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Patent Term Adjustment and Terminal Disclaimers: Are the Terms of Patents Being Decided Ad Hoc?

Emily M. Hinkens

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PATENT TERM ADJUSTMENT AND TERMINAL DISCLAIMERS: ARE THE TERMS OF PATENTS BEING DECIDED AD HOC?

The intersection of statutory law, common law, and administrative rulemaking prevents any certain predictions regarding the term of a patent that has been adjusted, extended, and/or terminally disclaimed in various combinations. This Comment poses a hypothetical situation in which the term of a terminally disclaimed patent is linked to another patent with term adjustment, and discusses the implications of such a linkage were the term of the former patent to be litigated. This Comment explores whether case law on terminal disclaimers, term extension, term adjustment, and judicial deference can help predict the outcome of such litigation, and ultimately concludes that it cannot. Rather, one of two things is needed for better predictability regarding a patent's term: a shift in the judicial deference that the Court of Appeals for the Federal Circuit pays to decisions of the Patent and Trademark Office, or a more comprehensive statutory scheme that is capable of handling such hypothetical situations.

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I. INTRODUCTION

In May 2001, the pharmaceutical company Bayer AG sought to extend its monopoly over a patent despite having previously dedicated a portion of the patent’s term to the public,¹ meaning that after a certain point in time, the patent’s term would expire and anyone with the know-how could make or use the patented drug. The United States Court of Appeals for the Federal Circuit (an appellate court that deals mostly with patent and trademark cases) allowed Bayer the extension it sought.² Thus, Bayer retained and extended its monopoly over the antibiotic ciprofloxacin, which is used to treat victims of anthrax.³ Retaining a monopoly over such an important drug keeps its price high, thereby making it less available to the public in times of need. Maybe not so ironically, this litigation lasted from the spring of 2001 to the summer of 2002,⁴ in the middle of the well-publicized and sensational anthrax-via-mail scares.⁵

Many already realize the benefit the patent system brings to the advancement of science in our country: the promise of a limited-term monopoly gives patentees an increased incentive to innovate. What many may not realize, however, is the importance of the length of time that a patent’s term lasts; hopefully the above example has illustrated

1. See *Bayer AG v. Carlsbad Tech., Inc.*, 298 F.3d 1377, 1378–79 (Fed. Cir. 2002).

2. *Id.* at 1383.

3. See CDC.gov, Anthrax Q&A: Treatment, <http://www.bt.cdc.gov/agent/anthrax/faq/treatment.asp> (last visited Dec. 29, 2010).

4. See *Bayer*, 298 F.3d at 1379.

5. See, e.g., Eric Lipton & Jim Rutenberg, *Anthrax Reports Widen, but No Link Is Found*, N.Y. TIMES, Oct. 14, 2001, at A1.

the criticality of a patent term. A patent's term governs the period of time during which the patent is enforceable against another.⁶ Only during the patent's term can the patent be used to prevent others from making, using, selling, or offering to sell the patented invention in the United States.⁷ This Comment discusses the effects of patent term extension and adjustment, which lengthen the time during which a patentee holds an exclusive monopoly, on terminal disclaimers, which shorten the monopoly period. The many rules governing patent term determination—and conflicts in these rules as stated by the Patent and Trademark Office (PTO) and the Court of Appeals for the Federal Circuit (Federal Circuit)—have caused patentees and the public strife in litigation and reliance.

Complex rules govern the term during which any given patent will be enforced. In general, a patent applied for today will have a term⁸ that ends twenty years from the date on which the patent application was filed.⁹ However, in certain situations a patentee may wish to shorten or extend this term. A patentee may agree to shorten the term of his patent in order to render it non-obvious when it is compared to another of his patent applications.¹⁰ In this situation, the patentee concedes that his invention is very similar to a previous invention for which he has applied for a patent and agrees that the term of his second patent will last only as long as that of his first patent.¹¹ In return, the patent

6. *See Bayer*, 298 F.3d at 1378.

7. 35 U.S.C. § 271(a) (2006).

8. This term is in accord with the provisions of 35 U.S.C. § 154(a)(2) (2006), which was amended by the Uruguay Round Agreements Act (URAA), Pub. L. No. 103-465, 108 Stat. 4809 (1994) (codified in scattered sections of title 35 of the U.S. Code). The statute takes effect for patent applications filed on or after June 8, 1995.

9. 35 U.S.C. § 154(a)(2) (“Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States . . .”).

10. Non-obviousness is one of the requirements for the grant of a patent in the United States. 35 U.S.C. § 103(a) (2006). “‘Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.’” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)). Allowing someone to patent something “obvious” would unfairly grant a monopoly over an advance that would have been apparent to someone skilled in that particular technology. It also would disincentivize inventors because they would have no reason to come up with greater advances in the technological field if merely a slight change to an invention were patentable.

11. In this situation, a patent examiner would reject the patentee’s second application for what is called “obviousness-type double patenting.” *See infra* text accompanying notes 74–75.

examiner allows the second patent application to move forward in the patenting process.¹² This process is known as filing a terminal disclaimer: the second patent's term is "disclaimed" and shortened to the same term as that of the first patent.¹³

On the other hand, a patentee may lengthen the term of his patent with patent term adjustment or patent term extension. First, patent term adjustment is provided for in 35 U.S.C. § 154(b)¹⁴ and extends the term of a patent that the PTO failed to process within reasonable time limits set out in the statute.¹⁵ Patent term adjustment is not something that the patentee need apply for; it is automatically granted by the PTO.¹⁶ Second, patent term extension is available for pharmaceutical patents. Under the Hatch-Waxman Act, patentees can add time to their patents' terms for delays caused by the Food and Drug Administration (FDA) as the FDA tests the drug before approval.¹⁷

What this Comment does is twofold: first, it poses a hypothetical situation in Part II to illustrate potential complications that can arise when a patent has both patent term adjustment and is terminally disclaimed to another patent,¹⁸ and second, it attempts to predict the

12. See BLACK'S LAW DICTIONARY 531 (9th ed. 2009).

13. See *id.*

14. There are actually two types of extensions provided for in § 154. Patents filed between June 8, 1995, and May 29, 2000, can obtain extension of their terms under the statute as amended according to the URRA. Patents filed after May 29, 2000, can obtain patent term adjustment for delays in the PTO. See 65 Fed. Reg. 56,366, 56,367 (Sept. 18, 2000).

Therefore, patents (other than reissue or design) issued on applications filed on or after June 8, 1995, but before May 29, 2000, are subject to the patent term extension provisions of 35 U.S.C. [§] 154(b) as amended by § 532(a)(1) of Pub. L. 103-465 and § 1.701, whereas patents (other than reissue or design) issued on applications filed on or after May 29, 2000, are subject to the patent term adjustment provisions of 35 U.S.C. [§] 154(b) as amended by § 4402 of the American Inventors Protection Act of 1999.

Id. Right now, we will focus on the second type of adjustment for the sake of the hypothetical posed in Part II and running throughout this Comment.

15. For example, patent term adjustment will accrue for each day after the fourteen-month time period in which an examiner must respond to an application. 35 U.S.C. § 154(b)(1)(A)(i) (2006).

16. Changes to Implement 20-Year Patent Term and Provisional Applications, 60 Fed. Reg. 20,195, 20,204 (Apr. 25, 1995) (to be codified at 37 C.F.R. pts. 1 & 3).

17. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 35 U.S.C. § 156 (2006)).

18. Dennis Crouch recently proposed that a patentee bring a test case before the PTO to see if a patent's term could be adjusted despite it also being terminally disclaimed to another patent. Dennis Crouch, *Terminal Disclaimers and PTO: Proposal for a Test Case*, PATENTLYO, June 17, 2010, <http://www.patentlyo.com/patent/2010/06/terminal-disclaimers-and-pt-proposal-for-a-test-case.html#comments>. Crouch proposes that a patentee modify

outcome of the hypothetical while commenting on the lack of coherent law relating extensions and adjustments of patent term to terminal disclaimers. The main thrust of this Comment is that current judge-made law interpreting the Patent Act is inadequate to provide a predictable outcome regarding a given patent's term for two reasons: (1) varying Federal Circuit deference to PTO decisions, and (2) a lack of either statutory or common law directly on point.

I must point out the structure of this Comment in order that the reader not get bogged down in complicated terminology mixed into the discussion of intricate patent-related fact patterns. Part III of this Comment lays out three decisions of the Federal Circuit: each case deals with the relationship between different elements that contribute to the calculation of a patent's term and offers insight into how a court might calculate a patent's term if faced with the hypothetical from Part II. Because the terminology in each case is likely not familiar to the reader, each case is preceded by subsections that identify and explain the core concepts important to understanding the Federal Circuit's reasoning in that particular case.

Part IV, then, introduces the administrative law concept of judicial deference to an agency's decision and applies it specifically to the Federal Circuit's deference to the PTO's interpretive decisions in two of the cases described in Part III.

Next, Part V applies the precedential teachings of the three above-mentioned cases to the hypothetical in Part II. Nonetheless, as mentioned above, this predicted outcome is not certain because it is

the language of PTO form SB-0025 commonly used by patentees to terminally disclaim one patent to another such that the language of the terminal disclaimer disclaims the second patent's term to that of the first patent, plus any patent term adjustment. When challenged that this could not be done because 35 U.S.C. § 154 already governs the issue, Asdf, Comment to *Terminal Disclaimers and PTO: Proposal for a Test Case*, PATENTLYO (June 17, 2010, 2:05 PM), <http://www.patentlyo.com/patent/2010/06/terminal-disclaimers-and-pto-proposal-for-a-test-case/html#comments>, Crouch elaborated that the terminal disclaimer's language would specifically state that the date to which the second patent's term was disclaimed would not be that of the first patent, but that of the first patent plus any patent term adjustment earned by the second patent. Dennis Crouch, Comment to *Terminal Disclaimers and PTO: Proposal for a Test Case*, PATENTLYO (June 17, 2010, 2:20 PM), <http://www.patentlyo.com/patent/2010/06/terminal-disclaimers-and-pto-proposal-for-a-test-case/html#comments>. One commentator suggested that this might render the patent invalid. IANA, Comment to *Terminal Disclaimers and PTO: Proposal for a Test Case*, PATENTLYO (June 17, 2010, 5:44 PM), <http://www.patentlyo.com/patent/2010/06/terminal-disclaimers-and-pto-proposal-for-a-test-case/html#comments>. Another noted that this would be an awfully expensive test case and that any given patentee was unlikely to risk his own patent's integrity for the sake of resolving the issue. Lurking less, Comment to *Terminal Disclaimers and PTO: Proposal for a Test Case*, PATENTLYO (June 19, 2010, 10:21 AM), <http://www.patentlyo.com/patent/2010/06/terminal-disclaimers-and-pto-proposal-for-a-test-case/html#comments>.

based on two shaky foundations: (1) assuming that the Federal Circuit will apply a given degree of deference to the PTO's current stance on the issue; and (2) statutory and common law requiring interpretation according to scanty legislative intent, plain meaning of the Patent Act, and policy relating to patent term.

Finally, Part VI concludes with a suggestion that the uncertainty facing patentees and consumers could be ameliorated: either the Federal Circuit could consistently give the correct level of deference to the PTO's decisions, or legislators could pass a comprehensive act explaining all the interactions between the mechanisms for lengthening and shortening patent term likely to arise and the way a patent's term should be calculated in any situation. Either way, the system as it is now cannot stand because neither patentees nor consumers can be certain of what their patent's term will be.

II. THE HYPOTHETICAL

Let us say that an owner has two patents, A and B. B is terminally disclaimed to A for obviousness-type double patenting reasons.¹⁹ The terminal disclaimer means that B's term will expire on the same day that A's term will expire. So far, the situation is straightforward. If we add patent term adjustment into the mix it becomes more complicated. If the term of A or B is adjusted, the effect on the other patent is not specifically laid out by law. All we do know is that, according to statute, the term of B cannot be adjusted beyond the expiration date of A.²⁰

If A's term is lengthened with patent term adjustment (i.e., it now has a later expiration date), B's term has some room to extend while still fitting within the bounds of § 154(b)(2)(B). But would B automatically be entitled to the patent term adjustment that A earned?²¹ In other

19. This means that the subject matter of B is obvious, or would have been mere routine modification, according to the subject matter of A. In other words, B is so like A that it does not deserve a term that extends the patentee's monopoly beyond that of the monopoly already given by A. See *supra* text accompanying note 10.

20. 35 U.S.C. § 154(b)(2)(B) (2006) ("No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer."). This makes sense, seeing as the reason that B is terminally disclaimed to A is to prevent the patentee of both patents from extending his monopoly over the subject matter claimed in A with extra term from the very similar B.

21. A similar question might also arise: if B acquires its own patent term adjustment, can B use this patent term adjustment so long as it does not extend the term of B beyond that of A? Only one author has addressed this same hypothetical and correctly concluded that patent B, if its own term were adjusted, could use this extra term up to the date to which A was adjusted. Scott E. Kamholz, *Patent Term Adjustment for Fun and Profit*, INTELL. PROP. TODAY, Aug. 2006, at 24. Kamholz relied on personal communication with the PTO for his answer to this question. See *id.* at 27 nn.11, 23. However, he failed to address the corollary

words, would B's term automatically be adjusted so that B expired on the same later date as A? A call to the PTO reveals the legal department's view on this question:²² B may earn patent term adjustment of its own so long as its term is not extended beyond that of A's, but B does not automatically benefit from the patent term adjustment that A earned. One might correctly guess, however, that the PTO is not the final authority on this matter. Such a decision could potentially be reviewed by the Federal Circuit.²³

This hypothetical might be better explained with the use of a graphic, shown in Figure 1, which follows. As the top two bars in Figure 1 depict, the term of patent B cannot be adjusted beyond the term of patent A, according to § 154(b)(2)(B).²⁴ The top bar shows that patent A's term has been lengthened by five years to a total term of twenty-five years. The second bar shows that even if patent B gains six years of patent term adjustment, § 154(b)(2)(B) prevents its term from extending beyond twenty-five years because a total term of twenty-five years is the "expiration date [of A] specified in the disclaimer."²⁵ For this reason, the second bar labels this situation as "not allowed."

In contrast, the bottom two bars show that the term of B may be adjusted so long as it does not go beyond that of A. The third bar shows that A once again has five years of patent term adjustment, bringing its total term to twenty-five years. B's term has only been adjusted by four years to a total of twenty-four years, however, as shown by the bottom bar. This situation is "allowed" according to § 154(b)(2)(B). Our

situation posed in my first question above: why B could not automatically gain the term adjustment of A if A had more term adjustment than B?

22. Telephone Interview with Kery Fries, Office of Patent Legal Admin., U.S. Patent and Trademark Office (Jan. 29, 2010). Mr. Fries informed me that the PTO itself does not make determinations of a patent's term, but merely offers advice to patentees on how long their patents can be enforced, such as by "providing a list of variables to help determine an expiration such as filing date, continuity data, [terminal disclaimer], [and] patent term adjustment or extension." E-mail from Kery Fries, Office of Patent Legal Admin., U.S. Patent and Trademark Office, to Emily M. Hinkens (Aug. 31, 2010, 11:43 CST) (on file with author); *see also* MANUAL OF PATENT EXAMINING PROCEDURE ch. 2700 (Magdalen Y. C. Greenlief ed., 8th ed. 2010), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep_e8r5_2700.pdf [hereinafter MPEP]. Furthermore, Fries opined that a terminal disclaimer is a limitation against the patent's term and not a way to get extra term. "The statutory requirement [of 35 U.S.C. § 253] would not provide authority to increase the term [of a patent] by the filing of a disclaimer." E-mail from Kery Fries, Office of Patent Legal Admin., U.S. Patent and Trademark Office, to Emily M. Hinkens (Sept. 22, 2010, 06:50 CST) (on file with author). This view would militate against patent B automatically gaining the term of patent A.

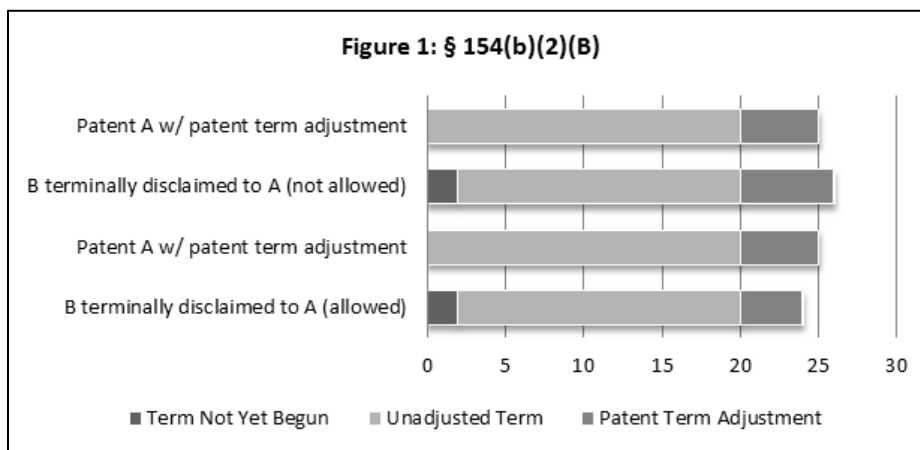
23. *See infra* Part IV.

24. *See supra* text accompanying note 20.

25. *See* 35 U.S.C. § 154(b)(2)(B) (2006).

hypothetical asks: why can't B automatically gain the term adjustment of A—in this case, bringing its term to a total of twenty-five years?²⁶

The above hypothetical will help to illustrate the interplay between decisions made by the PTO and the Federal Circuit and to highlight the numerous uncertainties that plague the issue of patent term determination. The PTO has decided the issue of whether B automatically gets the adjusted term of A without any intervention from



legislators or the courts, forcing patentees and consumers into a state of uncertainty regarding the length of time that a patent can be enforced.

III. USING THE FEDERAL CIRCUIT'S DECISIONS REGARDING THE URAA, THE HATCH-WAXMAN ACT, AND TERMINAL DISCLAIMERS TO PREDICT THE OUTCOME OF THE HYPOTHETICAL

The following section describes three Federal Circuit cases that can help predict the outcome of the hypothetical posed in Part II. First, in *Merck & Co. v. Kessler*,²⁷ the Federal Circuit decided to allow Hatch-Waxman term extension on top of term adjustment under the Uruguay Round Agreements Act (URAA).²⁸ Second, in *Bayer AG v. Carlsbad*

26. One might automatically answer, "Because B did not earn this adjustment itself." However, remember the close relationship between patents A and B. If A and B lay out such similar technology that B was required to be terminally disclaimed to A in the first place, then extending B's monopoly to the same term as A's seems logical. Whatever "advance" B describes most likely provides the owner of the two patents with a very small amount of extra protection for a variation on the invention described in patent A.

27. 80 F.3d 1543 (Fed. Cir. 1996).

28. See *id.* at 1553.

Technology, Inc.,²⁹ the Federal Circuit decided that a patent's term that was "due to" another patent's term by a terminal disclaimer could be extended under the URAA.³⁰ Third, in *Merck & Co. v. Hi-Tech Pharmacal Co.*,³¹ the Federal Circuit ruled that Hatch-Waxman extension could be added onto the term of a terminally disclaimed patent.³² The reasoning behind the court's decision in each case—including its deference to decisions of the PTO, its policy arguments, its treatment of the plain meaning of the statute, and its consideration of legislative intent—is instructive in predicting the outcome of the hypothetical posed in Part II.

A. *Merck & Co. v. Kessler—The URAA
and the Hatch-Waxman Act Collide*

In *Kessler*,³³ the Federal Circuit focused on the interplay between the extension of patents' terms from seventeen years from issuance to twenty years from filing and the extension of pharmaceutical patents' terms for FDA delays under the Hatch-Waxman Act.³⁴ The court in this case chose to follow its own interpretation of the Patent Act rather than the PTO's interpretation, and relied on the policy behind the Hatch-Waxman Act as a backdrop for its decision. Before discussing this case, an overview of patent term calculation under the URAA and the ramifications of the Hatch-Waxman Act is in order. The court's treatment of these laws in conjunction with one another can help predict the outcome of our hypothetical above.

1. Calculating Patent Term After the URAA

Any patent whose application was filed on or after June 8, 1995, will have a term beginning on the date the application was issued as a patent and ending twenty years from the date of filing of the application.³⁵ This became the rule after enactment of the URAA, which was meant to make U.S. laws on patent term consistent with those of its trade partners.³⁶ Before enactment of the URAA, the U.S. granted a term of seventeen years from the date of the patent's issue.³⁷ In order to ease

29. 298 F.3d 1377 (Fed. Cir. 2002).

30. *See id.* at 1382–83.

31. 482 F.3d 1317 (Fed. Cir. 2007).

32. *See id.* at 1318.

33. 80 F.3d 1543.

34. *See id.* at 1550–53.

35. 35 U.S.C. § 154(a)(2) (2006).

36. *See Kessler*, 80 F.3d at 1547.

37. 35 U.S.C. § 154 (1988).

the shift in the law, 35 U.S.C. § 154(c)(1) provides that “any patent that is in force on or that results from an application filed before [June 8, 1995,] shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant.” This means that any patent in force on June 8, 1995, or any patent resulting from an application filed before June 8, 1995, that took fewer than three years from filing of the application to issuance as a patent will have its term “extended”³⁸ by the difference between twenty years from its filing date and seventeen years from its issue date.

For example, if two patents were filed on the same day, January 1, 1990, and one issued on January 1, 1992, while the other issued on January 1, 1994, only the first patent’s term would be “extended” under the URAA. According to § 154(c)(1), the first patent would be set to expire on either January 1, 2009, (seventeen years from issue) or January 1, 2010, (twenty years from filing). Because the twenty-year from filing date provides a greater term, the first patent’s term would expire on January 1, 2010.

On the other hand, the second patent’s term would not be “extended.” Under the seventeen-year from issue date, the second patent would expire on January 1, 2011. If the term was calculated as twenty years from filing, the patent would expire on January 1, 2010. The first date provides a longer term, thus it is set per § 154(c)(1). Therefore, the shift in law provides no “extension” of the second patent’s term because it took longer than three years to issue after it was first filed. This situation is summarized in Table 1 below:

38. This is not the same type of extension as provided for by the Hatch-Waxman Act. *See supra* text accompanying note 14; *see also supra* note 17; *infra* Part III.A.2. Therefore, I will use quotation marks when I speak of “extension” under the URAA.

TABLE 1: EFFECTS OF THE URAA ON PATENT TERM

Filing Date	Issue Date	Expiration Date under old law ³⁹	Expiration Date under new law ⁴⁰	Amount term was “extended”
1/1/1990	1/1/1992	1/1/2009	1/1/2010	1 year
1/1/1990	1/1/1994	1/1/2011	1/1/2011	0 years

This general rule that a patent’s term expires either seventeen years from issue or twenty years from filing has numerous subtleties, but we need not concern ourselves with these here. Suffice it to say that for applications claiming priority to other patents, the rules change a bit depending on the type of priority claimed.⁴¹

2. Patent Term Extension Under the Hatch-Waxman Act

The Hatch-Waxman Act⁴² allows for patentees to extend the terms of pharmaceutical patents to make up for time lost to the process of obtaining FDA approval of the drug.⁴³ The policy behind the Act is a quid pro quo in which a patentee gains this benefit in exchange for allowing generic drug manufacturers who wish to produce the drug once its patent expires to do so without having to conduct any testing program of their own.⁴⁴ The generic manufacturer can instead rely on the tests that the FDA previously conducted; this speeds the marketing of FDA-approved generic drugs.⁴⁵ Various limitations govern the amount of time that the patent term can be extended under the Act, depending on the patent’s issue date or when drug testing began.⁴⁶

Much litigation has sprung up concerning the Hatch-Waxman Act in

39. 35 U.S.C. § 154 (1988).

40. 35 U.S.C. § 154(c)(1) (1994).

41. To “claim priority” means to assert that the invention that the patentee currently seeks to patent was actually disclosed in a prior patent application but never claimed as the patentee’s property at the end of the disclosure. By claiming priority, a patentee can avoid a PTO examiner’s use of prior art that came between the original disclosure of the invention and the invention of the current pending application. *See* MPEP, *supra* note 22, at § 201.11. 35 U.S.C. § 154(a)(2)–(3) (2006) provides different rules for determining the term of a patent depending on whether it is a continuation, continuation-in-part, divisional, or international patent under the Patent Cooperation Treaty. *See, e.g.,* MPEP, *supra* note 22, at §§ 13.03, 2701; *see also infra* text accompanying note 208.

42. 35 U.S.C. § 156 (2006).

43. *See, e.g.,* Changes to Implement 20-Year Patent Term and Provisional Applications, 60 Fed. Reg. 20,195, 20,196 (Apr. 25, 1995) (“The patent term extension provisions of 35 U.S.C. [§] 154(b) are designed to compensate the patent owner for delays in issuing a patent, whereas the patent term extension provisions of 35 U.S.C. [§] 156 are designed to restore term lost to premarket regulatory review after the grant of a patent.”).

44. *See* Merck & Co. v. Kessler, 80 F.3d 1543, 1546–47 (Fed. Cir. 1996).

45. *See id.* at 1546.

46. *See* 35 U.S.C. § 156(c)(3) (2006); *see also* 35 U.S.C. § 156(g)(6)(B)–(C) (2006).

conjunction with other provisions of the Patent Code: more specifically, with the new patent terms under the URAA⁴⁷ and with the effect of a terminal disclaimer.⁴⁸ As for the effect of the URAA, the Federal Circuit held that pre-June 8, 1995 patents were entitled to term extension under § 156 on top of the extension from a seventeen-year to a twenty-year term granted under § 154.⁴⁹ As for the effect of a terminal disclaimer, the Federal Circuit ruled that any term extension under § 156 could be added on to the end-date of the patent's term as determined by the terminal disclaimer.⁵⁰

3. *Merck & Co. v. Kessler*

With a general understanding of the rules defining the term of a post-URAA patent and how it can be extended according to the Hatch-Waxman Act, the reader can better follow the case law regarding interaction between the two. In *Merck & Co. v. Kessler*,⁵¹ the Federal Circuit ruled that patent term extension from the Hatch-Waxman Act could be added onto the end of the term of a patent that had already been "extended" under the URAA.⁵² The plaintiffs in *Kessler* held patents with original seventeen-year terms. All of their patents were in effect on June 8, 1995; some because the seventeen-year term was not yet up, and some because of term extensions under the Hatch-Waxman Act.⁵³

The plaintiffs had submitted requests to the FDA that the FDA republish their patents' expiration dates to take into account the new twenty-year term provided by the URAA.⁵⁴ The FDA refused to do so based on a "Final Determination" from the PTO ruling that patent term extension could not be added on to the end of the new twenty-year term under the URAA.⁵⁵ The PTO had based its "Final Determination" on the understanding that emphasis should be placed on § 156(a) in the following manner: "[t]he term of a patent . . . 'shall be extended in

47. See generally *Kessler*, 80 F.3d 1543.

48. See, e.g., *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317 (Fed. Cir. 2007).

49. *Kessler*, 80 F.3d at 1550. Note that patents which were kept in effect past June 8, 1995, solely due to § 156 extensions of their terms are excepted from this ruling. *Id.*; see also *infra* text accompanying note 66. See *infra* Part III.A.3 for a detailed analysis of this case.

50. *Hi-Tech*, 482 F.3d at 1324. For further details on this holding, see *infra* Part III.C.

51. See *Kessler*, 80 F.3d at 1543.

52. *Id.* at 1550.

53. *Id.* at 1548.

54. *Id.*

55. Determination of New Expiration Dates of Certain Patents, 60 Fed. Reg. 30,068, 30,069-71 (June 7, 1995).

accordance with this section from the ORIGINAL EXPIRATION DATE of the patent.”⁵⁶ Therefore, the PTO understood the interaction between patent term extension and the URAA to mean that the patentee was entitled to seventeen years from issue plus extension *or* twenty years from filing without extension, whichever was greater.⁵⁷

The PTO interpreted the words “original expiration date” to mean the seventeen-year from issue date.⁵⁸ Because the patentee-plaintiff’s patents would have shorter terms under the twenty-year from filing/no extension calculation than under the seventeen-year from issue/plus extension calculation, the FDA reasoned that it should not change the patents’ expiration dates.⁵⁹

The defendants (Commissioners of Food and Drugs) argued that the PTO’s interpretation of § 156(a) in its Final Determination should control the court’s holding. The defendants relied on *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*⁶⁰ for the proposition that “where Congress has authorized an agency to promulgate substantive rules under a statute it is charged with administering, we must uphold the agency’s interpretation of an ambiguity or omission in that statute if the interpretation is a reasonable one.”⁶¹ However, the Federal Circuit refused to expand the *Chevron* ruling this far: “[O]nly statutory interpretations by agencies WITH RULEMAKING POWERS deserve substantial deference.”⁶² The Federal Circuit explained that the Commissioner of the PTO could make rules that applied to the proceedings of the PTO, but could not make rules that had substantive effect as law.⁶³ The court held that the PTO’s regulations were to be given deference, if at all, only because of the “thoroughness of [the PTO’s] consideration and the validity of its reasoning, *i.e.*, its basic power to persuade if lacking power to control.”⁶⁴

In rejecting the PTO’s interpretation of the words “original expiration date,” the Federal Circuit relied mostly on the legislative history behind § 156. The “original expiration date” limitation was connected to a limitation that the same patent could not have its term

56. *Kessler*, 80 F.3d at 1548 (quoting 35 U.S.C. § 156(a)).

57. *Id.* at 1548.

58. *See id.*

59. *See id.*

60. 467 U.S. 837, 844 (1984).

61. *Kessler*, 80 F.3d at 1549.

62. *Id.* (quoting *Atchison, Topeka & Santa Fe Ry. Co. v. Pena*, 44 F.3d 437, 441 (7th Cir. 1994) (en banc)).

63. *Kessler*, 80 F.3d at 1549-50.

64. *Id.* at 1550.

extended twice under the Hatch-Waxman Act;⁶⁵ the language of § 156(a)(2) had been amended to deny patent term extension to any patent that had already been “extended under subsection (e)(1) of this section [§ 156].”⁶⁶ Thus the court ruled that the term “original expiration date” was meant to refer to the statutory date on which the patent’s term would end (whether it be under the old or new § 154) and that the limitation meant that a patent could receive just one term extension under the Hatch-Waxman Act, not one term extension in total.⁶⁷ Finally, the court cited the provision in § 156(a) that a patent could receive both patent term adjustment under § 154(b)(2) and patent term extension under § 156 to support the interpretation that the “original expiration date” need not be solely the seventeen-year from issue date, but could include extension under the URAA to which extension under § 156 could then be added.⁶⁸

The policy behind the Hatch-Waxman Act is also an important backdrop to the court’s decision. The Hatch-Waxman Act provides for quicker injection of generic drugs into the market by allowing them to piggy-back off the FDA approval of the corresponding patented brand-name drug.⁶⁹ The Hatch-Waxman Act offers a patentee extension of the term of his patented drug for the time it took him to obtain regulatory approval from the FDA as a way to get him to agree to these terms.⁷⁰ If the patentee did not allow the generic drug producer to piggy-back off his FDA approval, there would be delays as generic producers would

65. *See id.* at 1550–51.

66. *Id.* at 1551 (citing 35 U.S.C. § 156(e)(1) (2006)).

[A] determination that a patent is eligible for extension may be made by the Director [of Food and Drugs] solely on the basis of the representations contained in the application for the extension. If the Director determines that a patent is eligible for extension . . . the Director shall issue to the applicant for the extension of the term of the patent a certificate of extension.

35 U.S.C. § 156(e)(1). The court also ruled that five of the plaintiffs’ patents could not receive extension under both the URAA and the Hatch-Waxman Act because the only reason they were in effect on June 8, 1995, was due to term extension under the Hatch-Waxman Act, and therefore, their terms had already been extended under subsection (e)(1) and could not be extended once more. *Kessler*, 80 F.3d at 1552. This rule is mentioned for the sake of including the court’s full holding but is not crucial to an understanding of the court’s treatment of term extensions in conjunction with one another or an understanding of the court’s deference to the PTO’s decisions.

67. *See id.*

68. *See id.* at 1551.

69. *Id.* at 1546. Before the Hatch-Waxman Act, generic drug producers had to conduct their own testing programs for their drugs. *See id.*

70. *See id.* at 1546–47.

need to have their versions of the drug tested before sending them to market. This delay would result in a longer period of time during which the patentee had a monopoly over the higher-priced brand-name drug.

*B. Bayer AG v. Carlsbad Tech., Inc.—Effects of the URAA
on Terminal Disclaimers*

The Federal Circuit's decision in *Bayer AG v. Carlsbad Technology, Inc.*⁷¹ can also help predict the Federal Circuit's ruling regarding the hypothetical in Part II, if the issue should ever make it that far. The *Bayer* court decided how a terminal disclaimer would be affected by the extension of a patent's term from seventeen years to twenty years under the URAA. In doing so, the court relied heavily on interpretations of law made by the PTO, and denied that its ruling would set bad policy by disfavoring the public. Before coming to the case law, a brief introduction to terminal disclaimers is required.

1. Terminal Disclaimers

a. Reasons to File a Terminal Disclaimer

A terminal disclaimer disclaims or dedicates to the public the end portion of the term of a patent;⁷² in effect, the patentee agrees not to enforce his patent against others after a certain date in exchange for his own benefit. This benefit comes in different forms: the patentee may avoid an obviousness-type double patenting rejection of his second patent application from the PTO;⁷³ he may avoid a finding of obviousness in a reexamination proceeding;⁷⁴ and he may avoid a finding of obviousness in subsequent litigation.⁷⁵ The public receives a benefit

71. 298 F.3d 1377 (Fed. Cir. 2002).

72. 35 U.S.C. § 253 (2006).

73. See 37 C.F.R. § 1.321(c) (2006).

74. *Id.* A reexamination is a second examination of a patent after it has already been granted. Any person may request reexamination of a patent at any time while the patent is enforceable so long as a substantial new question of patentability exists. 35 U.S.C. § 302 (2006); see also MPEP, *supra* note 22, at § 2209. The requestor must provide the new prior art references he wishes the examiner to compare to the patent or must present previously-considered prior art references in a new light. MPEP, *supra* note 22, at § 2216. Once the examiner has determined that reexamination is in order, the process for reexamination is much like that for initial examination. Therefore, the patentee is allowed to terminally disclaim any portion of his patent's term if it turns out the new prior art cited by the requestor might render his patent obvious.

75. 3A DONALD S. CHISUM, CHISUM ON PATENTS § 9.04[4][b] (2005). This option has been attempted in only a few cases, according to Chisum. For example, one district court allowed the plaintiffs' filing of a terminal disclaimer to overcome the defendant's counterclaim of invalidity due to obviousness, even though the plaintiffs filed the terminal

in each of these situations seeing as the patentee agrees that he will not extend his monopoly by pursuing a second patent that has very similar subject matter to a first patent of his. He can obtain a second patent with new but obvious claims, but he cannot enforce it any longer than he can enforce his first patent that renders this second patent obvious.

In the most common situation, a patentee files a terminal disclaimer to avoid an obviousness-type double patenting rejection while his patent application is being examined at the PTO. The basic idea behind the need for a terminal disclaimer is that a patentee may not obtain a patent on an invention that would have been obvious in light of his own previous patent application(s).⁷⁶ Therefore, if a patentee wishes to patent something that might be considered obvious in light of claims in his other application(s) when combined with prior art, he may file a terminal disclaimer releasing the end portion of the term of his second application so that it does not extend beyond the term of the first application that would have rendered the second obvious.

For example, if application B might be considered obvious in light of application A, the patentee of both applications can disclaim any of B's term that extends beyond A's term. If A were filed on January 1, 2000, and were to expire on January 1, 2020, and B were terminally disclaimed to A, then even if B were filed on October 1, 2001, its term would end on January 1, 2020, instead of October 1, 2021. In this way, the patentee does not extend the term of A (through a patent over the obvious variation B) beyond the statutory limit of twenty years from filing date.⁷⁷

disclaimer at the beginning of trial. *Technicon Instruments Corp. v. Coleman Instruments, Inc.*, 255 F. Supp. 630, 636, 641 (N.D. Ill. 1966). Similarly, a court in another case stated: "We thus conclude that the question of delay is irrelevant to the filing of a terminal disclaimer." *Bayer AG v. Barr Labs.*, 798 F. Supp. 196, 199 (S.D.N.Y. 1992). The same district court that decided *Technicon*, however, later did not allow this method of preventing a finding of invalidity. *See CMI Corp. v. Lakeland Constr. Co.*, 184 U.S.P.Q. (BNA) 721, 727 (N.D. Ill. 1975).

76. *See In re Longi*, 759 F.2d 887, 892-93 (Fed. Cir. 1985).

77. This would be the effect of allowing B to have its full statutory term because B is basically the same patent as A, only with an obvious addition to B's claims.

b. Calculating the Term of a Patent that Has a Terminal Disclaimer

The language of a terminal disclaimer is crucial to figure out the date on which the disclaimed patent's term ends. If the disclaimer disclaims the end portion of patent B that extends beyond the expiration date of patent A, then patent B's term is "due to" that of patent A.⁷⁸ If, on the other hand, patent B's term is disclaimed beyond a specified date, then it is "independent of" the expiration date of A.⁷⁹ The terms "due to" and "independent of" have become terms of art in the wake of a Senate Report published around the time of the enactment of the URAA, which stated:

A patent whose term has been disclaimed under section 253 of Title 35 *due to* another patent [in order to overcome obviousness-type double patenting] shall expire on the date of the other patent. A patent whose term has been disclaimed under section 253 of Title 35 *independent of* another patent shall be reduced by the length of the originally disclaimed period.⁸⁰

A patent that is due to another patent is one that disclaims the term of the second patent beyond the full statutory term of the first patent, such as by saying "the term of patent B is disclaimed beyond the full statutory term of patent A." A patent that is independent of another patent disclaims its term beyond a specified date, such as by saying "the term of patent B is disclaimed beyond January 1, 2000."⁸¹ Table 2 sums

78. *See* Bayer AG v. Carlsbad Tech., Inc., 298 F.3d 1377, 1382 (Fed. Cir. 2002).

79. *Id.*; *see also* 65 Fed. Reg. 56,366, 56,378 (Sept. 18, 2000) ("The term of any patent which has been disclaimed beyond a date certain may not receive an adjustment beyond the expiration date specified in the disclaimer.").

80. S. REP. NO. 103-412, at 229 (1994) (emphasis added); *see also* MPEP, *supra* note 22 § 2701 ("Expiration Date of Patents with Terminal Disclaimers").

81. *See also* USPTO.gov, Questions and Answers Regarding the GATT Uruguay Round and NAFTA Changes to U.S. Patent Law and Practice (Feb. 23, 1995), <http://www.uspto.gov/web/offices/com/doc/uruguay/QA.html>. The answer to question 8, which asks, "How does a terminal disclaimer affect the term of a patent that is entitled to the longer of the 17 or 20-year patent term?" states:

Assume that there are two patents. The first patent was issued [with]in 18 months [of the filing of the application for the patent] and received a 17-year patent term. Under the 17 or 20-year provision, the patent term would be essentially 18.5 years after the original patent date. The second patent B was issued after patent A with a terminal disclaimer that said the terminal portion of the term of this patent is disclaimed beyond the expiration date [or full statutory term] of patent A. What is the effect on the patent term in patent B? Patent B would be entitled to the difference

up the previous explanation:

TABLE 2: INTERPRETING LANGUAGE OF A TERMINAL DISCLAIMER

Language in Terminal Disclaimer	Classification of Relation	Can B's Term be Adjusted/Extended?
"the term of patent B is disclaimed beyond the full statutory term of patent A"	due to	yes
"the term of patent B is disclaimed beyond January 1, 2000"	independent of	no

2. *Bayer AG v. Carlsbad Technology, Inc.*

Using what we now know about terminal disclaimers, coupled with the discussion of the URAA in Part III.A.1, we now move on to a case that unites the laws on these two components of patent term. In *Bayer AG v. Carlsbad Technology, Inc.*,⁸² the Federal Circuit applied a straightforward rule that the new twenty-year term under the URAA applied to patents that had been terminally disclaimed, but with the added complication of deciding whether the terminally disclaimed patent was "due to" or "independent of" the first patent.⁸³

On February 21, 1992, Bayer executed a writing that terminally disclaimed the terminal part of one of its patents:

Bayer . . . disclaims the terminal part of U.S. Patent No. 4,670,444 ["the '444 patent"] which extends beyond October 01, 2002, the earlier of the expiration dates of U.S. Patent Nos. 4,544,658 (issued October 01, 1985) ["the '658 patent"] and 4,556,658 (issued December 03, 1985), and hereby agrees that U.S. Patent No. 4,670,444 shall be enforceable only for and during such period that legal title to U.S. Patent No. 4,670,444 shall be the same

between the 17 or 20-year patent term for the underlying patent A, which would be 18 months in our example unless patent B would not have been entitled to 18 months based on the difference between the terminally disclaimed 17 year and 20-year patent term as to patent B. Note that there are two limitations here—the term of the underlying patent and the term of the patent containing the [terminal disclaimer]. The terminal disclaimer that was addressed in this example was linked to the expiration date [or full statutory term] of the underlying patent A. A different result is possible if the terminal disclaimer was couched in terms disclaiming a terminal portion of the patent beyond a *specific date*.

Id. (emphasis added).

82. 298 F.3d 1377 (Fed. Cir. 2002).

83. *See id.* at 1380.

as legal title to U.S. Patent Nos. 4,544,658 and 4,556,658.⁸⁴

This disclaimer, had the URAA not been enacted, would have meant that the second patent's (the '444 patent's) term would end on October 1, 2002, which was seventeen years from the issuance of the '658 patent. This was the date that Carlsbad wanted the term of the '444 patent to end.⁸⁵ Bayer, on the other hand, argued that the term of the '444 patent ended on December 9, 2003—twenty years from the filing of the application that issued as the '658 patent.⁸⁶ The issue was not whether the URAA applied to the term of the '658 patent,⁸⁷ but whether the term of the '444 patent was independent of or due to the term of the '658 patent because the disclaimer mentioned both a specified date (October 1, 2002) and the statutory terms of the '658 patents.

After passage of the URAA, Bayer had filed to amend its terminal disclaimer.⁸⁸ The PTO found that the terminal disclaimer on the '444 patent was ambiguous as to whether it was due to or independent of the '658 patent, and set the date at December 9, 2003,⁸⁹ using the new URAA twenty-year provision to do so.⁹⁰ When Carlsbad notified Bayer it intended to start making a generic version of the drug to which the patents pertained, Bayer filed an infringement suit.⁹¹ The district court granted summary judgment for Bayer and kept the expiration date of the '444 patent at December 9, 2003.⁹² On appeal, Carlsbad argued that the terminal disclaimer on the '444 patent was not due to the term of the '658 patent, but instead independent of it, and based on the specified date of October 1, 2002.⁹³ In its brief, Carlsbad maintained that "[o]nly a disclaimer which disclaims the term 'due to another patent' may be

84. *Id.* at 1380 (emphasis omitted).

85. *Id.* at 1379.

86. *Id.*

87. Of course it did, seeing as 35 U.S.C. § 154(c)(1) allowed extension of term to twenty years from filing, subject to any terminal disclaimers. *See also* Changes to Implement 20-year Patent Term and Provisional Applications, 60 Fed. Reg. 20,195, 20,207 (Apr. 25, 1995).

88. *Bayer*, 298 F.3d at 1379.

89. *Id.* (citing U.S. PTO, Decision on Petition, Application No. 06/614,923, at 5 (Jan. 31, 1996)).

90. The PTO interpreted its own regulation, 37 C.F.R. § 1.182, as granting it the authority to take this course of action. *Bayer*, 298 F.3d at 1379 n.*. This provision allows the PTO to address situations not specifically provided for in the accompanying section describing how unsatisfied patentees may petition the PTO for review of their patents' examinations. *See* 37 C.F.R. § 1.181 (2008); *see also infra* note 145.

91. *Bayer*, 298 F.3d at 1379.

92. *See id.*

93. *Id.* at 1380.

affected by the URAA.”⁹⁴ Carlsbad claimed that because the ‘444 patent’s terminal disclaimer recited the specific date of October 1, 2002, it could not be affected by the URAA, and the twenty-year from filing date did not apply.⁹⁵ The Federal Circuit disagreed with this argument.⁹⁶

The Federal Circuit gave great deference to the PTO’s decision regarding the patent’s expiration date in making its own decision in favor of Bayer.⁹⁷ The Federal Circuit cited two cases to support its reliance on the PTO’s decision. First, an agency’s own interpretation of its own regulations is given judicial deference if the interpretation is reasonable.⁹⁸ Second, the court is “obligated by clear Supreme Court precedent to give deference to the PTO’s own interpretation of its regulations.”⁹⁹ It was reasonable that the district court and the PTO

94. Brief of Defendant-Appellant at 21, *Bayer AG v. Carlsbad Tech., Inc.*, No. 02-1077 (Fed. Cir. Feb. 11, 2002). See also the MPEP, *supra* note 22, § 2701, which reads:

To determine the “original expiration date” of a patent subject to a terminal disclaimer, it is generally necessary to examine the language of the terminal disclaimer in the patent file history. If the disclaimer disclaims the terminal portion of the term of the patent which would extend beyond the expiration date of an earlier issued patent, then the expiration date of the earlier issued patent determines the expiration date of the patent subject to the terminal disclaimer. Before June 8, 1995, the terminal disclaimer date was printed on the face of the patent; the date was determined from the expected expiration date of the earlier issued patent based on a seventeen year term measured from grant. When 35 U.S.C. [§] 154 was amended such that all patents (other than design patents) that were in force on June 8, 1995, or that issued on an application that was filed before June 8, 1995, have a term that is the greater of the “twenty year term” or seventeen years from the patent grant, the terminal disclaimer date as printed on many patents became incorrect. If the terminal disclaimer of record in the patent file disclaims the terminal portion of the patent subsequent to the full statutory term of a referenced patent (without identifying a specific date), then the date printed on the face of the patent is incorrect when the full statutory term of the referenced patent is changed as a result of 35 U.S.C. [§] 154(c). That is, the referenced patent’s “twenty year term” is longer than the seventeen year term. In such a case, a patentee may request a Certificate of Correction under 37 CFR 1.323 to correct the information printed on the face of the patent. However, if the terminal disclaimer of record in the patent file disclaims the terminal portion of the patent subsequent to a specific date, without reference to the full statutory term of a referenced patent, then the expiration date is the date specified.

95. See *Bayer*, 298 F.3d at 1380.

96. See *id.* at 1383.

97. *Id.* at 1381.

98. *Id.* (citing *United States v. Cleveland Indians Baseball Co.*, 532 U.S. 200, 220 (2001)).

99. *Id.* (quoting *Dethmers Mfg. v. Automatic Equip. Mfg.*, 272 F.3d 1365, 1379 (Fed. Cir. 2001) (Dyk, J., concurring in part and dissenting in part)).

found that the ‘444 patent was due to the ‘658 patent and not independent of it, despite the fact that a specific date was mentioned in the disclaimer.¹⁰⁰ The PTO’s reasoning was persuasive, if not controlling: “The PTO thoroughly considered the effect of the URAA on this terminal disclaimer and gave persuasive reasons for correcting its records to reflect the December 2003 expiration date for the ‘444 patent.”¹⁰¹ This thorough consideration was enough to support the PTO’s resolution of the ambiguity in favor of the patent being “due to” the previous patents.

The court refused to side with Carlsbad’s application of patent policy, which was that any ambiguity in the terminal disclaimer should be resolved in favor of the public.¹⁰² Carlsbad argued that because the specific date of October 1, 2002, was recited in Bayer’s terminal disclaimer, the public had a right to rely on this date as the date after which it could use the technology in Bayer’s patent.¹⁰³ The court did not necessarily disagree with the policy of providing notice of a patent’s term to the public, but with Carlsbad’s application of such policy. The court said that because the terminal disclaimer had been part of the public record—as it was in the PTO’s written decision—for more than five years, the interested public had ample time to discover when the term of the patent was to expire.¹⁰⁴ Furthermore, the court noted that Bayer had only terminally disclaimed the ‘444 patent’s term in order to overcome an obviousness-type double patenting rejection in light of its ‘658 patent and that the point of this was that the ‘444 patent would be enforced only until the ‘658 patent expired.¹⁰⁵ When the date on which the ‘658 patent expired was automatically adjusted by law, the court reasoned the date of the ‘444 patent should automatically be adjusted as well, seeing as this would accord with the reason for a terminal disclaimer in the first place.¹⁰⁶

C. Merck & Co. v. Hi-Tech Pharmacal Co.—Effects of Terminal Disclaimerson Patent Terms Extended Under the Hatch-Waxman Act

In *Merck & Co. v. Hi-Tech Pharmacal Co.*,¹⁰⁷ the Federal Circuit did not explicitly rely upon the PTO’s rulings, nor did it discuss a greater

100. *Id.* at 1382–83.

101. *Id.* at 1381.

102. *Id.* at 1382.

103. *Id.*

104. *Id.*

105. *Id.*

106. *See id.* at 1382–83.

107. 482 F.3d 1317 (Fed. Cir. 2007).

policy reason behind its decision regarding the relationship between terminal disclaimers and patent term extension under the Hatch-Waxman Act, making it difficult to draw a predictive pattern from these factors such as we might with *Kessler* and *Bayer*.¹⁰⁸ Nonetheless, the analogous facts of *Hi-Tech* are helpful in order to best predict the outcome of our hypothetical in Part II: whether patent B would automatically be granted the term adjustment of patent A, to which B was terminally disclaimed. The hypothetical from Part II involves a patent with a terminal disclaimer and patent term *adjustment*, while the situation in *Hi-Tech* involves a patent with a terminal disclaimer and patent term *extension*.

Hi-Tech differs from both cases described above because the *Kessler* court held that Hatch-Waxman extension could be added onto a patent's term that had already been extended under the URAA, but did not discuss terminal disclaimers.¹⁰⁹ The *Bayer* court held that "a URAA term extension operates to extend the term of the related terminally disclaimed patent as a matter of law[.]" but did not confront Hatch-Waxman extension.¹¹⁰ In contrast, in *Hi-Tech*, the Federal Circuit ruled that patent term extension under the Hatch-Waxman Act could be added onto the term of a second patent that had been terminally disclaimed according to 35 U.S.C. § 253 even though the term of the first patent to which the second patent was disclaimed had been extended under the URAA.¹¹¹ Thus, neither *Bayer* nor *Kessler* was controlling precedent.

Merck's patent in question was U.S. Patent Number 4,797,413 ("the '413 patent"), which had been terminally disclaimed to run only for the term of U.S. Patent Number 4,677,115 ("the '115 patent") in order to overcome an obviousness-type double patenting rejection.¹¹² The term of the '115 patent had been extended under the URAA to end on December 12, 2004.¹¹³ Because the '413 patent's term was "due to" that of the '115 patent, its term also was extended by operation of law to December 12, 2004.¹¹⁴ Merck applied to the PTO and obtained term extension under the Hatch-Waxman Act because part of the term of the '413 patent had been shortened due to time taken in obtaining

108. *See id.*

109. *Id.* at 1323.

110. *Id.* (citing *Bayer*, 298 F.3d at 1381–82).

111. *Id.* at 1324.

112. *Id.* at 1318–19.

113. *Id.* at 1319.

114. *Id.*

regulatory review from the FDA.¹¹⁵ The PTO added term extension onto the date December 12, 2004, making the new date of termination April 28, 2008.¹¹⁶ Hi-Tech Pharmacal Company, wishing to begin production of a generic version of Merck's patented drug, then asserted that it did not infringe Merck's patent because the term of the '413 patent should have ended on December 12, 2004, and Merck could not obtain extension of the terminally disclaimed '413 patent under the Hatch-Waxman Act.¹¹⁷ Merck sued Hi-Tech for infringement and the trial court granted Merck's motion for judgment on the pleadings.¹¹⁸

In deciding that the extension could be applied to the terminally disclaimed '413 patent, the Federal Circuit reasoned that the language of the Patent Act stating that "[t]he term of a patent . . . *shall* be extended in accordance with this section"¹¹⁹ was crucial.¹²⁰ If all of the requirements of § 156 were met, there should be no reason that a patent could not receive term extension. Hi-Tech argued that to grant term extension under § 156 would allow the term of the terminally disclaimed '413 patent to extend beyond that of the '115 patent to which it was linked, and would thus obviate the purpose of a terminal disclaimer.¹²¹ The court disagreed with this reasoning and found Merck's reasoning more persuasive: not only did the language say the term *shall* be extended if all conditions were met, but there was no provision stating that terminally disclaimed patents were to be excluded from the provisions of the Hatch-Waxman Act concerning patent term *extension*.¹²² This was in stark contrast to patent term *adjustment* provisions, which were limited by terminal disclaimers according to § 154(b)(2)(B).¹²³

Thus, with no specific limitation preventing a terminally disclaimed patent from obtaining Hatch-Waxman extension, the Federal Circuit chose to allow it. Furthermore, in response to Hi-Tech's concern that this rule would obviate the purpose of a terminal disclaimer, the court said, "The expiration date of the patent set by the terminal disclaimer

115. *Id.*

116. *Id.*

117. *Id.* at 1319–20.

118. *Id.* at 1320.

119. 35 U.S.C. § 156(a) (2006) (emphasis added).

120. *Hi-Tech*, 482 F.3d at 1321–23.

121. *Id.* at 1321.

122. *See id.* at 1321–22.

123. "No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer." *See* 35 U.S.C. § 154(b)(2)(B) (2006).

remains in place. The computation of a Hatch-Waxman patent term extension is from the expiration date resulting from the terminal disclaimer and not from the date the patent would have expired in the absence of the terminal disclaimer.”¹²⁴ Because the Hatch-Waxman extension was for independent reasons relating to regulatory delays in obtaining the ‘413 patent, it was completely separated from the fact that the patent had been terminally disclaimed to the ‘115 patent for obviousness-type double patenting reasons.¹²⁵

In making its decision, the Federal Circuit ultimately made the same decision that the PTO had already made in its regulations,¹²⁶ but it did not rely on the PTO’s interpretive authority to do so. Instead, the court focused on the plain meaning of the statute¹²⁷ and its legislative history.¹²⁸ The legislative history showed that Congress was aware of the problems that could occur if certain types of related patents gained term extension and that it chose to head off these problems by allowing a patentee to extend the term of his choice of only one of the related patents.¹²⁹ If Congress allowed this choice for certain types of related patents, then it would certainly allow this choice for terminally disclaimed patents, reasoned the court.¹³⁰

124. *Hi-Tech*, 482 F.3d at 1322–23.

125. *See id.* at 1323.

126. 37 C.F.R. § 1.775(a) (2006) allows the PTO to add Hatch-Waxman extension onto the term of terminally disclaimed patent:

If a determination is made pursuant to [37 C.F.R.] § 1.750 [the enabling section corresponding to 35 U.S.C. § 156] that a patent for a human drug, antibiotic drug or human biological product is eligible for extension, the term shall be extended by the time as calculated in days in the manner indicated by this section. The patent term extension will run from the original expiration date of the patent or any earlier date set by terminal disclaimer.

127. *See Hi-Tech*, 482 F.3d at 1322.

128. *See id.* at 1323.

129. *Id.* The patents referenced here are continuing applications that have “parent and child” relationships and are beyond the scope of this Comment. Suffice it to say that the term of a child patent is linked to the term of a parent patent such that its term does not exceed that of the parent. *See supra* part III.B.1; *see also* 35 U.S.C. § 120 (2006); MPEP, *supra* note 22, at § 201.07 (“Continuation Application”).

130. *Hi-Tech*, 482 F.3d at 1323.

IV. LOOKING AT THE FEDERAL CIRCUIT'S DEFERENCE TO THE PTO'S DECISIONS¹³¹

In Part I of this Comment, I noted that it would be much easier to solve the hypothetical posed in Part II if the Federal Circuit consistently treated decisions of the PTO with the same level of deference each time it was presented with an issue on appeal.¹³² However, this is not the case, and thus this Comment described case law concerning patent terms in Part III because this precedent is likely what the Federal Circuit will follow should any case resembling the hypothetical ever reach it. However, because the court does sometimes defer to the PTO, although not with the consistent standards laid out below, it is still worth describing these standards as both (hopefully) normative goals and as rules the court has occasionally relied on in the past.

An obvious dissimilarity exists in the deference with which the Federal Circuit treated the interpretive decisions of the PTO in the three cases in Part III. The *Kessler* court gave no deference to the PTO's decision,¹³³ while the *Bayer* court did.¹³⁴ Meanwhile, the *Hi-Tech* court did not even address the issue of deference.¹³⁵ The history of the Federal Circuit's treatment of the PTO's decisions is convoluted and no clear pattern emerges. Yet it will not suffice to say that the inconsistent deferential treatment of the PTO's decisions is merely typical of the Federal Circuit: a bit more depth is required to predict what the court will do in the future, specifically as regards the hypothetical posed in Part II.

A. General Law Regarding Court-Agency Review

Administrative law allows for judicial review of an agency action in two situations: if a statute expressly authorizes it, or if it is a "final

131. Stuart Minor Benjamin and Arti K. Rai provide a comprehensive look at the history of the Federal Circuit's willingness to defer to the PTO's decisions. Stuart Minor Benjamin & Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 GEO. L.J. 269 (2007). Benjamin and Rai look at *Chevron* and *Skidmore* deference in reference to the PTO's determination of validity of patents and suggest that "realistic changes to the existing process [incorporating the APA standards of review] might be attractive in light of that theory and doctrine." *See id.* at 272.

132. I recognize that the PTO's "decision" right now not to automatically apply the term adjustment of patent A to patent B is not technically a decision, much less a rule. *See supra* note 22. However, it is likely that before this issue reaches the Federal Circuit, it will go through the PTO, which will decide based on this informal rule.

133. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-51 (Fed. Cir. 1996).

134. *Bayer AG v. Carlsbad Tech., Inc.*, 298 F.3d 1377, 1381 (Fed. Cir. 2002).

135. *See generally Hi-Tech*, 482 F.3d at 1317.

agency action for which there is no other adequate remedy in a court.”¹³⁶ Review of the PTO’s actions is not authorized by statute, so any review by the Federal Circuit must be of a final agency action. Final agency action includes agency proceedings such as rulemaking and adjudication, as well as rules, orders, licenses, sanctions, and relief.¹³⁷ The PTO’s actions in the area of terminal disclaimers, patent term adjustment, and patent term extension do not fall neatly into any of these categories.¹³⁸

For example, in *Kessler*, the PTO’s action was labeled a “Final Determination.”¹³⁹ The PTO’s actions in *Bayer* included a “Decision” made in response to a petition under 37 C.F.R. § 1.182¹⁴⁰ and an implementing regulation.¹⁴¹ It is possible to view the “Final Determination” as rulemaking¹⁴² and the implementing regulation as a rule,¹⁴³ made under the grant to the PTO of the power to “establish regulations . . . which . . . govern the conduct of proceedings in the [PTO].”¹⁴⁴ The “Decision,” on the other hand, was made according to regulations that the PTO had implemented to deal with situations more adjudicatory in nature.¹⁴⁵ Although the PTO does not actually call any

136. 5 U.S.C. § 704 (2006).

137. 5 U.S.C. § 551 (2006); *see also* 5–43 JACOB A. STEIN ET AL., ADMINISTRATIVE LAW § 43.01 (2009); Kali Murray, *First Things, First: A Principled Approach to Patent Administrative Law*, 42 J. MARSHALL L. REV. 29, 57 (2008).

138. *See* Murray, *supra* note 137, at 57–58. Murray lists the PTO’s decision-making actions as:

(1) the examination of patent application by patent examiners; (2) the conduct of interference between two patent applicants; (3) the review of examination and interference proceedings before the BPAI; (4) the ability to restore patent term under the Hatch-Waxman Act; (5) the ability to conduct a review of reissued patents, terminal disclaimers, and certificate of corrections issued for agency and patentee mistakes; and (6) the conduct of *ex parte* reexamination and optional *inter partes* proceedings.

Id. at 58 (citation omitted). Only (4) and (5) concern us here.

139. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1548 (Fed. Cir. 1996).

140. *Bayer AG v. Carlsbad Tech., Inc.*, 298 F.3d 1377, 1379 n.* (Fed. Cir. 2002).

141. *Id.* at 1380.

142. The PTO set forth several choices for the interaction between the Hatch-Waxman extension and the new term adjustment under the URAA, asked for comments from the public, and eventually made a determination of the new rule. Determination of New Expiration Dates of Certain Patents, 60 Fed. Reg. 30,068, 30,069 (June 7, 1995).

143. These regulations were codified in 37 C.F.R. pts. 1 & 3. Changes to Implement 20-Year Patent Term and Provisional Applications, 60 Fed. Reg. 20,195 (Apr. 25, 1995).

144. 35 U.S.C. § 2(b)(2) (2006).

145. *See* 37 C.F.R. § 1.181 (2008) (allowing applicants to take petition to the Director “[f]rom any action or requirement of any examiner in the *ex parte* prosecution of an application, or in the *ex parte* or *inter partes* prosecution of a reexamination proceeding which

of these actions rulemakings, rules, or adjudications—and although the PTO’s actions do not truly fit any of those categories¹⁴⁶—it is still safe to say that actions like these are reviewable by the courts. Moreover, the *Kessler* and *Bayer* courts did actually review these actions, suggesting that the Federal Circuit would be likely to do so again.

To further complicate the matter, once an agency’s action is deemed judicially reviewable, there are varying levels of deference that a court can give the agency’s actions. Basically, an agency can make three types of findings: findings of fact, law, and policy. First, the PTO’s findings of fact are to be reviewed according to the standards set forth in the Administrative Procedure Act.¹⁴⁷ Section 706 of this Act calls for review of facts found during an informal proceeding according to an “arbitrary, capricious, [or] an abuse of discretion”¹⁴⁸ standard. Review of facts found during a formal proceeding is according to a standard of whether or not the facts are “unsupported by substantial evidence.”¹⁴⁹

Second, legal findings are to be reviewed according to *United States v. Mead Corp.*,¹⁵⁰ and accorded varying degrees of deference based on whether or not Congress has delegated rulemaking authority to the agency.¹⁵¹ *Mead* states that if Congress does not delegate rulemaking authority to the agency, then the rule laid out in *Skidmore v. Swift & Co.*¹⁵² applies.¹⁵³ According to *Skidmore*, “The weight [accorded to an administrative] judgment in a particular case will depend upon the

is not subject to appeal to the Board of Patent Appeals and Interferences or to the court”); § 1.182 (“All situations not specifically provided for in the regulations of this part will be decided in accordance with the merits of each situation by or under the authority of the Director . . .”).

146. “[R]ule’ means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency . . .” 5 U.S.C. § 551(4) (2006). “[R]ule making’ means agency process for formulating, amending, or repealing a rule.” 5 U.S.C. § 551(5). “[A]djudication’ means agency process for the formulation of an order.” 5 U.S.C. § 551(7).

147. *Dickinson v. Zurko*, 527 U.S. 150, 161 (1999). The *Dickinson* Court did not decide whether the findings of the PTO were informal or formal findings of fact, but the Federal Circuit in decided that the “substantial evidence” standard would apply. *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000) (“Because our review of the [Patent and Trademark Office Board of Patent Appeals and Interferences] decision is confined to the factual record compiled by the Board, we accordingly conclude that the ‘substantial evidence’ standard is appropriate for our review of Board factfindings.”).

148. 5 U.S.C. § 706(2)(a) (2006).

149. 5 U.S.C. § 706(2)(e) (2006).

150. 533 U.S. 218 (2001).

151. *See id.* at 227–28.

152. 323 U.S. 134, 140 (1944).

153. *See Mead Corp.*, 533 U.S. at 227–28.

thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.”¹⁵⁴ On the other hand, if Congress does delegate rulemaking authority to the agency, then the rule laid out in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.* applies. According to *Chevron*, the court should give much more deference to the interpretations of an agency with rulemaking powers and should only review its decision for reasonableness.¹⁵⁵

The greatest rulemaking power that the Commissioner of the PTO has is to “promulgate regulations directed only to ‘the conduct of proceedings in the [PTO].’”¹⁵⁶ Because the PTO does not have substantial rulemaking powers,¹⁵⁷ it is likely that all its legal decisions are entitled to is *Skidmore* deference from the Federal Circuit.¹⁵⁸

A different standard is to be applied when the court reviews an agency’s interpretation of its *own* rules and regulations. According to *Bowles v. Seminole Rock & Sand Co.*, these types of interpretations are to be given *substantial* deference.¹⁵⁹ Nonetheless, the Federal Circuit has been reluctant to apply this standard to its review of PTO decisions, even after the Supreme Court made it clear in *Dickinson v. Zurko*¹⁶⁰ that the standards of the Administrative Procedure Act apply to the Federal Circuit in reviewing the PTO.¹⁶¹

For example, in *Dethmers Manufacturing Co. v. Automatic*

154. *Id.* at 228 (quoting *Skidmore*, 323 U.S. at 140).

155. *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984).

156. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996) (quoting 35 U.S.C. § 6(a) (1988)). This ability of the Patent Office to make its own rules is now provided for in 35 U.S.C. § 2(b)(2) (2006) (“The Office . . . may establish regulations, not inconsistent with law, which . . . shall govern the conduct of proceedings in the Office.”).

157. *See, e.g.*, *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991)); *Tafas v. Dudas*, 541 F. Supp. 2d 805, 813 (E.D. Va. 2008) (“[T]he USPTO does not have the authority to issue substantive rules, and it does not have the authority to make substantive declarations interpreting the Patent Act.” (citing *Kessler*, 80 F.3d at 1549–50)). The Federal Circuit agreed with this statement in *Tafas v. Doll*, 559 F.3d 1345, 1352 (Fed. Cir. 2009).

158. *See Murray*, *supra* note 137, at 45–46 (outlining the benefits of using *Skidmore* deference even to agency rulemaking by the PTO).

159. 325 U.S. 410, 414 (1945) (holding that “the ultimate criterion” for judicial construction of an unclear agency regulation “is the administrative interpretation, which becomes of controlling weight unless it is plainly erroneous or inconsistent with the regulation”).

160. 527 U.S. 150, 160–61 (1999).

161. *Id.*; *see also Dethmers Mfg. Co. v. Automatic Equip. Mfg. Co.*, 272 F.3d 1365, 1378–79 (Fed. Cir. 2001) (Dyk, J., concurring in part and dissenting in part); *supra* text accompanying note 147.

Equipment Manufacturing Co.,¹⁶² a majority of the Federal Circuit refused to give deference to the PTO's interpretation of its own rule, instead relying on Federal Circuit case precedent interpreting the PTO's rule, and conducted a *de novo* review based on this interpretation.¹⁶³ The dissent in *Dethmers* cried foul at the majority's decision to ignore the rule set out in *Dickinson* and argued that *Bowles* and *United States v. Cleveland Indians*¹⁶⁴ controlled.¹⁶⁵

Third and finally, a court reviewing findings of policy should apply the standards of the Administrative Procedure Act if no standard of review is provided in the statute granting the agency policymaking power: the court reviews to see if the policy decision was “‘arbitrary, capricious, [or] an abuse of discretion.’”¹⁶⁶ However, the Federal Circuit usually reviews the PTO's policy decisions in a manner that treats them as decisions of fact or law, sometimes combined with policy.¹⁶⁷

B. Specifics Regarding the Federal Circuit and the PTO

Of course, it often happens that the decisions the PTO makes are not clear-cut findings of law, fact, or policy, but rather a mixture of two or all three. For example, look at *Kessler* and *Bayer*. The *Kessler* court dealt with a “Final Determination” of the PTO in its interpretation of the effects of § 154 on patents already extended under § 156.¹⁶⁸ This is then the PTO's legal finding regarding two federal statutes, and as the PTO has no rulemaking power under § 154, its finding is entitled to *Skidmore* deference.¹⁶⁹ However, *Kessler* was decided before *Mead*, so the Federal Circuit did not at that time have the Supreme Court's clarification regarding the level of deference due to the PTO's legal finding.¹⁷⁰ Somehow, the *Kessler* court nonetheless applied the correct

162. *Id.*

163. *See id.* at 1369–70.

164. *United States v. Cleveland Indians Baseball Co.*, 532 U.S. 200, 220 (2001) (“Because that [agency's] interpretation is reasonable, it attracts substantial judicial deference.”).

165. *Dethmers*, 272 F.3d at 1378–79 & n.1 (Dyk, J., concurring in part and dissenting in part).

166. *See Interstate Commerce Comm'n v. Bhd. of Locomotive Eng'rs*, 482 U.S. 270, 278–79 (1987) (quoting 5 U.S.C. § 706(2)(A) (2006)); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Ins. Co.*, 463 U.S. 29, 43 (1983).

167. *See, e.g., In re Bogese*, 303 F.3d 1362, 1366 (Fed. Cir. 2002); *In re McDaniel*, 293 F.3d 1379, 1382 (Fed. Cir. 2002).

168. *See Determination of New Expiration Dates of Certain Patents*, 60 Fed. Reg. 30,069, 30,069–71 (June 7, 1995). The PTO determination was in response to a public hearing it had held regarding the effects of these two statutes upon one another. *Id.* at 30,069.

169. *See supra* text accompanying notes 156–158.

170. Benjamin and Rai would argue that even if the Federal Circuit had *Mead* to rely on,

standard when it refused to rely at all on the PTO's decision, noting *Chevron* and a Seventh Circuit decision¹⁷¹ in support of its ruling that only agencies with rulemaking powers deserved deference.¹⁷² The *Kessler* court further relied on *Skidmore* (which would later be ruled appropriate according to *Mead*), although only fortuitously, when it stated that it would defer to the PTO's decision only if it had the "basic power to persuade."¹⁷³ The *Kessler* court, however, did not go on to look at the "thoroughness evident in [the PTO's] consideration, the validity of its reasoning, [or] its consistency with earlier and later pronouncements."¹⁷⁴ Rather, without even mentioning the extensive discussion of this issue that the PTO undertook in a process that allowed for comments from the public,¹⁷⁵ the *Kessler* court relied instead solely upon the legislative history behind the statutes to make its decision.¹⁷⁶

In *Bayer*, interpretation and application of both a federal statute (35 U.S.C. § 154) and the PTO's own regulations (37 C.F.R. § 1.182)¹⁷⁷ was at issue. The Federal Circuit affirmed the district court's application of *Skidmore* deference to the PTO's decisions on both § 154 and section 1.182.¹⁷⁸ Thus, the *Bayer* court arguably applied the correct level of deference (i.e., *Skidmore* deference) to the PTO's rulings on federal law concerning 35 U.S.C. § 154 and automatic adjustment of patent term according to the URAA.¹⁷⁹ On the other hand, the findings of law on 37 C.F.R. § 1.182 as to whether it was appropriate for the PTO to change the expiration date of the terminally disclaimed patent regarded the PTO's own rules and regulations, and more deferential treatment was in order according to *Bowles*.¹⁸⁰ The Federal Circuit did cite the *Dethmers*

it still would not have accorded the PTO's decision any deference. See Benjamin & Rai, *supra* note 131, at 299–300 nn.159–62.

171. *Atchison, Topeka & Santa Fe Ry. Co. v. Pena*, 44 F.3d 437, 441 (7th Cir. 1994).

172. See *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549 (Fed. Cir. 1996).

173. *Id.* at 1550 (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

174. This is the language the *Skidmore* Court used to describe the type of review that should be undertaken. See *Skidmore*, 323 U.S. at 140.

175. See *Determination of New Expiration Dates of Certain Patents*, 60 Fed. Reg. 30,069, 30,069–71 (June 7, 1995).

176. See *Kessler*, 80 F.3d at 1550–51; see also *supra* notes 64–67 and accompanying text.

177. 37 C.F.R. § 1.182 (2008) allows the PTO to address "questions not specifically provided for." See *supra* note 90 and accompanying text.

178. *Bayer AG v. Carlsbad Tech., Inc.* 298 F.3d 1377, 1381 (Fed. Cir. 2002) ("The district court properly accorded deference to the to the [sic] PTO's implementing regulations and to the PTO's interpretative 'Decision', which it found complied with 35 U.S.C. §§ 154 (a)(2) and (c)(1), in accordance with *Skidmore v. Swift & Co.*"); see also Benjamin & Rai, *supra* note 131, at 300 n.162.

179. See *supra* text accompanying notes 155–59.

180. See *Murray*, *supra* note 137, at 45–46.

dissent in its opinion,¹⁸¹ but it did not explicitly say that it was granting substantial deference to only the PTO's decision concerning section 1.182. The court's opinion instead mixed *Cleveland Indians* law and the *Dethmers* citation (and remember this was a citation to the *dissenting* opinion!) with *Skidmore* law, which should have been applied only to the PTO's interpretations of federal law concerning the effect of 35 U.S.C. § 154, not the findings concerning 37 C.F.R. § 1.182.¹⁸² In all, the deference the *Bayer* court gave to the PTO was extremely messy in its application. In the *Bayer* court's defense, it would be very difficult to separate out the findings of law, fact, and policy in this case and accord them each the correct amount of deference in turn.¹⁸³

Thus, we see that the Federal Circuit has given the PTO's decisions varying degrees of deference in the past. This deference has often been of the wrong degree, or if of the right degree, only incidentally rather than purposefully. Therefore, application of the standards of deference ideally due to the PTO has been mixed and messy. If the Federal Circuit were to ascertain and consistently apply a certain level of deference to the PTO's decisions according to the Administrative Procedure Act and the case law interpreting the Act, this might enable better prediction of the Federal Circuit's holdings in the future.

V. APPLICATION TO THE HYPOTHETICAL IN PART II

Finally, we come to the hypothetical posed in Part II: if patent B is terminally disclaimed to patent A for obviousness-type double patenting reasons, and patent A's term is adjusted under § 154 for delays caused by the PTO, can patent B automatically gain the benefit of patent A's patent term adjustment? Before applying case precedent to the hypothetical however, a review of the trends in case precedent is in order.

TABLE 3: RE-CAP OF CASE PRECEDENT

Case	Holding	Deference to	Legislative History	Policy
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181. *Bayer*, 298 F.3d at 1381. Recall Justice Dyk argued that *Bowles'* level of review (substantial deference) applied to such findings. *Dethmers Mfg. Co. v. Automatic Equip. Mfg. Co.*, 272 F.3d 1365, 1378–79 & n.1 (Fed. Cir. 2001) (Dyk, J., concurring in part and dissenting in part).

182. *See Bayer*, 298 F.3d at 1381.

183. Even if the Federal Circuit had separated out the different types of determinations, according to Benjamin and Rai, it might still not have applied the correct standard of deference. *See Benjamin & Rai, supra* note 131, at 299–300. The fact that the Federal Circuit referenced *Skidmore* at all seems to be an anomaly. *See id.* at 300 n.162. The same goes for the *Merck* court's refusal to extend *Chevron* deference to the PTO's findings of law. *See id.* at 299 n.157 and accompanying text.

		PTO		
<i>Kessler</i>	§ 156 Hatch-Waxman term extension allowed on top of term “extension” (§ 154) under the URAA	refuses to apply <i>Chevron</i> deference, but does not explicitly apply <i>Skidmore</i>	limitation was connected to the limitation that the same patent could not have its term extended twice under Hatch-Waxman Act ¹⁸⁴	beneficial to consumers to get generic drug into the market quickly after patent expires ¹⁸⁵
<i>Bayer</i>	a patent’s term that was “due to” another patent’s term by a terminal disclaimer could be “extended” under the URAA (§ 154)	applies mix of <i>Skidmore</i> , <i>Cleveland Indians</i> , and dissenting opinion from <i>Dethmers</i>	relies on Senate Report No. 103-412, at 229 (1994) stating difference between “due to” and “independent of” terminal disclaimers ¹⁸⁶	ambiguity in terminal disclaimer does not harm public because it was recorded according to the law then in effect ¹⁸⁷
<i>Hi-Tech</i>	§ 156 Hatch-Waxman extension can be added on to the term of a terminally disclaimed patent	no discussion of PTO’s power	Congress allows for choice of which patent in a group of related patents will obtain extension ¹⁸⁸	extension of a terminally disclaimed patent does not ignore the waiver of term that the terminal disclaimer was meant to effect ¹⁸⁹

A. Predicting the Degree of Deference Due to the PTO

Because the degree of deference that the Federal Circuit has been willing to grant decisions of the PTO has been so varied, it is difficult to tell what deference the court will give in any situation. Remarkably, the court seems to have applied the correct standard in both *Kessler* and *Bayer*,¹⁹⁰ but some argue that the Federal Circuit has applied an incorrect standard in far more instances.¹⁹¹ According to both *Kessler* and *Bayer*, the Federal Circuit would be most likely to apply *Skidmore* deference, even if the court did not label it as such.

Skidmore deference is also correct per administrative procedure law. In our hypothetical, the PTO’s interpretation of the Patent Act is not an official policy or rule; it is only guidance that the PTO gives to patentees who happen to find themselves with patents fitting the hypothetical.¹⁹² Likely, such a advice will be entitled to only *Skidmore* deference, as it

184. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550–51 (Fed. Cir. 1996).

185. *See id.* at 1546–47.

186. *Bayer*, 298 F.3d at 1382.

187. *See id.*

188. *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1323 (Fed. Cir. 2007).

189. *Id.* at 1322–23.

190. *See supra* Part IV.

191. *See Benjamin & Rai, supra* note 131, at 301.

192. *See supra* text accompanying note 22.

best fits a finding of law concerning 35 U.S.C. §§ 154 and 253 without any support of PTO rulemaking power.¹⁹³

However, if the PTO's stance were accorded *Skidmore* deference, this would create complications. We have no way of knowing whether the court will think that the PTO's view is valid in its reasoning, thorough, or consistent with its earlier interpretations of law.¹⁹⁴ For example, in *Kessler*, the court did not follow the PTO's interpretive decision because it felt that the decision lacked the power to persuade.¹⁹⁵ In contrast, in *Bayer*, the court was willing to rule in the same way as the PTO because the court found the PTO's decision to be well thought out and persuasive.¹⁹⁶ Because *Skidmore* deference is not really deference at all, it allows the Federal Circuit to decide the issue basically *de novo*. Further, we have no guarantee that the court would apply *Skidmore* deference in the first instance, even if this degree of deference is the correct degree due. In fact, the majority law from *Dethmers* indicates that applying case precedent with *no* deference to the PTO is something the Federal Circuit is likely to do anyhow.¹⁹⁷

193. See *supra* text accompanying notes 157–59.

194. See *Skidmore v. Swift*, 323 U.S. 134, 140 (1944).

195. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996).

196. *Bayer AG v. Carlsbad Tech., Inc.*, 298 F.3d 1377, 1381 (Fed. Cir. 2002).

197. *Dethmers Mfg. Co. v. Automatic Equip. Mfg. Co.*, 272 F.3d 1365, 1369–70 (Fed. Cir. 2001) (applying case precedent for the interpretation of a rule as it was interpreted in *Nupla Corp. v. IXL Mfg. Co.*, 114 F.3d 191, 193 (Fed. Cir. 1997) and in *In re Constant*, 827 F.2d 728, 729 (Fed. Cir. 1987)).

B. Predicting Based on Case Precedent

In both of the above-predicted cases, it is still prudent to look at case precedent and draw analogies between similar facts and policies culled therefrom. If the Federal Circuit chooses to apply *Skidmore* deference to the PTO's interpretation of law, then it will still need to determine whether the PTO's reasoning was valid, which can only be done by a comparison to interpretations of law by the Federal Circuit itself. Moreover, if the Federal Circuit decides that no deference is due to the PTO, in the fashion of *Dethmers*, then the court will also need to rely on case precedent to reach an outcome. Either way, we must compare and contrast the hypothetical above with the facts and policies sifted from the holdings of case precedent.

Recall that in *Kessler*, the court was willing to allow term extension under the Hatch-Waxman Act in addition to term "extension" under the new post-URAA § 154.¹⁹⁸ In the case of our Part II hypothetical, this willingness to grant longer patent term points to allowing B the windfall of A's term adjustment. If the *Kessler* court was willing to add extension under the Hatch-Waxman Act on top of extension under the URAA, despite the PTO's interpretive decision to the contrary, this might mean the court would be willing to go against the PTO's position in limiting patent term adjustment to only patent A and not automatically to patent B. On the other hand, "extension" under the URAA is meant to apply to all patents that issued within a certain timeframe and to aid the shift between the old and new law governing patent term.¹⁹⁹ That law was to apply to all qualifying patents, unlike patent term adjustment, which technically applies to only the patent affected by delay in the examination process.

In *Bayer*, the court ruled that the URAA extension, for patents that fell into the special zone where a twenty-year-from-filing term was longer than a seventeen-year-from-issue term, was automatically applied to all eligible patents.²⁰⁰ This was the same outcome that the PTO had reached in determining that the second patent was "due to" the first, and not "independent of" it, and thus could have its term extended.²⁰¹ Were the court to decide that patent B in our hypothetical does not automatically deserve the term adjustment of patent A, it would be following a valid PTO interpretation: it was patent A that the PTO delayed in examining, not patent B. Patent B should not gain a windfall

198. *Kessler*, 80 F.3d at 1550.

199. *See Bayer*, 298 F.3d at 1380.

200. *Id.* 298 F.3d at 1381.

201. *See id.* at 1379.

from the delay in issuance of patent A. On the other hand, if term “extension” under the URAA applies to both the first and second patents,²⁰² maybe term adjustment should apply to both as well. Allowing a windfall term for B would not truly increase the patentee’s monopoly because the two patents were closely related enough to require a terminal disclaimer in the first place. The patentee is already giving up term on B by disclaiming it to A, so he should get, in return, extra term on B as well.

Maybe one can look at the “independent of” and “due to” issue discussed in *Bayer* in a different way. It could be said that all “due to” terminal disclaimers are *really* “due to” the term of the first patent. According to such a plain meaning interpretation, the terminally disclaimed patent might be entitled to the extra term that the first patent lost. The language of a terminal disclaimer supports this interpretation:

The owner . . . of . . . the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number ____, filed on ____, as such term is defined in 35 U.S.C. [§] 154.²⁰³

The “full statutory term . . . as such term is defined in 35 U.S.C. 154” could very well mean the twenty-year term accorded by 35 U.S.C. § 154(a)(2) *plus* the patent term adjustment provided for in 35 U.S.C. § 154(b). Both provisions are included in § 154, and read literally, this is all the wording of the terminal disclaimer mandates. No other statute prevents this interpretation of the terminal disclaimer, seeing as it would not extend B’s term *beyond* that of A’s, only extend B’s term *up to* that of A’s.²⁰⁴

Perhaps *Hi-Tech* is the closest analogous case because it deals with terminal disclaimers and the lengthening of patent term. The court in this case allowed Hatch-Waxman extension of a terminally disclaimed patent.²⁰⁵ However, the court allowed it for only the second patent (in our hypothetical, B) and did not address whether it would be allowed for the first patent (in our hypothetical, A) as well. The court did cite

202. *See id.* at 1382–83.

203. PTO form SB-0025, *available at* <http://www.uspto.gov/web/forms/sb0025.pdf>; *see also supra* text accompanying note 18.

204. *See* 35 U.S.C. § 154 (b)(2)(B).

205. *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1324 (Fed. Cir. 2007).

legislative history showing Congress wanted to allow extension of only one patent out of a parent-child relationship,²⁰⁶ but these types of patents do not have exactly the same policy behind them as terminally disclaimed patents have.

Continuing applications with parent-child relationships are usually used to obtain a patent based on a disclosure in a prior application.²⁰⁷ A patentee will use a continuing application in order to get an earlier filing date so that he can pre-date a prior art reference or so that a statutory bar of 35 U.S.C. § 102 does not prevent him from obtaining a patent.²⁰⁸ Thus, a patentee will use a continuing application to his own benefit without being asked to do so by the PTO.

A terminal disclaimer, on the other hand, is something the PTO asks of the patentee. Yet, it is to the patentee's benefit in that his second application is more likely to be issued (otherwise it would have been obvious in light of his first application).²⁰⁹ He does not get an earlier filing date like the patentee of patents related by parent-child status. He accepts the trade-off of a shorter term in order to ease the patenting process. A patentee of a continuing application who purposefully wanted his patent's term to begin earlier for reasons of patentability might be expected to confine any patent term adjustment to just one patent. The same might not be expected of a patentee who begrudgingly files a terminal disclaimer because the PTO fought him on obviousness.

C. Predicting Based on Legislative History

There is not much legislative history concerning § 154 and its intersection with the law of terminal disclaimers. Because the court in all three seminal cases dealing with extension, adjustment, and terminal

206. *See id.* at 1323.

207. Continuations are used when a second patent contains the same disclosure as the first patent, with no new matter added. Continuations-in-part are used for the same disclosure, but with new matter added. Claims in the second application that are directed toward the new matter cannot have the filing date of the first application. Divisional applications are used when one disclosure describes two different inventions and the PTO has asked that the applicant split the inventions into two separate applications. *See generally* CHISUM, *supra* note 75, at § 13.03.

208. This section covers novelty and loss of rights of the patentee. *See* 35 U.S.C. § 102 (2006). The idea behind § 102 is to prevent there being two patents for the same invention. *See id.* Also, § 102 prevents a patentee from selling his invention to the public for a long period of time before he applies for a patent, which would mean he had a monopoly over his invention for a period of time longer than just the term of his patent (seeing as he was the only one with the knowledge of how to make and use his invention during that period before disclosure of his invention in a published patent application). *See* § 102(b).

209. *See supra* Part III.B.1.

disclaimers has been willing to examine legislative history, however, it is still worth consideration. The one notable event in the legislative history is the change in § 154(b) from the way it was prior to November 29, 1999, which is when the Act allowing patent term adjustment for PTO delays was enacted, to the way it is now.²¹⁰ Section 154(b) used to have a provision stating that any patent that had been terminally disclaimed to another patent could not gain patent term adjustment for any time delay caused by appellate review of the examiner's determination of patentability.²¹¹ Now, however, a patent can gain adjustment even if it is terminally disclaimed; it just cannot have its term extended beyond the date in the disclaimer.²¹² This change could show a shift in legislative intent to be more lenient in allowing adjustment of terminally disclaimed patents' terms—in favor of giving B the term adjustment of A—but this is only conjecture based on skimpy legislative history.

D. Predicting Based on Policy

Policy rationales behind the Federal Circuit's decisions are also not extremely helpful in predicting the court's holding on the above hypothetical because they are conflicting. In *Kessler*, the court found a policy of quickly providing a less expensive product to consumers an important factor in its decision.²¹³ This would point to not allowing B the term adjustment of A, because allowing the adjustment would extend the monopoly over a first invention according to patent A and a separate second invention according to patent B. On the other hand, one could argue that if the patents were closely related enough to require a terminal disclaimer in the first place for obviousness-type double patenting reasons, then this is not granting too much more

210. Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. 56,366, 56,366 (Sept. 18, 2000) (detailing the enactment date and effective date of the American Inventors Protection Act of 1999, Pub. L. 106-113, 113 Stat. 1501 (1999)).

211. See 35 U.S.C. § 154(b)(2) (1994), which reads:

EXTENSION FOR APPELLATE REVIEW.—If the issue of a patent is delayed due to appellate review by the Board of Patent Appeals and Interferences or by a Federal court and the patent is issued pursuant to a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended for a period of time but in no case more than 5 years. A patent shall not be eligible for extension under this paragraph if it is subject to a terminal disclaimer due to the issue of another patent claiming subject matter that is not patentably distinct from that under appellate review.

212. 35 U.S.C. § 154(b)(2)(B) (2006).

213. See *Merck & Co. v. Kessler*, 80 F.3d 1543, 1546–47 (Fed. Cir. 1996).

market power to the patentee.²¹⁴

In *Bayer*, the court addressed the policy behind notice to the public of when a patent's term is due to expire.²¹⁵ Because the PTO has decided that patent B cannot gain the patent term adjustment of patent A automatically,²¹⁶ and many have probably relied on this interpretation of law for a while, the court might be loathe to disagree with the PTO's view. Doing so would mean reconfiguring many patent docketing systems and would require many who rely on being able to make and use the patented technology for their own benefit after a certain expiration date to revisit their future plans.

The policy regarding a terminal disclaimer as a waiver of patent term was considered by the *Hi-Tech* court.²¹⁷ In our hypothetical, the patentee did agree that his application for B was obvious according to patent A, and that it would be unfair for him to have a longer monopoly over very similar technology covered by B solely because he filed B later than A. In fact, he openly dedicated the term of B that extended beyond the term of A to the public.²¹⁸ The *Hi-Tech* court noted that one reason it would allow § 156 extension after the date to which a patent is terminally disclaimed was because that patent itself had been affected by regulatory delays.²¹⁹ In our hypothetical, however, it was A that the PTO delayed in examining, not B. There would be no policy reason according to *Hi-Tech*, then, to allow B the windfall extra term of A.

214. See *supra* text accompanying notes 19 and 26.

215. See *Bayer AG v. Carlsbad Tech., Inc.*, 298 F.3d 1377, 1382 (Fed. Cir. 2002).

216. See *supra* text accompanying note 22.

217. See *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1322–23 (Fed. Cir. 2007).

218. See *supra* text accompanying note 203.

219. See *Hi-Tech*, 482 F.3d at 1323.

VI. CONCLUSION

There is no real conclusion to the hypothetical above. Even if the court discussed the ideal level of deference due to the PTO's view on the hypothetical, the court is likely to re-evaluate the interaction between patent term adjustment and terminal disclaimers itself. Based on case precedent, the court most likely would rule that the term adjustment of A does not automatically apply to B. Legislative history in this area is scant and of little to no help. In addition, policy considerations show that B's term is likely not to be extended automatically to that of A's: this would increase the length of a monopoly over two inventions rather than just one; the public has been relying on the PTO's current calculation of patent term; and the patentee has dedicated the end portion of patent B to the public and cannot go back on this dedication. On the other hand, the court might reason that the patentee's monopoly is not extended very much by adjusting the term of the second patent that was linked to the first only because they were so closely related in the first place.

With a plethora of terminally disclaimed patents and patents with term adjustment, there are many patents in force that encounter the situation posed in the Part II hypothetical. Nevertheless, a case such as this may never appear before the PTO or the Federal Circuit. Patentees may go on following the PTO's advice that B's term ends when A's term originally would have ended²²⁰ ad infinitum if no one ever questions such advice. It is this idea that leads this Comment to question whether the decisions of the PTO are being given deference in an ad hoc manner by the Federal Circuit. It is frustrating that the Federal Circuit does not treat the PTO's decisions uniformly: the Federal Circuit sometimes sides with the PTO's interpretations and sometimes sides against the PTO's interpretations.

As this Comment has shown, this ad hoc treatment is sometimes due to policy, sometimes to legislative history, and sometimes simply to what the Federal Circuit thinks is a reasonable interpretation of the statute. This inconsistency does not provide certainty for patentees, prosecutors, litigators, infringers, licensees, or consumers, all of whom rely on a patent's term in making their plans. Perhaps a uniform rule is in order, such as a comprehensive law that describes the effect of each type of disclaimer, adjustment, and extension on one another. Even if the only change is that the Federal Circuit begins consistently giving deference to the PTO's decisions, as it should under *Skidmore* or *Bowles*, then it

220. See *supra* text accompanying note 22.

would be much easier for patentees to plan according to the PTO's interpretations because they would know the likely outcome if an issue such as that posed in the Part II hypothetical ever reached the Federal Circuit.

EMILY M. HINKENS*

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