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 AMICI CURIAE REGENERON PHARMACEUTICALS, INC., BAYER AG, and BEONE MEDICINES INC. IN SUPPORT OF APPELLANT

INTRODUCTION

The following amicus curiae brief is submitted by Regeneron Pharmaceuticals, Inc., Bayer AG, and BeOne Medicines Inc. in support of the patent applicant/Appellant in the matter of *Ex Parte Baurin*, PTAB Appeal No. 2024-002920, pursuant to the Director's March 5, 2026 Appeals Review Panel Order authorizing amicus briefing.

Amici are pharmaceutical and biotechnology companies who create new treatments for serious diseases and who are constantly innovating to deliver life-transforming medicines to patients. Amici invest heavily in developing pioneering treatments and depend on robust and predictable intellectual property rights in order to protect the results of their work and to allow them to continue bringing new technologies to market.

The primary purpose of the judicially-created obviousness-type double patenting ("ODP") doctrine is to prevent unjustified patent term extension. *See Allergan USA, Inc. v. MSN Labs. Private Ltd.*, 111 F.4th 1358, 1367 (Fed. Cir. 2024) ("The doctrine's primary goal is to prevent an unjustified timewise extension of patent exclusivity beyond the life of a patent."). Amici submit that, to the extent this doctrine is still viable in a post-GATT world, this purpose should guide any application of the ODP doctrine. A contrary approach would disincentivize cutting-edge, life-transforming research in

the pharmaceutical and biotechnology industries and would undermine the USPTO's mission of protecting and fostering innovation.

QUESTION 1: "FIRST-FILED" ANALYSIS

The Examiner's analysis in *Baurin* conflicts with the purpose of ODP, *i.e.*, to prevent a second patentably indistinct patent from extending the term of a "first filed" patent having an earlier effective filing date. In addition, the Examiner's approach would produce the unjust outcome that a first application whose disclosures are indisputably full prior art to a second, patentably distinct patent, could be invalidated by that second patent. *See* Dec. on Appeal, 9. The Federal Circuit has never held that a second-filed patent so unrelated to a first (*i.e.*, where the first patent is full prior art to the second) was a "first filed" or proper ODP reference patent.[1] The judicially-

[1] In *Lilly v. Barr*, the subject patent claimed priority back to 1974 but arose from a continuation-in-part (CIP) application filed in 1986, more than three years after the effective filing date of the reference patent. In finding the CIP patent invalid for ODP, the court did not address the effective filing date of the subject patent's claims nor the availability of either patent as prior art to the other. *Eli Lilly and Co. v. Barr Labs., Inc.*, 251 F.3d 955, 960, 962, 968 n.7 (Fed. Cir. 2001) ("[The subject] patent issued in December 1986, approximately eight months after a continuation-in-part

created ODP doctrine should not be applied here to override the more fundamental statutory prior art inquiry that assesses whether a second patent is worthy of an independent grant. That statutorily mandated assessment includes asking whether its claims are obvious not just in view of prior claims but in view of entire documents. ODP inquiries in a post-GATT world should be limited to situations where neither the reference nor subject patent is available as prior art under 35 U.S.C. § 103. *Lilly*, 251 F.3d at 973 ("The judge made law of obviousness-type double patenting was developed to cover the situation where patents are not citable as a reference against each other and therefore can not be examined for compliance with the rule that only one patent is available per invention. Double patenting thus is applied when neither patent is prior art against the other, usually because they have a common priority date.") (Newman, J., dissenting).

The doctrine of ODP should remain focused on the key inquiry: whether issuing the subject claims would result in an *unjustified extension* of a "first filed" patent, where the "first filed" patent is the patent that properly qualifies as a reference patent. Most importantly, ODP should not be applied

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was filed . . . ."), ("On May 20, 1986, the [reference] patent issued from an application filed on April 8, 1983.").

in a manner to convert later-filed applications and patents with patentably distinct claims into "first filed" (reference) patents and thereby invalidate patents issuing from applications with earlier effective filing dates. A contrary approach would hinder crucial research in the pharmaceutical and biotechnology industries because developing and patenting new innovations would still be subject to a constant threat of invalidation by prior patents. This is a particularly unjust outcome where, as in the present appeal, the claims of the later patent are nonobvious over the disclosures, including the claims, of the subject patent. *See* Dec. on Appeal, 9.

In the biopharmaceutical sector, the process of developing a candidate molecule into an approved medicine is a complex process which lasts many years. Drug development requires sustained investment and innovation, including generation of the active molecule itself, development and optimization of drug formulation(s), and rigorous testing to ensure maximum bioavailability, safety, and clinical benefit to patients. This innovation results in improved medicines—yielding, for example, improved dosing convenience, greater stability, needle-free routes of administration, increased onset and duration of relief, and reduced side effects. Improved formulations or drug delivery platforms may also transform a previously ineffective therapeutic candidate into a viable treatment. Testing frequently reveals new

populations of patients who can benefit from treatment.

Inventive contributions made throughout this process merit patent protection. The patenting process frequently parallels the step-by-step nature of the drug development process itself, with protection being sought for new advancements and refinements throughout a development program. Continued investment throughout the prolonged and stepwise drug development process is put at risk if the ODP doctrine is extended beyond its traditional moorings.

The Examiner's approach in the present appeal means that an earlier-filed genus claim can face ODP rejections over later-filed, patentably distinct species claims, because the earlier foundational application directed to the genus often takes longer to prosecute, while the later application directed to a patentably distinct species may be quicker to issue. The ability to separately patent both of those inventions is fair and essential to incentivize investment in improvements, thereby ensuring patient access to safe and effective therapeutics.

ODP should neither disincentivize patent owners from disclosing inventions and filing patent applications on subsequent patentably distinct improvements (including, for example, the ability to treat other diseases), nor encourage the continued maintenance (i.e., by paying maintenance fees)

of otherwise unneeded patents, solely out of a fear of losing other legal rights. *See Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1347, 1349 (Fed. Cir. 2010) (patentee unable to file a terminal disclaimer to overcome invalidity due to double patenting over an expired patent). Such an approach would undermine the patent system's core goal of encouraging disclosure and innovation.

QUESTION 2: WHETHER EXAMINERS SHOULD DETERMINE PROJECTED EXPIRATION DATES

As set forth above in response to Question 1, examiners should not need to determine projected expiration dates for the purpose of conducting an ODP analysis where, as here, the patents/applications are so unrelated that the disclosures of one are prior art to the other. *See* Dec. on Appeal, 9. If, however, the Office determines patents so unrelated should be subject to ODP analysis, then the application of ODP must involve determining whether the subject patent's term would extend beyond the later filed reference patent. Under Federal Circuit precedent, performing this inquiry ***requires*** determining patent expiration dates. *See Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1215 (Fed. Cir. 2014) ("[I]t is the comparison of Gilead's patent expiration dates that should control . . . .").

An examiner may not know *everything* regarding a pending

application's ultimate term (because, *e.g.*, PTA has not yet been awarded), but that does not mean that the examiner cannot know *something* about that term. One exemplary scenario is illustrated by the present case, where the expiration date of the pending claims would undisputedly not extend beyond that of the alleged reference patent, in light of terminal disclaimers already filed. Dec. on Appeal, 5. Because PTA cannot extend patent term beyond a terminal disclaimer's stated date, any uncertainty regarding future PTA is irrelevant in a case where the maximum possible term is known due to the filing of a terminal disclaimer. *See Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1322 (Fed. Cir. 2007) ("§154(b)(2)(B) expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for PTO delays").

Ultimately, if the facts underlying any such preliminary determination change in the future (e.g., a terminal disclaimer is withdrawn[2], or different PTA is awarded), as the Majority noted in the Decision on Rehearing in the present appeal, "the onus should rest with the patentee to voluntarily file a terminal disclaimer prior to the expiration of the patent . . . if they want to avoid a litigation based ODP challenge that could potentially invalidate any

[2] As the Examiner postulated could hypothetically occur. *See* Reh'g Dec., 13.

issued patent." Reh'g Dec., 15. The presence of some uncertainty regarding patent terms should not prevent an examiner from performing a legally required analysis using available information—and declining to make an ODP rejection where that information makes clear that the application under examination will not have a patent term extending beyond the reference patent's expiration date.

QUESTION 3: WHETHER RISK OF SEPARATE OWNERSHIP IS A SUFFICIENT SOLE BASIS FOR ODP

Concerns over harassment appear to be exaggerated—we are aware of no evidence that separate ownership of patents covering obvious variants has led to systematic harassment of accused infringers.

Conversely, allowing harassment concerns to serve as a *sole* basis for the application of ODP presents real risks to research and innovation. Any such policy would increase the risk of standard employee mobility imperiling a company's intellectual property. Because a common inventor alone can support the application of ODP, there are situations in which a terminal disclaimer *cannot* be filed to remove an ODP rejection due to lack of common ownership. This risk is illustrated in *In re Hubbell*, 709 F.3d 1140 (Fed. Cir. 2013). There, a patent jointly owned by ETHZ and Universität Zurich (filed after an inventor moved from CalTech) was used to reject

claims of CalTech's patent application (naming two common inventors). Due to lack of common ownership, CalTech could not file a terminal disclaimer that otherwise would have removed the ODP rejection.

Finally, biotechnology companies often collaborate, aligning expertise and background technologies to create innovative technologies and therapeutics that otherwise would not have been possible or would have been developed more slowly. Permitting harassment concerns as a sole basis for ODP would increase the risk associated with inter-company collaborations and result in fewer innovation partnerships which advance scientific progress. Earlier-filed applications filed by one party to the collaboration *before the commencement of the collaboration* may be rendered unpatentable by later-filed applications or patents directed to the results of the collaboration even where there is no unjustified term extension of the earlier filed patents. This is because, if the rejected application predates the collaboration, it may not be possible to file an appropriate terminal disclaimer to remove the ODP rejection over the later-filed reference patent, at least under the Office's current regulations. *See* 37 C.F.R. §§ 1.104(c)(4)(ii) (disqualification of prior art reference), 1.321(d) (terminal disclaimer over such a disqualified reference). Allowing innovations arising from such collaborations to more easily disrupt patenting of the background

technologies will ultimately hinder scientific advancement.

CONCLUSION

In conclusion, in keeping with its purpose of preventing unjustified extensions of first-filed patents, ODP should not be applied—as the Examiner did here—to treat a patent having a later effective filing date and patentably distinct claims as a proper ODP reference. Expiration dates are not relevant in such circumstances, but examiners should determine them where needed to support ODP rejections of properly situated patents and applications. The hypothetical concern of harassment by separate owners is outweighed by real-world concerns of the creation of aberrant, potentially incurable ODP determinations. Findings to the contrary in each of these scenarios would improperly broaden the scope of ODP, to the detriment and disincentivization of valuable therapeutic innovations.

Respectfully Submitted,

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