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Adjustments, Extensions, Disclaimers, and Continuations: When Do Patent Term Adjustments Make Sense?

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ADJUSTMENTS, EXTENSIONS, DISCLAIMERS, AND CONTINUATIONS: WHEN DO PATENT TERM ADJUSTMENTS MAKE SENSE?

STEPHANIE PLAMONDON BAIR

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I. INTRODUCTION

The United States patent system represents a measured trade-off between two competing policy considerations: providing sufficient incentives to encourage the innovation and development of new and socially useful inventions; and ensuring that such inventions are readily available to the public at an affordable price. From 1861 to 1995, this trade-off was achieved by granting the owner of a patent a seventeen-year term of exclusivity to market the patented product. Congress deemed this period to be sufficiently long for inventors to recoup their research and development costs and to earn a profit, while not depriving the public of affordable versions of inventions for an inordinate duration. In 1995, the patent term was modified to twenty years from the earliest date of patent filing in accordance with the Uruguay Round Agreements Act (URAA) to achieve uniformity among patent terms internationally.

Although the default patent term is now twenty years from filing, various features of, and changes to, the patent system over the years have allowed patent owners potentially to extend the duration of their patent monopolies, sometimes for several years. Such extensions, although seemingly insignificant when compared to the full patent term, have an enormous impact on patent holders, their competitors, and the public. In

3 This assumption has been criticized. E.g., Eric E. Johnson, Calibrating Patent Lifetimes, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 269, 283 (2006).
some cases, an extension merely corrects a deficiency in the patent balancing system and ensures equilibrium between incentives and access.\footnote{The Hatch-Waxman extension arguably achieves this goal in the pharmaceutical industry, where regulatory review periods often significantly truncate patent terms in an industry where research and development costs are high. \textit{See, e.g.}, Colleen Kelly, \textit{The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond}, \textit{66 FOOD \\& DRUG L.J.} 417, 418 (2011).} In other cases, however, an extension may result in a socially harmful enlargement of the patent holder’s monopoly, allowing the patentee to collect a windfall beyond what was necessary to incent the invention’s development, while stifling competition and depriving the public of affordable access to the invention.\footnote{\textit{See} Kenneth W. Dam, \textit{The Economic Underpinnings of Patent Law}, 23 \textit{J. LEGAL STUD.} 247, 248 (1994).} In all cases—whether justified according to the patent balancing formula—these extensions delay competition and access while introducing uncertainty about the expiration of the patent. It is thus beneficial to distinguish situations where extensions are justified to provide adequate research and development incentives from situations where extensions are not justified.

Unfortunately, a systematic parsing of socially valuable and socially harmful extensions has not been undertaken because the various opportunities for a patent term extension have arisen in a piecemeal fashion. Due to the evolution of the patent system, a patent may be eligible for several extensions concurrently. Rather than conducting a holistic analysis, the United States Patent and Trademark Office (USPTO) and the Federal Circuit have addressed each potential extension situation as it has arisen. Underlying each evaluation, analyses have variously relied on policy considerations, statutory interpretation, administrative deference, or a combination of these factors.\footnote{\textit{See, e.g., Emily M. Hinkens, Patent Term Adjustment and Terminal Disclaimers: Are the Terms of Patents Being Decided Ad Hoc?}, 94 \textit{MARQ. L. REV.} 375, 413 (2010).} This has led to a complex set of rules governing patent extensions that has been criticized as having arisen ad hoc, without a systematic evaluation of potential policy implications.\footnote{\textit{Id.}}

This Article clarifies the current law governing the various forms of patent extensions and their interactions, and evaluates this law from a policy perspective. Part II explains the various situations where a patentee may extend the patent term and the current state of the law applicable to each of these situations. Part III examines the advent of each of these rules, including any relevant Federal Circuit decisions, and asks whether
the rules and any justifications for these rules are consistent with a proper balancing of incentives to innovate with competition and public access. This Article concludes that although the Federal Circuit’s reasoning in cases involving patent extensions can indeed be characterized as ad hoc, the court’s holdings in these cases mostly promote the goals of the patent system. Further, for those situations not yet litigated before the Federal Circuit, the USPTO has been relatively successful in instituting practices that promote the goals of the patent system, with a few notable exceptions. Part IV concludes by suggesting some modifications to the current law that will better align the rules for patent expiration adjustments with the goals of the patent system. The part also suggests that, when appropriate, the Federal Circuit should give due deference to current USPTO regulations and practice.

II. OPPORTUNITIES FOR ADJUSTING THE PATENT TERM

A. The Uruguay Round Agreements Act

The most straightforward opportunity to extend the duration of a patent was made available to patent holders subsequent to the passing of the URAA in 1994. The URAA made changes to U.S. patent law contemplated in the Trade Related Aspects of Intellectual Property Rights Convention (TRIPs) signed by the United States and other World Trade Organization members. Many provisions of TRIPs were drafted with the goal of harmonizing diverse international patent law regimes. In particular, to advance this goal, the URAA changed the duration of the patent term in the United States from seventeen years from the date of patent issue (where it had remained consistently since 1861) to twenty years from the date of earliest filing of a patent application. Under the URAA, any patent application filed after June 8, 1995, is given a default term of twenty years calculated from the earliest date of filing.

To facilitate the transition from the previous patent term to the new patent term implemented under the URAA, U.S. patent law allows any patentee with a patent application filed or granted prior to June 8, 1995, and still in effect on that date to “extend” the term of the patent to

10 Hasson, supra note 4, at 377–78.
11 Id. at 376.
12 Id.
longer of twenty years from filing or seventeen years from issuance. This automatic "extension" allows a patentee with a patent application filed prior to 1995, and previously bound to a seventeen-year term, to add up to three years to the patent term. Conversely, a patentee with an application filed but not granted prior to 1995 that would suffer under the URAA because of a more than three-year interval between filing and issuance would have its patent term effectively extended by claiming a full seventeen years from patent issuance. The term adjustment under these provisions is granted automatically; a patentee who meets the requirements outlined in 35 U.S.C. § 154(c)(1) need not petition the USPTO nor comply with other formalities to obtain the benefit of the longer patent term.

1. Terminally Disclaimed Patents and the URAA

a. Generally

Terminally disclaimed patents complicate the URAA scheme of adjustments. A terminally disclaimed patent is a patent with a term that has been shortened at the election of the patentee. The patentee truncates the patent's term to comply with the patentability requirements of the

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15 Id. § 154(c)(1). Note that the twenty-year term will not always result in the longer patent term because it is calculated from the date of filing, whereas the seventeen-year term is calculated from the date of patent issuance. Thus, if more than three years had elapsed between the time of filing and the patent's issuance, the seventeen-year term would grant the patentee a longer patent term.

16 The three year maximum extension assumes the interval between filing and issuance could be as low as zero. In reality, patent prosecution usually takes significantly longer than this. The USPTO's Performance and Accountability Report for 2012 reported that the average total pendency of a patent application for that year was 32.4 months. U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT, FISCAL YEAR 2012, at 14, http://www.uspto.gov/about/stratplan/ar/USPTOy2012PAR.pdf.

17 The degree of this effective "extension" would vary based on the actual interval between filing and issuance. For example, if four years elapsed between filing the patent application and patent issuance, then the patent term would effectively be extended by one year under this provision. The patent term under the UAAA would only be sixteen years (twenty years from filing less the four-year delay), but the patentee could claim a full seventeen-year term. See 35 U.S.C. § 154(c)(1).

18 Section 154(c)(1) states simply that the patent term of such a patent "shall be the greater of" the twenty-year term or seventeen years from grant. Id.

19 See id. § 253; Hinkens, supra note 8, at 389.
In particular, a terminally disclaimed patent is one that the USPTO would otherwise reject because the underlying invention is obvious in light of a patent previously issued to or submitted by the patentee. The second patent would thus violate the well-established prohibition on "double patenting." A patentee can overcome this obstacle by disclaiming the term of the second, obvious patent that extends beyond the term of the reference patent. The second patent is thus tied to the reference patent and expires on the same date as the reference patent. This practice is socially beneficial because it prevents the patentee from reaping an unwarranted time extension to the monopoly granted by the reference patent. The terminal disclaimer is also beneficial to the patentee because it allows the second, disclaimed patent to issue with a term of exclusivity, albeit truncated, for the additional innovations claimed in the disclaimed patent. Additionally, a terminal disclaimer protects the patentee from having the second, disclaimed patent rejected in a reexamination proceeding or in litigation on obviousness grounds.

b. Interaction of the Terminal Disclaimer with a URAA Adjustment

What is the effect of the URAA on a terminally disclaimed patent filed or granted prior to June 8, 1995? As explained, the changes to U.S. patent law due to implementing the URAA provide that a patent filed at the

20 See Hinkens, supra note 8, at 389–90. The patentability requirements are found in 35 U.S.C.A. §§ 101, 102, 103, 112 (West 2013 & Supp.).

21 Hinkens, supra note 8, at 390.

22 There are two types of double patenting. The first is grounded in statutory language providing that an inventor may obtain "a patent" on an invention, 35 U.S.C. § 101 (emphasis added), and prohibits an inventor from obtaining more than one patent on a single invention. The second type, which is of concern here, is termed "non-statutory" or "obviousness-type" double patenting, and is a "judicially created doctrine grounded in public policy that ‘prevents the extension of the term of a patent . . . by prohibiting the issuance of the claims in a second patent not patentably distinct from the claims of the first patent.’" Otsuka Pharm. Co. v. Sandoz, Inc., 678 F.3d 1280, 1297 (Fed. Cir. 2012) (quoting In re Longi, 759 F.2d 887, 892 (Fed. Cir. 1985)).


24 See Hinkens, supra note 8, at 390. This general outcome has various exceptions that this Article explores.


26 See 37 C.F.R. § 1.321(c) (2012).
appropriate time automatically garners the benefit of a term equal to the
greater of seventeen years from grant or twenty years from filing.\(^{27}\) For
example, a reference patent to which a second patent is terminally
disclaimed will have its term automatically adjusted under this provision.\(^{28}\)
However, the second, terminally disclaimed patent will only benefit from
the adjustment to the term of the reference patent under certain
circumstances.\(^{29}\) According to USPTO regulations, if the terminal
disclaimer expressly disclaims the terminal portion of its term by
referencing the “full statutory term” of the reference patent and does not
mention a specific date, then the term of the terminally disclaimed patent is
automatically adjusted to terminate concurrently with the first patent.\(^{30}\)
If the terminally disclaimed patent does not reference the first patent,
however, but merely states a date after which the terminally disclaimed
patent will expire, it may not claim the benefit of the URAA adjustment
granted to the first patent and expires on the listed date.\(^{31}\)

B. Patent Term Adjustments Due to USPTO Delay

Section 154(b) provides a second means by which the initial term of a
patent may be extended. Following the changes the URAA made to U.S.
patent law, patentees raised the concern that a patent term would
effectively be reduced relative to the previous seventeen-year term when
application processing delays cause the patent to issue more than three
years after the application’s filing.\(^{32}\) Further, for all patent applications
filed after June 8, 1995, patentees could not take advantage of the URAA’s
automatic alternative term calculation that is available for applications
filed prior to this date and were bound instead to the new twenty-years-
from-filing term.\(^{33}\) In response to these concerns, the Patent Term

\(^{27}\) 35 U.S.C. § 154(c)(1).
\(^{28}\) Id.
\(^{30}\) MPEP, supra note 29, § 2701. This extension takes place automatically and simultaneously with the extension of the first patent.
\(^{31}\) Id.
\(^{33}\) See 35 U.S.C. § 154(c)(1).
Guarantee Act, a subset of the American Inventors Protection Act, was passed in 1999.

The Patent Term Guarantee Act applies to patent applications filed on or after May 29, 2000, and provides for an adjustment of a patent’s term based on USPTO delays in processing the application. The statute and accompanying regulations recognize processing delays by category (commonly referred to as A-, B-, and C-type delays): A-type—failure to act; B-type—delays resulting in the pendency of an application for more than three years; and C-type—delays arising from interferences, successful appeals, and secrecy orders. Under the failure to act provisions, the USPTO is required to take certain processing actions by specified deadlines. A one-day adjustment is added to the patent term for each day beyond the deadline that the USPTO fails to take a given action (A-type delay). Under the three-year pendency provisions, a one-day adjustment is added to the patent term for each day beyond three years from the date of filing that the patent is not issued (B-type delay). Under the delays arising from interferences, appeals, and secrecy order provisions (C-type delay), a one-day adjustment is added to the patent term for each day that the patent application is delayed due to one of these proceedings. Positive adjustments are reduced by any delays attributable to patent applicants. There is no cap on the amount of time that can be added to

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37 Id. § 154(b)(1)(A)–(C). The provisions permitting adjustments for C-type delays were actually implemented by the URRA itself. Therefore, such adjustments are available for patents filed after June 8, 1995, but prior to May 29, 2000. See 35 U.S.C. § 154(b) (1994).


39 Id. § 154(b)(1)(B). This provision effectively “guarantees” that a patent term under the post-URAA term calculation will not be less than the pre-URAA seventeen-year term—hence the legislation’s title, the “Patent Guarantee Act.” Id.

40 Id. § 154(b)(1)(C).

41 Id. § 154(b)(2)(C). Examples of such applicant delays include late payment of application fees, failure to respond to USPTO notices or actions within a three-month grace period, and filing a reply with the USPTO that contains an inadvertent omission. 37 C.F.R. § 1.704 (2012).
the patent term pursuant to these adjustments. Further, these adjustments are calculated automatically by the USPTO without request from the patentee.

1. Availability of a USPTO Delay Adjustment for a Patent Previously Adjusted Under the URAA

A patent that has received a term adjustment under the URAA transition provisions may not also take advantage of a term adjustment due to USPTO delay. Both the relevant statutes and USPTO regulations preclude this result. The Patent Term Guarantee Act, which provides for adjustments due to USPTO delay, applies only to patent applications filed on or after May 29, 2000. In contrast, under the URAA, a patent must have been filed before June 8, 1995, to take advantage of a URAA adjustment. Thus, in many cases, a single patent will not be eligible to take advantage of both of these adjustments. Due to a special type of patent application called a continuation, wherein a later application benefits from an earlier filing date, it is sometimes possible, at least in theory, for a patent to be eligible for both types of adjustments. USPTO regulations, however, make it clear that a patent may not claim an adjustment for USPTO delay if it has already benefitted from a URAA adjustment, even if such an adjustment would otherwise be available.

2. Availability of a USPTO Delay Adjustment for a Terminally Disclaimed Patent

In general, a patent that has been terminally disclaimed to an earlier patent to avoid obviousness-type double patenting issues may not obtain a term adjustment under §154(b) even if the USPTO has delayed the

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42 See Wyeth v. Kappos, 591 F.3d 1364, 1371–72 (Fed. Cir. 2010).
43 37 C.F.R. § 1.705. Patentees may request a correction if they believe that the adjustment was calculated incorrectly, and in fact, should request such a correction if an error is made in their favor because such favorable errors may provide the basis for inequitable conduct claims against patentees. See id.
46 Continuation applications are explained in more detail infra Part II.D.
47 See MPEP, supra note 29, § 2701.
prosecution of the terminally disclaimed patent.\textsuperscript{48} Section 154(b)(2)(B) of the Patent Guarantee Act states: "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."\textsuperscript{49} The Federal Circuit in \textit{Merck & Co. v. Hi-Tech Pharmacal Co.},\textsuperscript{50} explained that this section "expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for PTO delays."\textsuperscript{51}

\textit{a. If a Reference Patent Has Received an Adjustment for USPTO Delay}

An exception to the general rule precluding a terminally disclaimed patent from claiming an adjustment for USPTO delay applies when the reference patent to which the later patent has been disclaimed is granted such an adjustment.\textsuperscript{52} In this case, according to USPTO practice, the terminally disclaimed patent may also benefit from an adjustment for USPTO delay if two conditions are met.\textsuperscript{53}

First, the terminally disclaimed patent must independently qualify for such an adjustment.\textsuperscript{54} To illustrate this requirement, consider a patent $\beta$ that has been terminally disclaimed with reference to patent $\alpha$, such that $\alpha$ and $\beta$ have the same expiration date $D$. If patent $\alpha$ qualifies for a § 154(b) adjustment because of statute-specified delays during prosecution, then $\alpha$'s expiration date will be adjusted to $D + \text{adjustment} = D_\alpha$. However, although patent $\beta$ is terminally disclaimed to patent $\alpha$, $\beta$ does not automatically reap the benefit of $\alpha$'s extension. Instead, $\beta$'s expiration date remains at date $D$ and will not be adjusted unless there were also delays in prosecuting patent $\beta$ that independently entitle it to a § 154(b) adjustment. If this is the case, patent $\beta$'s new expiration date will not be $D_\alpha$, but some other date, $D_\beta$, determined by the qualifying delays accrued during the prosecution of $\beta$.

Second, the adjusted expiration date of the terminally disclaimed patent must not extend beyond the adjusted expiration of the reference patent.\textsuperscript{55} Using the previous example, this means that patent $\beta$ can qualify

\begin{footnotesize}
\textsuperscript{49} Id.
\textsuperscript{50} 482 F.3d 1317 (Fed. Cir. 2007).
\textsuperscript{51} Id. at 1322.
\textsuperscript{52} See Hinkens, \textit{supra} note 8, at 380–81.
\textsuperscript{53} See id. at 381.
\textsuperscript{54} See id.
\textsuperscript{55} See id.
\end{footnotesize}
for an adjustment in time up to, but not later than, $D_o$, even if delays in the prosecution of patent $\beta$ qualify it for a later expiration. Although this situation has not been litigated, the USPTO most likely adopts this stance based on the same statutory language used by the Federal Circuit in Hi-Tech to explain the general rule precluding a terminally disclaimed patent from qualifying for a § 154(b) adjustment.\footnote{See 35 U.S.C. § 154(b)(2)(B) (2006).}

C. The Hatch-Waxman Act

1. Generally

A third statutory mechanism for extending the duration of a patent is available to pharmaceutical products, medical devices, and other products subject to Food and Drug Administration (FDA) regulatory review under the Drug Price Competition and Patent Term Restoration Act.\footnote{Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585.} This statute, commonly known as the Hatch-Waxman Act, was passed in 1984 in response to concerns that the proper balancing of incentives and public access sought by the patent system was not being achieved in the pharmaceutical industry.\footnote{Matthew Avery, Note, Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments, 60 HAST'NGS L.J. 171, 174–77 (2008).} This imbalance resulted from an interaction of regulatory requirements and patent law doctrines, and served to stifle public access to new drugs.\footnote{Id. at 174–75.} In particular, the FDA’s requirement that each new pharmaceutical product undergo clinical testing demonstrating the product’s safety and efficacy as part of a New Drug Application (NDA) before being approved for marketing and sale was problematic for would-be competitors of patented drugs. Such testing is often prohibitively expensive for firms that cannot recoup these costs via patent monopoly pricing.\footnote{See id.; Benjamin N. Roin, Unpatentable Drugs and the Standards of Patentability, 87 TEX. L. REV. 503, 509–11 (2009).} The problem was further exacerbated by the fact that any efforts by generic manufacturers to comply with these regulatory requirements would in all likelihood infringe the competitor’s patent.\footnote{Avery, supra note 58, at 175.}
Pharmaceutical Co., these efforts did not qualify as non-infringing experimental uses. Thus, any potential competitor not deterred by the cost of clinical trials would still be forced to wait until its competitor’s patent expired before beginning these trials. Because the trials take several years, the patentee’s monopoly was effectively extended, and competition and access were stifled for the extended time period.

To end this effective extension of patent monopolies in the drug industry and restore the balance of research incentives and public access, the Hatch-Waxman Act allows generic drug manufacturers to take advantage of an accelerated regulatory approval process, called an Abbreviated New Drug Application (ANDA). Rather than conducting clinical trials for a pharmaceutical product from scratch, a generic drug manufacturer may receive marketing approval for a drug based solely on a showing that the product is biologically equivalent to a patented drug. Costly barriers to competition are thereby removed. Further, the Hatch-Waxman Act overruled the Federal Circuit’s holding in Roche, such that a generic manufacturer may conduct the necessary tests required to file an ANDA without infringing a competitor’s patent. A generic manufacturer can thus be ready with an FDA-approved marketable product at the moment the competitor’s patent expires.

62 733 F.2d 858 (Fed. Cir. 1984).
63 Id. at 863.
64 Avery, supra note 58, at 175.
66 Id. § 355(j)(2)(A)(iv). The reasoning is as follows: Because clinical trials demonstrating the safety and efficacy of the patented drug were conducted prior to that drug’s approval, the trials do not need to be conducted again for the generic product after showing that the two drugs are biologically equivalent. See Avery, supra note 58, at 174–75.
67 Avery, supra note 58, at 176. Hatch-Waxman designates tests that are conducted with the goal of acquiring FDA approval as experimental uses. Id.
68 See id. Hatch-Waxman further incents competition by allowing a generic manufacturer to challenge the validity of its competitor’s patent prior to the patent’s expiration. Id. at 176–77. If the challenger is successful, either because the pioneer’s patent is deemed invalid or because the generic manufacturer’s product is deemed not to infringe the pioneer’s patent, the generic manufacturer is rewarded with a 180-day exclusivity period. Id. The pharmaceutical industry has abused this system—broadly referred to as “Paragraph IV litigation” in reference to the relevant section of the statute—leading Congress to amend the Hatch-Waxman Act in 2003. See id. at 184. A complete discussion of the policy implications of Paragraph IV litigation and the efficacy of the 2003 (continued)

The Hatch-Waxman Act provides to pharmaceutical innovators the possibility of a patent term extension as quid pro quo for shouldering the burden of conducting clinical trials and enduring regulatory review for the benefit of their generic competitors. 69 In particular, a patented drug is eligible for a patent term extension equal to the duration of the NDA regulatory review period plus half the duration of any Investigational New Drug (IND) regulatory review period. 70 The maximum extension available under these provisions depends on the patent’s issue date. If both a drug patent issued and clinical testing for such drug began prior to the enactment of the Hatch-Waxman Act on September 25, 1984, then the maximum available extension is two years. 71 For patents issued after September 24, 1984, 72 and for patents issued before this date but for which clinical trials had not yet begun, 73 the maximum available extension is five years, and the final expiration date of the patent can be no more than fourteen years after the date of first FDA approval. 74

amendments in curbing abuses of the Paragraph IV system is beyond the scope of this Article, but has been discussed elsewhere. E.g., id. at 179–86.


71 See 35 U.S.C. § 156(g)(6)(C). The rationale for this abbreviated extension for drugs already in clinical trials is to focus on incentivizing innovation of future drugs rather than rewarding past innovation. Lechner-Fish, supra note 70, at 392.


73 Id. § 156(g)(6)(B).

3. Concurrent Availability of a Hatch-Waxman Extension and a URAA Adjustment

The rules governing the concurrent availability of a Hatch-Waxman extension and an adjustment under the URAA were outlined by the Federal Circuit in *Merck & Co. v. Kessler.*


The Federal Circuit in *Kessler* considered whether a patent that had previously qualified for but not yet used a Hatch-Waxman extension by June 8, 1995, could take advantage of a URAA adjustment while maintaining the Hatch-Waxman extension. The court disagreed with the position taken by both the USPTO and the FDA and held that such a patent could indeed take advantage of both a URAA adjustment and a Hatch-Waxman extension.

b. Availability of a Hatch-Waxman Extension and a URAA Adjustment for a Patent in Force on June 8, 1995, Solely Due to a Hatch-Waxman Extension

The court in *Kessler* also considered whether a patent in force on June 8, 1995, solely because of a partially-expended Hatch-Waxman extension, could receive a URAA adjustment and also have the full term of the previously granted Hatch-Waxman extension added onto the newly adjusted term. The Federal Circuit disagreed with the district court and held that such a patent may not have a full Hatch-Waxman extension renewed after a URAA adjustment has been made. Further, the court decided that such a patent could not “split” a Hatch-Waxman extension pre- and post-URAA adjustment. For example, if a patent has utilized six months of a two-year Hatch-Waxman extension when the patent term is adjusted in accordance with the URAA, the patent loses the remaining eighteen months of the Hatch-Waxman extension.

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75 80 F.3d 1543, 1550–53 (Fed. Cir. 1996).
76 Id. at 1550.
77 Id. at 1550–52.
78 Id. at 1552–53.
79 Id.
80 Id. at 1552.

The potential availability of a Hatch-Waxman extension for a terminally disclaimed patent was addressed by the Federal Circuit in Hi-Tech. \(^{81}\) In Hi-Tech, the patent at issue had been terminally disclaimed to a reference patent to avoid a finding of obviousness-type double patenting; both patents thus expired on the same date. \(^{82}\) The Federal Circuit found that such an extension was permissible despite the fact that the disclaimed patent and the reference patent would now expire on different dates. \(^{83}\) Therefore, a patentee may seek a Hatch-Waxman extension of a terminally disclaimed patent and thereby extend the expiration of the disclaimed patent beyond the expiration date of the reference patent.


The Federal Circuit has not explicitly addressed whether a Hatch-Waxman extension is available for a patent previously adjusted for USPTO delay under § 154(b). It is clear based on express statutory language, however, that a patent may be granted both a Hatch-Waxman extension and an adjustment for USPTO delay. The statutory provision governing Hatch-Waxman extensions states: “The term of a patent . . . shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), . . .” \(^{84}\) This suggests that a patent previously adjusted under § 154(b) is eligible for a Hatch-Waxman extension if the requirements for such an extension are met.

6. Availability of More than One Hatch-Waxman Extension for a Single Product

According to the language of the Hatch-Waxman Act, a patentee may not receive more than one Hatch-Waxman extension for a single patent. \(^{85}\)

\(^{81}\) Merck & Co. v. Hi-Tech Pharmacal Co., 482 F.3d 1317, 1318 (Fed. Cir. 2007).
\(^{82}\) Id. at 1318–19.
\(^{83}\) Id. at 1324.
\(^{85}\) See id. § 156(a)(2). This section states that a patent may not receive a Hatch-Waxman extension if it has been “extended under subsection (e)(1) of this section.” Id. The Federal Circuit in Kessler stated that in light of this provision, “[c]learly, a patent may
Further, a patentee may not obtain more than one Hatch-Waxman extension for a given regulatory review of a product, even if there is more than one patent covering that product. Finally, a drug must be classified as "new" to be eligible for a Hatch-Waxman extension, with "new" defined as a drug that has not previously been approved for marketing by the FDA. These rules together generally preclude the possibility of more than one Hatch-Waxman extension being granted to a single product. In narrow circumstances, however, a single product can reap the benefit of two or more Hatch-Waxman extensions. Such circumstances exist when a single drug undergoes more than one regulatory review, each regulatory review corresponds to a separate patent application, and each regulatory review period terminates on the same date. This last requirement renders it unlikely that such a situation will arise with any frequency; however, it has arisen at least once. In one case, the drug Lyrica was undergoing regulatory review for two uses: to treat diabetes-related neuropathic pain, and separately, to treat herpes-zoster-related neuropathic pain. The NDAs for each of these uses were approved on the same date, and the holder of the relevant patents, Warner-Lambert Company, argued that each patent should qualify for a Hatch-Waxman extension because there was no previous regulatory approval of the same drug to prevent each drug from being classified as "new" under the statute. The USPTO and FDA receive only one [Hatch-Waxman] extension." Merck & Co. v. Kessler, 80 F.3d 1543, 1551 (Fed. Cir. 1996).

86 35 U.S.C. § 156(c)(4) ("[N]o event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product.").

87 Id. § 156(f)(2)(A).

88 See id. § 156(a)(5)(A).


90 This could occur, for example, if a single drug product is undergoing clinical trials for more than one indication, and a separate patent has been obtained for each use of the drug. See id. at 662.

91 See id. Because each regulatory review period ends on the same date, each patent in this case may claim that it involves a "new" drug under the statute because the same drug has not been previously approved.

92 See id. at 662–63.

93 Id. at 662.

94 Id. at 662–63.
agreed with this reasoning and granted an extension for each of the patents.95

D. Continuations

Strictly speaking, a patent continuation is not an extension of a patent term. However, patent continuations interact in important ways with the term adjustments discussed in this Article, and a discussion of the implications of these interactions is warranted. Briefly, a patent continuation is a mechanism whereby a patent applicant can "reset" the patent prosecution process following a final rejection of a patent application or at any other time prior to the patent issuing or applicant abandoning the application.96 Following a final rejection, a continuation provides a means of having an application reconsidered, in most cases by the same patent examiner.97 Following an allowance of one or more claims, a continuation allows an applicant to pursue claims broader than those that were allowed for possible later issue.98 A continuation application provides an attractive alternative to filing a new application for these broader claims because the continuation application effectively continues the initial application, allowing an applicant to claim the initial filing date for these claims, and thereby avoiding the possibility that intervening innovations (or the parent application itself) will act as prior art that renders the later, broader claims unpatentable.99 There is no limit to the number of continuation applications that may be filed.100

95 Id. at 663.
97 Id. A patent application facing a final rejection of its claims may also appeal this finding before the Patent Trial and Appeal Board. See 35 U.S.C.A. § 6(b) (West 2012). In fact, the appeal process is the formal mechanism contemplated for appealing final rejections, and some consider the continuation process to be an inappropriate mechanism for appeal. Lemley & Moore, supra note 96, at 97. For a complete discussion of abuses of the continuation system, see generally id.
98 Lemley & Moore, supra note 96, at 68.
100 There have been many attempts—both legislative and administrative—to limit the number of available continuations. The most recent attempt was in 2007, when the USPTO proposed new regulations that would limit the number of available continuations arising from a single parent application. Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716 (Aug. 21, 2007). The USPTO was sued and the (continued)
Various types of patent continuations exist, and each may be treated differently under the law of patent adjustments. The main categories of continuation applications include continuations, requests for continued examination (RCEs, which are technically a subset of continuations), continuations-in-part (CIPs), and divisionals.\textsuperscript{101} Applicants file traditional continuation applications when they wish to argue for broader claims after some claims have been allowed. When no claims have been allowed and a final rejection has been issued, a continuation is labeled as an RCE.\textsuperscript{102} In contrast to traditional continuations and RCEs, a CIP application allows the applicant to add new information to the continuation application.\textsuperscript{103} For CIPs, the priority date of the parent application is only available for those claims that do not make use of this additional information.\textsuperscript{104} Finally, a divisional application is usually filed following a finding by the USPTO that a single patent application contains two or more distinct inventions.\textsuperscript{105} The patentee may then file multiple related divisional applications, one for each distinct invention.\textsuperscript{106}

1. Availability of a URAA Adjustment for a Patent Based on a Continuation Application

The general rule governing term adjustments under the URAA is that a patent filed prior to June 8, 1995, receives a term corresponding to the greater of seventeen years from issue or twenty years from filing.\textsuperscript{107} For a patent based on a continuation application, the rule is slightly different. If a patent is based on a continuation application filed after June 8, 1995, the patent does not benefit from an alternative term calculation and is granted

\textsuperscript{101} See 37 C.F.R. § 1.53(b) (2012).
\textsuperscript{102} See id. § 1.114(a).
\textsuperscript{103} See 35 U.S.C. § 132(a); Agilent Techs., Inc. v. Affymetrix, Inc., 567 F.3d 1366, 1379 (Fed. Cir. 2009).
\textsuperscript{105} 35 U.S.C. § 121.
\textsuperscript{106} See id.
\textsuperscript{107} See id. § 154(c)(1).
a term of twenty years from filing, even if the initial application on which the continuation is based was filed prior to the URAA cutoff date. The continuation patent still claims the priority date of the parent application; thus, the patent's term is twenty years from the date of original filing, even though that date is prior to June 8, 1995.

2. Terminal Disclaimer of a Patent Based on a Continuation Application

A patent based on a continuation application may be terminally disclaimed just as a patent based on an original application may be terminally disclaimed. In fact, the terminal disclaimer once played a central role in situations where a continuation was filed in an attempt to patent broader claims after related narrower claims had been allowed. Broader claims in the continuation application were often unpatentable in light of the parent patent for obviousness-type double patenting reasons; the problem was solved by disclaiming the terminal portion of the child patent. The past tense is used here because following the passage of the URAA, the terminal disclaimer lost much of its practical effect in the case of continuation applications. Although obviousness-type double patenting is still a concern with continuation applications, and terminal disclaimers must still be used to overcome this concern, the parent and child patents will often expire on the same date. Simultaneous expiration occurs even without the disclaimer because expiration for both child and parent is calculated from the date the parent was filed. Parent and child patents do not always expire on the same date, however, because of the potential availability of other extensions and adjustments. Moreover, as Part III discusses, the terminal disclaimer may serve a useful purpose even when there is no patent term to be disclaimed.

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108 MPEP, supra note 29, § 2701.
109 Id.
111 See Lemley & Moore, supra note 96, at 87 n.92.
112 Id.
113 Id.
114 MPEP, supra note 29, § 804.02.
3. *Availability of a Hatch-Waxman Extension for a Patent Based on a Continuation Application*

A patent based on a continuation application must meet all of the statutory requirements to qualify for a Hatch-Waxman extension. These statutory requirements include restrictions on the availability of an extension for related patents and products. In practice, this means that a Hatch-Waxman extension is usually granted to the earliest patent in a series of related patents, and a patent based on a continuation application is thus ineligible for an extension. For example, the Hatch-Waxman Act requires that only one extension be issued per regulatory review period. Therefore, if a child patent includes claims related to the same compound as the parent patent, there was a single regulatory review of this compound, and the parent patent claimed a Hatch-Waxman extension based on this regulatory delay, then the child patent cannot also claim a § 156(a) extension.

4. *Availability of a USPTO Delay Adjustment for a Patent Based on a Continuation Application*

The rules governing the availability of a patent term adjustment based on USPTO delay for a continuation application depend upon both the type of continuation and the type of delay. First, a continuation application generally extinguishes any patent term adjustment for USPTO delay that has accrued before the continuation application was filed. This rule applies to continuation, CIP, and divisional applications (but not to RCEs), and includes all three types of potential USPTO delay (A, B, and C). For example, if a continuation application is filed after some claims have been allowed to argue for broader claims in a child patent, the parent

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116 See id. § 156(a)(2), (c)(4).
117 Id. § 156(c)(4).
118 However, the Hatch-Waxman Act does not prohibit an owner of multiple patents that are all based on a single regulatory review period from choosing which of the patents will reap the benefit of the § 156 extension. For example, if a child patent issues, which includes broader claims than the parent patent, then the patentee could claim an extension for the child patent and reap the benefit of longer protection for the broader claims. Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 381 F.3d 1371, 1384, 1386 (Fed. Cir. 2004).
119 See 37 C.F.R. § 1.704(c)(12) (2013) (stating that in the case of further prosecution via a continuing application, the period of adjustment “shall not include any period that is prior to the actual filing date of the application that resulted in the patent”).
120 See discussion supra Part II.B, II.D.
patent may be adjusted for delays accruing prior to its issuance, but the child patent may not.

This general rule does not apply to RCE applications.\textsuperscript{121} Unlike other types of continuations, an RCE application filed after a final rejection does not extinguish previously accrued adjustments of A-type, B-type, and C-type delays.\textsuperscript{122} Once an RCE has been filed, however, any further accrual of B-type delay is precluded.\textsuperscript{123} In other words, the three-year pendency clock is effectively stopped, although adjustments for subsequent delays resulting from USPTO failure to act and appeals may still be granted.

E. Other Specific Extensions

Finally, an individual patent covering a drug, food product, or medical device may potentially benefit from an additional extension based on regulatory delay. Sections 155 and 155A provided for extension of a patent's term in certain situations wherein regulatory approval was stayed or denied pursuant to FDA authority.\textsuperscript{124} These sections were very narrow in scope,\textsuperscript{125} and were recently repealed by the Leahy-Smith America Invents Act of 2011.\textsuperscript{126} Additionally, Congress has occasionally passed a private bill granting an extension to a single patent on the basis of extreme regulatory delay that left the patentee with a significantly truncated patent period.\textsuperscript{127}

\textsuperscript{121} See Tyson & Bahr, supra note 44.
\textsuperscript{122} Id.
\textsuperscript{123} Id.
\textsuperscript{125} These provisions basically acted as private laws, as the conditions for qualification were drafted with specific products in mind and applied narrowly only to these products. For example, the only product to take advantage of § 155 before it was repealed was the food product Aspartame, while the only product to take advantage of § 155A was the drug Forane. Patent Terms Extended Under 35 USC § 155, U.S. PATENT & TRADEMARK OFFICE, http://www.uspto.gov/patents/resources/terms/155.jsp (last visited Apr. 12, 2013).
III. Policy Implications of Patent Term Adjustments

The U.S. patent system provides for various adjustments of the default patent term of twenty years from filing, and these adjustments interact in ways that are not always clear to patent holders or their competitors. Perhaps even less clear is whether the law that has developed in this area serves the policy goals of the patent system by maintaining an appropriate balance between incentives to innovate and access to information. This part, mirroring the structure of Part II, examines each of the doctrines introduced in Part II, traces the evolution of each doctrine, including any relevant decisions in the Federal Circuit, and evaluates whether the current state of the law is in fact consistent with the goals of the patent system.

A. The Uruguay Round Agreements Act

1. Generally

The URAA changed the patent term in the United States from an issuance-based term to a filing-based term. In particular, the default patent term was seventeen years from the date of patent issuance, but now after the URAA's enactment, the default term is twenty years from the date of filing. This move to a filing-based term was not universally applauded; however, some positive results did flow from this change. First, it was a step towards accomplishing one of the main goals of the TRIPs agreement: to achieve a more uniform and harmonized international patent system. Second, the transition to a patent term calculated from the date of filing helped remedy an abuse of the U.S. patent system known as submarine patenting.

Submarine patenting is the act of filing multiple continuation applications, intending to delay the ultimate issuance of a patent until a later time when the patent is likely much more valuable. Prior to the

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128 Hasson, supra note 4, at 383.
129 Id.
130 Many of the criticisms centered around the worry that patentees would be deprived of a full seventeen-year term under the new regime. See, e.g., Rohrabacher, supra note 32, at 494–95. This particular concern spurred passage of the Patent Term Guarantee Act. Campbell, supra note 34, at 306–07.
131 For a discussion of how successful the URAA actually has been in achieving this goal, see Hasson, supra note 4.
133 Id. This increased value arises because other innovators in the industry, unaware of the submarine patent’s existence, may invest significant resources to develop products and
URAA, when the patent term was calculated from the date of patent issuance, an owner of a submarine patent could delay issuance indefinitely, waiting until the patent became most valuable—all without penalty.

The practice of submarine patenting does not serve the goals of the patent system. While it rewards the initial innovator and owner of the submarine patent, it does so disproportionately by allowing the patentee to extend the monopoly indefinitely. Further, it discourages subsequent innovators who may be reluctant to invest significant resources in the development of improvements on existing technologies for fear of being held up in the future by an undiscovered submarine patent. The change in patent term under the URAA helps discourage the practice of submarine patenting because a patentee is granted a term of twenty years from filing regardless of when the patent actually issues. Further, under the rules for USPTO delay-based adjustments, any delays in issuance attributable to the patentee are not eligible to extend the term of the patent, and filing a continuation application cuts off the benefit of any previously accrued adjustments for USPTO delays. In effect, a patentee loses a portion of the patent term to the same extent that the patentee delays patent issuance; if the patentee delays for more than twenty years, then all patent rights are lost.

The change in patent term under the URAA has not completely eliminated the practice of submarine patenting. In some cases it is worthwhile for a patentee to forfeit a portion of the patent term to reap the increased value that comes from surprising and holding up competitors and subsequent innovators. This may be particularly true in industries where the rate of technological advancement is rapid in relation to the patent term because a short time is all that is needed to create the holdup situation described above. For this reason, there have been attempts by both the legislature and the USPTO to limit the number of continuation applications services that rely on the submarine patent's technology. Id. at 79. After these investments are made, the innovators will be willing to pay much more to the owner of the submarine patent in license fees than they would have absent these investments. Id.

134 See id. at 80.

135 See discussion supra Part II.B.

136 This is not true in the case of an RCE continuation application. RCE continuation applications are used only when the initial application for a patent is rejected, and are therefore, not relevant to the practice of submarine patenting.

137 Lemley & Moore, supra note 96, at 84–85.

138 Id. at 85.
available for a single patent, as permitting an unlimited number of continuations primarily facilitates submarine patenting.\textsuperscript{139} A major critique of the switch from an issuance-based term calculation to a filing-based term calculation is that patent terms vary under the new system based on prosecution times.\textsuperscript{140} This introduces uncertainty for potential inventors and may reduce incentives to innovate. The system switch also implicates fairness concerns because two different patents may benefit from differing patent terms for reasons unrelated to the respective social value of the patented technologies. Although additional legislation adjusting patent terms based on regulatory and administrative delays in patent issuance may help to alleviate such concerns, it does not present a complete solution.\textsuperscript{141}

2. The URAA Alternative Term Calculation

If the URAA, switching to a filing-based term calculation, can be considered a positive development in the law, it might follow that a provision aiming to gather as many unexpired patents as possible under its auspices is also beneficial. That is what the URAA adjustment provisions aim to do by automatically recalculating the term of any unexpired patent issued prior to the URAA’s enactment to conform to the new law.\textsuperscript{142} The only pre-URAA patents that are excluded from such a recalculation are those that would suffer a reduced patent term under the new law.\textsuperscript{143} Although this initially appears to be an appropriate and fair means of transitioning to a new system, these statutory provisions, in all likelihood, have succeeded in little more than introducing unnecessary complexity to the patent system. Increased complexity is evidenced by the USPTO’s and

\textsuperscript{139} See Lemley & Moore, supra note 96, for an account of the USPTO’s latest attempt to limit continuations.

\textsuperscript{140} See, e.g., Rohrabacher, supra note 32, at 495–96. For example, a patent that takes one year to issue will benefit from a nineteen-year term, while a patent that only takes six months to issue will benefit from an additional six months of patent protection.

\textsuperscript{141} For example, as seen in this Article, such legislation also introduces complications and uncertainty, especially when several independent adjustment provisions interact in ways that are unclear to patentees and their competitors. Patent terms may still vary because of reasons unrelated to the social value of the patent or the incentives needed to spur the development of the invention.


\textsuperscript{143} Id. This would include patents that issued more than three years after filing, such that a seventeen-years-from-issuance term provides a longer term than a twenty-years-from-filing term.
the Federal Circuit’s struggles to determine how URAA provisions should interact with other term extensions and adjustments. Further, the Act has granted a windfall to pre-URAA patent owners with patents that—by luck or otherwise—have spent less than three years in prosecution. Because these patentees only expected a seventeen-year term when they developed the patented inventions, the additional term granted by the URAA adjustment was not necessary to incentivize their development. Although the URAA adjustment provisions accelerated the international uniformity sought by the TRIPs agreement, it arguably would have done little harm in this respect simply to have allowed pre-URAA patents to expire after their seventeen-year terms, while holding all post-URAA patents to the new term calculation. Under such an approach, all pre-URAA patents would have expired as of June 8, 2012. As it now stands, many pre-URAA patents still survive, and the complexities introduced by the URAA alternative term calculation continue to manifest themselves.

3. The Availability of a URAA Extension for a Terminally Disclaimed Patent

The rule governing the availability of a URAA adjustment for a terminally disclaimed patent is as follows: If a patent to which a second patent is terminally disclaimed is granted a term adjustment pursuant to the URAA, then the second, terminally disclaimed patent gets the benefit of this new expiration date only if the disclaimer expressly references the “full statutory term” of the first patent. If the terminal disclaimer

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144 See generally Part III for a description of these struggles.
145 This would not have delayed the improvement to the abusive practice of submarine patenting because this practice depends on the successive filing of continuation applications; all continuations filed after June 8, 1995, based on a pre-URAA patent, however, automatically receive a twenty-years-from-filing term. See MPEP, supra note 29, § 2701.
146 In 2004, the number of pre-URAA patents was estimated at 1.3 million. Lemley & Moore, supra note 96, at 83–84 n.81. That number shrinks every year as pre-URAA patents expire. One recent estimate surmised that of an estimated 2.1 million patents currently in force, 9% of these were issued prior to the URAA cutoff, leaving about 200,000 pre-URAA patents in force today. Dennis Crouch, How Many US Patents Are In-Force?, PATENTLY-O (May 4, 2012), http://www.patentlyo.com/patent/2012/05/how-many-us-patents-are-in-force.html. This estimate does not include pre-URAA patents that may have received other extensions, so the number is probably an underestimate. See id.
147 MPEP, supra note 29, § 2701.
references a specific date, then the terminally disclaimed patent expires on that date, regardless of any URAA term extension of the first patent.\textsuperscript{148}

This distinction based on the language of the terminal disclaimer came about as a result of the legislative history underlying the passage of the URAA.\textsuperscript{149} The relevant statutory provision states only that any term extension calculation under the URAA is "subject to" any preexisting terminal disclaimers.\textsuperscript{150} A Senate Report on the subject goes into greater detail, distinguishing between a patent that is terminally disclaimed "due to another patent on an invention that is not patentably distinct from" the terminally disclaimed patent and a patent that is terminally disclaimed "independent of another patent."\textsuperscript{151} According to this report, the first type of patent gains the URAA extension of the reference patent, while the second type of patent is bound to the "originally disclaimed period."\textsuperscript{152} The USPTO implements this distinction as follows: A patent with a terminal disclaimer referencing an earlier patent is extended concurrent with the reference patent, while a patent with a disclaimer referencing a specific date realizes no extension.\textsuperscript{153}

Although one may question whether it is wise to adjust the expiration date of the reference patent under the URAA’s alternative term calculation in the first place,\textsuperscript{154} once this adjustment has been made it makes sense, in light of the purpose of the terminal disclaimer, to grant the terminally disclaimed patent a concurrent adjustment. The goal of a terminal disclaimer is to ensure that a patentee does not inappropriately extend the monopoly beyond the term of an original patent by patenting obvious iterations of the original invention.\textsuperscript{155} No such risk is implicated when the term of the original patent has been adjusted subsequent to an unforeseen statute. Further, keeping the expiration dates of both patents identical

\textsuperscript{148} Id.
\textsuperscript{150} 35 U.S.C. § 154(c)(1). The statute provides that the new patent term under the URAA for qualifying patents would be "the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers." Id.
\textsuperscript{152} Id.
\textsuperscript{153} See MPEP, supra note 29, § 2701.
\textsuperscript{154} See Part III.A.2 for a discussion of this issue.
\textsuperscript{155} In re Van Ornum, 686 F.2d 937, 943–44 (C.C.P.A. 1982) (quoting In re Schneller, 397 F.2d 350, 354 (C.C.P.A. 1968)).
avoids unnecessary confusion and complexity and is consistent with the reasonable expectations of both patentees and their competitors.

In light of this rationale, it is unclear why the USPTO’s current practice of determining a terminally disclaimed patent’s eligibility for a URAA adjustment based on express language in the disclaimer is necessary. Although the Senate Report distinguishes between terminal disclaimers that are “due to” an earlier patent and those that are “independent of” an earlier patent, it is unclear why a patentee would disclaim a portion of a patent other than to avoid an obviousness-type double patenting rejection based on an earlier patent. In other words, most terminally disclaimed patents are likely “due to” a reference patent, although the text of the disclaimer may not unambiguously reveal this fact. Consistent with this rationale, the Federal Circuit upheld the district court’s affirmation of a USPTO finding that a terminal disclaimer ambiguously including both a specific date of disclaimer and a reference to an earlier patent could have its expiration date adjusted under the URAA concurrent with the reference patent. The USPTO regularly interprets such ambiguities in favor of the terminally disclaimed patent holder. The Federal Circuit reasoned that it would be unfair to deny the patentee an extension simply for failure to include specific language—the significance of which could not be appreciated at the time of filing—in the terminal disclaimer. In light of this reasoning, it seems equally unfair to deny an extension to a patentee who, equally unaware of the significance of including specific language in the terminal disclaimer at the time of filing,

156 The defendants in Bayer presented an example where a “patent owner . . . select[ed] a specific date upon which it w[ould] disclaim a term of a patent.” Bayer AG v. Carlsbad Tech., Inc., Civ. No. 01-867-B (LSP), 2001 U.S. Dist. LEXIS 24487, at *18 (S.D. Cal. Oct. 31, 2001), aff’d, 298 F.3d 1377 (Fed. Cir. 2002). The district court agreed with the USPTO that the URAA did not affect the expiration of this patent, but it was unclear why the patent owner in this case selected this date. Id. at *18–19. It may well have been that this date was chosen as the date upon which an earlier reference patent expired, and the patent owner simply failed to mention the reference patent in the disclaimer. See id. at *18.

157 Bayer AG v. Carlsbad Tech., Inc., 298 F.3d 1377, 1379, 1383 (Fed. Cir. 2002).

158 See MPEP, supra note 29, § 2701 (stating that a terminally disclaimed patent will not be adjusted under the URAA “if the terminal disclaimer . . . disclaims the terminal portion of the patent subsequent to a specific date, without reference to the full statutory term of a referenced patent” (emphasis added)).

159 See Bayer, 298 F.3d at 1382. The district court also pointed out that the USPTO does not require any specific language for a terminal disclaimer to be properly filed. Bayer, 2001 U.S. Dist. LEXIS 24487, at *17–18.
was unlucky enough to have included only a date and no reference to another patent in the terminal disclaimer. To be sure, the USPTO faces a practical problem in these cases because a terminal disclaimer that does not refer to another patent gives the USPTO no indication of what the new extended date of the patent should be. This problem can be overcome by granting a URAA adjustment in these cases only to those who both petition the USPTO and include in their petition evidence of a reference patent. Such a practice would eliminate the arbitrary distinction based on the language of the terminal disclaimer alone.

B. Patent Term Adjustment Due to USPTO Delay

The Patent Term Guarantee Act ensures that a patentee obtaining a patent after the URAA’s switch to a filing-based term will reap the benefits of at least a seventeen-year patent term. A patentee may also be granted a patent term adjustment based on specific types of delays arising during the USPTO’s processing of a patent application. The Patent Term Guarantee Act has been positively regarded as a fair means of maintaining appropriate incentives, while not unduly stifling competition. This system preserves incentives to innovate by providing a measure of certainty to potential innovators. It is also responsive to fairness concerns, as it promotes consistency in patent terms that might otherwise differ for reasons beyond the patentees’ control. Finally, the rules for calculating patent adjustments implemented under this statute, including provisions allowing for negative adjustments when delays are attributable to the patentee, minimize the potential for gaming and inappropriate extensions of the patent monopoly.

It has been pointed out that the Patent Guarantee Act’s guarantee of a seventeen-year term accomplishes little in the case of pharmaceutical innovations. Due to the regulatory process and the Hatch-Waxman Act’s limits on term extensions, a pharmaceutical patent will rarely

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160 This is accomplished by compensating a patent owner for pendency of an application that lasts beyond three years (B-type delay). 35 U.S.C. § 154(b)(1)(B) (2006).

161 Id. § 154(b)(1).


164 The Hatch-Waxman Act limits an extension to a maximum of fourteen years from the date of first FDA approval. 35 U.S.C. § 156(c)(3).
reach a term of seventeen years. This criticism ignores the fact, however, that the Patent Guarantee Act also provides for patent term adjustments in addition to the three-year pendency adjustment that serves to guarantee a seventeen-year term. Further, such adjustments can be added to any Hatch-Waxman extension earned by a pharmaceutical patent. In any case, this criticism is not a direct criticism of the Patent Term Guarantee Act. The concern of insufficient patent terms for pharmaceutical patents is best addressed by ensuring that the Hatch-Waxman system of extensions intended specifically to compensate for regulatory delay is operating adequately.

1. Availability of a USPTO Delay Adjustment for a Patent Previously Adjusted Under the URAA

According to USPTO regulations, a patent previously adjusted under the URAA transitional provisions may not take advantage of a patent term adjustment for USPTO delay. Although at first glance this rule may be easily understood in light of the impetus behind the Patent Term Guarantee Act, a more in-depth analysis reveals that in fact a different rule would preserve the policy considerations underlying the passage of both the URAA and the Patent Term Guarantee Act. An entirely separate question, however, is whether the current rule serves the ultimate goals of the patent system. The current rule does appear to serve these goals. To understand why, however, it is instructive to undertake a full analysis of the rule.

a. The Rule in Light of the Impetus Behind the Patent Term Guarantee Act

The Patent Term Guarantee Act's provision for patent term adjustments is a response to concerns that the switch to a new filing-date-based term calculation under the URAA would result in significantly shorter patent terms (compared to the fixed seventeen-year term previously granted) for patents subject to extensive prosecution delays. A main goal of the adjustments is thus to ensure that a patentee receives a patent term of at least seventeen years, consistent with the previous patent

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165 See id. § 154(b)(1).
166 See id. § 156(a).
167 See generally Avery, supra note 58, for a discussion of the success of the Hatch-Waxman Act and subsequent amendments.
168 See MPEP, supra note 29, § 2710.
169 Campbell, supra note 34, at 316–17.
A patent qualifying for the transitional term adjustment under the URAA may already expect such a patent term because the patent is entitled to the greater of a term of seventeen years from issue or twenty years from filing; if one of these alternative term calculations provides for a longer term, then the patent term is extended accordingly.\textsuperscript{170} To allow the patentee to further extend the patent monopoly by taking advantage of a USPTO delay adjustment would ostensibly result in an unfair application of a law meant to benefit those unable to take advantage of a URAA adjustment due to the timing of the relevant applications.

\textbf{b. The Rule in Light of Policy Considerations Underlying the URAA and the Patent Term Guarantee Act}

Although making a patent term adjustment for USPTO delay unavailable to a patent previously having benefitted from a URAA adjustment aligns logically with the Patent Guarantee Act’s goal of guaranteeing each patentee a minimum patent term of seventeen years, other policy considerations may justify granting these adjustments to all patents, regardless of their URAA-adjustment status. To see why, consider the following example of a hypothetical patent $a$ issued prior to the URAA adjustment cutoff date of June 8, 1995. The patent issued two years after filing and was granted a term of seventeen years. After the URAA’s enactment, $a$’s term was extended by an additional year because the twenty-years-from-filing calculation provided a longer term for this patent. For this hypothetical patent, however, one full year of the two-year prosecution time was attributable to USPTO delay. If $a$ qualified for an adjustment due to USPTO delay (it does not under current law) the patent term would be extended by an additional year, giving $a$ a nineteen-year total term.

This extra year may seem like an unwarranted extension of the patent monopoly for patent $a$. But consider now a second patent, $\beta$, issued after the URAA cutoff, receiving a patent term of twenty years from filing without the possibility of a URAA adjustment. Patent $\beta$ was also issued two years after prosecution, and like patent $a$, one year of this prosecution

\textsuperscript{170} Accordingly, one of the three main bases for an adjustment under these provisions is pendency of the application for more than three years, regardless of the specific reason for the delay (although the delay cannot be attributable to the putative patentee). See 35 U.S.C. § 154(b)(1)(B). However, the adjustments may result in a patent term that is longer than seventeen years total because pendency beyond three years is not the only means of calculating USPTO delay. See, e.g., \textit{id.} § 154(b)(1)(A).

\textsuperscript{171} 35 U.S.C. § 154(c)(1).
time was attributable to USPTO delay. Unlike patent α, however, patent β may take advantage of a USPTO delay adjustment and will be granted a term of nineteen years, while α will only benefit from an eighteen-year term. Given that each patent was subjected to a year of prosecution delays beyond the patentees' control, considerations of fairness and consistency would dictate that each should benefit from the same patent term. Further, patent α does not unfairly extend the patent monopoly. Patent α will not receive a longer term than a patent prosecuted under similar circumstances, and the owner of patent α has not manipulated the system because the adjustments received are entirely attributable to USPTO-initiated prosecution delay.

Allowing an individual patent to benefit from both a URAA adjustment and an adjustment for USPTO delay also makes sense in light of the motivations behind the respective statutes providing for each of these extensions. The URAA adjustment provisions were passed to ease the transition between the two patent term regimes by ensuring that a patent issued before the transition is not granted a shorter patent term than a patent issued under the new regime.\(^{172}\) Not allowing the earlier patent to take advantage of an adjustment for USPTO delay often results in the exact situation the URAA adjustments were designed to avoid,\(^{173}\) as seen in the hypothetical. Similarly, the Patent Term Guarantee Act adjustment provisions were passed to ensure that a patent issued after the URAA transition is not granted a shorter patent term than a patent issued prior to the passage of the URAA.\(^{174}\)

In sum, the overall purpose and effect of the two statutes is to bring a measure of consistency to patent terms, regardless of whether a patent was issued before or after the change in patent terms effected by the URAA. Because there is no clear relationship between date of issuance and social merit of a patent, this result is fair to patentees. The current USPTO rule

\(^{172}\) See Merck & Co. v. Kessler, 80 F.3d 1543, 1551 (Fed. Cir. 1996) (making the same argument in the context of URAA adjustments and Hatch-Waxman extensions).

\(^{173}\) That is, a shorter patent term for a patent passed prior to the URAA transition to the twenty-years-from-filing patent term.

\(^{174}\) See Campbell, supra note 34, at 316–17. The goal of the Patent Term Guarantee Act was not to ensure that a patent issued after the URAA transition would be granted a longer term than a pre-URAA patent. Further, another effect of the statute is that it brings consistency to patent terms not only among patents issued prior to and after the URAA, but also among individual patents issued post-URAA, because varying prosecution times can create differing twenty-years-from-filing terms.
that bars a patent issued prior to the URRA from taking advantage of an adjustment for USPTO delay, however, undermines this result.

c. The Rule in Light of the Overarching Goals of the Patent System

Allowing a URRA-adjusted patent to also take advantage of an adjustment for USPTO delay would help achieve consistency in patent terms, resulting in fair treatment to all patentees. However, fairness and consistency are not necessarily the main goals of the patent system. Instead, as discussed previously, the patent system is concerned with maintaining the proper balance between incentives to innovate and public access to technological innovation. The USPTO rule denying a USPTO delay adjustment to a patent previously adjusted under the URRA is likely correct in light of these broader policy considerations. The research and development process underlying all URRA-adjusted patents has already occurred, and thus term extensions are unnecessary to spur this innovation. Moreover, the owners of these patents expected no such extensions when they undertook the development process. To further reward the owners of these patents at the expense of delayed public access would result in a windfall to patent owners and deadweight loss to society.

This is not to say that fairness and consistency do not have a place in the patent system’s balancing act, however. A patent system that offers fair and consistent rewards to innovators encourages future innovation by boosting potential innovators’ confidence in the system and by providing past innovators with positive experiences such that they will be incentivized to innovate again. In this case—particularly since the rule has been in effect without observable detriment for twelve years, and because patents theoretically eligible for both adjustments concurrently are gradually expiring and leaving the patent system—considerations of fairness and consistency are insufficient to justify a change to a rule that promotes the goals of the patent system by denying overcompensation to patent holders.

175 See Beard et al., supra note 1, at 240.
176 See supra note 146 and accompanying text discussing the number of such patents currently in force.
2. Availability of a USPTO Delay Adjustment for a Terminally Disclaimed Patent

When a patent is obtained on the condition that it is terminally disclaimed to a reference patent to avoid an obviousness-type double patenting problem, the terminally disclaimed patent may not obtain a term adjustment for USPTO delay.\(^{177}\) This rule, implemented via USPTO regulations, arises from the Patent Term Guarantee Act—codified at § 154(b)(2)(B)—which states: “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.”\(^{178}\) The Federal Circuit in Hi-Tech confirmed that this section “expressly excludes” a terminally disclaimed patent from the benefit of a USPTO delay adjustment.\(^{179}\)

This rule is consistent with the role of the terminal disclaimer in preventing an unwarranted extension of the patent monopoly. Because a terminal disclaimer is a device used by a patentee to overcome an obviousness-type double patenting rejection, the terminally disclaimed patent covers only an obvious iteration of the invention disclosed in the patent to which it is terminally disclaimed.\(^ {180}\) The terminal disclaimer prevents the patentee from unfairly extending the monopoly of the reference invention by ensuring that the second patent, which also covers this invention (with obvious changes or improvements), does not extend in time beyond the expiration of the reference patent.\(^ {181}\) If a patentee were allowed to extend the duration of the second patent beyond the date of terminal disclaimer by claiming an adjustment for USPTO delay, the role of the terminal disclaimer in preventing unjustified extensions of the patent monopoly would be undermined.

Although allowing a terminally disclaimed patent to take advantage of an adjustment for USPTO delay would result in extending the monopoly of the initial invention, it is true that such an adjustment is only granted in the case of prosecution delay attributable to the USPTO.\(^ {182}\) Therefore, opportunities for patentees to manipulate the system to achieve unwarranted extensions of patent rights are minimized. Further, although

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\(^{178}\) Id.

\(^{179}\) Merck & Co. v. Hi-Tech Pharmacal Co., 482 F.3d 1317, 1322 (Fed. Cir. 2007).


\(^{181}\) See id.

the claims in a terminally disclaimed patent may be obvious in light of a reference patent, they are still different from the claims in the reference patent. For example, the disclaimed patent might include broader claims or various improvements to the reference invention. One reason to apply for such a patent, although it must be terminally disclaimed, is to acquire protection over these variations for the remaining term of the reference patent.\(^{183}\) If a terminally disclaimed patent suffers long prosecution times, that term is inevitably shortened, since the patent must expire on the same date as the reference patent. This also provides a reason to allow the terminally disclaimed patent to extend beyond the expiration of the reference patent.

These arguments are unconvincing, however. Although patentee opportunities to manipulate the system are minimized in this case, allowing the owner of a terminally disclaimed patent to take advantage of an adjustment for USPTO delay would result in an unwarranted extension of patent rights over the reference invention, regardless of whether the patent owner orchestrated this extension. The extension would be unwarranted because a delay in prosecution of the disclaimed patent is irrelevant to the duration of the reference patent and should not be used to effectively extend the term of the reference patent. Although a patentee may indeed suffer from a truncated period of protection over the broader claims or improvements claimed in the disclaimed patent, such claims are not independently patentable. The potential harm in granting a patentee an extended monopoly over a reference invention is greater than that arising from truncating the rights over claims that could not exist independently of that invention. Therefore, the rule preventing a terminally disclaimed patent from benefitting from a USPTO delay adjustment helps maintain the appropriate balance between incentives and access.

\textit{a. If a Reference Patent Has Received an Adjustment for USPTO Delay}

An exception to this rule exists if the reference patent itself receives an adjustment for USPTO delay.\(^{184}\) In this case, the terminally disclaimed patent may receive an independent adjustment extending the expiration of the terminally disclaimed patent up to, but not exceeding, the expiration date of the reference patent.\(^{185}\)

\(^{183}\) See Hinkens, \textit{supra} note 8, at 389–90.
\(^{184}\) See id. at 381–82.
\(^{185}\) See id.
This exception represents the current approach of the USPTO in relevant cases. Such a case has not been litigated before the Federal Circuit; however, it is worthwhile to inquire whether such an approach fits the overall policy goals of the U.S. patent system. Although the exception is potentially confusing to patent holders and their competitors, it does nevertheless strike an appropriate balance between relevant policy considerations. This can be seen most clearly by comparing the outcomes of alternative approaches to the outcomes of the approach currently adopted by the USPTO.

i. Approach (i): Eliminate the Cap on Adjustment for the Disclaimed Patent

One possible alternative to the current approach of the USPTO is to eliminate the reference-based cap on adjustment for the disclaimed patent. In other words, a patentee could claim whatever adjustment was due under the USPTO delay calculations for the terminally disclaimed patent regardless of the adjusted expiration of the reference patent. As an example of this approach, consider patent $\alpha$, which has been terminally disclaimed to patent $\alpha$, such that $\alpha$ and $\beta$ expire on date $D$. Patent $\alpha$ qualifies for and receives an adjustment based on USPTO delays during prosecution that total a year; thus, $\alpha$ has a new adjusted expiration date of $D + 1$. Patent $\beta$ qualifies for an adjustment based on USPTO delays during prosecution that total two years. Under this approach, once $\alpha$ has received an adjustment, $\beta$ could take advantage of the entire two years of delay-based adjustment, such that $\beta$ would now expire on date $D + 2$, one year later than $\alpha$.

This approach would be advantageous to an owner of a terminally disclaimed patent because the term for the claims in the disclaimed patent would not be truncated by prosecution delays that were beyond the owner’s control. This approach is unacceptable from a policy perspective, however, because it implicates the same concerns that the general rule forbidding a USPTO delay adjustment to a terminally disclaimed patent addresses. Namely, such a position would allow a patentee to effectively and inappropriately extend the monopoly over the reference patent based on delays in the prosecution of the disclaimed patent that are

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186 Although the USPTO advises patentees as to the term of enforceability of their patents, it does not make final decisions determining the durations of patents. *Id.* at 381 n.22.

irrelevant to the reference patent. Any detriment a patentee might suffer by not reaping the full adjustment period for the obvious improvements or modifications to the reference invention is outweighed by the harm caused by the unwarranted extension of monopoly rights.

ii. Approach (ii): Eliminate All USPTO Delay Adjustments for a Disclaimed Patent

A second possible approach is to disallow all USPTO delay adjustments for a terminally disclaimed patent, regardless of whether any such adjustments were granted to the reference patent. Consider once again patent α, to which patent β has been terminally disclaimed such that both patents expire on date D. Patent α qualifies for a one-year adjustment due to qualifying USPTO delays, so α's expiration date is thus adjusted to D + 1. Patent β qualifies for a two-year adjustment due to USPTO delays; however, under the rule contemplated here, β would receive no adjustment and would expire on date D, one year earlier than patent α.

This approach, unlike approach (i), would certainly prevent any inappropriate extension of the patent monopoly. It too is suboptimal, however, because it goes too far in the opposite direction, withholding patent protection from a patent owner when there is no compelling policy rationale for doing so. As discussed previously, the reason patent β is terminally disclaimed to α, a commonly owned patent, is to prevent the patent owner from using β to extend the monopoly over the invention claimed in α. As long as β expires concurrently with α, this goal is achieved. To maintain the expiration date of β at date D when α now expires a full year later, and when the patentee has suffered delays in prosecuting β caused by the USPTO, unnecessarily truncates the patentee's exclusivity rights over the inventions claimed in patent β.


A third approach is to automatically adjust the expiration of the terminally disclaimed patent to correspond to the new adjusted expiration of the reference patent. Consider patents α and β, which are linked by a terminal disclaimer and expire on date D. Once again, α qualifies for an adjustment shifting its expiration to D + 1. This time, however, patent β suffered no prosecution delays that would entitle it to an adjustment.

188 See id.
189 See id.
Nevertheless, β’s expiration date would automatically adjust to be concurrent with α’s adjustment such that it would also expire on date D + 1. Alternatively, patent β may have suffered prosecution delays that would theoretically entitle it to a two-year adjustment, but under this approach, β would only receive a one year extension and would be adjusted to a new expiration date of D + 1.

This approach carries with it the advantages of clarity and certainty for a patent owner and its competitors. The simple rule dictates that the disclaimed patent and reference patent expire on the same date, regardless of any USPTO delay adjustments claimed by the reference patent. This provision of clarity is particularly important in cases where the terminally disclaimed patent is disclaimed to the “full statutory term” of the reference patent and does not mention a specific expiration date. Further, this approach satisfies the purpose of the terminal disclaimer because the terminally disclaimed patent will never expire after the reference patent. A similarly simple rule for terminally disclaimed patents was adopted for URNA adjustments: a terminally disclaimed patent automatically benefits from any URNA adjustment granted to the reference patent.

Despite these advantages over the other approaches, this approach still does not represent the best approach because it grants patent owners an unwarranted extension of patent rights. With this approach, however, the concern is not the classic concern of extending the monopoly over the reference invention that the terminal disclaimer is meant to address, but the concern is instead of inappropriately extending the monopoly over the claims in the terminally disclaimed patent that differ from the reference invention. This extension might occur because, as in the hypothetical presented, there are delays in the prosecution of patent α that justify an expiration adjustment for that patent, but there are no (or fewer) delays for the terminally disclaimed patent, β. If β is allowed to take advantage of α’s adjustment, then the monopoly over the broader or additional claims of patent β is extended for reasons unrelated to β’s prosecution. Patent β has already benefitted from the full patent term to which it is entitled, and to

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190 Under current law, a terminal disclaimer must follow this format if the patentee wishes to take advantage of a URNA extension for the terminally disclaimed patent. See MPEP, supra note 29, § 2701.

191 This statement assumes that the disclaimed patent does not qualify for another extension, such as a Hatch-Waxman extension.

192 35 U.S.C. § 154(c)(1) (2006). This is the case unless the terminal disclaimer did not mention the “full statutory term” of the initial patent. See MPEP, supra note 29, § 2701.
grant it a term extension based on the prosecution history of patent $\alpha$ would be inappropriate.


Presented finally is the approach currently adopted by the USPTO when a reference patent tied to a terminally disclaimed patent has been granted an adjustment for USPTO delay. Under this rule, patent $\beta$, terminally disclaimed to patent $\alpha$ and expiring on date $D$, may claim only those adjustments for which it independently qualifies, up to but not exceeding the adjustments claimed by patent $\alpha$.$^{193}$ For example, if $\alpha$ qualifies for a one-year adjustment due to prosecution delays such that its expiration is shifted to $D + 1$, and $\beta$ only independently qualifies for a six-month adjustment due to prosecution delays, then $\beta$'s expiration date would be shifted from $D$ to $D + 0.5$. Conversely, even if $\beta$ independently qualifies for a two-year adjustment due to prosecution delays, $\beta$'s expiration date would shift only to $D + 1$ because $\alpha$'s expiration date places a cap on the term of $\beta$.

This is the best approach because the requirement that patent $\beta$ independently qualify for any prosecution delay adjustments prevents the unwarranted extension of monopoly right over the contents of patent $\beta$. Similarly, placing a cap on the latest expiration date of $\beta$ based on the adjusted expiration of $\alpha$ prevents the unwarranted extension of monopoly rights over the contents of patent $\alpha$. The disadvantage to this approach is that it uncouples the expiration dates of a terminally disclaimed patent and its reference patent, which may confuse patent owners and their competitors about the duration of patent rights. Such confusion could lead to inefficient decision making and expensive litigation. This potential confusion may be a necessary price to pay, however, to achieve the benefits of finely calibrated patent rights that are not inappropriately extended or truncated.

C. The Hatch-Waxman Act

1. Generally

The Hatch-Waxman Act provisions offering patent term extensions to pharmaceutical manufacturers$^{194}$ as a compromise in exchange for

$^{193}$ See Hinkens, supra note 8, at 389–90.

$^{194}$ Hatch-Waxman extensions are also available for patents covering medical devices, certain food products, and other inventions requiring FDA regulatory review prior to (continued)
statutory reforms allowing generic manufacturers to enter the market more quickly and efficiently have been generally viewed as a positive development in the law.\textsuperscript{195} A new pharmaceutical product must undergo lengthy regulatory review before being approved for marketing, and the period of review often substantially cuts into the term of patent protection.\textsuperscript{196} This is particularly true because post-URAA patent terms are measured from the date of filing rather than from the date of issue. Truncating patent terms raises the concern that pharmaceutical innovators may not be sufficiently incented to research and develop new products.\textsuperscript{197} This concern is particularly salient in the drug industry because of the possibility that the most innovative and socially valuable drugs are also those that require the lengthiest periods of clinical testing and regulatory review.\textsuperscript{198} The relevant Hatch-Waxman Act provisions allow a patent owner to recover some of this time by extending the duration of the patent based on regulatory review times for the patented invention.\textsuperscript{199} These provisions preserve incentives to innovate in a socially valuable industry. Further, provisions providing maximum caps on extensions\textsuperscript{200} and requiring merely that generic manufacturers secure regulatory approval to sell patented drug equivalents counterbalance research incentives by ensuring that public access to these innovations is not unduly curtailed. Finally, limiting the availability of extensions by other means\textsuperscript{201} reduces marketing. See Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585.

\textsuperscript{195} See, e.g., Thomas Chen, Note, Authorized Generics: A Prescription for Hatch-Waxman Reform, 93 VA. L. Rev. 459, 464 (2007); Lechner-Fish, supra note 70, at 383.

\textsuperscript{196} See Avery, supra note 58, at 172 n.10.

\textsuperscript{197} See Roin, supra note 60, at 508.

\textsuperscript{198} See id. at 509–13.

\textsuperscript{199} The exact period of extension is calculated as the duration of the NDA regulatory review period, plus one-half of the duration of any IND regulatory review period. 35 U.S.C. § 156(c) (2006).

\textsuperscript{200} For most patents, the Hatch-Waxman Act provides for a maximum five-year extension. Id. § 156(g)(6)(A). The total patent term cannot extend more than fourteen years past the date of regulatory approval. Id. § 156(c)(3). For patents issued (and for which regulatory testing of the patented product had begun) prior to the enactment of the Hatch-Waxman Act, the Act provides for a maximum extension of only two years, because incentives are not required; the development process had already begun. Id. § 156(g)(6)(C). See also Lechner-Fish, supra note 70, at 392.

\textsuperscript{201} These other limitations include the limitations of one extension per patent and one extension per regulatory review period. See 35 U.S.C. §§ 156(a)(2), (c)(4).
opportunities for gaming by the pharmaceutical industry\textsuperscript{202} and reduces the likelihood of granting an extension in a case where the extension does not incentivize innovation.\textsuperscript{203}

Thus, the Hatch-Waxman Act extensions serve the goals of the patent system by maintaining the appropriate balance between incentives and access. The picture becomes more complicated, however, when other opportunities for extensions and adjustments are layered onto the Hatch-Waxman Act provisions.

\section{URAA}

Two basic rules govern the interaction between a URAA adjustments and a Hatch-Waxman extension. These rules were delineated by the Court of Appeals for the Federal Circuit in \textit{Merck \& Co. v. Kessler}, where the Federal Circuit confronted two different situations involving the URAA and the Hatch-Waxman Act.\textsuperscript{204}

\textit{a. Availability of a Hatch-Waxman Extension and a URAA Adjustment for a Patent Not Yet Expired on June 8, 1995}

\textit{i. The Federal Circuit's Holding in Kessler}

The first situation involved a group of patents issued prior to June 8, 1995, that each qualified for URAA adjustments because the twenty-years-from-filing term would have resulted in a later expiration date than the previous seventeen-years-from-issuance term.\textsuperscript{205} These patents had also previously qualified for Hatch-Waxman extensions based on regulatory delays, but the extension period had not yet begun; thus, the original seventeen-year term of these patents had not yet expired.\textsuperscript{206} When the URAA went into effect, the owner of these patents asked the FDA to republish the patents with expiration dates consistent with the new twenty-years-from-filing term, while maintaining the previously granted Hatch-

\textsuperscript{202} Gaming by the pharmaceutical industry has been a problem with respect to other aspects of the Hatch-Waxman Act not discussed in detail here. The 2003 Hatch-Waxman Act amendments were meant to address these and other abuses. For a discussion about the success of these amendments, see \textit{Avery, supra} note 58, at 188--95.

\textsuperscript{203} Some have argued that these limitations, including the fourteen-year extension limitation, go too far. \textit{E.g.}, \textit{Wilson, supra} note 163, at 510.

\textsuperscript{204} \textit{Merck \& Co. v. Kessler}, 80 F.3d 1543, 1544 (Fed. Cir. 1996).

\textsuperscript{205} \textit{Id.} at 1550.

\textsuperscript{206} \textit{See id.}
Waxman extensions. Following the reasoning of the USPTO, the FDA refused to do so. The USPTO took the position that under the Hatch-Waxman Act, a patentee with a Hatch-Waxman extension could only be granted the greater of the original seventeen-years-from-issue term plus the relevant extension, or the new twenty-years-from-filing term without any Hatch-Waxman extension. The patentee could not take advantage of both the new twenty-year term and the Hatch-Waxman extension concurrently. This position was based on language in the Hatch-Waxman Act, which states that a Hatch-Waxman extension should be calculated “from the original expiration date.”

The Federal Circuit disagreed with that position, and held that a patentee can take advantage of both a URAA adjustment and a Hatch-Waxman extension. The court looked to the legislative history of the Hatch-Waxman Act and concluded that Congress included the language requiring the extension to be added to the “original” expiration date to prevent a single patent from receiving more than one Hatch-Waxman extension, not to prevent granting an extension to a patent that had benefitted from another type of extension. The court also took note of the district court’s argument that the policy goal of the URAA transitional provisions was to establish consistency in patent terms among patents issued before the term change and those issued after the term change. Under the USPTO’s reading of the statute, a patent granted after the URAA cutoff date that also qualifies for a Hatch-Waxman extension could take advantage of both a twenty-year term and a Hatch-Waxman extension; a patent granted before the cutoff date could not. The court found that this result would conflict with the policy underlying the grant of URAA adjustments.

207 The FDA is required to publish expiration dates of patents granted extensions under the Hatch-Waxman Act to help facilitate the communication of relevant information between patent owners and their generic competitors. Id. at 1547.
208 Id. at 1548.
209 Id.
211 Kessler, 80 F.3d at 1550–52.
212 Id. at 1550–51.
213 Id. at 1549.
214 Id. at 1551.
215 See id.
ii. Policy Implications

The Federal Circuit's reasoning in Kessler illustrates the difficulty of weighing statutory construction and policy considerations when two statutes enacted for different purposes interact in unexpected ways. In spite of this difficulty, the court's first holding—that a patent issued prior to the URAA cutoff with an original term not yet expired on that date may take advantage of both a URAA adjustment and a Hatch-Waxman extension—advances the patent system by promoting goals of both the URAA and the Hatch-Waxman Act, and is fair to both patent holders and their competitors. On the one hand, the URAA adjustment provisions aim to promote term consistency among patents issued both before and after the URAA cutoff date. As the Federal Circuit noted in Kessler, to deny such an adjustment to a patent issued prior to the cutoff date solely because it had been granted a Hatch-Waxman extension would undermine this consistency because a patent issued after the cutoff date may benefit from both a twenty-year term and any Hatch-Waxman extension for which it qualifies. On the other hand, the Hatch-Waxman extension provisions aim to provide research and development incentives to pioneer pharmaceutical companies and to deliver a quid pro quo to such firms in return for eased generic market entry. Denying a Hatch-Waxman extension to a patent taking advantage of a URAA adjustment would undermine not only the URAA's goal of patent term consistency, but also the incentives offered by the Hatch-Waxman Act, solely because a patent was issued prior to June 8, 1995. Although it could be argued that a Hatch-Waxman extension is unnecessary for such a patent because the product at issue has already been developed, this argument is inapposite in this situation. Unlike the case where a patentee would have developed the invention notwithstanding an incentive, for these patents, the inventions at issue were developed with the expectation that such incentives would be available. Removing such incentives after the fact because of a change

216 See id. at 1549.
217 See id. at 1551.
218 See Lechner-Fish, supra note 70, at 389–91.
219 An example discussed in this Article is that of a URAA-adjusted patent seeking an adjustment for USPTO delay. See supra Part III.B.1.c.
220 The difference here between a URAA-adjusted patent seeking a Hatch-Waxman extension and one seeking an adjustment for USPTO delay is the relative timing of the statutes at issue. The Hatch-Waxman Act was enacted in 1984, eleven years prior to the URAA, while the Patent Term Guarantee Act was passed in 2000, five years after the (continued)
in patent term beyond the patentee’s control—i.e., the enactment of the URAA—would be unfair and would undermine confidence in the system of incentives provided by the Patent and Hatch-Waxman Acts.

b. Availability of a Hatch-Waxman Extension and a URAA Adjustment for a Patent in Force on June 8, 1995, Solely Due to a Hatch-Waxman Extension

i. The Federal Circuit’s Holding in Kessler

A somewhat different situation led the court in Kessler to limit the general rule allowing a patent to benefit from a URAA adjustment and a Hatch-Waxman extension concurrently.\textsuperscript{221} Some of the patents at issue in Kessler were in force as of the URAA cutoff only because of a previously granted Hatch-Waxman extension.\textsuperscript{222} For example, one patent in force on June 8, 1995, had already expended seventeen months of its two-year Hatch-Waxman extension.\textsuperscript{223} The patentee argued that the full two-year Hatch-Waxman extension should be added to the new twenty-years-from-filing term granted under the URAA.\textsuperscript{224}

The Federal Circuit did not find improper the USPTO’s practice of granting URAA adjustments to patents in force on June 8, 1995, solely because of previously granted Hatch-Waxman extensions.\textsuperscript{225} The court did find, however, that for such a patent, a Hatch-Waxman extension could not be added to the URAA-adjusted patent term.\textsuperscript{226} The court reasoned that granting both a URAA adjustment and a Hatch-Waxman extension in such a case could only occur in one of two ways: either the full term of the Hatch-Waxman extension could be added onto the URAA-adjusted term, as the patentees requested, or the Hatch-Waxman extension could be “split,” for example, by adding six months to the URAA-adjusted term for a patent that had already expended seventeen months of its two-year Hatch-Waxman extension.\textsuperscript{227} The court found that the first method would

\textsuperscript{221} Kessler, 80 F.3d at 1552–53.
\textsuperscript{222} Id. at 1552.
\textsuperscript{223} Id.
\textsuperscript{224} See id.
\textsuperscript{225} The court did not explicitly consider this question. See id.
\textsuperscript{226} Id. at 1552–53.
\textsuperscript{227} See id. at 1552.
violate the Hatch-Waxman Act because it would result in a Hatch-Waxman extension greater than two years, a result explicitly forbidden by the Act for the patents at issue. As for the second method, the court noted that the patentees had not asked for such a remedy, and furthermore, that the Hatch-Waxman Act did not provide for such a “splitting” of extensions.

Thus, because neither method of adding a Hatch-Waxman extension complied with the Act, the court found such an addition impermissible. The court found that although consistency was indeed a goal of the URAA, it did not justify violating the explicit two-year statutory limitation on Hatch-Waxman extensions for these patents, as Congress “struck the balance it wished between [Hatch-Waxman] extensions and [the] early availability of generics.”

ii. Policy Implications

A proper analysis of the Federal Circuit’s second holding in Kessler is more complicated than the first. Although the court correctly found that a Hatch-Waxman extension should not be added in its entirety to a URAA-adjusted patent in this circumstance, the court’s opinion lacked a proper explanation. The court failed to reveal why a patent in this category should be granted a URAA adjustment in the first place, and why, if a patent is granted such an adjustment, it must lose any unexpended but earned Hatch-Waxman extension. Examining these questions reveals that denying a URAA adjustment, but allowing a full Hatch-Waxman extension best serves the goals of the patent system. However, a further examination reveals that these two incorrect rules interact to achieve basically the same effect on a patent’s term as would be achieved if both rules were corrected to conform to a more comprehensive policy analysis. Because of this, a change to these rules is unnecessary, as it would create costs without producing measurable benefits.

First, the Federal Circuit was correct to hold that a Hatch-Waxman extension should not be added in its entirety to a URAA-adjusted patent when the patent benefitted from the URAA adjustment solely because of a partially expended Hatch-Waxman extension. Allowing such a practice

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228 The Hatch-Waxman Act caps the maximum possible extension under its provisions at two years for patents issued prior to the passage of the Act. 35 U.S.C. § 156(g)(6)(C). The two-year maximum applied to the patents at issue in Kessler. Id. at 1553.

229 Id. at 1552.

230 Id. at 1553.

231 Id.
would grant a patent a longer Hatch-Waxman extension than it had "earned" due to regulatory delay. For example, if a patent had been granted a two-year Hatch-Waxman extension but had already expended seventeen months of this extension at the time of URAA adjustment, adding two full years to the new twenty-years-from-filing term would result in a total Hatch-Waxman extension of over three years for a patent that had only undergone two years of regulatory delay. Such an expansion of Hatch-Waxman rights for these patents would unnecessarily extend the monopoly of patentees because this additional incentive was neither anticipated by the patentee nor required to spur the innovation of the patented product. Further, the expansion serves no other obvious purpose, such as promoting consistency among patent terms.

Although the Federal Circuit was correct in this first finding, two issues remain related to the category of patents in force on July 8, 1995, solely because of a Hatch-Waxman extension. The first is whether a URAA adjustment is justified for a patent in this category. The Federal Circuit did not address this issue in Kessler; however, the answer is likely no. Granting a URAA adjustment to a patent in force at the time of transition only because of a Hatch-Waxman extension effectuates an unnecessary expansion of the patent monopoly. The URAA-based policy consideration of consistency is not so strongly implicated for such a patent, because but for the Hatch-Waxman extension, the patent would have already expired prior to the transition to the twenty-year term. With any Hatch-Waxman extension, such a patent will expire soon after the URAA's cutoff date.

The second issue is whether a patent in force at the time of transition only because of a Hatch-Waxman extension should nevertheless have these rights truncated due to the intervening URAA adjustment. This result

232 The total Hatch-Waxman extension in this case would be seventeen months plus twenty-four months, or forty-one months. Id. at 1552.

233 In fact, this practice would have the opposite result, as a patent in force at the time of URAA adjustment solely because of a partially expended Hatch-Waxman extension would be able to take advantage of an "extra" Hatch-Waxman extension not available to other patents. The goal of consistency would thus be undermined.

234 See id. (noting only that the patents received a term adjustment under the URAA).

235 Consistency is much more strongly implicated, on the other hand, for a patent issued on June 7, 1995, one day before the URAA's transition to a twenty-years-from-filing term. Without the benefit of a URAA adjustment, such a patent would expire seventeen years from that date, while a similar patent filed on June 9, 1995, would expire twenty years from filing.
occurs because under *Kessler*, a patent in this category may not "split" an earned Hatch-Waxman extension. 236 Such splitting would allow any portion of a Hatch-Waxman extension not expended prior to the URAA adjustment to be added to the new twenty-years-from-filing term. The Federal Circuit correctly noted that the patentees in *Kessler* did not ask for such splitting, and therefore did not evaluate this issue further. 237 Thus, the patentee loses any period of Hatch-Waxman extension unexpended at the time of URAA adjustment. However, this too appears to be an incorrect result when viewed from a policy perspective. Just as the court found in the first holding of *Kessler* that it would be unwise policy to deprive a patent of the benefit of an earned Hatch-Waxman extension in its entirety, 238 it is also unwise to partially deprive a patent of such an earned extension.

It appears, therefore, that a patent in force on June 8, 1995, because of a Hatch-Waxman extension should be able to realize the full Hatch-Waxman extension to which it is entitled without having such rights effectively truncated by an intervening URAA adjustment. On the contrary, such a patent likely should not benefit from a URAA adjustment at all. In practice, these two inappropriate rules together tend to achieve the same result that would be achieved if both rules were corrected. This occurs because, for an individual patent, the greater the portion of a Hatch-Waxman extension that has been expended at the time of URAA adjustment, the shorter that adjustment will necessarily be.

An example best illustrates this principle. Take patent α, which issued one year after filing on December 8, 1976, and has been granted a two-year Hatch-Waxman extension. On June 8, 1995, the date of URAA adjustment, α’s original seventeen-year term has expired, and α has expended eighteen months of its Hatch-Waxman extension. 239 Under current law, α receives a URAA term adjustment but loses any unexpended Hatch-Waxman extension. 240 Since α was filed on December 8, 1975, the

236 See id.
237 See id.
238 See id. at 1550–52.
239 The maximum available Hatch-Waxman extension for a patent in the category considered here is two years. The Hatch-Waxman Act provides for a two-year maximum extension for patents issued prior to the passing of the Act in 1984. 35 U.S.C. § 156(g)(6)(C) (2006). Patents in force solely due to a Hatch-Watchman extension on June 8, 1995, issued at least seventeen years prior to this date (1978 or earlier), and thus a Hatch-Waxman extension for such a patent is capped at two years.
240 *Kessler*, 80 F.3d at 1552–53.
new expiration under the URAA will be December 8, 1995, twenty years from filing. Now consider what would occur if, in accordance with the policy analysis, patent $\alpha$ keeps its full Hatch-Waxman extension but is denied a URAA adjustment. On June 8, 1995, $\alpha$ would not receive a URAA term adjustment but would have six months of Hatch-Waxman extension remaining. Again, $\alpha$ would expire on December 8, 1995.

Although the numbers do not work out to provide an identical expiration date in every case, the general principle illustrated by this example remains consistent. If a greater portion of the maximum two-year Hatch-Waxman extension has been expended at the time of URAA adjustment, the URAA adjustment will necessarily be shorter because more time has passed since the filing of the patent. Conversely, if a smaller portion of a Hatch-Waxman extension has been expended at the time of the URAA effective date, the patent will be entitled to a longer URAA adjustment simply because less time has passed since filing, making the twenty-years-from-filing date further in the future. Thus, although a URAA adjustment may not be justified for a patent in this category, any adjustment it does receive will roughly balance out the portion of the Hatch-Waxman extension that is inappropriately eliminated by the Federal Circuit's holding in Kessler.

3. Availability of a Hatch-Waxman Extension for a Terminally Disclaimed Patent

   a. Merck & Co. v. Hi-Tech Pharmacal Co. and King Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc.

A terminal disclaimer does not affect a patentee's ability to obtain a Hatch-Waxman extension of up to five years. The Federal Circuit announced this rule in Merck & Co. v. Hi-Tech Pharmacal Co. In Hi-Tech, the patent at issue had been terminally disclaimed to a reference patent to avoid a finding of obviousness-type double patenting; both patents thus expired on the same date. This expiration date had already been adjusted once under the URAA. The patent holder, Merck, sought

\begin{footnotes}
\footnote{35 U.S.C. § 156(a); Merck & Co. v. Hi-Tech Pharm. Co., 482 F.3d 1317, 1322 (Fed. Cir. 2007); King Pharm., Inc. v. Teva Pharm. USA, Inc., 409 F. Supp. 2d 609, 613–14 (D.N.J. 2006).}
\footnote{482 F.3d at 1322.}
\footnote{Id. at 1319.}
\footnote{Id.}
\end{footnotes}
an additional extension of the terminally disclaimed patent under the Hatch-Waxman Act based on the regulatory review of the terminally disclaimed drug (but not based on the reference drug).245 Granting such an extension effectively uncoupled the terminally disclaimed patent from the reference patent by extending the terminally disclaimed patent's expiration date beyond that of the reference patent. Hi-Tech, a manufacturer wishing to market a generic version of the patented drug, argued that Merck no longer had a valid patent because such an extension was impermissible.246 The Federal Circuit found that the extension was allowable despite the fact that the disclaimed patent and the reference patent would now expire on different dates.247 The court, following reasoning similar to that employed by the United States District Court for the District of New Jersey in a comparable case, examined the relevant section of the Hatch-Waxman Act: "'The term of a patent . . . shall be extended' if certain conditions are met,248 and explained that the word "shall" in the statutory provision "denotes the imperative."249 Therefore, according to the Federal Circuit, if the conditions for obtaining a Hatch-Waxman extension (which do not include the absence of a terminal disclaimer) are met, then the USPTO must grant the extension.250 USPTO regulations and practice also reflect this reasoning.251

The Federal Circuit in Hi-Tech also looked to the statutory provisions governing USPTO delay adjustments to support its holding.252 Section 154(b)(2)(B) states that "[n]o 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."253 The court in Hi-Tech explained that this section "expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for PTO

245 Id.
246 Id. at 1319–20.
247 Id. at 1321–23.
248 Id. at 1320–22 (quoting 35 U.S.C. § 156(a) (2006)) (emphasis added by the court).
249 Id. at 1322.
250 Id.
251 37 C.F.R. § 1.775 states that if a patent is eligible for extension, that extension "will run from the original expiration date of the patent or any earlier date set by terminal disclaimer." 37 C.F.R. § 1.775(a) (2012). The MPEP states: "A patent may be extended under 35 U.S.C. [§] 156 even though it has been terminally disclaimed." MPEP, supra note 29, § 2751.
252 Hi-Tech, 482 F.3d at 1322.
delays,” and used this explicit prohibition as evidence that a Hatch-Waxman extension is not prohibited for a terminally disclaimed patent because no similar statutory prohibition exists in 35 U.S.C. § 156(a).254

Although the holdings in Hi-Tech and King are based chiefly on statutory interpretation, each court briefly addressed the policy arguments of the parties. In response to Hi-Tech’s argument that granting a Hatch-Waxman extension to a terminally disclaimed patent “would be contrary to the purpose behind the use of terminal disclaimers because it would effectively uncouple the terminal disclaimer from the original expiration date” of the reference patent,255 the Federal Circuit responded that “[t]he purpose of the terminal disclaimer—to prevent extension of patent term for subject matter that would have been obvious over an earlier filed patent—remains fulfilled by virtue of the fact that the date from which any Hatch-Waxman extension is computed is the terminally disclaimed date.”256 In King, the court took a slightly different approach in handling the policy concerns of double patenting and the inappropriate extension of the patent monopoly.257 The court in King answered these concerns by pointing out that Congress had extended terminally disclaimed patents before; in particular, it had done so in connection with URAA adjustments, allowing a terminally disclaimed patent to claim the same term extension granted to the reference patent.258

Neither the Federal Circuit’s arguments nor the District Court of New Jersey’s arguments in this regard adequately addressed the concern of inappropriately extending patent monopolies via double patenting, a concern raised by the defendants in each case. First, the Federal Circuit reasoned that any double patenting concerns are resolved by the fact that the extension is calculated only from the date of terminal disclaimer.259 This logic fails to acknowledge that the terminally disclaimed patent with the Hatch-Waxman extension will extend in time beyond the expiration of the patent to which it is terminally disclaimed. The outcome, like that which would occur if a terminally disclaimed patent were able to benefit

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254 Hi-Tech, 482 F.3d at 1322.
255 Id. at 1321.
256 Id. at 1323.
258 Id.
259 Hi-Tech, 482 F.3d at 1322–23.
from an adjustment for USPTO delay, expands the patent monopoly rights over the inventions claimed in the reference patent for a purpose unrelated to the reference patent. In this case, the rights are expanded for the purpose of regulatory delay in the approval of the terminally disclaimed patent. Although this period of expansion is shortened because the extension is calculated from the date of terminal disclaimer, it is not eliminated. Thus, absent some clear justifying policy rationale, the expansion is inappropriate under the principles of double patenting.

Second, the District Court of New Jersey’s observation that Congress previously extended terminally disclaimed patents in connection with the URAA adjustment provisions does nothing to address the double patenting concern, because in the case of a URAA adjustment, a terminally disclaimed patent extends concurrently with the reference patent. Unlike a patent with a Hatch-Waxman extension, the terminally disclaimed patent does not extend in time beyond that of the reference patent, and thus no double patenting concerns are implicated.

b. Policy Implications

The Federal Circuit was likely correct in finding that the relevant statutory provisions unambiguously direct that a terminally disclaimed patent may take advantage of a Hatch-Waxman extension due to regulatory delay but not a term adjustment due to USPTO prosecution delay. However, both the Federal Circuit’s and the District Court of New Jersey’s inadequate responses to the policy arguments of the generic manufacturers in each case prompt an inquiry into whether such a distinction is justified. Although the Federal Circuit’s reasoning does not explicitly provide an answer, the distinction is likely justified. In each situation, granting an extension to a terminally disclaimed patent based on a consideration unrelated to the issuance of the reference patent, such that the terminally disclaimed patent is uncoupled from, and extends beyond, the term of the reference patent, raises a double patenting concern. Because the terminally disclaimed patent covers basically the same invention as the reference patent (with obvious modifications or additions), the monopoly over the reference invention is effectively extended absent justification due to a

\[260\] See supra Part III.B.2 for a more thorough discussion of the double patenting concerns that arise when a terminally disclaimed patent is granted an extension that is independent of the patent to which it is disclaimed.

\[261\] See Hi-Tech, 482 F.3d at 1322.
delay in prosecution or market release.\textsuperscript{262} In the case of a terminally disclaimed patent qualifying for a Hatch-Waxman extension—unlike a patent qualifying for an adjustment for USPTO delay—the improvements or modifications to the reference patent covered in the disclaimed patent have necessarily resulted in a potentially marketable product that has undergone regulatory review.\textsuperscript{263} This is the case either because the reference patent covered an earlier, unmarketable version of the product, or because the terminally disclaimed patent covers a new product that requires a separate regulatory review period.\textsuperscript{264} In either case, the fact that the invention in the terminally disclaimed patent undergoes regulatory review signifies that the patent will add value to society beyond that contributed by the invention covered in the reference patent, either because an earlier invention has reached a marketable stage, or because a product sufficiently different from an earlier invention to warrant a new regulatory review has been created. The need to preserve incentives for developing these socially valuable, albeit obvious, improvements is just as compelling as it is for any other pioneer pharmaceutical product that is granted a Hatch-Waxman extension. The social value justifies extending the patent monopoly beyond the original expiration of the terminal disclaimer. Conversely, the fact that a terminally disclaimed patent undergoes a delay in prosecution does not necessarily offer any information about the value of the terminally disclaimed patent as compared to the value of the reference patent. Therefore, there is no good reason to expand the patent monopoly of the original patent in this case.


a. 35 U.S.C. § 156(a)

A patent may take advantage of both an adjustment for USPTO delay and a Hatch-Waxman extension.\textsuperscript{265} The rule arises from language in the Hatch-Waxman Act, which states that “[t]he term of a patent . . . shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted

\textsuperscript{262} Otsuka Pharm. Co. v. Sandoz, Inc., 678 F.3d 1280, 1297 (Fed. Cir. 2012).
\textsuperscript{263} This is the case because otherwise the patent would not qualify for a Hatch-Waxman extension. See 35 U.S.C. § 156(a) (2006).
\textsuperscript{264} See id.
\textsuperscript{265} See id.
Although there is no case law directly addressing this issue, the analysis in *Hi-Tech* suggests that the Federal Circuit would uphold such an interpretation. The court in *Hi-Tech* held that although § 156(a) does not explicitly mention the availability of a Hatch-Waxman extension for a terminally disclaimed patent, it unambiguously directs the USPTO to grant such an extension if the necessary conditions are met. Thus, *a fortiori*, § 156(a) should also require the USPTO to grant a Hatch-Waxman extension to a patent that has received a term adjustment under § 154(b) because § 156(a) explicitly allows for such a possibility.

### b. Policy Implications

This rule serves the goals of the patent system. A patentee who loses some of its patent monopoly rights due to USPTO delay and then has its patent rights further truncated by a regulatory review period should be entitled to a remedy for each of these abridgments. Such an approach preserves incentives for innovators while not unduly expanding the patent monopoly. Further, the fact that the Hatch-Waxman extension calculation is made from the time of patent issue and not from the time of patent filing ensures that a patentee is not overcompensated by virtue of overlapping regulatory review and prosecution delay.

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266 *Id.* (emphasis added).


268 *Id.* at 1322.

269 See Boone, *supra* note 89, at 659. To understand this point, consider the following example. A patent is filed and the regulatory review process for the underlying invention is initiated on the same date D. Without any extensions, the patent would expire twenty years from filing, or on date D + 20. The patent takes three years to issue, two of which years are determined to be due to prosecution delay. The patent issues on date D + 3, but its expiration is extended for two years, such that it now expires on date D + 22. The regulatory review process takes five years total, such that it is complete on date D + 5. Instead of adding five years to the adjusted expiration date, the patent may only take advantage of the period of regulatory review extending past the issue of the patent—two years in this case. Thus, the patent will expire on date D + 24, an extension of four years in total. This expiration accounts for the fact that there was overlap between the regulatory review period and the prosecution delay period.
5. Availability of More than One Hatch-Waxman Extension for a Single Product

   a. The USPTO's Interpretation of the Hatch-Waxman Act

A product with a single regulatory review period may be granted only one Hatch-Waxman extension, even if there is more than one patent covering this product. Further, if a product has undergone a previous regulatory review, it may not claim a second extension for a later regulatory review period. These rules arise from the language of the Hatch-Waxman Act and usually preclude a single drug product from taking advantage of more than one Hatch-Waxman extension, regardless of the number of patents or regulatory review periods linked to that product. A quirk in the statutory language opens a loophole, allowing a single product to receive more than one extension when two separate regulatory review periods for a product that is tied to two separate patents happen to conclude on the same date. At least one drug has taken advantage of this loophole with the approval of the USPTO and FDA. The drug Lyrica was undergoing two separate regulatory reviews for use in treating neuropathic pain arising from two different disorders. The NDAs for each of these uses were approved on the same date, and the patent owner argued that each patent should qualify for a Hatch-Waxman extension because there was no previous regulatory approval of the same drug to prevent each drug from being classified as "new" under the statute. The USPTO and FDA agreed with this reasoning and granted an extension for each of the patents.

271 Id. § 156(c)(4).
272 A drug must be classified as a "new drug" to qualify for a Hatch-Waxman extension. Id. § 156(f)(2)(A). The statute further defines "new" as a drug that has not been previously approved for marketing by the FDA. Id. § 156(a)(5)(A). Thus, unless both regulatory review periods are terminated on the same date, the first review period to finish will preempt the availability of a Hatch-Waxman extension for the second review period and related patent because the drug for which the second extension is sought is no longer a "new" drug.
273 Boone, supra note 89, at 662–63.
274 Id. at 662.
275 Id. at 662–63.
276 Id. at 663.
b. Policy Implications

This statutory loophole was likely not contemplated by Congress. Further, it does not represent good policy. A goal of the Hatch-Waxman Act is to provide sufficient incentives for pioneer pharmaceutical manufacturers to research and develop new drugs. In this case, by allowing a single drug to take advantage of more than one Hatch-Waxman extension, the loophole in effect doubles the incentives with no concurrent reciprocal benefit in innovation, causing deadweight loss to the system. It could be argued that the incentives provided by the Hatch-Waxman Act are necessary to encourage a pharmaceutical manufacturer to undertake the regulatory review necessary before the drug can be put to a different and beneficial use. This is a valid argument, but it ultimately fails for the simple reason that it upsets the balance struck by Congress in enacting the Hatch-Waxman Act. Congress decided that a single drug product could not reap more than one Hatch-Waxman extension by denying such an extension to a drug that had previously undergone regulatory review. This choice seems reasonable given that a pharmaceutical manufacturer having once undergone the expense of developing a new drug will likely be willing to submit that drug for regulatory review for as many uses as possible, even if an extension cannot be secured for more than one of the regulatory review periods. A drug that is denied a second Hatch-Waxman extension because the drug’s two regulatory review periods end on separate dates is not significantly different from a second drug that earns two extensions because its two regulatory review periods end on the same date.” Allowing a small number of these drugs to reap a benefit based solely on this difference would not represent a valid incentive, but instead an arbitrary windfall to selected drug manufacturers. Therefore, if the Federal Circuit has the opportunity to evaluate this practice, it should overturn the USPTO’s position and find that multiple Hatch-Waxman extensions are not available in these circumstances.

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277 Id.
278 See Lechner-Fish, supra note 70, at 388–89.
279 In the case of Lyrica, for example, a reasonable argument is that each Hatch-Waxman extension was necessary to incentivize the separate clinical trials needed to gain approval as a drug for treating both herpes-zoster-related neuropathic pain and diabetes-related neuropathic pain.
D. Continuations

1. Availability of a URAA Adjustment for a Patent Based on a Continuation Application

a. MPEP § 2701

A patent based on a continuation application filed after June 8, 1995, may not benefit from a URAA term adjustment despite the fact that the parent application was filed prior to this date. Such a patent will thus be granted a term of twenty years from filing, calculated from the filing date of the parent application. This rule arises from USPTO practice and regulations. Section 2701 of the Manual of Patent Examining Procedure (MPEP) states: "A patent granted on a continuation...application that was filed on or after June 8, 1995, will have a term which ends twenty years from the filing date of earliest application...regardless of whether the application...was filed prior to June 8, 1995."283

b. Policy Implications

This rule serves the goals of the patent system because it further curtails the problem of submarine patenting that the transition to a twenty-years-from-filing term helped to remedy. The practice of submarine patenting is not socially beneficial because it disproportionately rewards the patentee at the expense of future innovators and the public. A switch to a term calculated from filing rather than from issue reduces the usefulness of a submarine patent to patentees because patentees lose monopoly protection for any term during which they deliberately delay issuance. If a patent based on a continuation filed after the URAA cutoff could profit from an alternative term calculation, the benefits of this switch would be undermined. A patentee with a patent filed prior to the cutoff could continue to file continuation applications based on this earlier date indefinitely without sacrificing any patent term. The current practice prevents such abuses. Therefore, if the Federal Circuit has the opportunity to evaluate this practice, it should uphold the USPTO's position on this matter.

281 See MPEP, supra note 29, § 2701.
282 Id.
283 Id.
284 Lemley & Moore, supra note 96, at 79–80.
285 Id. at 80.
2. Terminal Disclaimer of a Patent Based on a Continuation Application

A terminal disclaimer is equally available to a patent based on a continuation application and a patent based on an original application. However, the URAA transition from an issuance-based term to a filing-based term affected the significance of terminal disclaimers for overcoming obviousness-type double patenting concerns in continuing applications. Before the URAA was enacted, a terminal disclaimer helped ensure that a patentee’s monopoly was not improperly extended by filing multiple continuation applications covering basically the same invention as the parent patent. Because each patent based on a continuation application lasted seventeen years from the date of issue, a patentee could potentially extend the monopoly over the first invention indefinitely by using this technique. Requiring a patentee to disclaim the portion of a continuation patent that extended beyond the term of the parent patent prevented the improper extension of the monopoly over the parent invention. Under the URAA, patents based on continuation applications expire twenty years from the parent application filing date, and thus, the concern of improper extension is mitigated. In many cases, no portion of the term may be disclaimed because the parent and child already expire on the same date.

Despite the seeming insignificance of the terminal disclaimer for a patent based on a continuation application, the disclaimer must still be filed in this situation or the patentee risks having both the parent and the child patents invalidated. One might inquire whether this requirement serves any useful purpose, or instead, whether it places an unnecessary burden on patentees and provides a means of invalidating an otherwise valid patent on the basis of a mere formality.

The answer to this question is that the terminal disclaimer continues to play an important role in continuation applications for two reasons. First, due to the potential availability of various extensions to the child patent, the parent patent, or both the child and the parent may not automatically

287 See Lemley & Moore, supra note 96, at 87 n.92.
288 Id. at 79–80.
290 See Lemley & Moore, supra note 96, at 87 n.92.
291 MPEP, supra note 29, § 804.02.
expire on the same date.\textsuperscript{292} In such cases, the terminal disclaimer ensures that the obvious continuation patent does not effectively extend the monopoly over the parent patent.

Second, the terminal disclaimer serves another purpose beyond preventing the inappropriate extension of the patent monopoly.\textsuperscript{293} Each terminal disclaimer requires an affirmation that the disclaimed patent and the patent to which it is disclaimed are commonly owned; the relevant patents are invalidated if they cease to meet this requirement at any time.\textsuperscript{294} Absent this requirement of common ownership, a series of obvious patents could be sold by the patentee to several different buyers, each of whom could then independently enforce patent rights against a potential infringer.\textsuperscript{295} This scenario would result in terrible uncertainty for those wishing to use and improve upon the patented inventions and would chill future innovation.\textsuperscript{296} Thus, even if the child and the parent application expire on the same date, the terminal disclaimer serves an important role in ensuring that obvious iterations of an invention remain commonly owned.\textsuperscript{297} The rule requiring an obvious patent to be disclaimed even when the application is based on a continuation application is thus a necessary and beneficial rule that serves the goals of the patent system.

3. \textit{Availability of a Hatch-Waxman Extension for a Patent Based on a Continuation Application}

The Hatch-Waxman Act restricts the availability of Hatch-Waxman extensions for related patents and products:\textsuperscript{298} A patentee may not receive more than one Hatch-Waxman extension for a single patent;\textsuperscript{299} a product with a single regulatory review period may be granted only one Hatch-Waxman extension;\textsuperscript{300} and a product having previously undergone regulatory review may not claim a second extension for a later regulatory

\textsuperscript{292} For example, under the Federal Circuit's decision in \textit{Hi-Tech}, a terminally disclaimed patent may take advantage of a Hatch-Waxman extension such that its expiration uncouples from that of the reference patent. Merck & Co. v. Hi-Tech Pharm. Co., 482 F.3d 1317, 1322–23 (Fed. Cir. 2007).

\textsuperscript{293} See \textit{In re Fallaux}, 564 F.3d 1313, 1319 (Fed. Cir. 2009).

\textsuperscript{294} See 37 C.F.R. § 1.321 (2012).

\textsuperscript{295} See \textit{Fallaux}, 564 F.3d at 1319.

\textsuperscript{296} See id.

\textsuperscript{297} See id.

\textsuperscript{298} See, e.g., 35 U.S.C. §§ 156(a)(2), (c)(4).

\textsuperscript{299} Id. § 156(a)(2).

\textsuperscript{300} Id. § 156(c)(4).
review period. For a patent based on a continuation application, these restrictions generally mean that only the earliest patent in a series of related continuation applications may claim the benefit of a Hatch-Waxman extension.

These statutory restrictions help to prevent both gaming by pharmaceutical pioneers and the societal loss that arises from granting unnecessary extensions to patents based on continuation applications. However, for some time, pharmaceutical manufacturers were able to use the unique interaction of rules governing continuations and terminal disclaimers, along with other provisions of the Hatch-Waxman Act, to delay generic drugs from entering the market and to extend inappropriately their patent monopolies over patented drugs via a practice termed “evergreening.” Although evergreening was effectively terminated by the 2003 amendments to the Hatch-Waxman Act, it exemplifies how the interaction of disparate elements of patent law can interact to create unfortunate policy results.

a. Evergreening

Under the Hatch-Waxman Act, a generic manufacturer wishing to enter the market must first certify to the FDA that its product will not infringe any unexpired patents listed by pharmaceutical manufacturers in the FDA’s “Orange Book.” If the patent owner believes that the generic’s product will infringe such a listed patent, the patentee may ask the court for a thirty-month stay, during which the generic manufacturer may not enter the market unless the infringement dispute is first resolved in the generic manufacturer’s favor. The continuation and terminal disclaimer process allowed a pharmaceutical manufacturer to obtain various patents at different times that all covered basically the same invention, and to list each patent separately in the Orange Book. Each time a new patent was listed, the pharmaceutical manufacturer could apply for a new thirty-month stay. Under the 1984 Hatch-Waxman Act

301 Id. §§ 156(a)(5)(A), (f)(2)(A).
302 See Lemley & Moore, supra note 96, at 81–83.
305 See Lemley & Moore, supra note 96, at 81–83.
306 Id.
provisions, the number of such stays that could be obtained was unlimited; the pharmaceutical manufacturer could therefore delay market entry of generic manufacturers via frivolous stays until the original patent expired.\(^{307}\)

Congress effectively eliminated the practice of evergreening via its 2003 amendments to the Hatch-Waxman Act.\(^{308}\) These amendments provide that no more than one thirty-month stay can be granted for a single product, even if it is linked to many different patents.\(^{309}\) The practice of evergreening is a reminder, however, of how the interaction of disparate provisions of the patent code can leave room for practices that ultimately undermine the policy goals of the patent system.

4. Availability of a USPTO Delay Adjustment for a Patent Based on a Continuation Application

The rules governing the availability of a USPTO delay-based term adjustment for a patent filed as a continuation are complicated and depend on the type of continuation application that is being filed. These rules arise from USPTO practice and regulations and generally promote the goals of the patent system by preventing unjustified extensions of the patent monopoly.

a. USPTO Delay Adjustment for a Patent Based on a Continuation, Continuation-in-Part, or Divisional Application

In general, a patent based on a continuation (excluding RCEs), a CIP, or a divisional application may not take advantage of any USPTO delay adjustments (including A-, B-, and C-type adjustments) accruing before the continuation application was filed.\(^{310}\) This rule prevents unjustifiably extending the patent monopoly. To understand why, consider each type of application in turn. First, a continuation application is typically filed after some claims have been allowed, and argues for broader claims in a second patent.\(^{311}\) The rule thus prevents “double counting” delays in this case by preventing the new patent from taking advantage of any delays already accounted for in the expiration of the first patent. Similarly, a CIP application may be filed after some claims have been allowed, but it also adds new information to the application, something that is forbidden in a

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\(^{307}\) Id.

\(^{308}\) See Avery, supra note 58, at 184.

\(^{309}\) Id.

\(^{310}\) See 37 C.F.R. § 1.704(c)(11) (2012).

\(^{311}\) Lemley & Moore, supra note 96, at 64.
traditional continuation application. The rule that prohibits counting delays that accrue prior to filing the CIP prevents double counting, and also prevents a patentee from taking advantage of delays that are not necessarily related to the new and different information contained in the CIP. Finally, a divisional application is filed when the USPTO determines that a patent application contains more than one patentably distinct invention. As with the CIP application, this rule prevents granting an adjustment to the divisional patent based on delays unrelated to the prosecution of the specific claims of that patent.

b. USPTO Delay Adjustment for a Patent Based on an RCE

An RCE application, unlike the other types of continuations, does not extinguish previously accrued A-, B-, or C-type adjustments. Accrual of B-type delay is precluded after an RCE is filed, stopping the three-year pendency clock on filing the RCE. However, adjustments for A- and B-type delays accruing after filing may still be granted. This differential and more complicated treatment is justified by the purpose of the RCE application. An RCE application is filed after a final rejection of a previous application. Thus, unlike with continuation and CIP applications, there is no previously allowed patent to take advantage of any accrued delay adjustments, and allowing the RCE patent to take advantage of these adjustments would not constitute an inappropriate double counting of extensions. Further, just like continuation, CIP, and divisional applications, there is no unjustified extension inherent in allowing the RCE application to benefit from an adjustment for delays accruing due to USPTO inaction subsequent to the RCE's filing. An RCE application, however, may not take any further advantage of B-type delay (delay accruing due to a longer-than-three-year pendency in the USPTO) once it is filed. This final rule makes sense in light of the function of an RCE application. An RCE application operates as an appeal of a USPTO rejection. Although there is a separate appeal process, the RCE carries the advantage (in most cases) of retaining the same patent examiner and receiving a second chance to persuade that examiner that the invention is

314 See Tyson & Bahr, supra note 44.
315 See id.
316 See id.
317 See Lemley & Moore, supra note 96, at 64.
Because the application was rejected, however, there is no USPTO "fault" if the total pendency of the application is longer than three years. The patentee should not be entitled to an adjustment for time—not attributable to specific failures of the USPTO to act or in ancillary proceedings as in A- and C-type delays—spent prosecuting claims that, in the form presented, were ultimately deemed unpatentable.

E. Other Specific Extensions

Over the years, patent extensions have been granted, privately or publicly, to individual products based on extreme delays in regulatory approval. Between the years 1980 and 2002, seven such extensions were granted; six of these extensions involved food and drug products for human use, while the seventh was a drug product intended for veterinary use. The goal of this Article is not to examine each one of these extensions individually to determine whether each was justified in light of the policy goals of the patent system. In general, however, this type of extension should be avoided when possible. Although a private extension may arguably maintain the proper incentives by correcting the occasional patent term deviation—thereby ensuring that a patentee receives a reward consistent with expectations—the practice also introduces uncertainty to an already complex system of extensions and adjustments, and it may unfairly favor larger producers with more lobbying power.

IV. CONCLUSION AND RECOMMENDATIONS

The current default patent term in the U.S. is measured as twenty years from the date of patent filing. As can be seen from this Article, however, the actual duration of an individual patent can vary extensively due to diverse statutory opportunities for adjustment of the patent term. Moreover, a single patent may be eligible for more than one such adjustment, necessitating a determination of how these various statutes interact. This determination has proved to be complex. In some cases, Congress has clearly laid out the intended interaction among these statutes. In other cases, a determination of how these provisions should interact has been left to the USPTO, and when litigation has arisen, to the Federal

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318 See id.
Circuit, which has been criticized for inconsistent and ad hoc reasoning in these cases.\textsuperscript{320}

What results is a confluence of law that greatly affects the operation of the patent system and also creates uncertain policy implications. This Article systematically evaluates interactions among various statutory schemes affecting patent term adjustments in light of the overarching goals of the patent system—adequately incentivizing innovators and promoting public access to inventions. A summary of this analysis is presented in Table 1.

**Table 1.** Rules Governing the Interactions Among Various Patent Term Adjustments

<table>
<thead>
<tr>
<th>Statute</th>
<th>Rule</th>
<th>Source</th>
<th>Does the Rule Promote the Goals of the Patent System?</th>
</tr>
</thead>
<tbody>
<tr>
<td>URAA</td>
<td>Possible term adjustment for patents issued before June 8, 1995</td>
<td>Congress</td>
<td>No</td>
</tr>
<tr>
<td>Terminally disclaimed patent</td>
<td>URAA adjustment available, but based on language in disclaimer</td>
<td>USPTO</td>
<td>Yes, but distinction based on language unnecessary</td>
</tr>
<tr>
<td>Adjustment for USPTO delay (PTA)</td>
<td>Available to all patents issued after May 29, 2000</td>
<td>Congress</td>
<td>Yes</td>
</tr>
<tr>
<td>URAA adjusted patent</td>
<td>No PTA for a URAA adjusted patent</td>
<td>Congress &amp; USPTO</td>
<td>Yes</td>
</tr>
<tr>
<td>Terminally disclaimed patent</td>
<td>No PTA for a terminally disclaimed patent</td>
<td>Congress &amp; Fed. Cir.</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Exception:</strong> terminally disclaimed patent may claim independent adjustment up to expiration of reference patent</td>
<td>USPTO</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Hatch–Waxman (HW) extension</td>
<td>Extension available for food and drug products subject to regulatory delay</td>
<td>Congress</td>
<td>Yes</td>
</tr>
<tr>
<td>URAA adjusted patent</td>
<td>Extension available for patents unexpired on June 8, 1995</td>
<td>Fed. Cir.</td>
<td>Yes</td>
</tr>
</tbody>
</table>

\textsuperscript{320} See, e.g., Hinkens, supra note 8, at 377, 413.
A brief examination of Table 1 reveals that, in general, the assortment of rules that have arisen to govern the interactions of statutory patent term adjustments promotes the goals of the patent system. This does not mean that some legislative enactments—particularly Congress’s provision for a term adjustment for patents issued prior to June 8, 1995—have not been misguided. It also does not mean that criticisms of the ad hoc approach that the Federal Circuit applied to these cases are meritless. The Federal Circuit has employed varying policy rationales and has wavered about the degree of deference owed to the USPTO in deciding cases dealing with patent term adjustments. Moreover, the Federal Circuit’s finding in Kessler that a patentee must lose a previously earned Hatch-Waxman
extension was incorrect, yet it reached the correct policy result because the court failed to evaluate whether other unjustified extensions should be eliminated.\textsuperscript{321} Similarly, the Federal Circuit's finding in \textit{Hi-Tech} that a terminally disclaimed patent is eligible for a Hatch-Waxman extension but not an adjustment for USPTO delay is unjustified in light of the policy considerations the court actually examined, but the decision is justified in light of the broader goals of the patent system.\textsuperscript{322} While these cases reach the right result, this area of law warrants a more measured approach by the court in the future.

There remain a few sets of circumstances that have yet to be litigated before the Federal Circuit, which are currently governed by USPTO regulations and practice. In some cases, the USPTO has done well to formulate rules that promote the goals of the patent system: for example, USPTO regulations governing the interaction of continuation-based applications with various types of patent term adjustments. The Federal Circuit should accord appropriate deference to the USPTO in cases where such rules are contested. In other cases, such as with the USPTO's current stance that more than one Hatch-Waxman extension is sometimes available for a single drug, the Federal Circuit should closely examine the policy implications of the USPTO's position. Such an approach will ensure that the complicated scheme of patent term extensions continues to serve the goals of the patent system.

\textsuperscript{321} See Merck \& Co. v. Kessler, 80 F.3d 1543, 1552 (Fed. Cir. 1996).

\textsuperscript{322} See Merck \& Co. v. Hi-Tech Pharm. Co., 482 F.3d 1317, 1322-23 (Fed. Cir. 2007).