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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IMPACT BIOMEDICINES, INC., **Plaintiff,** **v.** **TEVA PHARMACEUTICALS, INC.,** **Defendant.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Impact Biomedicines, Inc. ("Impact"), by its undersigned attorneys, for its Complaint against Teva Pharmaceuticals, Inc. ("Teva") alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq*., arising from Teva's submission of Abbreviated New Drug Application ("ANDA") No. 218907 ("Teva's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture, use, import, distribute, offer to sell, and/or sell generic versions of Impact's Inrebic® (fedratinib) drug product prior to the expiration of United States Patent Nos. 10,391,094 (the "'094 patent") and 11,400,092 (the "'092 patent") (together, "the patents-in-suit"), both owned by Impact.

The Parties

2. Impact is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. On information and belief, Defendant Teva is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

The Patents-in-Suit

4. On August 27, 2019, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '094 patent, entitled, "Compositions and Methods for Treating Myelofibrosis." A copy of the '094 patent is attached hereto as Exhibit A.

5. On August 2, 2022, the USPTO duly and lawfully issued the '092 patent, entitled, "Methods of Treating Myeloproliferative Disorders." A copy of the '092 patent is attached hereto as Exhibit B.

The Inrebic® Drug Product

6. Impact holds an approved New Drug Application under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a) for fedratinib 100 mg capsules (NDA No. 212327), which is sold under the trade name Inrebic®.

7. The claims of the patents-in-suit cover, *inter alia*, pharmaceutical compositions comprising fedratinib and methods of using and administering fedratinib and pharmaceutical compositions comprising fedratinib.

8. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Inrebic®.

9. The FDA-approved prescribing information for Inrebic® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Inrebic® for the treatment of adults patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).

10. The FDA-approved prescribing information for Inrebic® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Inrebic® according to one or more of the methods claimed in the patents-in-suit.

Jurisdiction and Venue

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

12. On information and belief, Teva purposefully has conducted and continues to conduct business in this Judicial District.

13. On information and belief, Teva is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

14. On information and belief, Teva submitted ANDA No. 218907 seeking FDA approval to engage in the manufacturing, use, importation, distribution, offer to sell, and/or sale of the 100 mg fedratinib capsules that are the subject of Teva's ANDA ("Teva's Proposed Product"), throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patents-in-suit.

15. On information and belief, subject to the approval of ANDA No. 218907, Teva will make, use, import, sell, and/or offer for sale Teva's Proposed Product throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patents-

in-suit. On information and belief, this Judicial District is a likely destination for Teva's Proposed Product.

16. On information and belief, Teva is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450614134.

17. On information and belief, Teva has a regular and established, physical place of business in New Jersey at 400 Interpace Parkway, Parsippany, New Jersey, 07054. Teva's website states that its "US Headquarters" is located in Parsippany, New Jersey. *See* https://www.tevausa.com/contact-us (last visited October 23, 2023).

18. Teva has purposefully availed itself of the rights, benefits, and privileges of New Jersey, including by asserting counterclaims in this Court. *See, e.g.*, *GW Research Limited v. Teva Pharmaceuticals Inc., et al.*, No. 23-3914 (MEF)(AME) (D.N.J.) (D.I. 57).

19. Venue is proper in this Judicial District for Teva pursuant to 28 U.S.C. §§ 1391 and/or 1400(b).

Acts Giving Rise To This Suit

20. Pursuant to Section 505 of the FFDCA, Teva submitted its ANDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Teva's Proposed Product before the patents-in-suit expire.

21. On information and belief, following FDA approval of Teva's ANDA, Teva will make, use, sell, or offer to sell Teva's Proposed Product throughout the United States, or import such generic products into the United States.

22. On information and belief, in connection with the submission of its ANDA as described above, Teva provided a written certification to the FDA pursuant to Section 505 of the

FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Teva's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Teva's ANDA.

23. No earlier than September 11, 2023, Teva sent to Impact a written notice of Teva's Paragraph IV Certification ("Teva's Notice Letter"). Teva's Notice Letter alleged that the claims of the '094 and '092 patents are invalid and/or will not be infringed by the activities described in Teva's ANDA. Teva's Notice Letter conveyed that Teva seeks approval to market Teva's Proposed Product before the patents-in-suit expire.

Count I: Infringement of the '094 Patent

24. Impact repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

25. Teva's submission of its ANDA, with the accompanying Paragraph IV Certification and notice to Impact of same, to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '094 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

26. There is a justiciable controversy between the parties hereto as to the infringement of the '094 patent.

27. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '094 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

28. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '094 patent under 35 U.S.C. § 271(b) by

making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '094 patent and knowledge that its acts are encouraging infringement.

29. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '094 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes one or more claims of the '094 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

30. Impact will be substantially and irreparably damaged and harmed if Teva's infringement of the '094 patent is not enjoined.

31. Impact does not have an adequate remedy at law.

32. This case is an exceptional one, and Impact is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '092 Patent

33. Impact repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

34. Teva's submission of its ANDA, with the accompanying Paragraph IV Certification and notice to Impact of same, to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '092 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

35. There is a justiciable controversy between the parties hereto as to the infringement of the '092 patent.

36. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '092 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

37. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '092 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '092 patent and knowledge that its acts are encouraging infringement.

38. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '092 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes one or more claims of the '092 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

39. Impact will be substantially and irreparably damaged and harmed if Teva's infringement of the '092 patent is not enjoined.

40. Impact does not have an adequate remedy at law.

41. This case is an exceptional one, and Impact is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Impact respectfully requests the following relief:

(A) A Judgment that Teva has infringed the patents-in-suit by submitting ANDA No. 218907 with the accompanying Paragraph IV Certification and notice to Impact of same;

(B) A Judgment that Teva has infringed, and that Teva's making, using, selling, offering to sell, or importing Teva's Proposed Product will infringe one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 218907 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Impact is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Teva and its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from making, using, offering to sell, selling, or importing Teva's Proposed Product until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Impact is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Teva, its officers, agents, attorneys, and employees, and those acting in privity and/or concert with them, from practicing any of the subject matter claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Impact is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Teva's Proposed Product will directly infringe, induce infringement of, and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Teva, its officers, agents, attorneys and/or employees, or those acting in privity and/or concert with them, has committed any acts with respect to the subject matter claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Impact damages for such acts;

(H) If Teva, its officers, agents, attorneys, and/or employees, or those acting in privity and/or concert with them, engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Teva's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Impact resulting from such infringement, together with interest;

(I) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Impact its attorneys' fees incurred in this action;

(K) A Judgment awarding Impact its costs and expenses incurred in this action; and

(L) Such further and other relief as this Court may deem just and proper.

Dated: October 23, 2023

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, 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: October 23, 2023

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