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

2023-2254

Appeal from the United States District Court for the District of New Jersey in Nos. 2:20-cv-02576-CCC-LDW, 2:20-cv-02750-CCC-MF, 2:20-cv-02751-CCC-MF, 2:20-cv-

02786-CCC-MF, 2:20-cv-02787-CCC-MF, 2:20-cv-02892-CCC-MF, 2:20-cv-02909-CCC-MF, 2:20-cv-02964-CCC-MF, 2:20-cv-03007-CCC-MF, 2:20-cv-03068-CCC-MF, 2:20-cv-03072-CCC-MF, 2:20-cv-03112-CCC-MF, 2:20-cv-03117-CCC-MF, 2:20-cv-03270-CCC-MF, 2:20-cv-03314-CCC-MF, 2:20-cv-03795-CCC-MF, Judge Claire C. Cecchi.

Decided: March 13, 2025

DAVID M. KRINSKY, Williams & Connolly LLP, Washington, DC, argued for plaintiffs-appellees. Also represented by STANLEY E. FISHER, SHAUN PATRICK MAHAFFY, ASHWIN SHANDILYA; SHAYNA S. COOK, ALAN ERNST LITTMANN, DOUG J. WINNARD, Goldman Ismail Tomaselli Brennan & Baum LLP, Chicago, IL; SARAH GEERS, Jones Day, New York, NY; ANTHONY INSOGNA, San Diego, CA; ANDREA WEISS JEFFRIES, Los Angeles, CA.

ERIC THOMAS WERLINGER, Katten Muchin Rosenman LLP, Washington, DC, argued for all defendants-appellants. Defendants-appellants Mylan API US LLC, Mylan Pharmaceuticals Inc., Mylan Inc. also represented by TIMOTHY H. GRAY; JOSEPH JANUSZ, JITENDRA MALIK, Charlotte, NC; DEEPRO MUKERJEE, LANCE SODERSTROM, New York, NY BRIAN SODIKOFF, Chicago, IL; MATTHEW GREINERT, Mylan, Canonsburg, PA.

MAUREEN DONOVAN QUELER, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for amicus curiae Coke Morgan Stewart. Also represented by SARAH E. CRAVEN, AMY J. NELSON, FARHEENA YASMEEN RASHEED.

TIMOTHY H. KRATZ, Kratz & Barry LLP, Atlanta, GA, for defendants-appellants Aurobindo Pharma USA, Inc., Aurobindo Pharma Ltd., Eugia Pharma Specialties

Limited. Also represented by GEORGE BARRY, III; MICHAEL PATRICK HOGAN, Philadelphia, PA; R TOUHEY MYER, Wilmington, DE.

ROBERT FLORENCE, Parker Poe Adams & Bernstein LLP, Atlanta, GA, for defendant-appellant USV Private Limited. Also represented by TASNEEM DHARAMSI, Greenville, SC; ELIZABETH CROMPTON, Washington, DC.

IMRON T. ALY, ArentFox Schiff LLP, Chicago, IL, for defendant-appellant Gland Pharma Limited. Also represented by KEVIN MICHAEL NELSON; MATTHEW THOMAS WILKERSON.

DMITRY SHELHOFF, Shelhoff Canfield & Chin LLC, Short Hills, NJ, for defendants-appellants Mankind Pharma Ltd., Lifestar Pharma LLC. Also represented by KENNETH CANFIELD; JULIA S. KIM, EDWARD D. PERGAMENT, Pergament & Cepeda LLP, Florham Park, NJ.

BRIAN TIMOTHY BURGESS, Goodwin Procter LLP, Washington, DC, for defendants-appellants Fresenius Kabi USA, LLC, Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., Sandoz Inc., Lek Pharmaceuticals, d.d. Also represented by NATASHA ELISE DAUGHTREY, Los Angeles, CA; WILLIAM EVANS, ROBERT FREDERICKSON, III, EMILY L. RAPALINO, DARYL L. WIESEN, Boston, MA.

CHARLES B. KLEIN, Winston & Strawn LLP, Washington, DC, for defendants-appellants Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries Limited. Also represented by JOVIAL WONG.

Before DYK, MAYER, and REYNA, *Circuit Judges*.

DYK, *Circuit Judge*.

This case concerns patent term extensions ("PTEs") for reissued patents under the Hatch-Waxman Act. The Hatch-Waxman Act provides a process for extending patent terms by up to five years to compensate patent owners for time lost during the lengthy regulatory review of new drug applications. *See* 35 U.S.C. § 156. The formula for calculating PTE is set forth in subsection 156(c), which provides that "[t]he term of a patent . . . shall be extended by the time equal to the regulatory review period . . . occur[ring] after the date the patent is issued." *Id.* § 156(c) (emphasis added). The sole issue on appeal is whether PTE for a reissued patent should be calculated based on the issue date of the original patent or the reissued patent; in other words, whether the reference to "the patent" in subsection 156(c) is to the original patent or the reissued patent. Using the issue date of the reissued patent would usually result in shorter PTE because review that occurs before the issue date does not affect PTE.

Here, the United States Patent and Trademark Office ("PTO") granted an application for a five-year PTE for a reissued patent, U.S. Patent No. RE44,733 (the "RE'733 patent"), based on the issue date of the original patent, U.S. Patent No. 6,670,340 (the "'340 patent). We hold that, in the context of reissued patents, the reference to "the patent" in subsection 156(c) is to the original patent. Here, the '340 patent included claims directed to the active ingredient for a drug product (and the RE'733 patent retained those same claims). Under these circumstances, the RE'733 patent was entitled to a five-year PTE based on the '340 patent's issue date, since regulatory review effectively prevented the patent owner from enforcing the patent during that period. We thus affirm the district court's holding that the PTO correctly calculated the RE'733 patent's PTE.

BACKGROUND

I

The material facts of this case are not in dispute. Plaintiff-Appellee Merck[1] owned the '340 patent, which issued on December 30, 2003. The '340 patent was directed to a class of 6-mercapto-cyclodextrin derivatives. Claim 4 is exemplary:

> 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.

'340 patent, col. 20 ll. 51–64 (emphasis added). On April 13, 2004, four months after the '340 patent issued, Merck applied to the Food and Drug Administration ("FDA") for approval of 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin ("sugammadex"). Sugammadex

---

[1] Throughout this opinion, "Merck" refers to Merck Sharp & Dohme B.V. and Merck Sharpe & Dohme LLC as well as their predecessors-in-interest.

is the active ingredient in BRIDION®, a drug that is administered as an intravenous injection to reverse neuromuscular blockade, a form of paralysis induced by rocuronium bromide and vecuronium bromide in certain types of surgery.

While regulatory review was pending, Merck filed an application with the PTO to reissue the '340 patent. The reissue application retained the original claims of the '340 patent and included narrower claims directed specifically to sugammadex.[2] On January 28, 2014, the '340 patent was reissued as the RE'733 patent, retaining the '340 patent's original claims and adding twelve additional, narrower claims relating to sugammadex. Claim 21 is exemplary of the new claims:

> 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.

RE'733 patent, col. 22 ll. 29–32. None of the '340 patent's nine original claims was cancelled.

The regulatory review process continued until December 15, 2015, when sugammadex was approved. Merck thus could not market sugammadex for nearly twelve years of the '340 patent's original term, which was set to expire on January 27, 2021.[3] On February 10, 2016, Merck filed

---

[2] Merck filed this application after this court clarified that the addition of narrower claims may constitute a proper basis for seeking reissue, *see In re Tanaka*, 640 F.3d 1246, 1251 (Fed. Cir. 2011).

[3] The '340 patent's application filing date was November 23, 2000, corresponding to an original expiration

a PTE application for the RE'733 patent, seeking the maximum five-year PTE based on the '340 patent's original issue date. On February 4, 2020, the PTO granted a five-year PTE to the RE'733 patent based on the '340 patent's original issue date: "Since the regulatory review period for BRIDION® began on April 13, 2004, which is after the December 30, 2003[,] date of issuance for the '340 patent, the entire regulatory review period has been considered in the above determination of the [PTE] length[.]" J.A. 6815. The RE'733 patent's expiration date was accordingly shifted from January 27, 2021, to January 27, 2026.

II

From January to March 2020, after the RE'733 patent reissued and around the time the FDA granted Merck's PTE application, Defendants-Appellants (collectively "Aurobindo")[4] filed Abbreviated New Drug Applications ("ANDAs") with the FDA to obtain approval to sell generic versions of BRIDION®. Aurobindo submitted a Paragraph IV certification under 21 U.S.C.

---

date, without any extensions or adjustments, of November 23, 2020. The patent received sixty-five days of patent term adjustment under 35 U.S.C. § 154(b) and was thus set to expire on January 27, 2021.

[4] Separate suits were brought against the other appellants in the same district: Aurobindo Pharma USA, Inc., Aurobindo Pharma, Ltd., and Eugia Pharma Specialties Ltd.; Gland Pharma Ltd.; Mankind Pharma Ltd. and Lifestar Pharma LLC; Mylan API US LLC, Mylan Pharmaceuticals Inc., and Mylan Inc.; Sandoz Inc., and Lek Pharmaceuticals d.d.; Sun Pharmaceutical Industries, Inc. and Sun Pharmaceutical Industries Ltd.; Fresenius Kabi USA, LLC; Dr. Reddy's Laboratories, Inc., and Dr. Reddy's Laboratories, Ltd.; and USV Private Ltd. These cases were consolidated.

§ 355(j)(2)(A)(vii)(IV) as to the RE'733 patent. A Paragraph IV certification allows an ANDA applicant to certify, to the best of its knowledge, that a patent that claims the brand-name drug or use for such drug is "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* In accordance with the patent statute, 35 U.S.C. § 271(e)(2)(A), Merck treated this filing as an act of infringement and brought suit.

At trial, Aurobindo argued that the RE'733 patent was not entitled to a five-year PTE and had therefore expired. It argued that the PTO erred in calculating the RE'733 patent's PTE based on the '340 patent's original issue date, urging that the plain text of subsection 156(c) required the PTO to calculate PTE based on the issue date of "the patent" for which PTE was sought: the RE'733 patent. According to Aurobindo, the RE'733 patent was only entitled to a 686-day PTE (corresponding to an expiration date of December 14, 2022), since "only 686 days of the 4,265-day regulatory review period for BRIDION® 'occur[red] after the date the [RE'733] patent . . . issued.'" Defendants' Opening Brief on Their Patent Term Extension Invalidity Defense at 11, In re Sugammadex, 2023 WL 3966146 (D.N.J. June 13, 2023) (No. 20-cv-2576) (alterations in original) (quoting 35 U.S.C. § 156(c)).

The district court disagreed, finding that Aurobindo's construction of subsection 156(c) would undermine the purpose of the Hatch-Waxman Act. The district court concluded that section 156 should be read in light of 35 U.S.C. §§ 251, 252, and that "the patent" in subsection 156(c) must refer to the original patent, not the reissued patent. *See In re Sugammadex*, No. 20-cv-2576, 2023 WL 3966146, at *15–16 (D.N.J. June 13, 2023). Based on this

construction, the district court held that the RE'733 patent was entitled to a five-year PTE.[5]

Aurobindo appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1). On January 19, 2024, the PTO filed an amicus brief in support of affirmance. We invited the PTO to present oral argument.

DISCUSSION

Statutory construction is a question of law that is reviewed de novo. *Hawkins v. United States*, 469 F.3d 993, 1000 (Fed. Cir. 2006). Statutory construction begins "with the language of the statute itself," *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241 (1989), bearing in mind that "[s]tatutory language cannot be construed in a vacuum," *Sturgeon v. Frost*, 577 U.S. 424, 438 (2016) (internal citation and quotation marks omitted). The "[i]nterpretation of a word or phrase depends upon reading the whole statutory text, considering the purpose and context." *Dolan v. U.S. Postal Serv.*, 546 U.S. 481, 486 (2006).

The question on appeal is not, as the parties sometimes suggest, the meaning of the term "issue." Aurobindo is clearly correct that the date the reissued patent issues is the date of reissue (here, January 28, 2014). Rather, this

---

[5] The district court held a one-day bench trial in which expert witnesses testified as to the practices of the PTO in granting PTEs for reissued patents for the purpose of establishing an agency practice that may be entitled to deference. *Sugammadex*, 2023 WL 3966146, at *2. This was improper, since agency practice is determined by examining agency orders, not by the testimony of expert witnesses. *Rumsfeld v. United Techs. Corp.*, 315 F.3d 1361, 1369 (Fed. Cir. 2003). This error has no impact on this appeal.

case requires us to determine the meaning of the term "the patent" as used in subsection 156(c):

> The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued[.]

35 U.S.C. § 156(c) (emphasis added).

Aurobindo argues that, under the text's plain meaning, "the patent" refers to the reissued patent, since "the 'patent eligible for extension' is the [reissued] patent." Appellant's Br. 23 (quoting 35 U.S.C. § 156(c)). This is because "the reissue[d] patent is distinct from the original patent[,] [and] the latter ceases to exist on the date the former is issued." *Id.* at 27 (emphasis removed). Merck urges the opposite interpretation, arguing that subsection 156(c)'s "text, together with other patent statutes and the history of patent reissue, demonstrate that [subs]ection 156(c) refers to the original issue date." Appellee's Br. 17 (emphasis removed). We agree with Merck that the reference to "the patent" in subsection 156(c) refers to the original patent directed to a drug product.[6]

As the PTO points out, the language of subsection 156(c) standing alone is ambiguous. It is unclear whether "the patent" refers to the original or reissued patent. Because "[w]e cannot say that [this language] is altogether free of ambiguity," we "consider statutory text and context together." *Caraco Pharm. Lab'ys, Ltd. v. Novo*

---

[6] PTE is available for patents that contain drug product claims, method of using drug product claims, and method of manufacturing drug product claims. 35 U.S.C. § 156(b). This opinion collectively refers to these claims as claims "directed to a drug product."

Nordisk A/S, 566 U.S. 399, 412 (2012); *accord Chapman v. Hous. Welfare Rights Org.*, 441 U.S. 600, 608 (1979). The Supreme Court in *Caraco* provided important guidance for interpreting another provision of the Hatch-Waxman Act where, as here, the plain text of the statute was ambiguous.

In *Caraco*, the Court considered the meaning of a provision authorizing an ANDA applicant sued for patent infringement to bring a counterclaim "on the ground that the patent does not claim . . . an approved method of using the drug." 566 U.S. at 413 (alteration in original) (quoting 21 U.S.C. § 355(j)(5)(C)(ii)(I)). The patentee urged that "not an" meant "not any," such that an ANDA applicant could only bring this challenge if the patent did not claim any approved method of using the drug at all. *See id.* The ANDA applicant urged that "not an" meant "not a particular one," such that this challenge was available if the patent did not claim one of the methods of use for which the ANDA applicant sought to market the drug. *See id.* Recognizing that the meaning of "not an" was ambiguous, the Court looked to the broader "statutory context," explaining that "Congress understood[] [that] a single drug may have multiple methods of use" and concluded that "[t]he statutory scheme . . . contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones." *Id.* at 414–15. The Court concluded that "not an" must refer to "not a particular one" as suggested by the ANDA applicant because "[w]ithin [the Hatch-Waxman Act's] framework, the counterclaim naturally functions to challenge the brand's assertion of rights over whichever discrete use (or uses) the generic company wishes to pursue." *Id.* at 415. This was "because Congress meant (as it usually does) for the provision it enacted to fit within the statutory scheme." *Id.* at 416.

So, too, here, we must interpret the term "the patent" with reference to "the specific context in which that language is used, and the broader context of the statute as a

whole." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997); *see also Dep't of Homeland Sec. v. MacLean*, 574 U.S. 383, 393 (2015) (rejecting an interpretation that "could defeat the purpose of the . . . statute"); *Centripetal Networks, Inc. v. Cisco Sys., Inc.*, 38 F.4th 1025, 1031 (Fed. Cir. 2022) (explaining that in interpreting a statute, we "look to the provisions of the whole law, and [] its object and policy" (quoting *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 35 (1990)).

While Congress does not appear to have contemplated the situation presented by reissued patents in drafting section 156, the purpose of the section is clear: to compensate pharmaceutical companies for the effective truncation of their patent terms while waiting for regulatory approval of new drug applications. *See* H.R. Rep. No. 98-857, pt. 1, at 15 (1984) (stating that the purpose of PTE is to "create a new incentive for increased expenditures for research and development," where "[t]he incentive is the restoration of some of the time lost on patent life while the patent is awaiting pre-market approval" (emphasis added)); Drug Price Competition and Patent Term Restoration Act of 1984: Hearing on S. 2748 Before the S. Comm. on Lab. & Hum. Res. of the U.S. Senate at 2, 98th Cong. 1102 (1984) (statement of Sen. Orrin Hatch) ("The added research and development will flow from added patent protection which will compensate the research drug companies for the years of exclusive marketing time under their patents lost because of the lengthy FDA testing and review period.").

We have recognized that the purpose of the Hatch-Waxman Act is to "provid[e] patent holders with limited extensions of patent term in order to recover a portion of the market exclusivity lost during the lengthy process of development and FDA review." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997); *see also Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1323 (Fed. Cir. 2007); *PhotoCure ASA v. Kappos*, 603 F.3d 1372,

1374 (Fed. Cir. 2010). In particular, "[t]he statute contemplates a patentee receiving time lost in its patent term by reason of FDA delay, and the statute should be liberally interpreted to achieve this end." *Merck & Co. v. Kessler*, 80 F.3d 1543, 1552 (Fed. Cir. 1996).

We conclude that, in the context of reissued patents, the Hatch-Waxman Act contemplates PTE for those patents and only those patents with claims directed to drug products whose period of exclusivity was delayed by FDA review.[7] That purpose applies in this case, since construing "the patent" in subsection 156(c) as the original patent compensates Merck for the period of exclusivity lost due to regulatory delay. On the other hand, Aurobindo's construction denies Merck compensation for all but a small period of the delay. There is no reason why the Hatch-Waxman Act's purpose would be served by disabling extensions of the unexpired term solely based on a patent holder's decision to seek reissue, and Aurobindo offers none.[8]

Aurobindo, however, urges that "the patent" cannot refer to the original patent because the original patent is

---

[7] We note that the Hatch-Waxman Act was passed prior to the Uruguay Round Agreements Act, so the patent's expiration date was based on the issue date rather than the filing date. This does not change our analysis, since any period of regulatory review that occurs after the patent's issue date still disables the patent owner from commercially marketing the drug product during the lifetime of the patent.

[8] At oral argument, when asked why Congress would intend for a patent owner to lose PTE simply by seeking reissue, counsel for the defendants replied: "If the text is plain that's it. There might be policy reasons for why the statute might have been written differently, but that is for Congress to determine." Oral Arg. at 2:01–08.

"dead" upon reissue. Appellant's Br. 26 (quoting *Seattle Box Co. v. Indus. Crating & Packing*, 731 F.2d 818, 827 (Fed. Cir. 1984)); *see also Eby v. King*, 158 U.S. 366, 373 (1895) (holding that a patent owner may not rely on the original patent after the reissued patent is declared void because the original patent "is extinguished" (quoting *Peck v. Collins*, 103 U.S. 660, 664 (1880)); *Moffitt v. Garr*, 66 U.S. 273, 282–83 (1861) (holding that a suit for infringement of the original patent brought before the issuance of the reissued patent must "fail" because "[a] surrender of the patent [for reissue] . . . extinguishes the patent"). But whether the holder of the reissued patent has an enforceable right in the original patent's claims is irrelevant, since the reissued patent inherits "the unexpired part of the term of the original patent," 35 U.S.C. § 251(a), which now unambiguously "begin[s] on the date on which the patent issues and end[s] 20 years from the date on which the application for the patent was filed," *id.* § 154(a)(2), subject to patent term adjustment (not at issue in this case). Section 156 is designed to extend the term of the original patent, not to make the original patent enforceable after reissue. We have explained that a "reissue patent does not simply replace an original patent *nunc pro tunc*." *Intel Corp. v. Negotiated Data Sols., Inc.*, 703 F.3d 1360, 1364 (Fed. Cir. 2012). We accordingly conclude that Aurobindo's argument is foreclosed by the both the purpose of section 156 and related statutory context.

The only construction that comports with the purpose of the Hatch-Waxman Act is one that extends PTE to patent owners who were actually disabled from benefiting from patent protection during the pendency of regulatory review. We thus conclude that, in the context of reissued patents, "the patent" in subsection 156(c) refers to the original patent. A reissued patent is entitled to PTE based on the original patent's issue date where, as here, the original

patent included the same claims directed to a drug product subject to FDA review.[9]

---

[9] We do not find the parties' reliance on section 251 to be helpful, since it does not shed any light on the meaning of the term "the patent." We are also not persuaded by Merck's reliance on language in section 252 providing that 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." According to Merck, the "point of this clause" is to "backdat[e] reissued patents to the original patent date for assessing litigation defenses." Appellee's Br. 31.

While we agree that section 252 applies to assessing litigation defenses, we think the more plausible reading of section 252 is to backdate reissued patents to the original priority dates and critical dates of the original patents for the purpose of assessing defenses such as anticipation and obviousness. *See Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1337 (Fed. Cir. 2013) ("[T]his change was meant 'simply to correct an almost unbelievable and inequitable situation. . . . [that] if a patentee applies for a reissue, no matter for what purpose, all rights he had in and under the original patent are forfeited *ab initio* upon the grant of the reissue.'" (quoting S. Rep. No. 71-567, at 1)).

Merck's reliance on language that provides that reissued claims that are "substantially identical" to the claims in an originally patent "shall . . . have effect continuously from the date of the original patent" is similarly misplaced. The purpose of this provision is to clarify that a patent owner cannot enforce reissued claims before the reissued patent issues unless those claims are substantially identical to the original patent's claims. *See Seattle Box*, 731 F.2d at 827 ("Congress, in this statute, has explicitly

Our reading of subsection 156(c) is further confirmed by other statutory provisions of the Patent Act. Subsection 156(a) provides that "the term of a patent . . . shall be extended . . . from the original expiration date of the patent." 35 U.S.C § 156(a) (emphasis added). The most natural reading of this language is that "the patent" must be the original patent, since the "original expiration date" is tied to the filing date of the original patent, not the reissued patent. Subsection 154(a)(2) now provides that a patent's term "begin[s] on the date on which the patent issues and end[s] 20 years from the date on which the application for the patent was filed." The reference to "the patent" here must be to the original patent, not the reissued patent, which inherits the original patent term.[10]

While not binding, we note that the PTO has also revised its Manual of Patent Examining Procedure in a manner that substantially tracks with our analysis as applied in this case. It has been revised to provide 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. This

---

limited claim continuity to claims in the reissued patent identical to claims in the original patent.") We find no basis to conclude that Congress intended for this provision to apply outside the context of backdating priority dates.

[10] If the original patent included claims directed to a drug product subject to regulatory review and the patent owner subsequently cancels those claims, section 156 of course would not apply, whether the cancellation occurred before or after regulatory review. This is because cancelled claims are treated as void *ab initio*. *Fresenius*, 721 F.3d at 1346.

comports with the statutory scheme of the Hatch-Waxman Act, which is to award PTE only in those circumstances in which the patent owner is prevented from enjoying patent protection because of the pendency of regulatory review.[11]

CONCLUSION

We conclude that in the context of reissued patents, "the patent" in subsection 156(c) refers to the original patent that includes claims that are directed to a drug product. Because the '340 patent included claims directed to sugammadex and was issued before FDA approval of BRIDION®, we agree with the district court that the RE'733 reissue patent was entitled to the five-year PTE based on the '340 patent's issue date.

AFFIRMED

---

[11] Difficult questions arise in cases where the original patent did not include any claims directed to the drug product and was later reissued to include broader claims directed to such products. In such cases, a patent owner may or may not have had the opportunity to enforce the patent during review depending on whether the reissued patent was issued before or after regulatory review. Those questions are not presented by this case.