UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK	DOCUMENT ELECTRONICALLY FILED DOC #: DATE FILED: 2/22/2021
NOVARTIS PHARMA AG,	:
Plaintiff,	: 1:20-cv-00400-GHW :
-against-	: <u>CORRECTED</u> : <u>MEMORANDUM OPINION</u>
INCYTE CORPORATION,	: <u>AND ORDER</u>
Defendant.	· :
GREGORY H. WOODS. United States District Lud	11

Plaintiff Novartis Pharma AG ("Novartis") and Defendant Incyte Corporation ("Incyte") forged an agreement to work together to commercialize a valuable drug compound called ruxolitinib. Incyte had an innovative concept. Novartis provided financing to kickstart its development, and contributed Novartis's global reach and marketing expertise. The agreement formalizing their collaboration established separate sales territories: Incyte was to sell ruxolitinib in the United States, and Novartis everywhere else. The parties agreed to pay each other royalties based on sales in their respective domains and to cooperate on the development of new uses for ruxolitinib. But this fruitful collaboration turned sour in 2019, when Incyte unilaterally decided that it was entitled to reduce its royalty payments to Novartis by 50%, as a result of the loss of some of its regulatory protections for the drug in the United States.

In this action, Novartis challenges Incyte's decision to reduce its royalty payments to Novartis. The case presents a straightforward issue of contractual interpretation, in a not so straightforward contract. Incyte argues that the terms of the agreement unambiguously permitted it to reduce its royalty payments to Novartis. Novartis argues that the agreement is ambiguous because the two parties have each presented plausible interpretations of its provisions. Because the

Court concludes that one of the provisions of the parties' agreement is ambiguous, Incyte's motion to dismiss is DENIED.

### I. BACKGROUND<sup>1</sup>

## A. Novartis and Incyte Collaborate to Develop Ruxolitinib

On November 24, 2009, Novartis and Incyte entered into the Collaboration and License Agreement that is the subject of this dispute. Decl. Daniel P. Mach Supp. Incyte Corp.'s Mot. to Dismiss ("Mach Decl.") Ex. 1 (the "Agreement"), Dkt. No. 36-1; Compl. ¶ 1, Dkt. No. 1.<sup>2</sup> The Agreement provided a comprehensive framework for the relationship between the two parties to permit them to "collaborate with respect to the research, development and commercialization of certain pharmaceutical Compounds on a global scale." Compl. ¶ 14. Before entering into the Agreement, Incyte had several medicinal compounds in development, but the company did not sell or market any pharmaceutical products in the United States. *Id.* ¶ 1. Incyte could not effectively develop and commercialize its products on its own. *Id.* The Agreement with Novartis brought Incyte many benefits—the ability to leverage off of Novartis's know-how and global presence, and, not insignificantly, "hundreds of millions of dollars . . . in up-front and milestone payments to fund research and development activities relating to certain compounds." *Id.* 

The Agreement established a framework within which Novartis and Incyte could work together to develop and commercialize a number of clinically important medical products. *Id.*Broadly speaking, pursuant to the Agreement, the parties "agreed to collaborate and share expertise, intellectual property, and decision-making with respect to the development and commercialization of [those products]." *Id.* 

<sup>&</sup>lt;sup>1</sup> Unless otherwise noted, the facts are drawn from the complaint and the Agreement and are accepted as true for the purposes of this motion to dismiss. *See, e.g., Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152 (2d Cir. 2002). However, "[t]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Asheroft v. Iqbal*, 556 U.S. 662, 678 (2009).

<sup>&</sup>lt;sup>2</sup> The Agreement has since been amended five times. Mach Decl. Exs. 2–6, Dkt. Nos. 36-2–36-6.

One of the products developed by Incyte as part of its collaboration with Novartis—ruxolitinib—was a great success. *Id.* ¶ 3. Sold in the United States as "Jakafi®," ruxolitinib is a kinase inhibitor used to treat rare blood cancers and to support organ transplants. *Id.* ¶¶ 1, 23–24. Incyte's revenues have skyrocketed as a result of its sales of ruxolitinib. "Incyte has gone from approximately \$9.27 million in revenues in 2009 to approximately \$1.89 billion in revenues in 2018 . . . ." *Id.* ¶ 1. And their sales are expected to increase. *Id.* 

The Agreement establishes separate territories for Novartis and Incyte to sell products that are licensed under the Agreement. In essence, the two companies have divided the world into two spheres: "Novartis holds the rights to develop and commercialize any Licensed Products containing the Compounds outside the U.S. and Incyte holds the rights to market and sell products containing those same Compounds within the U.S." Id. ¶ 2.

The division of the companies' territories into these two geographic spheres is important in the analysis of the parties' royalty obligations. That is because each party pays royalties to the other "based on defined percentages of annual sales of Licensed Products in its respective territory." *Id.* Section 8.3(a) of the Agreement provides for the payment of royalties by Novartis to Incyte. Agreement § 8.3(a) ("Novartis shall pay to Incyte royalties on aggregate Net Sales of each License Product on a Licensed-Product-by-Licensed Product basis, at the followings rates: ...."). Section 8.3(b) of the Agreement provides for the payment of royalties by Incyte to Novartis. Agreement § 8.3(b) ("Incyte shall pay to Novartis a royalty, on a JAK Licensed Product-by-JAK Licensed Product basis, on annual Net Sales of such JAK Licensed Product in the JAK Field in the Incyte Territory at the following rates ...."). The royalty rate that Incyte must pay Novartis varies based on the aggregate annual net sales of a "JAK Licensed Product"—ranging from 2% for the first

<sup>&</sup>lt;sup>3</sup> Novartis sells the drug outside of the U.S. under the trade name "Jakavi." Compl. ¶ 14.

<sup>&</sup>lt;sup>4</sup> The Complaint describes the catapulting sales of ruxolitinib in the United States—Incyte's territory—but does not specify the amount of sales in Novartis's territory—the rest of the world.

\$100,000,000 in sales to 5% on annual net sales in excess of \$300,000,000. *Id.* While the rates are relatively low, when applied to a base of sales in the billions, the amount of the annual royalty payments is significant.

The obligations of the parties to pay royalties under the Agreement are not indefinite.

Section 8.3 of the Agreement describes circumstances in which the parties' obligations to pay royalties either terminate entirely or "step down" to a lower rate. This provision is at the heart of this dispute. It reads in full as follows:

Royalties payable under this Section 8.3 shall be paid by the applicable Party on a Licensed Product-by-Licensed Product and country-by-country basis from the date of First Commercial Sale of each Licensed Product with respect to which royalty payments are due for a period which is the longer of: (i) the last to expire of any Valid Claim of Licensed Patent Rights Covering such Licensed Product in such country; (ii) ten (10) years following the date of First Commercial Sale in such country; and (iii) the expiration of Regulatory Exclusivity for such Licensed Product in such country (each such term with respect to a Licensed Product and a country, a "Royalty Term"). Notwithstanding the foregoing, in the event that either (A) the Royalty Term continues solely due to clause (ii) (i.e. in a specific country the Licensed Product is neither Covered by a Valid Claim of Licensed Patent Rights nor is such Licensed Product subject to Regulatory Exclusivity) or (B) Generic Competition exists with respect to a Licensed Product in a country with respect to a royalty-reporting period, then the royalty rates in such country for such Licensed Product (for such royalty-reporting period, if applicable) will be reduced to fifty percent (50%) of the applicable rate in Section 8.3(a) or 8.3(b), based on the weighted average annual royalty rate in the Novartis Territory or the Incyte Territory, as the case may be, beginning on January 1st of the Calendar Year following the first Calendar Year in which there exists a situation described in (A) or (B) of this sentence in the applicable country.

Agreement  $\S$  8.3(c).

The first sentence of Section 8.3(c) describes the circumstances in which the parties' royalty obligations for a given product will terminate entirely. The obligation to pay royalties for a "Licensed Product" remains in effect from the date of its "First Commercial Sale" in a country until the last of one of the three contingencies identified in clauses (i), (ii), and (iii) occurs. Those contingencies are "(i) the last to expire of any Valid Claim of Licensed Patent Rights Covering such Licensed Product in such country; (ii) ten (10) years following the date of First Commercial Sale in

such country; and (iii) the expiration of Regulatory Exclusivity for such Licensed Product in such country . . . . " *Id*.

The second sentence of Section 8.3(c) is the "step down" provision. "Step down" because it provides that under certain circumstances the royalty rate steps down to 50% of the rate that would otherwise be applicable. *Id.* ("[I]n the event that . . . the Royalty Term continues solely due to clause (ii) . . . then the royalty rates in such country for such Licensed Product (for such royalty-reporting period, if applicable) will be reduced to fifty percent (50%) . . . ."). As relevant here, the step down provision applies if royalties remain payable solely because of the circumstances described in clause (ii) of the first sentence of Section 8.3(c)—that is, if the product is still within the 10 year period following the "First Commercial Sale" of the product within a given country. Put differently, the step down only applies if there is no continuing obligation to pay royalties under either clause (i) or (iii) of the first sentence of Section 8.3(c)—"i.e. in a specific country the Licensed Product is neither Covered by a Valid Claim of Licensed Patent Rights nor is such Licensed Product subject to Regulatory Exclusivity." *Id.* The parties' disagreement in this case turns on whether such an obligation persists under either of those clauses—and, thus, requires a close reading of them.

Like much of the Agreement, Section 8.3 uses a number of capitalized words for which the Agreement provides precise definitions. *See id.* art. I. It is impossible to understand the meaning of Section 8.3 without a glossary of a number of the relevant defined terms. So one is provided in the following note.<sup>6</sup> The Court examines the relevant definitions in depth below, but two defined terms

<sup>&</sup>lt;sup>5</sup> The royalty rate also steps down by 50% if there is "Generic Competition" for the relevant product in the relevant country. Neither party argues that this section of the step down provision is germane to the resolution of this dispute. Compl. ¶ 20.

<sup>&</sup>lt;sup>6</sup> "<u>Commercialization</u>" or "<u>Commercialize</u>" means any activities directed to obtaining pricing and/or reimbursement approvals, marketing, promoting, distributing, importing, offering to sell, and/or selling a product (including establishing the price for such product). Agreement § 1.19.

<sup>&</sup>quot;Covering" or "Covered" with respect to a product, technology, process or method, means that, but for a license granted to a Person under a Valid Claim included in the Patent Rights under which such license is granted, the Development, manufacture, Commercialization and/or other use of such product or the practice of such technology, process or method, by such Person would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet

merit brief attention here. Clause (i) refers to the expiration of "Licensed Patent Rights" covering the relevant product. "Licensed Patent Rights" means "with respect to the Patent Rights licensed to Novartis hereunder, the Incyte Patent Rights and with respect to the Patent Rights licensed to Incyte hereunder, the Novartis Patent Rights." *Id.* § 1.67. Clause (iii) refers to the expiration of "Regulatory Exclusivity" for the relevant product. "Regulatory Exclusivity" means "the ability to exclude Third Parties from Commercializing a Licensed Product in a country, either through data exclusivity rights, orphan drug designation, or such other rights conferred by a Regulatory Authority in such country, other than through Patent Rights." *Id.* § 1.101. These definitions are critical to the parties' dispute because, if any "Valid Claim of Licensed Patent Rights" and "Regulatory

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issued, would infringe such Valid Claim if it were to issue). Agreement § 1.23.

<sup>&</sup>quot;Incyte Patent Rights" means all Patent Rights that (a) are Controlled by Incyte or any of its Affiliates as of the Effective Date or during the Term; and (b) are necessary or useful to Develop, manufacture or Commercialize any of (x) c-MET Licensed Compounds and c-MET Licensed Products (the "c-MET Patent Rights"); and (y) JAK Licensed Compounds and JAK Licensed Products (the "JAK Patent Rights"); provided, however, that Incyte Patent Rights specifically exclude Joint IP. The c-MET Patent Rights that exist as of the Effective Date are set forth in Exhibit A-1 and the JAK Patent Rights that exist as of the Effective Date are set forth on Exhibit A-2. Agreement § 1.47.

<sup>&</sup>quot;Licensed Patent Rights" means with respect to the Patent Rights licensed to Novartis hereunder, the Incyte Patent Rights and with respect to the Patent Rights licensed to Incyte hereunder, the Novartis Patent Rights. In each case, Patent Rights forming part of the Joint IP shall be included, as applicable, in the Incyte Patent Rights and Novartis Patent Rights. Agreement § 1.67.

<sup>&</sup>quot;<u>Licensed Product</u>" means a c-MET Licensed Product or a JAK Licensed Product. As used in this Agreement, except where not appropriate in context, the Licensed Product also includes the Licensed Compound contained in the Licensed Product. Agreement § 1.68.

<sup>&</sup>quot;Novartis Patent Rights" means all Patent Rights that: (a) are Controlled by Novartis or its Affiliates as of the Effective Date or during the Term; and (b) are necessary or useful to Develop, manufacture or Commercialize all or any of the Licensed Compounds and Licensed Products; provided, however, that Novartis Patents Rights specifically excludes Joint IP. Agreement § 1.79.

<sup>&</sup>quot;Patent Rights" means all patents and patent applications in any country in the world, including any continuations, continuations-in-part, divisions, provisionals or any substitute applications, any patent issued with respect to any such patent applications, any reissue, reexamination, renewal or extension (including any supplemental protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all non-United States counterparts of any of the foregoing. Agreement § 1.86.

<sup>&</sup>quot;Regulatory Exclusivity" means the ability to exclude Third Parties from Commercializing a Licensed Product in a country, either through data exclusivity rights, orphan drug designation, or such other rights conferred by a Regulatory Authority in such country, other than through Patent Rights. Agreement § 1.101.

<sup>&</sup>quot;Valid Claim" means (a) a claim of an issued patent that has not expired or been abandoned, or been revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) or (b) a claim within a patent application that has not been revoked, cancelled, withdrawn, held invalid or abandoned and which has not been pending for more than seven (7) years from the date of its first filing. Agreement § 1.112.

Exclusivity" in a country with respect to a given product have both expired, the step down applies; if they have not expired, the step down does not apply.

# B. Patent Rights and Regulatory Exclusivity for Jakafi

In the United States, "Jakafi is covered by eight patents, which range in expiration from December 12, 2026 (the earliest expiration date) to June 12, 2028 (the latest expiration date)." Compl. ¶ 26. The patents associated with Jakafi are numbered "7598257, 8415362, 8722693, 8822481, 8829013, 9079912, 9814722, and 10016429 . . . ." *Id.* ¶ 26. As a result, "[p]atent coverage [for Jakafi] will continue until at least June 12, 2028 . . . ." *Id.* ¶ 4.

The U.S. Food and Drug Administration (the "FDA") regulates pharmaceutical products in the United States. As a general matter, federal law requires that any new prescription drug be shown to be safe and effective for its intended use before the drug can be marketed. The FDA is the gatekeeper for the marketing of new prescription drugs in the United States. The FDA has approved several uses for Jakafi. "Per the [FDA], Jakafi is indicated for the treatment of three medical conditions in certain patient populations: (1) intermediate or high-risk myelofibrosis; (2) polycythemia vera; and (3) steroid-refractory acute graft-versus-host disease." *Id.* 

"Incyte received approval from the FDA for its . . . New Drug Application ('NDA') for Jakafi's myelofibrosis indication on November 16, 2011. This indication relates to a rare form of blood cancer." *Id.* ¶ 23. The FDA's approval granted Incyte an "orphan drug exclusivity ('ODE') designation under the Orphan Drug Act." *Id.* ¶ 4. The ODE designation lasted for seven years. *Id.* ¶ 29. Therefore, "Incyte was aware that the ODE for Jakafi with respect to the myelofibrosis indication would expire in November 2018." *Id.* ¶ 23.

Incyte later submitted a number of supplemental NDA submissions to the FDA. "Certain of these supplemental NDA submissions (each a 'sNDA' and together the 'sNDAs') related to new indications for Jakafi." *Id.* ¶ 24. The FDA approved two sDNAs for new uses of Jakafi. On

December 4, 2014, the FDA approved an application to use Jakafi to treat polycythemia vera, another rare blood cancer. *Id.* And on May 24, 2019, the FDA approved an application to use Jakafi to treat "steroid-refractory acute graft-versus-host disease, which is a condition that occurs after an allogenic tissue transplant, whereby the donor cells view the host/recipient's body as 'foreign' and react accordingly by attacking the organs and/or tissue of the host." *Id.* The approvals for "both included seven-year ODE status." *Id.* The latter approval also included "New Clinical Investigation ('NCI') drug exclusivity" "which expires on May 24, 2022 (*i.e.*, three (3) years after FDA approval)." *Id.* ¶¶ 4, 28.

As a result, "[t]hree regulatory exclusivities are also still in effect in the United States for Jakafi . . . : (a) one ODE for the polycythemia vera indication, which expires on December 4, 2021 (*i.e.*, seven (7) years after FDA approval); (b) one ODE for the steroid-refractory acute graft-versus-host disease indication, which expires on May 24, 2026 (*i.e.*, seven (7) years after FDA approval); and (c) the NCI exclusivity for the steroid-refractory acute graft-versus-host disease indication, which expires on May 24, 2022." *Id.* ¶ 28. "Incyte's ODE for the myelofibrosis indication expired seven (7) years from approval of the NDA—*i.e.*, on November 16, 2018." *Id.* ¶ 29.

# C. Incyte Invokes the Step Down Provision

Incyte began to pay royalties to Novartis for U.S. sales of Jakafi in 2014. "Commencing in the second half of 2014 and through the fourth quarter of 2018, Incyte submitted quarterly royalty reports to Novartis consistent with Section 8.4 of the Agreement and then paid the corresponding royalty amounts." *Id.* ¶ 32. Each of those royalty reports described Incyte's sales of Jakafi for the quarter and then calculated the amount of royalties due to Novartis pursuant to the Agreement. *Id.* There appear to have been no issues with the billing and payment of royalties through 2018. Problems arose in 2019, however, following the November 2018 expiration of the Incyte's orphan drug exclusivity for the use of Jakafi for the myelofibrosis indication.

The year began normally. "On May 1, 2019, Incyte's Finance Director and Assistant Controller sent Incyte's royalty report for the quarter ending March 31, 2019 to Novartis, reporting \$375,611,113.00 in Net Sales for the quarter and a royalty payment owed of \$13,404,945.00 (the "Initial Q1 2019 Royalty Amount"). Novartis issued its invoice corresponding to the Initial Q1 2019 Royalty Amount on May 6, 2019, expecting it to be paid in full." *Id.* ¶ 37. It was not.

Instead, "[o]n May 16, 2019, without any prior notice following the expiration of the ODE for the first indication six months earlier, Incyte suddenly sent Novartis a revised royalty report for the quarter ending March 31, 2019, notifying Novartis that it was unilaterally reducing the royalty amount by 50% and demanding either a revised invoice or a credit memo. On June 17, 2019, Incyte notified Novartis that it had paid half of the Initial Q1 2019 Royalty Amount by wire transfer." *Id.* ¶ 38.

Novartis disagreed with Incyte's decision to step down the royalty rates as a result of the November 2018 expiration of the myelofibrosis ODE. "Novartis explained that ODE expiration for the myelofibrosis indication did not entitle Incyte to reduce royalties owed to Novartis, whether for the first quarter of 2019 or otherwise, under the express terms of the Agreement. Novartis also flagged that the Jakafi product was still subject to full patent protections." *Id.* ¶ 39. In response, "Incyte insisted that it would be reducing the royalty payments for Jakafi moving forward by email dated June 21, 2019." *Id.* In its complaint in this case, Novartis highlights the lack of notice before Incyte's decision to trigger the Agreement's step down provision. "Prior to the myelofibrosis ODE expiration, Incyte did not send any contemporaneous notification to Novartis that said that the Step Down was coming into effect. And after the myelofibrosis ODE expiration, Incyte did not advise Novartis that the Step Down provision should now apply (as it now contends)." *Id.* ¶ 43.

The parties worked to resolve their disagreement pursuant to the dispute resolution provisions of the Agreement. Following procedures set out in the Agreement, "the parties'

respective General Counsels engaged in discussions regarding the royalty dispute on July 26, 2019." *Id.* ¶ 45. The parties then "escalated the dispute to the Executive Officer level by correspondence dated August 21, 2019." *Id.* After those formal efforts to resolve the dispute, Novartis has "further conferred with Incyte on multiple occasions in good faith in an effort to resolve the parties' dispute as to the amount of royalties owed by Incyte." *Id.* ¶ 46. Despite those efforts, the parties have not been able to resolve their disagreement. *Id.* Instead, "Incyte has clung to its misreading of the Agreement and has refused to pay the full amount of royalties owed to Novartis for the 2019 fiscal year and moving forward." *Id.* As a result, Novartis brought this action.

Novartis claims that "Incyte unilaterally and improperly invoked Section 8.3(c) to reduce its royalty payments to Novartis by 50% through 2021" in violation of the Agreement. *Id.* ¶ 5.

Novartis alleges that "[w]hile Incyte's ODE status for one indication—the first indication, for intermediate or high-risk myelofibrosis—expired in November [of] 2018, patent protections exist for the overall product (six of which apply to the myelofibrosis indication) and regulatory exclusivities remain valid and unaffected on two indications." *Id.* ¶ 6. According to Novartis, it "never would have agreed to the Agreement if it understood the narrow Step Down in Section 8.3(c) to apply as Incyte now argues it should apply," and claims that "[u]ntil May [of] 2019, Incyte never conveyed, in words or substance, the position that it now apparently is advancing regarding the Step Down." *Id.* ¶ 44.

#### D. Procedural History

Novartis filed its complaint on January 15, 2020, asserting that Incyte had breached the parties' contract, and seeking a declaratory judgment requiring repayment of the delayed royalties with interest. *Id.* ¶ 7. On April 20, 2020, Incyte moved to dismiss Novartis's complaint. *See* Notice Mot. to Dismiss Compl. Pl. Novartis Int'l Pharm. AG, Dkt. No. 32; Mem. Law Supp. Incyte Corp.'s Mot. to Dismiss ("Mem."), Dkt. No. 35. On May 18, 2020, Novartis opposed Incyte's motion,

Novartis Int'l Pharm. AG's Mem. Law Opp'n to Incyte Corp.'s Mot. to Dismiss ("Opp'n"), Dkt. No. 43, and on June 1, 2020 Incyte replied. Reply Mem. Law Further Supp. Incyte Corp.'s Mot. to Dismiss ("Reply"), Dkt. No. 48.

### II. LEGAL STANDARD

## A. Rule 12(b)(6)

A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). If a complaint fails to meet this pleading standard, a defendant may move to dismiss it for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). In deciding a motion to dismiss under Rule 12(b)(6), the Court must "accept[] all factual allegations [in the complaint] as true and draw[] all reasonable inferences in the plaintiff's favor." DiFolco v. MSNBC Cable L.L.C., 622 F.3d 104, 110–11 (2d Cir. 2010) (alterations in original) (quoting Shomo v. City of New York, 579 F.3d 176, 183 (2d Cir. 2009)). To avoid dismissal, a complaint must allege "sufficient facts, taken as true, to state a plausible claim for relief." Johnson v. Priceline.com, Inc., 711 F.3d 271, 275 (2d Cir. 2013) (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555–56 (2007)). A claim is facially plausible when a plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Asheroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 556). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." Id.

In addition to the complaint, courts may consider the facts from "documents attached to the complaint as exhibits[] and documents incorporated by reference in the complaint," including contracts. *DiFolco*, 622 F.3d at 111 (2d Cir. 2010) (citing *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002) and *Hayden v. Cnty. of Nassau*, 180 F.3d 42, 54 (2d Cir. 1999)). And though the Court must accept the facts as alleged in the complaint as true, "[w]hen allegations contained within

the Court need not accept the allegations contained within the complaint as true." Rozsa v. May

Davis Grp., Inc., 187 F. Supp. 2d 123, 128 (S.D.N.Y. 2002) (citation omitted). In deciding this motion to dismiss, the Court has considered the Agreement and its amendments because they are integral to the complaint.

## B. Contract Interpretation Under New York Law

The Agreement is governed by New York law. Agreement § 14.1. Under New York law, to state a claim for breach of contract "the complaint must allege: (i) the formation of a contract between the parties; (ii) performance by the plaintiff; (iii) failure of defendant to perform; and (iv) damages." Orlander v. Staples, Inc., 802 F.3d 289, 294 (2d Cir. 2015) (quoting Johnson v. Nextel Comme'ns, Inc., 660 F.3d 131, 142 (2d Cir. 2011)). "When interpreting a contract, our 'primary objective is to give effect to the intent of the parties as revealed by the language of their agreement." Chesapeake Energy Corp. v. Bank of N.Y. Mellon Tr. Co., 773 F.3d 110, 113–14 (2d Cir. 2014) (ellipsis omitted) (quoting Compagnie Financiere de CIC et de L'Union Europeenne v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 232 F.3d 153, 157 (2d Cir. 2000)). "The words and phrases in a contract should be given their plain meaning, and the contract should be construed so as to give full meaning and effect to all of its provisions." Id. at 114 (brackets omitted) (quoting Olin Corp. v. Am. Home Assur. Co., 704 F.3d 89, 99 (2d Cir. 2012)).

As a "threshold question," courts must consider if "the terms of the contract are ambiguous." Alexander & Alexander Servs., Inc. v. These Certain Underwriters at Lloyd's, 136 F.3d 82, 86 (2d Cir. 1998) (citations omitted). "Whether or not a writing is ambiguous is a question of law to be resolved by the courts." Orlander, 802 F.3d at 294 (quoting W.W.W. Assocs., Inc. v. Giancontieri, 77 N.Y.2d 157, 162 (1990)). "Ambiguity is determined by looking within the four corners of the document, not to outside sources." CVS Pharmacy, Inc. v. Press Am., Inc., 377 F. Supp. 3d 359, 374

(S.D.N.Y. 2019) (quoting JA Apparel Corp. v. Abboud, 568 F.3d 390, 396 (2d Cir. 2009)); see also Brad H. v. City of New York, 17 N.Y.3d 180, 186 (2011) ("Ambiguity is determined within the four corners of the document; it cannot be created by extrinsic evidence that the parties intended a meaning different than that expressed in the agreement . . . .").

Courts consider a contract unambiguous when it has "a definite and precise meaning," unattended by danger of misconception . . . and concerning which there is no reasonable basis for a difference of opinion." Olin Corp., 864 F.3d at 99 (2d Cir. 2017) (quoting Hunt Ltd. v. Lifschultz Fast Freight, Inc., 889 F.2d 1274, 1277 (2d Cir. 1989)). Conversely, "[a] contract is ambiguous under New York law if its terms could suggest more than one meaning when viewed objectively by a reasonably intelligent person who has examined the context of the entire integrated agreement and who is cognizant of the customs, practices, usages and terminology as generally understood in the particular trade or business." Orchard Hill Master Fund Ltd. v. SBA Comme'ns Corp., 830 F.3d 152, 156–57 (2d Cir. 2016) (quoting Chesapeake Energy Corp., 773 F.3d at 114). "The language of a contract . . . is not made ambiguous simply because the parties urge different interpretations." Oppenheimer & Co. v. Trans Energy, Inc., 946 F. Supp. 2d 343, 348 (S.D.N.Y. 2013) (internal quotation marks omitted) (quotation omitted).

Courts analyze ambiguity using the "normal rules of contract interpretation: words and phrases should be given their plain meaning and a contract should be construed as to give full meaning and effect to all of its provisions." *Orchard Hill*, 830 F.3d at 157 (internal quotation marks omitted) (quoting *Orlander*, 802 F.3d at 295); *see also Brad H.*, 17 N.Y.3d at 185 ("To determine whether a writing is unambiguous, language should not be read in isolation because the contract must be considered as a whole."). But a court applying New York law "may neither rewrite, under the guise of interpretation, a term of the contract when the term is clear and unambiguous, nor redraft a contract to accord with its instinct for the dispensation of equity upon the facts of a given

case." Bank of N.Y. Mellon v. WMC Mortg., LLC, 12-cv-7096 (DLC), 2015 WL 2449313, at \*2 (S.D.N.Y. May 22, 2015) (quoting Cruden v. Bank of N.Y., 957 F.2d 961, 976 (2d Cir. 1992)). Rather, "a written agreement that is complete, clear and unambiguous on its face must be enforced according to the plain meaning of its terms." MHR Cap. Partners LP v. Presstek, Inc., 12 N.Y.3d 640, 645 (2009) (quotation omitted).

On a motion to dismiss, "a district court may dismiss a breach of contract claim only if the terms of the contract are unambiguous." *Orchard Hill*, 830 F.3d at 156; *see also Eternity Glob. Master Fund Ltd. v. Morgan Guar. Tr. Co. of N.Y.*, 375 F.3d 168, 178 (2d Cir. 2004) ("[I]f a contract is ambiguous as applied to a particular set of facts, a court has insufficient data to dismiss a complaint for failure to state a claim."). In other words, courts are not "obliged to accept the allegations of the complaint as to how to construe a contract," but they "should resolve any contractual ambiguities in favor of the plaintiff on a motion to dismiss." *Maniolos v. United States*, 741 F. Supp. 2d 555, 567 (S.D.N.Y. 2010), *aff'd*, 469 F. App'x 56 (2d Cir. 2012) (internal quotation marks omitted) (quoting *Subaru Distrib. Corp. v. Subaru of Am., Inc.*, 425 F.3d 119, 122 (2d Cir. 2005)).

## III. DISCUSSION

# A. Incyte's "Regulatory Exclusivity" Has Expired

Incyte's "Regulatory Exclusivity" over Jakafi has expired under the unambiguous terms of because Incyte can no longer prevent third parties from commercializing ruxolitinib to treat myelofibrosis. The expiration of the ODE for the treatment of myelofibrosis with Jakafi permits the sale of generic ruxolitinib to treat that condition. *See Sigma-Tau Pharms., Inc. v. Schwetz,* 288 F.3d 141, 145 (4th Cir. 2002) ("Congress made clear its intention that [section 360cc] was to be disease-specific, not drug-specific. In other words, the statute as written protects uses, not drugs for any and all uses."). The parties agree the expiration of the ODE for myelofibrosis permits the sale of generic versions of the drug for that indication.

The parties disagree, however, about whether the language of the step down provision related to the expiration of "Regulatory Exclusivity" requires that Incyte have lost the right to exclude generic competition for Jakafi for any purpose—or, instead, "Regulatory Exclusivity" continues so long as Incyte has the right to exclude generic competition for Jakafi for some purposes. Incyte takes the former position: because it has lost the ability to exclude generic competition for the myelofibrosis indication for ruxolitinib, it no longer has regulatory exclusivity. Novartis takes the latter position: even though generic competition is permitted for one indication of ruxolitinib, because Incyte can still protect against generic competition for other uses of the drug, Incyte retains regulatory exclusivity.

Much of the dispute centers on the meaning of the word "any" in the relevant provision of the Agreement. For the reasons that follow, the Court concludes that the language of the Agreement is unambiguous—to maintain regulatory exclusivity, Incyte must be able to exclude others from any sale of the product. They must be able to keep others from marketing the product for any purpose. "Any" in this context unambiguously means "all."

Here, again, is the relevant language from the Agreement:

Royalties payable under this Section 8.3 shall be paid by the applicable Party on a Licensed Product-by-Licensed Product and country-by-country basis from the date of First Commercial Sale of each Licensed Product with respect to which royalty payments are due for a period which is the longer of: . . . (iii) the expiration of Regulatory Exclusivity for such Licensed Product in such country . . . .

Agreement § 8.3(c). "Regulatory Exclusivity" means "the ability to exclude Third Parties from Commercializing a Licensed Product in a country . . . other than through Patent Rights." *Id.* § 1.101. A "Licensed Product" is "a product or product candidate that contains one or more JAK Licensed Compounds as the active ingredient[.]" *Id.* § 1.61. Jakafi is a "Licensed Product" containing the JAK Licensed Compound ruxolitinib. *See* Compl. ¶ 1. And "Commercialization" or "Commercialize" means "*any* activities directed to obtaining pricing and/or reimbursement

approvals, marketing, promoting, distributing, importing, offering to sell, and/or selling a product (including establishing the price for such product)." Agreement § 1.19 (emphasis added). Replacing the term "Commercializing" with the definition for the term "Commercialization," "Regulatory Exclusivity" means "the ability to exclude Third Parties from [any activities directed to obtaining pricing and/or reimbursement approvals, marketing, promoting, distributing, importing, offering to sell, and/or selling a product (including establishing the price for such product)] a Licensed Product in a country . . . other than through Patent Rights."

The parties dispute the meaning of the word "any" that is italicized in the text above.

Novartis argues that "the word 'any' is employed repeatedly throughout the Agreement to connote the equivalent of 'at least one' within a potential class of group, where there is an unknown quantity of things within the class or group." Opp'n at 18–19. So Novartis reads the provision to provide that Incyte maintains Regulatory Exclusivity so long as it can exclude third parties from "at least one" activity<sup>8</sup> "directed to obtaining pricing . . . ."

The replacement of the term "

<sup>&</sup>lt;sup>7</sup> The replacement of the term "Commercializing" here with the definition of the Agreement's defined term, "Commercialize," eliminates the gerund. "Ing" as the suffix to a verb refers to "action or process." *-Ing*, Merriam Webster Online Dictionary, https://www.merriam-webster.com/dictionary/-ing (last visited Feb. 9, 2021). The term "Commercializing," then refers to the action of undertaking "any activities directed to obtaining," rather than the activities themselves. Recognizing that the defined term "Regulatory Exclusivity" uses the gerund "Commercializing" strengthens the Court's interpretation of the provision. For simplicity, however, the Court has transposed only the definition of "Commercialize" here.

<sup>&</sup>lt;sup>8</sup> Note that explaining this argument requires the Court to modify the definition of the term "Commercialize" to refer to a singular "activity," rather than the "activities" described in the actual definition of the term.

<sup>&</sup>lt;sup>9</sup> In its opposition brief, Novartis cites four dictionaries to support its interpretation of the word "any":

Cambridge Dictionary defines "any" as "some, or even the *smallest* amount or number of." Oxford English Dictionary defines "any", including when used as an adjective with a "plural or mass noun"—*i.e.*, "any" before "activities" in the defined term "Commercialize"—as "of whatever sort or kind" (in the context of qualitative force in the positive or neutral sense) and "used" to refer to a number, however great or *small*, of (separable things), or a quantity or amount of (a substance, etc.), even the *smallest*" (in the context of quantitative force).

Oxford similarly defines "any," when being used as an adjective with a "plural or mass noun" and "[i]n interrogative, hypothetical, and conditional contexts," as "used to refer to an unspecified number or quantity of a thing or things, no matter how much or how many; *some*."

In relevant part, the American Heritage Dictionary defines "any" as "one or some; no matter which," "no matter how much or how *little*," and "no matter how much or how *few*, *some*," and the Merriam-Webster Dictionary defines "any" as "one or more—used to indicate an undetermined number or amount."

Opp'n at 21. However, Novartis's selective quotations obscure the relevant alternative meanings of "any" contained in the dictionaries it cites. For example, American Heritage Dictionary defines "any" also as "3. Every: Any dog likes

This is not the correct construction of the phrase. "Any" does have multiple meanings, but in this context—following the affirmative verb "exclude"—it means "all." To construe the contract's language, the court looks to its plain meaning. "Exclude" means "to prevent or restrict the entrance of" or "to bar from participation, consideration, or inclusion." *Exclude*, Merriam Webster Online Dictionary, https://www.merriam-webster.com/dictionary/exclude (last visited Feb. 10, 2021). *Garner's Modern English Usage* describes the uses and meanings of the word "any" as follows:

any. A. Uses and Meanings. As an adjective, any has essentially six uses. (1) The most common occurrence is in conditional, hypothetical, and interrogative sentences, where any means "a (no matter which)" or "some" <if you have any salt, I'd like to borrow some > < if any problem were to arise, what would it likely be? > < is there any evidence of the crime?>. (2) In negative assertions, it creates an emphatic negative, meaning "not at all" or "not even one" <it was not in any way improper> <she did not know any member who was at the event>. (3) In affirmative sentences, it means "every" or "all" <any attempt to flout the law will be punished > <you are required to produce any documents relating to the issue>. (4) In a sentence implying that a selection or discretionary act will follow, it may mean "one or more (unspecified things or people); whichever; whatever' < any student may seek a tutorial > < pick any books you like > <a good buy at any price >. (5) In a declarative sentence or imperative involving a qualitative judgment, it means "of whatever kind" < you'll have to take any action you consider appropriate>. In this sense, there is sometimes the implication that the quality may be poor <any argument is better than no argument>. (6) In a declarative sentence involving a quantitative judgment, it means "unlimited in amount or extent; to whatever extent necessary" <this computer can process any quantity of numbers simultaneously>. In a related colloquial sense, it may mean "of great size or considerable extent' when following a negative <we won't be able to make any real headway this week>. As an adverb, any is used before a comparative adjective or adverb in questions and in negative sentences <is he any better?> <they can't walk any faster>.

Any, Bryan A. Garner, Garner's Modern English Usage 57 (4th ed. 2016) (emphasis added). 10

meat." Any, American Heritage Dictionary, https://ahdictionary.com/word/search.html?q=any (last visited Feb. 10, 2021). The Merriam-Webster defines "any" also as "2b: All—used to indicate a maximum or whole // He needs any help he can get." Any, Merriam-Webster Online Dictionary, https://www.merriam-webster.com/dictionary/any (last visited Feb. 10, 2021). And Oxford English Dictionary defines "any" as "1c. With singular noun in affirmative contexts, frequently with emphatic force: used to refer to a member of a particular group or class without distinction or limitation (hence implying every member of the class or group, since every one may in turn be taken as representative)." Any, Oxford English Dictionary, https://www-oed-

com.libproxy.berkeley.edu/view/Entry/8973?redirectedFrom=any#eid1193234 (last visited Feb. 10, 2021).

<sup>&</sup>lt;sup>10</sup> As noted above, three of the dictionaries Novartis cites provide multiple meanings of the word "any" to be employed

As used in the definition of "Regulatory Exclusivity," the word "any" after "exclude" means all. That is an affirmative sentence, not a sentence implying that a discretionary act will follow.

Think about the language used in the definition of "Regulatory Exclusivity" in another context. If your doctor tells you to exclude any sweets from your diet, do you understand her to be telling you that you can eat as much cake as you want so long as you do not eat cookies? No, you know that you are supposed to exclude all sweets from your diet. If the lead lawyer on your team asks you to exclude any frivolous arguments from the brief, does that mean that you can include several arguments that are howlers so long as you include one good one? No, again, you know that you are expected to omit all frivolous arguments. If you ask your spouse to exclude your annoying neighbor from the invitation list to any barbecue at your house, are you saying that you will be happy for him to show up at five of the next six barbecues? No, you communicated that you never want your annoying neighbor to appear on the barbecue guest lists. If you said that you were able to exclude any pets from your house, would you mean that you could only exclude cats, but not dogs? No, you would be touting your ability to exclude all pets.

"Any" has multiple meanings, but as the *Garner's* explanation shows, in the English language, the meaning of the word can be definitely determined by its context. The fact that the word has multiple meanings in a different contexts does not create ambiguity: it has a clear meaning in the context of this definition. To have "Regulatory Exclusivity," Incyte must have the ability to exclude third parties from "any" activities to sell or market ruxolitinib.

This interpretation is only strengthened by the fact that "Regulatory Exclusivity" is focused on the exclusion from the commercialization of *the product*—not, as Novartis would argue, a particular use of the product. "Regulatory Exclusivity" means "the ability to exclude Third Parties from Commercializing *a Licensed Product*…." Agreement § 1.101 (emphasis added). By its express

in different contexts—not just "one or some," as Novartis describes.

terms the definition requires that the party be able to exclude commercialization of the product as a whole—not a particular indication of the product, as suggested by the interpretation proposed by Novartis.

In its argument regarding the interpretation of this provision, Novartis points out that there remains patent protection against the generic competition that might theoretically take advantage of the opportunity to sell ruxolitinib to treat myelofibrosis. Opp'n at 23 ("Incyte concedes ongoing 'patent protections,' which allows it to both delay and challenge any generic competitor's request for FDA approval. Incyte's suggestion that the expiration of the [myelofibrosis] designation has 'serious potential consequences,' thus leaps to the far-fetched scenario in which a potential generic competitor successfully challenges the validity of Incyte's patents and receives FDA approval to compete." (citation omitted)). But patent protections do not impact whether or not "Regulatory Exclusivity" exists, as defined in the Agreement. Again, "Regulatory Exclusivity" means "the ability to exclude Third Parties from Commercializing a Licensed Product in a country . . . other than through Patent Rights." Agreement § 1.101 (emphasis added). The plain language of the definition states that it does not matter whether Incyte's patents continue to protect against generic competition to determine whether "Regulatory Exclusivity" exists.

In sum, because Incyte no longer has the capacity to prevent generic competition for the myelofibrosis indication by means other than its patents, it no longer has "Regulatory Exclusivity"—it cannot exclude generic competitors from taking any activity to market or sell ruxolitinib. That Incyte continues to have sole access to the U.S. market for the other two FDA-approved indications for Jakafi does not provide it with "Regulatory Exclusivity" as defined in the Agreement.

# B. The "Relevant" "Licensed Patent Rights" Are Not Unambiguously Limited to Novartis Patent Rights

It is unclear how the defined term "Licensed Patent Rights" is to be applied in the context of Section 8.3(c). Both parties raise plausible interpretations of the language—unfortunately, the text

of the Agreement does not mandate one reading over the other. As a result, it is ambiguous. At the heart of the problem is the defined term "Licensed Patent Rights" as used in Section 8.3(c) of the Agreement.

Here, again, is the text of the relevant portion of Section 8.3(c) of the Agreement:

Royalties payable under this Section 8.3 shall be paid by the applicable Party on a Licensed Product-by-Licensed Product and country-by-country basis from the date of First Commercial Sale of each Licensed Product with respect to which royalty payments are due for a period which is the longer of: (i) the last to expire of any Valid Claim of Licensed Patent Rights Covering such Licensed Product in such country....

Agreement § 8.3(c). The term "Licensed Patent Rights" means "with respect to the Patent Rights licensed to Novartis hereunder, the Incyte Patent Rights and with respect to the Patent Rights licensed to Incyte hereunder, the Novartis Patent Rights. In each case, Patent Rights forming part of the Joint IP shall be included, as applicable, in the Incyte Patent Rights and Novartis Patent Rights." *Id.* § 1.67.

To help visualize the issue, here is the language from Section 8.3(c) of the Agreement, substituting the first sentence from the definition of "Licensed Patent Rights" for the defined term:

Royalties payable under this Section 8.3 shall be paid by the applicable Party on a Licensed Product-by-Licensed Product and country-by-country basis from the date of First Commercial Sale of each Licensed Product with respect to which royalty payments are due for a period which is the longer of: (i) the last to expire of any Valid Claim of [[A]with respect to the Patent Rights licensed to Novartis hereunder, the Incyte Patent Rights and [B] with respect to the Patent Rights licensed to Incyte hereunder, the Novartis Patent Rights] Covering such Licensed Product in such country....

*Id.*  $\S$  8.3(c) (with modifications).

The Court agrees with Incyte that the definition of "Licensed Patent Rights" establishes two separate "cases." Mem. at 14. For ease of reference, each of those "cases" is indicated above using the markers [A] and [B], which do not appear in the definition itself: [A] "with respect to the Patent Rights licensed to Novartis hereunder, the Incyte Patent Rights"; [B] "with respect to the Patent Rights licensed to Incyte hereunder, the Novartis Patent Rights."

Incyte also argues persuasively that the "use of the phrases 'with respect to' and '[i]n each case' in defining 'Licensed Patent Rights' creates a clear directionality." *Id.* at 15 (alteration in original). Incyte argues that if the defined term was not intended to create two separate, mutually exclusive, cases, the definition need not have included the words in the definition that indicate directionality: "Novartis invites this Court to rewrite by excising important words so that it would read, 'Licensed Patent Rights means ... the Incyte Patent Rights and ... the Novartis Patent Rights." *Id.* at 16.

The problem with Incyte's interpretation is that the Agreement does not clearly establish that both "cases" are mutually exclusive, or, if they are mutually exclusive, which case applies at a given time. Incyte fills in that gap with logical inference: it argues that "the Patent Rights *relevant to* Incyte's royalty payments for U.S. sales are any Novartis Patent Rights which Novartis licensed to Incyte, while the Patent Rights relevant to Novartis's royalty payments for foreign sales are any Incyte Patent Rights which Incyte licensed to Novartis." *Id.* at 15 (emphasis added).

The commercial logic Incyte presents to support this view seems reasonable. Incyte argues, in essence, that it would only agree to pay royalties if it needed to do so to sell its product—if Novartis did not have any patent rights that covered Incyte's sales of Jakafi in the U.S., it would be reasonable to stop paying royalties to Novartis. *See id.* at 15-17; Reply at 10. Incyte's economic reasoning leads it to the conclusion that only one of the two cases can exist at any time. And as an extension of this reasoning, Incyte concludes that the only case that is relevant to an assessment of its obligations to pay Novartis royalties on Jakafi is case [B]: it should only pay royalties on patent rights licensed to it by Novartis; once Novartis no longer has patent rights covering Jakafi that are licensed to Incyte, the royalty obligation should terminate, or be reduced. Mem. at 15–16.

That position finds some grounding in the language of the contract, because, as Incyte argues, the definition of "Licensed Patent Rights" describes two distinct "cases." But the language

of the contract does not unambiguously mandate this result. The contract does not say that the only Patent Rights relevant to Incyte's U.S. sales of Licensed Products are Novartis Patent Rights. It might have, but it does not. In their absence, Incyte fills those words into the contract based on its stated commercial expectations. Thus, as Novartis argues, Incyte's interpretation of the term "Valid Claim of Licensed Patent Rights," as applied, inserts "additional limitations into Section 8.3(c) that are not set forth in the Agreement." Opp'n at 13.

The defined term "Licensed Patent Rights" cannot be reviewed in isolation; it must be considered in the context of the sentence in which it is used. That language does not clearly support Incyte's position. The language that precedes clause (i) refers to royalty payments based on the sales of a "Licensed Product." There is not a clear link in the Agreement between the term "Licensed Product" in the clause that precedes clause (i) and the defined term "Licensed Patent Rights." *See* Agreement § 8.3(c) ("Royalties . . . shall be paid by the applicable Party on a *Licensed Product-by-Licensed Product . . . basis . . .* for a period which is the longer of: (i) the last to expire of any Valid Claim of [[A] *with respect to the Patent Rights* licensed to Novartis hereunder, the Incyte Patent Rights] . . . ." (emphasis added)). The introductory phrase refers to a product, clause (i) refers to a patent right; they are apples and oranges.

On the other hand, the language that follows the use of the defined term "Licensed Patent Rights" does provide a hook, explaining which patent rights are relevant—and that language does not support Incyte's interpretation of the provision. Clause (i) refers to "any Valid Claim of Licensed Patent Rights Covering such Licensed Product in such country . . . ." Id. (emphasis added). In that clause, the phrase "in such country" evidently refers to the country in which the relevant Licensed Product is sold. The language that follows the defined term "Valid Claim of Licensed Patent Rights" explains which Valid Claim of Licensed Patent Rights are relevant—those that cover the

Licensed Product in the relevant country. The text does not teach that only the patent rights of one of the two partners covering the product in the country are to be considered, as Incyte argues.

The word "any" is important in the analysis of this clause as well. Here, too, it means all. But with respect to this provision, that meaning of the word supports Novartis's interpretation of the Agreement. Again, clause (i) refers to "any Valid Claim of Licensed Patent Rights Covering such Licensed Product in such country." Id. (emphasis added). The reference to "any" Valid Claim does not unambiguously support Incyte's position that only one of the two cases ([A] and [B]) embedded in the definition of "Licensed Patent Rights" can apply at any time. Instead, the word can be read to support Novartis's position that Section 8.3(c) should be read to require the expiration of the last of "any" Valid Claim—whether that be a Valid Claim of Incyte Patent Rights or Novartis Licensed Patent Rights. 11

Novartis's proposed construction of clause (i) of Section 8.3(c) is plausible. Novartis argues that "Licensed Patent Rights' broadly encompasses both 'Patent Rights licensed to Novartis hereunder' and 'Patent Rights Licensed to Incyte hereunder.' The term thus broadly includes all Patent Rights, irrespective of which party to the Agreement owns an underlying patent and which party is granted a license to it." Opp'n at 12. For the reasons described above, this argument is supported by the text of the Agreement. Incyte focuses its interpretation of the Agreement on the defined term in isolation (and Novartis occasionally does too, as shown by the preceding quote from their opposition brief). But Novartis's position finds strong support in the the words surrounding the defined term "Licensed Patent Rights," which explain how the term should be applied.

<sup>&</sup>lt;sup>11</sup> But the use of the term "any" here does not unambiguously mandate the interpretation promoted by Novartis. The phrase could also plausibly be read to refer to each of the two cases embedded in the defined term "Licensed Patent Rights." So rather than "any" Valid Claim of [A] and [B], it could be read to refer to any of [A] or [B], depending on which case was applicable.

Like Incyte, Novartis advances a commercial rationale supporting its reading of the provision that seems reasonable. "[T]he parties agreed to share in the economic success of any drug they jointly developed and Commercialized, irrespective of the country of sale. To that end, full royalties are due while the Licensed Product enjoys a strong market position, and unless and until there is a deterioration in the value of the Licensed Product, which, in turn, justifies invocation of the Step Down." *Id.* at 24. But the parties' ability to muster reasonable economic rationales to support their respective interpretations of the Agreement proves little more than the wisdom of New York law: at this stage in the case, the Court looks to the language of the contract to apprehend its meaning, rather than the parties' economic justifications for their respective positions.

Because clause (i) of Section 8.3(c) of the Agreement suggests more than one meaning, that provision of the Agreement is ambiguous, and Incyte's motion to dismiss must be denied.

### IV. CONCLUSION

The language of clause (iii) of Section 8.3(c) is unambiguous. As alleged here, Incyte no longer has "Regulatory Exclusivity" with respect to Jakafi. But the term "Licensed Patent Rights" as used in clause (i) of Section 8.3(c) of the Agreement is ambiguous. As a result, Incyte's motion to dismiss is DENIED.

The Clerk of Court is directed to terminate the motion pending at Dkt. No. 32. SO ORDERED.

Dated: February 22, 2021

GREGORY H. WOODS
United States District Judge

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