Alembic's manufacture, marketing, use, offer for sale, sale, and/or importation of the products that are the subject of Alembic's ANDA No. 207974 have not infringed, do not

infringe, and will not, if marketed, directly infringe or induce or contribute to the infringement by others of any claims of the '283 patent, either literally or under the doctrine of equivalents.

67. Alembic is entitled to a declaratory judgment that Alembic does not infringe the claims of the '283 patent.

IX. SECOND CLAIM FOR RELIEF

(Declaratory Judgment of Invalidity of the '283 patent)

68. Alembic realleges paragraphs 1 to 67 above as if fully set forth herein.

69. There is an actual, substantial, and continuing justiciable case or controversy between Defendants and Alembic regarding the validity of the '283 patent.

70. The claims of the '283 patent are invalid at least for the failure to comply with the requirements for patentability of Title 35 of the U.S. Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

71. Alembic is entitled to a declaratory judgment that the claims of the '283 Patent are invalid.

X. PRAYER FOR RELIEF

WHEREFORE, Alembic respectfully requests this Court enter judgment as follows:

A. Declaring that Alembic's manufacture, marketing, use, offer for sale, sale, and/or importation of the products that are the subject of Alembic's ANDA No. 207974 have not infringed, do not infringe, and would not, if marketed, infringe or induce or contribute to the infringement by others of any claims of the '283 patent, either literally or under the doctrine of equivalents;

B. Declaring that the claims of the '283 patent are invalid; and

C. Awarding Alembic such other relief that the Court deems just and proper.

Dated: March 13, 2017

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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