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,
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APPEAL 2024-002920

APPLICATION 17/135,529

TECHNOLOGY CENTER 1600

BRIEF OF *AMICUS CURIAE* GLAXOSMITHKLINE PLC IN SUPPORT OF APPLICANTS

I. Interest of Amicus

Amicus GLAXOSMITHKLINE PLC ("GSK"), having a principal place of business at 79 New Oxford Street, London, WC1A 1DG, United Kingdom, spends billions of dollars annually in the United States developing innovative medicines, vaccines, and therapies.[1] Those efforts have yielded breakthroughs in the fight against COVID-19, HIV, cancer, shingles, meningitis, asthma, diabetes, malaria, and other diseases.

GSK submits this brief to address the three questions presented by the Appeals Review Panel of the Patent Trial and Appeal Board ("ARP") in its March 5, 2026 Order Convening Appeals Review Panel and Authorizing Amicus Briefing.

GSK seeks to assist the ARP in developing a coherent, administrable, and legally consistent framework governing obviousness-type double patenting ("OTDP" or "ODP") rejections in view of the Federal Circuit's decision in *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*, 111 F.4th 1358 (Fed. Cir. 2024). The questions presented have substantial implications for GSK and the pharmaceutical industry at large, as the Patent Office frequently rejects claims in pharmaceutical patent applications in view of the OTDP doctrine. *See, e.g.*, *Ex parte Di Benedetto,* No. 2026-001494 (appeal of OTDP rejections in Application No. 16/462,630, where

[1] This brief was not authored in whole or in part by any party's counsel; no person or entity other than GSK financially contributed to its preparation or submission; and GSK has no stake in the parties or case outcome.

GSK's wholly owned vaccine subsidiary GLAXOSMITHKLINE BIOLOGICALS SA is the appellant).

II. Argument

A. In *Allergan* The Federal Circuit Analyzed The Interaction of OTDP and Patent Term Adjustment

In *Allergan*, the Federal Circuit considered under what circumstances a "claim is a proper ODP reference" and the interaction between OTDP and Patent Term Adjustment ("PTA"). 111 F.4th at 1369. First, the Court considered the "fundamental purposes of ODP," which is to prevent "a second patent on a patentably indistinct invention to effectively extend the life of a first patent." *Id.*; *see also In re Cellect*, 81 F.4th 1216, 1226 (Fed. Cir. 2023) (OTDP is "'intended to prevent a patentee from obtaining a time-wise extension of patent for the same invention or an obvious modification thereof' and prevents an inventor from **claiming a second patent** for claims that are not patentably distinct from the claims of a first patent.") (citing *In re Lonardo,* 119 F.3d 960, 965 (Fed. Cir. 1997)) (emphasis added); *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1214 (Fed. Cir. 2014) ("[I]t is a bedrock principle of our patent system that when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention. . . . The double patenting doctrine has always been implemented to effectively uphold that principle.").

Second, the Court considered "the benefit Congress intended to bestow on patentees when codifying PTA," particularly "to account for patent term lost due to [Patent Office] delays in prosecution." *Id.* at 1367; *see also see Intra-Cellular Therapies, Inc. v. Iancu*, 938 F.3d 1371, 1374–75 (Fed. Cir. 2019) (summarizing congressional rationale for PTA).

Third, the Court recognized that a later-filed patent in a family could expire before an earlier-filed patent "due to an award of PTA." *Id.* at 1368.

With these principles in mind, the Federal Circuit held that a later-filed application **cannot** be used in an OTDP rejection of an earlier-filed application within the same family even when the earlier-filed application will expire **after** the patent that issued from the later-filed application due to PTA. *Id.* at 1358, 1371. Holding "otherwise—that a first-filed, first-issued parent patent having duly received PTA can be invalidated by a later-filed, later-issued child patent with less, if any PTA"—"would require patent owners . . . to file a terminal disclaimer disclaiming any term of the parent that extends beyond that of the child, which, given that the patents share a priority date, would amount to the disclaimer of *only* PTA." *Id.* at 1371 (emphasis in original). The Court held that such a requirement would contravene Congress' PTA intentions, while serving no doctrinal OTDP purpose; the later-filed application was not extending the life of a patent from the earlier-filed one. *Id.*

B. The Logic of *Allergen* Is Determinative

Here, the ARP considers a similar question: whether a patent or patent application with a later-patent term filing date could support an OTDP rejection of an earlier-patent term filed application. The main factual difference between this case and *Allergan* is that the reference patent and subject application are not in the same family and have different patent term filing dates. But *Allergan*'s logic makes that distinction irrelevant.

By pursuing claims with an earlier priority date, the applicants here are not extending any patent term beyond which they would otherwise be entitled. Just as in *Allergan*, applicants should not be forced to disclaim any PTA Congress intended to bestow, regardless of the status of the later application. *Allergan*'s reasoning governs, and the ARP should adopt a bright-line rule: a reference with a later filing date cannot serve as the basis for an OTDP rejection for an earlier-filed application.

C. *Allergan*'s Bright-Line Rule Allows for Refinement of Inventions

Allergan's bright-line rule reflects how, in practice, inventors refine their ideas from one invention to the next. When inventors improve on their original ideas, they may invent nonobvious features, which they may seek to protect in a second application with a later-patent term filing date. When the earlier-patent term filing date controls, the examiner can evaluate any features added to the later-patent term filed application to determine whether they are nonobvious and patentably

distinct. That is the appropriate use of the OTDP doctrine.

If an examiner could also consider the later-patent term filed application for an OTDP rejection of the earlier application, that examiner could find the later-filed (and refined) application renders the earlier application obvious and issue an OTDP rejection—forcing the applicant to file a terminal disclaimer and surrender potential PTA. That would be an inappropriate use of the OTDP doctrine and constitutes bad policy. It would discourage inventors from seeking patent protection for refinements, weakening a patent system designed to encourage innovative disclosure. *See, e.g.*, Sean B. Seymore, *Symposium: The Disclosure Function of the Patent System*, 69 VAND. L. REV. 1455 (2016) ("A fundamental goal of the patent system is to encourage the dissemination of technical knowledge.") (citing *Brenner v. Manson*, 383 U.S. 519, 533 (1966)); *PSC Computer Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1361 (Fed. Cir. 2004) (emphasizing "the important public notice function of patents").

D. Holding *Allegan* Inapplicable Would Create Conflicting Precedent

Failure to follow *Allergan*'s reasoning here would also create conflicting standards. The question of the legitimacy of an OTDP rejection (or later challenge in court) would turn on whether the references are in the same family. *Allergan* must continue to govern OTDP rejections within a family, and *Allergan* holds that the later-filed reference cannot serve as a basis of an OTDP rejection. But if the ARP

declines to follow *Allergan*, the later-patent term filed reference could serve as a basis of an OTDP rejection for unrelated applications. In the context of OTDP, there is no principled reason to treat applications in the same family differently from those in unrelated families.[2] Applicants would be incentivized to link priority claims between families to argue that the reference is in the same family, encouraging gamesmanship. The Patent Office and the public would then have to sort through more convoluted records to ascertain true priority and expiration dates.

Sidestepping *Allergan* also would create conflict between how the Patent Office treats PTA and Patent Term Extension ("PTE") under 35 U.S.C. § 156. In *Novartis AG v. Ezra Ventures LLC*, the Federal Circuit held that a later-filed patent could not serve as a basis for an OTDP rejection of an earlier-filed patent with PTE that extended the earlier-filed patent's expiration beyond that of the later-filed patent. 909 F.3d 1367, 1372 (Fed. Cir. 2018). The *Ezra* decision is rooted in the same principle that governed in *Allergan*: OTDP should not apply in cases where the patent owner is not "extending his exclusive rights to an invention through claims in a later-filed patent that are not patentably distinct from claims in the earlier filed patent." *Id.* at 1374 (quoting *Procter & Gamble Co. v. Teva Pharm. USA, Inc,* 566

[2] MPEP §804 should be updated to reflect *Allergan*, and a consistent decision from the ARP allows for consistent revisions to the MPEP for OTDP rejections across families.

F.3d 989,999 (Fed. Cir. 2009).[3]

E. Examiners Need Not Determine Projected Expiration Dates

Currently, Examiners do not determine projected expiration dates. This is because PTA calculations depend on the issue date, which examiners do not know when they are considering an application. Examiners could only at best guess what a PTA award may be—something the Supervisory Patent Examiner, the Director of the Technology Center, and the Deputy Commissioner for Patents (Legal) concede. *See, e.g.*, *Ex parte Baurin*, Request for Rehearing dated January 3, 2025 ("Examiners are not able to predict expiration dates because examiners cannot know how much patent term adjustment will be awarded for that patent that issues from an application under examination . . . . Requiring examiners to speculate as to the expiration date of a pending claims . . . would represent a significant departure from current examination practice and procedures."). The ARP should not require examiners to speculate, as that would only result in additional applicant challenges to the examiners' assumptions and uncertainty.[4]

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[3] With the passage of the Uruguay Round Agreements Act in 1995, patent terms are now 20 years from their patent term filing date instead of 17 years from issuance. That the applicant in *Ezra* filed the earlier patent before the change in patent term does not detract from the holding.

[4] Examiners also do not consider PTE, a calculation that requires interaction between the Patent Office and the Food and Drug Administration. Examiners could not calculate PTE either because Examiners do not know if the claims cover a commercial product subject to regulatory approval. *See* 35 U.S.C. § 156.

Basing OTDP rejections on expiration dates also would create the possibility of OTDP rejections in both directions. For example, an examiner could make an OTDP rejection in the later-filed application over the earlier-filed application, forcing a terminal disclaimer. Later on, upon seeing a delay in the issuance of the earlier-filed application, the examiner could then project PTA and make the reciprocal rejection. The applicant would be forced to file a second terminal disclaimer, losing all benefit of PTA that Congress intended to bestow.

Just as the filing date should remain the focus for all statutory anticipation and obviousness rejections, so too should the filing date control OTDP rejections across families. An earlier-patent term filed application cannot be subject to statutory anticipation and obviousness rejections citing a later-patent term filed application. That reasoning should apply equally for OTDP rejections. *See Allergan*, 111 F.4th at 1358; *see also Ezra*, 909 F.3d at 1367. A later-patent term filed application is subject to statutory anticipation and obviousness rejections. That reasoning should apply equally for OTDP rejections. *Id.*

Universally focusing on the filing date creates a clear and consistent policy. Examiners do not need to make projections nor deviate from the chronological analysis, which is consistent for all art-based rejections.

F. Speculative Risk of Separate Ownership and Harassment by Separate Owners Does Not Support an OTDP Rejection

Any speculative risk of future separate ownership does not justify holding

here that each unrelated patent or application can be an OTDP reference for the other, regardless of chronology.

Again, the judicially-created doctrine of OTDP exists "to prevent a patentee from obtaining a time-wise extension of patent for the same invention or an obvious modification thereof and prevents an inventor from **claiming a second patent** for claims that are not patentably distinct from the claims of a first patent." *In re Cellect*, 81 F.4th at 1226 (emphasis added). Requiring a terminal disclaimer reinforces the doctrine. *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1280 (Fed. Cir. 1992) ("obviousness-type double patenting . . . could be overcome by filing a terminal disclaimer, which had been provided for in section 253 of the 1952 Patent Act for that very purpose"); MPEP § 804.02; 37 C.F.R. § 1.321.

Under 37 C.F.R. § 1.321(c)(3), the terminal disclaimer must "include a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting."

But no court has ever held that risk of separate ownership alone suffices for an OTDP rejection in a first-filed application. While the Federal Circuit in *In re Cellect* acknowledged "a risk of separate ownership existed," 81 F.4th at 1229, it did not hold that this supports an OTDP rejection. As the Court noted in *Allergan*, the

patent owner in *In re Cellect* "did not challenge whether the reference claims used to invalidate the asserted claims were proper ODP reference claims. Therefore, under the principle of party presentation, the court did not consider that issue." 111 F.4th at 1369 n.6.[5]

Without any guidance from the courts or Congress, the ownership tail should not wag the OTDP dog. In any event, under *Allergan*, Examiners can still require a terminal disclaimer for the later-filed patent or application. This prevents both the extension of patent term by the later-filed application and the risk of separate ownership and harassment. There are already appropriate safeguards in place.

III. Conclusion

For the foregoing reasons, GSK respectfully requests that the ARP follow the reasoning in *Allergan* and create a bright-line rule that a reference with a later-patent term filing date cannot serve as the basis for an OTDP rejection for an earlier-patent term filed application.

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[5] In denying the request for rehearing in this case, the Board also correctly acknowledged how the principle of party presentation limited the application of the holdings of *In re Fallaux*, 564 F.3d 1313 (Fed. Cir. 2009) and *In re Van Ornum*, 686 F.2d 937 (Cust. & Pat. App. 1982). *Cf. Ex parte Baumeister*, No. 2026-000193 (declining to follow the Board's holding in this case and relying on *In re Fallaux* and *In re Van Ornum*).

Respectfully submitted,

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