**UNITED STATES PATENT AND TRADEMARK OFFICE**

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

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

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Appeal 2024-002920
Application 17/135,529

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# BRIEF OF *AMICUS CURIAE* AMGEN INC. IN SUPPORT OF APPELLANT

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## I. INTRODUCTION AND INTEREST OF *AMICUS CURIAE*

Amgen Inc. is one of the world's largest biotechnology companies and a pioneer in developing and manufacturing life-saving human therapeutics. As a manufacturer of both novel therapies used to treat patients with serious illnesses and of biosimilars, Amgen relies on a robust and predictable patent system to protect its continued innovation in life-saving research and to permit it to bring biosimilars to market at an appropriate time. Amgen submits this *amicus* brief because it is concerned about the uncertain and inconsistent application of obviousness-type double patenting.

Obviousness-type double patenting ("ODP") is a judge-made, equitable doctrine intended to prevent the unjustified extension of a patent term by pursuing obvious variations of a prior claimed invention in a later-filed patent application. Adopted under the prior term law of 17 years from patent issuance, ODP prevented patent applicants from extending effective patent protection by securing multiple patents claiming obvious variants and having later issue dates. But with the adoption of a patent term that is 20 years from filing date, ODP now focuses on filing dates and should apply only in a few narrow situations. Judges are uniquely positioned to apply ODP by assessing the facts and circumstances of each case and appropriately exercising their judicial discretion to prevent unjustified extensions of patent terms. In contrast, the Patent Office makes its decisions based on the

Patent Act, is not a court of equity, and cannot know the facts and circumstances that arise at the time of enforcement. Accordingly, the Office should not expand the doctrine beyond its narrow boundaries.

The Appeals Review Panel invited *amici* to address whether *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*, 111 F.4th 1358 (Fed. Cir. 2024), bears on this appeal, whether examiners should project expiration dates as part of their ODP analysis, and whether the Office should consider the question of common ownership. In sum, *Allergan* makes plain that later-filed patents should not be used as double-patenting references against earlier-filed applications, and thus no predictions about expiration dates are required.

Separately, examiners cannot reject claims based solely on the possibility that similar claims issued in commonly owned patents might in the future become owned by separate assignees who might, in turn, bring serial lawsuits and harass alleged infringers. This concern has never been a sole basis for applying ODP. A contrary approach here would upend a long line of precedent.

## II. ARGUMENT

### A. *Allergan* Forecloses Using a Later-Filed Patent to Reject Claims in an Earlier-Filed Application.

Although the *facts* in this case differ from those in *Allergan*, the court's reasoning and articulation of the fundamental principles of ODP apply with full force here. The Federal Circuit has long recognized that ODP "is designed to

prevent a patent owner from 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." *Procter & Gamble Co. v. Teva Pharms. USA*, 566 F.3d 989, 999 (Fed. Cir. 2009) (emphasis added). And, as explained further below, *Allergan* confirms that a patent issuing from an earlier-filed application cannot, under current patent term law, extend the term of a patent issuing from a later-filed one.

Prior to the effective date of the Uruguay Round Agreements Act ("URAA") of 1994, Pub. L. No. 103-465, 108 Stat. 4809—which changed the patent term from 17-years-from-issuance to 20-years-from-filing—the relevant metric for determining which patent would serve as a double-patenting reference against the other was the *issuance* date. *See Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1359, 1362 (Fed. Cir. 2018). In that pre-URAA system, a later-issuing patent ordinarily would expire later than an earlier-issuing one, which thus raised the question whether the second issuing patent effected an unjustified extension of the term of protection over the inventions claimed in the first.

But *Allergan* recognized the critical "role of filing dates" in assessing post-URAA patents. 111 F.4th at 1370. In the post-URAA world, an earlier-filed patent ordinarily will not expire after the term of a later-filed patent. *See generally id.* at 1371. And even when the earlier-filed patent does expire later as a result of a patent-term adjustment, the implication is clear: to allow a "first-filed, first-issued

parent patent" to be invalidated by a "later-filed, later-issued child patent with less, if any, PTA" would "not only run afoul of the fundamental purposes of ODP, but effectively abrogate the benefit Congress intended to bestow on patentees when codifying PTA." *Id.* Any result that compels patent owners to disclaim the term of an earlier-filed patent "would be untenable," as doing so would undo a "congressionally guaranteed" patent-term adjustment. *Id.*

Although the facts of *Allergan* involved a patent issuing from the *first* application in a family, the Federal Circuit's emphasis on the role of *relative* filing dates in a post-URAA world does not turn on whether a given patent is the first in a *family*. What matters is when the application issuing as the patent was filed *relative to* the other application.[1] Thus, a patent issued from an earlier-filed application cannot be portrayed as extending the term of patents issuing from later-filed applications. *See, e.g.*, *Arkose Labs Holdings, Inc. v. DataDome*, No. 23-cv-1467, 2025 WL 1885692, at *11–13 (D. Del. July 8, 2025) (recognizing that *Allergan*'s holding protects an "earlier filed (but not 'first-filed')" application); *see also Acadia Pharms. Inc. v. Aurobindo Pharma Ltd.*, 706 F. Supp. 3d 477, 488 (D. Del. 2023) ("a patent must be earlier-filed to be available as an OTDP reference"),

[1] As used here, the applicable "filing date" is the effective filing date, *i.e.*, the filing date of the earliest-filed application to which an application claims priority and from which the 20-year patent term is measured under 35 U.S.C. § 154(a).

*aff'd*, 2025 WL 1618201 (Fed. Cir. June 9, 2025). The Board was therefore right to follow the reasoning of *Allergan* and reverse the Examiner's rejections.

### B. Examiners Need Not and Should Not Project Expiration Dates.

The *Allergan* rule focuses on the "role of filing dates," 111 F.4th at 1370, and thus obviates any need for examiners to consider when patents might expire. As a general rule, patents will expire in the order in which they were effectively filed (or on the same date, for patents in the same family). This means a later-filed patent cannot serve as an ODP reference against an earlier-filed patent. *See id.* at 1371. Since the later-filed patent cannot be used as a reference either way, there is no need to calculate relative expiration dates.

Patent Office practice already reflects a recognition that predicting potential expiration dates during examination is difficult: Patent-term adjustments are no longer calculated until issuance, *see* MPEP § 2733,[2] which makes sense because adjustments are based on the fully completed examination of an application, including delays up to and through the issue date, which cannot be reliably predicted in advance. *See generally* 35 U.S.C. § 154(b). Furthermore, a rule requiring such predictions would place examiners in a position of issuing rejections

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[2] The Patent Office implemented this change in 2013 to "eliminate[] the need for the Office to provide an initial patent term adjustment determination with the notice of allowance and before the patent term adjustment . . . is known." MPEP § 2733.

based on patent expiration calculations that depend on adjustments that they themselves directly affect (*e.g.*, adjustments based on how timely Office Actions are issued). Patent examiners should not make assumptions about when a patent *might* expire, and there is simply no need to do so under *Allergan*.

### C. Speculation That Patents Issuing from Commonly Owned Applications Might One Day Result in Separate-Owner Problems Cannot Support an ODP Rejection.

The mere possibility that two applications that are commonly owned today might someday fall into separate hands is not a justification for an ODP rejection. Such a hypothetical approach finds no support in controlling precedent and, in fact, would undermine a long line of Federal Circuit cases that declined to apply ODP where there was no unjustified extension of patent term.

1. Speculation Regarding "Harassment" Cannot Support a Rejection.

As the Board correctly noted, no court has ever held that patent claims may be invalidated for obviousness-type double patenting based solely on the hypothetical concern of harassment. Rehearing Decision at 23. Although the Federal Circuit has invoked the "harassment by multiple assignees" policy, *see, e.g.*, *In re Fallaux*, 564 F.3d 1313, 1318–19 (Fed. Cir. 2009), the policy itself has never been the basis for a rejection or an invalidity determination. In both *Fallaux*, 564 F.3d at 1319 & n.5, and *In re Hubbell*, 709 F.3d 1140, 1148–49 (Fed. Cir. 2013), the applicant sought to file a terminal disclaimer to eliminate any concern

regarding a potential unjustified extension of term. But in both cases, the remedy of a terminal disclaimer was unavailable under Patent Office rules because the patents at issue in those cases were *already owned* by separate entities at the time the double-patenting issue was raised, which meant they could not file a terminal disclaimer. *See Fallaux*, 564 F.3d at 1319; *Hubbell*, 709 F.3d 1140, 1147 (Fed. Cir. 2013). The unavailability of the remedy of a terminal disclaimer in *Fallaux* and *Hubbell* does not suggest that examiners should rely on hypothetical anti-harassment concerns to reject claims based on the possibility of separate ownership of patents that would not otherwise be invalid for double patenting. Instead, it merely reflects a recognition that Patent Office rules, in particular 37 C.F.R. § 1.321(c)(3), require that such disclaimers include a provision tying together the ownership of patents subject to the disclaimer. *See generally In re Van Ornum*, 686 F.2d 937 (Fed. Cir. 1982).

2. The Federal Circuit's Predecessor Court Refused to Countenance Speculative Concerns Regarding Separate Ownership.

Controlling Court of Customs and Patent Appeals cases from before the 1971 promulgation of § 1.321(c)(3) make clear that the possibility of separate ownership is *not* an independent basis for applying double patenting. *See, e.g.*, *Application of Jentoft*, 392 F.2d 633 (C.C.P.A. 1968).

*Jentoft* is highly instructive. There, the applicant submitted a terminal disclaimer that eliminated any possibility of an unjustified extension, but the

disclaimer did *not* include a non-alienation provision that would satisfy what is now reflected in § 1.321(c). The court was therefore forced to directly consider the key question: Could anti-harassment support a rejection by itself? The court's answer was "no." The "mere possibility of harassment" could not serve as a basis for rejection. *Jentoft,* 392 F.2d at 641. The court further underscored the "unreality of the harassment theory" by noting that courts were not "bogged down with harassment suits," which in any event could be handled by the tools for deterrence available to district judges, including awards of "attorneys' fees." *Id.* at 641; *see also Application of Robeson*, 331 F.2d 610, 615 (C.C.P.A. 1964) (similarly rejecting freestanding "harassment" theory). *Jentoft* and *Robeson* confirm that the Patent Office cannot expand double-patenting law to deal with a problem that can arise only in courts and is best handled—if it arises at all—by judges.

3. The Federal Circuit Has Not Applied a Separate Ownership Test for ODP

ODP is a judge-made doctrine grounded in the federal court's authority to adjudicate suits in equity, where judges—with the benefit of discovery and adversarial presentation—are empowered to consider the specific facts and circumstances in each case. *See Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1059 (Fed. Cir. 2020). The Office's lack of both the full set of tools and the information available to courts in equity further underscores why the Office should not reject claims based solely on anti-harassment policy concerns.

Moreover, in cases where the Federal Circuit held that ODP should *not* be applied because a difference in term was *not* unjustified, the court did not reject or invalidate the patents at issue based on the potential for separate ownership in the future. The Office should not do differently.

*Allergan* is exemplary. In *Allergan*, the Federal Circuit held that a difference in term could *not* justify the application of double patenting to invalidate a first-filed, first-issuing patent—a conclusion the court described as the "only" one "consistent with the purpose of the ODP doctrine." 111 F.4th at 1369. The court did not consider the potential for future separate ownership as a reason to apply ODP. Doing so, as proposed by the Examiner here, would require a terminal disclaimer *even on the facts of* Allergan *itself*. The result would be to flip the equities of *Allergan* upside down, supplanting the Federal Circuit's implementation of double-patenting policy.

Other examples abound. The Federal Circuit has also refused to find double patenting where a difference in term was the result of a change in patent-term law, *Novartis v. Breckenridge.*, 909 F.3d 1355, or the result of statutory patent-term extension, *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018). In each case, the consequence of the court's holding was that no terminal disclaimer would be required, because there was no unjustified extension of patent term. Again, the court did not consider the potential of future separate ownership as a

reason to apply ODP. For the Office to require a terminal disclaimer to address such a future event, where the Federal Circuit did not, would undo the decisions in *Breckenridge* and *Ezra*. Indeed, such an approach would even require a terminal disclaimer where a difference in term is due solely to Patent Office delay—thus abrogating the two-way test for ODP, *see e.g.*, *In re Janssen Biotech, Inc.*, 880 F.3d 1315, 1325 (Fed. Cir. 2018)—because agency delays have nothing to do with the possibility of harassment by separate assignees. The Office should not adopt an approach on ODP that is inconsistent with Federal Circuit decisions.

## III. CONCLUSION

The Board properly applied Federal Circuit precedent and rejected the application of ODP to the facts here. The Panel should do the same.

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Respectfully Submitted,

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