

**IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA**

RIGEL PHARMACEUTICALS, INC.,	)	Civil Action No. 15-cv-4370
	)	
Plaintiff,	)	<b>Rigel Pharmaceuticals, Inc.’s Complaint</b>
	)	<b>for Patent Infringement</b>
vs.	)	
	)	<b>JURY TRIAL DEMANDED</b>
NOVARTIS PHARMACEUTICALS	)	
CORP.,	)	
Defendants.	)	
	)	
	)	

**COMPLAINT FOR PATENT INFRINGEMENT AND DEMAND FOR JURY TRIAL**

Plaintiff Rigel Pharmaceuticals, Inc. (“Rigel”), hereby pleads the following claims for relief against defendant Novartis Pharmaceuticals Corporation (“NPC” or “Defendant”) and alleges as follows:

**INTRODUCTION**

1. Rigel brings this action to remedy NPC’s infringement of Rigel’s intellectual property relating to a class of small molecule drugs called 2,4-pyrimidinediamines.

2. Rigel is a small, clinical-stage biotechnology company focused on the discovery and development of novel, small-molecule drugs for the treatment of cancers, inflammatory diseases, and autoimmune diseases. Rigel’s pioneering research focuses on signaling pathways that are critical to disease mechanisms, and serves to identify a variety of product candidates to develop itself, and in conjunction with pharmaceutical industry partners. Through this approach, Rigel is able develop drug technologies that meet patient needs for conditions not addressed by the research or the product pipelines of larger pharmaceutical companies. As a result, Rigel’s pipeline now has several drug candidates in clinical development, including in Phase 3 clinical trials.

3. Rigel is informed and believes, and on that basis alleges, that NPC is a wholly-owned subsidiary of Novartis AG (collectively, “Novartis”), one of the world’s largest pharmaceutical companies. Novartis designs, develops, manufactures, and commercializes in the United States and worldwide markets a wide variety of healthcare products, including oncology, primary care, and specialty medicines.

4. On April 29, 2014, the FDA granted accelerated approval to Novartis’s drug ZYKADIA™ (ceritinib), a 2,4-pyrimidinediamine anticancer drug that blocks proteins that promote the development of cancerous cells in patients with certain types of non-small cell lung cancer (“NSCLC”).

#### **THE PARTIES**

5. Rigel is a corporation organized and existing under the laws of Delaware with a principal place of business at 1180 Veterans Boulevard, South San Francisco, CA 94080.

6. Rigel is informed and believes, and on that basis alleges, that NPC is a corporation organized and existing under the laws of Delaware with a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

#### **JURISDICTION**

7. This Court has federal question jurisdiction over the matters pleaded herein under 28 U.S.C. §§ 1331 and 1338(a) because this is an action for patent infringement arising under the patent laws of the United States of America, 35 U.S.C. § 100, et seq., including § 271.

8. This Court has personal jurisdiction over NPC because, among other reasons, NPC regularly conducts business in the State of California and has substantial, systematic, and continuous contacts within this judicial District, including by maintaining and operating facilities at 150 Industrial Road, San Carlos, CA 94070 and at 2010 Cessna Drive, Vacaville, CA 95688;

because NPC has purposefully availed itself to the privileges of conducting business in this judicial District; because NPC has done business in this District, has committed and continues to commit acts of patent infringement in this District, and has harmed and continues to harm Rigel in this District, by, among other things, making, using, selling and offering to sell, and/or importing infringing products, including ZYKADIA™ in this District. On information and belief, NPC has placed infringing products into the stream of commerce by shipping those products into this District or knowing that the products would be shipped into this District.

**VENUE**

9. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (d) and 28 U.S.C. § 1400(b).

**INTRADISTRICT ASSIGNMENT**

10. Pursuant to Civil Local Rules 3-5(b) and 3-2(c), because this action is an intellectual property action, it is properly assigned to any of the divisions in this District.

**RIGEL'S PATENTS**

11. Rigel is the owner of the entire right, title, and interest of a family of patents entitled "2,4-Pyrimidinediamine Compounds and Their Uses." Among these patents are U.S. Patent Nos. 8,188,276 (the "'276 patent"); 8,835,430 (the "'430 patent"); and 9,018,204 (the "'204 patent"). True and correct copies of the '276, '430, and '204 patents are attached as Exhibits A-C.

**NOVARTIS'S ZYKADIA™ PRODUCT**

12. Ceritinib, which NPC markets under the trade-name ZYKADIA™, is a prescription medicine used to treat patients with certain types of NSCLC. The FDA granted NPC accelerated approval to market ZYKADIA™ on April 29, 2014.

13. Rigel is informed and believes, and on that basis alleges, that NPC's prescribing information for ZYKADIA™ describes the chemical structure of ceritinib as 5-Chloro-N4-[2-[(1-methylethyl)sulfonyl]phenyl]-N2-[5-methyl-2-(1-methylethoxy)-4-(4-piperidinyl)phenyl]-2,4-pyrimidinediamine. A copy of this prescribing information is attached as Exhibit D.

**COUNT ONE**  
**(Patent Infringement, '276 patent)**

14. Rigel re-alleges and incorporates by reference the allegations contained in paragraphs 1-13 above.

15. On May 29, 2012, the United States Patent and Trademark Office issued the '276 patent, entitled "2,4-Pyrimidinediamine Compounds and Their Uses."

16. Rigel is the owner of the entire right, title, and interest in and to the '276 patent. A copy of the '276 patent is attached as Exhibit A.

17. Rigel is informed and believes, and on that basis alleges, that NPC has infringed and continues to infringe one or more claims of the '276 patent, in violation of 35 U.S.C. § 271.

18. NPC infringes literally and/or under the doctrine of equivalents, by, among other things, making, using, offering for sale, selling, and/or importing within this judicial district and elsewhere in the United States, without license or authority, its drug ZYKADIA™, including as ZYKADIA 150 mg capsules and/or related products and dosage forms falling within the scope of one or more claims of the '276 patent.

19. Rigel alerted NPC of the existence of the '276 patent in a letter dated May 13, 2014. Rigel is informed and believes, and on that basis alleges, that NPC received the letter on, and therefore has been aware of the existence of the '276 patent since at least, May 14, 2014.

20. Rigel is informed and believes, and on that basis alleges, that NPC has infringed and continues to infringe the '276 patent in violation of 35 U.S.C. § 271(b) by actively inducing

infringement of the '276 patent, literally and/or under the doctrine of equivalents, with knowledge of the '276 patent and knowledge that it was inducing the infringement of the '276 patent, by, among other things, actively and knowingly aiding and abetting, assisting and encouraging others, including physicians and patients, to directly infringe the '276 patent with respect to the making, using, offering for sale, selling, and/or importing within this judicial district and elsewhere in the United States, without license or authority, ZYKADIA™ and related products and/or dosage forms falling within the scope of one or more claims of the '276 patent.

21. Rigel is informed and believes, and on that basis alleges, that NPC has infringed and continues to infringe the '276 patent in violation of 35 U.S.C. § 271(c) by contributing to infringement of the '276 patent, literally and/or under the doctrine of equivalents, by, among other things, selling, offering for sale, and/or importing within this judicial district and elsewhere in the United States, without license or authority, ZYKADIA™ and related products and/or dosage forms falling within the scope of one or more claims of the '276 patent, with knowledge of the '276 patent and knowing that such products and/or components are especially made or especially adapted for use in the infringement of the '276 patent, and not staple articles or commodities of commerce suitable for substantial noninfringing use.

22. Rigel is informed and believes, and on that basis alleges, that NPC's infringement of the '276 patent has been and continues to be willful and deliberate. NPC, with knowledge of the '276 patent and its infringement, engaged in objectively reckless conduct by selling and continuing to sell infringing products in the face of an objectively high risk that NPC was infringing Rigel's valid '276 patent.

23. NPC's acts of infringement have caused damage to Rigel in an amount to be proven at trial. As a consequence of NPC's infringement, Rigel is entitled to recover damages adequate to compensate it for the infringement complained of herein, but in no event less than a reasonable royalty.

24. Rigel has suffered irreparable injury as a direct and proximate result of NPC's infringement for which there is no adequate remedy at law. Unless NPC is enjoined, Rigel will continue to suffer such irreparable injury as a direct and proximate result of NPC's conduct.

**COUNT TWO**  
**(Patent Infringement, '430 patent)**

25. Rigel re-alleges and incorporates by reference the allegations contained in paragraphs 1-13 above.

26. On September 16, 2014, the United States Patent and Trademark Office issued the '430 patent, entitled "2,4-Pyrimidinediamine Compounds and Their Uses."

27. Rigel is the owner of the entire right, title, and interest in and to the '430 patent. A copy of the '430 patent is attached as Exhibit B.

28. Rigel is informed and believes, and on that basis alleges, that NPC has infringed and continues to infringe one or more claims of the '430 patent, in violation of 35 U.S.C. § 271.

29. NPC infringes literally and/or under the doctrine of equivalents, by, among other things, making, using, offering for sale, selling, and/or importing within this judicial district and elsewhere in the United States, without license or authority, its drug ZYKADIA™, including as ZYKADIA 150 mg capsules and/or related products and dosage forms falling within the scope of one or more claims of the '430 patent.

30. Rigel alerted NPC of the existence of the '430 patent in an email dated September 18, 2014. Rigel is informed and believes, and on that basis alleges, that NPC received the email

on, and therefore has been aware of the existence of the '430 patent since at least, September 18, 2014.

31. Rigel is informed and believes, and on that basis alleges, that NPC has infringed and continues to infringe the '430 patent in violation of 35 U.S.C. § 271(b) by actively inducing infringement of the '430 patent, literally and/or under the doctrine of equivalents, with knowledge of the '430 patent and knowledge that it was inducing the infringement of the '430 patent, by, among other things, actively and knowingly aiding and abetting, assisting and encouraging others, including physicians and patients, to directly infringe the '430 patent with respect to the making, using, offering for sale, selling, and/or importing within this judicial district and elsewhere in the United States, without license or authority, ZYKADIA™ and related products and/or dosage forms falling within the scope of one or more claims of the '430 patent.

32. Rigel is informed and believes, and on that basis alleges, that NPC has infringed and continues to infringe the '430 patent in violation of 35 U.S.C. § 271(c) by contributing to infringement of the '430 patent, literally and/or under the doctrine of equivalents, by, among other things, selling, offering for sale, and/or importing within this judicial district and elsewhere in the United States, without license or authority, ZYKADIA™ and related products and/or dosage forms falling within the scope of one or more claims of the '430 patent, with knowledge of the '430 patent and knowing that such products and/or components are especially made or especially adapted for use in the infringement of the '430 patent, and not staple articles or commodities of commerce suitable for substantial noninfringing use.

33. Rigel is informed and believes, and on that basis alleges, that NPC's infringement of the '430 patent has been and continues to be willful and deliberate. NPC, with knowledge of

the '430 patent and its infringement, engaged in objectively reckless conduct by selling and continuing to sell infringing products in the face of an objectively high risk that NPC was infringing Rigel's valid '430 patent.

34. NPC's acts of infringement have caused damage to Rigel in an amount to be proven at trial. As a consequence of NPC's infringement, Rigel is entitled to recover damages adequate to compensate it for the infringement complained of herein, but in no event less than a reasonable royalty.

35. Rigel has suffered irreparable injury as a direct and proximate result of NPC's infringement for which there is no adequate remedy at law. Unless NPC is enjoined, Rigel will continue to suffer such irreparable injury as a direct and proximate result of NPC's conduct.

**COUNT THREE**  
**(Patent Infringement, '204 patent)**

36. Rigel re-alleges and incorporates by reference the allegations contained in paragraphs 1-13 above.

37. On April 28, 2015, the United States Patent and Trademark Office issued the '204 patent, entitled "2,4-Pyrimidinediamine Compounds and Their Uses."

38. Rigel is the owner of the entire right, title, and interest in and to the '204 patent. A copy of the '204 patent is attached as Exhibit C.

39. Rigel is informed and believes, and on that basis alleges, that NPC has infringed and continues to infringe one or more claims of the '204 patent, in violation of 35 U.S.C. § 271.

40. NPC infringes literally and/or under the doctrine of equivalents, by, among other things, making, using, offering for sale, selling, and/or importing within this judicial district and elsewhere in the United States, without license or authority, its drug ZYKADIA™, including as



ZYKADIA 150 mg capsules and/or related products and dosage forms falling within the scope of one or more claims of the '204 patent.

41. Rigel alerted NPC of the existence of the '204 patent in an email dated April 30, 2015. Rigel is informed and believes, and on that basis alleges, that NPC received the email on, and therefore has been aware of the existence of the '204 patent since at least, April 30, 2015.

42. Rigel is informed and believes, and on that basis alleges, that NPC has infringed and continues to infringe the '204 patent in violation of 35 U.S.C. § 271(b) by actively inducing infringement of the '204 patent, literally and/or under the doctrine of equivalents, with knowledge of the '204 patent and knowledge that it was inducing the infringement of the '204 patent, by, among other things, actively and knowingly aiding and abetting, assisting and encouraging others, including physicians and patients, to directly infringe the '204 patent with respect to the making, using, offering for sale, selling, and/or importing within this judicial district and elsewhere in the United States, without license or authority, ZYKADIA™ and related products and/or dosage forms falling within the scope of one or more claims of the '204 patent.

43. Rigel is informed and believes, and on that basis alleges, that NPC has infringed and continues to infringe the '204 patent in violation of 35 U.S.C. § 271(c) by contributing to infringement of the '204 patent, literally and/or under the doctrine of equivalents, by, among other things, selling, offering for sale, and/or importing within this judicial district and elsewhere in the United States, without license or authority, ZYKADIA™ and related products and/or dosage forms falling within the scope of one or more claims of the '204 patent, with knowledge of the '204 patent and knowing that such products and/or components are especially made or

especially adapted for use in the infringement of the '204 patent, and not staple articles or commodities of commerce suitable for substantial noninfringing use.

44. Rigel is informed and believes, and on that basis alleges, that NPC's infringement of the '204 patent has been and continues to be willful and deliberate. NPC, with knowledge of the '204 patent and its infringement, engaged in objectively reckless conduct by selling and continuing to sell infringing products in the face of an objectively high risk that NPC was infringing Rigel's valid '204 patent.

45. NPC's acts of infringement have caused damage to Rigel in an amount to be proven at trial. As a consequence of NPC's infringement, Rigel is entitled to recover damages adequate to compensate it for the infringement complained of herein, but in no event less than a reasonable royalty.

46. Rigel has suffered irreparable injury as a direct and proximate result of NPC's infringement for which there is no adequate remedy at law. Unless NPC is enjoined, Rigel will continue to suffer such irreparable injury as a direct and proximate result of NPC's conduct.

#### **PRAYER FOR RELIEF**

WHEREFORE, Rigel prays for relief against NPC as follows:

- A. For a determination that NPC has directly infringed and continues to infringe the '276, '430, and '204 patents;
- B. For a determination that NPC has induced infringement of and continues to induce the infringement of the '276, '430, and '204 patents;
- C. For a determination that NPC has contributorily infringed, and continues to contributorily infringe the '276, '430, and '204 patents;

D. That NPC and any of its affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and all those acting for any of them and/or on any of their behalf, or acting in concert with any of them directly or indirectly, be enjoined from infringing, inducing others to infringe or contributing to the infringement of the '276, '430, and '204 patents;

E. For damages adequate to compensate Rigel for NPC's infringement of the '276, '430, and '204 patents, but in no event less than a reasonable royalty for the use made of the inventions, together with interest and costs under 35 U.S.C. § 284;

F. For a determination that NPC's infringement has been willful, wanton, and deliberate and that the damages against it be increased three times on this basis;

G. For an award of pre- and post-judgment interest on the damages assessed;

H. For an award of supplemental damages to Rigel, including without limitation interest;

I. For an order providing an accounting;

J. For a determination that this is an exceptional case under 35 U.S.C. § 285 and that an award of attorneys' fees and costs to Rigel is warranted in this action;

K. For entry of judgment against NPC and in favor of Rigel in all respects; and

L. For such other and further relief as the Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff Rigel hereby demands a trial by jury on all issues so triable of right by a jury raised in this Complaint.

Dated: September 23, 2015

Respectfully submitted,  
/s/ Andrei Iancu  
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