No. 23-2254

In the 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.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY, NO. 2:20-cv-02576 (CONSOLIDATED), THE HONORABLE CLAIRE CECCHI

CORRECTED BRIEF OF APPELLEES

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January 12, 2024

PATENT CLAIMS AT ISSUE

U.S. Patent No. RE44,733 E: Claims 4, 12, and 21 (Appx00069-00070)

4. A 6-mercapto-cyclodextrin derivative according to claim 1 selected from the group consisting of:

6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin;

6-per-deoxy-6-per-(3-carboxypropyl)thio-γ-cyclodextrin;

6-per-deoxy-6-per-(4-carboxyphenyl)thio-γ-cyclodextrin;

6-per-deoxy-6-per-(4-carboxyphenylmethyl)thio-γ-cyclodextrin;

6-per-deoxy-6-per-(2-carboxypropyl)thio-γ-cyclodextrin; and

6-per-deoxy-6-per-(2-sulfoethyl)thio-γ-cyclodextrin;

or a pharmaceutically acceptable salt thereof.

12. 6-Per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, sodium salt.

21. A method for reversal of drug-induced neuromuscular block in a subject, which comprises parenterally administering to said subject an effective amount of 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, sodium salt.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2023-2254

Short Case Caption Merck Sharp & Dohme B.V. v. Aurobindo Pharma USA, Inc.

Filing Party/Entity Merck Sharp & Dohme B.V.; Merck Sharp & Dohme LLC

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
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Date: 1/12/24

Signature: /s/ Sarah M. Harris

Name: Sarah M. Harris

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Merck Sharp & Dohme B.V.		Merck & Co., Inc.
Merck Sharp & Dohme LLC		Merck & Co., Inc.

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

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5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☐ Yes (file separate notice; see below) ☑ No ☐ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

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STATEMENT OF RELATED CASES

There are no related proceedings before this or any other court.

INTRODUCTION

This appeal involves Merck's patent on sugammadex, the active ingredient in Bridion®, an anesthesia-recovery drug. Both sides agree that the patent is valid and that Defendants infringed it by seeking Food and Drug Administration (FDA) approval for generic versions of sugammadex. Defendants' sole challenge is to the length of Merck's patent term.

To compensate patent owners for the FDA's lengthy review of new drugs, the Hatch-Waxman Act allows patent term extensions of up to five years. 35 U.S.C. § 156. Section 156(c) provides that "[t]he term of a patent … shall be extended by the time equal to the regulatory review period … which period occurs after the date the patent is issued." *Id.* § 156(c). And here, the Patent and Trademark Office (PTO) awarded Merck a five-year patent term extension to compensate for twelve years of regulatory delay that prevented Merck from marketing its innovation.

The patent Merck asserted in this suit is a reissued patent. Consistent with the statutory scheme governing reissue, longstanding precedent on the meaning and effect of reissue, and decades of established PTO practice, the PTO calculated the five-year extension under Section 156 using the patent's original issue date. Defendants protest that this was an error because "the

date the patent is issued" must refer to the reissue date instead. But read in the context of the remainder of Title 35—especially Sections 251 and 252, which govern reissue—the "issue[]" date refers to the *original* issue date. Section 251 provides that, once the criteria for reissue are met, "the Director [of the PTO] shall … reissue *the patent* for the invention disclosed in the original patent … for the unexpired part of *the term* of the original patent." *Id.* § 251(a) (emphases added). By its plain language, "the patent" is thus reissued for "the term," signifying the continuation of the original patent's term, which is defined by the original issue date. Section 252 confirms that in litigation, courts must treat reissued patents as if "originally granted in such amended form." *Id.* § 252. Section 252 also provides that where claims of a reissued patent are "substantially identical" to the original—and here, infringed claim 4 is fully identical—those claims have "effect continuously from the date of the original patent." *Id.*

In this case, all agree that Merck holds a valid patent. All agree that the original version of that patent issued in December 2003, covering sugammadex (and thus Defendants' generic products). All agree that the reissued version of that patent, containing all the original, unamended claims, inherited the original patent's remaining term, such that the reissued patent was due to

expire in January 2021. All agree that during the FDA's entire 12-year regulatory approval period—both before and after reissue—Merck was unable to exclusively market a drug protected by the original claims. And all agree that Merck could have obtained a full five-year patent term extension had Merck not sought reissue. Despite all that consensus, Defendants argue that Section 156 somehow limits Merck to a 686-day extension merely because Merck sought and obtained reissue during the regulatory review period. Nothing in any patent statute suggests that reissue has that kind of perverse and dramatic effect on patent term extension. This Court should affirm the district court's well-reasoned opinion.

STATEMENT

I. Statutory Framework

This appeal involves the intersection of statutory provisions governing the extension of patent terms to account for lengthy FDA review periods and provisions governing reissued patents.

A. Patent Term Extensions

Inventing and developing new drugs is a lengthy, expensive process. Patents make that investment worthwhile, granting innovator drug manufacturers exclusive rights over the drug beginning on the date the patent issues for a term calculated using 20 years from the filing date. *See* 35 U.S.C.

§ 154(a)(2). But before a manufacturer may market a new drug, the drug must get FDA approval—a process that can take upwards of a decade. *See generally* 21 U.S.C. § 355. If patent terms dwindle during FDA review without recompense of at least some portion of the patent term lost during regulatory review, manufacturers lose incentives to invest in innovations that can cost billions of dollars to develop and test.

Congress solved that problem with the 1984 Hatch-Waxman Act, which allows manufacturers to apply to the PTO to extend a patent's term, restoring "some of the time lost on patent life while [a] product is awaiting pre-market approval." *Pfizer Inc. v. Dr. Reddy's Labs., Ltd.*, 359 F.3d 1361, 1364 (Fed. Cir. 2004) (citation omitted). Congress provided that patents are eligible for patent term extensions if the invention the patent protects has been subject to a "regulatory review period"—like FDA new-drug approval—"before its commercial marketing or use." 35 U.S.C. § 156(a)(4). The patent must also not have "expired," and never have "been extended" before. *Id.* § 156(a)(1), (2).

Congress then prescribed a formula for extending patent terms to account for clinical testing and the subsequent FDA-review period, giving patentees at most five extra years and no more than 14 years of total term once

the drug is approved. *See* 35 U.S.C. § 156(c)(3), (g)(6)(A). The extension period is calculated by crediting "one half of the 'testing phase' plus full credit for the 'approval phase'" of FDA review that occurs after the patent issue date. *Astra v. Lehman*, 71 F.3d 1578, 1579 (Fed. Cir. 1995); 21 C.F.R. § 60.22(a)(1)-(2); 35 U.S.C. § 156(c). Thus, the critical starting point for patent term extension calculations is the "date the patent is issued." 35 U.S.C. § 156(c).

B. Patent Reissues

Congress authorizes patentees to seek reissue to fix certain errors. One type of error within the meaning of Section 251 is the omission of narrower claims. *In re Tanaka*, 640 F.3d 1246, 1251 (Fed. Cir. 2011). Thus, a patentee may seek reissue, as Merck did here, to include narrower claims that the patentee originally omitted from the patent. *Id.*

Following the PTO's examination and grant of reissue, the patentee must surrender the patent to the PTO and pay a fee. 35 U.S.C. § 251(a); *see* Manual of Patent Examining Procedure (MPEP) § 1402 (Oct. 2015), https://tinyurl.com/yfwmd3z7.[1] The PTO "shall" then "reissue *the patent* … for the unexpired part of *the term* of the original patent." 35 U.S.C. § 251(a)

[1] The hyperlink is to the entire MPEP. Except otherwise noted, citations are to the 2015 version.

(emphasis added). Thus, the reissued patent steps into the shoes of the surrendered original: "the patent" is "reissue[d]," and inherits the term of its prior incarnation. *Id.* In fact, Section 251(a) refers to only one patent—"the patent" that is reissued "in accordance with a new and amended application"—with one term—"the term of the original patent." *Id.*

Because reissued patents are corrected originals, reissued patents 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." *Id.* § 252. And "the reissued patent, to the extent that its claims are substantially identical with the original patent, shall constitute a continuation thereof and have effect continuously from the date of the original patent." *Id.* Undisputedly, many claims are "substantially identical" here—all claims from the original patent remain verbatim in the reissued patent, including the concededly infringed claim 4, which covers sugammadex, the active ingredient in Bridion®. *See* Appx00025 ("Defendants … d[o] not contest infringement."); Appx00037 (discussing claim 4).

C. PTO Policy on Reissued Patents

The PTO has consistently calculated patent extension applications involving reissued patents using the original issue date. Out of the 40

examples spanning nearly 40 years, the PTO used the original issue date in 36 of them. Appx00049; *see* Appx02087-03011 (applications). In the four cases in which the PTO considered the reissue date, it made no difference—either the calculation was the same either way, or the PTO did not ultimately issue an extension. Appx00049; *see* Appx03532. In no instance did the PTO use a reissue date in a way that affected a patent term extension ultimately granted by the PTO. Appx00049.

Consistent with that practice, the PTO's MPEP has long emphasized that a "reissued patent" would "be viewed as if the original patent had been originally granted in the amended form provided by the reissue." MPEP § 1460. In July 2022, the PTO amended the Manual to capture longstanding practice, providing that "[w]ith respect to calculating the amount of extension to which the reissued patent is entitled to receive, so long as the original patent claimed the approved product and the reissued patent claims the approved product, the original patent grant date would be used to calculate the extension to which the reissued patent would be entitled." MPEP § 2766 (2022).

II. Factual and Procedural Background

A. Bridion®'s Lengthy FDA Regulatory Review

Merck[2] is an American pharmaceutical company that develops and produces drugs, vaccines, and other products. Merck holds a patent covering sugammadex, the active ingredient in Bridion®, a drug that helps patients recover muscle function after doctors induce paralysis during surgery. Appx00009.

On December 30, 2003, the PTO issued the original patent covering the sugammadex compound, U.S. Patent No. 6,670,340 (the "'340 patent"). *See* Appx01343. Four months later, on April 13, 2004, Merck applied to the FDA to begin testing sugammadex. Appx00016. But the FDA took until December 15, 2015 to approve Bridion®. Appx00016. By then, Merck had lost 12 years of life on the '340 patent, and only just over five years remained until the '340 patent's 2021 expiration date.

In 2012, while FDA review stretched on, Merck sought patent reissue after this Court's 2011 decision that patentees could seek reissue to include narrower claims than those in the original patent—contradicting the PTO's

[2] "Merck" refers to both Merck and its predecessor in interest unless otherwise noted.

earlier position on this matter. Appx00012; *see In re Tanaka*, 640 F.3d at 1248. Here, while the '340 patent had always covered sugammadex (among other compounds), the patent lacked narrower claims directed solely to that compound. On January 28, 2014, the PTO reissued the '340 patent as U.S. Patent No. RE44,733 (the "RE'733 patent"), containing the original claims plus narrower ones. Appx00057. That patent assumed the remaining term of the original '340 patent, ending with the same January 27, 2021 expiration date. Appx00012. Defendants do not dispute that this reissue was proper.

B. The PTO Approves a Five-Year Patent Term Extension

In February 2016, after the FDA approved Bridion®, Merck applied to the PTO to extend the patent term to account for the FDA's 12-year review. Appx00011. Using the '340 patent's December 30, 2003 issue date as "the date the patent [was] issued," 35 U.S.C. § 156(c), Merck requested the maximum five-year patent term extension—which would only partially compensate Merck for the 12 years lost to regulatory review.[3] Appx03069.

[3] The PTO calculated the total length of the extension as 3,617 days, which resulted in the maximum five-year extension applying. Appx03070-71; Appx06815-16; *see* 35 U.S.C. § 156(g)(1)(B). Defendants do not dispute these calculations, and thus Merck's entitlement to the maximum five-year extension, if the December 2003 issue date governs.

The PTO granted Merck a five-year extension. Appx01035. Because "RE44733 is a reissue of … the '340 patent," the PTO used "the December 30, 2003 date of issuance for the '340 patent" and determined that the "entire regulatory review period" should be "considered in the … length of the extension period." Appx01035. The PTO thus extended Merck's patent term until January 2026. Appx01036.

C. Defendants' Infringement

Meanwhile, during the pendency of Merck's patent term extension application, sixteen companies[4] filed Abbreviated New Drug Applications (ANDAs) with the FDA seeking approval to launch generic versions of Bridion®. *E.g.*, Appx01002. In response, Merck brought multiple infringement suits, seeking judgments that manufacturing or distributing the generic products before the January 2026 expiration date would infringe the RE'733 patent. *E.g.*, Appx01015. The cases ultimately were consolidated in the U.S. District Court for the District of New Jersey. Appx01081.

[4] Aspiro Pharma Ltd., Aurobindo Pharma Ltd., Dr. Reddy's Laboratories, Inc., Fisiopharma S.r.l., Fresenius Kabi USA, LLC, Gland Pharma Ltd., Lupin Ltd., Mankind Pharma Ltd., MSN Laboratories Private Ltd., Mylan Pharmaceuticals Inc., Sandoz Inc., Sun Pharmaceutical Industries, Inc., Teva Pharmaceuticals USA, Inc., USV Private Ltd., Zenara Pharma Ltd., and Zydus Pharmaceuticals (USA), Inc., as well as related entities.

Though Defendants originally contested infringement and validity, they ultimately dropped their challenges to the patent itself. Instead, Defendants narrowed their arguments to a single defense: the PTO erred in calculating patent term extension using the original, December 30, 2003 issue date. Appx00025. Defendants argued that the PTO should have used the January 28, 2014 reissue date—such that Merck could receive only a 686-day extension, to December 14, 2022. Appx00025, Appx00028. Accordingly, all agree that if the PTO properly extended Merck's patent term, Merck would be entitled to relief under 35 U.S.C. § 271(e)(4), barring approval of Defendants' generic sugammadex at least through 2022. The only question before this Court is whether Merck's patent term for sugammadex extends through January 2026—based on the PTO's grant of patent term extension to Merck's RE'733 patent—or whether that patent has now expired.

III. The District Court's Decision Below

Following a bench trial, the district court granted final judgment for Merck, finding that Section 156(c) "unambiguously requires" the PTO to use the original patent's issue date when calculating a term extension for a reissued patent. Appx00042. To start, Section 156(c) "discusses extension specifically in the context of '[t]he *term* of a patent.'" Appx00031 (quoting 35

U.S.C. § 156(c)). And a reissued patent is not "an entirely new patent with a new term, but [is] an amended version of the original that takes on the original's term." Appx00031.

Other provisions confirmed that reading. Section 251, the court noted, recognizes that a reissued patent's "existence and length depend entirely on the term of the original." Appx00031. Plus, reading Section 156(c) to refer to the original issue date was the only way to comply with two provisions in Section 252. Appx00032; *see* 35 U.S.C. § 252. *First*, Section 252 mandates that a reissued patent has "the same effect and operation in law, on the trial of actions for causes thereafter arising, as if [it] had been originally granted in [its] amended form." *Id.* *Second*, Section 252 requires that a "reissued patent, to the extent that its claims are substantially identical with the original patent, shall … have effect continuously from the date of the original patent." *Id.*

The district court thus held that using the reissue date would be "inconsistent with § 251 … [and] would further disrupt the statutory scheme by creating conflict with § 252." Appx00033. Given those provisions, the court read the "words of [the] statute … in their context and with a view to their place in the overall statutory scheme," by using the original issue date to calculate the extension of the reissued patent. Appx00029 (citation omitted).

The court also concluded that using the original issue date advances the Hatch-Waxman Act's goal of "preserving the innovation incentive" for companies to invest in new drugs. Appx00043 (quoting *Pfizer*, 359 F.3d at 1366). If the PTO used the reissue date, the length of an extension would fluctuate based on "the happenstance of the date the PTO approves reissue and/or the date the FDA finishes its regulatory review—both of which are out of the control of the patentee." Appx00031.

Finally, the court explained, using the original issue date reflects the PTO's longstanding practice and its codification of that practice in the MPEP. As the court noted, both parties' experts on PTO policy agreed that in 36 of the 40 instances in which the PTO extended the term of a reissued patent, the PTO used the original issue date. Appx00049; *see* Appx03454, Appx03529-03530. In the remaining four cases, the PTO's choice ultimately made no difference. Appx00049. By contrast, Defendants' interpretation of Section 156(c) "conflict[ed] with multiple [other] provisions of the statutory scheme," while leading to "unworkable results that Congress could not have intended." Appx00040.

SUMMARY OF ARGUMENT

The district court correctly held that patentees can get patent term extension credit regardless of the date the PTO reissues a patent. That holding accords with statutory text, history, and the purpose of patent term extension.

I. The Hatch-Waxman Act lets patentees extend "[t]he term of a patent" to compensate for regulatory review after "the date the patent is issued." 35 U.S.C. § 156(c). Confirming that the Act refers to the original term and the original issue date, the reissue statute, 35 U.S.C. § 251, speaks only of a single "term." A reissued patent is not a brand-new patent with its own new term; the Director "reissue[s] the patent … for the unexpired part of the term" of the original. *Id.* § 251(a). Were there any doubt that the *original* issue date defines that term in Section 156 and everywhere else, the way Congress defined patent term when Section 156 was enacted confirms it. Congress enacted patent terms running seventeen years from the *original* issue date, reissued patent or not. 35 U.S.C. § 154 (1984).

Section 252 reinforces that reissued patents step into the shoes of the original. In litigation, as here, Section 252 requires courts to treat reissued patents as if "originally granted in such amended form." And both inside and

outside litigation, another clause in Section 252 ensures that where claims of a reissued patent are "substantially identical" to the original, those claims have "effect continuously from the date of the original patent." As the district court held, the only way to avoid inconsistency between the Hatch-Waxman Act and Section 252 is to read "issued" to refer to the original issue date.

Other patent statutes, such as the provisions determining a reissued patent's priority over prior art, point the same way. In every important respect, a reissued patent inherits the timing features of the original. That the patent statutes are consistent in this respect is no surprise, given the backdrop of 200 years of history in which Congress and the Supreme Court consistently viewed reissued patents as relating back to the original for timing purposes. As the Supreme Court put it in its very first decision on reissue: A reissued patent is deemed "in no respect" "independent of the first," so the "time of the privilege still runs from the date of the original patent." *Grant v. Raymond*, 31 U.S. 218, 244 (1832). The original patent thus remains important after reissue for fixing the patent's priority date and setting its term.

Defendants' position ignores that context and creates statutory anomalies. That interpretation makes the length of patent term extension turn on the arbitrary order in which administrative officials approve pending

reissue and regulatory review applications. Moreover, if reissue and original patents were truly separate, as Defendants claim, patentees could potentially seek more than one patent term extension on a single patent—a result Congress expressly barred. 35 U.S.C. § 156(a)(2). Under Defendants' reading, patentees could claim one term extension on the original patent and another on the purportedly distinct reissued patent—as long as Section 156's other criteria were satisfied. And in the many statutes where Congress stipulates that new legislation applies only to patents issued after a certain date, including the Hatch-Waxman Act, Defendants' position would bizarrely let patentees opt into new patent regimes just by seeking reissue.

Conversely, using the original issue date advances Congress's goals in establishing patent term extension and patent reissue. Patent term extension incentivizes innovation by giving inventors back time lost to regulatory review. Whether a patent is reissued before, during, or after regulatory review makes no difference: in each case, the patentee has lost valuable term to the FDA's regulatory process.

II. The PTO's consistent policy and practice of using the original issue date to calculate patent term extension further support affirmance. In 90% of all patent term extension applications for reissued patents, the PTO used the

original issue date. In the other 10%, the date made no difference. The PTO recently codified that practice in its Manual, and that position is eminently reasonable, aligning with the statutory text, context, and history of reissued patents. The PTO's longstanding position also confirms that the status quo carries no downsides and vindicates parties' reliance interests—unlike Defendants' novel interpretation, which would upend patentees' settled expectations.

ARGUMENT

I. Section 156(c) Refers to the Original Issue Date

Section 156 of Title 35—entitled "Extension of patent term"—establishes rules for extending "[t]he term of a patent which claims a product" that the FDA has subjected to certain regulatory delays. 35 U.S.C. § 156(a). Section 156(c) calculates those extensions using "the date the patent is issued," but does not define "issued." But as the district court correctly concluded, Section 156(c)'s text, together with other patent statutes and the history of patent reissue, demonstrate that Section 156(c) refers to the *original* issue date.

A. The Reissue Statutes Compel Interpreting Section 156 to Refer to the Original Issue Date

As this Court has recognized, the Hatch-Waxman Act—which included Section 156—should be read in light of "the combined effects" of other patent statutes. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1548 (Fed. Cir. 1996); *accord Syngenta Crop Prot., LLC v. Willowood, LLC*, 944 F.3d 1344, 1359-60 (Fed. Cir. 2019). The district court thus rightly interpreted Section 156(c)'s reference to "the date the patent is issued" alongside those other statutes. Appx00030-38. Section 251 makes clear that a reissued patent inherits the original patent's term, which in turn is defined by the original issue date. And Section 252 explains that reissued patents step into the original patent's shoes in certain contexts—including, as here, in litigation.

1. Section 251 Provides That a Reissued Patent Retains Its Original Term

Section 251, which authorizes reissue, provides: "Whenever any patent is … deemed wholly or partly inoperative or invalid," the PTO can "reissue *the patent*"—*i.e.*, the original patent that the owner "surrender[ed]" upon the grant of reissue—"for the unexpired part of *the term* of the original patent." 35 U.S.C. § 251(a) (emphasis added). By its express language, Section 251 does not endow a reissued patent with a new or different "term." *Id.* Rather,

a reissued patent steps into the place of the original and inherits the *same* term. As the district court put it, the "existence and length [of a reissued patent] depend entirely on the term of the original." Appx00031.

In turn, Section 154 defines patent "term" with reference to the original issue date: The "grant [of a patent] shall be for a term *beginning on the date on which the patent issues* and ending 20 years from the date on which the application … was filed." 35 U.S.C. § 154(a)(2) (emphasis added). Thus, even where there is a reissue, the issue date and filing date of the *original* patent define the beginning and end of the term. As this Court has held, moreover, Congress has used "the concept of patent 'term'" consistently across statutes regulating patent term—including Sections "156" (patent term extension), "154(a)" (setting the term of original patents), and "251" (setting the term of reissued patents). *In re Yamazaki*, 702 F.3d 1327, 1331-32 (Fed. Cir. 2012).

Read in light of these provisions, Section 156 unambiguously incorporates the original issue date for patent term calculations. Section 156 refers to the patent "term" more than 15 times to set the baseline for patent term extension calculations. Section 156(a) ties the availability of an extension to whether "the *term* of the patent has not expired" and whether "the *term* of the patent has never been extended." 35 U.S.C. § 156(a)(1), (2) (emphasis

added). Section 156(b) explains the effect of patent rights for the "period during which the *term* of the patent is extended." *Id.* § 156(b) (emphasis added). And Section 156(c) uses "[t]he term of a patent" as the cornerstone of calculating how much additional patent life to add. *Id.* § 156(c).

Applied to reissued patents, Section 156's references to "term" still mean the *original* patent's term, which the reissued patent inherits. *See id.* § 251. And, as the district court held, because Section 156(c)'s reference to the "term of a patent" is pegged to the original term, the phrase "the date the patent is issued" in Section 156(c) naturally refers to the original patent and original issue date as well. Appx00031. Section 156(c) thus reads as a unitary whole, prescribing that "[t]he term of a patent eligible for extension"—again, the term calculated using the original issue date—"shall be extended by" regulatory review "*after the date the patent is issued*" 35 U.S.C. § 156(c) (emphasis added). Congress ordinarily gives identical words the same meaning across provisions. *See Solar Energy Indus. Ass'n v. United States*, 86 F.4th 885, 897 (Fed. Cir. 2023). Congress plainly did so in Section 156(c), referring to the original patent's term and the original issue date throughout.

2. As Originally Enacted in 1984, Section 156(c) Clearly Referred to the Original Issue Date

The importance of Section 251(a)'s reference to a single patent "term" for the original and reissued patent is especially clear when Section 156 is considered as of its enactment in 1984. At that time, patent terms ran for seventeen years *from the issue date*. *See* 35 U.S.C. § 154 (1984). Then, as now, reissued patents inherited the "unexpired part of the term of the original patent." *Id.* § 251. Calculating a reissued patent's term thus required using the *original* issue date to determine how much time remained, making the original issue date a critical timing component of every reissued patent's "term."

Section 251's meaning in 1984 is key to interpreting Section 156(c) because "every statute's meaning is fixed at the time of enactment." *Wis. Cent. Ltd. v. United States*, 138 S. Ct. 2067, 2074 (2018). In 1984, the Hatch-Waxman Act's use of "patent term" and date "issued" plainly built upon the concepts introduced in Sections 154 and 251. And those provisions explained that a reissued patent's term was indelibly linked to the original issue date: The reissued patent, like the original patent, would expire 17 years after the

date of *original* issue. So the original issue date was Congress's natural focus when Congress referred to "the date the patent is issued" in Section 156(c).[5]

It is implausible that, when Congress shifted to a first-to-file patent system in 1995, Congress silently jettisoned that meaning of "issue[]" date. *See* Uruguay Round Agreements Act, Pub L. No. 103-465, 108 Stat. 4809 (1994). Though Congress amended Section 154 so that a patent's term now expires 20 years after the *filing* date, rather than a number of years after the issue date, Congress kept the issue date as the "beginning" of the patent's term. *Id.* § 532(a). And that term is still inherited by a reissued patent. *See id.* § 251. Congress deliberately amended other patent statutes to fit the new regime, even making a "conforming change" to Section 156 (inserting a statutory cross-reference). Pub. L. No. 103-465 § 532(c). But Congress did not amend Section 156(c), nor did it change the language in Section 251 conferring the original term on a reissued patent. Thus, today, as in 1984, the date "issued" in Section 156(c) means the date *originally* issued.

[5] Reissued patents, in this regard, behaved differently from continuation and divisional patents—quintessential examples of new patents claiming priority to the same original application. *See* 35 U.S.C. §§ 120, 121. Unlike reissues, those patents got 17-year terms of their own, running from their own separate issue dates. *In re Goodman*, 11 F.3d 1046, 1053 (Fed. Cir. 1993).

3. Defendants' Plain-Meaning Interpretation of Section 156 Is Incorrect

Short-circuiting these considerations, Defendants rest their argument on a supposed plain-language reading of Section 156(c). Defendants (at 25-26) claim that "the date the patent is issued," 35 U.S.C. § 156(c), must refer to the reissue date—not the original issue date. Nothing in the language of Section 156 itself compels that result—at best for Defendants, Section 156 standing alone, out of context, fails to specify what it means by issue date. Defendants (at 26) therefore play up that in Merck's application for a patent term extension Merck identified "the patent for which an extension is being sought" as the reissued patent and the reissue date as the "issue date" of that patent. *See* Appx03250-51. But Merck did not concede anything by straightforwardly listing the current patent number and both issue and reissue dates in its extension application. Appx03251.

In any case, one statutory phrase alone does not resolve this case, as "[s]tatutory language cannot be construed in a vacuum." *Sturgeon v. Frost*, 577 U.S. 424, 438 (2016) (internal quotation omitted). Section 251 confirms that reissued patents are not separate patents with separate terms. And the legal effect of the '340 patent's reissuance as the RE'733 patent must be

determined by the entire statutory context, which confirms that the operative date in Section 156(c) is the original issue date—not the reissue date.

To be sure, the reissue date *can* matter, but only where there is a specific need to contrast the substantive claim scope of the original and reissued patents. For instance, the reissue date matters for the intervening rights defense. 35 U.S.C. § 252. That defense applies when, "before the reissue date," an infringer "made, purchased, or used" products covered by a newly granted claim of the reissued patent. *John Bean Techs. Corp. v. Morris & Assocs., Inc.*, 988 F.3d 1334, 1338 (Fed. Cir. 2021) (citation omitted). So a court considering the defense must look to the infringer's actions between the original issue date and the reissue date. But, crucially, Congress did not refer to the latter date as a new, second "issue date." Instead, Section 252 refers to events "prior to the grant of a reissue" when it considers whether an accused infringer has engaged in conduct giving rise to intervening rights (which are not implicated by the reissue here). Every time Congress uses a date for term calculations, it uses the original issue date—Section 156(c) is no exception. *Infra* pp. 37-42.

In any case, Defendants' references to the reissue date do not undercut the fact that a reissued patent inherits the original patent's term, which starts

on the original issue date. Defendants claim (at 40-41) that *Yamazaki* shows that reissue and original patents have different terms because the Court contrasted "the term of a reissued patent" with "that of the original." 702 F.3d at 1331. That argument impermissibly parses *Yamazaki* "as though we were dealing with the language of a statute," focusing on small nuances in the Court's phrasing while missing the Court's key holding. *Brown v. Davenport*, 596 U.S. 118, 141 (2022) (citation omitted). *Yamazaki held* that reissue may not undo a terminal disclaimer. This Court reasoned that reissue cannot grant a new and different "term" because the "'term of the original patent' defines the outer limit of the PTO's reissue authority." 702 F.3d at 1331-32. And by observing that Section "156 codif[ies] additional mechanisms for varying the 'term' of an 'original patent' relative to that provided under § 154(a)," this Court confirmed that Section 156 refers to the original patent's term (and issue date) throughout. *Id.* at 1332. As the district court noted, Defendants' reading is "untenable" in light of *Yamazaki*. Appx00032.

4. Defendants' Additional Arguments Against Using the Original Issue Date Lack Merit

Defendants (at 30-31, 35) attack the district court's conclusion that a reissued patent "'inherits' the issue date of the original patent" by arguing that "issued" sometimes refers to the reissue date. Defendants point to Section

251(b), which authorizes the PTO to "issue several reissued patents," and Section 252, which provides that "[t]he surrender of the original patent shall take effect upon the issue of the reissued patent." 35 U.S.C. §§ 251(b), 252. But those provisions refer to the *act* of reissue. They do not attach significance to the *date* of reissue, and certainly not for backward-looking calculations such as patent term extensions. Section 251(b) does not even involve dates. And Section 252 stipulates that reissued patents relate back to the originals, even after surrender, *see infra* pp. 29-36—making the reissue date insignificant for most purposes.[6]

Defendants (at 31) further attempt to contrast Section 251's use of the word "issue" with its treatment of expiration, arguing that Congress "craft[ed] special rules" for the expiry of reissued patents, but not for their issue dates. This misreads the statute. When Section 251 explains that a reissued patent inherits the "unexpired part of the term of the original," that rule governs *both* a reissued patent's *issue* date and its *expiration* date because the two run together. *Id.* § 251(a). The "term of the original patent," *id.*, which the

[6] The same is true of Sections 151 and 153, which Defendants cite for the first time on appeal. Both provisions refer to the act of issue and have no bearing on patent term, while the only timing consideration in either (Section 151) concerns the payment of an administrative fee. *See* 35 U.S.C. §§ 151, 153.

reissued patent takes over, "begin[s] on the date on which the patent issues," *id.* § 154(a). Thus, as discussed *supra* pp. 18-21, when Congress used concepts like "term" and "issue[]" date in Section 156(c), Congress built upon Section 251's explanation of how those concepts apply to reissued patents. Far from ensuring that the "statutory scheme is coherent and consistent," *Intell. Ventures II LLC v. JPMorgan Chase & Co.*, 781 F.3d 1372, 1377 (Fed. Cir. 2015) (citation omitted), Defendants' reading "overlook[s] the dependency of the reissue's term on the original's term, and the relationship between the two," Appx00031.

Defendants (at 41) further claim that reissued patents do not inherit the original patent's term because "nothing in § 251 suggests the term of a reissue cannot be shorter" than the original patent term—*e.g.*, as the result of a terminal disclaimer. But Defendants' conclusion does not follow. Filing a terminal disclaimer after reissue would effectively shorten the single, original patent term, inherited by the reissued patent. As the district court observed, "a terminal disclaimer shortens the term of the original patent rather than creat[ing] a new term." Appx00048 (citing MPEP § 1490); *see also* Appx03515 (expert witness testifying to this at trial). Defendants offer no evidence to the contrary.

Finally, Defendants (at 50-51) contend that reading Section 156(c) to refer to the original issue date would allow patentees to get a windfall by using reissue to broaden a patent's claims. In that scenario, a reissued patent could hypothetically claim an approved drug even though the original patent did not. But that hypothetical is far removed from the present facts, where it is undisputed that claim 4 was present in the original patent, covers sugammadex, and is valid and infringed. This Court need not decide here how Section 156 would apply in Defendants' hypothetical. Defendants do not contend that their hypothetical has ever arisen in 40 years of extension practice. That scenario is therefore the type of "special problem[]" that "may arise in a few instances," on a "case-by-case basis," and may be addressed when and if it arises. *Kessler*, 80 F.3d at 1552. But in any event, even if the PTO were to allow this result, contrary to policy stated in 2022 MPEP Section 2766, the supposed "windfall" would consist, at most, of awarding a patentee a term extension compensating for regulatory review occurring during the 20-year term beginning when the patentee filed a patent application disclosing the invention. That is hardly a meaningful benefit given that the patentee could have obtained the broader claim earlier, and that because of the regulatory delay the claim was not yet economically useful.

5. Section 252 Confirms That Section 156(c) Refers to the Original Issue Date

Section 252 provides rules governing the "effect" of reissued patents, whereby "reissues are deemed by operation of law to replace the surrendered originals and, thus, are entitled to treatment as original patents." *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1341 (Fed. Cir. 2008). The district court correctly held that two clauses of Section 252 apply here, each requiring courts to "treat [the reissued patent's] issue date as if it were the original issue date" in particular circumstances. Appx00032. *First,* in litigation (like this case), courts must treat reissued patents "as if the same had been granted in such amended form." 35 U.S.C. § 252. *Second,* both inside and outside litigation, where a reissued patent's claims are "substantially identical" to the original patent's claims, those claims have "effect continuously from the date of the original patent." *Id.* As the district court held, interpreting Section 156(c) to refer to the reissue date would "conflict[]" with those provisions because 156(c) would treat reissued patents differently from originals in circumstances where Section 252 mandates the opposite.[7] Appx00032.

[7] Section 252's first paragraph contains an independent clause followed by three dependent clauses, each providing a different rule governing reissue:

a. Section 252's Same-Effect Clause

Section 252 provides 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). As the district court held, that rule applies squarely here. "This is a trial of a cause arising after reissue," *i.e.*, a post-reissue lawsuit, so "the Court must do as the statute requires" and give the reissued patent the same "operation in law" as the original. Appx00032. In those circumstances, "the literal application of [Section 252] … makes the operation of the reissue relate to the date of the original patent." *Keller v. Adams-Campbell Co.*, 264 U.S. 314, 317 (1924) (addressing earlier version of the

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> [1] The surrender of the original patent shall take effect upon the issue of the reissued patent,
>
> [a] *and 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*,
>
> [b] but in so far as the claims of the original and reissued patents are substantially identical, such surrender shall not affect any action then pending nor abate any cause of action then existing,
>
> [c] *and the reissued patent, to the extent that its claims are substantially identical with the original patent, shall constitute a continuation thereof and have* ***effect continuously*** *from the date of the original patent.*

35 U.S.C. § 252 (emphases added).

statute). Defendants cannot explain why a clause specifically addressing the effect of reissued patents in litigation does not apply in this litigation.

The district court's holding accords with the point of this clause: backdating reissued patents to the original patent date for assessing litigation defenses. Congress originally enacted this clause in 1836 to codify the Supreme Court's practice of treating reissued patents as originals in infringement litigation arising after reissue. *See Stimpson v. W. Chester R.R. Co*, 45 U.S. 380, 402-03 (1846). When a cause of action for patent infringement accrues after reissue, the same-effect clause lets a plaintiff assert the reissued patent *as if* it had the same priority as the original—thus overcoming a defendant's argument that his use of the invention before reissue rendered the invention unpatentable.[8] *Id.* Today, the same-effect clause still operates to backdate a reissued patent to the original during litigation arising after reissue. *See Cooper Techs.*, 536 F.3d at 1341 (relying on the same-effect clause

[8] Of course, today, the same-effect clause is now subject to the intervening-rights defense, which lets infringers who used a product before reissue continue using it afterwards, unless the original patent covered the product. 35 U.S.C. § 252. But intervening rights are irrelevant here—Merck's patent included a claim covering sugammadex from the outset, and no defendant sought FDA approval for a generic version until after reissue.

in an APA suit arising after reissue). That includes litigation over when a patent term is extended under Section 156.

Reinforcing the point, Congress expected that infringement proceedings might revisit the validity of PTO patent term calculations. Congress expressly provided that alleged infringers could raise the "invalidity" of an extension as a defense. 35 U.S.C. § 282(b). And Congress knew that, in such litigation, Section 252's same-effect clause has always ensured that reissued patents are treated "as if … originally granted in such amended form." *Id.* § 252. Those provisions work in tandem, ensuring that courts use the original issue date to assess the validity of term extensions when raised as an infringement defense.

Defendants (at 37) argue that if "a reissue patent steps into the shoes of the original patent for *all* purposes within the forum of litigation," there would be "no need for … [Section 252's later] clause addressing pre-existing claims." But Defendants elide the critical distinction between those clauses. The first clause of Section 252 ensures that where, as here, a cause of action arises *after* a patent is reissued, the reissued patent steps into the original's shoes. The second clause, referring to "substantially identical" claims, pertains to causes of action that arose *before* reissue. There is no surplusage because the two

clauses govern different causes of action. Confirming that point, Congress enacted Section 252's pre-existing claims clause to authorize suits on some causes of action arising before reissue, precisely because the earlier-enacted same-effect clause had *not* authorized those suits. *See Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1338 (Fed. Cir. 2013). And as this case is an after-arising action, the same-effect clause applies.

Defendants (at 36) object that, under Merck's and the district court's view, patent term extensions would "change radically based upon the forum." In Defendants' view, if Section 252's same-effect clause compels courts to use the original issue date in litigation, then that would create anomalies because Section 252 does not control the PTO's front-end administrative extension calculations. But any forum problem arises only from Defendants' strained reading of the date the patent "issued" in Section 156 to mean the "reissue" date. Following the plain meaning of Section 156(c) and using the original issue date eliminates any tension with Section 252. As the district court concluded, Section 252 reinforces the implausibility of Defendants' reading. Appx00032.

b. Section 252's Continuous-Effect Clause

Section 252's continuous-effect clause specifically provides that where the claims in a reissued patent are "substantially identical" to the claims in an original patent, those claims "shall … have effect continuously from the date of the original patent." 35 U.S.C. § 252. As the district court reasoned, where that clause applies, using the reissue date for patent term extension "would be inconsistent with § 252's command to give substantially identical claims continuous effect." Appx00037.

Here, Defendants do not contest that claim 4 of the reissued patent is "identical" to claim 4 of the original patent. Thus, following Section 252's plain terms, reissued claim 4 must be treated as a "continuation" of the original patent, with "effect" from "the date of the original patent," *i.e.*, from the original issue date. As the district court held, the only way that claim 4 can have "effect continuously" is if it is deemed to have "issued" on the original issue date. *See* Appx00037. *A fortiori*, the original issue date must be the date that counts for calculating patent term extensions under Section 156, too.

Defendants (at 39) object that applying the continuous-effect clause here "violates" the clause's own terms by "deeming the *entire* patent issued as of the date of the original patent" even though the clause applies only to

"substantially identical" claims. But that is only because Congress chose to define "patent term extension under § 156 [to] appl[y] to the term of the patent as a whole, *i.e.*, to all claims in the patent," rather than "on a claim-by-claim basis." *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics Inc.*, 655 F.3d 1291, 1300-01 (Fed. Cir. 2011). Moreover, when Congress made that choice, it also chose to "limit the effect of the extension" based on the particular claimed and approved product and use. *Id.* (explaining § 156(b)). In ordinary circumstances, the relevant drug or use is claimed from the outset in the original patent, mitigating Defendants' concern. That is the situation here: the original patent undisputedly covered sugammadex, in a claim that was unchanged by reissue. Appx00016; *compare* Appx06871, *with* Appx01032.

Defendants (at 36) contend that "the whole of § 252," including the continuous-effect clause is "specifically pegged to litigation liability and damages," and should not govern the PTO's patent term extension calculations, which are agency adjudications. But this Court has long rejected that sort of "simplistic" interpretation of Section 252, which ignores the statute's text. *Intel Corp. v. Negotiated Data Sols., Inc.*, 703 F.3d 1360, 1364 (Fed. Cir. 2012).

For starters, Section 252's independent clause clearly applies both inside and outside litigation: Reissued patents "take effect upon" the "surrender of the original patent" no matter the forum. 35 U.S.C. § 252. Similarly, unlike the other two dependent clauses, the continuous-effect clause is not textually tied to litigation.[9] If "Congress wanted" to limit the continuous-effect clause to litigation, it "knew how to do so" and could have specified the causes of action to which the clause applies, as Congress did for other clauses within Section 252. *See Pugin v. Garland*, 599 U.S. 600, 608 (2023). Yet Congress left out any such wording in the continuous-effect clause.

Defendants (at 38) add that because Congress enacted the pre-existing claims clause and the continuous-effect clause at the same time, both must be confined to litigation. But the two provisions are not textually dependent on one another; both rely on the same independent clause ("The surrender of the original patent shall take effect upon the issue of the reissued patent") at the start of the paragraph. 35 U.S.C. § 252. That strongly suggests Congress meant each clause to work as a standalone rule.

[9] *Compare* the same-effect clause (governing "causes thereafter arising") *and* the pre-existing claims clause (controlling "action[s] then pending" and "cause[s] of action then existing"), *with* the continuous-effect clause (substantially identical claims "shall constitute a continuation thereof and have effect continuously from the date of the original patent."). 35 U.S.C. § 252.

B. Congress, Courts, and the Patent Office Uniformly Rely on the Original Issue Date for Timing-Related Questions

As explained above, Sections 251 and 252 make plain that the timing-related characteristics of the original patent—including its filing date, its term, and its issue date—continue to control post-reissue. That is because a reissued patent is a *correction* of the original patent, not an entirely new patent. *See* 35 U.S.C. § 251(a) ("reissue *the* patent" (emphasis added)); *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 810 F.2d 1113, 1117 (Fed. Cir. 1987) ("sole purpose" of reissue is "correction of errors"). When confronted with *timing*-related questions about reissued patents, the Supreme Court, Congress, this Court, and the Patent Office have consistently looked to the dates of the *original patent*, not the reissued patent. That approach flatly rebuts Defendants' insistence (at 3) that the original patent is "'dead' upon the reissue" for all purposes.

By contrast, even Defendants' expert on PTO practice could not "think of any" way in which the reissue date is used "for the purposes of any calculation." Appx03493. There is simply no reason to believe that Congress intended to deviate from this longstanding practice in Section 156(c).

1. Reissued Patents Are Corrected Originals

As the district court recognized, the Supreme Court has long understood reissued patents to merely step into the shoes of the original for timing-related purposes. Appx00035. The Supreme Court in *Grant*—a seminal case that Defendants tellingly ignore—approved reissue of a patent with a defective specification, even though no statute then authorized such a "corrected patent." 31 U.S. at 241-43. *Grant* rejected the notion that the original patent invalidated the reissued patent, explaining that "the [reissued] patent, and the proceedings on which it issues, have relation to the original transaction…. The [reissue] application may be considered as appended to the original application." *Id.* at 244. The reissued patent, *Grant* emphasized, "is in no respect" "considered as independent of the [original patent]." *Id.* Consistent with the notion that the timing of the original patent controlled for validity purposes, *Grant* held that the *term* of the corrected patent "still runs from the date of the original patent." *Id.*

The Supreme Court's decision in *Peck v. Collins*, 103 U.S. 660 (1880), confirms that original patents still matter for timing purposes after reissue. In that case, the Court explained that the patent owner's substantive property rights in the original patent are extinguished upon reissue. *Id.* at 664. But

even after reissue, the Court emphasized that the original patent's dates matter for timing-related issues: "for the purpose of fixing a date to the title in a question of priority, and of limiting the period for which the patent is to run, the *date of the original patent is important.*" *Id.* (emphasis added). *Peck* is thus entirely consistent with the district court's holding that the original issue date remains relevant after reissue.

Incorporating that understanding, Congress has repeatedly enacted statutes affirming the importance of the timing of the original patent post-reissue. From 1832 through today, Congress has codified *Grant*'s holding that reissued patents maintain the original patent's term. *See* Patent Act of July 3, 1832, § 3, 4 Stat. 559; 35 U.S.C. § 251. Congress has also codified *Grant*'s holding that, in evaluating the validity of a reissued patent, it is the filing date of the *original* patent that matters. *See, e.g.*, 35 U.S.C. § 100(i)(2) ("The effective filing date for a … reissued patent shall be determined by deeming the claim to the invention to have been contained in the patent for which reissue was sought.").

This Court has similarly affirmed the importance of the original patent for timing-related matters. For example, in *Cooper Techs.*, this Court explained that the timing of an original patent application is critical for

determining whether *inter partes* reexamination is available on a reissued patent. 536 F.3d at 1331-32. Congress made such reexamination available for patents issued on "original applications filed after November 29, 1999." *Id.* at 1341. This Court rejected the notion that reissued patents—which issue "from a 'reissue application,' not an 'original application'"—could never be subject to *inter partes* reexamination. *Id.* In the Court's view, "reissues are deemed by operation of law to replace the surrendered originals and, thus, are entitled to treatment as original patents." *Id.* (citing 35 U.S.C. § 252). *Inter partes* reexamination, the Court explained, is thus available for "reissues of original applications filed after November 29, 1999." *Id.* Put differently, the original patent's application date matters for timing purposes, even after reissue. *See* Appx00032-33.

Defendants (at 42-43) minimize the importance of *Cooper*, claiming that this Court nowhere "redefine[d]" "the word 'issued'" or held that reissued patents replace originals "*nunc pro tunc*." But that argument attacks a strawman. Neither Merck nor the district court read *Cooper* to suggest that a reissued patent replaces the original for all purposes. *See* Appx00036. Instead, *Cooper* demonstrates that an original patent's timing features are still important after reissue.

The PTO also recognizes the continuing importance of original patents for timing purposes after reissue. Citing *Grant*, the PTO has explained that "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 (emphasis added). The PTO likewise relies on the original issue date when setting the maintenance fee schedule for reissued patents, as the district court highlighted. Appx00022. The PTO's regulations explain that the maintenance fee "period" on a "reissued patent" is "counted from the date of grant of the original non-reissue application on which the reissued patent is based." 37 C.F.R. § 1.362(h); *see* MPEP § 1415.01 ("The filing of a reissue application does not alter the schedule of payments of maintenance fees on the original patent."). In other words, the PTO consistently treats reissued patents as corrected originals.

Defendants (at 60) argue that MPEP Section 1440 does not address the reissued patent's issue date. But that provision confirms that when Congress and the PTO assess timing-related issues for reissued patents, they look to the original patent, not the reissue. There is no suggestion Congress deviated from that practice in Section 156(c). Defendants (at 60) add that Section

100(i)(2) proves that, "[w]henever Congress wanted a reissue patent to assume some characteristic of the original patent that it replaced, Congress explicitly said so." But, as discussed, *supra* pp. 38-39, Congress legislated against the backdrop of the common-law understanding that the original patent continues to control timing-related issues post-reissue.

In sum, from the common-law era to the present day, Congress, courts, and the PTO have consistently relied on the timing features of the *original* patent, even after reissue. That consistent treatment demonstrates that, in Section 156(c)—another timing-related provision—the "date … issued" refers to the date that the *original* patent issued.

2. Defendants Cite No Contrary Authorities

Defendants' cases (at 26-28) do not say different. None suggest that the original issue date and term cease to matter post-reissue. Defendants' cases merely confirm the undisputed point that an original patent cannot generally be the source of *property rights* after reissue.

Defendants (at 26-28) cite a pair of Supreme Court cases—but in each, the Court merely held that reissue extinguishes the original patent as a source of property rights. *See Peck*, 103 U.S. at 664; *Abercrombie & Fitch Co. v. Baldwin*, 245 U.S. 198, 209-10 (1917) (cited at Defts.' Br. 28). *Peck* held that

"if a reissue is granted, the patentee has no rights except such as grow out of the reissued patent. He has none under the original." 103 U.S. at 664. Similarly, *Abercrombie & Fitch* noted that on reissue "the patentee loses all in the way of an accounting under the original patent"—*i.e.*, the patentee may no longer assert the original patent. 245 U.S. at 209. Thus, a reissued patent is the only instrument securing the patentee's property rights after reissue.

But the Supreme Court in both cases also emphasized the connection between original and reissued patents for timing purposes. As discussed, *Peck* stressed that "the date of the original patent is important" after reissue. 103 U.S. at 664. And *Abercrombie & Fitch* noted that by fixing defects in an original patent, reissue "save[s] to the inventor the future" of the original patent by fixing a defect. 245 U.S. at 210. Thus, the term of the original patent still determines the duration and priority of patent rights, even though the reissued patent is a new source of those rights.

Defendants' citations (at 26-28) to this Court's cases paint the same picture. *Fresenius* concerns when patentees can assert *property rights* in the original patent after reissue, and interpreted the effect of the 1928 amendments to Section 252. 721 F.3d at 1332-33, 1336-37. Before 1928, reissue extinguished "*ab initio*" property rights in the original patent, preventing

patentees from recovering damages on "pending claims" for pre-reissue infringement. 721 F.3d at 1336-37 (citation omitted). In 1928, Congress amended Section 252, authorizing some claims arising under the original patent to "continue after reissue." *Id.* at 1337. *Fresenius* accordingly illustrates that Congress must act if it wishes to authorize patentees to assert property rights in the original patent after reissue. *Fresenius* does not, as Defendants (at 28) claim, show that Congress must create an "exception" for a reissued patent to take on any of the original's timing details.

Likewise, *Seattle Box Co.* (cited at 26) reiterated that after reissue, "[t]he original claims are dead." *Seattle Box Co. v. Indus. Crating & Packing, Inc.*, 731 F.2d 818, 827 (Fed. Cir. 1984). But that case says nothing about the timing features a reissued patent inherits from the original.

Defendants (at 32, 37, 41 and 59) also misread *Intel* to contend that reissued patents do not replace original patents for *any* purpose. 703 F.3d at 1364. But *Intel* says no such thing. Instead, this Court held that a reissued patent cannot simply "replace[] the original *nunc pro tunc*" because that would "ignore[] the specific language of the statute that grants intervening rights." *Id.* There is no risk of that here: using the original issue date for calculating patent term extension does not disrupt intervening rights because

alleged infringers can assert such rights even after term extension. *See* 35 U.S.C. § 252. In any case, the district court did not treat a reissued patent as replacing the original *nunc pro tunc*—instead, the court carefully interpreted Section 156(c) to hold that "issued" refers to the original issue date. Appx00030-33.

Finally, the Fourth Circuit's unpublished *Mylan Pharmaceuticals, Inc. v. FDA* decision is far afield. 594 F. App'x 791, 794, 797 (4th Cir. 2014) (cited at Defts.' Br. 27). That case involved a now-repealed statutory provision regarding the right to exclusively market generic drugs after a court decision holding a patent covering the drug invalid. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (repealed). The Fourth Circuit reasoned that a court decision holding the *original* patent invalid did not count as "a decision … holding the patent … invalid" after reissue because the original and reissued patents are "separate grant[s] of rights." 594 F. App'x at 796-97. At best, the court's decision merely reaffirms the basic rule that original and reissued patents are separate sources of property rights, but does nothing to challenge the fundamental principle that a reissued patent inherits its timing features from the original.

C. Defendants' Interpretation Creates Anomalies

"Constructions of statutes and regulations that lead to anomalous results are to be avoided if at all possible." *Frazier v. McDonough*, 66 F.4th 1353, 1358 (Fed. Cir. 2023) (internal quotation omitted). Yet by treating reissued patents as "legally distinct" patents that issue only on the reissue date, Defendants' interpretation (at 26) leads to results that Congress could not have intended. Defendants (at 49) acknowledge this problem but offer no solution.

First, if a reissued patent is "issued" only on its reissue date, then Section 156(c)'s provisions accounting for pre-Hatch-Waxman Act patents make no sense. Congress provided that for "patent[s] … issued after the date of the enactment of [Section 156]" the maximum regulatory review extension "may not exceed five years." 35 U.S.C. § 156(g)(6)(A). But for patents "issued before the date of the enactment of [Section 156]," different rules apply, limiting any patent term extension to "two years" or "three years." *See id.* § 156(g)(6)(C). For those pre-existing patents, the "length of the extension" is pegged to "the patented product's proximity to commercialization." *Hoechst Aktiengesellschaft v. Quigg*, 917 F.2d 522, 528 (Fed. Cir. 1990).

Yet on Defendants' reading, patentees could opt into the more favorable extension for post-enactment patents simply by seeking reissue—thus rendering the patent "issued" after Section 156's enactment. Courts do not normally read statutes to create such "nonsensical" results. *See Kirkendall v. Dep't of Army*, 479 F.3d 830, 844 (Fed. Cir. 2007) (en banc).

Worse, that anomaly would recur throughout other statutory provisions, since Congress often pegs the application of new patent statutes to existing patent issue dates. Take the America Invents Act, which pegs the effective date of various provisions to a patent's issue date. *See* 35 U.S.C. §§ 1 note, 273 note. If the "issue" date always means the date of *reissue* for reissued patents, as Defendants' arguments imply, that Act would apply (or not) depending on reissue, producing bizarre results.

For instance, in the America Invents Act, Congress "expanded" the prior-use defense to infringement, so that the defense is available for "any patented invention"—not just, as before, "business method patents." *See* 6 Pat. Law Fundamentals § 20:46.50 (2d ed. 2023). But the expanded defense applies only to "any patent issued on or after the date of the enactment of [the] Act." 35 U.S.C. § 273 note. If "issued" refers to *reissue*, as Defendants argue, then an alleged infringer's substantive defense would change dramatically if a

patent that predated the Act reissues after the statute's enactment. Patentees would bizarrely be disincentivized from seeking reissue, because the reissued patent would be subject to a much broader defense than the original.

Second, Defendants' interpretation would perversely let patentees seek repeated patent term extensions on a single patent. Section 156(a) requires, as a precondition of an extension, that "the term of the patent has never been extended" under Section 156. 35 U.S.C. § 156(a)(2). That rule prevents patentees from repeatedly extending the life of a patent after different regulatory review periods. *See id.* § 156(g) (listing kinds of regulatory review). Yet if Defendants' "legally distinct" view of reissued patents is correct, then patentees could seek one extension on an original patent, then—if the reissued patent also claims a second, distinct drug—get a second, separate extension based on the second drug through reissue. On their view, even if the PTO has extended the original patent's term, "the term of the patent"—*i.e.*, the term of the reissued patent—has never previously been extended and would therefore be eligible for extension. *Id.* § 156(a)(2). But that interpretation would let patentees use reissue to evade a clear statutory limit on patent term extensions. *Id.* The only way to avoid creating such a loophole is to read the

"term of the patent" to refer to the term of the original patent as carried over to the reissued patent.

In other contexts, this Court has refused to read statutes to allow patentees to "insulate a patent" from new provisions by "going through the reissue process." *Cooper Techs.*, 536 F.3d. at 1341. This Court should similarly reject that notion here.

D. Using the Original Issue Date Advances Congress's Aims in the Hatch-Waxman Act

This Court aligns statutory interpretation with the statute's broader "object and policy." *Centripetal Networks, Inc. v. Cisco Sys., Inc.*, 38 F.4th 1025, 1031 (Fed. Cir. 2022) (citation omitted). And because Section 156 specifically "contemplates a patentee receiving time lost in its patent term by reason of FDA delay, … the statute should be liberally interpreted to achieve this end." *Kessler*, 80 F.3d at 1552. Here, interpreting the "date … issued" in Section 156(c) to refer to the original issue date effectuates Congress's broader object of compensating patentees for patent term lost to regulatory review. That reading protects Congress's "carefully crafted" balance between "the need for pharmaceutical innovation [and] the need for generic drug competition." *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1294 (Fed. Cir. 2008).

1. Congress Intended the Hatch-Waxman Act to Compensate Patentees for Regulatory Delay

When Congress enacted the Hatch-Waxman Act, one of Congress's goals was to compensate patentees for "time lost in [their] patent term by reason of FDA delay," thus incentivizing drug manufacturers to innovate. *Kessler*, 80 F.3d at 1552. Before 1984, patentees would waste "years of the patent term … obtaining premarket approval for the patented invention rather than generating profits." *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1260-61 (Fed. Cir. 2008).

Congress's solution was Section 156, which "create[d] a new incentive for increased expenditures [on] research and development" of products requiring regulatory approval, by restoring "some of the time lost on patent life while the product [was] awaiting pre-market approval." *Pfizer*, 359 F.3d at 1365 (citation omitted).

As the district court held, using the original issue date for extension calculations involving reissued patents aligns with that aim. Appx00044. Section 156's point is to compensate patentees for their inability to market the products protected by their patent while regulatory review delays product launches. That loss happens from the moment the patent is "issued." 35 U.S.C. § 156(c). The patentee, moreover, has suffered that same loss even if,

during the regulatory review, the patent is formally surrendered and replaced by a reissued patent that inherits the original patent's term. Section 156 thus uses the original issue date for reissued patents because the prejudice from the lengthy review period remains the same before and after reissue. For instance, here, claim 4 of both the original and reissued patents covers sugammadex, so the FDA's delay denied Merck the ability to exclusively market the drug throughout the entire regulatory review period—both before and after reissue. Under Defendants' interpretation, Merck would lose all compensation for regulatory delay that preceded reissue, to which it otherwise would have been entitled. Defendants never explain why Congress would have intended such a bizarre result.

2. Defendants' Reading Undermines the Statutory Scheme

This Court has rejected "proposed interpretation[s]" that contradict "the stated purposes of the Hatch–Waxman Act." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1359 (Fed. Cir. 2003). Yet Defendants' interpretation would upend Congress's goal of balancing the "patent term extension benefit [given] to patentees" with "new benefits to generic producers." *Pfizer*, 359 F.3d at 1364.

For example, here, the Hatch-Waxman Act allowed Defendants to develop generic counterparts and rely on testing data generated from Bridion®'s regulatory approval. Appx00043-44. Meanwhile, Merck's compensation for delays in regulatory approval is, at most, a five-year patent extension. 35 U.S.C. § 156(g)(6)(A). Using a reissue date to calculate patent term extension would shrink patentees' compensation further. Allowing generic manufacturers to benefit from the entire approval process because of reissue, while further limiting a patentee's compensation for that same approval process, would upset the Hatch-Waxman Act's balance and unevenly skew its benefits in generic manufacturers' favor.

Further, calculating patent term extensions based on the reissue date would also introduce intolerable arbitrariness into the patent system, by making the length of extensions turn on the order of PTO and FDA decisions. For example, had the FDA approved Merck's application three years earlier in December 2012—while Merck's reissue application was still pending—Merck would undisputedly be entitled to a full five-year patent term extension based on the original issue date. *See* Appx00038-39. Because the FDA took even *longer*, approving Merck's drug application only after the PTO reissued the patent, Defendants perversely insist that Merck is entitled to a much

shorter extension. As the district court put it: "That *more* FDA delay should result in *less* restored term," "cannot be squared" with the Hatch-Waxman Act's goal of compensating patentees for patent life lost during regulatory review. Appx00039.

Worse still, as Defendants admit (at 51), the length of an extension could depend on a single day's difference in timing between the PTO's approval of pending reissue and its issuance of patent term extension. Suppose FDA approval comes between the original issue date and the reissue date, and the patentee files an application for patent term extension. If the PTO grants patent term extension on Monday and reissue approval on Tuesday, a patentee could get the full extension; vice versa and the patentee gets nothing (since the regulatory review finished before the reissue date). A few days of difference in PTO action, all outside the patentee's control, could mean years of difference in patent term extension. A statutory scheme that fluctuates so significantly would undermine Congress's aim to provide a predictable, stable incentive to encourage investment in new drugs—the centerpiece of the Hatch-Waxman Act. *Pfizer*, 359 F.3d at 1364.

The absurd swing in patent term extension caused by reissue might even force patentees to choose between seeking reissue and seeking patent term

extension. Defendants (at 49) call this "[h]olding … [patent owners] to the consequences of [their] … decisions." But forcing that choice would undermine the point of reissue—allowing patentees to fix errors and omissions to better protect the inventions they created. *In re Weiler*, 790 F.2d 1576, 1582 (Fed. Cir. 1986).

Indeed, Merck proactively tried to better protect its invention here, by filing for reissue once this Court decided *Tanaka*, 640 F.3d at 1251. Defendants (at 49-50) blame Merck for not exercising "basic diligence" by filing for reissue sooner, claiming that this Court's decision in *Tanaka* "did not make new law" and that Merck "never argued that it relied upon *Tanaka* in deciding when to file a reissue application." But Merck's counsel explicitly identified the connection between the *Tanaka* decision and Merck's reissue application at trial. Appx03373. And regardless of whether *Tanaka* made new law, this Court reversed the PTO's earlier rejection of reissue applications attempting to include narrower claims. In fact, the PTO publicly revised its reissue policy as a result of the decision, allowing "the addition of claims that are narrower in scope." *Clarification of Criteria for Reissue Error in View of* In re Tanaka, 1369 Off. Gazette 230 (Aug. 23, 2011). After that policy change, Merck filed for reissue.

Regardless, penalizing Merck on these facts would be draconian. Merck brought a new, innovative compound to market as a drug, and lost years of patent term due to regulatory delays. Appx00012. Defendants contend that they should be permitted to launch competing generic products right away solely because Merck sought and obtained a reissue with narrower patent claims in addition to the original claims—one of which Defendants concede is both valid and infringed. *See* Appx00025. Congress surely did not intend the Hatch-Waxman Act's "compensat[ion] for the delay in obtaining FDA approval," to be slashed from five years to under two simply because of when the patent was reissued. *Kessler*, 80 F.3d at 1547.

II. The PTO's Consistent Interpretation of Section 156(c) Disfavors Upending the Status Quo

Alternatively, as the district court held, "even if" Section 156(c) is "ambigu[ous]," the PTO's consistent use of the original issue date to calculate patent term extensions disfavors Defendants' approach. Appx00055. Since Congress enacted the Hatch-Waxman Act in 1984, the PTO has consistently interpreted the term "issued" in Section 156(c) to refer to the original issue date, not the reissue date, for extensions involving reissued patents. That longstanding policy and practice, which reflects the PTO's expertise in administering a complex patent-law framework, underscores the lack of any

adverse consequences from the status quo, and the dramatic changes Defendants' position would invite.

A. Parties Rely Upon the PTO's Longstanding Framework for Calculating Reissued Patent Extensions

The PTO's longstanding practice refutes any workability problems or grave consequences from the status quo. Instead, this framework has for years encouraged patentees to diligently pursue regulatory approval and correct any application errors through the reissue process. It has also encouraged companies to invest in new drug development, confident in their ability to recoup some regulatory costs through a settled, stable system of patent term extensions.

By contrast, Defendants encourage this Court to upend 40 years of settled expectations among patentees, generic manufacturers, and the PTO, disregarding reliance interests and patentees' expectation that reissue is a favored path to better protect inventions. This Court should not risk diluting the Hatch-Waxman Act's carefully calibrated incentives for a novel, ahistorical view of reissued patents.

B. The PTO's Longstanding Practice, Which Reflects Its Expertise and Reasoned Consideration, Merits Deference

The PTO's consistent use of the original issue date to calculate patent term extensions reflects the agency's thorough consideration and expertise, and aligns with statutory text and context. This Court relies on these same factors to apply so-called *Skidmore* deference "to informal agency interpretations of ambiguous statut[es]." *Stephenson v. Off. of Pers. Mgmt.*, 705 F.3d 1323, 1330 (Fed. Cir. 2013) (citation omitted) (discussing *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944)). Deference depends on the consistency, thoroughness, and reasonableness of the agency's position. *Id.*

This Court defers to an agency's considered interpretation even when some of those factors are missing. *See Deckers Outdoor Corp. v. United States*, 714 F.3d 1363, 1366-68, 1375 (Fed. Cir. 2013) (deferring to an informal Treasury definition that the agency issued without any reasoning). Defendants (at 53-54) are thus incorrect that only comprehensive agency explanations get *Skidmore* deference, and their cited cases (at 53-54) do not hold otherwise. Those cases declined deference to agency's assertions on topics beyond the agency's authority and expertise, including the "scope of federal courts' jurisdiction," *Maglioli v. Alliance HC Holdings LLC*, 16 F.4th 393, 404 (3d Cir. 2021), or preemption of state law, *Wyeth v. Levine,* 555 U.S.

555, 576 (2009). Here, the PTO's consistency and expertise on this complex issue have created settled and reasonable expectations that patentees rely on.

1. The PTO has Consistently Interpreted Section 156(c)

"Deference is particularly appropriate when [an] agency interpretation has been consistently applied." *Gose v. U.S. Postal Serv.*, 451 F.3d 831, 837 (Fed. Cir. 2006). And at trial, both sides agreed that since Congress enacted the Hatch-Waxman Act in 1984, the PTO had granted patent term extensions for reissued patents 40 times. Appx00049. The district court found that in 36 of 40 instances—90%—the PTO used the original issue date to calculate the patent term extension. Appx00049-50. A 90% consistency rate exceeds the "uneven" consistency of other interpretations that received deference. *Fed. Exp. Corp. v. Holowecki*, 552 U.S. 389, 399-400 (2008). And it bears no resemblance to the scattershot approach this Court refused to defer to in *PhotoCure ASA v. Kappos*, 603 F.3d 1372, 1376 (Fed. Cir. 2010) (cited by Defendants at 63).

In the remaining four out of 40 instances, the PTO used the reissue date to calculate patent term extensions. But the district court properly discounted these four instances because the PTO's decision made no difference. Appx00049. In two of the cases, using either date yielded the same patent

term extension. In the other two, the PTO never actually issued extensions based on the reissue date. Appx00023-24; Appx00049; Appx00052. As the district court noted, "the overwhelming majority of instances across the last four decades, paired with the distinguishable nature of the limited outliers, shows consistency." Appx00053 (citation omitted).

Defendants ignore this near-unbroken track record of PTO practice. Instead, they (at 54-61, 63) call the PTO's position inconsistent based on supposedly "disparate decisions and musings." But at trial, as the district court noted, "Defendants could not identify any PTO policy guidance using the *reissue date* for any purpose, nor could their expert point to any experience from her time at the PTO when the reissue date was used for any reason." Appx00048.

Defendants' failure at trial is unsurprising. For many years, including when this case was litigated, the PTO's MPEP treated a reissued patent as inheriting the original patent's term. For example, Section 1415.01 sets the maintenance fee schedule for the reissued patent based on the original patent's term. *See supra* p. 41. Similarly, Section 1405 demonstrates that a reissued patent's term is not distinct from the original term, since the PTO "transfer[s] … the term of the original patent to the reissue patent."

Appx00048 (citing MPEP § 1405). The Manual also stipulates that reissued patents use other timing features of an original patent, including its priority date. MPEP § 1440. Finally, Section 1460 reflects 35 U.S.C. § 252's mandate that a reissued patent is an amended original. *See supra* pp. 29-36.

The 2022 Manual makes explicit the PTO's longstanding use of the original issue date to calculate patent term extensions, and also reflects the PTO's consistent treatment of reissued patents as relating back to the originals for the purposes of maintenance fees, priority dates, and the like. The Manual specifies that "the original patent grant date [will] be used to calculate the [patent term] extension" if both the original and reissued patent "claim[ed] the approved product." MPEP § 2766 (2022).[10]

Defendants' purported evidence of inconsistency does not withstand scrutiny. Defendants first object (at 56) that the 2022 MPEP Section 2766 provision somehow undercuts the idea that all reissued patents relate back to the originals for timing purposes, since Section 2766 backdates only reissued patents that "claim[] the approved product." But the Manual just builds in

[10] While the PTO adopted the 2022 Manual's updates as of July 2022, the PTO did not publish the 2022 Manual until February 2023, after the trial in this case. 88 Fed. Reg. 13437, 13438 (Mar. 3, 2023).

Section 156's other criteria for patent term extensions—namely, that only "the term of a patent *which claims a product*" subject to regulatory review can be extended. 35 U.S.C. § 156(a) (emphasis added). This case does not present the rare (if not entirely hypothetical) situation where a "patent" did not "claim[] a product" from the beginning. *Id.* Thus, were the Court to adopt the PTO's rule, including the 2022 Manual's limiting provision, that would still compel affirmance. *See* Appx00040 (discussing hypothetical).

Defendants (at 56) also challenge the 2022 and 2020 versions of MPEP § 2766, claiming that both provisions treat the relationship between reissued patents and original patents in a way that contradicts the Patent Trial and Appeal Board and the FDA. Defendants contend that by treating reissued patents as amended originals, the Manual conflicts with *Eizo Corp. v. Barco N.V.*, which noted that a reissued patent is a "distinct property right." 2015 WL 4381586, at *4 (PTAB July 14, 2015). Defendants also claim a conflict with the FDA's policy that a reissued patent is "separate and distinct" from the original. Defts.' Br. 57 (citing the FDA's rulemaking in Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. 69580, 69601 (Oct. 6, 2016)). But neither the PTAB's decision nor the cited portion of the FDA's rulemaking have anything to do with patent terms. And while a reissued

patent may offer property rights "distinct" from the original patent, *supra* pp. 42-45, a reissued patent *also* inherits the unexpired portion of the original patent's term, as recognized by the MPEP.

2. The PTO's Interpretation Reflects Its Thorough Consideration and Expertise

Even if an agency "does not explain the reasoning behind [its] adoption of [an] interpretation," deference remains warranted if the agency "consistently applie[s]" the interpretation and the reasons behind the interpretation "are not difficult to discern." *Hagans v. Comm'r of Soc. Sec.*, 694 F.3d 287, 305 (3d Cir. 2012).[11] That is the case here. Though the PTO had not published a formal interpretation of Section 156(c) when this case was tried, the PTO's consistent treatment of reissued patents and its specialized expertise in administering patent laws show the PTO took care in crafting and applying its position. The PTO's 2022 decision to codify this longstanding practice in the Manual, after yet further deliberation, reinforces that intuition.

[11] Defendants (at 54 n.10) try to limit *Hagans* to its facts, stating that this rule applies only if the agency's ruling "expressly addressed the precise question presented." But *Hagans* announced a broader principle: agency interpretations can warrant *Skidmore* deference, despite not explaining "how or why [the agency] reached its interpretation," if the agency's interpretation adequately represents its "considered judgment" on the issue. 694 F.3d at 302-03.

3. The PTO's Interpretation is Reasonable

Finally, the reasonableness of the PTO's interpretation points towards deference, even if the court "might not have adopted that construction without the benefit of the agency's analysis." *Cathedral Candle Co. v. U.S. Int'l Trade Comm'n*, 400 F.3d 1352, 1366 (Fed. Cir. 2005). As discussed, the PTO's interpretation best aligns with the statutory text, context, and history of reissued patents. Defendants' interpretation ignores this context, and instead subjects the Hatch-Waxman Act's incentive structure to the whims of a date that has little other practical significance. Defendants' view also upsets the settled expectations of patentees, who for 40 years have relied on the PTO's expertise and sensible framework in this complex area of patent law.

CONCLUSION

The judgment of the district court should be affirmed.

Respectfully submitted,

JANUARY 12, 2024

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CERTIFICATE OF SERVICE

I, Sarah M. Harris, counsel for appellees and a member of the Bar of this Court, certify that, on January 12, 2024, a copy of the attached Brief of Appellees Merck Sharp & Dohme B.V. and Merck Sharp & Dohme, LLC was filed with the Clerk and served on the parties through the Court's electronic filing system. I further certify that all parties required to be served have been served.

JANUARY 12, 2024

/s/ Sarah M. Harris
SARAH M. HARRIS

CERTIFICATE OF COMPLIANCE
WITH TYPEFACE LIMITATION AND WORD-COUNT

I, Sarah M. Harris, counsel for appellees and a member of the Bar of this Court, certify, pursuant to Federal Rule of Appellate Procedure 32(a)(7)(B), that the attached Brief of Appellees Merck Sharp & Dohme B.V. and Merck Sharp & Dohme, LLC is proportionately spaced, has a typeface of 14 points or more, and contains 13,209 words.

JANUARY 12, 2024

/s/ Sarah M. Harris
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