United States Court of Appeals for the Federal Circuit

INCYTE CORPORATION,
Appellant

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.,
Appellee

2023-1300

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. PGR2021-00006.

Decided: May 7, 2025

MARK J. FELDSTEIN, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC, argued for appellant. Also represented by DREW CHRISTIE, JASON LEE ROMRELL; J. DEREK MCCORQUINDALE, Reston, VA.

WILLIAM M. JAY, Goodwin Procter LLP, Washington, DC, argued for appellee. Also represented by HARRISON GUNN, EMILY L. RAPALINO, DARYL L. WIESEN, Boston, MA.

Before MOORE, *Chief Judge*, HUGHES and CUNNINGHAM, *Circuit Judges*.

Opinion for the court filed by *Chief Judge* MOORE.

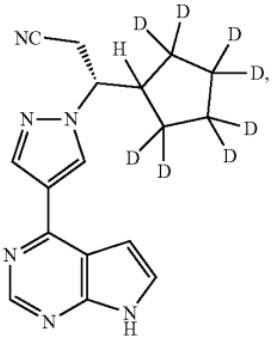
Concurring opinion filed by *Circuit Judge* HUGHES.

MOORE, *Chief Judge*.

Incyte Corporation (Incyte) appeals a post-grant review (PGR) final written decision from the Patent Trial and Appeal Board (Board) holding Incyte failed to prove claims 1–7 and 9–21 of U.S. Patent No. 10,561,659 were unpatentable. Because Incyte fails to establish an injury in fact sufficient to confer standing to appeal, we dismiss.

BACKGROUND

Sun Pharmaceutical Industries, Inc. (Sun) owns the '659 patent, which discloses deuterium modification, a technique for improving a drug's metabolic properties by replacing one or more hydrogen atoms with deuterium atoms. '659 patent at 2:7–24. The '659 patent further discloses deuterium modification of ruxolitinib, a compound used to treat autoimmune diseases. *Id.* at 2:51–3:15. The '659 patent teaches a method of treating hair-loss disorders like alopecia areata using precise dosages of deuterated analogs of ruxolitinib, including Compound (I). *Id.* at 3:9–15. Claims 1–3 are illustrative:

> 1. A method of treating a hair loss disorder in a mammalian subject, the method comprising administering to the subject 16 mg/day or 24 mg/day of a compound represented by the following structural formula:
>
> Compound (I)
>
> 

> or a pharmaceutically acceptable salt thereof, wherein each position in Compound (I) designated specifically as deuterium has at least 95% incorporation of deuterium.
>
> 2. The method of claim 1, wherein the hair loss disorder is alopecia areata.
>
> 3. The method of any one of claim 1, wherein the compound is administered orally.

Id. at 24:31–57.

Incyte petitioned the Board for PGR of claims 1–21 of the '659 patent, arguing the claims were unpatentable as obvious. Sun then disclaimed claim 8. The Board held Incyte failed to show claims 1–7 and 9–21 were unpatentable. *Incyte Corp. v. Concert Pharms., Inc.*, No. PGR2021-00006, 2022 WL 1613509 (P.T.A.B. May 11, 2022). Incyte filed a rehearing request, which the Board denied. *Incyte Corp. v. Concert Pharms.*, Inc., No. PGR2021-00006, 2022 WL 11703590 (P.T.A.B. Oct. 11, 2022). Incyte appeals. We have jurisdiction to review final decisions of the Board pursuant to 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

Sun argues Incyte lacks Article III standing to appeal. Appellee Br. 25–43. Article III standing is "a threshold jurisdictional issue" that must be addressed before a court can reach the merits of an appeal. *Abraxis Bioscience, Inc. v. Navinta LLC*, 625 F.3d 1359, 1363 (Fed. Cir. 2010) (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992)). Although a party does not need Article III standing to file a PGR petition or to obtain a Board decision, a party must establish Article III standing once it seeks review of a Board decision in this Court. *Consumer Watchdog v. Wis. Alumni Rsch. Found.*, 753 F.3d 1258, 1261 (Fed. Cir. 2014).

As the party seeking judicial review, Incyte bears the burden of proving it has standing. *Phigenix, Inc. v.*

Immunogen, Inc., 845 F.3d 1168, 1171 (Fed. Cir. 2017). We accept an appellant's material representations of fact as true for purposes of assessing its standing. *Gen. Elec. Co. v. Raytheon Techs. Corp.*, 983 F.3d 1334, 1342 (Fed. Cir. 2020). An appellant must have standing at the time of filing its appeal. *See Hollingsworth v. Perry*, 570 U.S. 693, 705 (2013). Incyte must therefore establish standing as of December 12, 2022, the date it filed its notice of appeal. Dkt. No. 1.

To show standing, an appellant must have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). To establish an injury in fact, an appellant must show it has "suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Id.* at 339 (quoting *Lujan*, 504 U.S. at 560).

Incyte asserts it has standing to appeal the Board's decision based on (1) its potential infringement liability and (2) the competitor standing doctrine. Appellant Br. 51–63. Sun argues Incyte's recent development efforts and conclusory witness declarations are insufficient to establish standing and the competitor standing doctrine is not applicable.[1] Appellee Br. 25–43. We conclude Incyte has failed to meet its burden to establish standing on either ground.

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[1] Sun argues the timing of Incyte's development activities, and the *de minimis* amount of funding allocated to initial development efforts in comparison to other projects, shows Incyte's efforts are a ploy to create standing. Appellee Br. 27–29. Because Incyte's plans are too speculative to confer standing, we do not reach this issue.

I. Potential Infringement Liability

Incyte argues it has suffered an injury in fact based on the potential infringement liability stemming from its development of a topical deuterated ruxolitinib product for treating alopecia areata. Appellant Br. 51–58. Where an appellant relies on potential infringement liability as a basis for injury in fact, "it must establish that it has concrete plans for future activity that creates a substantial risk of future infringement or likely cause the patentee to assert a claim of infringement." *JTEKT Corp. v. GKN Auto. LTD.*, 898 F.3d 1217, 1221 (Fed. Cir. 2018).

Incyte argues the original and supplemental declarations of Dr. Jim Lee, the head of Incyte's Inflammation and Autoimmunity Group, and the declaration of Dr. Keith Mikkelson, the head of Incyte's Business Development and Licensing team, support standing. Oral Arg. at 1:40–2:25[2]; J.A. 11356–66 (Lee Decl.); J.A. 11367–81 (Mikkelson Decl.); J.A. 12059–70 (Supp. Lee Decl.). Before addressing Incyte's standing argument, we must determine whether Incyte can rely on the supplemental declaration of Dr. Lee.

A. Incyte Cannot Rely on the Supplemental Lee Declaration

Sun argues we should not consider the supplemental declaration of Dr. Lee because it was untimely. Appellee Sur-Reply Br. 1, n.1; Dkt. No. 66. During briefing, Incyte moved for leave to submit the supplemental declaration in conjunction with filing its reply brief, arguing the supplemental declaration was properly submitted because it responds to arguments Sun made in its response brief and provides no new material. Dkt. No. 64 at 8–21. Sun opposed the motion, arguing we should not consider the supplemental declaration because it improperly submits new

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[2] Available at https://oralarguments.cafc.uscourts.gov/default.aspx?fl=23-1300_02052025.mp3.

factual evidence in reply that was available to Incyte at the time it filed its opening brief. Dkt. No. 66 at 4–8. The motions panel deferred to the merits panel to determine whether to consider the supplemental declaration. Dkt. No. 70 at 2.

We have held that when the appellant's standing is not self-evident, it must identify relevant evidence, such as affidavits, demonstrating standing "'at the first appropriate' time, whether in response to a motion to dismiss or in the opening brief." *Phigenix*, 845 F.3d at 1173 (quoting *Sierra Club v. EPA*, 292 F.3d 895, 900 (D.C. Cir. 2002)). We reached this conclusion based on the D.C. Circuit's decision in *Sierra Club*. There, the D.C. Circuit allowed an appellant to submit affidavits in support of standing with its reply brief but warned future litigants that, "[a]bsent good cause shown," they must submit evidence on standing "at the first appropriate point in the review proceeding." *Sierra Club*, 292 F.3d at 900.

While *Phigenix* requires an appellant to submit evidence at the first appropriate time, it is not an inflexible rule, and we retain discretion to allow additional submissions in reply. *See Apple Inc. v. Qualcomm Inc.*, 992 F.3d 1378, 1382 (Fed. Cir. 2021) (citing *Am. Library Ass'n v. FCC*, 401 F.3d 489, 493 (D.C. Cir. 2005)). When doing so, the D.C. Circuit considers whether the submission makes standing patently obvious, raises new theories of standing, or prejudices the appellee. *Nat'l Council for Adoption v. Blinken*, 4 F.4th 106, 111–13 (D.C. Cir. 2021). If the supplemental declaration merely shores up the original declaration and makes standing obvious, this supports allowance. *Id.* Conversely, if the supplemental declaration raises new theories of standing or prejudices the appellee, this does not support allowance. *Id.*

Incyte was on notice that it was required to submit evidence of its standing at the earliest possible opportunity and that its standing was not self-evident because Sun's

docketing statement asserted its intent to challenge standing. Dkt. No. 4 at 2. Incyte, however, did not submit the supplemental Lee declaration at the "earliest possible opportunity" with Incyte's opening brief. *Phigenix*, 845 F.3d at 1173. We therefore must determine whether Incyte has shown good cause for us to allow the supplemental declaration. *Sierra Club*, 292 F.3d at 900.

Incyte provides no justification for its delay, other than arguing it was responding to arguments made by Sun, and does not contest that the facts in the supplemental declaration were known to Incyte as of the time it filed the original Lee declaration with its opening brief. Moreover, the supplemental Lee declaration does not make standing patently obvious and inserts a new theory as to how Incyte's product will satisfy the dosage limitation. *See infra* n.5. Because Incyte has not shown good cause for its delayed submission, we decline to exercise our discretion and hold Incyte cannot rely on the supplemental Lee declaration.

B. No Concrete Plans

The issue before this court is whether Incyte established it has concrete plans for future activity that creates a substantial risk of future infringement. The claimed method requires: (1) treating a hair loss disorder like alopecia areata (2) using deuterated ruxolitinib and (3) administering it at a specific dose of either 16 or 24 mg/day. '659 patent at claims 1–2. Incyte must therefore show it has concrete plans to develop and bring to market a deuterated ruxolitinib product to treat hair loss and that the product will be administered at 16 or 24 mg/day.

To show it has concrete plans to develop and bring to market a deuterated ruxolitinib product, Incyte relies on Dr. Lee's original declaration and Dr. Mikkelson's declaration. Appellant Br. 53–54; Appellant Reply Br. 26–28. Dr. Lee testified that, since the early 2000s, Incyte has made substantial investments in developing and obtaining FDA approval for ruxolitinib-based drugs. J.A. 11358–60 ¶¶ 3–

8. Dr. Lee also testified that, as of November 2022, Incyte had concrete plans to develop and launch a deuterated ruxolitinib product to treat alopecia areata because Incyte had allocated funding for this project and had experience developing non-deuterated ruxolitinib products. J.A. 11360 ¶ 7, J.A. 11362 ¶ 13, 11364–65 ¶¶ 18–19. Dr. Mikkelson testified to many of the same facts. J.A. 11372–78 ¶¶ 9–21.

The Lee and Mikkelson declarations show Incyte allocated a small amount of funds one month before filing this appeal for initial development of two topical drugs to treat alopecia areata: one with the active ingredient implicated by the claims at issue, deuterated ruxolitinib, and the other with non-deuterated ruxolitinib, which undisputably would not be covered by the claims at issue. J.A. 11360 ¶ 7, 11362 ¶ 13, 11365 ¶ 19 (Lee Decl.); J.A. 11375 ¶ 15 (Mikkelson Decl.). The testimony does not identify what portion of the initial funding was allocated to either product.[3] The testimony shows that, when it filed this appeal, Incyte faced significant manufacturing, formulation, testing, and regulatory hurdles to bring either product to market. J.A. 11363–65 ¶¶ 15–18 (Lee Decl.); J.A. 11375–77 ¶¶ 15–18 (Mikkelson Decl.).

Incyte's development plans amount to an expression of intent to create a product that runs a substantial risk of infringement if it is able to clear all development hurdles, secure FDA-approval, and bring its product to market. This is too speculative to show concrete plans to develop a deuterated ruxolitinib product to treat hair loss at specific

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[3] At oral argument, counsel for Incyte argued the entire initial funding allocation was equally applicable to both the deuterated and non-deuterated products but admitted Incyte did not make this argument in its briefs. Oral Arg. at 5:55–6:25. The argument is therefore waived. *Sistek v. Dep't of Veterans Affs.*, 955 F.3d 948, 957–58 (Fed. Cir. 2020).

dosages. *See JTEKT*, 898 F.3d at 1221; *see also Allgenesis Biotherapeutics Inc. v. Cloudbreak Therapeutics, LLC*, 85 F.4th 1377, 1380–81 (Fed. Cir. 2023). As of the time of filing, just one month after allocating a small amount of seed money to develop both deuterated and non-deuterated ruxolitinib products, given the facts of this case it is entirely unreasonable to conclude this suffices to create a concrete plan for future activity which runs a substantial risk of infringement. It is not clear that Incyte will have any deuterated ruxolitinib product which will potentially infringe. This record creates, at best, a wish to enter the market with no concrete plan how to do so.

Incyte also fails to demonstrate it has concrete plans to develop and market a deuterated ruxolitinib product that will be administered at the *claimed dosage*. Incyte argues its product will be delivered "at an amount equivalent to the oral dose of at least 16 mg/day." Appellant Br. 55. As support, Incyte relies on a single sentence from the Lee declaration and Mikkelson declaration. J.A. 11363–64 ¶ 16 ("Incyte anticipates the topical formulation will have to deliver the equivalent of 16 mg of [deuterated ruxolitinib] per day."); J.A. 11376 ¶ 16 ("Incyte believes that to achieve a commercially viable level of efficacy, topical [deuterated ruxolitinib] will need to be delivered at an amount equivalent to at least 16 mg/day oral dose.").

The Lee and Mikkelson conclusory testimony is too speculative to show concrete plans for the Incyte product to be administered at the required dosage. *Allgenesis, LLC*, 85 F.4th at 1381. First, they fail to explain why Incyte believes its deuterated ruxolitinib product will be administered at an amount equivalent to the claimed dosage. Second, they fail to explain how the claimed weight-based dosage rates in mg/day used for oral products can be satisfied by the concentration-based dosage rates used by Incyte's topical product. Appellant Reply Br. 25–26; J.A. 11376 ¶ 16. While the independent claims are arguably broad enough to cover both oral and topical administration,

it is unclear how concentration-based dosages of topical products can be converted into the claimed weight-based dosages of oral products. Third, they provide no evidence of the concentration of Incyte's topical deuterated ruxolitinib product, so even if a conversion was known it could not be calculated. J.A. 11363 ¶ 15. Fourth, they provide no evidence describing how the product will be labeled, so Incyte's claim that it will face infringement liability from marketing its product is entirely speculative. Appellant Br. 55. Simply put, Incyte's factual allegations leave too much "to the imagination." *Gen. Elec.*, 983 F.3d at 1343.

Incyte argues that it anticipates spending significantly more money in the coming years—after it concludes initial development activities—to formulate, test, and gain regulatory approval. Appellant Br. 53; J.A. 11365 ¶ 19 (Lee Decl.). This argument is unavailing because it does not change any of the facts as of the date Incyte filed this appeal. Incyte also argues that its substantial investment into researching and developing ruxolitinib-based products shows it has concrete, non-speculative plans to develop a deuterated ruxolitinib product. Appellant Br. 53–54; J.A. 11364–65 ¶ 18 (Lee Decl.). We do not agree. While "significant involvement in research and commercial activities involving the claimed subject matter" supports standing, ruxolitinib is not the claimed subject matter. *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1005 (Fed. Cir. 2018) (citation omitted and cleaned up). Incyte has failed to prove that its prior research and development efforts for a different compound not covered by the claims at issue overcomes its lack of development activities for the claims at issue.[4]

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[4] One prior research and development project Incyte relies upon was for a topical ruxolitinib product to treat alopecia areata, which failed after clinical trials in 2017. J.A.

Incyte further argues it faces risk because Sun is a litigious company and Sun's predecessor-in-interest, from whom it bought the '659 patent, publicly stated it would protect its technology. Appellant Br. 56–58. There is no evidence, however, that Sun or its predecessor has filed any suits over the claims at issue. *AVX Corp. v. Presidio Components, Inc.*, 923 F.3d 1357, 1365 (Fed. Cir. 2019) ("It does not matter that Presidio has sued AVX over capacitors that did not contain the [claimed technology].").

Because Incyte fails to establish it has nonspeculative, concrete plans for future activity that creates a substantial risk of future infringement, we conclude Incyte has failed to show injury in fact based on potential infringement liability.[5]

11361–62 ¶¶ 11–12. If anything, this undermines Incyte's claim that it is at substantial risk of producing a potentially infringing product.

[5] Our analysis would not change if we considered Dr. Lee's supplemental declaration. The supplemental declaration confirms the timing and amount of Incyte's initial funding allocation. *See, e.g.*, J.A. 12061 ¶ 4. It also confirms the funding was for a project to develop deuterated and non-deuterated ruxolitinib topical products. *Id.* But it does not specify what portion of that investment was for deuterated ruxolitinib or provide evidence that any development activities, other than earmarking funds, occurred prior to the date of filing the appeal. And it provides a new theory as to how the claimed dosage amount will be satisfied—a patient one day will administer the topical product to enough of his skin to satisfy the claimed dosage rate. J.A. 12064–69 ¶¶ 12–22. Dr. Lee's testimony is too speculative to show Incyte has concrete plans to develop a product that will be used according to the patented method in a

II. Competitor Standing Doctrine

Incyte argues it has suffered an injury in fact based on the doctrine of competitor standing. Appellant Br. 60–63. Specifically, Incyte argues Sun is developing a deuterated ruxolitinib product that will directly compete with Incyte's products under development and those licensed to other manufacturers.

The doctrine of competitor standing "relies on economic logic to conclude that a plaintiff will likely suffer an injury-in-fact when the government acts in a way that increases competition or aids the plaintiff's competitors." *Canadian Lumber Trade All. v. United States*, 517 F.3d 1319, 1332 (Fed. Cir. 2008) (citing *Clinton v. City of New York*, 524 U.S. 417, 433 (1998)). We have recognized that standing based on competitive harm requires "the challenged government action nonspeculatively threatened economic injury to the challenger by the ordinary operation of economic forces." *AVX*, 923 F.3d at 1364. Generally, this occurs in the regulatory context "where the government action has a natural price-lowering or sales-limiting effect on the challenger's sales (compared to what prices or sales would be in the absence of the government action), either by directly lowering competitors' prices for competing goods or by opening the market to more competitors." *Id.*

In the patent context, we have held the government's action in "upholding of specific patent claims, which do not address prices or introduce new competitors, but rather give exclusivity rights over precisely defined product features" is "quite different" compared to actions the government takes in the regulatory context. *Id.* at 1365. While we recognize a "patent claim *could* have a harmful competitive effect on a would-be challenger if the challenger was

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manner that creates a substantial risk of future infringement. *Allgenesis*, 85 F.4th at 1381.

currently using the claimed features or nonspeculatively planning to do so in competition," the government's action in upholding specific patent claims "does not, by the operation of ordinary economic forces, naturally harm a [challenger] just because it is a competitor in the same market as the beneficiary of the government action (the patentee)." *Id.* (emphasis in original). In other words, it is not enough to show a benefit to a competitor to establish injury in fact; the party seeking to establish standing must show a concrete injury to itself.

As discussed, Incyte has not shown it is currently engaging in, or has nonspeculative plans to engage in, conduct covered by the claims of the '659 patent. Because our caselaw has clearly resolved this issue, we conclude Incyte cannot rely on the competitor standing doctrine to confer standing. *AVX*, 923 F.3d at 1365–67 (holding the competitor standing doctrine does not apply when appellant lacked concrete plans); *see also Gen. Elec. Co. v. United Techs. Corp.*, 928 F.3d 1349, 1357 (Fed. Cir. 2019) (Hughes, J., concurring) ("[I]f the petitioner is not currently engaged in infringing activity and has no concrete plans to do so in the imminent future, we held [in *AVX*] that the Board's decision to uphold a challenged patent does not invoke the competitor standing doctrine.").

CONCLUSION

We have considered Incyte's remaining arguments and find them unpersuasive. Because Incyte fails to establish an injury in fact sufficient to confer Article III standing, we dismiss the appeal for lack of jurisdiction.

DISMISSED

COSTS

Costs to Sun.

United States Court of Appeals for the Federal Circuit

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HUGHES, *Circuit Judge*, concurring.

I join my colleagues in holding that Incyte lacks Article III standing to bring this appeal before us because that is the result compelled by our precedent. I wrote a concurrence in *General Electric Co. v. United Technologies Corp.* because "I believe that precedent has developed an overly rigid and narrow standard for Article III standing in the context of appeals from *inter partes* review proceedings." 928 F.3d 1349, 1355 (Fed. Cir. 2019) (Hughes, J., concurring). I write separately in this case because I continue to hold that belief in the context of appeals from administrative post-grant proceedings generally, and the facts of this case present a circumstance in which I believe our precedent dictates an outcome inconsistent with the spirit of

Article III standing. Our precedent on whether parties have standing to appeal to this court from an adverse administrative post-grant review is too restrictive and creates a special standing rule for patent cases. The existence of this narrower special rule is even more pronounced in the pharmaceutical space, where our precedent leads to the (in my opinion, improper) conclusion of no standing for the inventor of the underlying compound.

I

The Article III standing requirement is not meant to be a high barrier; the Supreme Court has characterized it as setting "the irreducible constitutional *minimum*." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (emphasis added). The purpose of the standing requirement is to ensure that "a plaintiff must have 'alleged such a personal stake in the outcome of the controversy as to warrant *his* invocation of federal-court jurisdiction.'" *Salazar v. Buono*, 559 U.S. 700, 711 (2010) (quoting *Horne v. Flores*, 557 U.S. 433, 445 (2009)) (emphasis in original). The Supreme Court specified in *Lujan* that, to meet this minimum standing requirement, a plaintiff must establish that he has suffered "an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." 504 U.S. at 560 (internal quotations and citations omitted).

Our caselaw evaluating injury in fact based on future plans in appeals from failed administrative patent challenges generally holds that where the appellant's potentially infringing future plans are either too vague or uncertain to determine that infringement is substantially likely, there is insufficient showing of a material and imminent injury. Here, evaluating Incyte's alleged injury in fact, the majority states "Incyte's . . . expression of intent to create a product that runs a substantial risk of infringement if it is able to clear all development hurdles, secure FDA-approval, and bring its product to market . . . is too

speculative to show concrete plans to develop a deuterated ruxolitinib product to treat hair loss at specific dosages." Majority Op. at 8–9. While I agree that our caselaw requires this conclusion, I find it difficult to imagine a more compelling set of facts for establishing an injury in fact where the patent challenger has such a significant personal stake in the outcome.

Our caselaw more often finds insufficient injury in fact, and thus, no standing, in cases that implicate pharmaceutical patents than in cases that implicate patents from other industries. For example, in *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1003–05 (Fed. Cir. 2018) and *General Electric Co. v. Raytheon Technologies Corp.*, 983 F.3d 1334, 1341 (Fed. Cir. 2020), the mere "operat[ion of] a plant capable of infringing the . . . patent" or the earmarking of funds for development of potentially infringing products were each sufficient for standing in the chemical engineering and aviation industries respectively. In contrast, in *Allgenesis Biotherapeutics Inc. v. Cloudbreak Therapeutics, LLC,* we declined to find standing to appeal an adverse IPR outcome based on patent challenger Allgenesis' development of a new drug that had *already been developed* and completed Phase II clinical trials. 85 F.4th 1377, 1380–81 (Fed. Cir. 2023). The panel explained that Allgenesis provided only conclusory statements of intention to proceed with further development without any allocated funds or concrete evidence supporting these future plans, which were not sufficiently nonspeculative and concrete so as to create a substantial risk of future infringement. *Id.* at 1381.

As a practical matter, pharmaceutical drugs generally have long development timelines, which inherently means there is more uncertainty about whether a drug will ever reach the market or infringe a given patent. Here, for instance, there is admittedly still uncertainty about the final drug dosage of the modified form, as the majority opinion notes. *See* Majority Op. at 9–10. But unpredictability in the

development of drugs in the pharmaceutical space should cut both ways. A party seeking to develop a drug that may infringe an existing patent has a significant interest in trying to invalidate that patent before making the large financial and time investments such development efforts demand. Requiring these investments to be made before finding standing, which seems to be, given our current precedent, something that would only happen on the eve of FDA approval or commercial launch, is inefficient and contradicts the spirit of Article III standing as setting a minimum threshold to ensure the party initiating a suit has a real personal stake in the outcome. A party like Incyte clearly has a sufficient personal stake in the outcome of this appeal.

The drug at issue here is the deuterated version of the known and approved drug, ruxolitinib, and deuteration is a known method of drug modification used to reduce the speed of metabolism and reduce the development of toxic byproducts to improve drug efficacy. Incyte, the company that invented ruxolitinib (and has been working with it since 2004), argues deuteration is the smallest structural change it could make to ruxolitinib. *See* Incyte's Opening Br. at 17. Indeed, Concert, Sun's predecessor-in-interest, based its entire business model on the deuteration of known drugs. Concert's CEO was quoted in an article as saying "we've never seen any biologically relevant differences in target selectivity or potency of a drug when we deuterate it," J.A. 2101, and a research paper on deuteration noted that where "known drugs are used as the starting point for the deuterium-for-hydrogen switch, efficacy and safety have already been established and the risk of failure is much lower." J.A. 7545. Unlike in *Allgenesis*, Incyte has shown that it allocated funds to develop its deuterated ruxolitinib and offered concrete evidence supporting these future plans. *See* Incyte's Opening Br. at 53. As far as drug development goes, the facts of this case, based on the parties' representations, present

perhaps the least uncertain version of drug development there could be, which sets it apart from the drugs in development that we have concluded in prior cases are too uncertain to support injury in fact in this context before they have undergone testing to prove efficacy and safety. *See also* Incyte's Reply Br. at 26–28.

Insofar as the majority opinion entertains Sun's argument that Incyte manufactured sham standing by dedicating what it concludes are minimal funds to its development efforts on the eve of filing its appeal, *see* Majority Op. at 9, I see this merely as Incyte's attempt to meet our circuit's stricter standing requirement in this context. I do not think the quantity of funds dedicated to development before appeal should be afforded significant import in our standing inquiry.

II

Because I am bound by our existing precedent, I join the majority opinion. But absent our existing caselaw, I would conclude that Incyte has established Article III standing to appeal the Board's adverse decision.