

No. 23-2254

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**In the United States Court of Appeals for the Federal Circuit**

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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.*

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Appeal from the U.S. District Court for the District of New Jersey, No. 2:20-cv-02576 (Consolidated), Hon. Claire Cecchi

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**CORRECTED REPLY BRIEF FOR THE APPELLANTS**

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## INTRODUCTION

The word “issued” has a readily ascertainable meaning that neither Merck nor the Director challenge: “to be put forth officially” or “to promulgate.” Opening.Br. 24. Plug that definition into 35 U.S.C. § 156(c), and the statute has a plain meaning: The term of a patent may be extended for a time “equal to the regulatory review period for the approved product which period occurs after the date the patent is [put forth officially].” Here, it is undisputed that “the patent” is the ’733 patent, which “issued” on January 28, 2014, and is now expired if PTE is calculated using the ’733 patent’s actual issue date.

Merck and the Director ask this Court to supplant the plain text of the statute with the legal fiction that a reissued patent “inherits” the issue date of the original patent that is extinguished upon promulgation of the new patent. They support their preferred outcome with an intricate dance through various provisions of the Patent Act—principally §§ 251, 252, and 154—insisting Congress intended for reissued patents to “step into the shoes” of the cancelled original. Should the Court stumble through this routine, they ask that it just defer to the PTO’s unreasoned decision making under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). But “it is not the

responsibility or function of this court to perform linguistic gymnastics in order to upset the plain language of Congress.” *St. Martin Evangelical Lutheran Church v. S. Dakota*, 451 U.S. 772, 791 n.4 (1981) (Stevens, J., concurring) (cleaned up). Yet that is ultimately what Merck and the Director ask this Court to do.

Consider their treatment of § 251. They use the word “term” as a springboard for an elaborate analysis of three different statutory provisions. This exercise begins with the claim that a reissued patent takes the original patent’s “issue date” as part of its “term” and ends with the assumption that “the date the patent issued” means “the date the [*original*] patent issued.” But, at every step, this argument trips over the plain language of the statute: Reissued patents issue “for the *unexpired* part of the term of the original patent” and do not inherit the original patent’s full “term”; Merck and the Director’s understanding of a reissued patent’s “term” clashes with § 154 and would render § 251 partially superfluous; and, when read in full context, Congress used the word “term” in § 156 to refer to the *end* of the patent’s term. On top of all that, their argument ignores the confounding fact that § 251 itself uses the word “issue” according to plain, dictionary meaning.

Their treatment of § 252 is worse. Merck dissects its language into four parts—a division that flies in the face of legislative history—and then examines these pieces in isolation to demonstrate that the reissued patent should be treated as a wholesale continuation of the original patent. It claims the so-called “same effect” and “continuous effect” clauses compel “backdating” the issue date of a reissued patent to that of the original patent. Merck’s argument fails because it excises choice language from the statute and divorces it from the specific context Congress addressed in § 252: determining how a patentee may assert reissued claims in patent litigation.

Merck and the Director cannot hide behind *Skidmore* deference. The Director admits the PTO has *never* expounded upon the proper statutory interpretation of § 156(c). Without an articulation of how the PTO thought the statute should be construed when it granted Merck’s PTE application, there’s no purposed statutory construction to which to defer. And, even if the Court were to look past this gating issue, the Director fails to demonstrate why the PTO’s vague and ever-changing position on how reissue patents should be treated warrants *Skidmore* deference.

At bottom, the position urged by Merck and the Director is a policy argument masquerading as flawed statutory analysis. Whether it is good



policy for a reissue patent to “step into the shoes” of the original patent for purposes of calculating PTE is irrelevant. Congress said PTE must be calculated from “the date the patent is issued,” and the plain meaning of that command must control.

## ARGUMENT

### I. “THE DATE THE PATENT IS ISSUED” REFERS TO THE DATE THE PTO ISSUED THE PATENT FOR WHICH THE APPLICANT SEEKS PTE.

#### A. Section 156 Supports a Plain-Text Reading of the Statute.

Statutory construction begins with the words Congress chose. *Perrin v. United States*, 444 U.S. 37, 42 (1979). A “fundamental canon of statutory construction is that, unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning.” *Id.* The classic way to determine a statute’s “well-understood meaning” is to consult a dictionary. *Solar Energy Indus. Ass’n v. United States*, 86 F.4th 885, 895 (Fed. Cir. 2023). Here, “issued” has an undisputed dictionary definition, Opening.Br. 24, which lends itself to a plain-text construction of § 156(c): PTE is “equal to the regulatory review period for the approved product which period occurs after the date the patent is [put forth officially].”

Merck does not offer a competing definition of the word “issued,” nor the broader phrase “the date the patent is issued.” In fact, Merck devotes only one paragraph in its brief to the text of § 156(c), in which it states (at 23) that “[n]othing in the language of Section 156 itself compels [the] result” that “‘the date the patent is issued’ . . . refer[s] to the reissue date” rather than “the original issue date.” That’s backwards. The literal meaning of the words “compels [the] result.” Courts do not define statutory text based upon outcomes; rather, they use well-established tools of statutory construction to discern the meaning of the statute and then apply it to determine the appropriate result.

The Director doesn’t dispute the ordinary meaning of “issued” either. PTO.Br. 5. But she nonetheless maintains this plain meaning “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.” *Id.* How so? The Director cannot explain. The object of the phrase—“the patent”—refers to the ‘733 patent, which is the patent for which Merck sought PTE. The “date the [‘733] patent [was] issued” is January 28, 2014.

The Director tries to muddle the plain meaning of “issue” by asserting (at 6-7) it can have varied meaning depending upon whether it is used to

refer to an original (*e.g.*, §§ 151-153) or a reissued patent (*e.g.*, §§ 251-252). But there is no textual support for this distinction. To the contrary, Congress explicitly linked §§ 151-153 (the provisions the Director relies upon for the “issue” of original patents) to §§ 251-252 (which she points to for the “issue” of reissued patents). 35 U.S.C. § 251(c); PTO.Br. 6 & n.3 (conceding the same in a footnote). The word “issue” can and should have a consistent dictionary meaning across these provisions.

Only in the rarest of cases will courts forsake the plain meaning of the statutory text. And only then if the literal application of broad statutory language clashes with canons of construction that establish specific congressional intent. *E.g.*, *Yates v. United States*, 574 U.S. 528, 536 (2015) (rejecting the literal definition of “tangible object” because applying semantic canons confirmed Congress intended a narrower definition). But here, Merck and the Director never explain how “issued” is susceptible to a different definition, let alone show how the statutory text clearly demonstrates Congress intended it. They instead invite this Court to blue-pencil the statute to write in an ultra-specific caveat that “issued” refers to the issuance of the extinguished original patent for the limited purpose of applying § 156(c) to a reissued patent. The Supreme Court and this Court

swore off such judicial second-guessing of Congress decades ago. *E.g.*, *Allergan, Inc. v. Alcon Lab'ys, Inc.*, 324 F.3d 1322, 1345 (Fed. Cir. 2003).

**B. Section 251 Supports a Plain-Text Reading of the Statute.**

Unable to defend their preferred outcome under the text of § 156(c), Merck and the Director lean heavily on § 251. But, as Defendants explained in their opening brief (at 40-42), this provision is consistent with a plain-text reading of § 156(c). It confirms that a “reissue[d]” patent is a separate legal instrument from the original, “surrendered” patent. Congress chose separate words to refer to each. Section 251(b) also confirms that reissued patents are distinctly and separately “issue[d],” a point reinforced by § 252 *see infra* § I.C. Applying the dictionary definition of “issued” harmonizes the usage of the word across §§ 156, 251, 252, and other provisions of the Patent Act.<sup>1</sup> Finally, § 251 shows that Congress knew how to explicitly create special rules for reissued patents when it intended to do so. Congress created

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<sup>1</sup> Merck asserts in passing that these provisions “refer to the *act* of reissue” and not “the *date* of reissue.” Merck.Br. 26. But Merck offers no support for this distinction beyond its own say-so. The distinction is also self-defeating. Section 156(c) pegs PTE to the date the act of issuance takes place — “the date the patent is issued.”

an explicit cap on the term of reissued patents, which trumps § 154(a)'s general rule for determining the length of a patent term.

Merck responds (at 18) by reimagining how § 251 works. The argument—which requires bounding across three provisions of the Patent Act—goes like this:

(a) Section 251 states that a reissued patent is issued “for the unexpired part of the term of the original patent.” Merck plucks the word “term” out of this provision.

(b) Merck then hops over to 35 U.S.C. § 154(a), which explains every patent “grant” by the PTO “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 for the patent was filed.” Based upon this, Merck declares (at 19) the word “term” is “define[d] . . . with reference to the original issue date.”

(c) Armed with the “definition” it contrived, Merck leaps to § 156, which it says “unambiguously incorporates the original issue date for patent term calculations” because it “refers to the patent ‘term’” to “set the baseline for patent term extension calculations.”

Merck's argument amounts to "linguistic gymnastics" aimed at thwarting the plain meaning of § 156(c). It fails for three reasons.

**1. Merck misreads § 251 and ignores this Court's decision in *Yamazaki*.**

*First*, Merck misreads § 251. A reissue patent does not "inherit" the full "term" of the original patent. It issues "for *the unexpired part* of the term of the original patent." *Id.* (emphasis added). True, the original patent's term influences the term of the reissued patent. But that influence operates *prospectively*. The expiration date of the original patent sets the *end* of the reissued patent's term, but the *beginning* of the term is the date of the reissue patent's issuance. *Yamazaki* confirms this: When the PTO promulgates a reissued patent, the new patent gets its *own* "term." *In re Yamazaki*, 702 F.3d 1327, 1331 (Fed. Cir. 2012). And "the 'term of the original patent' defines the *outer limit* of the PTO's reissue authority under § 251, *i.e.*, the term of a reissued patent may not extend beyond that of the original." *Id.* (emphasis added).

Merck and the Director brush off *Yamazaki*. Merck (at 25) dismisses the relevant language as "small nuances in the Court's phrasing" unrelated to "the Court's key holding." Hardly so. Establishing the meaning of § 251 set

the stage for addressing the main issue presented in *Yamazaki*. The Director asserts (at 10) that this Court said in *Yamazaki* that “a patent’s ‘unexpired term’ refers to the baseline term established by 35 U.S.C. § 154(a).” But what the Court actually said is: “§ 154(a) establishes a baseline term for original U.S. Patents,” which can then be varied by other provisions of the Patent Act. *Yamazaki*, 702 F.3d at 1332. As explained next, the point of § 251 is to vary the “baseline” term of a reissued patent. It does not, as the Director suggests, import the original patent’s issue date into this new term.

## **2. Merck’s definition of “term” is wrong.**

*Second*, Merck’s argument reads words into § 154(a) that don’t exist, creates distinctions that don’t exist, and creates superfluity where none should exist. The statute doesn’t provide a dictionary-like definition of “term.” *Contra* 35 U.S.C. § 100. It explains how to calculate a “term” for “the patent” in question. Here, “the patent” is the ’733 patent, which indisputably “issue[d]” with a different issue date and a different application date than the surrendered ’340 patent. Opening.Br. 23-27. Absent § 251, the ’733 patent would get a fresh 20-year term based on the plain application of § 154(a). Foreclosing this result is why Congress said reissued patents issue only “for *the unexpired part* of the term of the original patent.” 35 U.S.C. § 251.

Merck reads § 154(a) to apply differently to reissue patents than it would to first-time grants. To Merck, the “term” for a reissued patent begins “on the date on which the [*surrendered original*] patent issue[d]” – not “on the date on which the patent issues.” Merck.Br. 19. Wrong. Merck not only reads words and distinctions into the statute that simply don’t exist, but its interpretation also conflicts with the broader context of § 154. Section 154(a) sets the “baseline” formula for calculating patent “term[s]” for *all* patents: “Every patent shall contain . . . a grant to the patentee . . . of the right to exclude” and “such grant shall be for a term” as calculated by § 154(a)(2). The provision applies equally to *every* patent, with no special rules for reissued patents.

Critically, applying a plain reading to § 154(a) harmonizes it with § 251, whereas Merck’s results-driven reading renders § 251 partially superfluous. Congress provided in § 251 that reissued patents would be granted only “for the unexpired part of the term of the original” to deviate from the “baseline” term calculation provided by § 154(a) and cap the “outer limit” of the PTO’s authority. *Yamazaki*, 702 F.3d at 1331-32. If Merck were right, and “the issue date and filing date of the *original* patent” defined the term of the reissued patent under § 154(a)(2), Merck.Br. 19, there would be



no reason to state separately in § 251 that the term of the reissued patent is capped at “the unexpired part of the term of the original.” That would happen by automatic operation of the qualifications Merck would read into § 154.

Finally, Merck’s invocation (at 21) of the 1984 version of 35 U.S.C. § 154 is a red herring. True, prior to the 1994 Uruguay Round Agreements Act, U.S. patents expired 17 years from the “grant” of the patent. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990). But the fact that the end of a “term” previously keyed off the day the patent was “grante[d]” rather than “the date on which the application . . . was filed” does not fill the holes in Merck’s argument.

**3. Merck’s flawed understanding of a reissued patent’s “term” does not disturb the plain meaning of § 156(c).**

*Third*, Merck’s flawed reading of § 251 and § 154 does not alter the plain meaning of § 156(c) in all events. Merck argues the phrase “the date the patent is issued” necessarily incorporates the concept of the patent’s “term” – which, per Merck, incorporates the original patent’s issue date – because § 156(c) begins by stating: “The *term* of a patent eligible for extension

under subsection (a) shall be extended . . . .” Merck.Br. 20. This is more linguistic gymnastics, and Merck fails to stick the landing.

In full context, § 156(c) refers to the “term” of the “patent eligible for extension.” Here, that’s the ’733 patent. Moreover, § 156 generally uses the word “term” to refer to the *end* of the term, not the beginning. For example, § 156(a) says a patent is eligible for PTE if “the *term* of the patent has not *expired* before an application is submitted” and if “the *term* of the patent has never been *extended*” under § 156(e)(1) (emphasis added). When the “term” began is irrelevant for purposes of § 156, and per the operation of § 251, the end of the “term” of a reissued patent is “the unexpired part of the term of the original patent.” Conversely, Congress used the word “issued” to define parameters for which PTE is *calculated*. Merck makes no attempt to explain how, under these circumstances, the meaning of “term” alters the plain meaning of “issued.”

#### **4. The Director’s arguments are equally meritless.**

The Director by-and-large adopts Merck’s flawed reading of § 251. PTO.Br. 10-12. She further claims (at 11) that a plain-text reading of § 251 will bring it into conflict with § 156(e). That’s incorrect. Section § 156(e) says, once the PTO has determined a patent is eligible for PTE, “the Director shall issue

to the applicant for the extension of the term of the patent a certificate of extension,” which “shall be recorded in the official file of the patent and shall be considered as part of the original patent.” The upshot of this provision is clear: The Director issues a certificate of extension, the certificate is placed in “the official file of the patent” (here, the ’733 patent), and the certificate is treated as though it were part of the patent file from its inception (“part of the original patent”). Congress used the same language to describe terminal and subject-matter disclaimers, 35 U.S.C. § 253, which operate the same way. The Director never explains how this provision is inconsistent with a plain-text reading of § 251 or a dictionary definition of “issued.”

**C. Section 252 Supports a Plain-Text Reading of the Statute.**

Merck and the Director also rely on § 252. But it too lines up with a plain-text reading of § 156(c). Opening.Br. 28-30. The statute uses the word “issue” to refer to the distinct act of promulgating the reissue patent: “The surrender of the original patent shall take effect upon *the issue of the reissued patent*” (emphasis added). Section 252 also embraces the long-standing rule that the surrendered patent is extinguished upon the promulgation of the reissued patent, which is a separate legal device. Opening.Br 29-30; *Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 721 F.3d 1330, 1346 (Fed. Cir. 2013). Congress

provided limited exceptions to this rule to preserve certain accrued claims and existing actions prior to reissue. Nowhere did Congress say – as Merck (at 29-36) and the Director (at 7-10) urge – that the reissued patent “inherits” the surrendered original’s issue date.

**1. Merck’s division of § 252 into four distinct clauses is wrong.**

Merck misconstrues § 252 by compartmentalizing the text in a way Congress never intended. As Defendants explained in their opening brief (at 28-29), the first paragraph of § 252 breaks down into two parts. The first half – everything before “but” – reflects the classic rule that a reissued patent is a new instrument that supplants the now-cancelled original patent for all future litigation matters. *Fresenius USA, Inc.*, 721 F.3d at 1346. This language has appeared in the statutory text in substantially similar form since the Patent Act of 1836. Act of July 4, 1836, ch. 357, § 13, 5 Stat. 122; *see also* Rev. Stat. § 4916 (U.S. Compiled Stat. 1901, p. 3393) (same provision just before 1928). Congress added the second half – from “but” to the end of the paragraph – in the Patent Act of 1928, ch. 730, 45 Stat. 732 (May 24, 1928). It added this language to alleviate some of the harsh consequences of the cancellation of the original patent by authorizing “actions for infringement

of the original claims to continue after reissue, but *only* ‘to the extent that [the reissued patent’s] claims are substantially identical with the original patent.’” *Fresenius USA, Inc.*, 721 F.3d at 1337 (alteration in original) (quoting 45 Stat. 732).

Ignoring statutory history, Merck carves the statute into four pieces: “an independent clause followed by three dependent clauses, each providing a different rule governing reissue.” Merck.Br. 29 n.7, 36 n.9. The point of Merck’s subdivision is subtle but important: It segregates textual references to litigation—the very thing Congress intended to address with this provision—so Merck can interpret cherry-picked language out of § 252 as a free-floating command to treat reissued patents as continuations of the original. This theme manifests several times in Merck’s analysis, and it is wrong.

## **2. Merck’s analysis of § 252’s “same effect” language is wrong.**

Merck first addresses what it calls the “same-effect clause.” This language serves a modest purpose, as Merck acknowledges (at 31). By allowing “a plaintiff [to] assert the reissued patent *as if* it had the same priority as the original,” the clause heads off “a defendant’s argument that

his use of the invention before reissue rendered the invention unpatentable.” Merck.Br. 31; *see Grant v. Raymond*, 31 U.S. 218, 244 (1832) (holding to same effect prior to codification).

Merck twists this basic proposition to support a much broader assertion. Per Merck (at 31), this provision “operates to backdate a reissued patent to the original during litigation arising after reissue” – apparently for all conceivable things that might arise in litigation, including statutory construction. But Merck’s argument has no support in the statute or precedent. The text says the reissued patent will have the “same effect” for “the trial of actions for causes thereafter arising.” The point of this provision (as Merck concedes) is establishing the priority of the reissued claims for purposes of assessing the merits of infringement and invalidity arguments in litigation. *Seattle Box Co. v. Indus. Crating & Packing, Inc.*, 731 F.2d 818, 829-30 (Fed. Cir. 1984) (explaining the same). The only question here, however, is one of statutory construction: What does “issued” mean and how does that meaning apply within the context of § 156(c)? To be sure, the outcome of this exercise will influence defenses to Merck’s causes of action. But statutory construction is not a trial on the defense itself.

Merck's "backdating" theory would also result in the anomalous situation that the word "issued" means something different in the context of patent litigation involving a reissued patent than it does anywhere else. Merck responds (at 33) that this problem only arises if one applies a dictionary meaning of "issued" to circumstances outside of litigation involving reissued patents, which apparently is good reason not to do so. But that turns the statutory-construction exercise on its head. Merck can't give § 252 a tortured construction and then use the ensuing disharmony as justification for ignoring the plain meaning of the statutory language. Indeed, § 252 itself uses the word "issue" in its plain sense—"issue of the reissued patent"—a hard fact Merck never convincingly explains away.

Like the district court, Merck and the Director rely upon a single, out-of-context line from this Court's decision in *Cooper Technologies Co. v. Dudas*, 536 F.3d 1330 (Fed. Cir. 2008), to support the assertion that § 252 "operates to backdate a reissued patent to the original during litigation arising after reissue." Merck.Br. 31-32; PTO.Br 7. As Defendants explained in their opening brief (at 42-43), *Cooper Technologies* is far off point. The Court there considered the meaning of "original application" as used in the American Inventors Protection Act of 1999 for determining the effective date of the

*inter partes* reexamination procedure established by Congress in the AIPA. 536 F.3d at 1331-32. The Court considered the meaning of this phrase within the context of *Chevron* deference and in the light of an express regulatory definition of “original application” promulgated by the PTO. *Id.* at 1333. Nowhere did the Court purport to construe the word “issued” or § 156(c). Critically, the snippet relied upon by Merck and the Director comes from the Court’s *Chevron* Step Two analysis, at which point the Court had declared the language ambiguous and was bound to defer to the PTO’s permissible interpretation. *Id.* at 1340-41. Against the backdrop of these wildly different circumstances, neither Merck nor the Director can explain how *Cooper Technologies* has any bearing on this case.

The Director takes a slightly different position, arguing (at 8-9) that § 252’s same-effect clause applies to the PTO’s calculation of PTE because “litigation concerning a patent extended by PTE and litigations concerning PTE calculations” under the APA are “trials of actions.” But that ignores the text and history of § 252. When Congress referred to “trial of actions for causes thereafter arising,” it referred to causes *arising under the patent itself*—*e.g.*, infringement actions. Indeed, Congress promulgated this language (1836) over a century before the APA even existed (1946).



**3. Merck’s analysis of § 252’s “continuous effect” language is wrong.**

Merck next turns to what it calls the “continuous-effect” clause. As Defendants explained (at 29-30), this clause is part of a limited exception to the general rule that a surrendered patent is “void *ab initio*.” *Fresenius*, 721 F.3d at 1346. Congress “did not overrule the application of that principle,” but instead modified it to allow for the continuation of certain claims and pending suits that would have otherwise died with the original patent. *Id.*

Merck again takes a basic point and stretches it past its breaking point. Merck says (at 34) the *entire* reissued patent must be deemed issued as of the date of the surrendered original—for all purposes, litigation and otherwise—to give effect to this clause. Wrong. By its plain text, the “continuous-effect” clause operates on a claim-by-claim basis and only in the context of litigation. Reissued patents “constitute a continuation” of the original, but only “to the extent that its claims are substantially identical with the original patent.” 35 U.S.C. § 252. Merck does not (because it cannot) explain how this provision supports the argument that the *entire* reissued patent must be deemed “issued” as of the date of the original—particularly for the non-litigation purposes of determining the meaning of the statute.

At this point, Merck's argument collapses into circular reasoning. To support its reading of § 252 – which Merck invokes to challenge the plain-text construction of § 156(c) – Merck points back to § 156 itself. Merck says (at 34-35) there's no problem with deeming the entire reissued patent "issued" as of the date of the original – § 252's claim-by-claim limit notwithstanding – because PTE under § 156(c) applies to the whole patent. This lays bare the problem with Merck's position: Merck has to assume its desired conclusion is correct for its proof of that conclusion to make any sense. Only by assuming reissued patents "inherit" the issue date of the surrendered original does Merck's explanation of how reissued patents "inherit" the issue date of the surrendered original make any sense. This reason-from-a-result approach to statutory construction is fundamentally incorrect.

Merck also tries (at 35-36) to decouple the "continuous-effect" clause from the specific context (litigation) Congress designed it to address. Instead of reading the "but" clause of § 252 as a single exception to the general rule laid out in the first half of § 252, *supra* pp. 15-16, Merck uses its artificial division of the statute to argue the "continuous-effect" clause broadly applies both inside and outside litigation. But, as explained above, neither

the history of the statute nor this Court's precedent support this tortured reading of § 252.

**D. Precedent Supports a Plain-Text Reading of the Statute.**

A plain-text reading of § 156(c) aligns neatly with Supreme Court and Federal Circuit precedent. Opening.Br. 25-29. Both have long held a surrendered patent is extinguished upon promulgation of a reissued patent—it's "dead." *Seattle Box Co.*, 731 F.2d at 827. And they have held reissued patents are distinct instruments that do not merely "step into the shoes" of the surrendered patent. *Intel Corp. v. Negotiated Data Sols., Inc.*, 703 F.3d 1360, 1364 (Fed. Cir. 2012).

Merck responds to this settled law by rejecting it. Merck says (at 36-40) a reissued patent is "not an entirely new patent" and it "merely step[s] into the shoes of the original for timing-related purposes." Merck relies (at 38) upon *Grant v. Raymond*, 31 U.S. 218, 244 (1832) for the proposition that a reissued patent "is in no respect" "considered as independent of the [original patent]." But, for two reasons, Merck reads too much into *Grant*:

*First*, *Grant* is factually far afield. *Grant* addressed whether the Secretary of State could reissue a patent upon surrender of the original. *Id.* at 241. The case pre-dates the codification of this power. *See id.* The Supreme

Court made the observation that Merck plucks out of context in rejecting the argument that the surrendered original patent could invalidate the reissued patent. *Id.* at 244. Accepting this hardly means a reissued patent inherits the issue date of the surrendered original. To the contrary, *Grant* observes, upon surrender and cancellation of the original, the Secretary of State would “*issue a new patent* for the unexpired part of the fourteen years for which the original had been granted.” *Id.* at 240 (emphasis added).

*Second*, Merck attacks a straw man. Defendants have never argued a reissued patent is fully “independent” of the surrendered original. But the fact that a reissue patent takes on certain characteristics of the surrendered original does not imply a reissued patent must inherit the issue date of the original as well.

*Peck v. Collins*, 103 U.S. 660 (1880) doesn’t help Merck either. Merck acknowledges *Peck* holds a “patent owner’s substantive property rights in the original patent are extinguished upon reissue.” Merck.Br. 38 (citing 103 U.S. at 664). Nevertheless, Merck latches onto the following language: “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.” *Peck*, 103 U.S. at 664. But this phrase doesn’t prove

Merck's point. It simply means the "date of the original patent" matters for purposes of determining when the reissued patent *expires*. In the very next clause, the Supreme Court said: "no damages can be recovered for any acts of infringement committed prior to the reissue" – a point irreconcilable with Merck's position that Merck never addresses in its brief.

Finally, Merck's attempts (at 42-45) to distinguish the on-point cases cited by Defendants in their opening brief all fail. Merck discounts *Peck* and *Abercrombie & Fitch Co. v. Baldwin*, 245 U.S. 198 (1917), stating (at 42) they "merely confirm the undisputed point that an original patent cannot generally be the source of *property rights* after reissue." Contrary to Merck's suggestion, the Supreme Court clearly stated it is not just the "property rights" of the original patent that die upon a reissue. *The whole patent dies*. As *Peck* says: "[I]f a reissue is granted, the patentee has no rights except such as grow out of the reissued patent. He has none under the original. That is extinguished." 103 U.S. at 664. Not just "no [property] rights" in the original, but no rights in the original whatsoever. The original patent is "canceled in law." *Fresenius*, 721 F.3d at 1336.

Relatedly, this Court (and the Supreme Court) have said in no uncertain terms: "When a reissue patent issues, a *new patent* with

presumably valid claims *exists*.” *Seattle Box Co.*, 731 F.2d at 829 (emphasis added); *see also Grant*, 31 U.S. at 218 (“[A] *new patent* . . . ought to be issued.”) (emphasis added). And this, of course, accords with the statutory text itself. 35 U.S.C. § 252 (“The surrender of the original patent shall take effect upon the *issue of the reissued patent*.”) (emphasis added). The cancellation of the surrendered original patent and the promulgation of a “new” reissued patent defeat Merck’s suggestion that the original patent maintains some type of vitality following a reissue.

Merck makes a similar point (at 43-44) to distinguish this Court’s decisions in *Fresenius* and *Seattle Box Co.* That argument fails for all the reasons just discussed. As expected, Merck tries (at 44-45) to limit this Court’s admonishment in *Intel Corp. v. Negotiated Data Solutions, Inc.*, that “a reissue patent does not simply replace an original patent *nunc pro tunc*,” to cases involving intervening rights. 703 F.3d at 1364. Defendants explained in their opening brief (at 32 n.5) why this is a misreading of *Intel*, but Merck did not (and cannot) respond. Finally, Merck (at 45) dismisses the Fourth Circuit’s decision in *Mylan Pharmaceuticals, Inc. v. FDA* for the same reasons it brushes aside *Peck*, *Abercrombie*, *Fresenius*, and *Seattle Box Co.* Once again, this argument fails.

Simply put, precedent is squarely against Merck and the Director. This Court and the Supreme Court have long held, upon reissue, the surrendered original patent is dead and a new patent arises. The reissued patent takes on certain characteristics of the extinguished original patent—but only as prescribed expressly by statute. Deciding in Defendants’ favor in this case would not be an unduly harsh result. Rather, it would be consistent with Congress’s and the courts’ longstanding practice of taking a strict (not results-oriented) approach to reissue patents.

**E. Policy Arguments Are No Basis for Disturbing the Plain-Text Reading of the Statute.**

Last, Merck and the Director make an appeal to policy. As Defendants explained (at 44-48), policy should hold no sway here. Strict adherence to the text is crucial here, given that the Hatch-Waxman Act is “a complex statutory framework that tries to balance generic and brand interests within the pharmaceutical industry.” *Celgene Corp. v. Mylan Pharms. Inc.*, 17 F.4th 1111, 1117 (Fed. Cir. 2021). The Supreme Court has repeatedly held “[s]trict adherence to the language and structure of the Act is particularly appropriate where . . . a statute is the result of a series of carefully crafted

compromises.” *Cnty. for Creative Non-Violence v. Reid*, 490 U.S. 730, 748 n.14 (1989) (collecting cases).

Merck first argues (at 46-48) an ordinary-meaning definition of “issue” would lead to absurd results. However, Merck cannot find any real-world examples of any alleged absurdity. So it hypothesizes (at 47) that applying an ordinary-meaning definition of “issue” would create problems whenever Congress promulgates a new patent statute, “since Congress often pegs the application of new patent statutes to existing patent issue dates.” For example, it claims a dictionary definition of “issue” would lead to a “nonsensical” application of 35 U.S.C. § 156(g)(6)(C), which addressed the application of the Hatch-Waxman Act to patents that were issued just before and after the 1984 enactment of the statute. The fact that Merck has no examples of a nearly 40-year-old “anomaly” is telling. Merck tries again with the America Invents Act of 2011. But again, it can offer nothing more than hypotheticals. Speculative problems potentially related to a small subset of patents that straddle the implementation of new congressional edicts are not good reasons for deviating from the plain text of the statute.

Next, Merck claims (at 48-49) a plain-text reading “would perversely let patentees seek repeated patent term extensions on a single patent.” This



argument is flat wrong. Congress expressly provided a reissued patent promulgates “for the unexpired part of the term of the original patent.” 35 U.S.C. § 251. The reissue patent takes the back end of “the term of the original patent” subject to any limitations there may be on the end of the term—*e.g.*, a terminal disclaimer. *Yamazaki*, 702 F.3d at 1331; *see also* 35 U.S.C. § 156(e) (stating a PTE extension becomes part of the term of the original patent).

Finally, embracing the liberal-construction canon, Merck claims (at 49-55) enforcing the plain meaning of the words Congress wrote into law will somehow thwart congressional intent. Defendants explained in their opening brief (at 44-48) why this analysis fails as a matter of law. Merck’s view of the policy merits on enforcement of § 156(c) is debatable at best. *Id.* 45-48. This Court should leave policy to Congress and enforce the statute as written. *Cnty. for Creative Non-Violence*, 490 U.S. at 748 n.14.

## **II. THE PTO’S POSITION IS NOT ENTITLED TO DEFERENCE.**

### **A. The PTO Did Not Have a Reasoned or Consistent Interpretation of the Statute.**

The PTO is not entitled to *Skidmore* deference because the agency has never articulated a construction of the phrase “the date the patent is issued.”

The Director acknowledges this fact, as she must. PTO.Br. 21-22. The Director's amicus brief in this appeal is (as far as Defendants know) the first time the agency has ever articulated a rationale for treating reissued patents as though they promulgated on the same day as the expired original patent. This alone precludes deference. Courts may defer to an agency's "explanation" and analysis of the statute, not its bare "conclusion" as to what it means. *Wyeth v. Levine*, 555 U.S. 555, 576 (2009).

Merck claims (at 57) this Court may defer to agency action "issued without any reasoning." Wrong. It is long-settled law that, "[w]here the agency has shown little evidence of the reasoning that went into its contemporaneous position, that position has been accorded little deference." *N. Colo. Water Conservancy Dist. v. FERC*, 730 F.2d 1509, 1519 (D.C. Cir. 1984). Summary orders "without a concomitant exegesis of the statutory authority for" such orders leave the Court to "speculate as to the [agency's] reasons for reaching the conclusion that it did." *S.E.C. v. Sloan*, 436 U.S. 103, 118 (1978). A bare conclusion "obviously lacks power to persuade as to the existence of such authority." *Id.* (cleaned up).

"This lack of specific attention to the statutory authorization" for the PTO's decision making "is especially important" in the context of *Skidmore*

deference. *Adamo Wrecking Co. v. United States*, 434 U.S. 275, 287 n.5 (1978).

The thoroughness and validity of the agency's interpretation of the statute — *i.e.*, when does a reissued patent “issue” — is what gives the agency's position the “power to persuade.” *Id.* When, as here, there's no “concomitant exegesis of the statutory authority” for what the agency has done, the agency's decision making “obviously lacks power to persuade.” *Sloan*, 436 U.S. at 118.

The Director, for her part, says the PTO's conclusion is entitled to deference because “the rationale behind the agency's use of the original issue date is ‘not difficult to discern.’” PTO.Br. 21-22 (quoting *Hagans v. Comm'r of Soc. Sec.*, 694 F.3d 287, 305 (3d Cir. 2012)). That argument fails for all the reasons just discussed, and *Hagans* does not alter the conclusion. As Defendants explained in their opening brief (at 54 n.10), and as the Director does not protest,<sup>2</sup> *Hagans* dealt with a narrow set of facts in which the agency had issued a ruling that expressly addressed the precise question presented,

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<sup>2</sup> Merck claims “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.” Merck.Br. 62 n.11 (quoting *Hagans*, 694 F.3d at 302-03). But the PTO never articulated an “interpretation” of the statute to begin with. And the PTO's summary decision making and off-point MPEP citations do not reflect a “considered judgment” of how § 156(c) should be construed.

and the agency had “consistently applied th[e] policy” for 20 years. 694 F.3d at 305.

The circumstances here are nowhere close to those in *Hagans*, and the Director admits as much. The PTO had not taken any discernable position on the application of § 156(c) to reissued patents – now embodied at MPEP § 2766 – until *after* the issue arose in this case. PTO.Br. 23 (conceding this). Knowing this fact is devastating for her case, the Director redirects the Court to MPEP § 1460, claiming MPEP § 2766 merely “reflects long-standing agency practice and conforms with § 1460’s broader articulation.” *Id.* But § 1460 itself is nothing more than a broad conclusion devoid of any statutory analysis. And even then, § 1460 explicitly does no more than summarize 35 U.S.C. § 252. MPEP § 1460 (“The effect of the reissue of a patent is stated in 35 U.S.C. 252.”). The Director does not explain how the PTO’s convoluted construction of § 156(c) expounded for the first time in this appeal should have been “not difficult to discern” from § 1460.

**B. Even if the PTO Had a Policy, It Did Not Merit Deference.**

*Thoroughness.* As explained above, the PTO has not articulated *any* “analysis of the statutory issue,” let alone a “careful” one. *Cathedral Candle Co. v. U.S. Int’l Trade Comm’n*, 400 F.3d 1352, 1366 (Fed. Cir. 2005). The PTO’s

sparse history of granting unreasoned PTE decisions that reach the outcome advocated here does not make up for the absence of a thorough and careful analysis of the statute. *Sloan*, 436 U.S. at 118 (explaining “the existence of a prior administrative practice” does not “relieve [courts] of [their] responsibility to determine whether that practice is consistent with the agency’s statutory authority”).

**Consistency.** The PTO has not taken a “consistent” view of statutory interpretation because it hasn’t taken any position on statutory interpretation to begin with. Further, Merck and the Director fail to convincingly distinguish *Eizo Corp. v. Barco N.V.*, 2015 WL 4381586 (PTAB July 14, 2015), or *PhotoCure ASA v. Dudas*, 622 F. Supp. 2d 338, 349 (E.D. Va. 2009), *aff’d sub nom. PhotoCure ASA v. Kappos*, 603 F.3d 1372 (Fed. Cir. 2010). The Director tries (at 25-26) to distinguish *Eizo* by arguing it does not address whether “a reissue patent maintains privileges of the original patent, including its issue date,” but this superficial distinction fails for the reasons discussed above. As for *PhotoCure*, the Director claims (at 26) it is off point because “the USPTO’s interpretation here is entirely consistent with the MPEP.” But as explained above and in Defendants’ opening brief (at 63), that is incorrect.

*Validity.* Finally, the PTO's decision making is not reasonable because it is inconsistent with the statute. *Skidmore* does not "permit[] a court to defer to an incorrect agency interpretation." *PhotoCure ASA*, 603 F.3d at 1376.

### CONCLUSION

The district court's judgment should be reversed.

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LIMITATIONS**

I hereby certify that the foregoing complies with the word limitation of Fed. Cir. R. 32(b)(1) because it contains 6,999 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b)(2). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it was prepared in Microsoft Word 365 using a proportionally spaced typeface (Book Antiqua) in 14-point font.

Dated: March 8, 2024

/s/ Deepro R. Mukerjee

## CERTIFICATE OF SERVICE

I hereby certify that I caused a copy of the foregoing document to be filed on March 8, 2024, with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit using the Court's electronic filing system, which will send a notice of electronic filing to all attorneys appearing in this matter.

/s/ Deepro R. Mukerjee