UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE SUGAMMADEX	Civil Action No.: 20-2576 (CCC) (LDW) (CONSOLIDATED) **OPINION**

CECCHI, District Judge.

Plaintiffs Merck Sharp & Dohme B.V. and Merck Sharp & Dohme LLC (collectively, "Plaintiffs" or "Merck") bring this consolidated action under the Hatch-Waxman Act against defendants Aurobindo Pharma USA, Inc., Aurobindo Pharma Ltd., and Eugia Pharma Specialties Ltd. (collectively, "Aurobindo"); Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL"); Gland Pharma Ltd. ("Gland"); Mankind Pharma Ltd. and Lifestar Pharma LLC (collectively, "Mankind"); Mylan API US LLC, Mylan Pharmaceuticals Inc., and Mylan Inc. (collectively, "Mylan"); Sandoz Inc., and Lek Pharmaceuticals d.d. (collectively, "Sandoz"); Sun Pharmaceutical Industries, Inc. and Sun Pharmaceutical Industries Ltd. (collectively, "Sun"); and USV Private Ltd. ("USV") (Aurobindo, DRL, Gland, Mankind, Mylan, Sandoz, Sun and USV are collectively referred to herein as "Defendants").

Merck holds the patent covering sugammadex sodium ("sugammadex"), the active ingredient in a drug called Bridion®, which assists patients' recovery of muscle function after a form of paralysis is induced during surgery. That patent, U.S. Patent No. 6,670,340 (the "'340 Patent"), was subsequently reissued as U.S. Patent No. RE44,733 (the "RE'733 Patent"). The Patent and Trademark Office (the "PTO") granted the RE'733 Patent a five-year extension from its original expiration date of January 27, 2021 to January 27, 2026, due to the nearly 12-year regulatory review of Bridion® by the Food and Drug Administration ("FDA"). Defendants contest

the validity of Claims 4, 12, and 21 of the RE'733 Patent by way of a challenge to the portion of the patent term extension ("PTE") granted by the PTO to the RE'733 Patent after December 14, 2022.[1] ECF No. 389 ("Final Pretrial Order") at 2. Specifically, Defendants contend that calculation of a patent term extension for a reissued patent must be based on the date the *reissued* patent issued, pursuant to § 156(c) of the Patent Act. *See* 35 U.S.C. § 156(c). Defendants argue that reading § 156(c) in this way entitles Merck to only 686 days of a patent term restoration, rather than the five years granted by the PTO. Defendants' validity challenge, if meritorious, would render the portion of the patent after December 14, 2022 invalid under 35 U.S.C. § 282(c).

By contrast, Merck argues that § 156(c)'s reference to "the date the patent is issued," when read in its proper statutory context including 35 U.S.C. §§ 251 and 252, refers to the date the *original* patent is issued. Merck also contends that Defendants' interpretation is contrary to well-established PTO policy and practice. Under Merck's interpretation, the PTO was correct to award a five-year patent term extension, and the PTO's determination should be left undisturbed. Defendants do not contest infringement of the RE'733 Patent. Therefore, the only the issue for this Court to decide is whether the portion of the extension of the RE'733 Patent's term after December 14, 2022 is invalid under 35 U.S.C. § 282(c).

The Court held a one-day bench trial in this matter on December 19, 2022. ECF No. 390. The parties briefed the patent term extension issue before trial (ECF Nos. 335, 336, 341, 342), then submitted post-trial briefing and proposed findings of fact and conclusions of law. ECF Nos. 401 ("DFOF"), 401-1 ("Def. Br."), 402 ("Pl. Br."), 403 ("PFOF"). Thereafter, the parties submitted responsive briefs. ECF Nos. 404 (*corrected at* 407 ("Def. Reply Br.")), 405 ("Pl. Reply Br.").

[1] Prior to trial, Defendants withdrew all previously asserted invalidity defenses, with the exception of the PTE defense.

Closing arguments were held on February 3, 2023. ECF No. 409 ("Closing Tr.").

This Opinion constitutes the Court's findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a). The findings of fact are based on the Court's observations and credibility determinations of the witnesses who testified at trial, and a thorough review of all the evidence admitted at trial. While the Court has reviewed the entirety of the record, the Court includes references only to the evidence most pertinent to its analysis. For the reasons set forth below, the Court finds that the extension of the RE'733 Patent's term after December 14, 2022 is not invalid under 35 U.S.C. § 282(c).

I. BACKGROUND

The facts of this case are almost entirely undisputed. The original patent covering sugammadex, the '340 Patent, issued on December 30, 2003. Although the patent issued in December 2003, sugammadex could not be marketed until December 15, 2015—nearly 12 years later—when the FDA completed its regulatory review of Bridion®. The December 15, 2015 FDA approval of Bridion® left Merck with approximately five years of market exclusivity (based on an original expiration date of January 27, 2021), even though 35 U.S.C. § 154(a)(2) provides for a term "ending 20 years from the date on which the application for the patent was filed." Congress, however, passed the Hatch-Waxman Act in 1984 in part to allow for restoration of a patent term lost to lengthy FDA regulatory review. On February 10, 2016, pursuant to the Hatch-Waxman Act and specifically 35 U.S.C. § 156, Merck sought a patent term extension for the maximum allowable five-year period to compensate for the almost 12 years of marketability lost during the FDA's regulatory review. The PTO reviewed Merck's application and granted that request on February 4, 2020, restoring five years of the lost patent term.

None of this would be cause for dispute between the parties if not for the sequencing of the *reissue* of the patent. In March 2012, while the FDA was in the midst of what would eventually be its nearly-12-year review process, Merck's predecessor-in-interest sought reissue of the '340 Patent because it had omitted narrower claims directed more specifically to sugammadex. Notably, the Federal Circuit had just clarified in 2011 that the addition of narrower claims was a proper basis for seeking reissue. *See In re Tanaka*, 640 F.3d 1246 (Fed. Cir. 2011). On January 28, 2014, the '340 Patent was reissued as the RE'733 Patent, containing the nine original claims in identical form and an additional 12 narrower species claims directed specifically to sugammadex. At that point, the RE'733 Patent inherited the "unexpired part of the term of the original patent," and thus was set to expire on the original expiration date of January 27, 2021. 35 U.S.C. § 251. Even when reissue was approved by the PTO on January 28, 2014, Merck still had to wait nearly another two years to market Bridion® because FDA approval would not be completed until December 15, 2015.

Accordingly, when Merck applied for a patent term extension in 2016, the original '340 Patent had been surrendered and the RE'733 Patent put in effect in its place. Understanding "the date the patent is issued" in § 156(c) to refer to the term of the original patent which the reissue patent had inherited, Merck calculated that it was entitled to the maximum allowable five-year patent term extension. The PTO agreed with Merck's understanding and calculation, and granted the five-year patent-term extension Merck sought, extending the RE'733 Patent through January 27, 2026.

Defendants presented an invalidity defense at trial that challenged the patent term extension calculation by Merck and the PTO. As noted above, instead of relying on the date of issue of the original patent (as Merck and the PTO did), Defendants assert that the date on which the *reissue*

patent (RE'733) issued must form the basis of that calculation under 35 U.S.C. § 156. Consequently, Defendants maintain that Merck is only entitled to 686 days of restoration—compared to the five years the PTO actually granted. This corresponds to an expiration date of December 14, 2022 under Defendants' theory, versus the expiration date of January 27, 2026 which the PTO assigned upon the patent term extension. With the facts almost entirely stipulated, *see* Final Pretrial Order, Section 3, Defendants contend, purely as a matter of statutory interpretation, that the PTO's use of the original patent's issue date was incorrect and thus represents a material failure to comply with § 156(c). This trial ensued to determine if Defendants' PTE defense established the invalidity of the RE'733 Patent—at least insofar as Defendants allege the term was erroneously extended beyond December 14, 2022, the date on which the RE'733 Patent would expire under Defendants' determination of the patent term extension.

A. Jurisdiction and Parties

Because this action arises under the patent laws of the United States, *see* 35 U.S.C. § 271 *et seq.*, this Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). No party contests jurisdiction or venue. *See* Final Pretrial Order, Section 1.

Plaintiff Merck Sharp & Dohme B.V., the owner by assignment of the '733 Patent, is a corporation organized and existing under the laws of the Netherlands, and has its principal place of business at Waarderweg 39, Haarlem, Netherlands 2031 BN. Merck Sharp & Dohme B.V. is an indirect, wholly owned subsidiary of Merck & Co., Inc., a New Jersey corporation, which has its principal place of business at 126 East Lincoln Ave, P.O. Box 2000, Rahway, NJ 07065 USA. Final Pretrial Order, Section 3.A ¶ 7; PFOF ¶ 2. Plaintiff Merck Sharp & Dohme LLC, which holds approved New Drug Application No. 022225 for Bridion®, is a limited liability company

formed and existing under the laws of New Jersey, having its corporate offices and principal place of business at 126 East Lincoln Ave, P.O. Box 2000, Rahway, NJ 07065 USA. Merck Sharp & Dohme LLC is a direct, wholly owned subsidiary of Merck & Co., Inc. Section 3.A ¶ 8; PFOF ¶ 3.

Defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Final Pretrial Order, Section 3.B. Defendant Aurobindo Pharma Ltd., which filed Abbreviated New Drug Application ("ANDA") No. 214307, is a corporation organized and existing under the laws of India, with a place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad, Telangana, 500038 India. *Id.* Defendant Eugia Pharma Specialties Ltd. is a corporation organized and existing under the laws of India, with a principal place of business at Galaxy, Floor: 22-24, Plot No.1, Sy No.83/1 Hyderabad Knowledge City, Raidurg Panmaktha, Hyderabad, Telangana – 500032, India. *Id.*

Defendant Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540. *Id.* Section 3.C. Defendant Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India, having a place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500034, India. *Id.*

Defendant Gland is a corporation organized and existing under the laws of India, with a place of business at Survey No. 143-148, 150 & 151 Near Gandimaisamma 'X' Roads D.P. Pally, Dundigal Gandimaisamma Mandal Medchal-Malkjgiri District, Hyderabad, Telangana, 500043 India. *Id.* Section 3.D.

Defendant Mankind Pharma Ltd. is a corporation organized and existing under the laws of

India, with a place of business at 208 Okhla Industrial Estate Phase III, New Delhi, 110020 India. *Id.* Section 3.E. Defendant Lifestar Pharma LLC is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1200 MacArthur Blvd., Mahwah, New Jersey 07430. *Id.* Lifestar Pharma LLC is a subsidiary of Mankind Pharma Ltd. *Id.*

Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia 26505. *Id.* Section 3.F. At the time of the filing of the Complaint, Defendant Mylan API US LLC was a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 45 Napoleon Court, Somerset, New Jersey 08873. *Id.* Defendant Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 1000 Mylan Boulevard, Robert J. Coury Center, Canonsburg, Pennsylvania 15317. *Id.*

Defendant Sandoz Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540. *Id.* Section 3.G. Defendant Lek Pharmaceuticals d.d. is a corporation organized and existing under the laws of Slovenia, having a place of business at Verovškova 57, 1526 Ljubljana, Slovenia. *Id.*

Defendant Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1 Commerce Drive, Cranbury, New Jersey 08512. *Id.* Section 3.H. Defendant Sun Pharmaceutical Industries Limited is a corporation organized and existing under the laws of India, having a place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, 400063 India. *Id*.

Defendant USV is a corporation organized and existing under the laws of India, having a place of business at Arvind Vithal Gandhi Chowk, B.S.D. Marg, Station Road, Govandi East, Mumbai, Maharashtra, 400 088 India. *Id.* Section 3.I.

B. Patent-in-Suit and Relevant Prosecution History

The RE'733 Patent, issued on January 28, 2014 and entitled "6-Mercapto-Cyclodextrin Derivatives: Reversal Agents For Drug-Induced Neuromuscular Block," is a reissue of the '340 Patent. PFOF ¶ 17; DFOF ¶¶ 23-28. Approximately ten years before the reissue, on December 30, 2003, the '340 Patent issued with nine claims covering a group of compounds including sugammadex, and methods of using sugammadex. PFOF ¶ 18. On March 28, 2012, "Merck's predecessor-in-interest filed a reissue application to add erroneously omitted claims narrowly directed to sugammadex," including the narrower species claims 10-21. PFOF ¶ 21; *see also id.* ¶ 22; DFOF ¶ 25; Trial Transcript ("Trial Tr.") 194:4–25 (Mojica). The RE'733 Patent subsequently issued on January 28, 2014 with 21 claims: original claims 1 through 9 (unchanged from the '340 Patent); and the 12 newly-added narrower species claims (10-21). PFOF ¶ 22; JTX-1.14–15. When the RE'733 Patent issued, its original expiration date was January 27, 2021. DFOF ¶ 27.

C. Regulatory Review Process for Bridion®

On April 13, 2004, four months after the issuance of the '340 patent, Merck's predecessor-in-interest filed Investigational New Drug ("IND") application No. 68,029 for the sugammadex compound. PFOF ¶ 24. On October 31, 2007, Merck's predecessor-in-interest filed New Drug Application ("NDA") No. 022225, seeking commercial approval for Bridion®. PFOF ¶ 25; DFOF ¶ 32. Bridion® was ultimately approved by the FDA on December 15, 2015. PFOF ¶ 26; DFOF ¶ 33.

The FDA determined that the period from the filing of the IND to approval of the NDA for

Bridion® (the "Regulatory Review Period") lasted 4,265 days. PFOF ¶ 36; DFOF ¶ 39. Pursuant to 35 U.S.C. § 156(g)(1), the Regulatory Review Period included the Testing Phase—determined by the FDA to be April 13, 2004 to October 31, 2007 (1,297 days)—and the Approval Phase—determined by the FDA to be October 31, 2007 to December 15, 2015 (2,968 days). PFOF ¶ 36; DFOF ¶¶ 34-37. As discussed, when the FDA ultimately granted approval to market sugammadex on December 15, 2015, nearly 12 years had elapsed since the start of the application process.

D. The Patent and Trademark Office's Determination of Patent Term Extension

1. General Calculation of Patent Term Extension

Section 156(c) requires calculation of PTE based on the "regulatory review period for the approved product" which "occurs after the date the patent is issued." The "regulatory review period" is the sum of the testing and approval phases for the drug product. *See* 35 U.S.C. § 156(g)(1). However, in calculating PTE, only half of the days in the Testing Phase are counted, but all the days in the Approval Phase are counted. *See id.* § 156(c)(2); *see also* 37 C.F.R. § 1.775. The applicant must subtract from this calculation any days in the Testing or Approval Phase preceding issuance of the patent. Finally, PTE is capped at a maximum of five years, and is further limited such that the remaining term of the patent plus PTE cannot exceed 14 years after FDA approval of the patented product. *See id.* § 156(g)(6)(A); *id.* § 156(c)(3). The parties do not dispute the math behind the calculation of PTE; they disagree on how to interpret "the date the patent is issued" as a matter of statutory construction.

2. Merck's Patent Term Extension Application

On February 10, 2016, within 60 days of FDA approval as required by 35 U.S.C. § 156(d)(1), Merck submitted an Application for Extension of Patent Term Under 35 U.S.C. § 156 ("PTE Application") for the RE'733 Patent based upon the FDA regulatory review of Bridion®.

PFOF ¶ 29; DFOF ¶ 40; JTX-3.1267–80. In its PTE Application, Merck explained that the RE'733 Patent was a reissue of the '340 Patent and identified both the original issue date (December 30, 2003) and the date of reissue (January 28, 2014). *See* JTX-3.1267–68. Specifically, Merck identified "the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue, and the date of expiration" as follows:

> **U.S. PATENT NO.: RE44,733**
>
> **INVENTORS: Mingqiang Zhang, Ronald Palin, and David Jonathan Bennett**
>
> **ISSUE DATE:**
>
> **FOR REISSUE PATENT (U.S. Patent No. RE44,733): January 28, 2014**
>
> **FOR ORIGINAL PATENT (U.S. Patent No. 6,670,340): December 30, 2003**
>
> **EXPIRATION DATE: January 27, 2021**

JTX-3.1273; *see also* PFOF ¶ 31; DFOF ¶ 45.

Based on a calculation using December 30, 2003 as "the date the patent is issued" under 35 U.S.C. § 156(c), Merck requested the maximum available five-year patent term extension, which would result in a modified expiration date of January 27, 2026. PFOF ¶¶ 32-33; DFOF ¶ 48; JTX-3.1284–87. In calculating the length of extension claimed, Merck subtracted "0 days" from the Regulatory Review Period for Bridion® (sugammadex) because that "is the number of days in the [T]esting and [A]pproval [P]hases on or before the issuance of the original U.S. Patent No. 6,670,340 on December 30, 2003, which was reissued as U.S. Patent No. RE44,733 patent on January 28, 2014." JTX-3.1286. Merck's PTE Application identified both original claims (including Claim 4) and new claims (including Claims 12 and 21) as covering sugammadex. JTX-3.1276–80. Merck also used "Claim 4 of the reissued '733 patent (and claim 4 of the original '340 patent)" to demonstrate the manner in which at least one patent claim read on the Approved Product. JTX-3.1276–80.

The FDA determined the total length of the Regulatory Review Period for Bridion® to be 4,265 days, with 1,297 days accruing in the Testing Phase and 2,968 days in the Approval Phase. These periods of time were derived from the following:

> (i) The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective: April 13, 2004. FDA verified the applicant's claim that the date the investigational new drug application became effective was on April 13, 2004.
>
> (ii) The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act: October 31, 2007. FDA verified the applicant's claim that the new drug application (NDA) for BRIDION (NDA 022225) was initially submitted on October 31, 2007.
>
> (iii) The date the application was approved: December 15, 2015. FDA verified the applicant's claim that NDA 022225 was approved on December 15, 2015.

Final Pretrial Order, Section 3.A ¶ 43; PFOF ¶ 36.

3. The Patent and Trademark Office's Notice of Final Determination

The PTO issued a Notice of Final Determination on February 4, 2020, determining the RE'733 Patent was eligible for a patent term extension under 35 U.S.C. § 156, with a period of extension of five years. PFOF ¶ 38; DFOF ¶ 52. The PTO's calculation of PTE for the RE'733 Patent was performed by attorneys at the Office of Patent Legal Administration. PFOF ¶ 37 (citing Trial Tr. 117:6–16 (Burke), 166:11–25 (Burke)). In the Notice of Final Determination, the PTO explained that the RE'733 Patent was a reissue of the '340 Patent and determined PTE based on the original issue date of December 30, 2003, stating:

> U.S. Patent No. RE44,733 is a reissue of U.S. Patent No. 6,670,340 ("the '340 patent"). The '340 patent issued on December 30, 2003. Since the [R]egulatory [R]eview [P]eriod for BRIDION® began on April 13, 2004, which is after the December 30, 2003 date of issuance for the '340 patent, the entire [R]egulatory [R]eview [P]eriod has been considered in the above determination of the length of the extension period under 35 U.S.C. § 156(c).

JTX-3.1798; *see also* PFOF ¶ 39; DFOF ¶ 53. Accordingly, the PTO used December 30, 2003 as "the date the patent is issued" under 35 U.S.C. § 156(c), and recognized the entire Regulatory Review Period for Bridion® to have occurred after December 30, 2003. PFOF ¶¶ 40-41; DFOF ¶ 54. With these inputs, it is uncontested that the length of the extension is five years under 35 U.S.C. § 156(c). Final Pretrial Order, Section 3.A ¶ 77.

On June 24, 2020, the PTO issued a certificate under 35 U.S.C. § 156 extending the patent term of the RE'733 Patent for a period of five years from its original expiration date (as defined in 35 U.S.C. § 156(a)) of January 27, 2021 to January 27, 2026. DFOF ¶ 56. No determination of a lack of due diligence under 35 U.S.C. 156(c)(1) was made with respect to the PTO's PTE determination for the RE'733 patent. PFOF ¶ 44; DFOF ¶ 55.

E. The Patent and Trademark Office's Treatment of Reissued Patents

1. General Treatment of Reissued Patents

At trial, the parties offered expert witnesses to opine on the PTO's policy and practice as to the treatment of reissued patents. *See* Final Pretrial Order at 3 (providing for live testimony of Lissi Mojica ("Mojica" or "Ms. Mojica") for Merck[2] and Dr. Julie Burke, Ph.D ("Burke" or "Dr.

[2] Ms. Mojica received her B.S. in Aeronautical Engineering from Embry Riddle Aeronautical University in 1988 and received her MBA in Legal Administration from Marymount University in 2000. After receiving her B.S. degree, Ms. Mojica worked in various roles and departments in the PTO, including as a Patent Examiner (1989-98), in the Office of Petitions (1998), as a Patent Cooperation Treaty Legal Advisor (1999-2000), as a Supervisory Programs Review Examiner (2000-03), and as the first Director of the Central Reexamination Unit (2003-08). Her responsibilities in her various positions included training Patent Examiners on reissue, reviewing reissue application declarations for compliance with PTO practice, addressing all issues regarding merged reissue and reexamination proceedings, working closely with the Office of Patent Legal Administration, and establishing policies to streamline and improve the patent examination process. *See* Final Pretrial Order, Section 10.A.

Burke") for Defendants[3]). Both witnesses explained that PTO office policy is outlined in the Manual of Patent Examining Procedure ("MPEP"), which is "a large volume of guidance for patent applicants and instructions for the examining corps that covers the more bread-and-butter type of situations that commonly crop up during the … course of patent examination." Trial Tr. 122:7–11 (Burke). The MPEP is "what all the patent office looks to for policy and procedure." *Id.* 190:15–16 (Mojica). Examiners "are authorized or required to follow" the policies set forth in the MPEP. *Id.* 154:24–155:14 (Burke).

Before reaching the issue concerning PTE of reissue patents, the experts opined on whether the PTO has an overarching policy concerning the effect of reissue patents generally. Ms. Mojica testified that, on the whole, the PTO treats the reissued patent as "step[ping] into the shoes of the original patent." Trial Tr. 203:8-21; *see also id.* 185:2-7 (same). In support, she referred to MPEP § 1460, which provides: "With respect to the Office treatment of the reissued patent, the reissued patent will be viewed as if the original patent had been originally granted in the amended form provided by the reissue." MPEP § 1460; *see* Trial Tr. 195:23-196:2. Ms. Mojica also explained that, pursuant to office policy, a reissue patent is not deemed to "have its own privileges" because it is not "an independent regular patent." *Id.* 197:15-22 (referring to MPEP § 1440). Instead, the reissue patent operates "merely [as] a continuation of the original patent's privilege." *Id.* Dr. Burke

[3] Dr. Burke holds a B.A. in Molecular and Cellular Biology from the Johns Hopkins University, a Ph.D. in Biochemistry from the Imperial College of Science, Technology and Medicine at the University of London, and completed a Post-Doctoral Research Fellowship at the Johns Hopkins University School of Medicine's Department of Biochemistry. Dr. Burke worked for the PTO for twenty years (1995–2015). After first working as a Patent Examiner, she was placed on detail to the Deputy Commissioner for Patent Examination Policy and assisted editors in revising the MPEP. She also worked as a Special Program Examiner and then a Quality Assurance Specialist at Technology Center 1600. In these roles, Dr. Burke developed quality initiatives and recommendations for Technology Center 1600, responded to applicant, examiner, and supervisor questions about patent examination, and trained supervisors and examiners on various aspects of examination practice. *See* Final Pretrial Order, Section 10.C.

did not expressly dispute this general policy and instead directed her testimony on PTO policy towards the PTO's choice concerning which issue date to use for PTE calculation of a reissued patent. *See id.* 114:17-21.

As to specific applications of the general PTO policy, Ms. Mojica also pointed to various areas of PTO practice in which the reissue patent is treated in line with MPEP § 1460's directive, including: assessing prior art relevant to a reissue, calculation of maintenance fees for reissued patents, terminal disclaimers, and transferring PTE applications filed on an original patent to a reissued patent where the reissue application was pending at the time the patentee files for PTE. *See* Trial Tr. 197:6–199:2 (prior art); *id.* 200:4-24 (terminal disclaimers); *id.* 202:19–21 (maintenance fees); *id.* 208:17–209:11 (transfer of PTE applications when reissue was pending).

2. The Patent and Trademark Office's Treatment of Reissued Patents for Purposes of Determining Patent Term Extension

The parties' experts also opined on whether the PTO had a specific policy regarding the determination of a patent term extension for reissued patents, and whether the PTO's treatment of such situations was consistent. Dr. Burke expressed her view that "[t]he patent office has no policy upon this topic." Trial Tr. 114:24. In contrast, Ms. Mojica opined that, pursuant to the PTO's broader policy concerning reissued patents, the date the patent is reissued never affects the patent's term, even in cases of term extension. *Id.* 199:10-25. In other words, the general policy concerning reissue patents also applies in the specific circumstances of patent term extension. *Id.* She raised various examples in which the PTO uses the original issue date or original application date for purposes of a reissue patent. *Id.* 197:6–199:2; 202:19–21. Ms. Mojica added that she believed the date of reissue is used solely for "administrative" purposes to track when the reissue occurred. *Id.* 204:4-14. Dr. Burke could not identify any PTO policy guidance using the reissue date for any

purpose and could not recall any experience she had in her time at the PTO when the reissue date was used for any reason. *Id.* 178:9-179:13.

When addressing the consistency of the PTO's practice, the experts analyzed a data set of relevant instances in which the PTO dealt with a reissued patent applying for patent term extension. Together, the experts identified a total of 40 examples spanning over the last four decades. PFOF ¶ 56; DFOF ¶ 60. Of those 40 PTE determinations, Ms. Mojica identified 36 in which the PTO used the original issue date to calculate PTE. Tr. 214:5–215:20. In all 36 of these instances, the PTO issued its notice of final determination after the patent reissued, consistent with its practice with the RE'733 Patent here. *Id*. 214:15–215:20 (Mojica). Ms. Mojica thus concluded that the PTO consistently used the original issue date when determining PTE for reissue patents. *Id.* 215:5-7; 217:1-22. Additionally, beyond the practice of the PTO, testimony at trial showed that some patentees expect the PTO to calculate PTE based on the original issue date because it is "self-evident" from the concept of reissue. *See* Dep. Tr. of Keith D. MacMillan ("MacMillan") 158:9–159:1, 159:12–25, 160:3–10.[4]

Dr. Burke identified four PTE determinations in which the PTO used the reissue date to calculate PTE. Trial Tr. at 139:7-12; *see also* DTX-4, DTX-8, DTX-9, DTX-10. In two of these, the choice of date had no effect on the PTE allowed—the extension would have been the same regardless of which issue date was used. Tr. 217:3–217:22 (Mojica discussing RE'30,811 and RE'34,712). And in the remaining two, the PTO never awarded the extension based on the date

[4] Mr. MacMillan is a former Merck in-house counsel, who was involved in the prosecution of Merck's patents related to sugammadex, including the RE'733 Patent and its patent term extension. Final Pretrial Order, Section 8.A(i). The parties agreed to submit up to 20 minutes of designations from Mr. MacMillan's deposition. *Id.* To the extent that the parties objected to the deposition testimony discussed in this Opinion, those objections are overruled. *See* Final Pretrial Order Section 11.A-B (listing deposition designations and objections).

of reissue (even though it used that date for calculation purposes), because the patentee ultimately chose to elect PTE on other patents, leading to withdrawal of the original PTE applications. *Id.* (Mojica discussing RE'42,072 and RE'43,691). The patentee in the latter two examples also chose to seek a shorter extension by seeking PTE based on the date of reissue. *See* DTX-9.621, 628 (PTE application for RE'42,072); DTX-10.101, 110 (PTE application for RE'43,691). Further, in the four instances in which the reissue date was used, the PTO did not expressly note that the subject patent was a reissued patent, as it did with its determination for RE'733. *Compare* DTX-4, DTX-8, DTX-9, DTX-10 *with* JTX-3.1798 ("U.S. Patent No. RE44733 is a reissue of U.S. Patent No. 6,670,340…."). When asked, Dr. Burke was unable to identify an instance where the PTO later re-calculated a patent term extension for any of Ms. Mojica's 36 examples. Trial Tr. 172:20-173:4. Dr. Burke concluded that, based on her examination of these 40 instances, "the PTO's practice has been mixed." Trial Tr. 115:17.[5] As noted above, Ms. Mojica rejected Dr. Burke's conclusion, opining that the existence of the four examples referenced by Dr. Burke did not undermine the PTO's overall consistency, given the examples' particularized circumstances. *Id.* 217:7-24.

Lastly, the Court notes that MPEP § 2766 (Processing of Patent Term Extension Applications When Reissue Has Been Filed) [R-07.2022] was recently amended to address situations where a patent term extension is sought on a reissue patent, as before the Court presently. Section 2766 now states the original patent grant date is used to calculate PTE, explaining:

> With 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

[5] Dr. Burke also testified that nine (9) of the 36 instances identified by Ms. Mojica involved situations in which an application for PTE was filed on the original patent before the patent was surrendered and the PTO issued a reissue patent. Trial Tr. at 139:1-6.

> calculate the extension to which the reissued patent would be entitled.

Although neither expert opined on the updated provision at trial, the Court may "take notice of public reports and filings, such as those prepared by an administrative agency or pursuant to government regulation, to extent they have indicia of authenticity." *In re Plum Baby Food Litig.*, No. 21-2417, 2022 WL 16552786, at *3 (D.N.J. Oct. 31, 2022) (citing *Sturgeon v. Pharmerica Corp.*, 438 F. Supp. 3d 246, 259 (E.D. Pa. 2020)).

II. ISSUE TO BE DECIDED

As stated above, prior to the commencement of trial, Defendants advised that they did not contest infringement. Final Pretrial Order at 2; *see also* ECF Nos. 249, 250, 252, 253, 254, 255, 276, 277, 357, 380, 381. Accordingly, the sole issue before this Court concerns Defendants' PTE defense: whether the portion of the patent term extension for the RE'733 Patent after December 14, 2022 is invalid under 35 U.S.C. §282(c). Final Pretrial Order at 2.

III. LEGAL STANDARD

Issued patents are presumed valid. *See* 35 U.S.C. § 282(a). To rebut this presumption, a defendant bears the burden of proving invalidity by clear and convincing evidence. *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009). Questions of statutory interpretation, however, are legal questions for the court to decide. *See Wyeth v. Kappos*, 591 F.3d 1364, 1369 (Fed. Cir. 2010); *see also Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 114 (2011) (Breyer, J., concurring) (clarifying that on an "invalidity question," the presumption of validity is an "evidentiary standard of proof [that] applies to questions of fact and not to questions of law").

IV. DISCUSSION

This Hatch-Waxman Act litigation requires the Court to determine how to treat a reissued patent for purposes of calculating a patent term extension under 35 U.S.C. § 156(c). Section 156

generally "provides the holders of patents on approved patented products with an extended term of protection under the patent to compensate for the delay in obtaining FDA approval." *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996) [hereinafter *Kessler*]. Broadly speaking, when a patentee loses part of its exclusivity to market a covered drug because the patentee is awaiting FDA approval, the patentee may seek to extend the patent up to five years, subject to certain other statutory exceptions that are not implicated here. 35 U.S.C. § 156(c). Section 156(c) specifically speaks to calculation of that extension, restoring to the term of the patent "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). It does not, however, expressly address the treatment of patents that are *reissued* pursuant to 35 U.S.C. § 251 ("Reissue of Defective Patents"). *See also id.* § 252 ("Effect of Reissue"). Accordingly, the crux of the legal dispute concerns whether the Patent Act requires a patent term extension of a reissued patent to be calculated based on the issue date of the original patent—the term of which is inherited by the reissue patent—or, conversely, based on the issue date of the reissued patent.

Defendants assert that the plain meaning of the language of § 156(c), read in isolation and using basic rules of grammar, requires using the issue date of the *reissued* patent. They contend there is no ambiguity, and thus there is no need to look past this provision's language. By contrast, Merck argues that § 156, understood in the statutory context of the provisions governing reissue (§ 251 and § 252) as it must be, unambiguously directs PTE to be calculated based on the issue date of the original patent which sets the term for the reissue. Although Merck maintains that the Court need not look further than the plain meaning established by the statutory scheme, Merck argues that to the extent there is ambiguity, it should be resolved by the Hatch-Waxman Act's remedial purpose of restoring portions of the patent's term lost to FDA delay and by deferring to

the PTO's consistent use of the original issue date.

For the reasons set forth below, the Court finds that § 156(c), when read in its proper context alongside the provisions of the Patent Act addressing reissue, unambiguously supports Merck's interpretation that the issue date of the original patent must be used for calculating PTE. Defendants' isolated interpretation of § 156 requires an untenable reading of the statutory scheme on the whole, creating conflict with various provisions of the Patent Act as well as unintended results. Moreover, Defendants' interpretation would undermine the purpose of the Hatch-Waxman Act, in contrast to Merck's interpretation, which aligns with it. Using the original issue date also comports with the PTO's policy and longstanding practice of treating reissued patents as if they were originally granted in amended form for purposes relevant to the PTO's administration of the Patent Act. And even if the underlying statutory language were ambiguous, the PTO's policy and consistent practice over the last four decades would be entitled to some deference pursuant to *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

A. Statutory Language

1. Overview of the Parties' Positions

Both parties contend that this issue can be decided by the unambiguous meaning of the relevant provisions of the Patent Act. Of course, they present different views of what that unambiguous meaning is. The Court turns first to Defendants, who argue that § 156(c), read on its own, requires a patent term extension to be determined based on the issue date of the reissue patent, namely the RE'733 Patent here. Defendants point to what they view as the operative provision of § 156(c): "*[t]he term of a patent eligible for extension* … 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). They assert that this provision "refers to only one patent, such that the same patent for which PTE is sought must be the same

patent whose issue date is used for calculating PTE." Def. Br. at 8-9. In other words, because "the definite article 'the' is 'a function word indicating that a following noun or noun equivalent is definite or has been previously specified by context,'" it follows that "the patent" in the second clause must refer to the same patent that is "eligible for extension" in the first. *Id.* at 9 (quoting *Nielsen v. Preap*, 139 S. Ct. 954, 965 (2019)). And, Defendants continue, there is no dispute that the "patent eligible for extension" here is the RE'733 Patent—the only patent in existence since the '340 Patent was surrendered years before applying for PTE, and the patent which was identified as eligible for extension in Merck's application. *Id.* Therefore, Defendants assert § 156(c)'s reference to "the date the patent is issued" must refer to January 28, 2014, the date the RE'733 Patent "issued." Under Defendants' theory, then, only 686 days of the Regulatory Review period should be restored to the patent's term—the time between the reissue date (January 28, 2014) and the FDA's approval of Bridion® (December 15, 2015).

Merck, for its part, argues that § 156, which does not reference reissue patents specifically, must be read in conjunction with § 251 and § 252, the provisions addressing reissue. Pl. Br. at 5. Once they are read together (as they must be under principles of statutory construction), Merck contends that it is unambiguous that the issue date of the original patent should be used for calculation of PTE. *Id.* at 5-6 (citing *Syngenta Crop Prot., LLC v. Willowood, LLC*, 944 F.3d 1344, 1359 (Fed. Cir. 2019)). Turning to § 252, Merck points out that this provision, entitled "Effect of Reissue," mandates 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 patent had been originally granted in amended form." *Id.* at 6 (citing 35 U.S.C. § 252). Merck explains that because there is no dispute that this is the trial of an action for a cause arising after reissue, § 252 requires the RE'733 Patent to be given "the same effect and operation in law . . . as if [the RE'733 Patent] had been originally

granted in amended form." *Id.* at 7 (citing *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1341 (Fed. Cir. 2008)). And to give the RE'733 Patent that same effect and operation as if it had been originally granted in amended form, the original issue date must be used. *Id.* Merck therefore contends that § 252 "resolves the parties' dispute regarding what effect to give the reissued RE'733 patent for purposes of this case." Pl. Br. at 6.

Moreover, Merck asserts that § 251 further supports its interpretation. *Id.* at 9-10. Section 251 speaks to the relationship between the original patent and the reissue: when "any patent" contains a correctable error, the PTO "shall … reissue *the* patent." *Id.* at 9 (citing § 251) (emphasis added in brief). Mirroring Defendants' reasoning, Merck suggests "the use of 'the' in § 251 demonstrates that a reissued patent is 'the' original patent in amended form and should be treated accordingly." *Id.* Further, because § 251 provides that the reissued patent takes on "the unexpired part of the term of the original patent," the "term" of a reissued patent is dictated entirely by the original patent. *Id.* Merck argues that not only do § 251 and § 252 affirmatively support its interpretation but Defendants' interpretation would create an unnecessary conflict between the reissue provisions and the patent term extension provision. *Id.* at 14-15. Merck thus concludes that a holistic view of the statutory scheme which gives effect to all relevant provisions requires using the original patent's issue date when calculating PTE under § 156(c).

2. Analysis

a) Principles of Statutory Construction

"It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *W. Virginia v. Envtl. Protec. Agency,* 142 S. Ct. 2587, 2607 (2022) (internal quotation omitted); *see also Syngenta Crop Prot., LLC v. Willowood, LLC*, 944 F.3d 1344, 1359 (Fed. Cir. 2019) ("The meaning of statutory language is determined by reference to the language itself, the specific context in which that

language is used, and the broader context of the statute as a whole.") (internal quotation omitted). Defendants' suggestion to begin and end with the language of § 156(c)—and disregard other provisions relevant to reissue—thus runs counter to standard principles of statutory interpretation. *See Turkiye Halk Bankasi A.S. v. United States*, 143 S. Ct. 940, 948 (2023) ("But this Court has a duty to construe statutes, not isolated provisions.") (internal quotation omitted); *Tyler v. Cain*, 533 U.S. 656, 662 (2001) ("We do not, however, construe the meaning of statutory terms in a vacuum."); *Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998) ("[S]tatutory interpretation is a holistic endeavor that requires consideration of a statutory scheme in its entirety.") (internal quotation omitted). Indeed, the Federal Circuit has already determined that this fundamental canon of construction applies specifically to § 156 when it relied on "the combined effects of [other Patent Act amendments] and the Hatch-Waxman Act" to construe the phrase "'original expiration date' in § 156(a)." *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996) (reaching conclusion after finding "[u]nder this interpretation, all provisions … can reasonably be given effect"). It is therefore incumbent upon this Court to interpret the Patent Act in a way that gives meaning to all provisions and avoids conflict. *See Baude v. United States*, 955 F.3d 1290, 1305 (Fed. Cir. 2020) (relying on "one of the most basic interpretive canons: that a statute … should be construed so that effect is given to all its provisions") (internal quotation omitted). Defendants' isolated interpretation of § 156(c), however, violates these principles of statutory construction by creating unnecessary conflict with § 251 and § 252, the provisions concerning reissued patents. The Court now turns to these provisions of the Patent Act.

b) Section 251

Defendants' interpretation, if accepted, would conflict with § 251, the initial provision governing the process for reissue and its term. Section 251 expressly states that the PTO must "*reissue* the patent" which contains an error—not issue a new patent. 35 U.S.C. § 251 (emphasis

added). Section 251 further directs that the reissued patent inherits "the unexpired part of the term of the original patent." *Id*. This provision thus treats the reissued patent not as an entirely new patent with a new term, but as an amended version of the original that takes on the original's term. In other words, § 251 provides that the term of a reissue patent lacks an independent basis; its existence and length depend entirely on the term of the original. *Id.* And § 251's focus on the identity of a patent term between the original and the reissue links back to § 156(c), which discusses extension specifically in the context of "[t]he *term* of a patent." *Id.* § 156(c) (emphasis added). Against this backdrop, Defendants' interpretation would overlook the dependency of the reissue's term on the original's term, and the relationship between the two. Instead, it would create two unrelated and distinct terms: the original term, which retains its statutory guarantee of up to five years' restoration based on FDA delay; and the reissue term, which would be dictated not necessarily by the requirements of § 251 but by 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. *See* Def. Br. at 11-12. Moreover, the Federal Circuit has already observed the requirement of reading § 156 and § 251 harmoniously, holding that a patent's "term" in the Act must be read consistently across the two provisions. *See In re Yamazaki*, 702 F.3d 1327 (Fed. Cir. 2012). There, after noting that § 156 and § 251 are among a series of statutes that "use[] the word 'term,'" the Federal Circuit explained that "[t]o hold that § 251 uses 'term' in a sense . . . distinct from §§ 155, 155A, 156, and 253 would be to endorse an untenable reading of the statutory scheme…." *Yamazaki*, 702 F.3d at 1332. Defendants' isolated interpretation does precisely that—

endorses an untenable reading of the statutory scheme established by § 251 and reaffirmed by the Federal Circuit in *Yamazaki*.[6]

c) Section 252

Similarly, Defendants' interpretation conflicts with § 252. Section 252 requires 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. As this is a trial of a cause arising after reissue, *see* Final Pretrial Order 3.B-I (Defendants filed their ANDAs in 2019, nearly six years after reissue), the Court must do as the statute requires: give the RE'733 Patent "the same effect and operation in law … as if [it] had been originally granted in such amended form." Pl. Br. at 6 (quoting 35 U.S.C. § 252). Moreover, as with any statute, the Court must strive to give meaning to every word in § 252. *See Sullivan v. McDonald*, 815 F.3d 786, 791 (Fed. Cir. 2016) ("[W]e attempt to give full effect to *all words* contained within that statute ….") (emphasis added) (quoting *Glover v. West*, 185 F.3d 1328, 1332 (Fed. Cir. 1999)). To give the RE'733 Patent the "same effect and operation in law" as if it had been "originally granted in amended form," then, the Court must also give meaning to "originally." 35 U.S.C. § 252. This, in turn, provides another reason to treat RE'733's issue date as if it were the *original* issue date. And the Federal Circuit observed as much in *Cooper Techs. Co. v. Dudas*,

[6] Merck also explains that § 251(a), by providing that the remainder of the original term carries over to the patent as reissued, "necessarily requires the expiration date of the reissued patent to be calculated based on the filing date of the original application, . . . not the reissue application filing date." ECF No. 335 at 9 (citing 35 U.S.C. § 154(a)(2) (term extends from issue date to 20 years after application filing)). Further underscoring the importance of the original patent's issue date to the term of the reissue patent, the Court notes that prior to 1995, the expiration date of a reissued patent was based not on the filing date of the original application but on the *issue date* of the original patent. *See Kessler*, 80 F.3d at 1547 ("Prior to June 8, 1995, U.S. patents had an expiration date under 35 U.S.C. § 154 measured as 17 years from the date the patent issued ….").

when it explained that "reissues are deemed by operation of law to replace the surrendered originals and, thus, are entitled to treatment as original patents." 536 F.3d 1330, 1341 (Fed. Cir. 2008) (rejecting argument that the statute establishing *inter partes* reexamination of "original applications" filed after a certain date would insulate reissue patents from such reexamination altogether because they issued from "reissue applications" instead of "original applications"). Therefore, in addition to being inconsistent with § 251, Defendants' interpretation would further disrupt the statutory scheme by creating conflict with § 252.

Defendants respond that this interpretation would misconstrue § 252 and its subject matter. *See* Def. Br. at 16-17. They assert that § 252, in contrast to Merck's understanding, is "really focused on … what is the effect of reissue in later litigation." Closing Tr. 18:17-18. Although that qualification might be taken to support Merck's interpretation (as this litigation commenced after reissue and involves its effects), Defendants maintain that § 252 must be understood in its context: namely, settling "complicated questions that arise sometimes with reissued patents" including infringement that occurs before reissue, and distinguishing claims that are carried over from the original patent from claims that are newly added by the reissue. *Id.* 20:16-17. Putting aside that Defendants ask the Court to view § 252 in statutory context they are unwilling to afford § 156, their argument is belied by *Cooper Techs.* There, the Federal Circuit used § 252 to ground its understanding of reissue patents even though it was reviewing an Administrative Procedure Act challenge to a PTO decision, and not infringement litigation. *Cooper Techs.*, 536 F.3d at 1341. Moreover, the language of § 252 itself is broadly stated; its text is not limited to specific questions arising in subsequent litigation such as damages or intervening rights, as Defendants have suggested. *See* Closing Tr. 18:12-16 (Defendants' counsel arguing § 252's import to "damages," and "intervening rights and equitable intervening rights"). Accordingly, § 252 provides an

explanation of reissue patents (and their relation to their predecessor patents) that is not as limited as Defendants propose.

Defendants also refute that their interpretation conflicts with § 252 because, they contend, reissue patents and original patents are "legally distinct." Def. Br. at 11. To justify that position, they offer three principal supporting arguments. First, Defendants note that in prior versions of the Patent Act, "the 'rights [a patentee] had in and under the original patent are forfeited *ab initio* upon the grant of the reissue.'" Def. Br. at 11 (quoting *Fresenius v. Baxter*, 721 F.3d 1330, 1337 (Fed. Cir. 2013)). Second, they assert that the Federal Circuit, in *Intel Corp. v. Negotiated Data Sols., Inc.*, 703 F.3d 1360 (Fed. Cir. 2012), already rejected the proposition that a reissue patent replaces an original. *Id.* at 12. And third, they point to other tribunals' decisions—namely the Fourth Circuit and the Patent Trial and Appeals Board ("PTAB")—which they believe support the proposition that original patents and reissues are always distinct. *Id.*

The Court is not persuaded. As an initial matter, whether the original patent and reissue patent are "legally distinct" mischaracterizes the question before the Court as well as the guidance provided by § 252. The question here is not whether the two patents are the same, for all conceivable purposes or in some abstract, theoretical sense. *Compare* Closing Tr. 18:2-9 *with id.* 44:18-45:2 (debating whether, and to what effect, Merck's theory is a "legal fiction"). Rather, the question presented is simply how to treat the reissued patent in this cause of action arising after reissue. Indeed, § 252 (as well as Merck, the PTO, and this Court) recognizes that the reissue does not *literally* issue on the date the original did. *See, e.g.*, Closing Tr. 54:7-9 ("Merck's position is not that reissues always go back in time and replace an original and we all pretend that the original never existed."). But § 252 nevertheless directs the Court, on actions arising after reissue, to give the reissue "the same effect and operation in law . . . *as if*" it issued on the date the original did. 35

U.S.C. § 252 (emphasis added). That is, for the purpose to which § 252 speaks—the effect of reissue on causes of action thereafter arising—the Court is directed to set aside the timeline and instead treat the reissue patent "as if" it were "originally granted in amended form." *Id.* Defendants' argument that the two patents are distinct may have some truth in certain other unrelated contexts, *see, e.g.*, *Aspex Eyewear, Inc. v. Marchon Eyewaer, Inc.*, 672 F.3d 1335 (Fed. Cir. 2012),[7] but fails to speak to the central issue here.

In any event, Defendants' supporting arguments are unavailing. As to Defendants' first argument, *Fresenius,* in its detailed history of § 252, noted that Congress found the idea that patentees forfeited all rights *ab initio* on reissue "an almost unbelievable and inequitable situation" and thus amended the Patent Act nearly a century ago to do away with this rule. *Fresenius*, 721 F.3d at 1337 (quoting S.Rep. No. 70-567, at 1 (1928)). And to the extent Defendants turn to prior eras of patent law, there is longstanding precedent that original and reissue patents are inextricably linked rather than distinct. *See, e.g.*, *Grant v. Raymond*, 31 U.S. 218, 244 (1832) (questioning whether "the second patent could be considered as independent of the first" but concluding that "it is in no respect so considered").

With respect to Defendants' second argument, *Intel* is distinguishable from the instant action, and the language Defendants cite therein is not as broad as they contend. 703 F.3d 1360 (Fed. Cir. 2012). *Intel* concerned a contract dispute over whether a license granted to original patents extended to reissue of those patents. *Id.* at 1362-63. Intel, the licensee, argued that (i) § 252 required the reissued patents to be given the same effect in the contract as if they were the

[7] Defendants point to *Aspex Eyewear*, in which the Federal Circuit "made clear that claim preclusion d[id] not apply" to a circumstance involving a reissue patent. Def. Br. at 12 (quoting *Aspex Eyewear,* 672 F.3d at 1341-42). As the Court finds with respect to the other cases Defendants cite for this proposition, *see infra*, the discussion of claim preclusion in *Aspex Eyewear* is inapposite to the issues presented here.

original patents, and (ii) the contract itself was intended to cover both original and reissued patents. *Id*. The court ruled in Intel's favor on the contract argument, but rejected Intel's "simplistic proposition that a reissue patent replaces the original *nunc pro tunc*." *Id.* at 1364. Defendants seize upon this language to argue that the Federal Circuit's statement in this licensing case applies with similar force here. *See* Def. Br. at 2. However, the Federal Circuit carefully explained that a reissue patent did not replace an original patent *nunc pro tunc* because that would "ignore[] the specific language of the statute that grants intervening rights to those who may infringe only new claims added by reissue." *Intel*, 703 F.3d at 1364. In other words, the court observed that treating a reissued patent as the original patent *for all purposes* would disregard § 252's provision of intervening rights to certain third parties. *See id.* (qualifying its assertion about reissue patents as applying "*[i]n this important aspect alone*") (emphasis added). Yet Merck makes no such broad, unqualified assertion. Indeed, Merck's interpretation here does not conflict with the treatment of intervening rights in § 252; it clearly allows for them. *See* Closing Tr. 54:10-11 ("If you [treat the original patent as having never existed for all purposes], you vitiate intervening rights."); *id.* 79:12-13 ("Intervening rights is the exception to treating a reissued patent as if originally granted in amended form."). Moreover, the *Intel* court ultimately found the licensing agreement had to be understood to cover reissue patents arising from those original patents as well, even if not explicitly set forth in the agreement. *See Intel*, 703 F.3d at 1367. Therefore, putting aside the distinguishable facts and narrow language, the *Intel* result is ultimately consistent with the treatment Merck seeks here.

Defendants' third argument, which relies on *Mylan Pharms., Inc. v. U.S. Food & Drug Admin.*, 594 F. App'x 791 (4th Cir. 2014), and *Eizo v. Barco N.V.*, IPR 2014-358, 2015 WL 43815867 (PTAB July 14, 2015) is similarly unavailing. *See* Def. Br. at 12-14. While each

decision suggests some degree of distinction between the original and reissue patent in certain other contexts, neither addressed the issue of patent term extension. *See Mylan*, 594 F. App'x at 797 (interpreting a different, since-amended statute to permit a new 180-day exclusivity period for generics upon a court decision concerning the infringement or validity of a reissued patent); *Eizo*, 2015 WL 4381586, at *5 (PTAB decision limiting its applicability to "the purposes of Section 315(b)," i.e., the *inter partes review* time-bar provision). Further, relying solely on Black's Law Dictionary's definition of "patent" may have been sufficient to resolve the 180-day exclusivity issue in *Mylan*, but its lack of engagement with § 251 and § 252 renders that case less persuasive here. And even if these cases had relevant facts or legal questions that applied to this context, neither *Mylan,* as an unpublished decision from outside the Federal Circuit, nor *Eizo*, a decision by the PTAB, has binding effect here. Accordingly, Defendants' supporting arguments cannot undo their interpretation's fundamental conflict with § 252's mandate to treat reissue patents in subsequent litigation as if they were originally granted in amended form.

Even if Defendants offered an argument that somehow sidestepped this conflict, Defendants' interpretation would still independently conflict with a separate clause of § 252. Section 252 also provides that "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. Of the claims at issue in this trial, Claim 4 of the RE'733 Patent is unamended from the '340 Patent and thus "substantially identical" under § 252. *See* JTX-1.14-15; *see also* JTX-3.1276-1278 (seeking PTE based on Claim 4). Therefore, imposing the RE'733 Patent's issue date on Claim 4 for purposes of patent term extension would be inconsistent with § 252's command to give substantially identical claims continuous effect "from the date of the original patent." 35 U.S.C. § 252. If, instead, a patent term

extension were calculated based on the date of reissue as Defendants propose, then none of the term lost for the identical claims of the '340 Patent would be restored. Defendants have offered no basis to conclude that Congress intended for § 156 to disrupt the continuous effect given to identical claims in a reissue patent, as has been the law for 100 years. *See Fresenius,* 721 F.3d at 1337.[8]

d) The Parties' Examples of Absurd Results

Notwithstanding these conflicts with § 251 and § 252, Defendants' interpretation also leads to results that Congress could not have intended. "Both the Supreme Court and [the Federal Circuit] . . . have repeatedly held over the years that [i]f a literal construction of the words of a statute be absurd, the act must be so construed as to avoid the absurdity." *Dupuch-Carron v. Sec'y of Health & Hum. Servs.*, 969 F.3d 1318, 1330 (Fed. Cir. 2020) (internal quotation omitted). As Merck posits, if the FDA had approved Merck's application three years *earlier* in 2012 (and thus after Merck applied for the RE'733 Patent but before the reissue was approved), Merck undoubtedly would be entitled to receive the full five years of restored term. *See* Pl. Br. at 19 ("If FDA approval came in December 2012, Merck would have applied for PTE on the original '340 patent because its reissue application, filed in March 2012, would have been pending. In that circumstance, the PTO would calculate PTE based on the issue date of the '340 patent, as it had done in every instance where a reissue application was pending at the time of the PTE application."); *see also* Trial Tr. 171:24-172:25 (Burke acknowledging the PTO determined PTE

[8] Defendants also argue Merck's proposed application of term extension to the entirety of the RE'733 Patent fails because § 252 gives continuous effect *only* to substantially identical claims in the reissue patent (and not newly added ones). *See, e.g.,* Closing Tr. 93:5-6. However, the Federal Circuit has explained that when it comes to term extension "[a] patent as a whole is extended even though its effect may be limited to certain of its claims." *Genetics Inst. LLC v. Novarties Vaccines & Diagnostics Inc.*, 655 F.3d 1291, 1301 (Fed. Cir. 2011); *see also Biogen Int'l GmbH v. Banner Life Scis. LLC*, 424 F. Supp. 3d 303, 308 (D. Del.) (same), *aff'd*, 956 F.3d 1351 (Fed. Cir. 2020).

based on the original issue date in every instance where a reissue application was pending at the time of the PTE application). That *more* FDA delay should result in *less* restored term, as Defendants argue here, cannot be squared with Congress' intent to restore "time lost in [a] patent term by reason of FDA delay" through § 156. *Kessler,* 80 F.3d at 1553; *see also infra* Section IV.B.

Merck highlighted an additional scenario at trial whereby a three-day change in the date the PTO approved reissue—from just one day before FDA approval to just two days after—would lead to drastically different amounts of patent term extension. *See* Closing Tr. 63:15-65:2 (detailing the dates and calculations).[9] In that circumstance, if the reissue occurred just before FDA approval it would lead to a *one-day* patent term extension. If, on the other hand, reissue occurred just after FDA approval, it would result in a patent term extension of the full five years. *See supra* n.9. To follow Defendants' reading of the statute would mean that a three-day change in the PTO's approval of reissue (which is out of the patentee's control) is the difference between a full five-year extension and a one-day extension.

[9] Merck's hypothetical proceeds as follows: in both of the following scenarios, the actual original issue date of December 30, 2003 and the FDA's actual approval date of Bridion® on December 15, 2015 remain unchanged. The first scenario assumes the PTO approved reissue on December 17, 2015. Merck would then receive the full five-year extension under Defendants' theory because the entire regulatory review period of 4,265 days occurred before the RE'733 Patent was approved, and so the only patent "in effect" to be plugged into § 156(c) would be the original '340 Patent. *See* 35 U.S.C. § 156(c) (directing restoration of "the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued"). But, on the other hand, in a scenario in which the PTO approved reissue just three days earlier—on December 14, 2015, or one day before FDA approval—Merck would now receive *one day* of restored term under Defendants' theory. This is because, with the RE'733 Patent being the operative patent at the time of FDA approval, "the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued" is reduced to just one day: December 14, 2015 (reissue approval) to December 15, 2015 (FDA approval). 35 U.S.C. § 156(c).

A statutory scheme that fluctuates so dramatically on variables outside the patentee's control appears contrary to a framework in which Congress provided patent term extensions to incentivize drug companies to invest in innovating new drugs. *See infra* Section IV.B. The balance which Congress struck is not for this Court to second-guess; yet there is little doubt Congress did not intend to create a system that would inhibit planning and disrupt settled expectations. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002) ("[C]ourts must be cautious before adopting changes that disrupt the settled expectations of the inventing community."); MacMillan Dep. Tr. 158:9–159:1; 160:3–10 (Merck used original issue date because it is "self-evident" from concept of reissue). Therefore, in addition to being inconsistent with § 251 and § 252, Defendants' interpretation would lead to unworkable results that Congress could not have intended.[10]

e) Summation of Statutory Analysis

In contrast to Defendants' interpretation which conflicts with multiple provisions of the statutory scheme, Merck's interpretation gives effect to all relevant provisions without creating conflicts or illogical results. First, reading "the date the patent is issued" in § 156(c) to mean the

[10] Defendants offer a hypothetical of their own based on Merck's interpretation that would lead, in their view, to just as "strange" a result as the hypotheticals posed by Merck. Def. Br. at 20. They contend that "where a patent is broadened through reissue, it is possible that an original patent would not cover a drug but a reissue patent would. In such a case, under Merck's interpretation using the issue date of the original patent, the patentee would receive a PTE for a period of time (issuance of original through issuance of reissue) when it did not have a patent that covered the product at issue." *Id.* Putting aside that this scenario speaks to a *broadened* reissue (which has its own limitations per § 251(d)), the Court is not convinced that the statute would operate this way where the original patent does not cover the product at issue. And indeed, the PTO has expressly disclaimed this possibility in its most recent MPEP. *See* MPEP (Ninth Edition), § 2766 [R-07.2022] ("With 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.") (emphasis added).

original patent's issue date gives force to § 251's mandate that the PTO "reissue the [original] patent" and give the amended version the "unexpired part of the term of the original patent." 35 U.S.C. § 251(a). Second, this interpretation also provides a consistent reading of "term" across § 156 and § 251—as required by the Federal Circuit in *Yamazaki*—by maintaining the relationship between the reissued patent's term and the original patent's term. *See Yamazaki*, 702 F.3d at 1332. Third, Merck's interpretation gives the RE'733 Patent "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. As explained above, since Defendants filed their ANDAs in 2019 (approximately six years after reissue in January 2014), this is a "trial of actions for causes thereafter arising." *Id.* Consequently, using the '340 Patent's issue date for calculating PTE effectuates § 252 by treating the RE'733 Patent the way the '340 Patent would have been treated in this trial if the '340 Patent had been originally granted with the RE'733 Patent's additional 12 narrower claims. Fourth, Merck's interpretation gives RE'733's Claim 4, which is "substantially identical" to Claim 4 in the '340 Patent, continuous effect "from the date of the original patent," as further required by an additional part of § 252. *Id.* And finally, Merck's interpretation avoids the absurd results of (i) more FDA delay leading to less restoration, and (ii) drastic swings in PTE hinging on the mere sequencing of the end dates of independent PTO and FDA processes—both of which are outside the patentee's control.

Accordingly, understanding § 156(c) within its place in the statutory scheme and alongside other relevant provisions of the Patent Act—as this Court must—it is clear that, for reissue patents seeking patent term extensions, "the date the patent is issued" refers to the date the original patent issued.

B. Purpose of the Hatch-Waxman Act and Patent Term Extension

Merck also argues that using the original date the patent issued for purposes of § 156(c)

effectuates the statute's remedial purpose of restoring time lost to extended regulatory review. Pl. Br. at 11-14. In response, Defendants contend that "Merck has turned to broad policy appeals" which are outside the "judicial role" and, in any event, are "unduly one-sided." Def. Br. at 17-18. While the Court finds that the text of the relevant provisions of the Patent Act's statutory scheme unambiguously requires Merck's interpretation of § 156(c), *see supra* Section IV.A.2, the underlying purpose of the Hatch-Waxman Act further confirms the appropriateness of that interpretation, and would resolve any ambiguity to the extent it exists.

Under traditional rules of statutory construction, a statute that "is remedial in nature … should be read broadly." *Wells Fargo & Co. v. United States*, 827 F.3d 1026, 1036 (Fed. Cir. 2016). The Federal Circuit has further recognized that "[i]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1355 (Fed. Cir. 2003) (internal quotation omitted). That is, the Court "considers not only the bare meaning of the words, but also their placement and purpose in the statutory scheme." *Superior Fireplace Co. v. Majestic Prod. Co.*, 270 F.3d 1358, 1369 (Fed. Cir. 2001) (brackets altered). Affirming that an interpretation conforms with a statute's purpose thus reflects fundamental principles of statutory interpretation. *See Thompson v. Cherokee Nation of Oklahoma*, 334 F.3d 1075, 1088 (Fed. Cir. 2003), *aff'd and remanded sub nom. Cherokee Nation of Oklahoma v. Leavitt*, 543 U.S. 631 (2005) (rejecting interpretation "directly contrary to the purpose of the" statute).

As an initial matter, the relevant provisions here are all remedial. *See In re Doyle*, 293 F.3d 1355, 1358 (Fed. Cir. 2002) (holding that § 251 "is remedial in nature, based on fundamental principles of equity and fairness, and should be construed liberally); *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 810 F.2d 1113, 1117 (Fed. Cir. 1987) (holding § 252 is a "remedial statute having as

its sole purpose the correction of errors"); *Medicines Co. v. Kappos*, 731 F. Supp. 2d 470, 478 (E.D. Va. 2010) ("Section 156 provides a remedy: an extended patent term to offset the loss of effective patent life during the period of regulatory review of a new drug product."); *In re Patent No. 4,146,029* (Comm'r Pat. July 12, 1988) at 3 ("Since § 156 was intended to restore a part of the effective patent life ..., § 156 can be viewed as remedial in nature."). In fact, the Federal Circuit has offered express guidance about the expansive construction § 156 is owed: "The 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." *Kessler*, 80 F.3d at 1552 (describing § 156). This initial examination of the nature of these statutes thus confirms that Merck's interpretation—the only one to "liberally interpret[]" § 156 to achieve restoration for time lost to extensive FDA review—effectuates their remedial purposes. Nevertheless, given Defendants' objection to the remedial statutes' canon as the "last redoubt of losing causes," Def. Br. at 18 (quoting *Dir., Off. of Workers' Comp. Programs, Dep't of Labor v. Newport News Shipbuilding & Dry Dock Co.*, 514 U.S. 122, 135 (1995)), the Court turns to a deeper examination of the context of the Hatch-Waxman Act.

When Congress enacted § 156 as part of the Hatch-Waxman Act in 1984, it "established a balance whereby the patent term extension is offset by facilitating generic entry when the extended term expires, yet preserving the innovation incentive." *Pfizer Inc. v. Dr. Reddy's Labs., Ltd.*, 359 F.3d 1361, 1366 (Fed. Cir. 2004). For the generics, that entailed the "freedom from infringement during production and testing of generic counterparts intended to be sold after patent expiration" and "the right to rely on the patentee's data and approved uses to support approval of their generic counterparts." *Id.* at 1364; *see also Kessler*, 80 F.3d at 1546 (noting the Hatch-Waxman Act "eliminated the pre-1984 requirement that a company seeking to market a generic version of a

patented drug had to conduct its own testing program"). On the other hand, the Act entitled innovator patentees to "restoration of some of the time lost on patent life while the product is awaiting pre-market approval." *Pfizer Inc.*, 359 F.3d at 1366 (quoting H.R.Rep. No. 98–857 at 15 (1984)). This extension to innovator patentees was intended to "ameliorate[] the loss incurred when patent terms tick away while the patented product is awaiting [FDA's] regulatory approval for marketing." *Kessler*, 80 F.3d at 1547 (quoting *Unimed, Inc. v. Quigg*, 888 F.2d 826, 829 (Fed. Cir.1989)). Balanced with the loosening of certain restrictions on generics, patent term extension was thus established by Congress "in recognition of the lengthy procedures associated with regulatory review of a new drug product . . . in order to preserve the economic incentive for development of new therapeutic products." *PhotoCure Asa v. Kappos*, 603 F.3d 1372, 1374 (Fed. Cir. 2010).

Against this context, using the original issue date to calculate a patent term extension aligns with the balance Congress established. As noted, the Hatch-Waxman Act was intended to create predictable incentives for innovator drug companies to invest in the costly process of developing new drugs. *See Medicines Co.*, 731 F. Supp. 2d at 472 ("The purpose of the Act is to encourage drug manufacturers to assume the increased costs of research and development of certain products which are subject to pre-marketing clearance.") (internal quotation and bracket omitted); H.R.Rep. No.98-857 at 41 ("By extending patents for up to five years for products developed in the future … the Committee expects that research intensive companies will have the necessary incentive to increase their research and development activities."). Not only would using Defendants' proposed reissue date for PTE calculation greatly reduce the incentive Congress provided here, the unpredictable nature of such a scheme would also frustrate Congress' intent to provide a predictable and workable system upon which brand names, generics, and the public could rely. *See*

Festo Corp., 535 U.S. at 739 (warning courts about "adopting changes that disrupt the settled expectations of the inventing community"); *cf. Pfizer, Inc.*, 359 F.3d at 1364 (noting "the legislation was 'designed to benefit makers of generic drugs, research-based pharmaceutical companies, and not incidentally the public.'") (quoting *Eli Lilly & Co. v. Medtronic, Inc.,* 496 U.S. 661, 672 (1990)); *see also* MacMillan Dep. Tr. 158:9-159:25, 160:3-10 (explaining reliance on original issue date for PTE calculations). Defendants correctly respond that "the Hatch-Waxman Act is not a statute that is merely in favor of the brand innovator" but "a statute that was adopted as [a] balance by Congress." Closing Tr. at 101:22-23. Yet, under the circumstances presented here, Defendants' interpretation would unduly disrupt that balance in their favor. Notably, Defendants have already received their benefit of this "bargain," *Pfizer Inc.*, 359 F.3d at 1366, namely "freedom from infringement during production and testing" and "the right to rely on the patentee's data and approved uses." *Id.* at 1364*; see also* Final Pretrial Order 3.B-I (detailing stipulations regarding Defendants' ANDAs). Merck, on the other hand, despite holding a patent that covered sugammadex since 2003—both as originally issued and reissued—would not be able to avail itself of the statutory guarantee of 5-years' restoration, despite nearly 12 years of FDA review for sugammadex. Defendants, in turn, have not pointed to anything about the "balance" of the Hatch-Waxman Act that supports curtailing the amount of patent life based solely on the timing of the date of reissue approval by the PTO.

Accordingly, the remedial nature of the relevant provisions of the Patent Act—particularly § 156—and the purpose of the Hatch-Waxman Act further support using the original issue date for purposes of calculating patent term extension, as required by the statutory language and scheme. *See Novartis AG v. Lee*, 740 F.3d 593, 601 (Fed. Cir. 2014) (affirming PTO interpretation because its "construction is supported by the statutory purpose and other aspects of the statutory structure").

C. The Patent and Trademark Office's Policy and Deference

Merck maintains that § 156, when properly read within the statutory scheme, unambiguously supports using the original issue date when calculating PTE. Nevertheless, to the extent any ambiguity exists, Merck argues in the alternative that it "can and should be resolved by deference to the PTO's well-reasoned and consistent treatment of reissued patents." Pl. Br. at 2. Specifically, Merck contends that "the evidence at trial demonstrated that PTO policy treats reissued patents as if they were originally granted in amended form in all respects, and that the PTO consistently followed this policy to calculate PTE for reissued patents." *Id*. at 20 (citing Trial Tr. 153:12-23, 156:15-157:1 (Burke); *id.* 184:11-20, 195:21-204:14 (Mojica)). This, in turn, warrants *Skidmore* deference in Merck's view. Pl. Br. at 20. Defendants dispute the existence of such a policy, its application to patent term extension calculations, and whether the PTO has consistently applied it. *See* Def. Br. at 20. As such, Defendants assert that "there is no basis to defer to the Patent Office, as its practice on this issue has been both unreasoned and inconsistent." *Id.*; *see also* Closing Tr. 88:14-15 (Defendants' counsel noting "at most there's a tiny amount of deference and I don't even think it gets there").

1. The Patent and Trademark Office's Policy and Practice

Before turning to deference, the Court addresses the parties' dispute about the existence and scope of the PTO's policy and practice concerning reissued patents. For the reasons discussed below, the Court finds that the PTO has a policy of treating reissued patents as if they had been originally granted in amended form for purposes relevant to the PTO's administration of the Patent Act. And the PTO has applied that policy when determining PTE for a reissued patent by consistently using the original patent's issue date. This policy and practice, in turn, further reinforces the interpretation which is required by the statute's language and is confirmed by its purpose.

The PTO's policy is generally established by the MPEP, which outlines PTO office procedure. *See Nebraska, Dept. of Health & Human Services v. U.S. Dept. of Health and Human Services*, 340 F. Supp. 2d 1, 21 (D.D.C. 2004) (noting documents presenting the agency's "fair and considered judgment … constitute authoritative departmental positions") (quotation omitted). The parties recognize the MPEP is the authoritative source of guidance for all the PTO's responsibilities, even if it lacks the force of law. Trial Tr. 122:8-11 (Burke); *id.* 190:14-16 (Mojica describing the MPEP as "our Bible" and "what all the patent office looks to for policy and procedure"). The MPEP provides, in its guidance concerning reissued patents: "With respect to the Office treatment of the reissued patent, the reissued patent will be viewed as if the original patent had been originally granted in the amended form provided by the reissue." MPEP § 1460 (interpreting 35 U.S.C. § 252). As Ms. Mojica explained at trial, this means that for all of the PTO's purposes, the reissued patent "steps into the shoes of the original patent and is as though anything that came out of that reissue was issued on the date that the original patent is issued." Trial Tr. 203:8-21 (Mojica).[11] Further, the MPEP directs examiners to treat the claims in a reissue application "as if they had the same effective filing date as the original patent" because "a reissue patent replaces the original patent, and thus is merely continuing the patent privilege of the original patent as opposed to being an independent (regular) patent with its own privilege (and its own term)." MPEP § 1440 (citing *Grant v. Raymond,* 31 U.S. 218, 214 (1832)); *see also* Tr. 197:6–199:2 (Mojica).

[11] Relatedly, Ms. Mojica testified that the PTO tracks the reissue date for "administrative" purposes, rather than for any substantive function. Trial Tr. 204:4–14. Merck suggested at trial that the PTO records the reissue date "so that in other contexts, perhaps outside the patent office, including intervening rights, that date can be used." Closing Tr. 67:16-17. As explained above, the reissue date is relevant to issues surrounding intervening rights, but, importantly, the PTO does not administer issues concerning these rights. *See* § 252; Closing Tr. 67:18-20.

This broad directive carries over to many areas within the PTO's purview, including, *inter alia*: the PTO's use of the original filing date to assess prior art (MPEP § 1440); the PTO "transfer[ring] over" the term of the original patent to the reissue patent (Trial Tr. 199:5-21 (Mojica referencing MPEP § 1405)); the PTO's understanding that a terminal disclaimer shortens the term of the original patent rather than creates a new term (MPEP § 1490); the PTO's use of the original issue date to calculate maintenance fees for reissued patents (MPEP § 1415.01); and the PTO's practice of transferring a PTE application filed on an original patent to a reissued patent if the reissue application was pending at the time the patentee files for PTE (MPEP § 2766). *See also* Trial Tr. 197:6-199:2 (Mojica testimony on § 1440); *id.* 200:21-24 (Mojica on terminal disclaimers); *id.* 202:19-25 (Mojica testimony on maintenance fees); *id.* 208:14-209:11 (Mojica testimony on § 2766); *id.* 172:3-173:4 (Burke testimony on transferring PTE application when pending reissue application is approved). In fact, 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. *See, e.g.*, *id.* 178:9-179:14 (Burke). And while the MPEP did not have a specific provision applying this overarching policy to reissued patents seeking term extension at the time Merck sought PTE,[12] that is understandable given the paucity of instances in which this issue arose relative to the PTO's overall responsibilities and other issues pertaining to reissued patents. *See* Closing Tr. 90:22-91:4 ("[T]he reason you have a regulation for maintenance fees but not PTE is explained by how often that issue comes up. There are tens of thousands of reissued patents. All of them have maintenance fees…. But when we're talking about PTE calculations for reissued patents, it's only a couple of dozen."); *see also* PTX-130 (summary of Ms. Mojica's 36 identifications); DTX-75 (summary of Dr. Burke's 4

[12] *But see infra* (explaining the MPEP was subsequently modified to reflect this policy).

identifications).

Further, although the Court finds the PTO has this policy based on the evidence submitted at trial, the Court notes that the PTO has since updated the MPEP to reflect its practice. *See* MPEP (Ninth Edition), § 2766 [R-07.2022], Processing of Patent Term Extension Applications When Reissue Has Been Filed ("With 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."). Relatedly, there was testimony at trial that § 2766 specifically operated to formalize "longstanding policy" of the PTO. Trial Tr. 208:14-209:11 (Mojica addressing prior version of § 2766).

Turning to the application of this policy, the Court also finds that the PTO has a consistent practice of applying this broad policy to PTE calculation for reissued patents. At trial, the parties presented 40 instances where a patent term extension was granted on a reissued patent since the 1980s. In 36 of these—or 90% of the time—the PTO used the original issue date for its calculation. *See supra* Section I.E.2. In the four remaining cases, neither the PTO nor the patentee would have had reason to challenge using the reissue date for various reasons. *See id.* (detailing circumstances of four exceptions, including that in two cases the choice of date for PTE had no effect on the amount of extension and in two the patentee ultimately elected PTE on another patent); *see also* Trial Tr. 217:3-22; PTX-130. These four instances thus appear to be outliers with unique circumstances that diminished the importance of the issuance date, rather than persuasive evidence of inconsistency. But even including those four outliers in the applicable data set, the overwhelming use of the reissue date demonstrates the overall consistency of the PTO's practice. *Cf. Fed. Exp. Corp. v. Holowecki,* 552 U.S. 389, 399-400 (2008) (rejecting a charge of

inconsistency even though "the agency's implementation of [its] policy has been uneven").[13]

Therefore, after considering (i) the language of the MPEP directing the PTO to treat the reissued patent "as if the original patent had been originally granted in the amended form provided by the reissue," MPEP § 1460 (citing 35 U.S.C. § 252), (ii) the other provisions in the MPEP applying this overarching policy to specific PTO functions, (iii) the lack of any guidance or practice by the PTO using the reissue date for any purpose, and (iv) the PTO's consistent use of the original issue date when calculating PTE for reissued patents, the Court finds that the PTO has a policy and practice that further reinforces the interpretation required by the statutory language and confirmed by the purpose of the Hatch-Waxman Act.

2. Deference

Having determined the PTO has a policy and practice of using the original issue date for patent term extensions of reissued patents, the Court turns to whether this practice warrants deference. Merck asserts, in the alternative to its principal argument focused on construction, that any ambiguity created by attempting to interpret § 156 in isolation should be resolved by deferring to "the PTO's consistent policies and practice regarding reissue patents generally and PTE calculations specifically." Pl. Br. at 20. Though the parties dispute whether deference is appropriate here, both agree that to the extent deference is available, it would be under the precepts of *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). *See* Def. Br. at 3; Closing Tr. 36:4-5. Defendants, however, contend that even *Skidmore* deference is not justified here because the PTO has been inconsistent in choosing between the original issue date and the reissue date when determining

[13] Dr. Burke attempted to distinguish 9 cases, reducing the relevant data set in her view to 31 total cases. *See supra* Section I.E.2, n.5. Assuming *arguendo* that these 9 cases should be discredited, the difference in consistency between using the original issue date in 27 out of 31 cases (87%) and 36 out of 40 cases (90%) is negligible. *See Holowecki*, 552 U.S. at 399-400.

PTE, and, moreover, has never thoroughly explained its rationale for that choice, to the extent it has made such a choice. Def. Br. at 20-25. As explained below, the Court finds that under *Skidmore*'s sliding scale rubric, deference to the PTO is appropriate.

To start, the Court agrees that insofar as deference to the PTO is warranted here, it would constitute *Skidmore* deference. *See Kessler*, 80 F.3d at 1550 (holding that PTO's final determinations about patent term extension are entitled to *Skidmore*, rather than *Chevron*, deference). Under *Skidmore*, courts may defer to an agency's practice based on "the thoroughness evident in [the agency's] consideration, the validity of its reasoning, [and] its consistency with earlier and later pronouncements." *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (quoting *Skidmore*, 323 U.S. at 140); *see also Kessler*, 80 F.3d at 1550 (explaining *Skidmore* deference results from the agency's "basic power to persuade if lacking power to control").[14] The Federal Circuit has also held that an agency's "specialized experience" may factor into *Skidmore* deference. *Heartland By-Products, Inc., v. United States*, 264 F.3d 1126, 1135-36 (Fed. Cir. 2001). Further, courts have understood "the *Skidmore* framework as a 'sliding-scale' test in which the level of weight afforded to an interpretation varies depending on [the] analysis of the enumerated factors." *Hagans v. Commr. of Soc. Sec.*, 694 F.3d 287, 304 (3d Cir. 2012) (citing *Mead,* 553 U.S. at 228); *Cathedral Candle Co. v. U.S. Intern. Trade Commn.*, 400 F.3d 1352, 1365–66 (Fed. Cir.

[14] Defendants also appear to question the force of *Skidmore* deference, suggesting, based on caselaw from other circuits that *Skidmore* "is of limited value" and merely "a statement of the obvious." *Id*. at 22 n.6 (quoting *Moore v. Hannon Food Serv., Inc.*, 317 F.3d 489, 497 n.14 (5th Cir. 2003) and *Hydro Res., Inc. v. U.S. E.P.A.*, 608 F.3d 1131, 1146 n.10 (10th Cir. 2010) (en banc)). The Federal Circuit, however, has expressly rejected this view. *See Cathedral Candle Co. v. U.S. Intern. Trade Commn.*, 400 F.3d 1352, 1366 (Fed. Cir. 2005) ("We are confident that the [Supreme] Court did not mean for [*Skidmore*] to reduce to the proposition that 'we defer if we agree.' If that were the guiding principle, Skidmore deference would entail no deference at all."); *accord Hagans v. Commr. of Soc. Sec.*, 694 F.3d 287, 305 (3d Cir. 2012) (affirming agency interpretation even though that interpretation "may not be the interpretation we would adopt if we were to engage in an independent review").

2005) (explaining that, under *Skidmore*, courts adjust "the degree of deference depending on the circumstances"); Kristin E. Hickman & Matthew D. Krueger, *In Search of the Modern Skidmore Standard*, 107 COLUM. L. REV. 1235, 1272 (2007) (concluding "the appellate courts overwhelmingly follow the sliding-scale approach"); *see also* Closing Tr. at 88:12-15 (discussing *Skidmore's* sliding scale).

As to Defendants' initial argument about inconsistency, the Court reiterates that with the exception of four outliers, the PTO has always used the original issue date for purposes of patent term extensions for reissued patents. *See supra* Section IV.C.1. In any event, an agency's interpretation may be persuasive under *Skidmore* notwithstanding the existence of distinguishable conflicting rulings. *See Honda of America Mfg., Inc. v. U.S.,* 607 F.3d 771, 775 (Fed. Cir. 2010) ("Honda also claims that Customs' decision deserves less deference because it conflicts with previous rulings. . . . Those rulings are distinguishable."). And here, the four outlier examples are indeed distinguishable. *See supra* Sections I.E.2, IV.C.1. As discussed above, in two, the choice was inconsequential—either the original or the reissue date would have led to the same amount of term restoration. *See supra* Section I.E.2 (discussing RE'30,811 and RE'34,712). In the other two, the PTO never awarded PTE based on the date of reissue because the patentee ultimately chose to elect PTE on another patent. *Id.* (RE'42,072 and RE'43,691). In all four, then, the patentee had no reason to seek reconsideration and thus there was no occasion for the PTO to reexamine its decision. Moreover, in contrast with the Notice of Final Determination for the RE'733 Patent, the Notices for the four outliers failed to expressly note that the subject patent seeking extension was reissued. *See* Closing Tr. 70:6-71:3; *see also* DTX-4, DTX-8, DTX-9, DTX-10, JTX-3.1798. This is especially pertinent because the PTO's practice flows from its understanding of § 252, whereby reissued patents should be treated as originally granted in amended form. Consequently, that the

PTO did not expressly acknowledge the subject patent was reissued in the four outliers at least suggests the possibility that the policy may have been mistakenly overlooked rather than inconsistently applied. *See Holowecki,* 552 U.S. at 400 ("Some degree of inconsistent treatment is unavoidable…."); *see also Heartland By-Products, Inc.*, 264 F.3d at 1136 (affording *Skidmore* deference despite "the ruling's lack of consistency with an earlier pronouncement"). On the whole, the PTO's use of the original issue date in the overwhelming majority of instances across the last four decades, paired with the distinguishable nature of the limited outliers, shows "consistency with earlier and later pronouncements." *Skidmore*, 323 U.S. at 140.

Defendants argue that deference is still unwarranted even if the PTO acted consistently, because the PTO has never sufficiently explained its reasoning behind the application of its policy concerning patent term extensions for reissued patents. *See* Def. Br. at 22 (citing *Packard v. Pittsburgh Transp. Co.*, 418 F.3d 246, 253 (3d Cir. 2005) (rejecting deference to agency's legal conclusions that "provide[d] no reasoning or analysis that a court could properly find persuasive")). Merck responds that the PTO's reasoning flows from its broad policy concerning reissued patents set forth in MPEP § 1460, which "the Patent Office follows [] in every single aspect of its practice." Closing Tr. 109:19-20. Because the PTO always views the reissued patent "as if the original patent had been originally granted in the amended form provided by the reissue," MPEP § 1460), Merck contends there was no compelling reason for the PTO to further elaborate in the context of PTE for reissued patents.

While the persuasive power of an agency's order is diminished when a relevant agency order "sets forth no reasoning in support of its conclusion," Def. Br. at 22 (quoting *Fed. Nat'l Mortg. Ass'n v. United States*, 379 F.3d 1303, 1308–09 (Fed. Cir. 2004)), deference to an agency decision is warranted even if the decision "does not explain the reasoning behind the [agency's]

adoption of its interpretation," so long as the reasons for the policy "are not difficult to discern" and the agency "consistently applie[s] this policy." *Hagans*, 694 F.3d at 305 (applying "an appropriately high level of deference under *Skidmore*" where the Social Security Administration "consistently applied [its] policy during the past 20 years"). The Court has already addressed the PTO's consistent application of its policy. As to whether the reasons for the policy "are not difficult to discern," as in *Hagans*, the PTO has elsewhere explained in detail that the language of § 252 requires this broad treatment for all the PTO's purposes. *See* MPEP § 1460; *see also id.* § 1440 (reasoning that *Grant* requires the claims in a reissued patent to be treated "as if they had the same effective filing date as the original patent" because "a reissue patent replaces the original patent, and thus is merely continuing the patent privilege of the original patent as opposed to being an independent (regular) patent with its own privilege (and its own term)"). In fact, neither expert identified another function of the PTO in which it uses the reissue date, confirming the widespread application of this principle. *See, e.g.,* Trial Tr. 176:10-14, 178:9-13 (Burke); *id.* 204:4-14 (Mojica). The reasonableness of the PTO's interpretation and explanation are further supported by the broad, unqualified language of § 252 and the PTO's analysis of longstanding precedent, including *Grant* (§ 1440).

In sum, the PTO has set forth a reasoned consideration of the broader principle concerning reissue patents, *see, e.g.,* MPEP §§ 1440, 1460, and applied that principle to all areas of its responsibilities. When combined with the PTO's institutional expertise and consistent practice on the precise question at issue here, the Court concludes deference is warranted. Even if the reasoning offered by the SSA in *Hagans* may have been more narrowly tailored to the underlying issue, *see* Def. Reply Br. at 9, *Skidmore*'s sliding-scale approach directs the Court to adjust "the degree of deference depending on the circumstances," rather than reject deference altogether.

Cathedral Candle Co., 400 F.3d at 1366. Consequently, if anything, the "high level of deference" given in *Hagans* might suggest a slight discount in the present circumstances. Nevertheless, because these factors combine to have the "power to persuade," *Mead*, 533 U.S. at 219, the PTO is entitled to at least a substantial level of deference, assuming *arguendo* the Court had found ambiguity in the statutory scheme.

Accordingly, the PTO's policy and practice not only reinforces the interpretation required by the statute's language, but, even if ambiguity were found to exist, that policy and practice would be afforded *Skidmore* deference to resolve the question of statutory interpretation in Merck's favor.

V. CONCLUSION

For the foregoing reasons, the Court finds that the PTO correctly used the original issue date to calculate PTE for the RE'733 Patent. Therefore, the Court holds that no portion of the PTE for the RE'733 Patent is invalid. An appropriate Order accompanies this Opinion.

Dated: June 13, 2023

CLAIRE C. CECCHI, U.S.D.J.