2023-2254

United States Court of Appeals
for the Federal Circuit

MERCK SHARP & DOHME B.V., MERCK SHARP & DOHME, LLC,

Plaintiffs-Appellees

v.

AUROBINDO PHARMA USA, INC., AUROBINDO PHARMA LTD., USV PRIVATE LIMITED, GLAND PHARMA LIMITED, MANKIND PHARMA LTD., LIFESTAR PHARMA LLC, FRESENIUS KABI USA, LLC, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., SUN PHARMACEUTICAL INDUSTRIES, INC., SUN PHARMACEUTICAL INDUSTRIES LIMITED, SANDOZ INC., LEK PHARMACEUTICALS, D.D., MYLAN API US LLC, MYLAN PHARMACEUTICALS INC., MYLAN INC., EUGIA PHARMA SPECIALTIES LIMITED,

Defendants-Appellants

LUPIN LTD., LUPIN PHARMACEUTICALS, INC., LUPIN INC., TEVA PHARMACEUTICALS USA, INC.,

Defendants

Appeal from the United States District Court for the District of New Jersey in Nos. 2:20-cv-02576-CCC-LDW, 2:20-cv-02750-CCC-MF, 2:20-cv-02751-CCC-MF, 2:20-cv-02786-CCC-MF, 2:20-cv-02787-CCC-MF, 2:20-cv-02892-CCC-MF, 2:20-cv-02909-CCC-MF, 2:20-cv-02964-CCC-MF, 2:20-cv-03007-CCC-MF, 2:20-cv-03068-CCC-MF, 2:20-cv-03072-CCC-MF, 2:20-cv-03112-CCC-MF, 2:20-cv-03117-CCC-MF, 2:20-cv-03270-CCC-MF, 2:20-cv-03314-CCC-MF, and 2:20-cv-03795-CCC-MF, Judge Claire C. Cecchi.

Corrected Brief for the Director – U.S. Patent and Trademark Office as Amicus Curiae in Support of Plaintiffs-Appellees and Affirmance

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I. STATEMENT OF INTEREST

The United States Patent and Trademark Office (USPTO) respectfully submits this amicus brief pursuant to Rule 29(a) of the Federal Rules of Appellate Procedure. The USPTO is responsible for, *inter alia*, reissuing patents under 35 U.S.C. § 251, determining whether a patent is eligible for a patent term extension (PTE) under 35 U.S.C. § 156, and determining the term of any such PTE. *See* 35 U.S.C. §§ 156, 251; *see also* 37 C.F.R. §§ 1.741, 1.750. This appeal concerns the statutory interpretation of 35 U.S.C. § 156 as it relates to determining the term of PTE for a reissue patent, and thereby directly implicates the USPTO's function as the agency responsible for such determinations. The resolution of this appeal will have a direct impact on the USPTO's policy and practice for calculating the PTE for reissue patents. All of this together makes this appeal of particular interest to the USPTO, and therefore the USPTO appreciates the opportunity to provide its views on these issues.

II. SUMMARY OF THE ARGUMENT

The Hatch–Waxman Act provides for patent term extensions (PTE) to compensate patentees for the patent term lost while seeking premarket regulatory approval (e.g., FDA approval). The sole question on appeal is whether the PTE granted to a reissue patent should include the time spent seeking regulatory approval that occurred after the original patent was issued but before the patent was reissued.

This question turns on the construction of 35 U.S.C. § 156(c)'s phrase "the date the patent is issued," the starting point for calculating PTE. Section 156(c) provides that the term of the extension is based on the time of "the regulatory review period for the approved product which period occurs *after the date the patent is issued*," thereby excluding any review period occurring before issuance. 35 U.S.C. § 156(c) (emphasis added). This appeal concerns what starting date to use for a patent that has been *reissued* to correct an error that rendered the original patent "wholly or partly inoperative or invalid." 35 U.S.C. § 251.

Consistent with its long-standing practice, the USPTO used the issue date of the original patent when calculating the PTE for the reissue patent at the center of this appeal, RE 44,733. The district court confirmed the correctness of the USPTO's practice, providing a well-reasoned analysis of § 156's statutory text in the context of the Patent Act as a whole, including those provisions directly concerning reissue patents (35 U.S.C. §§ 251 and 252). In doing so, the district court determined that the issue date in § 156(c) refers to the issue date of the original, not the reissue, patent. The district court rejected Defendants'[1] contrary interpretation, one that relies on the issue date of the reissue patent, because it myopically focused on the word "issued" in § 156(c). As the district court held, Defendants' blinkered approach

[1] Consistent with the Opening Brief, the USPTO will refer to Defendants-Appellants collectively as "Defendants" and to Plaintiffs-Appellees as Merck. Br. at 1, n.1; *see* Appx0009.

fails to consider the relevant statutory language in context and within the overall statutory scheme. Defendants' statutory construction therefore does not pass scrutiny.

Section 156(c) states that PTE calculations only include regulatory review periods occurring "after the date the patent is issued," but does not define "issued" or address reissue patents. The meaning of the word "issued," on its own, also may refer back to the issuance of the original patent or may refer to the date the patent is reissued. But those provisions directly concerning reissue patents—§§ 251 and 252—clarify that a PTE calculation under § 156(c) should be based on the issue date of the original patent. Section 252 explicitly states that a reissue patent has the effect as if it "had been originally granted in such amended form," and § 251 dictates that a reissue patent has the "unexpired part of the term of the original patent." Thus, the effect and term of a reissue patent are directly tied to that of the original patent.

The district court's interpretation is fully consistent with the policies behind both granting PTE and allowing reissue patents—i.e., to compensate the patentee for the marketing time lost due to FDA review and to allow the patentee to correct errors appearing in their patent, respectively. This Court has explained that both §§ 156 and 252 should be construed liberally, and using the issue date of the original patent prevents a patentee from being penalized for availing themselves of reissue practice and avoids the wholly anomalous result of *more* FDA delay resulting in *less* PTE.

Even if the statutory language were ambiguous, this Court should accord the USPTO's interpretation *Skidmore* deference. The agency's longstanding and consistent approach to calculating PTE for reissue patents reflects its expertise and a careful consideration of the relevant issues.

III. ARGUMENT

A. The Proper Interpretation of "the date the patent is issued" in 35 U.S.C. § 156(c), Based on the Language and Context of the Patent Act as a Whole, Is the Original Patent's Issue Date

It is a fundamental canon of statutory construction that the language of the statute must be read "by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *Robinson v. Shell Oil Co*., 519 U.S. 337, 341 (1997). Here, the relevant statutory language states that the amount of PTE granted to a patent is based on the regulatory review period for the approved product "which period occurs after the date the patent is issued." 35 U.S.C. § 156(c).

In isolation, the word "issue" in § 156(c) may refer to either the issue date of the original patent or the reissue patent. It is therefore necessary to construe the term in light of its statutory structure and context, most specifically those provisions defining the characteristics and effects of reissuing a patent—§§ 251 and 252. Under such an analysis, it is clear that a reissue patent maintains many of the characteristics of the original patent. The district court properly considered the language of § 156(c)

within this overall context and correctly concluded that the "date the patent is issued" for a reissue patent, refers to the issue date of the original patent. Appx29-41.

Defendants' contrary construction, which focuses heavily on the meaning of the word "issued" in isolation, ignores the rest of the Patent Act (*see* Br. at 18-19)[2], and is therefore contradictory to the principle of interpreting statutes "as a symmetrical and coherent regulatory scheme." *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (internal quotations and citations omitted); *see also Obsidian Sols. Grp., LLC v. United States*, 54 F.4th 1371, 1374 (Fed. Cir. 2022) (explaining that statutory text must not be considered "in a vacuum" but rather within its statutory context); Appx30.

1. In Isolation, the Phrase "Is Issued" in § 156(c) May Refer to the Issue Date of the Original Patent or to the Issue Date of the Reissue Patent

As noted, the calculation of PTE under § 156(c) depends, in part, on "the date the patent is issued." As Defendants acknowledge, the Patent Act does not define the word "issue." Br. at 23. But the ordinary meaning of "issue," put forth by Defendants ("[t]o be put forth officially" (*see* Br. at 24)), fails to elucidate whether "the date the patent is issued" in § 156(c) refers to the issue date of the original or of the reissued patent.

[2] Citations to the Joint Appendix are denoted as "Appx___." Citations to Defendants' Brief are denoted as "Br. at __."

In certain contexts, the word "issue" or "issued" refers to the issuance of the original patent on which a reissue is based. The face of a reissue patent, for example, uses the word "issued" to identify the issue date of the original patent. Appx57. Similarly, §§ 151-153, on which Defendants rely (Br. at 24-25), are directed to the issuance of an original patent, whereas § 251 instructs the Director to "reissue the patent." *Compare* 35 U.S.C. §§ 151-153 *with* 35 U.S.C. § 251(a). Congress confirmed in the 1952 Patent Act that § 152 concerns the issuance of original patents whereas § 251 addresses the "reissue" of such patents. *See* S. Rept. No. 82-1979 at 23 (June 27, 1952) (noting that § 152 did not refer to "reissue" because that was addressed in § 251); *see* 35 U.S.C. § 44 (1946) (provision predating § 152, distinguishing between patents that are "issued or reissued").[3]

In other contexts, however, the word "issue" is used to refer to issuance of the reissue patent. As Defendants note, the front cover of the certified copy of RE 44,733 gives the "issue date" as the date the reissue patent was granted. Appx56. Likewise, Merck's PTE application used the term "issue date" to refer to both the date the original patent was issued and the date the patent was reissued. Appx6290. Sections 251 and 252, the provisions relating to reissue patents, also use the term "issue" with

[3] Only through § 251(c) are the provisions of §§ 151-153 applicable to an application for reissue. 35 U.S.C. § 251(c); see also S. Rept. No. 82-1979 at 26 (noting that § 251 incorporates the provisions related to "other applications" so as to apply to "application[s] for reissue").

respect to the reissue patent. 35 U.S.C. § 251(b) (stating that the "Director may issue several reissued patents"); 35 U.S.C. § 252 (stating that the "surrender of the original patent shall take effect upon the issue of the reissued patent").

Accordingly, the word "issued" standing alone refers in some contexts to the grant of an original patent from which a patent later reissues, and in others contexts refers to the grant of a reissue. In *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330 (Fed. Cir. 2008), this Court found the similar phrase "issues from" to be ambiguous on its own, sometimes referring to the final application in a chain and other times reaching back and referring to the original, parent, application. *Id*. at 1340. Without a definitive meaning, the statutory interpretation of § 156(c) does not "begin[] and end[] with the meaning of the word 'issued'," as Defendants assert (Br. at 18; *see* Appx30). The district court therefore properly went beyond analyzing the meaning of "issued" in § 156(c) in isolation and considered the meaning of the term in the context of the statutory provisions governing reissued patents, §§ 251 and 252. Appx30; *see Merck & Co. v. Kessler*, 80 F.3d 1543, 1550-1551 (Fed. Cir. 1996) (finding that the phrase "original expiration date" in § 156(a)(2) could identify more than one date and thereby interpreting the phrase in view of other statutory sections).

2. Section 252 Requires a Reissue Patent to Have the Same Effect and Operation in Law as if Originally Granted in Amended Form

Section 252, which is entitled "Effect of reissue," ties a reissue patent back to

the original patent grant and dictates that the relevant issue date for § 156(c) is that of the original patent. *See* Appx32-33. Specifically, § 252 states that "every reissued patent shall have the same effect and operation in law, on the trial of actions for causes thereafter arising, *as if the same had been originally granted in such amended form*." 35 U.S.C. § 252 (emphasis added). This language first appeared in the statute in 1836, following the establishment of reissue practice by the Supreme Court in *Grant v. Raymond*, 31 U.S. 218 (1832). *See* Pub. L. 24–357, 5 Stat. 117, enacted July 4, 1836. And the language of the statute implements *Grant*'s holding that a reissued patent is not independent but rather has "relation to the original transaction" such that "[t]he time of the privilege still runs from the date of the original patent." *Id*. at 244. The holding in the very case that established the concept of a reissue therefore confirms that a reissue patent retains many of the characteristics of the original patent, including its issue date. Thus, "the date the patent is issued" in § 156(c) naturally refers to the date the original patent issued, consistent with § 252's requirement that a reissue patent have the same effect stemming back to the original patent grant. Appx32-33; *see Grant*, 31 U.S. at 244.

Defendants submit that § 252 is inapplicable because, they assert that the USPTO's PTE determination is not a "trial of action." *See* Br. at 35-36. But even if the USPTO's determination of PTE is not a "trial of action," litigation concerning a patent extended by PTE and litigations concerning PTE calculations, such as the

present case or an Administrative Procedure Act challenge to a PTE determination, *are* trials of action. *See* Appx32 (noting the present litigation is a trial of action arising after reissue). The USPTO's use of the original patent date, in accordance with § 252, for calculating PTE—which directly impacts later "trials of action"—effectuates the requirement in § 252 that a reissue patent in litigation has "the same effect and operation in law" as if it were the original patent. It would be counter-intuitive for a reissue patent to have the effect as if it were the original patent in litigation, but not have this same effect in an administrative proceeding before the USPTO, that may lead to or affect litigation. Here, using the issue date of the reissue patent would deprive the reissue patent of the full amount of PTE that would have been available if the original patent had been granted in "amended form." *See* 35 U.S.C. § 252. Moreover, any inconsistent outcomes due to forum (*see* Br. at 36), would be avoided by giving proper effect to § 252 in both litigation as well as in the calculation of PTE.

Defendants' assertion that § 252 is limited to just liability and damages in litigation (*see* Br. at 20, 35) is equally unavailing. To start, the language of the statute is not so limited, but rather refers broadly to the "effect and operation in law" of a reissue in any "trial of action[]." 35 U.S.C. § 252. Accordingly, no court has held that the privileges of a reissue that run from the date of the original patent are limited to just liability or damages. To the contrary, this Court in *Cooper* implicitly rejected

such a narrow reading by using § 252 to aid in the interpretation of another statute regarding administrative inter partes reexamination proceedings. *See* 536 F.3d at 1341 (noting that based on § 252 "reissues are deemed by operation of law to replace the surrendered originals and, thus, are entitled to treatment as original patents."). Defendants' atextual limitation on the effect of § 252 therefore should be rejected.

3. Section 251 Further Supports Using the Issue Date of the Original Patent

Use of the issue date of the original patent for PTE calculations under § 156(c) for reissue patents is also consistent with the other reissue statute, 35 U.S.C. § 251. Appx30-32. Section 251 sets the term for a reissue patent as the "unexpired part of the term of the original patent." That language evinces Congress's desire to maintain parity between the term of a reissue patent and the original it replaces. It is therefore logical that PTE under § 156(c) be based on the issue date of the original patent to maintain equivalency between the original patent's term and the reissue patent's term.

Indeed, this Court has held that a patent's "unexpired term" refers to the baseline term established by 35 U.S.C. § 154(a), as extended or disclaimed by any other term-adjustment provisions. *In re Yamazaki*, 702 F.3d 1327, 1332 (Fed. Cir. 2012). Under present-day § 154(a)(2), the beginning of that baseline term is when the original patent issues, and the end of the term is calculated based on the filing date of the original application. Appx32, n.6. Prior to the 1994 Uruguay Round

Agreements Act, the beginning of the baseline term was also the issue date and the end of the term was calculated based on the date the original patent issued. *Merck*, 80 F.3d at 1547; Appx32, n.6. Accordingly, under §§ 251 and 154, the term of a reissue patent extended by PTE under § 156(c) has always been based on the term of the original patent (beginning on the issue date and ending on a date calculated from the issue or application date). Keying the calculation of the amount of PTE under § 156(c) that extends that term to the issue date of the original patent maintains consistency with this statutory scheme. There is also no question that if PTE was granted on the original patent, it would be based on the original issue date, and that extended term would be inherited by any subsequent reissue under § 251.

In addition, the statute provides that PTE becomes part of the term of the original patent. 35 U.S.C. § 156(e) (specifying that the certificate awarding PTE "shall be considered as part of the original patent"). Using a date tied to the reissue patent *only* for calculating the amount of PTE, which then becomes part of the original patent, defies logic and fails to interpret § 156 in conjunction with § 251.

Defendants criticize the district court's reliance on § 251, arguing that it is irrelevant that the term of a reissue is based on the term of the original patent, because the reissue term is still a "new term" and the reissue patent is not an "amended version of the original." Br. at 40-42. Defendants' implication that a reissue patent is entirely independent from the original patent is belied by the plain

language of §§ 251 and 252 and is inconsistent with a century of precedent. *See Grant*, 31 U.S. at 244. Furthermore, even if the term of a reissue patent is a new term, that new term is still based on the term of the original patent, which in turn depends on the issue/application dates of the original patent.

Defendants further urge that because Congress carved out an exception for the term of a reissue patent in § 251, but did not do so in § 156 for PTE, an exception cannot be read into the latter. Br. at 31. But there was no need to create a special provision for reissue patents in § 156(c) because Congress legislated with full knowledge of the relationship between the term of a reissue patent and the original patent. *See Yamazaki*, 702 F.3d at 1332. Thus, the lack of a specific reference to the date to use for calculating PTE for a reissue patent does not compel a conclusion that Congress intended the issue date of the reissue patent to be used. Rather, it is the opposite conclusion that maintains fidelity to all provisions of §§ 156, 251, and 252. *See* Appx41.

In sum, the phrase "the date the patent is issued" in § 156(c), when viewed in combination with the language of §§ 251 and 252, refers to the date the original patent issued.

B. Surrender of the Original Patent Does Not Render a Reissue Patent Completely Independent with no Ties to the Original Patent

Defendants repeatedly assert that because the "surrender" of a patent under §§ 251 and 252 renders the original patent "dead," the term "issued" in § 156(c)

cannot refer to the issue date of the original patent. *See* Br. at 3, 27-28, 43. But the cases highlighted by Defendants only stand for the undisputed proposition that the legal instrument that is the original patent cannot be enforced upon reissue. *See, e.g., Seattle Box Co. v. Indus. Crating & Packaging, Inc.*, 731 F.2d 818, 827 (Fed. Cir. 1984) (explaining that "[a]n original patent cannot be infringed once a reissue patent has issued, for the original patent is surrendered"). Therefore, subject to exceptions in § 252 for substantially identical claims carried over into a reissue patent, *pending suits* based on the original patent "fall with the surrender." *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1336-1337 (Fed. Cir. 2013) (quoting *Moffit v. Garr*, 66 U.S. 273, 283 (1861)). Nothing in the cases cited by Defendants negate that a reissue patent still carries forward, for all subsequent actions, those aspects of the original patent that allow it to have the same effect and operation in law as the original patent. *See* 35 U.S.C. § 252.

In a similar vein, Defendants rely heavily on this Court's statement in *Intel Corp. v. Negotiated Data Sols., Inc*., 703 F.3d 1360 (Fed. Cir. 2012) that "a reissue patent does not simply replace an original patent *nunc pro tunc*." *Id*. at 1364; Br. at 37, 37, 41. Contrary to Defendants argument, however, using the issue date of the original patent for a PTE calculation does not go beyond the holding in *Intel*. Rather, *Intel* rejected a *nunc pro tunc* replacement theory because of the intervening rights provided for under § 252. *Id*. Using the issue date of the original patent to calculate

PTE does not impact intervening rights, which remain precisely the same regardless of the calculation of PTE. The court in *Intel* did not address or interpret any aspects of a reissue that are treated as the original or any other aspects of the statutory scheme that inform how to interpret § 156 in view of the provisions of §§ 251 and 252. *Id*.

Other relevant caselaw confirms the relationship between a reissue patent and the original patent, notwithstanding the surrender of the original. As the Supreme Court explained nearly two centuries ago, a reissue "ha[s] relation to the original transaction" and "[t]he time of the privilege still runs from the date of the original patent." *Grant*, 31 U.S. at 244. Likewise, this Court in *Cooper* held that a reissue patent connects back to the original patent's filing date for purposes of determining whether it could be subjected to an inter partes reexamination, even though the reissue patent arises from a separate application. *Cooper*, 536 F.3d at 1341. The Fourth Circuit in *Mylan Pharms., Inc. v. FDA*, 594 F. App'x 791 (4th Cir. 2014) further recognized that "elements of the reissued patent overlap with those of the original patent." *Id*. at 797. And, this Court held that the effective filing date of a reissue patent is that of the original patent, despite not being able to claim priority under 35 U.S.C. § 120 to the original patent. *See In re Bauman*, 683 F.2d 405, 410 (C.C.P.A. 1982) ("Only a reissue application can be entitled to the filing date of a

patent in the absence of copendency.").[4] Thus, the case law confirms that surrender of the original patent does not sever all ties between the reissue patent and the original patent.

C. The Policies Behind Granting PTE and Allowing Reissue Patents Support Using the Issue Date of the Original Patent

As the district court determined, the interpretation of § 156(c) is clear from the language of the statute and its statutory context alone. Appx41; *see Bostock v. Clayton Cnty*., 140 S. Ct. 1731, 1749 (2020) ("This Court has explained many times over many years that, when the meaning of the statute's terms is plain, our job is at an end."). Nevertheless, the purpose behind PTE and reissue practice additionally supports the district court's holding. *See* Appx41-45.

Section 156 was enacted to compensate patent holders for the time spent obtaining FDA approval, during which the patented product cannot be marketed. *Merck*, 80 F.3d at 1546-1547. This Court has explained that "[t]he statute contemplates a patentee receiving time lost in its patent term by reason of FDA delay, and the statute should be liberally interpreted to achieve this end." *Merck*, 80

[4] While Defendants assert that 35 U.S.C. § 100(i)(2) is the basis for the equivalency in effective filing date between the claims of a reissue patent and an original patent, and thus Congress knew how to provide exceptions to the impact of surrendering the original patent (Br. at 31, 60), they neglect to appreciate that this provision was only first added in 2011. Additionally, the legislative history for this provision explains that claims of a reissue application maintain the filing date of the original application because a "reissue is treated as an amendment to the patent," consistent with § 252. *See* 157 Cong. Rec. S1368 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl).

F.3d at 1552. Here, there is no dispute that both the original patent and the reissue patent covered the approved product and that Merck was unable to market the product following grant of the original patent due to ongoing FDA review. *See* Appx11; *see also* Appx45. Thus, construing § 156(c) to use the issue date of the original patent achieves the statute's purpose. *See* Appx44-45. Moreover, using the issue date of the original patent does not extend the total patent term beyond seventeen total years, which was a motivator behind including this provision. *See* Alan D. Lourie, *Patent Term Restoration: History, Summary, and Appraisal*, 40 Food Drug Cosm. L. J. 351, 356 (1985) (explaining that counting only the time of regulatory review after patent issuance "is of little importance owing to other limitations in the law").

As the district court additionally explained, using the issue date of the original patent avoids the incongruous outcome where *more* FDA delay would lead to *less* PTE, an outcome directly contrary to the purpose behind PTE. Appx38-40. For example, if the FDA issued its approval before an application for reissue was filed or while a reissue application was pending, it is undisputed that PTE would be calculated based on the original patent's issue date, and that term would be adopted by any later reissue patent. Appx38-39. But, under Defendants' theory, if the FDA regulatory period lasted *longer* and the FDA issued its approval after reissue was granted, the time of PTE would be *shorter*, including only the time of review after

the reissue was granted. *See* Appx39. Such an anomalous result contradicts Congress's intent to "compensate for the delay in obtaining FDA approval." *Merck*, 80 F.3d at 1547; Appx39. Furthermore, it is unlikely that Congress intended such a dramatic loss in PTE and disparate results to arise from a patentee's correction of an error through reissue, a practice not intended to deprive patentee of the privileges granted under the original patent. *See In re Willingham*, 282 F.2d 353, 354–55 (C.C.P.A. 1960) (observing that the reissue statute is "based on fundamental principles of equity and fairness and should be so applied to the facts in any given case that justice will be done both to the patentee and to the public"); *see also Grant*, 31 U.S. at 244.

Defendants agree that under its theory, a difference in days between when the reissue patent issues may result in a substantial difference in PTE, yet asserts that it is not uncommon in the law for minor differences to have a substantial impact. Br. at 51. Defendants' examples, however, relate either to compliance with statutory deadlines and/or concern factors that can be controlled, such as the filing of a notice of appeal, the filing of a patent application, or the proper designation of a patent application. *Id*. But as the district court correctly explained, the date of FDA approval and the grant of a reissue patent are mostly out of a patentee's control. *See* Appx39-40. Thus, Defendants' assertion that using the reissue date is simply holding a patentee to the consequences of its actions misses the mark, and does not

persuasively rebut the district court's determination that using the reissue date would lead to unusual results that Congress in no way intended.

Likewise, Defendants' hypothetical regarding a broadening reissue does not inform the analysis. *See* Br. at 50. To the best of the Director's knowledge, such a scenario has never been presented to the USPTO. That makes sense given the short 2-year time frame for filing a broadening reissue and the low percentage of PTE certificates granted on reissue patents. *See* 35 U.S.C. § 251(d); *see* Appx48 (noting the USPTO has handled only a "couple of dozen" PTE calculations for reissued patents); *see also* https://www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156 (last visited Jan. 10, 2024) (providing a spreadsheet listing all the PTE certificates issued by the USPTO). As this Court determined in *Merck* with respect to remedies for different extension types, Defendants' hypothetical "is more illusory than real," and "the majority of patents should not be denied extensions because of a mere possibility that special problems may arise in a few instances." *Merck*, 80 F.3d at 1551-1552.

D. The USPTO's Long-standing Policy of Using the Issue Date of the Original Patent for PTE Calculations Is Entitled to Deference

The district court properly determined that to the extent there is ambiguity in the statutory scheme, the USPTO's interpretation of § 156(c) is entitled to deference under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). Appx55. This Court should find the same in the event it finds the statute ambiguous.

Skidmore requires courts to accord deference to agency interpretations of statutory provisions that fall within the agency's particular subject-matter expertise, to the extent that those decisions have the power to persuade. *See* 323 U.S. at 140. In determining whether to defer to an agency's interpretation, courts look to, *inter alia*, agency expertise, the thoroughness of the decision, and the decision's consistency with earlier and later pronouncements. *See id*.; *see also Cathedral Candle Co. v. ITC*, 400 F.3d 1352, 1366 (Fed. Cir. 2005).

1. The USPTO Has Substantial Expertise in Administering the PTE and Reissue Statutes

The USPTO has a high level of expertise in administering the statutes at issue. Congress has given the USPTO sole authority to issue patents in the first instance, to reissue them, and to grant PTE[5]. Administering the Patent Act is the central purpose of the USPTO and the agency has developed substantial expertise in reissuing patents for over 150 years and granting PTE for almost 40 years. *See Hagans v. Comm'r of Soc. Sec*., 694 F.3d 287, 305 (3d Cir. 2012) (giving a "high level" of *Skidmore* deference to the Social Security Administration's statutory interpretation based in part on the agency's expertise in administering disability insurance). Given the USPTO's expertise in administering the complex PTE scheme

[5] Although the FDA has a role in the determination of PTE, including determining the regulatory review period of the product at issue, that role has no bearing on the question of the issue date to use in calculating PTE. *See* 35 U.S.C. § 156(d)(2).

to reissue patents, it is well situated to interpret the statutes governing such practices. *See Heartland By-Prods., Inc. v. United States*, 264 F.3d 1126, 1135-1136 (Fed. Cir. 2001). Defendants do not contest the district court's finding that the USPTO's "institutional expertise" adds to the persuasive force of the agency's interpretation. *See* Appx54.

2. The USPTO Thoroughly Articulated Its Long-Standing Rationale For Treating a Reissue Patent as an Amended Version of the Original Patent

The thoroughness and long-standing nature of the USPTO's rationale for treating a reissue patent as an amended version of the original patent lends additional persuasive power to the agency's interpretation of § 156(c). *See* Appx46-49; *see also* Appx53-54. The USPTO has clearly articulated its view of the effect of a reissue patent, based on its interpretation of the statutes, in the Manual of Patent Examination and Procedure (MPEP). As the district court recognized, and Defendants do not dispute, the MPEP is "the authoritative source of guidance for all the PTO's responsibilities." Appx47; *see* Br. at 55. In section 1460 of the MPEP, the USPTO states, citing to § 252, that for "Office treatment," a reissue patent "will be viewed as if the original patent had been originally granted in the amended form provided by the reissue." MPEP § 1460; Appx47. Thus, § 1460 leaves no question as to how the USPTO interprets the language of § 252 in the context of agency proceedings. *See* Appx47. The MPEP has reflected this same interpretation since

2000. *See* MPEP § 1460 (Rev. 1, Feb. 2000). Section 1440 of the MPEP builds on this understanding and explains that the effective filing date of the claims of a reissue application will be that of the original patent because "a reissue patent replaces the original patent, and thus is merely continuing the patent privilege of the original patent as opposed to being an independent (regular) patent with its own privilege (and its own term)." MPEP § 1440 (*citing Grant*, 31 U.S. at 244).

The USPTO, through §§ 1460 and 1440 of the MPEP, has therefore thoroughly explained that, based on the statutory language of § 252 and Supreme Court precedent, it interprets § 252 to require the agency to give a reissue patent the same effect as if originally granted in amended form. Appx46-47; Appx53. This interpretation was applied in the USPTO's calculation of PTE in this case, where it expressly noted that RE 44,733 is a reissue patent, noted the issue date of the original patent, and then used the issue date of the original patent in its calculation. *See* Appx1035. Defendants raise three arguments challenging the district court's finding that the USPTO has sufficiently explained its statutory rationale, but all lack merit.

First, Defendants assert that because the USPTO's final determination did not set forth the rationale for using the issue date of the original patent, it is entitled to no deference. Br. at 53-54, 62. This argument ignores, however, that the MPEP sets forth the effect of a reissue patent and expressly states that it applies to all "Office treatment of the reissued patent." *See* MPEP § 1460. Therefore, while not contained

in the final determination of PTE, the rationale behind the agency's use of the original issue date is "not difficult to discern." *See Hagans*, 694 F.3d at 305 (giving deference to agency interpretation despite the ruling in question not explaining the reasoning behind adopting the interpretation when the reasons were "not difficult to discern"); Appx53-54.

Second, Defendants challenge the rationale set forth in the MPEP as inadequate because it does not specifically address PTE calculations or directly interpret the language in § 156(c). Br. at 55. But Defendants' argument again ignores § 1460's broad directive on the effect of a reissue patent that applies to all "Office treatment." The lack of specificity as to PTE calculations does not detract from clear overarching guidance set forth in § 1460. Furthermore, the district court factored in the breadth of the MPEP, and still determined that together with the USPTO's "institutional expertise and consistent practice on the precise question at issue," the USPTO's interpretation had the "power to persuade" and is entitled to deference. Appx54-55 (quoting *United States v. Mead Corp.*, 533 U.S. 218, 219 (2001)); *see infra* III.D.3 (addressing the USPTO's consistent practice).

Moreover, as the district court explained, the lack of a section on PTE calculations for reissue patents is not surprising given the low percentage of PTE applications filed on reissue patents. *See* Appx48. The USPTO also recently amended the MPEP to reflect its long-standing practice of treating reissue patents as

amended versions of original patents. Appx49. In particular, MPEP § 2766 was amended to clarify that the "original patent grant date would be used to calculate the extension to which the reissued patent would be entitled" when both the original and reissued patent claim the approved product.[6] Although the amendment occurred after the PTE calculation in this case, MPEP § 2766 reflects long-standing agency practice and conforms with § 1460's broader articulation. This case is therefore unlike *Gose v. United States Postal Service,* 451 F.3d 831 (Fed. Cir. 2006), relied on by Defendants (Br. at 58-59), where there was no evidence of the intent of the agency prior to litigation and the agency's interpretation was inconsistent with its own regulations. *Id*. at 840.

Finally, §§ 1460 and 1440 are not inapposite as Defendants assert. Br. at 59-60. In particular, § 1460 is not limited to infringement actions, but instead is broadly directed to "Office treatment," which includes PTE practice. Defendants' attempt to cabin a section of the MPEP, which provides guidance on agency matters, to only addressing infringement actions that do not take place before the agency, does not withstand scrutiny. Furthermore, § 1460's recognition of a caveat for intervening

[6] This section of the MPEP does not say that the reissue date will be used when the reissued patent covers the approved product for the first time (MPEP § 2766), as Defendants contend (*see* Br. at 58). As discussed *supra* the unlikely scenario of a reissue covering the approved product for the first time is not at issue here and, to the best of the Director's knowledge, has never been presented to the USPTO. *See supra* III.C. Thus, the failure of the MPEP to address this obscure hypothetical scenario does not affect the analysis in this case.

rights also ensures that agency guidance is consistent with this Court's decision in *Intel*. And while § 1440 is directed to discussing the effective filing date of the claims of a reissue application, it also details in no uncertain terms that the rationale for treating reissued patents as an amended form of the original patent stems directly from *Grant*. The USPTO's rationale, as laid forth in the MPEP, is therefore long-standing, well-reasoned, and explicit.

3. The USPTO Has Consistently Treated Reissue Patents As Amended Versions of the Original Patent

The USPTO's consistency in treating a reissue patent as an amended version of the original patent, including using the original patent's issue date for purposes of PTE calculations, further adds to the persuasive force of the USPTO's interpretation of § 156(c). *See* Appx48-49; *see also* Appx52-53. As the district court explained, the USPTO consistently follows the broad directive of MPEP § 1460 and treats the reissue patent as an amended version of the original. For example, 35 U.S.C. § 41(b) sets the due date for maintenance fees based on the date of the patent grant, which the USPTO interprets to be the issue date of the original patent. *See* 37 C.F.R. § 1.362(h); *see also* MPEP § 1415.01. The USPTO also uses the filing date of the original application for the claims of the reissue application (MPEP § 1440), transfers the term of the original patent over to the reissue patent (MPEP § 1405) consistent with § 251, and transfers over the PTE application filed on an original patent to a reissue patent (MPEP § 2766).

The USPTO has further been consistent in specifically using the issue date of the original patent for PTE calculations of reissue patents. Appx23-24; Appx52. The district court found that in 36 out of 40 cases, the USPTO used the original issue date for PTE calculations for a reissue patent. Appx23-24. And Defendants do not dispute that the four outliers were distinguishable for the reasons found by the district court. Appx52-53. Minor deviations from the agency's ordinary practice, particularly in distinguishable factual circumstances, do not preclude giving deference to an agency's interpretation. *See Warner-Lambert Co. v. United States*, 425 F.3d 1381, 1386 (Fed. Cir. 2005).

Defendants assert, however, that the USPTO's interpretation is inconsistent with the USPTO's decision in *Eizo Corp. v. Barco N.V.*, 2015 WL 4381586 (PTAB July 14, 2015), and with the FDA's 2016 Final Rule Package concerning Abbreviated New Drug Applications. *See* Br. at 56-57. Not so. In both *Eizo* and the FDA's Final Rule, a reissue patent was treated as a separate legal instrument from the original patent. *Eizo*, 2015 WL 4381586 at *4 (finding that a complaint based on an original patent does not trigger a 35 U.S.C. § 315(b) bar to inter partes review of a reissue patent); Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. 69580, 69600-601 (Oct. 6, 2016) (stating that it "considers reissued patents as separate and distinct from the original patent"). But as discussed above the treatment of a reissue patent as a distinct legal instrument for enforcement

purposes does not speak to, nor is it inconsistent with, the notion that a reissue patent maintains privileges of the original patent, including its issue date. *See supra* III.B. Indeed, the FDA recognized that "elements of the reissued patent overlap with those of the original patent." 81 Fed. Reg. at 69600 (quoting *Mylan*, 594 F. App'x at 797). Furthermore, unlike the situation in *PhotoCure ASA v. Dudas*, 622 F. Supp. 2d 338 (E.D. Va. 2009), highlighted by Defendants (Br. at 63-64), the USPTO's interpretation here is entirely consistent with the MPEP. *PhotoCure*, 622 F. Supp. 2d at 349-350.

IV. CONCLUSION

This Court should affirm the district court's finding that the phrase "the date the patent is issued" in section § 156(c) for the calculation of the PTE of a reissue patent unambiguously refers to the issue date of the original patent. To the extent this Court views the language to be ambiguous, the USPTO's interpretation should be accorded deference.

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Respectfully submitted,

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RULE 32(a)(7)(C) CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g)(1), the undersigned certifies that the foregoing **Corrected Brief for the Director – U.S. Patent and Trademark Office as Amicus Curiae in Support of Plaintiffs-Appellees and Affirmance** complies with the type-volume limitation required by the Court's rule. The total number of words in the foregoing brief, excluding the parts exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2), is 6,818 as calculated using the Word® software program.

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