

No. 14-647

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IN THE  
**Supreme Court of the United States**

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GILEAD SCIENCES, INC., HOFFMANN–LA ROCHE, INC.,  
F. HOFFMANN–LA ROCHE, LTD., AND GENENTECH, INC.,  
*Petitioners,*

v.

NATCO PHARMA LIMITED AND NATCO PHARMA, INC.,  
*Respondents.*

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**On Petition for a Writ of Certiorari  
to the United States Court of Appeals  
for the Federal Circuit**

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**REPLY BRIEF**

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## REPLY

The Federal Circuit's rewrite of the obviousness-type double-patenting doctrine in this case directly conflicts with this Court's double-patenting decisions, which have clearly defined the doctrine for over a century. Natco does not—and cannot—dispute that a court of appeals cannot disregard this Court's cases based on policy concerns or changes in related areas of the law. Instead, Natco tries to repackage the Federal Circuit's erroneous reasons for altering this longstanding doctrine, but this repackaging cannot diminish the conflicts created by the Federal Circuit's decision here or the need for this Court's intervention.

Natco principally argues that the Federal Circuit's decision to focus on expiration dates, rather than which patent issued first, is consistent with this Court's decisions because the double-patenting doctrine has supposedly never permitted a patent holder to own duplicative patents with different expiration dates. But that premise is false—an entire legal doctrine exists within the double-patenting jurisprudence that allows two patents to issue with independent and full terms if the PTO is the cause of the delay in the grant of the patents. And contrary to Natco's assertions, the Court's double-patenting cases have never been concerned with making the expiration dates of patents consistent, regardless of which patent issued first. Rather, the core reason for the doctrine is to prevent a second-issuing patent from extending the *statutory period of exclusivity* granted by a first-issued patent. Provided the public's expectation set by the first-issued patent is not upset by a later-issuing patent, the double-patenting doctrine plays no role. The Federal Circuit's conclusion that a

second-issuing patent can invalidate the first-issued patent is an “obvious[s] ... misapprehension” of the law. *Suffolk Co. v. Hayden*, 70 U.S. (3 Wall.) 315, 319 (1865). Absent a terminal disclaimer, “[t]he last, not the first, is void.” *Id.*

Like the Federal Circuit, Natco also simply ignores that when Congress legislates against the backdrop of a well-established common-law doctrine like the double-patenting doctrine, Congress must speak directly to the issue addressed by the common law in order to alter it. Thus, the adoption of terminal disclaimer practice cannot explain the conflict between the Federal Circuit’s decision here and the decisions of this Court. Congress left undisturbed the legal basis *why* a terminal disclaimer might even be required (i.e., that there was double-patenting under this Court’s longstanding doctrine). And indeed, every time Congress has addressed issues touching on the double-patenting doctrine, it has embraced that doctrine and not attempted to alter it. Pet. 22–24.

Certiorari is warranted to correct the conflict created by the decision below on an important issue of patent law. Patent holders, the public, and the PTO have all operated under a consistent set of double-patenting principles for over a century. The Federal Circuit’s decision in this case upsets these settled expectations and creates considerable uncertainty.

**I. THE FEDERAL CIRCUIT’S DECISION IN THIS CASE DIRECTLY CONFLICTS WITH THIS COURT’S PRECEDENT AND THAT OF LOWER COURTS.**

a. Certiorari is warranted because the decision below directly conflicts with this Court’s decisions on the double-patenting doctrine, as well as with the de-

cisions of lower courts. Pet. 15–21. Natco offers two meritless responses.

*First*, Natco argues that there is no conflict between the Federal Circuit’s decision and this Court’s cases because the expiration date was what really mattered in this Court’s cases and the language quoted by Gil-ead “is merely a linguistic artifact of the then-operative patent laws.” Opp. 17, 19. This revisionist reading does not withstand scrutiny. Contrary to Natco’s assertions, this Court’s double-patenting cases do not focus on the expiration dates of the related patents, and shorten the longest term to match the term of the earliest expiring of these patents. To the contrary, the Court stated that, under its precedent, “it is the *issue date* ... which determines priority to patents issued to the same inventor” and “the later must be declared void.” *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 196–97 (1894) (emphasis added). The issue date, and the statutory term derived from that date, set the metric against which double patenting is evaluated. If the later-issuing patent also expires later, then the later-issuing patent may be invalid. Thus, as a factual matter, the patents that could be invalidated would have had a later expiration date than the first-issued patents, but that does nothing to diminish the explicit holding in these cases: the *issue date* and the statutory term that flows from that date determine whether a second-issuing patent will be invalidated.

If the Federal Circuit had applied the explicit holding of these cases, the result would be different here. Although the application leading to the ’375 patent was filed first, the ’483 patent was the first to issue. Nonetheless, the Federal Circuit held that because the ’375 patent has an earlier application date, and therefore earlier expiration date under the URAA,

the first-issued '483 patent should be held invalid. That directly conflicts with this Court's holding that, under the double-patenting doctrine, only the second-issuing patent is "void, although the application for it was first filed," because "the issue date, and not the filing date ... determines priority to patents issued to the same inventor." *Miller*, 151 U.S. at 197.

Natco's assertion that expiration dates in isolation are the departure point for the double-patenting doctrine also contradicts the core rationale behind this Court's cases, which is that issuance of the first patent exhausts the statutory right granted by Congress. Pet. 17. According to Natco, the initial grant of a patent on an innovation is meaningless if a second patent has an earlier expiration date. That is fundamentally inconsistent with this Court's reasoning that the prohibition on double patenting arises "because the *first patent* exhausts the statutory right secured by the act of Congress." *Caliga v. Inter Ocean Newspaper Co.*, 215 U.S. 182, 189 (1909) (emphasis added). Under the Patent Act, the "grant" of rights to an invention is tied to the patent's issue date, and through that, the statutorily mandated term is defined. See 35 U.S.C. § 154(a)(2). Natco's reasoning would make that initial grant meaningless.

*Second*, Natco argues that somehow the "creation of the terminal disclaimer in the Patent Act of 1952" can be used to distinguish this Court's double-patenting cases. Opp. 17. But the later introduction of terminal disclaimers actually rests on this Court's clear and consistent double-patenting case law—when Congress provided for terminal disclaimers, it did not alter the underlying legal standard that defines when double patenting exists. Rather, it provided the terminal disclaimer authority to enable patent applicants to avoid the unjust result of having their

later-issuing patents invalidated; the terminal disclaimer allows the later issuing patent to remain valid if its term is restricted to match that of the first-issued patent. Indeed, that is precisely the process that Gilead followed here—after the '483 patent issued, Gilead filed a terminal disclaimer in the application leading to the '375 patent, disclaiming any period of time beyond the expiration of the '483 patent. Pet. App. 3a.

As Gilead demonstrated, when Congress legislates against the backdrop of well-established common law principles, it must speak directly to the question addressed by those principles in order to alter them. Pet. 2, 22–23. Natco does not dispute this. That principle disposes of Natco's argument.

b. Natco uses these same two faulty arguments (Opp. 19–20) in an attempt to harmonize the discord between the Federal Circuit's decision in this case and the decisions of other lower courts that have faithfully followed this Court's well-established double-patenting precedent. See Pet. 19–21. That effort fails. See *supra*, at 6–7. Natco also tries to distinguish the Federal Circuit's prior, conflicting decision in *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 1354 n.5 (Fed. Cir. 2009), by highlighting that “there was a terminal disclaimer in the later-issued patent, presumably removing the danger that it could unjustifiably extend the term of the first-issued patent.” Opp. 21 n.4. But that is precisely what happened here. See *supra*, at 7.

Moreover, contrary to Natco's assertion, the denial of rehearing does not suggest any absence of a conflict. See Opp. 21. It shows only that a majority of active judges did not vote to rehear the case. And what makes the situation intolerable is that future panels will have to decide double-patenting questions while



confronting two directly contrary decisional principles, viz., a panel cannot disregard a prior panel decision and a panel cannot ignore a controlling decision of this Court.

At bottom, Natco merely echoes the Federal Circuit's argument that changed circumstances should warrant a different rule. See Pet. App. 12a; see also Pet. 27. But Natco has no response to the well-established principle that a court of appeals cannot reject this Court's decisions merely because Congress enacts an intervening change in law. Pet. 22.

## **II. NATCO CANNOT SALVAGE THE FAULTY RATIONALE UNDERLYING THE FEDERAL CIRCUIT'S DECISION.**

Natco does not dispute that when Congress legislates against the backdrop of well-established common law principles, as it did here, it must speak directly to an issue in order to alter that principle. Pet. 22–23. The Federal Circuit's reasoning that changed circumstances warrant a recasting of the double-patenting doctrine conflicts with this fundamental principle. *Id.*

a. Natco responds that the Federal Circuit did not change the double-patenting doctrine. Opp. 21–22. That assertion is meritless. Natco does not—and cannot—dispute the explicit holding of this Court's cases that the “issue date” determines patent priority and that the second-issued patent, not the first, is void. Rather, Natco argues principally that the adoption of the terminal disclaimer in the Patent Act of 1952 and the change in how a patent term is measured explain why a different rule is appropriate in this case. *Id.* at 22. But Congress enacted both of those changes against the backdrop of this Court's well-established doctrine and gave no indication that it was altering

the doctrine. Pet. 22–24. In fact, it affirmatively approved the established doctrine. *Id.* at 23–24.

Natco also contends that the Federal Circuit’s decision is consistent with the purpose of the Patent Law Amendments of 1984 by block quoting a snippet of legislative history. Opp. 22–23. Natco seems to be focusing on the statement that a terminal disclaimer can be used to disclaim “the terminal portion of the term of *the later patent*, thereby eliminating the problem of extending patent life.” *Id.* at 23 (quoting 130 Cong. Rec. H10,527 (1984)) (emphasis added). But that language actually embraces the well-established common-law principle that only the second-issued (i.e., “the later”) patent could be invalidated. This legislative history merely echoed the many cases holding that a terminal disclaimer can avoid invalidation of the later (i.e., second-issued) patent by curtailing its term to match the term of a previously issued patent. See, e.g., *Miller*, 151 U.S. at 198 (reason for the double-patenting rule is “that a new and later patent for the same invention would operate to extend or prolong the monopoly beyond the period allowed by law”); *In re Kaplan*, 789 F.2d 1574, 1579–80 (Fed. Cir. 1986).

b. Natco also cannot counter the fact that the Federal Circuit’s new expanded obviousness-type double-patenting rule will upset settled expectations and cause uncertainty for innovators and the public. See Pet. 30. Natco contends that the public’s expectation regarding patent rights is set by the expiration date of the earliest expiring patent, regardless of which patent issued first. Opp. 23–24. Natco’s argument ignores this Court’s precedent. The Court explained that a reason for the double-patenting doctrine is that “the power to create a monopoly is exhausted by the first patent” to issue. *Miller*, 151 U.S. at 198. And as

explained in *Odiorne v. Amesbury Nail Factory*, 18 F. Cas. 578 (C.D.C. Mass. 1819) (No. 10,430), the public’s expectation is set by this first-issuing patent: the “public have by the *first patent* acquired an inchoate interest” in the invention. *Id.* at 579 (emphasis added).

The rule advocated by Natco and adopted by the Federal Circuit would expand the obviousness-type double-patenting doctrine and create tremendous uncertainty. See, e.g., Pet. 30; Br. of PhRMA as Amicus Curiae 5–7, 9. If the public’s expectation may be reset, as Natco would have it, whenever a later patent issued, then patent holders and the public would be constantly at sea. For any given patent, there would always be a question of whether another patent may issue, or already has issued, with an earlier expiration date, creating tremendous uncertainty for both the patent holder and the public alike. In contrast, basing all expectations on the term established by the first issuance of a patent establishes a concrete way to measure patent rights—the period of exclusivity defined by the first patent grant. If a second-issuing patent has a later expiration date, then a terminal disclaimer is necessary (or the patent is invalid). If it does not have a later expiration date, no disclaimer is necessary, and there is no disruption of the public’s previously fixed expectations.

Natco also echoes the Federal Circuit’s policy concern that this Court’s double-patenting doctrine renders “gamesmanship ... possible.” Opp. 25. But Natco has no response to the fact that this policy concern is for Congress, not courts. Pet. 26. Nor does Natco respond to the fact that Congress already addressed gamesmanship in the URAA and did not alter the double-patenting doctrine. *Id.* In any event, such policy concerns certainly do not permit a court of appeals

to disregard well-established Supreme Court precedent. *Id.* at 22.

Nor can Natco find any comfort in the MPEP. Opp. 25–26. Natco does not dispute that the provision of the MPEP cited by the Federal Circuit applies to *pending applications* and not to issued patents. See Pet. 29. Indeed, the PTO practice operates on the basis that there is a first-issued patent, beyond which the possible term of a patent issuing from the application will extend. Nonetheless, Natco argues that the provision is consistent with the Federal Circuit’s new rule for obviousness-type double patenting. Opp. 26. That is simply incorrect. The MPEP provision cited by the Federal Circuit was in existence long before the URAA’s change in how patent terms are calculated, and the provision cannot justify the Federal Circuit’s change to the obviousness-type double-patenting doctrine.

### **III. CERTIORARI IS WARRANTED ON THIS IMPORTANT ISSUE OF FEDERAL LAW.**

The issue presented by this case is an important one of federal law that warrants this Court’s review. Pet. 30–33. Natco counters that the doctrine of obviousness-type double patenting is an “infrequently asserted” defense and thus “lacks the general importance of the patent cases where the Court grants certiorari.” Opp. 27. But this Court does not define “importance” as Natco does. Natco maintains that obviousness-type double patenting is a “relevant defense” to patent infringement, and this Court has recently recognized the importance of issues related to patent infringement defenses. See *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 752 (2014) (whether good-faith belief of invalidity can be a defense to induced infringement). And here the Federal Circuit has now flouted this Court’s well-established case law

on just such a defense. Moreover, in doing so, the Federal Circuit's decision breathed new life into the obviousness-type double-patenting doctrine and expanded it beyond its original bounds. See PhRMA Amicus 5–10. The expansion of this doctrine and conflict created by the Federal Circuit warrant this Court's review.

Moreover, the Federal Circuit's decision will upset innovators' expectations and will upset other well-established patent doctrines. Pet. 30–31. Natco contends that innovators' expectations will not be upset because the law has never permitted patentees to own duplicative patents with different expiration dates. Opp. 28. But that is false—the law allows for independent terms of patents that would otherwise be found to raise double-patenting concerns if the PTO is the source of delays that give rise to the different terms. See *In re Emert*, 124 F.3d 1458, 1461 (Fed. Cir. 1997). And, contrary to Natco's suggestion, the obviousness-type double-patenting doctrine has never been premised on ensuring that the expiration dates of patents match. It has focused on whether a later-issuing patent extends the period of exclusivity for an already issued patent. See Pet. 4–5, 15–21. Under the Federal Circuit's recasting of the doctrine, patents that have long-since issued under well-established standards are now drawn into question. And an already-issued patent may at any time be put in jeopardy by the issuance of a sufficiently related patent with a shorter effective expiration date. Patent holders and the public no longer have a constant (the first-issued patent) by which to set their expectations and conform their conduct.

Natco's other arguments are equally unavailing. Gilead showed that the Federal Circuit's rule may upset other patent law doctrines. Pet. 30–31. Natco's

consistent and myopic response is that those doctrines do not address the “patents in *this* case.” Opp. 29–30. But this misses the point, which is that the Federal Circuit’s rule in this case will have collateral and harmful effects on other areas of patent law. To this, Natco has no response.

Finally, Gilead showed that the Federal Circuit’s alteration of the double-patenting doctrine will upset the PTO’s operations. Pet. 32–33. Natco argues that the MPEP procedures already account for the change in law. Opp. 31. Natco again misses the mark. The change in law could have profound effects on the PTO’s operation because patent holders may need to file terminal disclaimers for already issued patents if a later-issuing patent has a shorter effective expiration date. Moreover, the PTO has operated under a consistent set of double-patenting principles established by this Court over a century ago. A fundamental change in the doctrine will undoubtedly disrupt the PTO’s operations. If there is any question about the impact the Federal Circuit’s rule will have, the Court, at a minimum, should seek the United States’ views.

**CONCLUSION**

For the foregoing reasons and those stated in the Petition, the petition for certiorari should be granted.

Respectfully submitted,

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