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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CIPLA LTD. Plaintiff v. NOVARTIS AG and NOVARTIS PHARMACEUTICALS CORP., Defendants.	Civil Action No. _____ **FILED UNDER SEAL**

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Cipla Ltd. ("Plaintiff" or "Cipla"), by its attorneys brings this action against Defendants Novartis AG and Novartis Pharmaceuticals Corp. (collectively, "Defendants" or "Novartis") for declaratory judgment that Cipla's generic deferasirox 180 mg tablets ("Cipla's

180 mg deferasirox tablets") do not and will not infringe any valid claim of U.S. Patent No. 9,283,209 (the "'209 patent").

Nature of the Action

1. This case arises under the Hatch-Waxman Act, which governs the U.S. Food and Drug Administration's ("FDA's") approval of both new and generic drugs. *See* 21 U.S.C. § 355. The Hatch-Waxman Act allows an Abbreviated New Drug Application ("ANDA") holder to bring a declaratory judgment action seeking a declaration that a patent listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book") will not be infringed by the ANDA holder's proposed drug product. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)–(cc). This declaratory judgment provision aims to, among other things, prevent brand-name drug companies from using tactics that forestall the competing generic drug makers from entering the market. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008). For example and relevant here, "when 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 trigger the 'failure to market' provision and force the first generic to market." *Id.* (quoting 149 CONG. REC. S15885 (Nov. 25, 2003)).

2. Cipla has submitted ANDA No. 211852 ("Cipla's ANDA") to FDA seeking approval to manufacture, use, import, offer for sale, and sell a generic version of Novartis's JADENU® (deferasirox), 90 mg, 180 mg, and 360 mg tablets as described in Cipla's ANDA ("Cipla's ANDA products").

3. Novartis has two patents listed in the FDA's Orange Book as covering JADENU: the '209 patent and U.S. Patent No. 6,465,504 (the "'504 patent"). Based on the Orange Book

listing, under the Hatch-Waxman Act, Cipla was required to submit patent certifications to the '209 and '504 patents.

4. [redacted]

5. Cipla's ANDA contains a paragraph IV certification that Cipla's ANDA products will not infringe Novartis's '209 patent. *Id.* § 355(j)(2)(A)(vii)(IV).

6. For the '209 patent, Cipla notified Novartis of the paragraph IV certification and provided an Offer of Confidential Access to its ANDA. *See id.* § 355(j)(2)(B); 21 C.F.R. § 314.95.

7. [redacted]

8. Novartis did not sue Cipla for patent infringement within 45 days of receiving notice of Cipla's paragraph IV certification. *See* 21 U.S.C. § 355(j)(5)(B)(iii), (j)(5)(C).

9. [redacted]

10. To the extent Novartis does contend Cipla's 180 mg deferasirox tablets infringe any claim of the '209 patent, there is a substantial and continuing controversy between the parties, and a declaration that Cipla's 180 mg deferasirox tablets do not infringe any valid claim of the '209 patent is both necessary and appropriate. Cipla needs certainty as to whether Cipla's 180 mg deferasirox tablets infringe the claims of the '209 patent. By, among other things, listing

the ’209 patent in the Orange Book, but failing to bring an action for patent infringement, Novartis has injected uncertainty and insecurity into Cipla’s pursuit of regulatory approval and commercialization of Cipla’s 180 mg deferasirox tablets.

11. To the extent Novartis does not contend Cipla’s 180 mg deferasirox tablets infringe any claim of the ’209 patent, there is still a substantial and continuing controversy between the parties and a declaration of rights is both necessary and appropriate because another ANDA applicant’s eligibility for 180-day exclusivity prevents the FDA from approving Cipla’s 180 mg deferasirox tablets. *See Teva Pharm. USA, Inc. v. Eisai Co.*, 620 F.3d 1341, 1347 (Fed. Cir. 2010), *vacated on procedural grounds*, 426 F. App’x 904 (Fed. Cir. 2011) (“We hold that this case presents an actual controversy. Here, as in *Caraco*, a favorable judgment ‘would eliminate the potential for the [DJ patents] to exclude [Teva] from the drug market.’” (citation omitted)). Even where the patent owner provides a covenant not to sue to the subsequent applicant, there is still an actual controversy based on the potential for the patents to exclude the subsequent ANDA applicant from the market. *See id.* at 1345, 1348 n.3.

12. The first applicant to file a substantially complete ANDA containing a paragraph IV certification to an Orange Book-listed patent and to provide appropriate notice to the NDA holder and patent owner for a particular generic product, is eligible for a 180-day period of generic marketing exclusivity against other companies that subsequently file ANDAs referencing the same branded drug product. *See* 21 U.S.C. § 355(j)(5)(B)(iv). FDA will not grant final approval to any subsequently filed ANDA containing a paragraph IV certification if FDA has deemed that a first ANDA applicant is eligible for 180 day exclusivity. *See id.* § 355(j)(5)(B)(iv)(I).

13. FDA has deemed that an applicant is eligible for 180-day marketing exclusivity for the 180 mg strength of deferasirox tablets. An excerpt of FDA's Paragraph IV Patent Certifications dated November 5, 2019 set forth below shows that FDA has determined that for deferasirox 180 mg tablets an applicant is eligible for 180-day exclusivity status.

Paragraph IV Patent Certifications
November 5, 2019

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Dapaglifozin and Metformin Hydrochloride	Extended-release Tablets	5 mg/500 mg 5 mg/1000 mg 10 mg/500 mg 10 mg/1000 mg	Xigduo XR 205649	1/8/2018						
Dapsone	Gel	7.5%	Aczone 207154	2/13/2017	1	Eligible	7/2/2019	6/26/2019		11/18/2033
Daptomycin	For Injection	500 mg/vial	Cubicin 21572	11/19/2008	1	Extinguished				
Darifenacin Hydrobromide	Extended-release Tablets	7.5 mg and 15 mg	Enablex 21513	12/22/2008						
Darunavir Ethanolate	Tablets	75 mg, 150 mg and 300 mg	Prezista 21976	6/23/2010	1					12/26/2026
Darunavir Ethanolate	Tablets	400 mg	Prezista 21976	6/23/2010	2					12/26/2026
Darunavir Ethanolate	Tablets	600 mg	Prezista 21976	6/23/2010	3	Deferred	7/2/2019	11/21/2017		12/26/2026
Darunavir Ethanolate	Tablets	800 mg	Prezista 21976	5/14/2013	1					12/26/2026
Dasatinib	Tablets	80 mg and 140 mg	Sprycel 21986	6/17/2011						
Dasatinib	Tablets	20 mg, 50 mg, 70 mg and 100 mg	Sprycel 21986	6/28/2010						
Deferasirox	Tablets for Suspension	125 mg, 250 mg, and 500 mg	Exjade 21882	10/28/2011	1	Eligible	7/2/2019	1/26/2016	3/22/2019	4/5/2019
Deferasirox *	Tablets	90 mg and 360 mg	Jadenu 206910	10/19/2015	1	Extinguished	7/16/2019			4/5/2019
Deferasirox	Tablets	180 mg	Jadenu 206910	4/21/2016	1	Eligible	7/16/2019			11/21/2034
Deferiprone	Tablets	500 mg	Ferriprox 21825	1/29/2016	1	Eligible	8/13/2019	2/8/2019		6/28/2021
Deoxycholic Acid	Injection	10 mg/mL (2 mL)	Kybella 206333	7/13/2018						
Desflurane	Inhalation	99.9%	Suprane 20118	9/11/2008						
Desloratadine	Tablets	5 mg	Clarinex 21165	6/21/2006						
Desloratadine	Orally Disintegrating Tablets	2.5 mg and 5 mg	Clarinex 21165	6/21/2006						
Desloratadine	Oral Solution	0.5 mg/mL	Clarinex Syrup 21300	5/8/2008						

(Paragraph IV Patent Certifications List (Exhibit 1)).

14. [redacted]

15. The expiration date of the qualifying patent, November 21, 2034, is the expiration date of the '209 patent.

16. Novartis has suggested that Actavis is the first ANDA applicant to submit paragraph IV certifications for each strength. Memorandum in Support of Motion to Dismiss at 15, *Piramal Healthcare UK Ltd. v. Novartis Pharm. Corp.*, No. 2:19-cv-12651 (D.N.J. Oct. 7, 2019), ECF No. 59 (Exhibit 3).

17. On November 20, 2019, FDA granted final approval for 90 mg and 360 mg deferasirox tablets to three ANDA applicants, Zydus Worldwide DMCC ("Zydus"), MSN Laboratories Private Ltd. ("MSN"), and Alembic Pharmaceuticals Ltd. ("Alembic"). (*See* Exhibits 4–6). An excerpt below from FDA's Orange Book reflects these approvals for 90 mg and 360 mg deferasirox tablets.

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Mkt.Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	DEFERASIROX	JADENU SPRINKLE	N207968	GRANULE	ORAL	90MG		RLD		NOVARTIS PHARMACEUTICALS CORP
RX	DEFERASIROX	JADENU SPRINKLE	N207968	GRANULE	ORAL	180MG		RLD		NOVARTIS PHARMACEUTICALS CORP
RX	DEFERASIROX	JADENU SPRINKLE	N207968	GRANULE	ORAL	360MG		RLD	RS	NOVARTIS PHARMACEUTICALS CORP
RX	DEFERASIROX	DEFERASIROX	A211824	TABLET	ORAL	90MG	AB			ALEMBIC PHARMACEUTICALS LTD
RX	DEFERASIROX	DEFERASIROX	A210945	TABLET	ORAL	90MG	AB			MSN LABORATORIES PRIVATE LTD
RX	DEFERASIROX	DEFERASIROX	A211383	TABLET	ORAL	90MG	AB			ZYDUS WORLDWIDE DMCC
RX	DEFERASIROX	DEFERASIROX	A211824	TABLET	ORAL	360MG	AB			ALEMBIC PHARMACEUTICALS LTD
RX	DEFERASIROX	DEFERASIROX	A210945	TABLET	ORAL	360MG	AB			MSN LABORATORIES PRIVATE LTD
RX	DEFERASIROX	DEFERASIROX	A211383	TABLET	ORAL	360MG	AB			ZYDUS WORLDWIDE DMCC
RX	DEFERASIROX	JADENU	N206910	TABLET	ORAL	90MG	AB	RLD		NOVARTIS PHARMACEUTICALS CORP
RX	DEFERASIROX	JADENU	N206910	TABLET	ORAL	180MG		RLD		NOVARTIS PHARMACEUTICALS CORP
RX	DEFERASIROX	JADENU	N206910	TABLET	ORAL	360MG	AB	RLD	RS	NOVARTIS PHARMACEUTICALS CORP

(Exhibit 7).

18. The FDA has not granted final approval to Zydus, MSN, or Alembic for 180 mg deferasirox tablets. (*Id.*; *see also* Exhibits 4–6).

19. Alembic issued a press release stating that "Alembic Pharmaceuticals Ltd has received final approval from US Food & Drug Administration (FDA) for deferasirox tablets in the strengths of 90 mg and 360 mg . . . . The company also received tentative approval from US FDA for deferasirox tablets in the strengths [sic] of 180 mg." (Exhibit 8).

20. The FDA's decision to grant final approval for Alembic's 90 mg and 360 mg deferasirox tablets—and to not grant final approval for Alembic's 180 mg deferasirox tablets that are tentatively approved—suggests that FDA has determined that an applicant is eligible for 180 day generic marketing exclusivity for 180 mg deferasirox tablets and that this exclusivity eligibility is blocking final approval of Alembic's 180 mg deferasirox tablets.

21. Actavis's ANDA No. 208697 still only has tentative approval for all three strengths, including the 90 mg and 360 mg strengths. (Exhibit 9). This suggests that Actavis has not sought final approval from the FDA, and may be waiting until a later date to seek it.

22. On information and belief, the first applicant's eligibility for 180-day exclusivity on the 180 mg strength of deferasirox tablets remains parked. On information and belief, unless the first applicant forfeits the 180-day exclusivity, FDA will not approve Cipla's 180 mg deferasirox tablets until 180 days after the first applicant launches its 180 mg deferasirox product or the '209 patent expires in November 2034.

23. Congress, however, never intended the 180-day generic exclusivity period to improperly delay the start of generic competition. The Hatch-Waxman Act, therefore, provides various mechanisms to trigger forfeiture of the first applicant's 180-day marketing exclusivity. The failure to market forfeiture provision, at issue here, requires, among other things, the entry of a final judgment of non-infringement or invalidity with respect to the patents against which a first ANDA filer has filed and lawfully maintained a paragraph IV certification, regardless of whether those patents are asserted against subsequent ANDA applicants. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

24. [redacted]

[redacted]

25. The FDA can, however, grant Cipla final approval to Cipla's 180 mg deferasirox ANDA product if Cipla "triggers" the failure to market forfeiture of the first applicant's exclusivity by obtaining a declaratory judgment of non-infringement. As such, a subsequent applicant has an incentive to file a declaratory judgment action to obtain patent certainty and be able to launch its product. It will trigger the failure to market forfeiture provision, forcing the first applicant to either launch its product and enjoy the 180-day exclusivity, or forfeit the 180-day exclusivity by failing to market within 75 days of a final court decision under 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb).

26. Cipla contends that it has a right to engage in making, using, offering to sell, and selling its products described in Cipla's ANDA without a license from Novartis.

27. Cipla's declaratory judgment action is necessary to remove the '209 patent as a barrier to Cipla's market entry for 180 mg deferasirox tablets because but for Novartis's decision to cause the '209 patent to be listed in the Orange Book, final FDA approval of Cipla's 180 mg deferasirox tablets would not be delayed. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I).

28. Without a judgment, Cipla will be barred from selling its 180 mg deferasirox tablets—possibly until 2034—causing injury to Cipla by depriving it of sales revenue that it could have earned during that time.

An Article III Case Or Controversy Exists

29. There is an actual and ongoing controversy between Cipla and Novartis with respect to infringement of the '209 patent that can be resolved by a declaratory judgment from this Court. FDA has determined that an applicant was the first to submit an ANDA referencing the 180 mg strength of JADENU and retains eligibility for 180-day exclusivity, which blocks approval of any subsequently filed ANDA, such as Cipla's ANDA. A judgment of non-infringement will trigger the failure to market forfeiture of the first applicant's exclusivity, allowing Cipla to bring its deferasirox products to market at the earliest possible date. This controversy is of sufficient immediacy and reality to empower the Court to issue a declaratory judgment. *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1362–63 (Fed. Cir. 2015) (holding the statute authorizes a declaratory judgment action to trigger forfeiture); *see also* Opinion at 17, *Piramal Healthcare UK Ltd. v. Novartis Pharm. Corp.*, No. 19-12651 (D.N.J. Oct. 16, 2019), ECF No. 75 ("Piramal Opinion") (denying Novartis's motion to dismiss because a similarly situated ANDA filer established a justiciable case and controversy existed to trigger forfeiture of the first applicant's 180 day exclusivity for 180 mg deferasirox tablets) (Exhibit 10).

30. The present dispute between Cipla and Novartis 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 1291.

31. 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." *Id.* (citing *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102–03 (1998)).

32. In a related Hatch-Waxman action brought by Piramal Healthcare UK Limited ("Piramal") in this Court, Piramal filed a declaratory judgment action against Novartis seeking a court decision that its 180 mg deferasirox product did not infringe the '209 patent. *See* Piramal Opinion at 3. Novartis attempted to destroy subject matter jurisdiction by providing a covenant not to sue Piramal for infringement of the '209 patent and filed a motion to dismiss for lack of subject matter jurisdiction. *Id.* at 3–5. Piramal explained that a blocking injury existed and came "forward with substantial evidence indicating that another ANDA filer (whose name remains confidential in accordance with FDA policy) retains the right to the 180-day commercial exclusivity as to the generic 180 mg deferasirox product, which precludes Piramal from obtaining final FDA approval of its product." *Id.* at 11. Novartis attempted to rebut this showing by arguing that "the FDA must be wrong" (*id.* at 12), but "jump[ed] to conclusions and dismiss[ed] the FDA database indicating that existence of a 180-day exclusivity period for the subject drug" (*id.* at 15). The Court found that subject matter jurisdiction existed by virtue of a blocking injury and denied Novartis's motion to dismiss for lack of subject matter jurisdiction with the opportunity to renew it if it could find "concrete evidence" that no injury exists. *Id.* at 16–17.

33. There is no factual basis for the Court to find that subject matter does not exist in this case and should find, just as the Court in Piramal found, that subject matter does exist due to at least the same blocking injury.

34. The FDA has determined that the '209 patent currently confers 180-day exclusivity eligibility on the first applicant, which precludes Cipla from marketing its non-

infringing generic 180 mg deferasirox tablets until the exclusivity expires or is forfeited. Under the Hatch-Waxman Act, an ANDA filer is not legally free to enter the market without FDA approval. Novartis's listing of the '209 patent, Cipla's filing of ANDA No. 211852 with the FDA under 21 U.S.C. § 355(j) seeking approval to market generic versions of 90 mg, 180 mg, and 360 mg deferasirox tablets, Novartis's failure to bring suit against Cipla in connection with Cipla's filing of its ANDA for 180 mg deferasirox tablets, and Novartis's apparent refusal to provide a consent judgment to other applicants, such as Piramal, as to the 180 mg deferasirox tablets' non-infringement of the '209 patent are blocking generic competition in general and final approval of Cipla's 180 mg deferasirox tablets in particular. Thus, the listing of the '209 patent creates a bottleneck to Cipla's 180 mg deferasirox tablets causing injury-in-fact to Cipla. *Teva Pharm. USA, Inc.*, 620 F.3d at 1347 ("*Caraco* holds that the exclusion of non-infringing generic drugs from the market can be a judicially cognizable injury-in-fact.").

35. To the extent Novartis argues that the "the FDA must be wrong" as it did in the Piramal case, that statement is a red herring. Novartis has no evidence that the FDA believes it is wrong or is, in fact, finally approving applications despite its determination that an applicant retains eligibility for 180 days of generic marketing exclusivity.

36. Moreover, on information and belief, Novartis declined to provide a consent judgement of non-infringement of the '209 patent to Piramal even though it was willing to provide a covenant not to sue Piramal for infringement of the '209 patent. *See* Exhibit 11 to Novartis's Motion to Dismiss, *Piramal Healthcare UK Ltd. v. Novartis Pharm. Corp.*, No. 2:19-cv-12651 (D.N.J. Aug. 16, 2019), ECF No. 39-11 (Exhibit 11). A consent judgment would trigger the failure to market forfeiture provision while a covenant not to sue does not. Novartis has not provided an explanation publicly for declining to provide a consent judgment even

though both would have substantially the same effect on Novartis regarding its ability to sue Piramal for infringement of the ’209 patent.

37. If approval of Cipla’s 180 mg deferasirox tablets is blocked by 180-day marketing exclusivity, Cipla will be monetarily harmed as it will lose sales of its 180 mg deferasirox tablets by virtue of not being able to enter the market at the earliest possible date under the applicable statutory and FDA regulatory provisions and be deprived of an opportunity to compete in the market for deferasirox 180 mg tablets.

38. Cipla’s injury is directly traceable to Novartis because, for example, but for Novartis’s listing the ’209 patent in the Orange Book, the FDA would not have determined that an ANDA filer is entitled to 180 days of marketing exclusivity for the deferasirox 180 mg tablets based on the listing of the ’209 patent in the Orange Book, blocking final approval of Cipla’s ANDA. Novartis has created an independent barrier to FDA approval of Cipla’s ANDA.

39. Novartis also chose not to sue Cipla after receiving notice of Cipla’s paragraph IV certification. Suing Cipla would have allowed Cipla to obtain a final judgment of non-infringement on the ’209 patent. On information and belief, Novartis has chosen not to sue other applicants. But for Novartis avoiding litigating the infringement of the ’209 patent, final approval of Cipla’s 180 mg deferasirox tablets would not be artificially delayed. But for Novartis’s actions, Cipla’s market entry for its 180 mg deferasirox tablets would not be delayed by any first applicant’s 180 day exclusivity.

40. The 180-day exclusivity, combined with the Novartis’s avoidance of litigation concerning the validity or infringement of the ’209 patent, delays FDA approval of a subsequent ANDA and thus delays a subsequent applicant’s entry into the market. This constitutes a “blocking injury,” which is a sufficient injury-in-fact to satisfy Cipla’s standing to sue Novartis.

41. Cipla's injury is redressable. Judgment of non-infringement of the '209 patent from this Court will activate the forfeiture of the first applicant's exclusivity period allowing Cipla and other generic competitors to enter the market at the earliest possible date. In other words, the block to final approval can only be cleared by a judgment of non-infringement.

42. Absent a judgment from this Court declaring that Cipla's 180 mg deferasirox tablets do not infringe the '209 patent, Cipla will be unable to sell its generic 180 mg deferasirox tablets possibly until 2034, thereby injuring Cipla by depriving it of sales revenue that it could earn for that period of time. [redacted]

43. The action is ripe. Determining 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." *Caraco*, 527 F.3d at 1278 (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)). [redacted]

44. The mootness doctrine requires that the parties must maintain a requisite personal stake. Only a judgment from this Court through an adjudication or consent decree can alleviate the harm to Cipla. Any covenant not to sue would not moot this case because Cipla's 180 mg deferasirox tablets will still be blocked from the market, preventing Cipla from selling that product. Piramal Opinion at 10 (collecting cases).

The Parties

45. Plaintiff Cipla Ltd. is a corporation organized under the laws of India, having a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai – 400013, Maharashtra, India.

46. On information and belief, Defendant Novartis AG is a corporation organized and existing under the laws of Switzerland and has its principal place of business in Basel, Switzerland.

47. On information and belief, Defendant Novartis Pharmaceuticals Corp. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business in East Hanover, New Jersey.

48. On information and belief, Defendant Novartis Pharmaceuticals Corp. is the holder of New Drug Application ("NDA") No. 206910 for JADENU.

49. On information and belief, Defendants currently market deferasirox 90 mg, 180 mg, and 360 mg tablets, under the trade name JADENU pursuant to FDA's approval of NDA No. 206910.

50. On information and belief, Defendant Novartis AG is the assignee of record with the United States Patent and Trademark Office for the '209 patent.

Jurisdiction and Venue

51. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) based on an actual, substantial, and continuing justiciable case or controversy between Cipla and Novartis arising under the Patent Laws of the United States, 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).

52. This Court has personal jurisdiction over Novartis Pharmaceuticals Corp. because, on information and belief, Novartis Pharmaceuticals Corp. has a principal place of business in East Hanover, New Jersey and conducts business in and has regular and systematic contact with the State of New Jersey, including this District. On information and belief, Novartis Pharmaceuticals Corp. has purposefully availed itself to this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities.

53. On information and belief, Novartis Pharmaceuticals Corp. has sued for patent infringement in this District, and has therefore availed itself to this forum in at least the following cases: *Novartis Pharm. Corp. v. Macleods Pharm., Ltd. et al.*, No. 19-19345 (D.N.J. Oct. 25, 2019); *Novartis Pharm. Corp. v. Aurobindo Pharma Ltd. et al.*, No. 15-4427 (D.N.J. June 25, 2015); *Novartis Pharm. Corp. v. Apotex, Inc. et al.*, No. 15-3634 (D.N.J. May 29, 2015); *Novartis Pharm. Corp. v. Heritage -Pharma Holdings, Inc.*, No. 15-1872 (D.N.J. Mar. 12, 2015); *Novartis Pharm. Corp. et al. v. Actavis, Inc. et al.*, No. 15-8978 (D.N.J. Dec. 31, 2015); *Novartis Pharm. Corp. v. Sagent Pharm., Inc.*, No. 14-7556 (D.N.J. Dec. 3, 2014); *Novartis Pharm. Corp. et al. v. Dr. Reddy's Labs. Ltd. et al.*, No. 15-7964 (D.N.J. Nov. 6, 2015).

54. Novartis Pharmaceuticals Corporation and Novartis Pharma AG purposefully availed themselves to this forum by filing an action specific to deferasirox tablets in the District of New Jersey in *Novartis Pharm. Corp. et al. v. Actavis, Inc. et al.*, No. 15-8978 (D.N.J. Dec. 31, 2015) (Exhibit 12).

55. This Court has personal jurisdiction over Novartis AG based on Novartis AG's systematic and continuous contacts with New Jersey, including this District. On information and belief, Novartis AG has conducted and continues to conduct business directly or through its

subsidiaries, agents, and alter egos, including Novartis Pharmaceuticals Corp. in this District. On information and belief, Novartis AG has purposefully availed itself to this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities.

56. On information and belief, Novartis AG has sued for patent infringement in this District, and has therefore availed itself to this forum in at least the following cases: *Novartis AG et al. v. Aurobindo Pharma Ltd. et al.*, No. 17-389 (D.N.J. Jan. 19, 2017); *Novartis Pharm. Corp. et al. v. Actavis, Inc. et al.*, No. 15-8978 (D.N.J. Dec. 31, 2015); *Novartis Pharm. Corp. et al. v. Dr. Reddy's Labs., Ltd. et al.*, No. 15-7964 (D.N.J. Nov. 6, 2015); *Novartis AG et al. v. HEC Pharm. Co. et al.*, No. 15-1647 (D.N.J. Mar. 5, 2015); *Novartis AG et al. v. Actavis. Inc. et al.*, No. 14-7849 (D.N.J. Dec. 17, 2014); *Novartis AG et al. v. Apotex, Inc. et al.*, No. 09-5614 (D.N.J. Nov. 3, 2009); *Novartis AG et al. v. Teva Pharm. USA, Inc. et al.*, No. 11-2289 (D.N.J. Apr. 21, 2011).

57. This Court also has personal jurisdiction over Novartis AG pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Cipla's claims arise under federal law; (2) Novartis AG is a foreign corporation; and (3) Novartis AG has sufficient contacts with the United States. These contacts include, but are not limited to, Novartis AG's contacts through its subsidiaries, agents, and/or alter egos, including Novartis Pharm. Corp. directing the manufacture, importation, offer for sale, and/or sale of pharmaceutical products that are distributed throughout the United States, applying for and obtaining U.S. patents, and litigating cases in United States courts as mentioned above.

58. Furthermore, Novartis Pharmaceuticals Corp. and Novartis AG have previously agreed not to contest personal jurisdiction in this District. *See, e.g.*, Plaintiffs' Answer to HEC's Counterclaims ¶¶ 10–11, *Novartis AG et al. v. HEC Pharm. Co., Ltd. et al.*, No. 15-1647 (D.N.J. June 8, 2015), ECF No. 19 (Exhibit 13).

59. Novartis Pharmaceuticals Corp. and Novartis AG have also previously submitted to jurisdiction in this District without objecting on the basis of lack of personal jurisdiction in at least Answer ¶ 14, *Piramal Healthcare UK Ltd., v. Novartis Pharmaceuticals Corp. and Novartis AG*, No. 19-cv-12651-SRC-CLW (D.N.J. Oct. 30, 2019), ECF No. 72 (Exhibit 14).

60. Venue is proper in this Court pursuant to 28 U.S.C. § 1391.

Regulatory Background

61. Congress passed the Drug Price Competition and Patent Term Restoration Act in 1984, which is commonly known as the Hatch-Waxman Act. Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). The Hatch-Waxman Act represented a compromise between the generic and branded pharmaceutical industries, and, among other things, created avenues to encourage and allow for generic products to enter the market, while preserving incentives for development of innovative and new branded products. *See* H.R. Rep. No. 98-587, pt. 1 at 14–15 (1984).

62. Under this framework, a company seeking approval of a new drug must submit an NDA to FDA. 21 U.S.C. § 355. In addition to this application, the brand company must identify the patents that cover the drug substance, the drug product, and/or the method of using the drug product. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2). FDA will list these patents in the Orange Book once the NDA is approved. Generally, this new branded drug is referred to as a reference-listed drug.

63. A company seeking approval of a generic version of the branded drug must also submit an application, known as an ANDA. As an "abbreviated" application, the generic company may rely on the branded company's preclinical and clinical data to support the safety and efficacy of the drug if the generic product is "bioequivalent" to the reference-listed drug. 21 U.S.C. § 355(j)(4)(F).

64. A generic company must include certain certifications to the patents listed in the Orange Book for the reference-listed drug in its ANDA. These certifications are as follows: (I) there are no patents in the Orange Book; (II) there are patents listed in the Orange Book, but they have expired; (III) the generic company will not market its generic product before the patents listed in the Orange Book expire; and (IV) the generic company believes the listed 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."

65. A generic company must certify to each listed patent, but these certifications can be different. For example, a generic company may opt to wait for the expiration of patent A that will expire before the generic company anticipates it will receive approval, but may also submit a paragraph IV certification for patent B that it believes it does not infringe.

66. If a generic company's ANDA contains a paragraph IV certification, the generic company must notify the NDA holder and the patentee in writing of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B). This is generally referred to as a "notice letter." The notice letter will include a detailed statement of the factual and legal bases that the patent is invalid and/or not infringed. *Id.* § 355(j)(2)(B)(iv).

67. The notice letter usually also includes an Offer of Confidential Access to the ANDA, which allows the NDA holder and patent owner to review the ANDA subject to confidentiality restrictions, to determine whether the ANDA product will infringe an Orange Book listed patent. *Id.* § 355(j)(5)(C)(i)(III).

68. The Hatch-Waxman Act also created a framework to allow for generic and branded companies to resolve their patent disputes promptly. Therefore, once the NDA holder and patentee receive the notice letter, they may bring suit against the generic company for patent infringement. *Id.* § 355(j)(5)(B)(iii). The NDA holder and patentee have an incentive to file suit within 45 days because if they do, the suit triggers an automatic 30-month stay of FDA approval of the ANDA. *Id.*

69. If the generic company serves the notice letter, along with an Offer of Confidential Access, and neither the NDA holder nor the patent owner file suit within 45 days, the generic company may bring a declaratory judgment action to obtain patent certainty. *Id.* § 355(j)(5)(C)(i).

70. Generic companies also have incentives to promptly file their generic applications. The Hatch-Waxman Act qualifies the first applicant who files a substantially complete ANDA containing a paragraph IV certification to an Orange Book listed patent (known as a "first applicant") an 180-day exclusivity period of marketing. *Id.* § 355(j)(5)(B)(iv). There can be more than one first applicant if multiple generic companies filed their ANDAs on the first day an ANDA is filed. The 180-day exclusivity period will not begin to run until the first applicant markets its product. During this period of exclusivity, subsequent ANDA filers may

not receive final approval[1] until the first applicant's exclusivity runs or is forfeited. *Id.* § 355(j)(5)(B)(iv).

71. This 180-day exclusivity period can be forfeited, in which case the exclusivity will no longer prevent FDA from approving a subsequently filed ANDA. Congress enacted the Medicare Modernization Amendments to the Hatch-Waxman Act, which included various scenarios where a first applicant would forfeit its 180-day exclusivity that generally include (1) failure to market; (2) withdrawal of application; (3) amendment of paragraph IV certification; (4) failure to obtain tentative approval; (5) agreement with another applicant, NDA holder, or patentee that violates antitrust laws; and (6) expiration of all Orange Book listed patents that qualified the first applicant for exclusivity. *See id.* § 355(j)(5)(D); *see also* CENTER FOR DRUG EVALUATION AND RESEARCH ET AL., GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY QUESTIONS AND ANSWERS (2017), *available at* https://www.fda.gov/media/102650/download.

72. Congress authorized declaratory judgment actions by subsequent ANDA applicants to trigger forfeiture of the first applicant's 180-day exclusivity by obtaining a judgment of non-infringement, invalidity, or unenforceability. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA); *see also Caraco*, 527 F.3d at 1284 ("subsequent Paragraph IV ANDA filers can trigger the first Paragraph IV ANDA filer's 180-day exclusivity period via the court-judgment trigger."). As explained by a Court in this District, "[t]he 180-day exclusivity, combined with the branded drug manufacturer's avoidance of litigation concerning the validity or infringement of an Orange-Book-listed patent, delays FDA approval of a subsequent ANDA

[1] FDA will not finally approve an ANDA if there are unexpired patents or if there are applicants eligible for exclusivities. An ANDA holder in this situation would receive "tentative approval," and would not be able to market the product until it receives final approval. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd).

and thus delays a subsequent applicant's entry into the market." Piramal Opinion at 9 (citing *Caraco*, 527 F.3d at 1285).

Cipla's 180 mg Deferasirox Tablets are Blocked From Final Approval

73. Novartis holds the NDA for JADENU (deferasirox), 90 mg, 180 mg, and 360 mg tablets that are indicated for the treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older and for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia syndromes, and with a liver iron concentration of at least 5 mg iron per gram of dry weight (Fe/g dw) and a serum ferritin greater than 300 mcg/L.

74. At the time Cipla filed its ANDA, two patents were listed in the Orange Book in connection with each strength of JADENU: the '209 patent and the '504 patent. Novartis requested the listing of '504 and '209 patents in the Orange Book in connection with JADENU, where "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." 21 U.S.C. § 355(b)(1), (c)(2). Cipla was required to submit a patent certification to the '504 patent and the '209 patent. *See id.* § 355(j)(2)(A)(vii)(I)–(IV); 21 C.F.R. § 314.94(a)(12).

75. [redacted]

76. Cipla's paragraph IV certification to the '209 patent, certifies that Cipla would not infringe the '209 patent. The '209 patent expires on November 21, 2034.

77. Cipla's Notice Letter included, among other things, Cipla's detailed factual and legal basis for the paragraph IV certification regarding the '209 patent as it pertains to Cipla's

ANDA Products and an Offer of Confidential Access to Cipla's ANDA Product in accordance with 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

78. [redacted]

79. [redacted] Novartis chose not to sue Cipla for patent infringement relating to the '209 patent within the 45-day period as provided by the statute.

80. Although FDA does not disclose the identity of the first applicant, FDA will publish the date of submission of the first substantially complete ANDA containing a paragraph IV certification for each product. (Exhibit 1). For JADENU 90 mg and 360 mg strengths, FDA reports the date of submission as October 19, 2015, and for the 180 mg strength, FDA reports the date of submission as April 21, 2016. (*Id.*)

81. FDA further reports that the 180-day exclusivity of the first applicant has been "extinguished" for the 90 mg and 360 mg strengths. There are different 180-day exclusivity periods for each strength, as each strength is a "separately listed drug." *See Apotex, Inc. v. Shalala*, 53 F. Supp. 2d 454, 456 (D.D.C. 1999). In other words, the first applicant, upon information and belief, has withdrawn its paragraph IV certification and has forfeited its exclusivity for the 90 mg and 360 mg strengths, which Novartis has confirmed. Memorandum in Support of Motion to Dismiss at 6, *Piramal Healthcare UK Ltd. v. Novartis Pharm. Corp.*, No. 19-12651 (D.N.J. June 28, 2019), ECF No. 10-1 (Exhibit 16); Stipulation and Order of Dismissal with Prejudice ¶ 2, *Novartis Pharm. Corp. v. Actavis, Inc.*, No. 15-1219 (D. Del. Sept. 18, 2017), ECF No. 123 (Exhibit 17).

82. On information and belief, the first applicant submitted a substantially complete ANDA containing a paragraph IV certification for the 180 mg deferasirox tablets on April 21, 2016. The FDA has determined that a first applicant is still eligible for the 180-day marketing exclusivity for the 180 mg strength, and thus the FDA will not finally approve later-filed ANDAs.

83. Without a final decision by a court triggering the failure to market forfeiture provision, these later-filed ANDAs cannot obtain final approval and subsequently enter the market for the 180 mg product until the expiration of the ’209 patent (November 2034) or the launch of the first applicant’s product.

84. Cipla submitted its ANDA after April 21, 2016, and is a subsequent filer. As discussed above, as a subsequent filer, Cipla is blocked from marketing its 180 mg deferasirox tablets.

Cipla’s ANDA Product

85. Cipla has submitted an ANDA with the FDA seeking approval to manufacture and sell a generic version of Novartis’s JADENU (deferasirox), 90 mg, 180 mg, and 360 mg tablets as described in Cipla’s ANDA No. 211852.

86. [redacted]

Cipla's 180 mg Deferasirox Tablets Do Not Infringe Any Claim of the '209 Patent

87. Cipla's ANDA products do not infringe any claim of the '209 patent literally or under the doctrine of equivalents.

88. "To prove infringement, the patentee must show that an accused product embodies all limitations of the claim either literally or by the DOE [i.e., doctrine of equivalents]." *Amgen Inc. v. F. Hoffman-La Roche, Ltd.*, 580 F.3d 1340, 1374 (Fed. Cir. 2009) (citations omitted). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Id.*

Cipla Does Not Literally Infringe the '209 Patent

89. The '209 patent, entitled "Oral Formulations of Deferasirox," is directed to compositions of deferasirox and attached hereto as Exhibit 19. '209 patent at col. 1, ll. 5–10.

90. The '209 patent contains three claims, each of which is reproduced below.

> 1. A tablet for oral administration consisting of 90 mg deferasirox;
> 53.61 mg microcrystalline cellulose;
> 3.65 mg poly vinyl pyrrolidone K-30;
> 11.34 mg crospovidone;
> 0.16 mg poloxamer;

0.81 mg fumed silica;
2.43 mg magnesium stearate; and
4.86 mg seal-coat.

2. A tablet for oral administration consisting of 180 mg deferasirox;
107.23 mg microcrystalline cellulose;
7.29 mg poly vinyl pyrrolidone K-30;
22.68 mg crospovidone;
0.32 mg poloxamer;
1.62 mg fumed silica;
4.86 mg magnesium stearate; and
9.72 mg seal-coat.

3. A tablet for oral administration consisting of 360 mg deferasirox;
215.45 mg microcrystalline cellulose;[2]
14.58 mg poly vinyl pyrrolidone K-30;
45.36 mg crospovidone;
0.65 mg poloxamer;
3.24 mg fumed silica;
9.72 mg magnesium stearate; and
19.44g seal-coat.

91. All three claims of the '209 patent recite "a tablet for oral administration consisting of. . . "

92. "The phrase 'consisting of' is a term of art in patent law signifying restriction and exclusion." *Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377, 1382–83 (Fed. Cir. 2000) (citation omitted). "In simple terms, a drafter uses the phrase 'consisting of' to mean 'I claim what follows and nothing else.'" *Id.* at 1383. A claim containing the transitional phrase "consisting of" is considered a closed claim. In contrast, a claim containing the transitional

[2] The '209 patent was previously involved in litigation. In an Order entered July 27, 2017, the parties stipulated that Claim 3 should be judicially corrected to read "214.45 mg microcrystalline cellulose," rather than "215.45 mg microcrystalline cellulose." Joint Stipulation and Order, *Actavis Elizabeth LLC v. Novartis Pharm. Corp. et al.*, No. 16-604 (D. Del. July 27, 2017), ECF No. 59 (Exhibit 24).

phrase "comprising" is open-ended, and does not exclude additional, unrecited elements or method steps. *See, e.g., Mars, Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376 (Fed. Cir. 2004).

93. The '209 patent does not evidence any different meaning for the phrase "consisting of." For example, the patentees did not act as their own lexicographer to change the meaning of "consisting of" from its well accepted meaning signifying restriction and exclusion. Instead, the intrinsic evidence confirms that "consisting of" as used in the '209 patent is meant to signify restriction to the listed ingredients and amounts in the claims and exclude any ingredients or amounts not listed in the claims.

94. Because the patentee chose to use the phrase "consisting of" to describe claim 1 of the '209 patent, claim 1 would be literally infringed only by a tablet containing each of the following ingredients and nothing more:

90 mg deferasirox;
53.61 mg microcrystalline cellulose;
3.65 mg poly vinyl pyrrolidone K-30;
11.34 mg crospovidone;
0.16 mg poloxamer;
0.81 mg fumed silica;
2.43 mg magnesium stearate; and
4.86 mg seal-coat.

95. Because the patentee chose to use the phrase "consisting of" to describe claim 2 of the '209 patent, claim 2 is literally infringed only by a tablet containing each of the following ingredients in the claimed quantities and nothing more:

180 mg deferasirox;
107.23 mg microcrystalline cellulose;
7.29 mg poly vinyl pyrrolidone K-30;
22.68 mg crospovidone;
0.32 mg poloxamer;
1.62 mg fumed silica;
4.86 mg magnesium stearate; and
9.72 mg seal-coat.

96. Because the patentee chose to use the phrase "consisting of" to describe claim 3 of the '209 patent, claim 3 is literally infringed only by a tablet containing each of the following ingredients in the claimed quantities, and nothing more:

360 mg deferasirox;
214.45 mg microcrystalline cellulose;
14.58 mg poly vinyl pyrrolidone K-30;
45.36 mg crospovidone;
0.65 mg poloxamer;
3.24 mg fumed silica;
9.72 mg magnesium stearate; and
19.44g seal-coat.

97. [redacted]

98. The ANDA specification may directly resolve the infringement inquiry because it defines a proposed generic product such that it either meets the limitations of an asserted patent claim or is outside the scope of the claim. *See Ferring B.V. v. Watson Labs., Inc.-Florida*, 764 F.3d 1401, 1408 (Fed. Cir. 2014).

99. [redacted]

A. [redacted]

a. [redacted]

100. [redacted]

101. [redacted]

102. [redacted]

103. [redacted]

104. [redacted]

105. [redacted]

b. [redacted]

106. [redacted]

B. [redacted]

a. [redacted]

107. [redacted]

108. [redacted]

109. [redacted]

110. [redacted]

b. [redacted]

111. [redacted]

112. [redacted]

C. [redacted]

a. [redacted]

113. [redacted]

114. [redacted]

115. [redacted]

b. [redacted]

116. [redacted]

117. [redacted]

118. [redacted]

119. [redacted]

Cipla Does Not Infringe the '209 Patent Under the Doctrine of Equivalents

120. Novartis does not claim that Cipla infringes under the doctrine of equivalents.

121. To the extent Novartis later attempts to claim infringement under the doctrine of equivalents, Novartis is estopped under the doctrine of prosecution history estoppel.

122. The prosecution history of the '209 patent shows that the applicants narrowed the scope of the claims by adding the term "consisting of" during prosecution in order to obtain issuance of the patents. It was only after the applicant narrowed the scope of the claims that the examiner allowed the claims over the prior art of record. This narrowing of the claims was a clear and unmistakable surrender of all components and amounts other than those components and amounts listed in the claim. As a result, the patentee cannot recapture the scope of the claims given up during prosecution. *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1251 (Fed. Cir. 2000).

123. The application leading to the '209 patent was originally filed with twenty-four claims. The applicants canceled some claims in a December 12, 2015 Preliminary Amendment. (Exhibit 20). The remaining claims recited the transitional phrase "comprising." The pending claims were as follows:

25. (New): A tablet for oral administration comprising 90 mg deferasirox; and,

(i) at least one filler in a total amount of about 10% to 40% by weight based on the total weight of the tablet;

(ii) at least one disintegrant in a total amount of about 1% to 10% by weight based on the total weight of the tablet;

(iii) at least one binder in a total amount of about 1% to 5% by weight based on the total weight of the tablet;

(iv) at least one surfactant in a total amount of about 0.0% to 2% by weight based on the total weight of the tablet;

(v) at least one glidant in a total amount of about 0.1% to 1% by weight based on the total weight of the tablet;

(vi) at least one lubricant in a total amount of less than about 0.1% to 2% by weight based on the total weight of the tablet; and

(vii) a coating, wherein the coating further comprises a polymer; and,

wherein the tablet possesses a disintegration time of 5-10 minutes when measured by a standard USP disintegration test.

26. (New): A tablet for oral administration according to claim 25 comprising,

24.45 mg microcrystalline cellulose PH101;
29.16 mg microcrystalline cellulose PH102;
3.65 mg poly vinyl pyrrolidone K-30;
11.34 mg crospovidone;
0.16 mg pluronic F68;
0.81 mg aerosil;
2.43 mg magnesium stearate; and
4.86 mg opadry blue coating.

27. (New): A tablet for oral administration comprising 180 mg deferasirox; and,

(i) at least one filler in a total amount of about 10% to 40% by weight based on the total weight of the tablet;

(ii) at least one disintegrant in a total amount of about 1% to 10% by weight based on the total weight of the tablet;

(iii) at least one binder in a total amount of about 1% to 5% by weight based on the total weight of the tablet;

(iv) at least one surfactant in a total amount of about 0.0% to 2% by weight based on the total weight of the tablet;

(v) at least one glidant in a total amount of about 0.1% to 1% by weight based on the total weight of the tablet;

(vi) at least one lubricant in a total amount of less than about 0.1% to 2% by weight based on the total weight of the tablet; and

(vii) a coating, wherein the coating further comprises a polymer; and,
wherein the tablet possesses a disintegration time of 5-10 minutes when measured by a standard USP disintegration test.

28. (New): A tablet for oral administration according to claim 27 comprising,
48.91 mg microcrystalline cellulose PH101;
58.32 mg microcrystalline cellulose PH102;
7.29 mg poly vinyl pyrrolidone K-30;
22.68 mg crospovidone;
0.32 mg pluronic F68;
1.62 mg aerosil;
4.86 mg magnesium stearate; and
9.72 mg opadry blue coating.

29. (New): A tablet for oral administration comprising 360 mg deferasirox; and,
(i) at least one filler in a total amount of about 10% to 40% by weight based on the total weight of the tablet;
(ii) at least one disintegrant in a total amount of about 1% to 10% by weight based on the total weight of the tablet;
(iii) at least one binder in a total amount of about 1% to 5% by weight based on the total weight of the tablet;
(iv) at least one surfactant in a total amount of about 0.0% to 2% by weight based on the total weight of the tablet;
(v) at least one glidant in a total amount of about 0.1% to 1% by weight based on the total weight of the tablet;
(vi) at least one lubricant in a total amount of less than about 0.1% to 2% by weight based on the total weight of the tablet; and
(vii) a coating, wherein the coating further comprises a polymer; and,
wherein the tablet possesses a disintegration time of 5-10 minutes when measured by a standard USP disintegration test.

30. (New): A tablet for oral administration according to claim 29 comprising,
97.81 mg microcrystalline cellulose PH101;
116.64 mg microcrystalline cellulose PH102;
14.58 mg poly vinyl pyrrolidone K-30;
45.36 mg crospovidone;
0.65 mg pluronic F68;
3.24 mg aerosil;
9.72 mg magnesium stearate; and
19.44 mg opadry blue coating.

124. On January 5, 2015, Applicants initiated an interview with the Examiner, to discuss the pending claims (claims 25–30), and invalidity under sections 103 and 112. (Exhibit 21). The Interview Summary states "Applicants' representative discussed possible claim amendments to place the claims in condition for allowance. Examiner agreed that changing claims 26, 28, and 30 to 'consisting of' type claims to exclude the additional components taught by the prior art would render the claims free of prior art." (*Id.*). The "prior art" discussed during the January 5, 2015 Interview was U.S. Pre-Grant Publication (2012/0196909). (*Id.*) (Exhibit 22). The applicants authorized the examiner to make the amendments discussed. (Exhibit 21).

125. U.S. Publication 2002/0196909 ("Deffez") is entitled "Deferacirox Dispersible Tablets" and was published on August 2, 2012. (Exhibit 22). Deffez lists Novartis AG as the assignee. Deffez discloses, for example, various formulations of deferasirox containing various amounts of, among other things, deferasirox, microcrystalline cellulose, crospovidone, PVP K30, lactose, and magnesium stearate. (Exhibit 22 at Example 2). These are some of the same ingredients Novartis was attempting to claim in the application leading to the '209 patent.

126. On or around January 21, 2016, the Examiner issued a Notice of Allowance with an Examiner's Amendment. (Exhibit 23). As discussed during the January 5, 2015 Interview, the examiner amended claims 26, 28, and 30 to remove the transitional phrase "comprising" and replace it with "consisting of" "to exclude the additional components taught by the prior art." (Exhibit 21). In the Reasons for Allowance, the examiner stated "the above amended claims are allowable over the prior art because the picking and choosing of components and amounts from the prior art required to arrive at the instant claims would be too excessive to be considered *prima facie* obvious." (Exhibit 23).

127. The Notice of Allowance clearly and unmistakably evidences a disavowal of scope in both components and amounts of the tablet in order to obtain issuance of the '209 patent.

128. In short, the applicants authorized the examiner to narrow the claims from the broad transitional phrase "comprising" to "consisting of." This narrowing amendment creates a presumption of estoppel.

129. Although there are limited ways to rebut the presumption of estoppel, Novartis does not contend that any apply here. For example, by amending the claims from the broad transitional phrase "comprising" to "consisting of" it was foreseeable that claim scope would be lost. The examiner even explained that, after the amendment, the claims would "exclude the additional components taught by the prior art." (Exhibit 21). The amendment of the claims was also not tangential to patentability. The examiner explained that the amendment "would render the claims free of the prior art."

130. The doctrine of equivalents also does not apply based on the doctrine of claim vitiation. [redacted] If the claim scope were expanded, it would vitiate the well-understood meaning of "consisting of" claim language that the applicants added to obtain issuance of the '209 patent. Use of the doctrine of equivalents under the facts of this case is not permitted because it is "inconsistent with the language of the claim." *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1317 (Fed. Cir. 1998) (affirming district court's rejection of infringement by equivalents); *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1362 (Fed. Cir. 2005) (holding that "translational and rotational motion" cannot be equivalent to "slidably mounted" without reading the limitation "completely out of the claims,"

which "is the precise type of overextension of the doctrine of equivalents that the claim vitiation doctrine is intended to prevent").

COUNT I
(Declaratory Judgment of Non-infringement of Cipla's 180 mg Deferasirox Tablets)

131. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 130 of this Complaint as if fully set forth herein.

132. The claim arises under the Patent Laws of the United States, 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).

133. Novartis listed the '209 patent in the Orange Book in connection with the 180 mg strength of JADENU.

134. Cipla filed ANDA No. 211852 with a paragraph IV certification stating, among other things, that the '209 patent is not and will not be infringed by Cipla's 180 mg deferasirox tablets.

135. Cipla intends to sell its 180 mg deferasirox tablets, as described in ANDA No. 211852, once it receives final approval from FDA.

136. There is a real, actual and continuing justiciable case and controversy between Cipla and Novartis relating to the infringement of the '209 patent by Cipla's 180 mg deferasirox tablets.

137. For reasons explained above and in Cipla's notice letter and detailed statement, the manufacture, use, offer for sale, sale, and/or importation of Cipla's 180 mg deferasirox tablets will not infringe the '209 patent.

138. Accordingly, Cipla seeks and is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, and/or importation of Cipla's 180 mg deferasirox tablets does not and will not infringe, directly or indirectly, any valid claim of the '209 patent.

Prayer for Relief

WHEREFORE, Cipla prays that this Court enter judgment against Defendants:

A. Declaring that the manufacture, use, sale, offer for sale, and/or importation of Cipla's 180 mg deferasirox tablets do not and will not directly or indirectly infringe any valid and enforceable claim of the '209 patent, either literally or under the doctrine of equivalents;

B. Awarding Cipla its costs and expenses incurred in this action;

C. Declaring that this an exceptional case in favor of Cipla and awarding Cipla its reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

D. Awarding Cipla such other and further relief as the Court may deem proper.

DATED: November 26, 2019

Respectfully submitted,

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Attorneys for Cipla Ltd.

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, the undersigned hereby certifies that the patent at issue in this action, U.S. Patent No. 9,283,209, is the subject of an action pending before this Court, *Piramal Healthcare UK Ltd. v. Novartis Pharm. Corp.*, Case No. 2:19-cv-12651. The undersigned further certifies that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: November 26, 2019

s/Loly G. Tor
Loly G. Tor

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned hereby certifies that this action involves complex legal issues and the legal issues predominate over the factual issues; therefore, the matter is not appropriate for compulsory arbitration.

Dated: November 26, 2019

s/Loly G. Tor
Loly G. Tor