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**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| INCYTE CORPORATION and INCYTE HOLDINGS CORPORATION,<br><br>Plaintiffs,<br><br>v.<br><br>SUN PHARMACEUTICAL INDUSTRIES LTD.; and SUN PHARMACEUTICAL INDUSTRIES, INC.,<br><br>Defendants. | Civil Action No. 24-6944<br><br>*Document Electronically Filed* |

**COMPLAINT**

Incyte Corporation and Incyte Holdings Corporation (collectively, "Incyte" or "Plaintiffs"), by their attorneys, hereby allege as follows:

**NATURE OF THE ACTION**

1. This is a declaratory judgment action for infringement of Incyte's U.S. Patent No. 9,662,335 ("the '335 Patent") (Ex. A) under 28 U.S.C. §§ 2201, 2202, and the patent laws of the United States, Title 35, United States Code, by Sun Pharmaceutical Industries Ltd. ("Sun Ltd.") and Sun Pharmaceutical Industries, Inc. ("Sun Inc.") (collectively, "Sun" or "Defendants").

2. This declaratory judgment action relates to Sun's infringement of the '335 Patent by its imminent commercial market launch, and pre-launch activities in support of an imminent

commercial market launch, of a deuterated ruxolitinib ("deuruxolitinib") product[1] immediately following the marketing approval—expected July 2024—of Sun Ltd.'s New Drug Application ("Sun Ltd.'s NDA") by the U.S. Food and Drug Administration ("FDA"). By virtue of Sun's imminent commercial market launch of deuruxolitinib and its pre-launch activities in support of that commercial market launch, Sun has and/or will infringe one or more claims of the '335 Patent under 35 U.S.C. § 271(a) by engaging in the commercial manufacture, use, offer for sale, sale, or importation into the United States of deuruxolitinib prior to the expiration of the '335 Patent owned by Incyte.

## BACKGROUND

### A. Incyte's Development of Janus Kinase Inhibitors

3. Incyte is a research-driven, patient-focused biopharmaceutical company that develops novel therapies for rare cancers and other serious, life-threatening diseases. Incyte was founded in 2002 by a small group of research scientists, chemists, and biologists. Over 20 years later, Incyte has grown into a global pharmaceutical company with over 2,500 employees, nearly half of whom work in research and development. Incyte has always focused on investing in research and development of innovative treatments for rare diseases, and, despite its growth, that initial commitment remains steadfast today. Research and development of Incyte's flagship product Jakafi® (ruxolitinib) began in 2004, and ruxolitinib has been a cornerstone of Incyte's scientific and business efforts for more than two decades.

4. Since Incyte's founding, Incyte's drug development programs have prioritized

[1] The deuruxolitinib product that is the subject of Sun Ltd.'s NDA is also referred to as "CTP-543"; (3*R*)-3-(2,2,3,3,4,4,5,5-$D_8$)cyclopentyl-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl]propanenitrile.,1*H*-pyrazole-1-propanenitrile, β-(cyclopenytl-2,2,3,3,4,4,5,5,-d8)-4-(7*H*-pyrrolo[2,3-*d*]pyrimidin-4-yl)-, (βR)-; C-21543; and $D_8$-ruxolitinib.

Janus Kinase inhibitors (so-called "JAK" inhibitors) to treat certain serious diseases that implicate JAK-signaling pathways. Through years of painstaking research and critical drug development activities, Incyte discovered and developed ruxolitinib and its deuterated analogs claimed in the '335 Patent. *See* Ex. A ('335 Patent to *Rodgers et al.*). Ruxolitinib is a JAK inhibitor designed to "mediate the signaling of a number of cytokines and growth factors that are important for hematopoiesis and immune function." *See* Ex. B at 30. Incyte brings this action to protect, *inter alia*, the significant intellectual property rights that it has obtained based on its development of JAK inhibitors such as ruxolitinib and its deuterated analogs.

5. Ruxolitinib is a first-of-its-kind treatment, marketed by Incyte as orally-administered Jakafi® for treatment of several rare cancers and serious, life-threatening diseases: (1) intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis in adults; (2) polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea; (3) steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12-years and older; and (4) chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older. Ex. B at 1.

6. Incyte has also developed and currently markets ruxolitinib as a topical cream, Opzelura®, indicated for the treatment of: (1) certain types of atopic dermatitis and (2) nonsegmental vitiligo. Opzelura® was the first ever FDA-approved treatment for nonsegmental vitiligo, and is the only FDA-approved treatment available on the market today. Ex. C.

7. Incyte is continuing to actively develop innovative products using highly versatile ruxolitinib and its deuterated analogs for the treatment of additional indications to fulfill critical treatment needs of patients with serious diseases, e.g., prurigo nodularis, lichen sclerosis, lichen

planus, and alopecia areata.

8. While Incyte was investing into research and development of ruxolitinib, it also discovered another highly effective JAK inhibitor identified as "baricitinib." Incyte licensed the intellectual property underlying baricitinib to Eli Lilly and Company in 2009, and in 2022, the FDA approved Olumiant® (baricitinib) as the first-ever systemic treatment for adults with severe alopecia areata (AA), an autoimmune hair loss disorder. Ex. D. Incyte continues to earn substantial royalties from Lilly for its sales of Olumiant® in the U.S., Ex. AA at 2, not only for the treatment of AA but also from sales of its other indications, including rheumatoid arthritis. *See generally* Ex. D; Ex. AA.

### B. Sun's Predecessor Concert Pharmaceuticals, Inc. and Its Deuteration Strategy

9. Concert Pharmaceuticals, Inc. ("Concert") is the predecessor-in-interest of Sun Inc. *See* Ex. O at 2 (describing the consolidation of Concert); *see also* Ex. DD at 1-2 (*Incyte Corporation v. Sun Pharmaceutical Industries, Inc.*, No. 23-1300, D.I. 13-2 (Fed. Cir. April 10, 2023) (Sun filed in pending appeal the "Certificate of Merger of Concert Pharmaceuticals, Inc. with and into Sun Pharmaceutical Industries, Inc.," dated March 28, 2023)). Founded in 2006, Concert's focus was taking FDA-approved drugs already invented and developed by others, and modifying their structure via "deuteration," i.e., replacement of one or more of the molecule's hydrogen atoms with deuterium, a shortcut in the drug development process it openly touted. *See* Ex. E at 3 ("CoNCERT compounds are based on drugs with known efficacy and safety that address clinically validated targets. This allows CoNCERT to rapidly create novel, differentiated compounds with substantially reduced R&D risk, time and expense."). Replacing one or more hydrogen atoms of an innovator's compound with deuterium—a stable isotope of hydrogen having a nucleus of one proton and one neutron—does not affect a drug's pharmacodynamics, e.g., the

drug's biological selectivity and potency. *See id*. at 2-3. According to Concert's President & CEO: "At Concert, 'we've never seen any biologically relevant differences in target selectivity or potency of a drug when we deuterate it.'" Ex. F at 5.

10. Concert soon identified Incyte's highly versatile ruxolitinib compound as an ideal target for its deuteration business strategy. Concert continued developing its deuruxolitinib products even though deuterated ruxolitinib was *already* patented by Incyte in the '335 Patent, a fact that Concert's public business disclosures candidly acknowledged:

> Our deuruxolitinib compound is based, and potential future product candidates may be based, on products that are covered by issued patents or patent applications, the holders of which may attempt to assert claims against us. . . . For example, deuruxolitinib is a deuterated analog of ruxolitinib. Incyte owns patents covering ruxolitinib . . . . ***Incyte also owns a U.S. patent that broadly claims deuterated analogs of ruxolitinib***.

Ex. Q at 88 (Concert 10Q, "[f]or the quarterly period ended September 30, 2022") (emphasis added). Concert also admits that it developed its deuruxolitinib product called "CTP-543" by starting with Incyte's ruxolitinib and adding deuterium: "Concert invented CTP-543 by modifying the drug ruxolitinib with deuterium atoms at eight key locations." Ex. V at 1.

11. Sun's predecessor-in-interest Concert knew about the '335 Patent since at least June 27, 2017, when it filed a petition with the U.S. Patent and Trademark Office ("USPTO") for post-grant review ("PGR"), challenging the patentability of claims 1-6 of the '335 Patent. Ex. G at 1. The Patent Trial and Appeal Board ("PTAB") determined on January 11, 2018, however, that Concert had not demonstrated that claims 1-6 of the '335 Patent lack support under 35 U.S.C. § 112 in any parent non-provisional application to which it claims priority and denied institution of Concert's PGR on the '335 Patent. Ex. H at 13-14.

12. Notwithstanding the fact that the '335 Patent survived the PTAB's post-grant

review unscathed and remains a valid and enforceable property right for Incyte, *see id.*, Concert publicly doubled-down on its deuruxolitinib product development plans. *See* Ex. I at 1 (stating that "Concert filed a PGR petition challenging the validity of Incyte's '335 patent covering deuterated ruxolitinib analogs" but despite learning that USPTO "decided not to grant the Company's Post Grant Review (PGR) petition challenging the validity of [the '335 patent]," Concert's President & CEO Roger Tung is still quoted as saying: "'[W]e will continue with our plans to develop CTP-543 for alopecia areata. We don't expect any disruption to our clinical timelines.'"); *see also* Ex. Q at 88 ("*Third parties may sue us alleging that we are infringing their intellectual property rights, and such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates*. . . . In January 2018, the PTAB did not grant our petition to challenge the validity of Incyte's ['335] patent. In May 2018, our request for reconsideration was denied.") (emphasis original); Ex. J at 1-2 (demonstrating that "Deuruxolitinib (CTP-543)" had advanced to a "Late-Stage Clinical Asset for Alopecia Areata" by "11/2022"). As of February 16, 2023, "Deuruxolitinib [wa]s the only drug in Concert's pipeline." Ex. K at 2.

**C. Sun's Acquisition of Concert and Imminent Infringement of the '335 Patent**

13. In early 2023, Sun acquired Concert for $576 million in equity value and merged the company into Sun, an India-based pharmaceutical company that manufactures and sells generic drug products worldwide. Ex. DD (merger formalization dated March 28, 2023); Ex. K at 1-2. In February and March of 2023, Sun openly declared its intent to continue developing and marketing deuruxolitinib in the United States and around the world. *See* Ex. K at 2 ("Sun Pharma is building a global dermatology and ophthalmology franchise. . . . The acquisition of Concert adds a late-stage, potential best-in-class treatment for Alopecia Areata in deuruxolitinib."); Ex. L at 1 ("By bringing together Concert's talented team with Sun Pharma's global reach and commercial

capabilities, this acquisition is an opportunity to bring deuruxolitinib to market globally and make a meaningful difference to alopecia areata patients around the world.").

14. By October 6, 2023, Sun pressed forward with its intention to bring a deuruxolitinib treatment for alopecia areata to market by filing—and the FDA formally accepting—"the New Drug Application (NDA) for deuruxolitinib, an investigational oral selective inhibitor of Janus kinase JAK1 and JAK2, for the treatment of adults with moderate to severe alopecia areata." Ex. M at 1. Pursuant to pharmaceutical regulatory practice, a "PDUFA date" was assigned as the deadline by which the FDA would render its decision regarding Sun Ltd.'s NDA for market approval: July 2024, i.e., ten months after NDA acceptance. *See* Ex. N at 2 (Sun Press Release entitled "Sun Pharma report Q2FY2024 results" announces the "Next milestone" for "deuruxolitinib" is a "PDUFA date in Jul-2024").

15. On information and belief, Sun plans to launch its infringing deuruxolitinib product into the market imminently—as soon as July 2024—as evidenced by Sun's pre-launch commercial activities and public commitments to investors and others. For example, on a November 2023 earnings call, Dilip Shanghvi, Managing Director at Sun Ltd. answered the question "whether we'll be able to launch deuruxolitinib post approval *immediately*?" by affirming that Sun's "plan is to launch the product *on* approval." Ex. O at 14 (emphasis added); *see also* Ex. N at 2 (describing "Jul-24" as the putative approval deadline). Dilip Shanghvi on that same earnings call affirmed that Sun was "not expecting any disruption" with respect to launch of the product at the level of the manufacturing partner:

> **Kunal Dhamesha [Macquarie Group]:** "First one on the Specialty business. So one of our CDMO partner [i.e., a third-party Contract Development and Manufacturing Organization] for one product had some issues with U.S. FDA, so do you expect any disruption related to the [deuruxolitnib] product?

> **Dilip Shanghvi [Sun Ltd.]:** I mean my understanding is that we are not expecting any disruption.
>
> **Kunal Dhamesha:** Sure, sir. And secondly, now that we have one big product up and probably only one supplier, would we be looking to derisk that and add one more supplier?
>
> **Dilip Shanghvi:** Yes, I think that is the approach that we have for all major innovative products, we would like to have one additional source.
>
> **Kunal Dhamesha:** Sure. And second on the deuruxolitinib, so that would also be a CDMO manufactured kind of opportunity? Or would that be manufactured in-house?
>
> **Dilip Shanghvi:** Currently, when we licensed the product, the product was manufactured by CDMO. So it will be launched from CDMO.

Ex. O at 14-15.

16. In Sun's most recent earnings call of May 22, 2024, the ongoing pre-launch activities were discussed, and the imminent post-July 2024 commercial market launch of deuruxolitinib was once again confirmed to be "on track" by Abhay Gandhi, CEO (North America Business) Sun Ltd.:

> **Neha Manpuria [Bank of America]:** And the Deuruxo launch approval, which is due in July, launch-related cost for that would start coming through in the second half of this year, will that be a fair assumption? I mean, just wanted to get a sense on the launch timeline for Deuruxo, assuming we get approval in July?
>
> **Abhay Gandhi [Sun Ltd.]:** *There are small costs that we are incurring even today for all the pre-launch activities*. But I think the major cost will obviously hit our numbers when we actually launch the product.
>
> **Neha Manpuria:** Which would be when, based on the July '24 timeline for approval?
>
> **Abhay Gandhi:** *So we are on track to launch it post the PDUFA date*. Do remember, it takes a little bit of time to actually enter the market with all the pre-launch activities that need to be done. *But we are on track as of now*.

Ex. P at 7 (italics added). From these commitments to investors and others, Sun is clearly already making investments and taking pre-launch steps to commercialize deuruxolitinib with the assistance of partners and intends to imminently launch deuruxolitinib into market in or around July 2024. *Id.*; Ex. O at 14-15; *see also* Ex. Q at 45 (Concert 10Q) ("We are conducting pre-commercial activities, with the intent of commercializing deuruxolitinib in the United States ourselves or with the assistance of strategic partners."); Ex. R at 9 (describing "no slow down" in 8 mg deuruxolitinib dose).

17. Sun's pre-launch activities and its immediate post-approval commercial market launch plans, *see* Exs. L-R, EE, BB, have violated and/or will violate Incyte's rightful intellectual property in the valid and enforceable '335 Patent. The imminent and/or ongoing infringement by Sun will cause irreparable harms and drastically devalue Incyte's related investments, including investments made into Jakafi® and multiple other products.

18. Because of Sun's imminent commercial market launch of deuruxolitinib and its admitted pre-launch activities in support of that commercial market launch, *see id.*, Sun will knowingly infringe the valid and enforceable '335 Patent. Incyte files this declaratory judgment action to request that the Court enjoin Sun from continuing its infringing activities with respect to the '335 Patent and afford all other remedies in law and at equity, as described below.

## THE PARTIES

### A. Incyte Corporation and Incyte Holdings Corporation

19. Plaintiff Incyte Corporation is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803.

20. Plaintiff Incyte Holdings Corporation is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803.

21. Incyte Corporation and Incyte Holdings Corporation are the owners of the ’335 Patent by virtue of assignment and hold all rights in the ’335 Patent.

**B. Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc.**

22. Defendant Sun Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2 Independence Way, Princeton, New Jersey 08450. On information and belief, Sun Inc. is in the business of making, importing, and selling pharmaceutical products that are marketed and sold throughout the United States, including in this Judicial District of New Jersey.

23. Defendant Sun Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, 400063, India. On information and belief, Sun Ltd. is an international pharmaceutical company that develops and manufactures generic pharmaceutical products that are imported, marketed, and sold throughout the United States, including in this Judicial District of New Jersey, either directly or through its United States partners, affiliates, and subsidiaries.

24. On information and belief, Sun Inc. is a wholly owned subsidiary and United States agent of Sun Ltd.

25. On information and belief, Sun Inc. and Sun Ltd. work in concert and will continue to work in concert with each other with respect to manufacturing, marketing, sale, and distribution of deuruxolitinib in this Judicial District of New Jersey and throughout the United States.

## JURISDICTION AND VENUE

26. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, et seq., and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

27. This Court has personal jurisdiction over Sun Inc. under the New Jersey long-arm statute and consistent with due process of law, at least because Sun Inc. maintains its principal place of business in New Jersey.

28. This Court also has personal jurisdiction over Sun Inc. under the New Jersey long-arm statute and consistent with due process of law, because Sun Inc.: (1) has substantial, continuous, and systematic contacts with New Jersey; (2) manufactures, markets, sells, and/or distributes pharmaceutical drug products to residents of New Jersey; (3) intends to manufacture, market, sell, and/or distribute deuruxolitinib to residents of New Jersey; and (4) enjoys substantial income from sales of its pharmaceutical products in New Jersey.

29. Consistent with its principal place of business being in New Jersey, and its substantial, continuous, and systematic contacts with New Jersey, Sun Inc. is currently registered with the New Jersey Department of Health as a drug "Manufacturer and Wholesale" out of Cranbury, New Jersey. *See* Ex. S ("Drug and Medical Device Certificate of Registration," Reg. No. 5003437, expires "01/31/2025").

30. Consistent with its principal place of business being in New Jersey, and its substantial, continuous, and systematic contacts with New Jersey, Sun Inc. is actively hiring at its manufacturing facility in New Brunswick, New Jersey. *See* Ex. T at 1 (May 14, 2024) (seeking employee to "[s]upport Quality activities at Contract Manufacturing Organizations (CMO) by providing timely and effective quality oversight").

31. This Court also has personal jurisdiction over Sun Inc. because it has previously been sued in New Jersey and has not challenged personal jurisdiction and/or it has affirmatively availed itself of the jurisdiction of this Court by filing claims and counterclaims in the District of New Jersey. *See, e.g.*, *Astellas Pharma Inc. v. Sun Pharm. Industries, Inc.*, Civ. Action No. 22-7357 (D.N.J.); *Orexo AB v. Sun Pharm. Industries Ltd.*, Civ. Action No. 21-17941 (D.N.J.); *Orexo Ab v. Sun Pharm. Industries Ltd.*, Civ. Action No. 21-13320 (D.N.J.); *Aurina Pharms. Inc. v. Sun Pharm. Industries Inc.*, Civ. Action No. 20-19805 (D.N.J.); *Orexo AB v. Sun Pharm. Industries Ltd.*, Civ. Action No. 20-12588 (D.N.J.); *Allergan Pharms. Int'l Ltd. v. Sun Pharm. Industries Ltd.*, Civ. Action No. 20-10176 (D.N.J.); *Janssen Products, L.P. v. Evenus Pharms. Labs. Inc.*, Civ. Action No. 20-09369 (D.N.J.); *Galephar Pharm. Research, Inc. v. Upsher-Smith Labs., LLC*, Civ. Action No. 19-2546 (D.N.J.); *Eisai R&D Management Co., Ltd. v. Sun Pharm. Industries Ltd.*, Civ. Action No. 19-21857 (D.N.J.); *Sun Pharm. Industries Ltd. v. Novartis Pharmaceuticals Corp.*, Civ. Action No. 19-21733 (D.N.J.); *Corcept Therapeutics, Inc. v. Sun Pharm. Industries, Inc.*, Civ. Action No. 19-15678 (D.N.J.); and *Celgene Corp. v. Sun Pharm Industries, Inc.*, Civil Action No. 19-10099 (D.N.J.).

32. This Court has personal jurisdiction over Sun Ltd. under the New Jersey long-arm statute and consistent with due process of law, because Sun Ltd.: (1) has substantial, continuous, and systematic contacts with New Jersey; (2) manufactures, markets, sells, and/or distributes pharmaceutical drug products to residents of New Jersey; (3) intends to manufacture, market, sell, and/or distribute deuruxolitinib to residents of New Jersey; and (4) enjoys substantial income from sales of its pharmaceutical products in New Jersey.

33. On information and belief, Sun Ltd. has substantial contacts with and within New Jersey, and has purposefully conducted and continues to conduct business in this Judicial District, including that this Judicial District is a destination of Sun's deuruxolitinib product.

34. Sun Ltd. has its United States "headquarters [] in Princeton, New Jersey," according to its webpage. Ex. U at 2. Sun Ltd. also does business in New Jersey through Sun Inc., a company registered with the New Jersey Department of Health as a manufacturer and wholesaler. Ex. S.

35. On information and belief, Sun Ltd. will imminently and immediately import, market, distribute, offer for sale, and/or sell deuruxolitinib in the United States, including in New Jersey, either directly or through its United States affiliate Sun Inc., and will derive substantial revenue from the sale of its deuruxolitinib product in New Jersey. *See* Ex. O at 14 (answering in response to the question "whether we'll be able to launch deuruxolitinib post approval *immediately*?" that Sun's "plan is to launch the product *on* approval") (emphasis added); *id*. at 14-15 (describing the manufacture and launch of the product by a contract development and manufacturing organization ("CDMO") without "expecting any disruption"); Ex. N at 2 (describing PDUFA date in July 2024 for deuruxolitinib); Ex. Q at 45 ("We are conducting pre-commercial activities, with the intent of commercializing deuruxolitinib in the United States ourselves or with the assistance of strategic partners."); Ex. R at 9 (describing "no slow down" in 8 mg deuruxolitinib dose); Ex. P at 7 ("on track to launch it post the PDUFA date"); Exs. BB ("Sun Pharma Gearing Up for US Launch of Specialty Drug in July"), EE (same); *see also* Exs. T, W, X, Y (hiring, on information and belief, employees with product launch experience in dermatology division for positions related to the commercial market launch of deuruxolitinib).

36. On information and belief, Sun will imminently import, market, distribute, offer for sale, and/or sell deuruxolitinib across the United States, and deuruxolitinib will be prescribed by

healthcare providers practicing in New Jersey and administered by healthcare providers to patients located within New Jersey, all of which will have a substantial effect on New Jersey.

37. Incyte will be irreparably harmed by the importation, marketing, distribution, offer for sale, and/or sale of deuruxolitinib across the United States, including in New Jersey.

38. Alternatively, this Court has personal jurisdiction over Sun Ltd. pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because Sun Ltd. is a foreign entity, Plaintiffs' claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because Sun Ltd. has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing pharmaceutical products, either directly to United States customers or through its subsidiaries and/or affiliates to United States customers.

39. Venue is proper in this Judicial District with respect to Sun Inc. under 28 U.S.C. § 1400(b) for at least the reason that it maintains a regular and established place of business in this Judicial District. Sun Inc. has a regular and established place of business in New Jersey under the meaning of 28 U.S.C. § 1400(b) because, *inter alia*, its principal place of business is in New Jersey. As set forth above, on information and belief, Sun Inc. maintains regular and established places of business in New Jersey including offices, laboratories, and/or facilities at least at: 14 Terminal Rd., New Brunswick, NJ 08901; 2 Independence Way, Princeton, NJ 08450; and 1 Commerce Drive, Cranbury, NJ 08512. *See, e.g.*, Exs. T, U, Z.

40. Venue is proper in this Judicial District with respect to Sun Ltd. under 28 U.S.C. §§ 1391 and 1400(b) for at least the reason that it is a foreign corporation not residing in any United States district and may be sued in any judicial district that has personal jurisdiction, including this Judicial District. Under *In re HTC Corp.*, 889 F.3d 1349, 1356 (Fed. Cir. 2018), venue for foreign

corporations is governed by the general venue statute, which provides that "a defendant not resid[ing] in the United States may be sued in any judicial district." 28 U.S.C. § 1391(c)(3); *see also* Ex. U at 2 ("USA – Sun Pharmaceutical Industries Ltd." and "Our US headquarters are in Princeton, New Jersey.").

**THE PATENT-IN-SUIT**

41. On May 30, 2017, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '335 Patent, entitled "Heteroaryl Substituted Pyrrolo[2,3-B] Pyridines and Pyrrolo[2,3-B] Pyrimidines as Janus Kinase Inhibitors," naming James D. Rogers and Stacey Shepard as inventors. A true and correct copy of the '335 Patent is attached hereto as Exhibit A. The claims of the '335 Patent are valid and enforceable, and "entitled to a priority date of at least December 12, 2006," *see* Ex. H at 6.

42. Incyte lawfully owns all right, title, and interest in the '335 Patent, including the right to sue and to recover for past infringement thereof.

43. The '335 Patent generally relates to heteroaryl substituted pyrrolo[2,3-b]pyridines and heteroaryl substituted pyrrolo[2,3-b]pyrimidines that modulate the activity of Janus kinases.

44. On June 27, 2017, Concert, Sun's predecessor-in-interest, filed a PGR petition with the USPTO, seeking to have the PTAB hold claims 1-6 of the '335 Patent unpatentable. A true and correct copy of the Petition for Post-Grant Review is attached hereto as Exhibit G. The PTAB declined to institute the PGR for any challenged claims, concluding that Concert failed "to demonstrate that it is more likely than not that the '335 patent is eligible for post-grant review," Ex. H at 2, because Concert's "lack of enablement argument fail[ed], as [did] its argument that the alleged lack of enablement limits the '335 patent claims to a PGR-eligible June 3, 2016 filing date." Ex. H at 13-14 (*Concert Pharms., Inc. v. Incyte Corp.*, PGR2017-00034, Paper No. 9 (PTAB

Jan. 11, 2018)); *see also* Exs. I, Q at 88. A true and correct copy of the PTAB Decision is attached hereto as Exhibit H. Concert filed a Request for Rehearing, which the PTAB denied. *Concert Pharms., Inc. v. Incyte Corp.*, PGR2017-00034, Paper Nos. 12-13 (PTAB, May 2018).

**DEFENDANTS' INFRINGING ACTS**

45. Plaintiffs reallege, and incorporate fully herein, each of the proceeding paragraphs 1-44.

46. Sun's CTP-543 deuruxolitinib product infringes the '335 Patent. It is admitted that Concert developed "CTP-543 by modifying the drug ruxolitinib with deuterium atoms at eight key locations," Ex. V at 1, and that the '335 Patent in fact claims deuterated ruxolitinib, *see* Ex. G at 1 ("[J]ust one month after Concert announced initiation of Phase 1 clinical testing of a deuterated ruxolitinib analog (CTP-543) to treat alopecia areata—Incyte… file[d] claims to cover Concert's clinical drug candidate. Those claims issued in the '335 patent . . . ."). Indeed, Sun's predecessor-in-interest acknowledged in 2022 that "[D]euruxolitinib is a deuterated analog of ruxolitinib. . . . Incyte also owns a U.S. patent that broadly claims deuterated analogs of ruxolitinib." Ex. Q at 88.

47. On information and belief, the commercial market launch of an infringing deuruxolitinib product in the United States by Sun is imminent. In October 2023, the FDA accepted Sun's NDA for a deuruxolitinib product. Ex. M at 1. Sun's NDA seeks approval to market deuruxolitinib for the treatment of alopecia areata. *Id.* ("[T]he New Drug Application (NDA) for deuruxolitinib, an investigational oral selective inhibitor of Janus kinases JAK1 and JAK2, [is] for the treatment of adults with moderate to severe alopecia areata. In the NDA, Sun has submitted 8mg twice daily regimen of deuruxolitinib for FDA review."). The PDUFA date for Sun's NDA is in July 2024 and the launch is expected "immediately" thereafter. *See* Ex. O at 14-15 ("assumption and plan is [sic] to launch the product on approval"); Ex. N at 2 ("Jul-24"); Ex. P at

7 ("we are on track as of now"). Sun's NDA, if approved by the FDA in July 2024, will allow Sun to imminently market and sell deuruxolitinib for the treatment of alopecia areata in the United States, thereby infringing the '335 Patent. This is widely recognized, and yet Sun persists without right, authority, permission or license. *See, e.g.*, Ex. Q at 88 ("If any third-party patents or patent applications are found to cover our product candidates or their methods of use, we may not be free to manufacture or market our product candidates as planned without obtaining a license. . . ."); Ex. AA at 2 ("**Risk:** Concert's ongoing litigation with Incyte over patents for Ruxolitinib and Deuruxolitinib. For a smooth launch, Sun Pharma is expected to settle with Incyte by giving a royalty payment until the expiry of the patent (Eli Lilly pays up to 20% royalty for its product).") (emphasis original).

48. On information and belief, Sun has already conducted pre-launch activities in support of making, using, selling, offering to sell, and/or importing deuruxolitinib, including at least the manufacture of deuruxolitinib through a CDMO. *See* Ex. O at 14-15 (describing manufacture of deuruxolitinib by CDMO and the plan to "launch the product on approval"); Ex. Q at 45 (describing even as early as 2022, "conducting pre-commercial activities, with the intent of commercializing deuruxolitinib in the United States ourselves or with the assistance of strategic partners"). On information and belief, on or around May 24, 2024, an article from the Economic Times, entitled "Sun Pharma Gearing Up for US Launch of Specialty Drug in July," quotes Sun Ltd's Abhay Gandhi as saying preparations remain "on track" for imminent market entry and that pre-launch preparations have already begun:

# Sun Pharma Gearing Up for US Launch of Specialty Drug in July

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**Mumbai:** Sun Pharma is gearing up to launch its much-awaited specialty drug deuruxolitinib in July this year in the US market.

"The preparations are in full swing and I think the launch remains on track," said Abhay Gandhi, CEO - North America Business of Sun Pharma in an interview to **ET**.

Gandhi said preparations are underway for some months involving priming the market by meeting doctors, meeting payers trying to gain access for customers when the product is available.

"We feel this is an exciting launch, the product is pretty strong. All the doctors who are part of the trial have bought into the product big time, so we feel that we have a great opportunity here to create another strong product in the overall mix, Gandhi added.

Deuruxolitinib is used for treatment of adults with moderate to severe alopecia areata, an autoimmune disease in which the immune system attacks hair follicles, resulting in partial or complete baldness. The disease affects up to 2.5% of the US population. There are currently limited treatment options available for alopecia areata.

**READY TO EXPAND**

The company is always open for acquisitions to bolster its specialty portfolio

**ABHAY GANDHI**
CEO - North America Business of Sun Pharma

Sun Pharma will have a five-year marketing exclusivity for the product and there are no pending queries from the USFDA for the product.

Sun Pharma early last year took a big leap with the acquisition of US-based Concert Pharma. Sun Pharma said it will be paying $576 million (₹4,600 crore) upfront, added with conditional sales-based milestone payments, for the acquisition. The deal gave Sun Pharma rights to its lead candidate deuruxolitinib, a drug that is being portrayed as a "potential best-in-class" drug.

Sun Pharma global specialty business of which majority of the sales comes from US has surpassed $1 billion sales milestone in FY24. Global specialty sales that contributed about 18% of Sun Pharma revenue grew 19% YoY to $ 1.04 billion in FY24.

Out of Sun Pharma's specialty portfolio - Ilumya (tildrakizumab), which is used to treat people with moderate to severe plaque psoriasis alone reported sales of $580m growing at around 21.7% YoY in FY24.

The success of specialty business is enabling Sun Pharma to spend more on developing a pipeline of specialty products.

Gandhi said specialty portfolios alone account about 39% of total R&D spend.

Sun Pharma has guided that the total R&D spend would be at 8-10% of sales in FY25.

Gandhi said the company is always open for acquisitions to bolster its specialty portfolio.

"Having a cash chest of close to $2.5 billion inclusive of Taro, it enables us to pursue mid to large size transactions as well," Gandhi said.

*See* Ex. BB; Ex. EE (May 24, 2024). Sun Ltd.'s CEO (North America Business) states in the Economic Times article that: "The preparations are in full swing and I think the launch remains on track," including the conduct of pre-launch commercial activities that have been "underway for some months involving priming the market by meeting doctors, meeting payers trying to gain access for customers when the product is available." Ex. EE; Ex. BB; *see also* Ex. P at 7 (describing Sun's investment into "all the pre-launch activities").

49. On information and belief, Sun is currently or will imminently import, manufacture, market, offer for sale, and/or sell deuruxolitinib throughout the United States and this Judicial District without right, permission, license, or authorization from Incyte. *See, e.g.*, Exs. L-R, BB, EE.

50. Sun's infringement of the '335 Patent will irreparably harm Incyte. For example, imminent commercial market launch of Sun's CTP-543 product will cause immediate and irreparable erosion to Incyte's share of the commercial market for Jakafi®, in addition to erosion of the price of Jakafi® when deuruxolitinib is prescribed off-label for the conditions Jakafi® is approved to treat, all of which in turn will negatively and irreparably impact Incyte's ability to continue to make investments into oncology research and development and its commercial operations. Further, under its agreement with Lilly, Incyte receives royalties for sales of Olumiant® (baricitinib), which has been on the market only since 2022 for treatment of AA; but Sun's CTP-543 deuruxolitinib product for the same indication will inevitably diminish market share of Olumiant®, which will lead to downward pricing pressure and a reduction in royalty revenue for Incyte. Such decreases in revenue from Jakafi® and Olumiant® would have a substantial negative impact on Incyte that would be very difficult to quantify, and would result in cutbacks and reductions to current developmental programs in alopecia areata, innovative research, employee retention, support services for patients in need, goodwill and reputation, and public outreach. In addition, decreases in the revenue for Jakafi® and Olumiant® would negatively impact Incyte's ability to educate physicians and patients about the rare, serious and life-threatening diseases Jakafi® is approved to treat, resulting in irreparable harms that are impossible to quantify.

**COUNT I**
**(Declaratory Judgment of Infringement of the '335 Patent)**

51. Plaintiffs reallege, and incorporate fully herein, each of the proceeding paragraphs 1-50.

52. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

53. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

54. Defendants' deuruxolitinib product, upon approval and marketing, will infringe, either literally or under the doctrine of equivalents, at least one claim, including claims 1 and 3 of the '335 Patent under 35 U.S.C. § 271(a). The '335 Patent generally claims ruxolitinib wherein one or more hydrogen atoms are replaced by deuterium or a pharmaceutically acceptable salt thereof. *See* Ex. A. Claim 1 recites: "A compound, which is 3-cyclopentyl-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl]propanenitrile, wherein one or more hydrogen atoms are replaced by deuterium; or a pharmaceutically acceptable salt thereof." *Id*., 366:13-17. Claim 3 recites: "A compound, which is (3R)-3-cyclopentyl-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl]propanenitrile, wherein one or more hydrogen atoms are replaced by deuterium; or a pharmaceutically acceptable salt thereof." *Id*., 366:21-24.

55. Sun's deuruxolitinib product is ruxolitinib wherein eight hydrogen atoms are replaced with deuterium. Ex. V at 1 (CTP-543 is "the drug ruxolitinib with deuterium atoms at eight key locations."); *see also* Ex. G at 1 ("[J]ust one month after Concert announced initiation of Phase 1 clinical testing of a deuterated ruxolitinib analog (CTP-543) to treat alopecia areata—Incyte… file[d] claims to cover Concert's clinical drug candidate."); Ex. Q at 88 ("[D]euruxolitinib

is a deuterated analog of ruxolitinib. . . . Incyte also owns a U.S. patent that broadly claims deuterated analogs of ruxolitinib."). Sun seeks FDA approval in the U.S. to commercially market deuterated ruxolitinib which is claimed in the '335 Patent. Ex. A at 366:13-17, 21-24.

56. Sun's NDA for deuruxolitinib was accepted by the FDA in October 2023. Ex. M at 1. The next milestone for deuruxolitinib and Sun's NDA is the PDUFA date, which is in July 2024, and marks the date on which the FDA must complete its 10-month review process. *See* Ex. N at 2. Sun has repeatedly and publicly made commitments to investors that its pre-launch and launch activities are tied to that approval in July 2024 and that commercial launch of deuruxolitinib is expected "immediately" thereafter. *See* Ex. O at 14-15; Ex. N at 2; Ex. P at 7; Ex. EE; Ex. BB. On information and belief, Sun is currently hiring employees with product launch experience to support the imminent commercial market launch of deuruxolitinib and preparing for marketing of the product. *See* Exs. T, W, X, Y.

57. Pre-launch activities also infringe the '335 Patent. Inasmuch as Sun's plan is to immediately "launch [deuruxolitinib] on approval," and "the preparations are in full swing" to do so, on information and belief this means that Defendants, themselves or through their agents, have already or are currently manufacturing deuruxolitinib. *See* Ex. O at 14-15 (describing further how the product was manufactured by CDMO); Exs. EE; BB.

58. Upon FDA approval and commercial market launch, Defendants will continue their current manufacture, and will immediately and imminently offer for sale, sell, and/or import deuruxolitinib. *See* Exs. L-R, EE, BB.

59. On information and belief, Defendants had actual knowledge of the '335 Patent prior to the submission of Sun's NDA to the FDA. *See* Exs. G-J, Q. Defendants have been aware of the '335 Patent since at least no later than June 27, 2017, when Sun's predecessor-in-interest,

Concert, filed a PGR challenging the '335 Patent (Ex. G), or at least no later than Jan. 12, 2018 when the PTAB declined to institute the PGR and Concert's CEO commented publicly that "[w]e are disappointed that the PTAB has denied our petition on the '335 patent" (Exs. H, I), or at least no later than January 31, 2023, when Sun announced on an earnings call that it was aware of the ongoing litigation between Incyte and Concert (Ex. CC at 17); *see also Incyte Corporation v. Sun Pharmaceutical Industries, Inc.*, No. 23-1300, D.I. 22 (Incyte Non-Confidential Opening Brief) at 21-22 (Fed. Cir. May 30, 2023) ("Before Concert came even into existence, Incyte invented the subject matter claimed in U.S. Patent No. 9,662,335 ("the '335 patent") to *Rodgers*. . . . Incyte's '335 patent covers deuterated ruxolitinib.").

60. If Defendants' manufacture, marketing, offering for sale, and sale of deuruxolitinib prior to the expiration of the '335 Patent and all other relevant activities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

**COUNT II**
**(Declaratory Judgment of Willful Infringement of the '335 Patent)**

61. Plaintiffs reallege, and incorporate fully herein, each of the preceding paragraphs 1-60.

62. On information and belief, Defendants' infringement of the '335 Patent will be willful. Indeed, Defendants have been aware of the '335 Patent since at least no later than June 27, 2017, when Sun's predecessor-in-interest, Concert, filed a PGR challenging the '335 Patent (Ex. G), or at least no later than Jan. 12, 2018 when the PTAB declined to institute the PGR and Concert's CEO commented publicly that "[w]e are disappointed that the PTAB has denied our petition on the '335 patent" (Exs. H, I), or at least no later than January 31, 2023, when Sun announced on an earnings call that it was aware of the ongoing litigation between Incyte and

Concert (Ex. CC at 17); *see also Incyte Corporation v. Sun Pharmaceutical Industries, Inc.*, No. 23-1300, D.I. 22 (Incyte Non-Confidential Opening Brief) at 21-22 (Fed. Cir. May 30, 2023) ("Before Concert came even into existence, Incyte invented the subject matter claimed in U.S. Patent No. 9,662,335 ("the '335 patent") to *Rodgers*. . . . Incyte's '335 patent covers deuterated ruxolitinib.").

63. On information and belief, Defendants' predecessor-in-interest challenged the '335 Patent because they were aware that a deuruxolitinib product would infringe the '335 Patent. *See, e.g.*, Ex. V at 1; Ex. G at 1; Ex. I; Ex. Q at 88. Defendants' continued pre-launch activities and commercialization of deuruxolitinib in the United States will constitute willful infringement. *E.g.*, Ex. V at 1; Ex. G at 1; Ex. I; Ex. Q at 88; Ex. AA.

64. For the same reasons set forth above in paragraphs 9-18 and 45-60, Defendants have knowledge of the '335 Patent and that their acts will constitute infringement. Defendants have acted and are continuing to act in the face of an objectively high likelihood that their actions will constitute infringement of valid claims of the '335 Patent or with reckless disregard of that likelihood.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

A. A declaration under 28 U.S.C. § 2201 that the manufacture, use, offer for sale, sale and/or importation of deuruxolitinib before expiration of the '335 Patent will infringe the '335 Patent;

B. An order enjoining Defendants and their affiliates, subsidiaries, officers, agents, employees, attorneys, and all persons in active concert or participation with any of them, or acting on their behalf, from infringing the '335 Patent;

C. A judgment that, upon launch of deuruxolitinib, Defendants have infringed one or more claims of the ’335 Patent by making, using, selling, and offering to sell deuruxolitinib within the United States and/or importing deuruxolitinib into the United States;

D. An award for Plaintiffs, upon launch of deuruxolitinib, of damages and other pecuniary awards in an amount sufficient to compensate Plaintiffs for Defendants’ infringement of the ’335 Patent, together with prejudgment and post-judgment interest and costs under 35 U.S.C. § 284;

E. An award for Plaintiffs, upon launch of deuruxolitinib, of enhanced damages pursuant to 35 U.S.C. § 284 for Defendants’ willful infringement of the ’335 Patent;

F. A declaration that this case is an exceptional case under 35 U.S.C. § 285, and an award for Plaintiffs of reasonable attorneys’ fees and costs;

G. An order, upon launch of deuruxolitinib, requiring Defendants to provide an accounting of Defendants’ infringing activities through trial and judgment; and

H. An award of such other and further relief as this Court may deem just and proper, including all appropriate remedies at law and in equity.

Dated: June 11, 2024

s/ William P. Deni, Jr.

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