UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE APPEALS REVIEW PANEL OF THE PATENT TRIAL AND APPEAL BOARD

Ex parte NICOLAS BAURIN, CHRISTIAN BEIL, CARSTEN CORVEY, CHRISTIAN LANGE, DANXI LI, VINCENT MIKOL, ANKE STEINMETZ, and ERCOLE RAO

Appeal 2024-002920
Application 17/135,529
Technology Center 1600

BRIEF OF AMICUS CURIAE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) RESPONDING TO ORDER CONVENING APPEALS REVIEW PANEL AND GRANTING *SUA SPONTE* REHEARING

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I. INTRODUCTION AND INTEREST OF *AMICUS CURIAE*

Non-statutory double patenting (NSDP), also called obviousness-type double patenting (OTDP), is a judicially created doctrine adopted "to prevent patentees from obtaining a second patent on a patentably indistinct invention to effectively extend the life of a first patent to that subject matter." *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*, 111 F.4th 1358, 1369 (Fed. Cir. 2024) (emphases omitted). If not properly guided, patent examiners might erroneously apply this doctrine during examination to improperly reject claims, as happened here. Thus, clarity is needed.

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the Director's invitation for *amicus* briefs to address NSDP. As a voluntary, nonprofit association whose members include the country's leading research-based pharmaceutical and biotechnology companies, PhRMA speaks on behalf of a broad membership of innovators with a direct stake in how NSDP doctrine is applied. These companies develop life-saving and life-enhancing medicines and rely on patent protection to support those efforts.

A fair patent system must adequately protect the wide array of innovations that inventors make for a new medicine or treatment, such as types of compounds, formulations, and methods of treatment, to name a few. Drug products and methods are routinely covered by multiple patents as a result of continuous research and innovation, and patent rights are critical to the investment needed to bring these innovations to market for the benefit of patients.

If NSDP is not predictable and properly applied during prosecution, innovation is discouraged. This would harm PhRMA members and other innovators from timely and rightfully patenting their inventions. And a properly functioning examination system requires NSDP analysis dependent on facts, not hypotheticals or uncertain projections, and on maintaining focus

on the underlying purpose of NSDP—*improper* timewise extensions. This is especially true where examiners considering potential NSDP rejections are not applying statutory law but instead a judicial doctrine that, if not carefully adhered to, can become improperly unmoored from congressional mandates and requirements in the Patent Act.

II. NSDP IS A NARROW EQUITABLE DOCTRINE THAT CANNOT OVERRIDE STATUTORY MANDATES.

PhRMA's responses to the three questions in the Director's Order are grounded in the origins and limited scope of this judicially crafted doctrine.

NSDP's animating principle is "equitable," *In re Cellect, LLC*, 81 F.4th 1216, 1221 (Fed. Cir. 2023): preventing *unfair* extension of patent exclusivity by another patent or application that is not patentably distinct. NSDP "is based on the core principle that, in exchange for a patent, an inventor must fully disclose his invention and promise to permit free use of it at the end of his patent term." *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1212 (Fed. Cir. 2014); *see also, e.g.*, *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1059 (Fed. Cir. 2020) (NSDP is an "equitable doctrine."); *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014) ("The ban on double patenting ensures that the public gets the benefit of the invention after the original period of monopoly expires."); *In re Zickendraht*, 319 F.2d 225, 232 (C.C.P.A. 1963) (Rich, J., concurring) ("[T]he public should be able, upon seeing the issued patent, to act on the assumption that the patentee's protection is limited to what he claims and that what is not claimed, in the way of obvious modifications, alternatives, and the like, will be free of protection through any later patents issued to the patentee."). The fundamental concern is an "*improper* timewise extension of the patent right." *In re Braat*, 937 F.2d 589, 592 (Fed. Cir. 1991) (emphasis in original). An improper timewise extension only occurs "when a patent expires and the public is nevertheless barred from practicing *obvious modifications* of the

invention claimed in that patent because the inventor holds another later-expiring patent with claims for obvious modifications of the invention." *Gilead*, 753 F.3d at 1214 (emphasis added); *see also Georgia-Pac. Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1326 (Fed. Cir. 1999) (NSDP serves to "prevent[] the extension of the term of the original patent via the patenting of an *obvious variation*."), *opinion amended on reh'g on other grounds*, 204 F.3d 1359 (Fed. Cir. 2000) (emphasis added).

NSDP law "is still only case law," *In re Van Ornum*, 686 F.2d 937, 946 (C.C.P.A. 1982), so it cannot be applied contrary to statute or defeat an inventor's statutorily authorized right to enjoy an invention's full patent term where no concern of an *unjustified* timewise extension exists. *See Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1375 (Fed. Cir. 2018) (This judge-made doctrine cannot "cut off a statutorily-authorized time extension."); *see also* 35 U.S.C. §§ 154(b) (patent term adjustment (PTA)), 156 (patent term extension (PTE)). The doctrine is of limited scope given the Patent Act's provisions ensuring that only novel, nonobvious, and adequately disclosed inventions receive patent protection. *See Bilski v. Kappos*, 561 U.S. 593, 609 (2010) ("In order to receive patent protection, any claimed invention must be novel, § 102, nonobvious, § 103, and fully and particularly described, § 112," and meet § 101 eligibility.).

Furthermore, NSDP originated in an era when patent terms were measured from issuance date, but the doctrine's relevance has shifted under the current statutory framework. Prior to the Uruguay Round Agreements Act of 1994 (URAA), patent terms ran from issuance, *i.e.*, "issuance dates and expiration dates were inextricably intertwined." *Allergan*, 111 F.4th at 1367. If applicants filed *seriatim* applications, there was risk that patents for the same invention could issue and expire later, thus effectively extending the patent term. Since 1995, however, patent terms run from "effective filing, or priority, date, *i.e.*, the earlier of (1) the filing date of the application and

(2) the filing date of an application from which the patent claims priority." *Id.* (citing 35 U.S.C. § 154(a)(2)). "In many cases, this means that, post-URAA, there is little risk of an unjustified extension of term subject to [NS]DP because all patents to an invention that share a priority date are expected to expire on the same day." *Id.* For example, where patents do not share a priority date, terminal disclaimers can "tie" expiration dates together and "obviate" NSDP concerns. *See id.* at 1368. As a result, NSDP, when properly applied, has become "less significant in post-URAA patent disputes." *AbbVie*, 764 F.3d at 1373.

Proper application of NSDP during prosecution cannot lose sight of these origins and principles. Since NSDP's creation, the Federal Circuit has emphasized that applying NSDP to any case must comport with the scope and purpose of the doctrine and its fundamental concern of an improper timewise extension. If equity does not compel its use, the doctrine should not apply.

The Federal Circuit's most recent discussion of NSDP in *Allergan* reiterates these principles. *Allergan* emphasized that NSDP's fundamental purpose is preventing "an *unjustified* timewise extension of patent exclusivity beyond the life of a patent." 111 F.4th at 1367 (emphasis added). *Allergan* held there was no such concern in that case, where the alleged NSDP reference patents, although earlier-expiring, were *later-filed and later-issued* than the patent at issue and all shared a common priority date, making the references "unquestionably 'second' to" the patent-at-issue. *Id.* at 1369. "Because the [patent-at-issue] was the first patent in its family to be filed and to issue, it does not *extend* any period of exclusivity on the claimed subject matter." *Id.* at 1370 (emphasis in original). *Allergan* drew on the scope and purpose of the doctrine, refusing to apply NSDP where doing so would be "antithetical to the principles." *Id.* at 1366, 1369, 1371.

III. THE DOCTRINE'S EQUITABLE PURPOSES AND LIMITED SCOPE INFORM THE ANSWERS TO EACH OF THE DIRECTOR'S QUESTIONS.

With these guiding principles in mind, PhRMA addresses each of the Director's questions

as presented in the Order convening the ARP.

A. The Guidance From *Allergan* Applies Here, Including What Constitutes "First-Filed."

In response to "the applicability, if any, of *Allergan*" here and "what constitutes 'first-filed' for OTDP purposes," Order at 2, PhRMA submits that *Allergan* applies—but not because this case or others need to fit *Allergan*'s specific factual pattern. Rather, *Allergan* reiterates the purpose of NSDP and the proper inquiry to apply. A narrow view of *Allergan* would erroneously prevent application of its foundational teachings regarding when equity may—or does not—trigger NSDP. Ignoring the broad teachings of NSDP case law and making NSDP analyses bespoke to each patent or application puts innovation at risk because of the uncertainty in gaining patent protections.

In *Allergan*, a first-filed, first-issued, later-expiring patent claim was challenged by later-filed, later-issued, earlier-expiring reference claims, all sharing a common priority date. 111 F.4th at 1369; *id.* at 1363-64 (timeline showing relationship between filing, issuance, and expiration dates of challenged patent and NSDP references). The Federal Circuit held the asserted references could not be NSDP references, applying equitable principles and confirming this was "the only conclusion consistent with the purpose of the ODP doctrine." *Id.* at 1369. Emphasizing "the role of filing dates," *Allergan* found it "untenable" for a parent patent to be limited by its own child and not "receive the benefit of its congressionally guaranteed patent term." *Id.* at 1370-71 (citing 35 U.S.C. § 154(b)). Because the parent, even though later-expiring (due to PTA), was first-filed and first-issued, there was no unjustified timewise extension and no basis for NSDP. *Id.* at 1370.

Allergan's consideration of "first-filed" is not limited to the first-filed application in a patent family, but applies across separate patent families. Just as *Allergan* teaches—and consistent with statutory provisions on patent terms—an application is "first-filed" for NSDP purposes if its

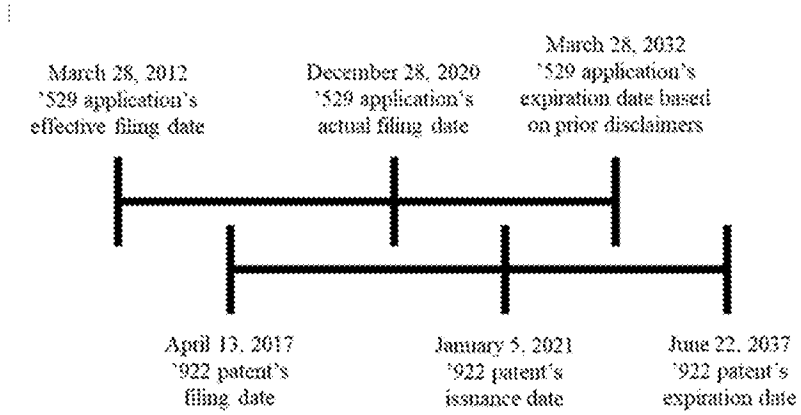
"effective filing, or priority, date, *i.e.*, the earlier of (1) the filing date of the application and (2) the filing date of an application from which the patent claims priority," is earlier (or at least no later) than such filing date of the alleged NSDP reference, regardless of whether the two share a common family. *Id.* at 1367 (citing 35 U.S.C. § 154(a)(2)). Such effective filing dates are relevant to NSDP analysis to assess whether the application at issue or the asserted NSDP was first, including but not limited to situations where the two are from the same family.

Accordingly, for NSDP purposes, "first-filed" refers to the invention with the earlier effective filing date, not necessarily the date of actual filing at the USPTO. This distinction is critical because NSDP's equitable concern is improper timewise extension of exclusivity, and the effective filing date determines when the patent term begins to run. On this question, too, it would be improper to reject *Allergan*'s broad teachings simply because it did not concern the precise factual scenario here. The Examiner mistakenly diminished *Allergan*'s use of "first-filed" to its precise scenario. *See* Request for Rehearing, at 2-5 (Jan. 3, 2025).

Here, compared to the asserted NSDP references at issue, the pending '529 application was first-filed.[1] It is also first-expiring—a patent that issues from the application will expire before the later-filed references.[2] Below is a representative comparison to the '922 patent:

[1] The '529 application claims priority to a provisional application filed March 28, 2011, whereas the priority dates of the asserted NSDP references "all post-date" that date. Decision on Appeal, at 5-6 & n.2 (Nov. 8, 2024).

[2] By virtue of terminal disclaimers submitted to overcome other asserted NSDP references, the '529 application will expire no later than March 28, 2032, whereas all of the NSDP references at issue here will expire "several years" later. Decision on Appeal, at 6-7 & n.5 (Nov. 8, 2024).



In these circumstances, just like in *Allergan*, there would be no unjustified extension of patent exclusivity.[3] Although the facts of *Allergan* differ, its holding controls. A first-filed patent application cannot be invalidated under NSDP by a later-filed patent. Also, where two inventions are patentably distinct, as here, the NSDP doctrine does not even apply. Under *Allergan* and NSDP principles, there is no equitable basis to use these later-filed patents to claim an improper timewise extension. Simply put, "this case is 'a prime example' of when [NS]DP does not apply," and it would be "untenable" if it did. *Allergan*, 111 F.4th at 1371; *cf. Gilead*, 753 F.3d at 1210 (timeline showing relationship between filing, issuance, and expiration dates of challenged patent and NSDP reference). NSDP is a narrow doctrine applied only where an unjustified timewise extension exists—and none exists here where later-filed patents are asserted against the first-filed application.

B. There is No Basis to Speculate an Expiration Date for Pending Patent Applications.

As to "whether examiners should determine projected expiration dates to support OTDP rejections during prosecution," Order at 2, PhRMA submits that examiners may calculate a

[3] In addition, the alleged NSDP references are patentably distinct from the '529 application. Decision on Appeal, at 9-10 (Nov. 8, 2024).

projected expiration date for pending patent applications by relying on available information, such as the 20-year patent term or terminal disclaimers that would control an expiration date, but they should not speculate about PTA.[4] During prosecution, grants of PTA are hypothetical and speculative; they are a moving target and not fixed until patent issuance. *See* 35 U.S.C. § 154(b)(3)(B)(i) (rules on adding and subtracting days for PTA). Attempting to predict PTA before it is realized would be premature and contrary to § 154. Such an exercise would also be contrary to NSDP's equitable principles because examiners themselves create the delays that trigger PTA. For pending applications, examiners should not attempt to project PTA.

The MPEP is consistent with this approach. Section 804 instructs examiners that they "must determine whether the grant of a second patent *would* give rise to an unjustified extension of the rights granted in the first patent." MPEP § 804.I.A (emphasis added); *see also Gilead*, 753 F.3d at 1216 (observing that MPEP § 804 advises "looking to the expiration date instead of issuance date"). This authorizes NSDP analysis to project 20-year terms for pending applications, shortened by terminal disclaimers if applicable; these calculations can readily be discerned based on existing facts to assess whether issuance "*would* give rise to an unjustified extension." MPEP § 804.I.A (emphasis added). This comports with *Allergan*'s instruction that reference claims "are

[4] In calculating expiration dates, the Examiner here would erroneously disregard the terminal disclaimers for the pending '529 application because of a hypothetical potential for withdrawal. *See* Request for Rehearing, at 8 (Jan. 3, 2025). The ARP should reject this. Although terminal disclaimers do not take effect until patent issuance, that does not alter the fact that a disclaimer exists, and, unlike with PTA, this situation requires no projection or guesswork. Indeed, as the Federal Circuit has instructed, "[a]n applicant must always overcome every rejection to gain issuance of a patent," such as by "the pre-issuance timing requirement of a terminal disclaimer to overcome a double patenting rejection," and so "[a] terminal disclaimer can indeed supplant a finding of invalidity for double patenting" during prosecution. *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005). Moreover, the circumstances to warrant a disclaimer's withdrawal are narrow, and, if necessary, NSDP issues can be addressed as part of that process. But where a pending application is subject to a terminal disclaimer, examiners should apply that existing fact to determine the expiration date for NSDP analysis. *See* 35 U.S.C. § 154(a)(2).

not proper [*NS*]*DP references*" where that is "the only conclusion consistent with the purpose" of the doctrine. 111 F.4th at 1369. By contrast, the MPEP does not authorize speculating about projected PTA for pending applications. Attempting to analyze NSDP based on projected hypothetical facts contrasts with what should be its limited scope. Because NSDP during prosecution can be only evaluated based on hypothetical, not actual, facts, as opposed to NSDP during reexamination or litigation when all required information is finally known, reliance on NSDP is particularly inapt and contrary to its limited scope and underlying equitable principles.

C. A Hypothetical Risk of Separate Ownership Should Not Be Considered, Much Less as an Independent Basis for NSDP.

With respect to whether examiners should speculate about and consider hypothetical scenarios regarding whether a common owner could someday assign two otherwise valid patents separately—as an independent basis for an NSDP rejection during prosecution—PhRMA submits that the answer is "no." *Allergan* is also instructive on this point.

Allergan acknowledged a concern in NSDP case law with risk of separate ownership, noting such concern is "commonly obviated" by terminal disclaimers tying expiration dates and ownership together. 111 F.4th at 1368 (citing *Boehringer Ingelheim Int'l GmbH v. Barr Lab'ys, Inc.*, 592 F.3d 1340, 1346 (Fed. Cir. 2010)).[5] While risk of separate ownership may be "one of the two public policy concerns underlying" NSDP, Request for Rehearing, at 10 (Jan. 3, 2025), there is no basis in case law to treat it as a standalone basis. When reversing an NSDP invalidity determination given no unjustified timewise extension, *Allergan* did *not* proceed to evaluate risk of separate ownership, even though it acknowledged that aspect of the doctrine. 111 F.4th at 1369.

The Examiner's reliance on *Cellect* is misplaced, appearing to argue that *Cellect* permits

[5] *Boehringer*, cited by *Allergan*, made no reference to ownership. *See* 592 F.3d at 1346.

reliance on a risk of separate ownership as the sole basis for an NSDP rejection—even if there is no timewise extension issue. *See* Request for Rehearing, at 10-11 (Jan. 3, 2025). In *Cellect*, the Federal Circuit focused on the common ownership question because "[n]either Cellect nor the USPTO dispute[d] that the asserted claims in the challenged patents would have been obvious variations of the respective claims in the invalidating [NS]DP references." *Cellect*, 81 F.4th at 1229. *Cellect* did not endorse risk of separate ownership as an independent basis.

Moreover, examiners should not speculate about hypothetical risks of separate ownership, particularly where the Federal Circuit has not done so, and the Patent Act does not require common ownership. *See Perricone*, 432 F.3d at 1375 (where a "hypothetical does not correspond to the record," there is no basis to rely on it). Such speculation would exceed Patent Office authority.

Here, with the application and alleged NSDP references commonly owned, hypothetical future ownership changes have no place as the *sole basis* for an NSDP rejection. The USPTO should not lose sight of NSDP's fundamental purpose—preventing improper timewise extensions.

IV. CONCLUSION

The USPTO should apply NSDP according to its proper scope—a judicially created doctrine with limited applicability that must always be viewed through its equitable purpose: to prevent "an unjustified timewise extension of patent exclusivity." *Allergan*, 111 F.4th at 1367. Here, where the '529 application is first-filed and earlier-expiring, it involves no unjustified timewise extension, so the doctrine does not apply. A contrary decision would contradict the guiding principles of *Allergan*, other Federal Circuit jurisprudence, and statute.

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