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WILL COPYRIGHTS EXPIRE IN 2019? REVISITING THE COPYRIGHT CLAUSE: “LIMITED TIMES” AND COPYRIGHT TERM EXTENSIONS IN THE WAKE OF GOLAN

Alex P. Garens†

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ABSTRACT
In the early 2012 case Golan v. Holder, the Supreme Court rejected
the notion that Congress was attempting to create perpetual
copyrights. Yet the Court deliberately made an effort to note that such
conduct would be constitutionally impermissible. In just a few short
years, in approximately 2019, the Court is very likely to be faced with
this specter of perpetual copyrights again. If Congress passes another
copyright extension, the Court will likely have to rule on its
constitutionality, much like 2003’s Eldred v. Ashcroft. But in 2019,
the case against copyright extensions is likely to be fundamentally
different in nature and context. This Article aims to explore the
language and reasoning in Eldred and Golan in search of analytic
cues as to how the Supreme Court is likely to evaluate a future
copyright extension the next time famous copyrighted works and
characters face imminent entrance into the public domain. Ultimately,
this Article concludes that absent significant international lengthening
of copyright terms, the future United States extension will have no
legitimate justification other than a naked desire to create perpetual
copyrights. In such a case, the Supreme Court would find such a
future act an unconstitutional attempt to bypass the “limited Times”
provision of the Constitution.
I. INTRODUCTION

Writing for the majority in the recent Supreme Court opinion Golan v. Holder, Justice Ruth Bader Ginsberg explained that “as long as Congress legislated in installments, perpetual copyright terms would be achievable.” 1 Such conduct, she proceeded, would constitute “legislative misbehavior.” 2 Although the Supreme Court found such conduct to be “far afield” 3 from the circumstances in Golan, the language echoes the Court’s earlier condemnations of perpetual copyrights in Eldred v. Ashcroft and Dastar v. Fox. 4 In fact, Golan was the first time that the Supreme Court discussed the Copyright Clause since Eldred in 2003, when the Court upheld a twenty-year extension of copyright terms. In light of this recent disapprobation on attempts to create perpetual copyrights, attention is paid to the fact that in the not-so-distant-future—2019, approximately—the Court may again have to rule on the constitutionality of yet another copyright extension.

Why? Because, in 2019, copyrights will again begin to expire and the public domain will resume growing. 5 Indeed, the public domain has not grown since 1998, when it was frozen in time due to the Sonny Bono Copyright Term Extension Act (“CTEA”), 6 which extended the duration of all existing copyrights by twenty years. 7 As a result of the

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2 Id.
3 Id.
4 Eldred v. Ashcroft, 537 U.S. 186, 209 (2003) (“As the Court of Appeals observed, a regime of perpetual copyrights ‘clearly is not the situation before us.’ Nothing before this Court warrants construction of the [Copyright Term Extension Act]’s 20-year term extension as a congressional attempt to evade or override the ‘limited Times’ constraint.” (citation omitted)); Dastar Corp. v. Twentieth Century Fox Film Corp., 539 U.S. 23, 37 (2003) (“To hold [for plaintiff] would be akin to finding that § 43(a) [of the Lanham Act] created a species of perpetual patent and copyright, which Congress may not do.”). The Supreme Court had also earlier noted, in more general terms outside the context of Congress’s authority, that “copyright protection is not perpetual.” Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417, 443 n.23 (1984).
CTEA, the copyrights that would have expired and entered the public domain in 1999 were instead protected for an additional twenty years.\(^8\) But on January 1, 2019, the extra years granted to these copyrights by the CTEA will begin to expire.\(^9\) Soon thereafter, the copyrights in works such as Robert Frost’s *New Hampshire* poems, Virginia Woolf’s *Mrs. Dalloway*, Ernest Hemingway’s *The Sun Also Rises*, Alfred Hitcock’s *The Lodger*, Disney’s *Steamboat Willy*, and characters like Mickey Mouse will finally enter the public domain.\(^10\)

That is, of course, unless Congress passes another copyright extension first. And there are good reasons to believe that such an extension will happen.\(^11\) If it does, the enactment will likely be challenged on constitutional grounds, just as the CTEA was challenged in *Eldred*. The big question, of course, is what will happen if the Supreme Court grants certiorari? Will the Court uphold the extension as constitutional (as it did in *Eldred*), or will it find that this time Congress is in fact impermissibly seeking to create a perpetual copyright through installments (a “legislative misbehavior” the Court recently condemned once again)?

This Article aims to analyze the constitutional viability of future copyright term extensions. Enough ink has been spilled criticizing *Eldred v. Ashcroft* and the CTEA. By accepting the past, however erroneous or unwise, the intention of this Article is to find clues in the *Eldred* and *Golan* opinions about the Court’s current attitudes on the

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\(^8\) See Peter B. Hirtle, *Copyright Term and the Public Domain in the United States*, COPYRIGHT INFORMATION CENTER (Jan. 1, 2012), http://copyright.cornell.edu/resources/docs/copyrightterm.pdf (explaining when a copyright will expire based on when the work was published).

\(^9\) For example, the copyrights that were originally set to expire on January 1, 1999 will expire on January 1, 2019, and each subsequent year copyrights will expire after their twenty-year extension has run its course. See Sonny Bono Copyright Term Extension Act § 102.


\(^11\) See LAWRENCE LESSIG, *FREE CULTURE: HOW BIG MEDIA USES TECHNOLOGY AND THE LAW TO LOCK DOWN CULTURE AND CONTROL CREATIVITY* 215-18 (2004) (explaining how the content industry and heirs to famous authors actively and successfully lobby Congress to extend copyrights when copyrights of commercially valuable works are about to expire). Thus, it seems plausible, even likely, that Disney, the Motion Picture Association of America, the Recording Industry Association of America, and the estate of Robert Frost, among others, will again go to Capitol Hill as 2018 approaches to indirectly “buy” another bill extending copyrights. For more on the generally corruptive potential of money in politics and campaign donations, see LAWRENCE LESSIG, *REPUBLIC, LOST: HOW MONEY CORRUPTS CONGRESS–AND A PLAN TO STOP IT* (2011).
Copyright Clause, deference to Congress, and copyright terms, in order to predict how the Court may evaluate a future copyright extension circa 2018.

Section II will lay the background of the discussion by summarizing the CTEA and *Eldred*, as well as the recent case, *Golan v. Holder*. Section III then analyzes the *Eldred* and *Golan* opinions, gleaning clues about the Court’s treatment of the Copyright Clause and its deference to Congress in enacting intellectual property legislation. Section IV brings us to the present (and soon future) by introducing a hypothetical future copyright term extension act, and then evaluates how the future copyright term extension act would likely fare against a constitutional challenge. Ultimately, this Article predicts that the next copyright term extension will carry with it a strong suspicion, if not a presumption, of an impermissible intent to achieve perpetual copyrights. Absent a good faith justification to negate this suspicion of impropriety, such as harmonization with international copyrights laws, the Court will likely find any subsequent extension to be an unconstitutional attempt to bypass the “limited Times” provision: Art. I, § 10, cl. 18. Section V addresses the analytic and theoretical difficulties of determining just when an extension of copyright terms might be constitutional or not. Section VI concludes with an unique observation of how the increasingly technologized access to copyrighted works may be globalizing copyright law in a way that essentially allows the public to ignore lengthy United States copyright terms that it perceives as exceeding foreign copyright terms by an unacceptable degree.

**II. COPYRIGHT EXTENSIONS AND THE COPYRIGHT CLAUSE, FROM *Eldred v. Ashcroft* TO *Golan v. Holder***

**A. The CTEA and Eldred v. Ashcroft**

The issue of copyright extension became highly contentious in the late 1990s in response to the Sonny Bono Copyright Term Extension Act, which sought to extend all existing and future copyright terms twenty years.12 Individuals with a strong interest in using works in the public domain, and thus a desire to see the public domain continue to grow, filed a constitutional challenge against the extension in 1999.13

12 See Sonny Bono Copyright Term Extension Act § 102.
13 Brief for Petitioners at 3, Eldred v. Ashcroft, 537 U.S. 186 (2003) (No. 01-618) [hereinafter “Eldred Petitioners’ Brief”]. In addition to the plaintiffs in Eldred, which included various book and film companies and associations dependent on using works in the public domain, many other groups filed amicus briefs challenging continued . . .
The claim alleged that the CTEA violated the Copyright Clause by impermissibly extending copyrights.\(^\text{14}\) By 2003, the case reached the Supreme Court in \textit{Eldred v. Ashcroft}.\(^\text{15}\) In a 7-2 decision, the Court upheld the copyright extension as constitutional and within Congress’s authority, but expressed doubt that the CTEA was wise policy.\(^\text{16}\)

Copyright extensions are nothing new—since the nascence of the United States federal copyright system in 1790,\(^\text{17}\) terms have been extended in 1831,\(^\text{18}\) 1909,\(^\text{19}\) and 1979\(^\text{20}\) with no constitutional challenge.\(^\text{21}\) So what was the big deal with the CTEA?

According to the plaintiffs, the problem with the CTEA was that extending the term of existing copyrights (a retroactive extension) violates the Copyright Clause, which guarantees authors exclusive rights in their works only for “limited Times.”\(^\text{22}\) If a work’s term,
once granted, could be extended, then it would no longer be “limited” as contemplated in the Constitution, because Congress could indirectly achieve perpetual copyrights by repeatedly extending copyrights once they near expiration. Copyrights must be limited, the argument goes, so the public is ensured that copyrighted works will enter the public domain eventually. And a rich public domain is vital to the promotion of science and the useful arts, the underlying goal of the Copyright Clause. Thus, the syllogistic argument was that retroactive extensions are unconstitutional because they create the potential for perpetual copyrights, and because the CTEA included such a retroactive extension, the CTEA must be unconstitutional.

This blanket argument against retroactive extensions was highly problematic. As the Court noted, each of the previous copyright acts also retroactively extended copyrights, past courts have long upheld

23 Eldred Petitioners’ Brief, supra note 13, at 14 (“[W]hether extensions for works already created prevent copyrights from being for ‘limited Times,’ and exceeds a power to ‘promote the Progress of Science,’ is a judgment that this Court can appropriately make. The line between prospective and retroactive extensions is a clear one. If ‘limited Times’ is to have any meaningful content, it is a line this Court must draw.”).

24 Id. at 18 (“Thus, the sole issue is whether Congress may achieve indirectly what it cannot achieve directly—a perpetual term ‘on the installment plan.’”).

25 See Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417, 429 (1984) (“The monopoly privileges that Congress may authorize are neither unlimited nor primarily designed to provide a special private benefit. Rather, the limited grant is a means by which an important public purpose may be achieved. It is intended to motivate the creative activity of authors and inventors by the provision of a special reward, and to allow the public access to the products of their genius after the limited period of exclusive control has expired.”) (emphasis added); id. at 443 n.23 (“Moreover, since copyright protection is not perpetual, the number of . . . works in the public domain necessarily increases each year.”).

26 See Eldred, 537 U.S. at 241 (Stevens, J., dissenting) (“[A]s our cases repeatedly and consistently emphasize, ultimate public access is the overriding purpose of the constitutional provision.”); id. at 246 (Breyer, J., dissenting) (explaining that the Copyright Clause is designed to benefit the public interest, and as to “increase and not to impede the harvest of knowledge,” operates on a premise that works will enter the public domain for public access and consumption); LAWRENCE LESSIG, THE FUTURE OF IDEAS: THE FATE OF THE COMMONS IN A CONNECTED WORLD 50 (2001) (“[A]ll the stuff protected by copyright law is in one sense the same: It all depends fundamentally upon a rich and diverse public domain. Free content, in other words, is crucial to building and supporting new content.”).

27 See Eldred, 537 U.S. at 198 (“[c]oncerning petitioners’ assertion that Congress might evade the limitation by stringing together ‘an unlimited number of ‘limited times’”).

28 Id. at 200-01; see id. at 193 (“As in the case of prior extensions, principally in 1831, 1909, and 1976, Congress provided for application of the enlarged terms to existing and future copyrights alike.”); id. at 200-01 (“History reveals an unbroken continued . . .
the extension of existing patents,\textsuperscript{29} and, semantically speaking, “limited” does not necessarily mean “fixed.”\textsuperscript{30} Thus, the Court rejected the petitioners’ premise that retroactively extending copyrights is categorically beyond Congress’s authority under the Copyright Clause.\textsuperscript{31}

The narrower and perhaps more salient argument for the petitioners would have been that even if Congress were allowed to retroactively extend copyrights, the CTEA specifically was nonetheless an impermissible congressional attempt to bypass the Copyright Clause’s “limited Times” provision and create perpetual copyrights.\textsuperscript{32} Although plaintiffs noted the possible threat of perpetual copyright terms on the “installment plan,”\textsuperscript{33} any CTEA-specific argument was understated and largely overshadowed by the categorical challenge to retroactive extensions.\textsuperscript{34} The Court addressed this concern briefly, finding that “[n]othing before this Court warrants construction of the CTEA’s 20–year term extension as a congressional attempt to evade or override the ‘limited Times’ constraint.”\textsuperscript{35}

congressional practice of granting to authors of works with existing copyrights the benefit of term extensions . . . . Congress has regularly applied duration extensions to both existing and future copyrights.

\textsuperscript{29}See id. at 201 (“Because the Clause empowering Congress to confer copyrights also authorizes patents, congressional practice with respect to patents informs our inquiry. We count it significant that early Congresses extended the duration of numerous individual patents as well as copyrights.”).

\textsuperscript{30}See id. at 199 (“The word ‘limited,’ however, does not convey a meaning so constricted. At the time of the Framing, that word meant what it means today: ‘confine[d] within certain bounds,’ ‘restrain[ed],’ or ‘circumscribe[d],’ . . . . Thus understood, a timespan appropriately ‘limited’ as applied to future copyrights does not automatically cease to be ‘limited’ when applied to existing copyrights.”).

\textsuperscript{31}See id. (“Text, history, and precedent, we conclude, confirm that the Copyright Clause empowers Congress to prescribe ‘limited Times’ for copyright protection and to secure the same level and duration of protection for all copyright holders, present and future.”).

\textsuperscript{32}See id. at 208 (“Petitioners contend that even if the CTEA’s 20-year term extension is literally a ‘limited Tim[e],’ permitting Congress to extend existing copyrights allows it to evade the ‘limited Times’ constraint by creating effectively perpetual copyrights through repeated extensions.”).

\textsuperscript{33}See Eldred Petitioners’ Brief, supra note 13, at 18 (“Thus, the sole issue is whether Congress may achieve indirectly what it cannot achieve directly—a perpetual term ‘on the installment plan.’”).

\textsuperscript{34}See id. at 13, 19 n.7 (arguing that retroactive extensions creates a line-drawing problem of when a term becomes too extended, urging that the Court draw the line at the CTEA, and claiming that “the Act violates the Constitution” and “crosses the line of any plausible limit”). Unfortunately, the petitioners did not develop this brief argument or attempt to distinguish the CTEA from past extensions.

\textsuperscript{35}Eldred, 537 U.S. at 209-10 (“As the Court of Appeals observed, a regime of perpetual copyrights ‘clearly is not the situation before us.’ Nothing before this continued . . .
Curiously enough, certain language in the majority opinion seemingly suggests that the Court wanted the petitioners to make this, or any, argument specific to the CTEA’s constitutionality. For example, the Court gave great weight to the history of previous retroactive extensions,\(^{36}\) expressed hesitance to rule against centuries of these congressional actions,\(^{37}\) and explicitly faulted petitioners for failing to meaningfully distinguish the CTEA in a constitutionally significant way.\(^{38}\) The Court wanted to hear how the CTEA violated the “limited Times” provision in a way that was different from previous extensions; likely because such an argument would have provided the Court with an avenue to strike down the CTEA without implicating the validity of all the previous Copyright Act extensions.\(^{39}\) Yet, without this avenue before the Court, the petitioners’ principal challenge to the CTEA was simply that it extended existing copyrights, something that every previous copyright act had also done.\(^{40}\) Thus, the Court seemed constrained to find that the CTEA was constitutional.

Finding no violation of the “limited Times” provision, the Court then employed a very deferential rational review of the statute in light of the Copyright Clause’s objectives.\(^{41}\) Largely persuaded by Congress’s claim that the CTEA would promote the objectives of the Court warrants construction of the CTEA’s 20–year term extension as a congressional attempt to evade or override the ‘limited Times’ constraint. Critically, we again emphasize, petitioners fail to show how the CTEA crosses a constitutionally significant threshold with respect to ‘limited Times’ that the 1831, 1909, and 1976 Acts did not. . . . Those earlier Acts did not create perpetual copyrights, and neither does the CTEA.”) (citations omitted).

\(^{36}\) See id. at 213 (“Such consistent congressional practice is entitled to ‘very great weight, and when it is remembered that the rights thus established have not been disputed during a period of [over two] centur[ies], it is almost conclusive.’”).

\(^{37}\) See id. at 221-22 (“If petitioners' vision of the Copyright Clause held sway, it would do more than render the CTEA's duration extensions unconstitutional as to existing works. . . . The 1976 Act's time extensions, which set the pattern that the CTEA followed, would be vulnerable as well.”).

\(^{38}\) See id. at 209-10 (“Critically, we again emphasize, petitioners fail to show how the CTEA crosses a constitutionally significant threshold with respect to ‘limited Times’ that the 1831, 1909, and 1976 Acts did not.”).

\(^{39}\) See supra note 37 and accompanying text.

\(^{40}\) See Eldred, 537 U.S. at 200 (“History reveals an unbroken congressional practice of granting to authors of works with existing copyrights the benefit of term extensions so that all under copyright protection will be governed evenhandedly under the same regime.”).

\(^{41}\) See id. at 204 (“Satisfied that the CTEA complies with the ‘limited Times’ prescription, we turn now to whether it is a rational exercise of the legislative authority conferred by the Copyright Clause. On that point, we defer substantially to Congress.”).
Copyright Clause by achieving significant international harmonization with foreign copyright laws, the Court found the CTEA had a rational basis, which could not be questioned.\textsuperscript{42} The Court then mentioned that Congress had also considered “demographic, economic, and technological changes” and projections that longer terms would add incentives for authors to create.\textsuperscript{43} While the Court subtly expressed its skepticism of the CTEA’s wisdom (twice),\textsuperscript{44} it deferred to Congress’s judgment in establishing an intellectual property policy that best carries out the purpose of the Copyright Clause “to promote the Progress of Science.”\textsuperscript{45}

Justice John Paul Stevens and Justice Stephen Breyer each wrote separate dissenting opinions.\textsuperscript{46} Justice Stevens’ dissent largely relied on analogies to patent law to conclude that Congress, in enacting the CTEA, exceeded its power under the Copyright Clause because the extension advanced neither twin purpose of the clause: encouraging new works and adding knowledge to the public domain.\textsuperscript{47} Justice

\textsuperscript{42} See id. at 205-06 (“As respondent describes . . . a key factor in the CTEA’s passage was a 1993 European Union (EU) directive instructing EU members to establish a copyright term of life plus 70 years. Consistent with the Berne Convention, the EU directed its members to deny this longer term to the works of any non-EU country whose laws did not secure the same extended term. By extending the baseline United States copyright term to life plus 70 years, Congress sought to ensure that American authors would receive the same copyright protection in Europe as their European counterparts.”) (citations omitted).

\textsuperscript{43} See id. at 206-07 (“In addition to international concerns, Congress passed the CTEA in light of demographic, economic, and technological changes, and rationally credited projections that longer terms would encourage copyright holders to invest in the restoration and public distribution of their works.”) (citations omitted); see also Brief for Respondent at 33-34, Eldred v. Ashcroft, 537 U.S. 186 (2003) (No. 01-618) [hereinafter “Eldred Respondent’s Brief”]; H.R. REP. NO. 105–452, at 4 (1998) (explaining the term extension “provide[s] copyright owners generally with the incentive to restore older works and further disseminate them to the public”).

\textsuperscript{44} See Eldred, 537 U.S. at 208 (“[W]e find that the CTEA is a rational enactment; we are not at liberty to second-guess congressional determinations and policy judgments of this order, however debatable or arguably unwise they may be.”); see id. at 222 (“Beneath the facade of their inventive constitutional interpretation, petitioners forcefully urge that Congress pursued very bad policy in prescribing the CTEA’s long terms. The wisdom of Congress’s action, however, is not within our province to second-guess.”).

\textsuperscript{45} Id. at 212 (“[W]e have said that ‘[t]he primary objective of copyright’ is ‘[t]o promote the Progress of Science.’ . . . We have also stressed, however, that it is generally for Congress, not the courts to decide how best to pursue the Copyright Clause’s objections.”).

\textsuperscript{46} See id. at 222-42 (Stevens, J., dissenting); id. at 242-69 (2003) (Breyer, J., dissenting).

\textsuperscript{47} Id. at 226-27 (Stevens, J., dissenting) (“Neither the purpose of encouraging new inventions nor the overriding interest in advancing progress by adding knowledge to the public domain is served by retroactively increasing the inventor’s
Stevens concluded by criticizing the majority’s extreme deference to Congress\(^{48}\) and ultimately opined that all retroactive extensions of copyright terms inherently “frustrate the central purpose of the [Copyright] Clause.”\(^{49}\) Justice Breyer’s dissent also criticized the majority for its excessive deference to Congress,\(^ {50}\) but focused specifically on the CTEA, lambasting the extension as so lacking in any rational basis as to be unconstitutional.\(^ {51}\) Dispatching with the justifications proffered for the CTEA one by one,\(^ {52}\) Justice Breyer

compensation for a completed invention and frustrating the legitimate expectations of members of the public who want to make use of it in a free market. Because those twin purposes provide the only avenue for congressional action under the Copyright/Patent Clause of the Constitution, any other action is manifestly unconstitutional.”).

\(^ {48}\) *Id.* at 223 (“Because the majority's contrary conclusion rests on the mistaken premise that this Court has virtually no role in reviewing congressional grants of monopoly privileges to authors, inventors, and their successors, I respectfully dissent.”); *id.* at 242 (“By failing to protect the public interest in free access to the products of inventive and artistic genius—indeed, by virtually ignoring the central purpose of the Copyright/Patent Clause—the Court has quitclaimed to Congress its principal responsibility in this area of the law. Fairly read, the Court has stated that Congress'[s] actions under the Copyright/Patent Clause are, for all intents and purposes, judicially unreviewable. That result cannot be squared with the basic tenets of our constitutional structure.”).

\(^ {49}\) *Id.* at 241 (“*Ex post facto* extensions of existing copyrights, unsupported by any consideration of the public interest, frustrate the central purpose of the Clause.”).

\(^ {50}\) *Id.* at 244-45 (Breyer, J., dissenting) (“[I]t is necessary only to recognize that this statute involves not pure economic regulation, but regulation of expression, and what may count as rational where economic regulation is at issue is not necessarily rational where we focus on expression—in a Nation constitutionally dedicated to the free dissemination of speech, information, learning, and culture. In this sense only, and where line-drawing among constitutional interests is at issue, I would look harder than does the majority at the statute's rationality.”); *id.* at 264 (“We cannot avoid the need to examine the statute carefully by saying that ‘Congress has not altered the traditional contours of copyright protection,’ . . . for the sentence points to the question, rather than the answer. Nor should we avoid that examination here. That degree of judicial vigilance—at the far outer boundaries of the Clause—is warranted if we are to avoid the monopolies and consequent restrictions of expression that the Clause, read consistently with the First Amendment, seeks to preclude. And that vigilance is all the more necessary in a new century that will see intellectual property rights and the forms of expression that underlie them play an ever more important role in the Nation's economy and the lives of its citizens.”).

\(^ {51}\) *Id.* at 245 (“Thus, I would find that the statute lacks the constitutionally necessary rational support (1) if the significant benefits that it bestows are private, not public; (2) if it threatens seriously to undermine the expressive values that the Copyright Clause embodies; and (3) if it cannot find justification in any significant Clause-related objective. Where, after examination of the statute, it becomes difficult, if not impossible, even to dispute these characterizations, Congress'[s] ‘choice is clearly wrong.’”).

\(^ {52}\) *Id.* at 254-63.
ultimately concluded that the act’s extensions of both existing and future copyrights “cannot be understood rationally to advance a constitutionally legitimate interest,” and that the extension therefore “falls outside the scope of legislative power that the Copyright Clause . . . grants to Congress.”

And so ended the Eldred saga. The CTEA emerged constitutional, Congress was battered by the media for its lack of wisdom, Disney and company were (imaginably) happy to be granted another twenty years of economic prosperity from their intellectual property assets, and the Court’s opinion became the subject of volumes of criticism. Eldred passed into precedent, enshrining the CTEA as “good law” but bad policy.

As explained above, perhaps the Court wanted to strike down the CTEA but could not do so, without throwing all the previous extensions into doubt. This was especially so given the limited questions before the Court on certiorari: To the Court, the CTEA’s validity depended on whether Congress had the authority to extend existing copyrights. Upon concluding that Congress had such authority, and without any demonstration by the plaintiffs that the CTEA itself uniquely violated the “limited Times” clause, the CTEA had to be deemed constitutional.

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53 Id. at 266-67.
55 See supra note 44 and accompanying text.
56 See supra note 37 and accompanying text.
57 See Eldred, 537 U.S. at 198 (addressing two issues: “whether the CTEA's extension of existing copyrights exceeds Congress'[s] power under the Copyright Clause; and whether the CTEA's extension of existing and future copyrights violates the First Amendment.”).
58 Throughout the majority’s opinion, the Court frames the issue in broad, categorical terms of whether Congress had the authority to extend existing copyrights, the blanket conduct petitioners challenged as unconstitutional. See id. at 199 (“Text, history, and precedent, we conclude, confirm that the Copyright Clause empowers Congress to prescribe ‘limited Times’ for copyright protection and to secure the same level and duration of protection for all copyright holders, present and future.”); id. at 204 (“[W]e cannot agree with petitioners' submission that extending the duration of existing copyrights is categorically beyond Congress'[s] authority under the Copyright Clause.”); id. at 208 (“Accordingly, we cannot conclude that the CTEA—which continues the unbroken congressional practice of treating future and existing copyrights in parity for term extension purposes—is an impermissible exercise of Congress'[s] power under the Copyright Clause.”); id. at 218 (“For the several reasons stated, we find no Copyright Clause impediment to the CTEA's extension of existing copyrights.”).
59 Id. at 209-10 (“Critically, we again emphasize, petitioners fail to show how continued . . .
recognize what was not meaningfully before the Court. The claim that the CTEA’s term length in itself exceeded “limited Times” was conceded, and the claim that Congress enacted the CTEA, specifically, with the impermissible intent to create a perpetual copyright, was generally alluded to in the abstract but was not adequately presented and developed.

A very interesting development came shortly after Eldred in another intellectual property case before the Supreme Court, Dastar Corporation v. Twentieth Century Fox Corporation. In Dastar, the plaintiff attempted to use trademark law (the Lanham Act) to protect a previously copyrighted work of authorship that had since entered the public domain. The Court rejected this effort, holding that trademark protection applies only to the origin of physical goods, and cannot be used to protect the creative content within those goods. Holding otherwise, the Court reasoned, would allow works to enjoy indefinite copyright protection cloaked in trademark law—what the Court called a “mutant” form of copyright law that would conflict with the mandatory regime of limited copyright duration. The Court stated the CTEA crosses a constitutionally significant threshold with respect to ‘limited Times’ that the 1831, 1909, and 1976 Acts did not.”).

See id. at 193 (“Petitioners do not challenge the ‘life–plus–70–years’ timespan itself. ‘Whether 50 years is enough, or 70 years too much,’ they acknowledge, ‘is not a judgment meet for this Court.’”; id. at 241 (Stevens, J., dissenting) (“Whether the extraordinary length of the grants authorized by the 1998 Act are invalid because they are the functional equivalent of perpetual copyrights is a question that need not be answered in this case because the question presented by the certiorari petition merely challenges Congress[‘s] power to extend retroactively the terms of existing copyrights.”) While this argument was not before the Court, the majority suggested, albeit in a footnote, that a boundary exists after which a term is so long that it violates “limited Times.” See id. at 211 n.17 (“Whether such referents [the CTEA’s term of life-plus-70-years] mark the outer boundary of ‘limited Times’ is not before us today.”); Brief for the Appellee at 17, Eldred v. Reno, 239 F.3d 372 (D.C. Cir. 2001) (No. 99-5430) (“It may well be that some term extensions are so long . . . that a court could conclude that the Congress has in effect created an unlimited term.”).

See Eldred Petitioners’ Brief, supra note 13, at 18 (“Thus, the sole issue is whether Congress may achieve indirectly what it cannot achieve directly—a perpetual term ‘on the installment plan.’”); see supra note 34 and accompanying text.

Dastar Corp. v. Twentieth Century Fox Film Corp., 539 U.S. 23 (2003).

Id. at 25.

Id. at 37 (“In sum, reading the phrase ‘origin of goods’ in the Lanham Act in accordance with the Act’s common-law foundations (which were not designed to protect originality or creativity), and in light of the copyright and patent laws (which were), we conclude that the phrase refers to the producer of the tangible goods that are offered for sale, and not to the author of any idea, concept, or communication embodied in those goods.”).

Id. at 33-34.
that perpetual copyrights were not permitted under the Copyright Clause, citing Eldred, reaffirming its earlier condemnation of perpetual copyrights.\textsuperscript{66} It would then be another nine years before the Supreme Court would again address the Copyright Clause or copyright duration in Golan v. Holder.\textsuperscript{67}

\section*{B. Eldred’s Postlude, Golan v. Holder}

In 2001, a group of plaintiffs filed a constitutional challenge against Congress’s adoption of provisions from the Uruguay Round Agreements Act (“URAA”), an international treaty that sought to harmonize international copyright laws.\textsuperscript{68} The effect of the adopted provisions in the United States would be to restore the copyright protection of many foreign works that had already entered the public domain,\textsuperscript{69} such as Sergei Prokofiev’s Peter and the Wolf and Dmitri Shostakovich’s Symphony 14, Cello Concerto (Op. 107).\textsuperscript{70}

The challenge asserted that by restoring these copyrights and removing works from the public domain, the URAA violated the “limited Times” provision of the Copyright clause because it would “turn[] a fixed and predictable period into one that [could] be reset or resurrected at anytime [sic], even after it expires.”\textsuperscript{71} Affirming Eldred, the Court held that “our decision in Eldred is largely dispositive of petitioners’ limited-time argument,” explaining again that “limited” does not mean static and unalterable, but “is best understood to mean ‘confine[d] within certain bounds.’”\textsuperscript{72}

As in Eldred, the petitioners again raised the further concern that allowing Congress to restore copyrights that have already expired could ultimately lead to perpetual copyrights.\textsuperscript{73} The authority to

\textsuperscript{66} Id. at 37 (“To hold [that trademark protection extends to the creative content of goods] would be akin to finding that [the Lanham Act] created a species of perpetual patent and copyright, which Congress may not do.” (citing Eldred v. Ashcroft, 537 U.S. 186, 208 (2003)).


\textsuperscript{70} Brief for Petitioners at 10-11, Golan v. Holder, 132 S. Ct. 873 (2012) (No. 10-545) [hereinafter “Golan Petitioners’ Brief”].

\textsuperscript{71} Golan, 132 S. Ct. at 884 (quoting Golan Petitioners’ Brief, supra note 71, at 22).

\textsuperscript{72} Golan, 132 S. Ct. at 884-85 (“The construction petitioners tender closely resembles the definition rejected in Eldred and is similarly infirm.”).

\textsuperscript{73} See id. at 885 (“Carried to its logical conclusion, petitioners persist, the Government's position would allow Congress to institute a second ‘limited’ term after the first expires, a third after that, and so on. Thus, as long as Congress

continued...
restore copyrights even further augmented the existing concern over perpetual terms: not only could Congress keep things from ever entering the public domain through term extensions, but under Golan v. Holder, Congress could remove works from the public domain and reinstate their copyright protection ad infinitum. In response to this specter of perpetual copyrights, the Court gave short shrift to the concern, once again dismissing it as exaggerated:

As in Eldred, the hypothetical misbehavior petitioners post is far afield from the case before us. . . . In aligning the United States with other nations bound by the Berne Convention, and thereby according equitable treatment to once disfavored foreign authors, Congress can hardly be charged with a design to move stealthily toward a regime of perpetual copyrights.

Again, finding no constitutional infirmity, the Court scrutinized the rationality of the URAA with respect to the Copyright Clause’s goal to “promote the Progress of Science and useful Arts.” Discussing the international motives of the act, the Court found “no warrant to reject the rational judgment Congress made” that “exemplary adherence to Berne would serve the objectives of the Copyright Clause.” As in Eldred, once satisfied that the act did not expressly violate the provisions of the Copyright Clause, the Court gave great deference to the rationality of Congress’s judgment in implementing intellectual property policy.

Again, though, Justice Ginsberg seemed to go out of her way to declare that a scheme to create perpetual copyrights would be

legislated in installments, perpetual copyright terms would be achievable.”); Golan Petitioners’ Brief, supra note 71, at 15-16 (“Removing works from the public domain violates the ‘limited [t]imes’ restriction by turning a fixed and predictable period into one that can be reset or resurrected at any time, even after it expires. The entry of a work into the public domain must mark the end of protection, not an intermission. Otherwise, the limit is meaningless.”).

Golan Petitioners’ Brief, supra note 71, at 23 (“A limit that can be reset even after it has been passed does not ‘restrain[]’ or ‘confine[]’ as the Copyright Clause requires. . . . If an unprotected work may become protected again decades after entering the public domain, the boundary between protected works and unprotected works is erased.”).

Golan, 132 S. Ct. at 885.

Id. at 887-88; U.S. CONST. art I, § 8, cl. 8.

Golan, 132 S. Ct. at 889.

Id. at 894 (“The judgment § 514 [of the URAA] expresses lies well within the ken of the political branches. It is our obligation, of course, to determine whether the action Congress took, wise or not, encounters any constitutional shoal. For the reasons stated, we are satisfied it does not.”).
impermissible, though such was not the case before the Court in either *Eldred* or *Golan*.\(^7\) But where exactly does this leave us with regard to the state of copyright law?

**III. The Current State of the Law Regarding the Copyright Clause, Copyright Extensions, and Deferece to Congress**

**A. Constitutionality of Extensions**

*Eldred* and *Golan* leave many questions unanswered, but they do tell us a few important things. First, extending the term of existing copyrights is definitively within Congress’s authority.\(^8\) That is, “limited Times” for copyright protection does not mean static and fixed terms once set.\(^9\)

That said, however, a second lesson from both cases is that not all retroactive extensions will necessarily be constitutional—an attempt to string together extensions to achieve perpetual copyright terms would be impermissible.\(^10\) Of course, in both *Eldred* and *Golan*, the Court summarily concluded that Congress lacked this pernicious motive.\(^11\) Nonetheless, the Court condemned such an act as “legislative misbehavior,” leaving open the possibility that if Congress ever intends for an extension to create perpetual terms, it would be unconstitutional for contravening the “limited Times” provision.\(^12\)

Similarly, in *Eldred*, Justice Ginsberg seemed to fault petitioners for failing to illustrate how the CTEA crossed “a constitutionally significant threshold” that former extensions had not.\(^13\) Thus, Justice Ginsberg deliberately created the possibility that some threshold for extensions exists, beyond which would render an extension impermissible.\(^14\)

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\(^7\) *Id.* at 885 (“As in *Eldred*, the hypothetical legislative misbehavior petitioners posit is far afield from the case before us.”).

\(^8\) *See* *Eldred* v. Ashcroft, 537 U.S. 186, 199 (2003) (“Text, history, and precedent, we conclude, confirm that the Copyright Clause empowers Congress to prescribe ‘limited Times’ for copyright protection and to secure the same level and duration of protection for all copyright holders, present and future.”).

\(^9\) *Golan*, 132 S. Ct. at 884. *See Eldred*, 537 U.S. at 199 (“The word ‘limited,’ however, does not convey a meaning so constricted. At the time of the Framing, that word meant what it means today: ‘confine[d] within certain bounds,’ ‘restrain[ed],’ or ‘circumscribe[d].’ . . . Thus understood, a timespan appropriately ‘limited’ as applied to future copyrights does not automatically cease to be ‘limited’ when applied to existing copyrights.”).

\(^10\) *See supra* notes 1, 76, and accompanying text.

\(^11\) *See supra* notes 1, 76, and accompanying text.

\(^12\) *Golan*, 132 S. Ct. at 885.

\(^13\) *Eldred*, 537 U.S. at 210; *see supra* note 35 and accompanying text.
unconstitutional.\textsuperscript{86} Although ambiguous, this “threshold” may be referring to the structure of the extension—how soon after the previous extension it was enacted, how many additional years it grants, how long the total term will become, and so forth.\textsuperscript{87} Whether an extension then crosses this amorphous threshold may also depend on how strongly the extension’s structure indicates a naked intent to create perpetual copyrights, rather than some other legitimate aim of Congress. That is, the Court may analyze the form of the extension as a way of determining Congress’s true motivation and intent. For if the extension differs significantly from previous extensions, such discrepancy may indicate an intent to create perpetual copyrights.

As illustrated by \textit{Eldred}’s and \textit{Golan}’s treatment of “limited Times” challenges, the analysis largely puts substance over form, focusing less on the challenged action itself than on Congress’s motivation in taking that action. Indeed, in each case, had the exact same conduct (extension or restoration of copyrights) been an overtly admitted attempt to create perpetual copyrights, the Court would have found that Congress had contravened the “limited Times” provision.\textsuperscript{88} Thus, in each case the constitutionality of \textit{what} Congress did depended on \textit{why} it did it.\textsuperscript{89} That said, it remains to be seen whether Congress, even with good intent and bona fide justifications, could nonetheless overstep the “boundary of ‘limited Times’” simply by extending copyright terms too far.\textsuperscript{90} Thus, a copyright term may become so long that it in itself becomes unconstitutional regardless of Congress’s intent. The \textit{Eldred} Court hinted at this possibility, but sidestepped addressing whether it fit the circumstances before it.\textsuperscript{91}

And if the extension or restoration was passed for plausible, legitimate reasons, the Court will not substitute its judgment for that of Congress regarding how to best advance the policy goals of the Copyright Clause.\textsuperscript{92}

\textsuperscript{86} \textit{Eldred}, 537 U.S. at 210 n.17; see supra note 35 and accompanying text.
\textsuperscript{87} See infra Section IV. B.
\textsuperscript{88} See \textit{Golan}, 132 S. Ct. at 885 (“In aligning the United States with other nations bound by the Berne Convention, and thereby according equitable treatment to once disfavored authors, Congress can hardly be charged with a design to move stealthily towards a regime of perpetual copyrights.”); \textit{Eldred}, 537 U.S. at 209-10 (suggesting that Congress’s justifications for the extension refuted any notion that the CTEA was “a congressional attempt to evade or override the ‘limited Times’ constraint”). These statements and their surrounding discussion show that an attempt to create perpetual copyrights that cannot be justified by any other legitimate aim would indeed be “legislative misbehavior” in violation of the Copyright Clause.
\textsuperscript{89} See supra note 89 and accompanying text.
\textsuperscript{90} See supra note 60 and accompanying text.
\textsuperscript{91} Id.
\textsuperscript{92} See supra notes 44, 79 and accompanying text.
B. Deference to Congress’s “Rational Judgment”

Third, we learn in both cases that once it finds no express violation of the Copyright Clause’s provisions, the Court is very deferential to Congress in setting intellectual property policy.93 So long as Congress has a “rational” foundation to believe that the policy will advance the goals of the Copyright Clause, the Court seems satisfied.94 Of course this means that absent a rational basis, an intellectual property-related act could nonetheless fail.95 Yet, the outer contours of what the Court is willing to accept as sufficiently rational remain unclear.

Fourth, and related to congressional deference, the Golan Court read the Copyright Clause very broadly and specified that an intellectual property act need not intend to incentivize or even benefit authors directly.96 Congress can rely solely on a non-incentive based rationale for a setting policy.97 Similarly, the Court is willing to consider benefits to the copyright-holding industry (not just to the “authors” specified in the Copyright Clause) when evaluating the validity of Congress’s putative rationales.98

Fifth, and again related to deference to Congress’s rational judgment and decision-making, both Courts were susceptive to, or at least adequately satisfied by, the argument of international harmonization.99 Indeed, international considerations were the sole

93 See supra notes 41, 44, 79 and accompanying text.
95 Indeed, the dissenting Justices in Eldred would have found the CTEA to be lacking a sufficient rational basis. See supra notes 47, 50 and accompanying text.
96 Golan, 132 S. Ct. at 888 (“The creation of at least one new work, however, is not the sole way Congress may promote knowledge and learning. . . . Nothing in the text of the Copyright Clause confines the ‘Progress of Science’ exclusively to ‘incentives for creation.’”).
97 Id. (suggesting that promoting dissemination could faithfully honor the goals of the Copyright Clause as well). One cannot help but find it myopic and ironic that the Court found the URAA to promote dissemination of works: the purported future increase in dissemination from the URAA (an expansion of “the foreign markets available to U.S. authors”) would come at the certain, immediate reduction of dissemination of works that would no longer be freely accessible in the public domain.
98 Id. at 889 (“Full compliance with Berne, Congress had reason to believe, would expand the foreign markets available to U.S. authors and invigorate protection against piracy of U.S. works abroad, . . . thereby benefitting copyright-intensive industries stateside and inducing greater investment in the creative process.”) (emphasis added). Accordingly, it seems that the Court would uphold as rational a congressional action pursuant to the Copyright Clause that primarily or solely benefits the copyright-industry, and not the authors themselves.
99 Id. at 885, 887-89; Eldred v. Ashcroft, 537 U.S. 186, 205-06 (2003); see supra note 42 and accompanying text.
justification in Golan and were given the most attention by the Court in Eldred.100

C. Miscellany and the Unanswered

Sixth and finally, each case gives some insight into the current Court’s view of the importance of the public domain in advancing the Copyright Clause’s purpose of promoting science and the useful arts. The dissenters in Eldred vehemently urged that it was crucial for works to enter the public domain to ensure the public can fully benefit from the work after the author’s limited monopoly.101 Yet, the Eldred majority only includes the phrase “public domain” two times, and in no place discusses the public domain’s role in promoting the useful arts and sciences.102

Similarly, while the Golan opinion discusses the public domain thoroughly, it ultimately finds that works in the public domain are not beyond the scope of the Copyright Clause or Congress’s actions.103 Again, the dissenting opinion vigorously argued that removing works from the public domain impedes their dissemination, imposes economic and non-economic costs on consumers,104 and “inhibits an important preexisting flow of information.”105 In the light of Eldred and especially Golan, it is unclear what role, if any, the public domain continues to play in advancing the goals of the Copyright Clause.

Many additional questions remain unanswered: What “threshold” was Justice Ginsberg contemplating? How can one identify or infer an impermissible congressional intent to create perpetual copyrights? What even constitutes a perpetual copyright on an installment plan? Could a copyright term in itself, regardless of congressional intent, be so long as to violate the “limited Times” provision? What degree of rationality is needed to justify an intellectual property act or another copyright extension act? And is the Court unaware of or just indifferent to the overt, instrumental role that major lobbying entities (e.g., Disney) have played and are likely to continue to play in enacting copyright extensions?

The Supreme Court might be forced to answer some of these

100 Golan, 132 S. Ct. at 887-89; Eldred, 537 U.S. at 205-06 (discussing Congress’s international harmonization justification first and in much greater detail than the other proffered justifications for the CTEA).
101 See supra notes 26, 47 and accompanying text.
103 Golan, 132 S. Ct. at 884 (“The text of the Copyright Clause does not exclude application of copyright protection to works in the public domain.”).
104 Id. at 899-900 (Breyer, J., dissenting).
105 Id. at 912 (Breyer, J., dissenting).
questions in the coming years if Congress again extends copyright
terms as the CTEA’s extensions draw to an end on January 1, 2019.\footnote{106} Indeed, perhaps Justice Ginsberg anticipated this eventuality by
mentioning the concern of a “perpetual copyright” in both \textit{Eldred}\footnote{107} and \textit{Golan}.\footnote{108} While the Court found that surreptitious perpetual
copyright schemes were “far afield” from those cases, the next
extension may not look quite as innocent as the CTEA and URAA.\footnote{109}

\section*{IV. Looking Forward to the Next Copyright Extension: How Will the
Court Respond Given the Court’s Attitudes in \textit{Eldred} and \textit{Golan}.}

As 2019 approaches, we might expect to see lobbying overtures
from the entertainment industry (Disney, et al.) for Congress to once
again extend copyrights.\footnote{110} Let us assume that such lobbying efforts
will succeed and Congress will pass another twenty-year extension to
become effective December 31, 2018.\footnote{111} For the sake of this thought
experiment, let us call this extension the Save Mickey Mouse Act ("SMMA").\footnote{112} Let us further assume that SMMA will be challenged
and the case will reach the Supreme Court in early 2020. How will the
future Supreme Court deal with the SMMA?\footnote{113}

We know from \textit{Eldred} that the act would not be unconstitutional
simply because it extends existing copyrights.\footnote{114} But \textit{Eldred} and

\footnotetext[106]{See supra notes 5, 9 and accompanying text.}
\footnotetext[107]{\textit{Eldred}, 537 U.S. at 209.}
\footnotetext[108]{\textit{Golan}, 132 S. Ct. at 885.}
\footnotetext[109]{\textit{Golan}, 132 S. Ct. at 885; see \textit{Eldred}, 537 U.S. at 209.}
\footnotetext[110]{See supra note 10 and accompanying text.}
\footnotetext[111]{From the content-industry perspective, it would be beneficial to have the next
extension come into effect \textit{before} the previous extension has run its course, as this
would ensure that no copyrighted works would enter the public domain. In this
instance, the effective date would have to be before January 1, 2019, when
copyrights are scheduled to resume expiring. See supra note 5 and accompanying
text.}
\footnotetext[112]{The CTEA itself was playfully nicknamed the “Mickey Mouse Protection
Act” in the media. See Lawrence Lessig, \textit{Copyright’s First Amendment}, 48 UCLA L.
REV. 1057, 1065 (2001).}
\footnotetext[113]{Assuming no major ideological shift in copyright jurisprudence from \textit{Eldred},
\textit{Dastar}, and \textit{Golan}. For another legal scholar’s predictions in a similar analysis of a
future hypothetical extension, see Thomas R. Lee, \textit{Eldred v. Ashcroft and the
(Hypothetical) Copyright Term Extension Act of 2020}, 12 TEX. INTELL. PROP. L.J. 1
(2003). Critically, however, this Article diverges from much of Lee’s reading of
\textit{Eldred}, his predictions of the Court’s method of analysis, and his ultimate
conclusion. Moreover, this Article enjoys the benefit of additional insight from
\textit{Golan}.}
\footnotetext[114]{See supra note 31 and accompanying text.}
Golan hinted that future extensions would not necessarily be constitutional either—if it appears that Congress is “legislative[ly] misbehaving” by attempting to create a perpetual copyright, the Court will likely not allow it.\(^{115}\) But how exactly can we tell if an extension is an attempt to create perpetual copyrights?

First, the Court could infer an improper congressional intent from a lack of legitimate, bona fide justifications for the extension. If the Court invalidates the extension in this way, let us call it an “inference from unjustifiability.”

Second, the Court could infer Congress’s intent to create perpetual copyrights by the nature and structure of the extension. That is, whether the extension violates the “limited Times” provision in a way that the previous extensions had not, by crossing some “constitutionally significant threshold.” This second approach can be called an “inference from structure.”

A. Inference from Unjustifiability: Would a lack of justifications for the SMMA suggest an impermissible congressional motive for re-extending copyrights?

A lack of a bona fide, legitimate justification for an extension may suggest that Congress’s true purpose is mischief—an attempt to achieve perpetual copyrights in installments. Based on what we have learned from Eldred and Golan, the constitutionality of the SMMA will hinge on the adequacy of Congress’s reasons justifying the extension.\(^{116}\)

What possible reasons could justify the SMMA? While it is impossible to foretell what justifications may be germane to the SMMA in 2018-2019, the justifications used to support the CTEA give some indication of what to expect.\(^{117}\) In concluding that “[n]othing before this Court warrants construction of the CTEA’s twenty-year term extension as a congressional attempt to override the ‘limited Times’ constraint,” the Court found that the CTEA was justified by international harmonization with foreign copyright policy as well as economic, demographic, and technological changes that suggested longer copyright terms would better incentivize authors to create new works.\(^{118}\)

Proponents of the CTEA argued that the extension was necessary to create uniformity and parity with the copyright terms accorded

\(^{116}\) See supra Section III. A.
\(^{117}\) See supra notes 42, 43 and accompanying text.
\(^{118}\) Eldred v. Ashcroft, 537 U.S. 186, 209 (2003); see also id. at 206-07.
under the Berne Convention—that is, the United States had to “catch up” to the rest of the signatories. The SMMA, however, may not have a substantial international norm to “catch up” to in 2019. In fact, the United States copyright terms are currently among the longest in the world, outdone by only Mexico and Cote d’Ivoire. Thus, unless there is a substantial movement toward extending copyrights abroad, it would appear that the SMMA could not seek shelter under the guise of international harmonization. Indeed, absent any international changes in copyright, if the SMMA were passed, it would create disharmony from the global norm.

How else may the SMMA be justified? Would the same “economic, demographic, and technological changes” that were used to justify the CTEA be available to the SMMA? To the minimal extent that the Court acknowledged those justifications, they would apply with even less force to the SMMA. In Eldred the government argued that extensions of copyright terms since 1900 have been justified because “the average life span has increased . . .; photocopying and digital media have lowered copying costs; new markets and media have increased the value and commercial life of works; and losses due to piracy have increased,” each of which “tends to justify a longer copyright term.” Accepting this questionable premise as true, these change-factors are still unlikely to justify the SMMA for the reasons given below.

Demographically speaking, the government in Eldred cited a thirty-year increase in lifespan since 1900 to support a claim that longer life-spans warranted longer copyright terms; thus, authors could be better assured that their children and possibly grandchildren would reap the benefits of the creative work. However, between the CTEA (in 1998) and the SMMA, some twenty years later, it seems unlikely that the average lifespan will increase by such a magnitude that would compel extending copyright terms. Indeed, the average life expectancy at birth in 1998 was 76.7 years, while in the most recent

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119 Id. at 205-06.
121 See supra Section III. A. Because the majority of countries currently have a life-plus-seventy copyright term, if the United States passed another extension, the new term would break from the current “harmony” with the majority and be longer than any other country in the world (again, assuming no other country extends their copyright).
122 See Eldred, 537 U.S. at 206-08 (mentioning these “changes” and giving them a very cursory treatment).
124 Id. at 25.
data from 2009, it is 78.5 years, only a 1.8 year increase. The United States Center for Disease Control and Prevention projects that life expectancy will be 78.9 years in 2015 and 79.5 years in 2020. Accepting these numbers as accurate approximations, between the CTEA in 1998 and the SMMA, roughly in 2020, the growth in life expectancy will be modest at only approximately 2.8 years. This is a far cry from the thirty-year growth cited to support the CTEA. Thus, absent any sudden and dramatic life-prolonging medical or technological advances, an increase in life expectancy is unlikely to be significant enough to plausibly justify another copyright extension.

Technologically and economically speaking, copying costs have gone down and losses due to piracy have gone up. But does that not actually caution for better rather than longer copyright protection? Piracy is undoubtedly a problem that ought to be combated, but extending copyright terms is hardly a solution. Indeed, excessively lengthy copyright protection may be encouraging piracy and infringement rather than counteracting it. People seeking access to older works may grow impatient with unduly lengthy copyright terms and choose instead to pirate, for example, a copy of a Hemingway e-book rather than pay for it.

And while technology has increased the public’s access to older works and thus has lengthened a work’s potential commercial life, that does not, ipso facto, justify extending copyrights. Our copyright system does not set a work’s protection to be coterminous with its commercial life-span. If that were so, then most works would enter the public domain just a few years after their inception.

128 Due to technology, making a copy of a work is now easy and inexpensive or free. Moreover, there is no limit to how many copies can be made. Compounding this, technology has permitted massive degrees of sharing these copies on the internet and through peer-to-peer networks. The content industry has reported increasing losses due to piracy. But, these figures should be taken with a grain of salt as they may be exaggerated.
129 See infra Section VI; Eldred Petitioners’ Brief, supra note 13, at 32. Of course, the content most commonly pirated is of a more contemporary nature, not silent films. But even some older works remain highly sought, such as the novels of Fitzgerald and Hemingway or classic films.
131 Eldred Petitioners’ Brief, supra note 13, at 7 (noting how few works remain
continued . . .
vast majority of the works that the CTEA extended, and that the SMMA would extend, retain little or no commercial value. To the contrary, when a work’s copyright term ends, it enters into the public domain regardless of its revenue-generating potential.

Furthermore, although an extension need not incentivize authors to be rationally supported, it is nonetheless implausible that another extension would actually yield any additional incentive for authors to create. Aside from the sheer economics of it—that twenty additional years are likely to add virtually zero economic incentive—there is also the cognitive behavior perspective to consider. An individual is unlikely to comprehend or perceive value in an extension of copyright so far into the hypothetical future, such as seventy years after the individual’s own death. When figures become so great or so remote, we struggle to accurately conceive of them. Take for example, an author who publishes a work on his deathbed in 2012. Currently his work would enjoy a copyright term of the life of the author plus seventy years—assuming the author dies in 2012, the copyright would expire in 2082. To that author, is there a meaningful difference in whether his work’s copyright expires in 2082 or if the SMMA extends the term another twenty years into 2102? Probably not. The future is so remote any future value becomes incalculable at a certain point. And this problem is magnified further in the more common scenario when an author is not creating a work on his or her deathbed, and thus the copyright will persist even further into the unknown future. Simply put, as the copyright term is increased, there is a distinct point of diminishing returns with regard to additional incentive to authors, economically and conceptually.

It is of course possible that Congress could proffer additional justifications not discussed here. But in the absence of bona fide

commercially viable (“surviving works”) that continue to earn royalties.

132 Id. (describing how the CTEA extended the copyrights of 50,000 commercially viable works along with 375,000 other works with no commercial value that were needlessly prevented from entering the public domain).

133 See supra Section III. B.

134 See Eldred, 537 U.S. at 255 (Breyer, J., dissenting) (noting that “from a rational economic perspective” the extra years granted by the CTEA “makes no real difference” to authors and potential authors) (emphasis omitted).

135 See Sonny Bono Copyright Term Extension Act, Pub. L. No. 105-298, § 102, 112 Stat. 2827, 2827-28 (1998); RICHARD DAWKINS, THE GOD DELUSION 414-20 (2006) (explaining this limit to human cognition to process very remote or extreme concepts, calling such limitation the “Middle World” that we all live in).

136 See Eldred, 537 U.S. at 254-58 (Breyer, J., dissenting) (expressing strong doubt that “somehow, somewhere, some potential author might be moved by the thought of great-grandchildren receiving copyright royalties a century hence . . .”).

137 See Sonny Bono Copyright Term Extension Act § 102.
justifications, there would be a strong inference that Congress will be attempting to create perpetual copyrights with the SMMA. This suspicion of improper legislative intent would be especially prevalent given the SMMA’s timing, becoming effective just before the CTEA would run its course and copyrighted works would begin to enter the public domain.

B. Inference from Structure: Does the SMMA’s structure differ significantly from prior extensions in a way that may cross a “constitutional threshold”?

Additionally, the structure of the SMMA would support an inference of the “legislative misbehavior” of attempting to create perpetual copyrights. In several ways the SMMA would diverge from previous copyright extensions with regard to the “limited Times” provision, perhaps placing the SMMA beyond the “constitutionally significant threshold” alluded to by Justice Ginsberg. These differences would offer evidence to support an inference of impermissible congressional intent to establish perpetual copyrights.

For example, the SMMA would become effective immediately before the prior extension’s additional term was about to expire. In contrast, all the previous copyright extensions came after the previous extension’s additional grant of time had “worn off.” Put differently, between each previous extension, copyrights were allowed to expire. If the SMMA were enacted immediately after the CTEA, no copyrights would be allowed to expire—a major difference from previous extensions; one that supports the claim that the SMMA would impermissibly violate the “limited Times” provision while other extensions had not.

138 See supra note 35 and accompanying text.
139 This would ensure that no copyrights extended under the CTEA would expire. See supra notes 6, 112 and accompanying text.
140 The 1831 Act extended the copyright term by fourteen years. The next extension did not come until much more than fourteen years later, in 1909. Thus, copyrights expired between the two acts. In turn, the 1909 Act extended copyrights another twenty-eight years. The next extension did not come until 1978, much more than twenty-eight years later. And again, copyrights expired. See 17 U.S.C. § 302. See also supra notes 17-20 and accompanying text.
141 See supra note 141 and accompanying text.
142 Arguably this same point could have been made to argue how the CTEA was markedly different from all the prior extensions—between the 1978 Act and the CTEA, copyrights only expired for one year, in 1997, before being re-extended in 1998 by the CTEA. Yet, little effort was made to substantively distinguish the CTEA from prior extensions. And now that the CTEA has been upheld as constitutional, any future extension must show how it crosses a threshold that even continued . . .
Similarly, the SMMA would be distinct from previous extensions in the fact that it would be granting many works their second extension and many more works their third extension. To illustrate, consider a work created in 1970 that had an initial copyright term of fifty-six years. The 1976 Act extended the copyright term an additional nineteen years (the first extension), the CTEA granted the work a second extension of twenty years, and the SMMA would grant the work a third extension. Historically, it was uncommon for any work to be granted a second extension, much less a third. The CTEA marked the first extension that significantly granted an extension to copyrights that had already been extended once (by the 1976 Act). But to date, no work’s copyright has been extended three times. The SMMA would do just that. Thus, again, due to its structure and timing, the SMMA would traverse a constitutional threshold that prior extensions had not, bolstering an inference that Congress is going beyond typical or historical copyright policy treatment and impermissibly seeking to create perpetual copyrights.

Finally, by adding twenty years to all existing copyrights, the full term for pre-1978 works would be 115 years, and for post-1978 works, it would be life of the author plus ninety years. In challenging the CTEA did not cross. But while the CTEA was deemed constitutional, one might think of it as at or near the edge of a constitutional copyright extension.

For a post-1978 work, the SMMA would be the second extension. For pre-1978 works, the SMMA would be the third extension.


See Copyright Act of 1976, 17 U.S.C. § 302 (2006) (granting a nineteen year extension to all existing copyrights [increasing the total term from fifty-six to seventy-five] and setting the copyright term for any subsequently created works as life of the author plus fifty years).


The 1978 Act extended only three years worth of copyrights that had been extended once before. Copyrights of works created in 1906, 1907, and 1908 were extended once by the 1909 Act, and a second time by the 1976 Act. See Act of Mar. 4, 1909, § 24, 35 Stat. 1075; Copyright Act of 1976, 17 U.S.C. § 302 (2006). To be precise, a work from 1906 had its copyright extended in 1909 to a potential full term of fifty-six years, meaning it would expire in 1962. But starting in 1962, various interim extensions were passed as place-holders until the 1978 Act was finalized. Thus, when the 1978 Act become effective, the work’s term was extended to seventy-five years from its 1906 publication date—1981.

The CTEA gave a second extension to fifty-five years of copyrights (1923-1978) that had already been extended once under the 1976 Act. See Sonny Bono Copyright Term Extension Act § 102; Copyright Act of 1976, 17 U.S.C. § 302 (2006). Again, this argument could have been made in Eldred to meaningfully distinguish the CTEA from the previous extensions.

Id.
SMMA, one could argue that such long terms in themselves far exceed what the Framers of the Copyright Clause had contemplated for “limited Times,” much more so than the terms granted by previous extensions. In *Eldred*, the petitioners did not contend that the terms granted under the CTEA (ninety-five years for pre-1978 works and life plus seventy years for post-1978) were unconstitutional. Thus, the Court needed not decide whether the lengthy term in itself violated the “limited Times” provision. But in a future challenge, the Court could consider this eloquently simple, yet pointed challenge: the term is simply too long to be constitutional. While still technically “limited,” terms extended under the SMMA would be so long that they would be tantamount to perpetual terms for all practical purposes.

While it is true that very long terms may certainly support an inference of congressional intent to create perpetual copyrights, at a certain point, a copyright term may become so long that it exceeds “the outer boundary of ‘limited Times’” and therefore becomes unconstitutional, regardless of Congress’s intent.

In sum, absent any legitimate claim of international harmonization, the SMMA extension would likely be the kind of congressional “design to move stealthily toward a regime of perpetual copyrights” that the Court once again vilified in *Golan*. And given the SMMA’s violation of the “limited Times” provision, the Court would not need to further explore its rationality in light of the Copyright Clause’s objectives.

V. HOW MUCH TIME MUST PASS BETWEEN EXTENSIONS TO BE CONSTITUTIONAL UNDER THE “LIMITED TIMES” PROVISION?

Changing the SMMA scenario slightly, imagine now that instead of becoming effective December 31, 2018, the SMMA will become

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150 *Eldred v. Ashcroft*, 537 U.S. 186, 246-48 (2003) (Breyer, J., dissenting) (discussing how the Framers feared monopolies but permitted them in the context of patents and copyrights, their fears assuaged by the limitation of the monopoly to only a brief period of time).

151 See *supra* note 23 and accompanying text.

152 See *supra* note 60 and accompanying text.

153 *Eldred*, 537 U.S. at 243 (Breyer, J., dissenting) (positing that the CTEA’s term was so long as to be virtually perpetual, not limited). While Justice Breyer largely focused on the economics of a work’s commercial value, just in terms of the actual time and numbers, 115 years is hardly “limited” in the same sense that the original term of fourteen years was limited.

154 See *id.* at 210 n.17 (suggesting that such an outer boundary on the term length itself exists).


156 See *supra* notes 41, 79 and accompanying text.
effective on December 31, 2021. In this new set of facts, copyrights would expire in the three years between the “wearing off” of the CTEA and the effective re-extension of the SMMA. Would this “gap” in extensions be sufficient to disprove a scheme to create perpetual copyrights through incremental acts?

A strong argument can be made that the “gap” is inconsequential. While three-years worth of copyrighted works were allowed to expire (and therefore were not de facto perpetual), the vast, remaining anthology would continue to enjoy seemingly endless protection. Specifically, the copyright works from 1923, 1924, and 1925 would expire respectively in 2019, 2020, and 2021, whereas the works from 1926 on would remain monopolized. Under such an extension-gap-extension scheme, Congress could extend copyrights repeatedly without ever technically having truly perpetual copyrights, because sooner or later (most likely later), each work would slip into a gap and expire. But this is a distinction without a difference. If each gap were for three years, and each extension were for twenty years, a copyright secured in 1940 would not expire until the year 2137, and a copyright secured in 1960 would not expire until the year 2298.

Thus, while any given work’s copyright term is technically still for “limited Times,” for all practical purposes the term would be virtually limitless. Indeed, Justice Ginsberg’s language of an intent to bypass the “limited Times” provision need not be drawn at the point of perpetuity. While such a scheme of repeated extensions spliced with brief gaps in which works entered the public domain clearly would not create any single perpetual copyrights, doubtless it would significantly undermine any meaningful notion of “limited Times.”

Just how many years must Congress wait then between copyright extensions? There is no clear answer. One inexact way of measuring

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157 Works created in 1926 currently have a copyright term of ninety-five years and will expire on January 1, 2022. See Sonny Bono Copyright Term Extension Act, Pub. L. No. 105-298, § 304(b), 112 Stat. 2827, 2827-28 (1998). Thus, the SMMA, effective on December 31, 2021, would extend the copyrights in those works another twenty years.

158 Essentially under this system, three years worth of copyrights will expire for every twenty-three years that pass. The first twenty years, no works will enter the public domain due to the extension, then three years of works will. For example from 1998-2021 the copyrights from 1923, 1924, and 1925 will expire, then the SMMA will extend all other existing copyrights twenty years until 2042. Then another three years of works would expire. Thus, it would take five cycles of extensions after the SMMA until works from 1940 slipped through the gaps between extensions.

159 See supra note 159 and accompanying text.


161 See id.
would be to ask whether enough time has passed as to negate any suspicion that the extension would be motivated by impermissible goals. That is, if enough time passes between each extension during which copyrights are allowed to expire that even a string of extensions would be ineffective at creating de facto perpetual copyrights.

A. An extension that does not violate the “limited Times” provision may theoretically still fail to rationally advance any copyright clause-based objective.

Assume, however, that enough time has passed between extensions that the Court finds no violation of the “limited Times” provision; the act must still be supported by Congress’s rational judgment that an extension promotes the policy goals of the Copyright Clause. While the Court has strongly suggested that it will continue to evaluate whether future congressional acts violate the “limited Times” provision, once the Court is satisfied that there is no explicit constitutional violation, the Court truly does seem to have “quitclaimed to Congress its principal responsibility” of honoring the “central purpose of the Copyright/Patent Clause.” Given that Eldred and Golan broadened the acceptable rational justifications for intellectual property policy, it seems probable that Congress would be able to conjure up a plausible rationale to the Court’s satisfaction. In Golan, the Court explained that Congress is tasked with designing a whole system of copyright that promotes science and progress, and that each individual act of Congress need not necessarily promote dissemination or incentivize creation. The Court went on to state that policies that benefit the copyright-holding industry are sufficient to justify a copyright act, despite the Copyright Clause’s emphasis on granting rights to “authors.”

162 If, for example, in the year 2050, copyrights have not been extended since the CTEA in 1998, and Congress has decided that copyright terms should once again be extended because our future-selves have much greater life expectancy, then the fifty-two year gap coupled with a reasonable justification ought to justify the extension. In a less clear case, what if the SMMA were to become effective in 2029, after ten years of copyrighted works entering the public domain and thirty years after the previous extension (the CTEA)? On one hand, a ten-year gap between the end of one extension and the start of another may seem sufficient, but on the other hand, what if Congress offered a plausible explanation to justify the extension?

163 See supra notes 41, 79 and accompanying text.
164 See supra Section III. A.
165 Eldred, 537 U.S. at 242 (Stevens, J., dissenting).
166 See supra Section III. B.
167 See id.
168 See id.
Of course one could argue, as many do, that a public-favoring policy of a growing, rich public domain would better promote the useful arts by increasing dissemination of works than would alternative public policies that favor copyright-holding industries and extend copyright terms.\(^{169}\) But the Court has explicitly passed along to Congress these judgment calls of which policy is wiser.\(^{170}\) Seemingly, as long as Congress offers some rational basis for how the extension policy plausibly advances the Copyright Clause’s objectives, even if indirectly or holistically, the Court will likely respect that policy, regardless of its questionable wisdom.\(^{171}\)

VI. GLOBALIZATION AND TECHNOLOGY CAUTION AGAINST OVERLY LENGTHY COPYRIGHT TERMS

Aside from whether Congress decides to extend copyright terms again and whether the Supreme Court allows Congress to do so, other social factors caution against overly lengthy copyright terms generally. Principally, technology and globalization are changing how the public views and consumes works in the public domain and may also be altering the public’s view of what it is willing to accept as a reasonable copyright term.

To illustrate this phenomenon, consider a popular book that has entered the public domain in the United Kingdom, but not yet in the United States, such as F. Scott Fitzgerald’s *The Great Gatsby*.\(^{172}\) A reader in the United States seeking to obtain an e-book of *The Great Gatsby* must pay $12.99 for what someone in London can get for free.\(^{173}\) Or, the United States reader, realizing this inequity, could easily obtain an e-book version from a public domain archive website (because the work is in the public domain in some places after all) without any verification that the reader is in the United States rather than the United Kingdom. If readers choose to “pirate” the online version meant for United Kingdom readers, rather than pay for the United States version, they will have essentially rejected the United

\(^{169}\) See supra note 26 and accompanying text.


\(^{171}\) See supra Section III. B.

\(^{172}\) *The Great Gatsby* was published in 1925 by F. Scott Fitzgerald (1896-1940). Thus, under 17 U.S.C § 304(b), the work will enter the public domain after ninety-five years, on January 1, 2021. But in the United Kingdom, under the Copyright, Designs and Patents Act, 1988, c. 48, § 12 (U.K.), the book’s term was life of the author plus seventy years, meaning that it entered the public domain on January 1, 2011. Australia would have worked for this hypothetical, as the *The Great Gatsby* is also in the Australian public domain.

\(^{173}\) Price of *The Great Gatsby* e-book from Amazon as of October 5, 2012.
States copyright term as being too long. In the aggregate, the effect is that the United States copyright term has been reduced to the United Kingdom term based on what the public is willing to accept as reasonable and fair.

Thus, in a way, the public domain itself has become global. If a work enters the public domain in one country and has been electronically uploaded to the internet for free, legal distribution within that country, citizens of other countries can download that work as well, even though it may still be copyrighted in their domestic country. Of course, this would be copyright infringement. But it lacks the sinister malevolence of piracy that colors the infringement of recently copyrighted works. Currently, citizens are on the honor system not to download any foreign-country public domain works that are still copyrighted in their home-country. But when presented with the option, consumers are unlikely to pay for an e-book that they could get, and readers abroad do get, for free.

This unlikelihood is compounded by two things. First, the consumer, not equipped with an understanding of copyright law, may genuinely believe that the work has entered the public domain in the United States, just as it has in the United Kingdom, and may download the work for free, not knowing he or she ought to be paying. Second,

174 Note that while the United States has a longer copyright than the United Kingdom, the reverse scenario is possible where a work is public domain here, but not in the United Kingdom. This could result from the copyright in a work not being properly renewed back before all renewal was made automatic. For example, Peter Pan is in the public domain in the United States but not in the United Kingdom. See Copyright How-To, GUTENBERG PROJECT (Mar. 25, 2012, 8:31 PM), http://www.gutenberg.org/wiki/Gutenberg:Copyright_How-To#Public_Domain_and_Copyright_Rules_for_the_other_countries.


176 As opposed to contemporary works, the works in these circumstances are free to citizens of other countries. Thus, the piracy is not an instance of stealing a work that one would otherwise pay for, but rather claiming that that work ought to be free for everyone.

177 It is not inconceivable that such websites would somehow verify the geographic source of the download-request to determine whether the work is available for legal distribution in that country. But as of right now, written disclaimers are the only things preventing individuals from one country downloading the public domain e-books from another country.
even if consumers do realize that lengthy United States copyright terms prohibit them from freely downloading the e-book, they may download the e-book for free anyways, compelled by a sense of inequality or unfairness that they must pay for something that other readers abroad can legally get for free.

Note, however, that this online globalization of the public domain and reduction of copyright terms to the lowest common denominator would only affect the copyright holder’s exclusive reproduction right in the work. E-book technology and the internet have greatly facilitated access to a work that has entered the public domain of one country; readers in the United States may easily and without detection be able to reproduce for their own consumption a version of the *The Great Gatsby* that was lawfully uploaded for distribution within the United Kingdom or Australia. But because the work is still copyrighted in the United States, the copyright holder would still be able to exercise his or her other exclusive rights aside from the reproduction right, such as the derivative work right to prevent film or stage adaptations.178

Thus, this potential phenomenon is not an adequate solution to the concern that Congress may attempt to impermissibly extend copyright terms to the detriment of the public interest of a thriving public domain. Instead it is a reaction, a reminder that the United States copyright laws no longer live in isolation from those of the rest of the world, and a caution that technology may permit the public to reject extended copyright terms that it deems unacceptably lengthy by accessing for free those works that it feels ought to be in the public domain by now, and therefore free to access and enjoy.

If the United States continues to expand its copyright terms to lengths far exceeding the rest of the world, the public is likely to view such a restriction as unfair and will reject the long copyright terms, turning to the “global public domain” to freely access the works. Indeed, in the modern era, the notion that each individual country still has its own “public domain” is a farce—the internet is ushering in a corpus of works that is globally public. Congress should take note of this reality and keep it in mind when contemplating the next extension of copyright terms.

**VII. CONCLUSION**

In the wake of *Eldred v. Ashcroft* and *Golan v. Holder*, a popular sentiment among detractors from the two opinions has been that the

178 And such kinds of infringement would be much more susceptible to detection than individual readers downloading e-books from foreign public domain archives.
Court gave Congress total carte blanche to extend copyrights forever.179 This is simply not an accurate reading of the cases. While the fear of perpetual copyrights is certainly a legitimate one, it is hyperbolic and paradoxical to claim that the Court has permitted Congress to create perpetual copyrights, when in fact the Court recently reiterated that doing so would be “legislative misconduct.” Indeed, throughout *Eldred* and the Court’s most recent discussion of the Copyright Clause in *Golan*, the Court provided more clues as to how it may respond to the next copyright extension. As 2019 grows nearer, so too does the prospect of another copyright extension. If Congress has not learned its lesson from the much-criticized CTEA and passes an extension such as the SMMA, the onus will be on the Supreme Court to recognize that Congress has overstepped its authority under the Copyright Clause. Ideally, this Article will provide guidance to both Congress and the Court in evaluating a future copyright extension.

In sum, *Eldred* and *Golan* have left open the possibility that the next extension could be struck down in at least two ways. If the next extension comes before or shortly after the CTEA’s extension is about to expire, there will be a strong presumption that Congress is linking together extensions in pursuit of establishing de facto perpetual copyright terms. In such a scenario, unless Congress can proffer a compelling and legitimate justification for yet another copyright term extension, the Court could (and probably should) find a violation of the “limited Times” provision based on an inference that Congress was attempting to create perpetual copyrights. Notwithstanding Congress’s intent to create perpetual copyrights, another twenty-year extension would result in terms so long that the terms would, in effect, no longer be “limited” in any meaningful sense as contemplated by the Framers, providing the Court yet another opportunity to definitively state that enough is enough. Rather than “saving” Mickey Mouse by further locking him up, perhaps it is time to let him rest and go free into the great Elysian Fields for timeless classics that is the public domain.

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179 See, e.g., David E. Shipley, *Congressional Authority Over Intellectual Property Policy After Eldred v. Ashcroft: Deference, Empty Limitations, and Risks to the Public Domain*, 70 ALB. L. REV. 1255, 1260 (2007) (“Given Congress’[s] exercise of general legislative powers, the Court’s deference to Congress’[s] judgment in exercising its considerable power under the Copyright Clause as well as its historic reluctance to strike down intellectual property legislation, the Clause’s limitations on congressional authority could become meaningless . . . .”).
THE VALIDITY CHALLENGE TO COMPOUND CLAIMS AND THE (UN?)PREDICTABILITY OF CHEMICAL ARTS

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I. INTRODUCTION

Pharmaceutical research and development ("R&D") is a lengthy and expensive endeavor with a possibility of high return, yet a low probability of success. In 2006, 105 drugs had annual sales of more than one billion US dollars, and the best-selling drug, Lipitor® from Pfizer, topped off at nearly $14 billion.\(^1\) Developing a drug, however, takes from ten to fifteen years with an average cost around $1.3 billion.\(^2\) For every 5,000 to 10,000 compounds investigated in medicinal chemistry, about 250 may progress into preclinical evaluation, five of which may enter clinical studies, and one lucky compound may eventually receive approval for marketing from the United States Food and Drug Administration (the "FDA").\(^3\)

Whether pharmaceutical companies that invest in drug discovery can recover their investment depends heavily on the patent protection of their drugs. If the patent expires or is declared invalid, the price of a drug decreases significantly under generic competition.\(^4\) The validity of those patent claims, especially compound claims, often is the subject of fierce litigation, the resolution of which may impact billions of dollars of business revenue. Often, the validity challenge to a compound claim is based on the theory that the claimed invention was obvious in light of the prior art available at the time of the invention to a person having ordinary skill in the art. While the general principle of obviousness analysis applies to chemical compound claims, the courts have also developed a special analysis for chemical compound cases because of the perceived unpredictability of the chemical art.\(^5\) However, as will be discussed in this article, this assumption may not always be true and should not be treated as it is.

Part II of this article will discuss the Hatch-Waxman Act, which


\(^3\) Id.

\(^4\) Frank R. Lichtenberg & Gautier Duflos, Time release: The Effect of Patent Expiration on U.S. Drug Prices, Marketing, and Utilization by the Public, MANHATTAN INST. FOR POL’Y RES. (October 2009), http://www.manhattan-institute.org/html/mpr_11.htm (stating that between twelve and sixteen years after launching, the average generics’ mean market share increases from eight percent to sixty-five percent while the mean price declines forty-four percent).

\(^5\) See In re Dillon, 919 F.2d 688, 698 (Fed. Cir. 1990).
was introduced in 1984 and created the generic drug pathway to the market. Within this framework, the validity of drug patents are often challenged based on various theories including that the claimed invention was obvious to a person skilled in the art. Part III will discuss the general legal principle of the obviousness analysis under the context of patent validity, including the impact of *KSR v. Teleflex* (“*KSR*”). Part IV will discuss the evolution of obviousness analysis for chemical compound claims, leading toward the development of the modern lead compound theory. Part V will survey applications of the lead compound theory in the Court of Appeals for the Federal Circuit (the “CAFC”) since 2006 and discuss the teachings of each case. As will be discussed in more detail, the lead compound theory and those decisions applying the lead compound theory are largely based on the presumption that properties of chemical arts are unpredictable and that a small change in chemical structure may cause a significant variation in properties. Therefore, according to the CAFC, structural similarity alone does not suffice to establish a prima facie case of obviousness. As will be discussed in Part VI, however, this is not always true. Many strategies and approaches used in modern drug discovery, such as structure activity relationship (“SAR”) analysis in medicinal chemistry and rational drug design, can be used to predict properties of chemical compounds. It should be recognized by the courts that properties of chemical arts are not always unpredictable and that a properly validated prediction can contribute to the obviousness analysis in patent validity litigation.

II. HATCH-WAXMAN ACT AND GENERIC DRUGS

The pharmaceutical industry is a heavily regulated industry, and a new drug cannot be marketed in this country without approval by the FDA. If the innovator company believes that its newly-discovered compound can be used to treat certain diseases, it may sponsor clinical trials of the drug by filing an Investigational New Drug Application (“IND”) with the FDA, which includes a summary of animal pharmacology and toxicity studies, chemistry and manufacturing information, and proposed clinical protocols. If the FDA does not object to the IND within thirty days, the innovator company may start

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8 See Carter, supra note 7, at 231.
the clinical trials outlined in the IND.9 After all clinical trials have been completed and all data have been analyzed, the innovator company may file a New Drug Application (“NDA”), outlining the route of administration, dosage, intended use, labeling, etc.10 Once the FDA approves the NDA, the innovator company may market the new drug in the United States.11

The innovator company, having invested heavily in the preclinical research, clinical trials, and approval process of the new drug, is entitled to an exclusive marketing right that is guaranteed by both patent law and the FDA data exclusivity provision, whichever is longer.12 As a patent holder, the innovator company has a right to exclude others from practicing the patented invention in the United States within the term of the patent, which is seventeen years from the date of issuance for patents filed on or before June 8, 1995, or twenty years from the date of filing for patents filed after that date.13 A patent term extension is available to compensate the patent holder for delays in the patent review and FDA approval processes if the patent holder acted with due diligence during the period.14 Parallel to the patent protection, the innovator company is also entitled to a five-year period of data exclusivity from the date of FDA approval if the new drug product contains a New Chemical Entity (“NCE”) never previously approved by the FDA alone or in combination with other chemical entities.15 Within the period of the data exclusivity, no generic drug application can be filed with the FDA unless accompanied by a paragraph IV certification.16

Paragraph IV is a provision in the Drug Price Competition and Patent Term Restoration Act, passed by Congress in 1984 to encourage competition.17 The Act was jointly sponsored by Senator Orrin Hatch and Representative Henry Waxman, and thus is commonly referred to as the Hatch-Waxman Act.18

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9 Id. at 231.
16 Id.
Waxman Act allows generic manufacturers to gain FDA marketing approval by filing an Abbreviated New Drug Application (“ANDA”) if they can demonstrate that the proposed generic drug and the original NDA drug are bioequivalent. To reduce market entry delays for generic drugs, the Hatch-Waxman Act has a safe harbor provision that exempts otherwise infringing activities that are solely and reasonably related to obtaining FDA approval for a drug. To file an ANDA, the generic manufacturer must provide one of the following paragraph certifications: (I) that no patent information on that brand name drug has been submitted to the FDA; (II) that the listed patent has expired; (III) that the listed patent will expire on a certain date, before which time the generic will not enter the market; or (IV) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the ANDA was submitted. If a generic manufacturer submits a paragraph IV certification, the five-year data exclusivity period for the original NDA sponsor is reduced to four years, which allows the FDA to accept and review the ANDA filing one year before the expiration of the original data exclusivity period. Additionally, the earliest ANDA filer who prevails in the infringement litigation receives 180 days of market exclusivity for the generic drug, creating a strong financial incentive for ANDA filings with a paragraph IV certification. While paragraph I to III certifications are relatively straightforward, the paragraph IV certification is not so simple.

The generic manufacturer that files a paragraph IV certification for its ANDA must notify the patent holder of the original NDA drug of its paragraph IV certification submission and provide a detailed legal and factual explanation to substantiate that its proposed generic drug does not infringe the relevant patent or that the patent is invalid. The mere filing of the paragraph IV certification is an act of infringement, based on which the original patent holder has forty-five days to file an infringement suit. If the patent holder does not file an infringement suit within forty-five days, the FDA can approve the ANDA.

19 See 21 U.S.C. § 355(j) (2006). (In general, the generic drug is defined as bioequivalent to the original NDA drug if its blood concentration deviates less than 20% from the NDA drug. Upon finding of bioequivalence, the ANDA can rely on the corresponding NDA’s finding of safety and efficacy without additional clinical trials).


immediately.\textsuperscript{26} However, if an infringement suit is filed, the FDA may not approve the ANDA within thirty months or until a court rules that the patent is invalid or not infringed, whichever is earlier.\textsuperscript{27}

The most typical and often-used defense to this kind of infringement suit is that the original patent is invalid because the relevant claim or claims were obvious to a person having ordinary skill in the art (“PHOSITA” or “skilled artisan”) in light of the prior art available at the time of the invention. This process is applicable to all patents cited for NDA drugs in the Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) published by the FDA.\textsuperscript{28} In order to assert their patent rights in FDA filings and related judicial proceedings, NDA filers must list in the Orange Book all patents relevant to each NDA drug, which includes dosage patents, salt patents, formulation patents, and, most importantly, compound patents, which are the focus of the present article. Before going into specific analysis of compound patents in section IV, the next section will discuss the general legal principles of obviousness analysis in the context of patent validity.

### III. THE GENERAL PRINCIPLE OF OBVIOUSNESS ANALYSIS

Pursuant to Title 35 of the United States Code, to be patentable an invention must be useful,\textsuperscript{29} novel,\textsuperscript{30} non-obvious,\textsuperscript{31} and described in sufficient detail to enable its use by one skilled in the art.\textsuperscript{32} Articulated in 35 U.S.C. § 103, the non-obviousness requirement prevents patenting when “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”\textsuperscript{33} In determining the non-obviousness of an invention, the Supreme Court, in \textit{Graham v. John Deere Co.}, enumerated three factors to be considered, including (1) the scope and

\textsuperscript{26} \textit{Id.}


\textsuperscript{29} 35 U.S.C § 101 (2011).

\textsuperscript{30} 35 U.S.C § 102 (2011).

\textsuperscript{31} 35 U.S.C § 103 (2011).

\textsuperscript{32} 35 U.S.C § 112 (2011).

\textsuperscript{33} 35 U.S.C § 103 (2011).
content of the prior art, (2) the differences between the claimed invention and the prior art, and (3) the level of ordinary skill in the art. 34 “As indicia of obviousness or nonobviousness,” some secondary factors, such as “commercial success, long-felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” 35 The Graham factors laid a foundation and provided a general guideline for obviousness analysis of an invention in light of the prior art.

To determine whether an invention derived from a combination of previously known elements is obvious in light of the prior art, the CAFC in Winner Int’l Royalty Corp. v. Wang introduced the teaching-suggestion-motivation (“TSM”) test. 36 In that case, both Winner and Wang owned patents claiming embodiments of anti-theft car immobilization devices commercially known as “The Super Club” and “The Gorilla Grip.” 37 While various features and elements of those devices were known in the prior art, one central dispute was whether the combination of those previously known elements was obvious to a person having ordinary skill in the art at the time of the invention. Applying the Graham factors to the case, the CAFC panel held that to find a patent obvious there must be something in the prior art to suggest, teach, or motivate the combination of the previously known elements, thus, the TSM test. 38 Evidence of a teaching, suggestion, or motivation to combine the prior art references, according to the CAFC, can be found from the references themselves, the knowledge of the ordinarily skilled artisan, or from the nature of the problem to be solved. 39 Moreover, although the prior art reference does not have to teach or explicitly suggest the combination of the previously known elements, the showing of combinability must be clear and particular. 40 In Winner, no evidence of a teaching, suggestion, or motivation to combine the previously known elements was found, thus the claimed

34 Graham v. John Deere Co., 383 U.S. 1, 17 (1966) (“While the ultimate question of patent validity is one of law . . . the § 103 condition, which is but one of three conditions, each of which must be satisfied, lends itself to several basic factual inquiries. Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.”).
35 Id. at 17–18.
37 Id. at 1342–43.
38 Id. at 1348.
39 Id.
40 Id. at 1348–49.
invention was not obvious to a skilled artisan at the time of the invention.41

While the TSM test serves the purpose of preventing hindsight bias, it has been criticized as being too rigid, which was addressed by the Supreme Court in \textit{KSR Int’l Co. v. Teleflex Inc.}42 In that case, Teleflex asserted that KSR infringed on Teleflex’s patent of connecting an adjustable vehicle control pedal to an electronic throttle control.43 In its defense, KSR argued that both elements (adjustable vehicle control pedal and electronic throttle control) were known in the prior art and that combining those elements was obvious to a person having ordinary skill in the art at the time of the invention.44 While the District Court ruled in KSR’s favor, the CAFC reversed, reasoning that the District Court did not strictly apply the TSM test.45 The Supreme Court disagreed with the CAFC on how the TSM test should be applied.46 In its unanimous opinion, the Supreme Court stated that “[t]he obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents.”47 As noted by the Supreme Court, the question is not whether the combination was obvious to the patentee but rather to a person having ordinary skill in the art at the time of the invention.48 Additionally, the element being combined does not need to come from the same field or be designed to solve the same problem.49 As stated by the court, “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.”50

In the \textit{KSR} opinion, the Supreme Court noted and encouraged the new trend in subsequent CAFC decisions that “elaborated a broader conception of the TSM test.”51 While \textit{KSR} did not overrule the TSM test, it lowered the bar for the TSM test and made it easier in general to challenge the validity of a patent based on obviousness. For chemical compound patents, however, the impact of \textit{KSR} is limited so

\begin{itemize}
  \item \textit{Id.} at 1350.
  \item \textit{Id.} at 406.
  \item \textit{See id.} at 399.
  \item \textit{Id.} at 400.
  \item \textit{Id.} at 419.
  \item \textit{Id.}
  \item \textit{Id.} at 420.
  \item \textit{See id.} at 420–21.
  \item \textit{Id.} at 421.
  \item \textit{Id.} at 421–22.
\end{itemize}
far.

IV. THE DEVELOPMENT OF THE LEAD COMPOUND THEORY

The obviousness analysis for chemical compounds has gone through several stages, focusing mainly on the issue of whether teachings beyond structural similarity are required for a prima facie case of obviousness. Established in 1950 and governing the field for twenty years, the Hass-Henze doctrine maintained that structural similarity alone was adequate to establish a prima facie case of obviousness for chemical compound cases. Overruling the Hass-Henze doctrine in 1971, the In re Stemniski court demanded a showing or teaching in the prior art beyond structural similarity. This view controlled the field for another twenty years and occasionally led to extreme results. In 1990 the CAFC issued a milestone en banc decision, In re Dillon, clarifying the prior confusion and setting forth a revised analysis that remains in use today. In re Dillon did not directly cite, but adhered to, the same principle as the TSM test. In 2000, the Yamanouchi court further developed the principle into a two-step process, thus formalizing what is now known as the lead compound theory.

A. The Hass-Henze Doctrine

The Hass-Henze doctrine, established by In re Hass and In re Henze and later overruled by In re Stemniski, was an early attempt by the United States Court of Customs and Patent Appeals (the “CCPA”), the predecessor of the CAFC, to analyze the obviousness of chemical arts for the purposes of patentability and validity. The doctrine, which predated the Graham Factors and the TSM test, was predicated on the court’s belief that chemical compounds of a homologous series shared similar chemical and physical properties which varied only gradually from member to member.

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54 In re Dillon, 919 F.2d 688, 696 (Fed. Cir. 1990) (en banc).
56 In re Hass, 141 F.2d 122 (C.C.P.A. 1944).
57 In re Henze, 181 F.2d 196 (C.C.P.A. 1950).
58 In re Stemniski, 444 F.2d at 587.
59 Hass, 141 F.2d at 125 (“It is well understood by chemists that the members of a homologous series of chemical compounds possess the same principal continued . . .
In *In re Hass*, the appellant filed a patent application claiming new and useful nitroolefins. The patent claims were rejected by the patent examiner based on prior art that disclosed compounds with similar structure but did not disclose any similar properties. The rejection was affirmed by the Patent Appeal Board, which led to the appeal to the CCPA. Hass asserted that without a similar property there was no teaching that could have led a skilled artisan to the claimed invention. Therefore, according to Hass, unexpected or unobvious properties should not have been required to establish patentability. However, the CCPA opined that compounds with similar structures often had similar properties; therefore, a similarity in property could be inferred from a structural similarity. Following this line of reasoning, the CCPA held that a prima facie case of obviousness could be established by showing a high similarity between the structure of the claimed invention and a structure in the prior art. This reasoning was later reaffirmed by the CCPA in *In re Henze*, thus leading to the Hass-Henze doctrine. Once the prima facie case of obviousness is established, according to the court, “[t]he burden is on the applicant to rebut that presumption by a showing that the claimed compound possesses unobvious or unexpected beneficial properties not actually possessed by the prior art homologue.”

The Hass-Henze doctrine remained on the books for two decades until it was explicitly overruled by the CCPA in *Stemniski*, where the appellant’s claims were rejected by the U.S. Patent and Trademark Office (the “USPTO”) based on prior art that disclosed structurally similar compounds without disclosing their utilities. The USPTO followed the Hass-Henze doctrine and ruled that the prima facie case

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*Id.* at 122.

*Id.* at 123; *see also* Henze, 181 F.2d at 201 (“[T]he nature of homologues and the close relationship the physical and chemical properties of one member of a series bears to adjacent members is such that a presumption of unpatentability arises against a claim directed to a composition of matter, the adjacent homologue of which is old in the art.”).

*Hass*, 141 F.2d at 123.

*See id.* at 124–25.

*Id.* at 125.

*Id.*

*Henze*, 181 F.2d at 202.

*Id.* at 201 (emphasis in original).

*In re* Stemniski, 444 F.2d 581, 587 (C.C.P.A. 1971).
of obviousness was established by the structural similarity between the claimed invention and the prior art and that the appellant failed to rebut the presumption of obviousness with any evidence of unexpected or unobvious properties.\footnote{Id. at 583 ("The crux of the Patent Office position seems to be, in other words, that where a prima facie case of obviousness of claimed compounds has been established by reason of close structural similarity to prior art compounds, and that case has not been rebutted by any evidence of unexpected or unobvious properties inhering in those novel compounds which do not actually or in fact inhere in the structurally related compounds of the principal prior art references, the rejection is proper under § 103, even though those in the art at the time appellant's invention was made may be unaware of any significant properties or uses possessed by the prior art compounds." (emphasis in original)).} Reversing the USPTO’s decision, the\textit{Stemniski} court questioned whether the Hass-Henze doctrine imposed the correct burden of proof for the prima facie case of obviousness and concluded that it did not.\footnote{Id. at 587.} Explicitly overruling the doctrine, the court announced that “\textit{Henze}, its predecessors and its progeny have met with their share of criticism over the years” and that “progress in the useful arts is ill-served by denying patents to inventors” following the Hass-Henze doctrine.\footnote{Id. (emphasis in original).}

\textbf{B. The Modern Obviousness Analysis for Chemical Compounds}

The general interpretation of \textit{Stemniski} is that, in addition to structural similarity, a teaching in the prior art is required to establish a prima facie case of obviousness. This interpretation has sometimes led to extreme decisions. To clarify its position, the CAFC rendered an \textit{en banc} decision in \textit{In re Dillon}, which is considered the most current case law in obviousness-type, claim validity analysis based on structural similarity of chemical compounds.\footnote{See \textit{In re Dillon}, 919 F.2d 688, 698 (Fed. Cir. 1990) (en banc).} In that case, the CAFC affirmed the judgment of the Board of Patent Appeals and Interferences (the “BPAI”) rejecting certain claims in Dillon’s patent application covering fuel additives.\footnote{Id.} According to the court, Dillon failed to overcome the presumption of obviousness, which was established based on the prior art that gave reason or motivation for a skilled artisan to make the claimed invention.\footnote{Id.}

Dillon’s patent described the discovery that adding certain tetra-orthoester compounds to fuel could reduce the emission of solid
particles during combustion.\textsuperscript{75} In its broadest composition claim, Dillon claimed a composition comprising a hydrocarbon fuel and a sufficient amount of at least one tetra-orthoester, while the broadest method claim covered the method of using such composition.\textsuperscript{76} The BPAI rejected both the composition claim and the method claim based on the prior art, shown in Table 1.\textsuperscript{77}

**Table 1.** Comparison of the prior art and the claimed invention:

<table>
<thead>
<tr>
<th>Prior art:</th>
<th>Claimed invention:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Tetra-orthoesters were a known class of compounds.\textsuperscript{78}</td>
<td>Adding tetra-orthoesters to fuel can reduce solid particle emissions during combustion.\textsuperscript{81}</td>
</tr>
<tr>
<td>2. Tri-orthoesters were known to be used for “dewatering” fuels.\textsuperscript{79}</td>
<td></td>
</tr>
<tr>
<td>3. Tri-orthoesters and tetra-orthoesters were known to be used as water scavengers in hydraulic (non-hydrocarbon) fluids.\textsuperscript{80}</td>
<td></td>
</tr>
</tbody>
</table>

The CAFC stated that a prima facie case of obviousness for a compound claim could be established by structural similarity between the claimed compound and the compound(s) in the prior art, if the prior art gave reason or motivation for a skilled artisan to make the claimed compound.\textsuperscript{82} Explicitly reversing the panel decision and overruling its prior holding in a non-compound case, In re Wright,\textsuperscript{83} the CAFC clarified that a prima facie case of obviousness did not

\textsuperscript{75} [Id. at 690]  
\textsuperscript{76} [Id. at 690-91]  
\textsuperscript{77} [Id. at 690]  
\textsuperscript{78} [Id. at 691]  
\textsuperscript{79} [Id.]  
\textsuperscript{80} [Id.]  
\textsuperscript{81} [Id. at 690]  
\textsuperscript{82} See id. at 692 (“[S]tructural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness.” (emphasis in original)).  
\textsuperscript{83} See In re Wright, 848 F.2d 1216, 1219 (Fed. Cir. 1988) (stating that a prima facie case of obviousness requires that the prior art suggest the claimed composition’s properties and the problem the applicant attempts to solve).
require showing in the prior art a suggestion or expectation that the claimed compound would have the same or similar utility as the one newly discovered by the applicant. The CAFC announced that “the statement that a prima facie obviousness rejection is not supported if no reference shows or suggests the newly-discovered properties and results of a claimed structure is not the law.”

Turning to the specific facts in In re Dillon, the court concluded that a prima facie case of obviousness had been established because the prior art provided the motivation to make the claimed composition, a fuel with a tetra-orthoester, in the expectation that they would have similar properties. Dillon had an opportunity to rebut the prima facie case, the court added, but did not present any data showing unexpected superior properties. Therefore, Dillon’s claims on the appeal “are not structurally or physically distinguishable from the prior art compositions by virtue of the recitation of their newly-discovered use.”

Rejecting the dissenting judges’ position that similarities of both structure and utility are required to establish a prima facie case of obviousness, the majority stated that properties

are relevant to the creation of a prima facie case in the sense of affecting the motivation of a researcher to make compounds closely related to or suggested by a prior art compound, but it is not required, as stated in the dissent, that the prior art disclose or suggest the properties newly-discovered by an applicant in order for there to be a prima facie case of obviousness.

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84 In re Dillon, 919 F.2d at 693 (“[I]t is not necessary in order to establish a prima facie case of obviousness that both a structural similarity between a claimed and prior art compound (or a key component of a composition) be shown and that there be a suggestion in or expectation from the prior art that the claimed compound or composition will have the same or a similar utility as one newly discovered by applicant.” (emphasis in original)).
85 Id. (emphasis in original).
86 Id.
87 Id.
88 Id. at 693 n.4.
89 Id. at 700 (Newman, J., dissenting) (“[D]etermination of whether a prima facie case of obviousness has been made requires consideration of the similarities and differences as to structure and properties and utility, between the applicant's new compounds or compositions and those shown in the prior art.” (emphasis in original)).
90 Id. at 697 (emphasis in original).
C. The Lead Compound Theory for Obviousness Analysis of Chemical Arts

Building on the same principle of the Graham factors and In re Dillon, the CAFC in Yamanouchi v. Danbury streamlined the obviousness analysis using the concept of lead compound.91 In Yamanouchi, the CAFC affirmed the decision granting a motion for judgment as a matter of law (“JMOL”) made by the trial court which upheld the validity of the U.S. Patent No. 4,283,408 (the “‘408 patent”) for famotidine.92 Yamanouchi was the patent holder of famotidine, which was approved by the FDA for the treatment of peptic ulcer and gastroesophageal reflux.93 Danbury, a generic drug manufacturer, filed an ANDA with a paragraph IV certification to the FDA seeking approval to market generic famotidine.94 In the paragraph IV certification, Danbury asserted that the relevant claim of the ’408 patent was invalid in light of the prior art available at the time of the invention.95

The central dispute of the case was whether one skilled in the art would have found motivation to combine a piece from one prior art with a piece from another prior art through a series of chemical manipulations.96 According to Danbury, a skilled artisan would have considered it obvious to select the compound of example 44 from Yamanouchi's U.S. Patent No. 4,252,819 and tiotidine from another patent as lead compounds for making famotidine because these compounds are three and eleven times more active, respectively, than the benchmark compound at the time of invention, as shown in Table 2.97 After selecting these two lead compounds, as asserted by Danbury, it would have been obvious for a skilled artisan to combine the polar tail from example 44 with the substituted heterocycle from tiotidine to form the intermediate compound.98 Additionally, Danbury claimed it would also have been obvious to perform a bioisosteric substitution of the carbamoyl (CONH2) group in the intermediate compound with a sulfamoyl group (SO2NH2) to create famotidine.99

92 Id. at 1340–42.
93 Id. at 1341–42.
94 Id. at 1342.
95 Id.
96 Id. at 1343.
97 Id. at 1343–44.
98 See id. at 1344.
99 Id.
Table 2. Comparison of prior art compounds and the claimed structure of famotidine:

<table>
<thead>
<tr>
<th>Prior art</th>
<th>Claimed invention</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Chemical Structure" /></td>
<td>Example 44, H₂ antagonist, three times more active than the benchmark compound.</td>
</tr>
<tr>
<td><img src="image2" alt="Chemical Structure" /></td>
<td>Intermediate compound, combining the urea tail of example 44 and the guanidinyl thiazol head of tiotidine.</td>
</tr>
<tr>
<td><img src="image3" alt="Chemical Structure" /></td>
<td>Tiotidine, H₂ antagonist, eleven times more active than the benchmark compound.</td>
</tr>
<tr>
<td><img src="image4" alt="Chemical Structure" /></td>
<td>Famotidine, ’408 patent, H₂ antagonist, inhibit gastric acid secretion.</td>
</tr>
</tbody>
</table>

Applying the Graham factors and In re Dillon to the facts of the Yamanouchi case, however, the CAFC pointed out that Danbury did not show the required motivation to select example 44 as a lead compound. According to Danbury, the motivation existed because example 44 was three times more active than cimetidine, which was used as the benchmark compound. However, as noted by the court, activity alone did not provide sufficient motivation because other prior art references disclosed compounds with H₂ antagonist activity up to ten times higher than cimetidine. “If activity alone was the sole motivation, other more active compounds would have been the obvious choices, not example 44.”

Also based on the facts in the case, according to the CAFC panel, Danbury failed to show the motivation to modify the lead compound to the claimed invention. Danbury argued that an ordinary medicinal chemist would have reasonably expected the resulting compound to exhibit the baseline level of H₂ antagonist activity.

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100 Id. at 1345.
101 Id.
102 Id.
103 Id.
104 See id.
because of the structural similarity. The baseline level of activity for the asserted lead compound is a mere 1/165th of the activity of the benchmark compound and the court reasoned that this percentage does not support a reasonable expectation of success. The CAFC panel reasoned that the success of the compound was not from discovering one of the tens of thousands of compounds that exhibit baseline H2 antagonist activity, but rather “finding a compound that had high activity, few side effects, and lacked toxicity.”

_Yamanouchi_ was the first case in which the CAFC panel formulated the obviousness analysis for chemical compound claims in terms of a lead compound: to establish a prima facie case of obviousness for a compound claim, it must be obvious for a skilled artisan to select the prior art compound as a lead compound and to modify the lead compound to the claimed invention, thus the lead compound theory. This theory reflects the general principle of obviousness analysis established in _Graham v. John Deere_ and is consistent with the CAFC’s holding in _In re Dillon_. As will be discussed in the following section, this theory survived _KSR_ and has been applied in all obviousness-type invalidity cases for chemical compounds.

V. RECENT CACF CASES APPLYING THE LEAD COMPOUND THEORY

This section will survey chemical compound cases decided by the CAFC since _Yamanouchi_, with special attention paid to those showing high structural similarity between the prior art and the claimed invention. As will be shown through those cases, the CAFC closely followed the lead compound theory in the obviousness analysis, especially the motivation requirement. So far, none of the generic manufacturers challenging the validity of NDA compound patents were able to satisfy the motivation requirement of the lead compound theory.

A. _Eli Lilly v. Zenith Goldline_

Decided in December 2006, _Eli Lilly v. Zenith Goldline_ is a pre- _KSR_ case, in which the CAFC applied the lead compound theory and

\[105\] See id.

\[106\] Id.

\[107\] Id.

\[108\] Id.

affirmed the decision by the U.S. District Court for the Southern District of Indiana, upholding the validity of Eli Lilly’s patent, U.S. Patent No. 5,229,382 (the “‘382 patent”).

The ’382 patent claims olanzapine, the active ingredient of Zyprexa®, approved by the FDA for the treatment of schizophrenia. Zenith Goldline Pharmaceuticals, Dr. Reddy’s Lab and Teva Pharmaceuticals (collectively referred to as “DRL” because the invalidity defense was asserted by Dr. Reddy’s Lab) sought FDA approval to market generic olanzapine by filing an ANDA, which triggered an infringement action by Eli Lilly. As part of the response to Eli Lilly’s infringement suit, DRL challenged the validity of the ’382 patent by asserting that the claim for olanzapine was obvious to a skilled artisan based on the prior art known at the time of the invention, such as flumezapine, ethyl flumezapine, and ethyl olanzapine, as shown in Table 3.

**Table 3.** Comparison of the prior art and olanzapine:

<table>
<thead>
<tr>
<th>Prior art</th>
<th>Claimed invention</th>
</tr>
</thead>
<tbody>
<tr>
<td>clozapine</td>
<td>olanzapine</td>
</tr>
<tr>
<td>flumezapine</td>
<td></td>
</tr>
<tr>
<td>ethyl flumezapine</td>
<td></td>
</tr>
<tr>
<td>ethyl olanzapine (comp. ’222)</td>
<td></td>
</tr>
</tbody>
</table>

DRL asserted that the prior art identified and disclosed compounds with the same biological utility in the same structural family as olanzapine, namely thienobenzodiazepines, such as clozapine, flumezapine, ethyl flumezapine, and ethyl olanzapine. The only difference between olanzapine and one of the prior art compound, ethyl olanzapine, is the methyl substitution for olanzapine versus the

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111 Id. at 1373.
112 Id.
113 See id. at 1374-75.
114 Id. at 1374, 1376.
ethyl substitution for ethyl olanzapine at the same position.\textsuperscript{115} Using \textit{In re Petering}\textsuperscript{116} and \textit{In re Schaumann}\textsuperscript{117} as support, IVAX (formerly Zenith Goldline Pharmaceuticals) argued that olanzapine, as claimed in the ’382 patent, was anticipated by the broader and inclusive genus disclosed in the prior art.\textsuperscript{118}

Distinguishing the \textit{Eli Lilly} case from \textit{In re Petering} and \textit{In re Schaumann}, the CAFC panel focused on the size of the genus disclosed in the prior art.\textsuperscript{119} As pointed out by the court, “[i]n Petering, the prior art disclosed a limited number of specific preferences from a specifically defined group of isoalloxazines. As a result, Petering actually disclosed to one skilled in the art a limited class of only ‘some 20 compounds . . . .’”\textsuperscript{120} “Similarly, the prior art in Schaumann disclosed 14 compounds, later further narrowed to 7, considering express preferences. Additionally, the structural formula of this prior art contained but a single variable.”\textsuperscript{121} On the contrary, as emphasized by the CAFC panel, the prior art in \textit{Eli Lilly} disclosed millions of compounds, including all proposed alternative substituents.\textsuperscript{122}

Applying the lead compound theory to the \textit{Eli Lilly} case, the CAFC panel affirmed the district court’s decision that the prior art did not support the identification of any prior art compound as the lead compound.\textsuperscript{123} While the court recognized that the structure of olanzapine is very similar to structures of several prior art compounds, it focused on the fact that the SAR in the prior art “expressed a preference for halogen-containing compounds (fluorine or chlorine), not hydrogen.”\textsuperscript{124} Even in the patent that disclosed ethyl olanzapine, the SAR “expressed a preference for halogen containing compounds and specifically those with a halogenated substituent on the benzene ring in a location analogous to the chlorine in clozapine.”\textsuperscript{125} Therefore, the court concluded:

[T]he defendants have not shown that a person ordinarily skilled in this art would have selected

\textsuperscript{115} See \textit{id.} at 1374–76.
\textsuperscript{116} \textit{In re Petering}, 301 F.2d 676, 682 (C.C.P.A. 1962).
\textsuperscript{117} \textit{In re Schaumann}, 572 F.2d 312, 315 (C.C.P.A. 1978).
\textsuperscript{118} \textit{Eli Lilly}, 471 F.3d at 1376.
\textsuperscript{119} \textit{Id.}
\textsuperscript{120} \textit{Id.} (citation omitted).
\textsuperscript{121} \textit{Id.}
\textsuperscript{122} \textit{Id.}
\textsuperscript{123} \textit{Id.} at 1378–79.
\textsuperscript{124} See \textit{id.} at 1376.
\textsuperscript{125} \textit{Id.} at 1378 (emphasis in original).
compound ’222 as a lead compound because it contained hydrogen rather than fluorine or chlorine. At the time of invention, the state of the art would have directed the person of ordinary skill in the art away from unfluorinated compounds like compound ’222.126

Relying on the same SAR, the CAFC held that “the prior art also did not suggest any of the other modifications necessary to reach olanzapine.”127 As reasoned by the court, “mere identification in the prior art of each component of a composition does not show that the combination as a whole lacks the necessary attributes for patentability, i.e. is obvious.”128 In order to establish a prima facie case of obviousness based on a combination of known elements in the prior art, a motivation is required to select the lead compound and to modify the lead compound to the claimed invention.129 The SAR in the Eli Lilly case, according to the CAFC, did not support such a motivation.130

B. Takeda v. Alphapharm

In June 2007, the CAFC rendered its first post-KSR opinion regarding the obviousness-based invalidity for chemical compounds, Takeda v. Alphapharm, in which the CAFC panel affirmed the district court’s decision by upholding the validity of U.S. Patent No. 4,687,777 (the “’777 patent”).131 Takeda owns the ’777 patent which covers pioglitazone, a PPAR-γ agonist and the active ingredient of Actos®, approved by the FDA for type-2 diabetes.132 Alphapharm filed an ANDA for Actos® and, in response to Takeda’s infringement suit, alleged that the ’777 patent was invalid due to obviousness in light of the prior art available at the time of the invention, as shown in Table 4.133 More specifically, Alphapharm asserted that pioglitazone would have been obvious over compound b, which the district court found that Alphapharm failed to prove by clear and convincing evidence.134

126 Id. at 1379.
127 Id.
128 Id.
129 See id.
130 See id. at 1380.
132 Id. at 1352-54.
133 Id. at 1353-54.
134 Id. at 1354.
Table 4. Comparison of the prior art and the claimed invention:

<table>
<thead>
<tr>
<th>Prior art</th>
<th>Claimed invention</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Compound b" /></td>
<td><img src="image" alt="Pioglitazone" /></td>
</tr>
</tbody>
</table>

Rejecting Alphapharm’s assertion that *KSR v. Teleflex* and *Pfizer v. Apotex* mandated reversal in this case, the CAFC reaffirmed its analysis for chemical compound cases in *In re Grabiak*, \(^{135}\) *In re Dillon*, \(^{136}\) *In re Jones*, \(^{137}\) and *In re Deuel*. \(^{138}\) According to the *Takeda* court,

> [w]hile the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation (‘TSM’) test in an obviousness inquiry, the Court acknowledged the importance of identifying ‘a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does’ in an obviousness determination.\(^{139}\)

Moreover, stated by the *Takeda* court, the idea underlying the TSM test is consistent with the *Graham* analysis and can provide

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\(^{135}\) *Id.* at 1356 (“‘In addition to structural similarity between the compounds, a prima facie case of obviousness also requires a showing of ‘adequate support in the prior art’ for the change in structure.’” (citing *In re Grabiak*, 769 F.2d 729, 731–32 (Fed. Cir. 1985))).

\(^{136}\) *Takeda*, 492 F.3d at 1356 (“‘[S]tructural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness.’” (citing *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990))).

\(^{137}\) *Takeda*, 492 F.3d at 1356 (“‘[I]n order to find a prima facie case of unpatentability in such instances, a showing that the ‘prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention’ was also required.’” (citing *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992))).

\(^{138}\) *Takeda*, 492 F.3d at 1356 (“‘[N]ormally a prima facie case of obviousness is based upon structural similarity, *i.e.*, an established structural relationship between a prior art compound and the claimed compound’ because ‘[s]tructural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds.’” (citing *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995))).

\(^{139}\) *Takeda*, 492 F.3d at 1356–57 (citing *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007)).
helpful insight for an obviousness inquiry, as long as the test is not applied as a rigid and mandatory formula.\textsuperscript{140} Therefore, the Takeda court held that “in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound.”\textsuperscript{141}

Turning to pioglitazone, the CAFC panel agreed with the trial court that nothing in the evidence would have made it obvious for a skilled artisan to select compound b as a lead compound for further optimization.\textsuperscript{142} Compound b was disclosed in a patent which covered “hundreds of millions of TZD [thiazolidinedione] compounds.”\textsuperscript{143} Although test results of nine compounds, including compound b, were provided to the USPTO during the patent examination, the Takeda court found nothing in the patent or its filing history “to suggest to one of ordinary skill in the art that those nine compounds, out of the hundreds of millions of compounds covered by the patent application, were the best performing compounds as antidiabetics, and hence targets for modification to seek improved properties.”\textsuperscript{144} On the contrary, in another cited publication, compound b was not selected as one of the three most favorable compounds, but rather singled out as causing “considerable increase in body weight and brown fat weight.”\textsuperscript{145} Therefore, the court concluded that Alphapharm did not make out a prima facie case of obviousness and that the relevant patent claims were valid.\textsuperscript{146}

Based on the analysis of the Takeda case, a prima facie case of obviousness cannot be established when (1) the prior art offered a broad range of compounds and did not give any reason to select any particular one for further modification; (2) the prior art taught away from using the asserted lead compound; and (3) there was no reasonable expectation of success to modify the lead compound to the claimed invention.\textsuperscript{147}

C. Eisai v. Dr. Reddy’s Lab

In July 2008, the CAFC affirmed the summary judgment decision

\begin{itemize}
  \item \textsuperscript{140} Takeda, 492 F.3d at 1357.
  \item \textsuperscript{141} Id.
  \item \textsuperscript{142} Id.
  \item \textsuperscript{143} Id.
  \item \textsuperscript{144} Id.
  \item \textsuperscript{145} Id. at 1358.
  \item \textsuperscript{146} Id. at 1362–63.
  \item \textsuperscript{147} See id.
\end{itemize}
of the U.S. District Court for the Southern District of New York and upheld the validity of Eisai’s U.S. Patent No. 5,045,552 (the “’552 patent”) against the obviousness challenge brought by Dr. Reddy’s Lab and Teva Pharmaceuticals.148

The ’552 patent claims rabeprazole, an H⁺K⁺ATPase inhibitor and the active ingredient for Aciphex®, which was approved by the FDA to treat duodenal ulcers, heartburn, and associated disorders.149 Dr. Reddy’s Lab and Teva each filed an ANDA for generic Aciphex® and alleged that the ’552 patent was invalid because it was obvious to a skilled artisan at the time of the invention in light of the prior art, such as lansoprazole and omeprazole, as shown in Table 5.150

Table 5. Comparison of the prior art and the claimed invention:

<table>
<thead>
<tr>
<th></th>
<th>Prior art</th>
<th>Claimed invention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><img src="image" alt="Lansoprazole" /></td>
<td><img src="image" alt="Rabeprazole" /></td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Omeprazole" /></td>
<td></td>
</tr>
</tbody>
</table>

Reaffirming its pre-KSR decisions in chemical compound cases including the lead compound theory, the CAFC panel in *Eisai v. Dr. Reddy’s Labs* noted that a prima facie case of obviousness for a chemical compound “requires ‘structural similarity between claimed and prior art subject matter . . . where the prior art gives reason or motivation to make the claimed compositions.’”151 “Obviousness based on structural similarity thus can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a

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148 *Eisai Co. v. Dr. Reddy's Labs.*, 533 F.3d 1353, 1362 (Fed. Cir. 2008). The Court also noted that while both Reddy and Teva asserted the unenforceability due to inequitable conduct Teva further argued that the patent was invalid due to obviousness.

149 *Id.* at 1356.

150 *Id.* at 1356–57.

151 *Id.* at 1357 (quoting *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc)).
particular way to achieve the claimed compound.”

Turning to the specific facts in the *Eisai* case, the court analyzed the prior art proffered by Teva including lansoprazole, omeprazole, and a scientific article describing the SAR of compounds with the same scaffold. Viewing the evidence most favorable to Teva, according to the CAFC panel, lansoprazole was twenty times more active than omeprazole and had certain more desirable features. Therefore, “one of skill in this art may have considered it a candidate for a lead compound in the search for anti-ulcer compounds.”

However, the court could find no support in the evidence that would have motivated a person skilled in the art to modify the lansoprazole toward rabeprazole. As recognized by the court, lansoprazole differed from rabeprazole mainly in its trifluoroethoxy (OCH$_2$CF$_3$) substitution at the 4-position on the pyridine ring, and omeprazole differed from rabeprazole even more with its methoxy (OCH$_3$) substitution at the pyridine ring 4-position. As testified by a Teva expert, there existed a prior art teaching that “fluorine-substituted groups increase lipophilicity,” which is considered a desirable feature to a skilled artisan. However, rabeprazole does not retain this trifluoroethoxy group, which, in fact, is the only difference between lansoprazole and rabeprazole. As pointed out by the court, the record “shows no discernible reason for a skilled artisan to begin with lansoprazole only to drop the very feature, the fluorinated substituent, that gave this advantageous property.” Therefore, the court did not believe that a case of obviousness had been established, as a matter of law.

The teaching of the case is that any compound may serve as a lead compound if there is a reason for a skilled artisan to start with the

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152 *Eisai*, 533 F.3d at 1357 (citing *Takeda*, 492 F.3d at 1356).
153 *See* *Eisai*, 533 F.3d at 1357.
154 *Id.* at 1358 (stating that “lansoprazole is twenty times superior to omeprazole for anti-ulcer action, as measured by an indomethacin-induced gastric lesion assay in rats. This court also assumes that lansoprazole has certain traits, including lipophilicity (the ability of a compound to cross lipid membranes) and low molecular weight, that would have made it desirable to a skilled artisan.”).
155 *Id.*
156 *Id.*
157 *Id.* at 1357.
158 *Id.*
159 *Id.* at 1358.
160 *See* *id.* at 1357.
161 *Id.* at 1358.
162 *Id.* at 1359.
compound and modify it toward the claimed compound.\textsuperscript{163} However, the modification would not be obvious if the prior art did not show any reason to motivate the particular modification leading to the claimed compound, especially when the prior art taught that the particular modification would destroy its desirable properties.

\textbf{D. Procter & Gamble v. Teva}

In May 2009, the CAFC panel affirmed a decision by the U.S. District Court for the District of Delaware upholding the validity of U.S. Patent No. 5,583,122 (the “’122 patent”) against the challenge for obviousness-type double patenting.\textsuperscript{164}

The ’122 patent relates to risedronate acid, the active ingredient in Actonel\textsuperscript{®} approved by the FDA for the treatment of osteoporosis.\textsuperscript{165} After Teva Pharmaceuticals filed an ANDA for generic risedronate, Procter & Gamble (“P & G”) filed suit against Teva for patent infringement.\textsuperscript{166} In response, Teva asserted that the ’122 patent was invalid due to obviousness in light of the prior art disclosed in P & G’s expired patent (U.S. Patent No. 4,761,406), particularly 2-pyr etidronate (EHDP), as shown in Table 6.\textsuperscript{167}

\begin{table}[ht]
\centering
\begin{tabular}{|c|c|}
\hline
\textbf{Prior art} & \textbf{Claimed invention} \\
\hline
\includegraphics[width=0.2\textwidth]{2-pyr-EHDP} & \includegraphics[width=0.2\textwidth]{risedronate-3-pyr-EHDP} \\
\hline
2-pyr EHDP & risedronate acid, 3-pyr EHDP \\
\hline
\end{tabular}
\caption{Comparison of the prior art and risedronate:}
\end{table}

The CAFC panel recognized that an obviousness argument based on structural similarity depends on a preliminary finding that a skilled artisan would have selected the prior art compound as a lead compound.\textsuperscript{168} However, the court did not feel it was necessary to reach this question because the evidence showed that even if a skilled artisan could have identified 2-pyr EHDP as a lead compound, it

\textsuperscript{163} See \textit{id}. at 1357 (citing Takeda Chem. Indus. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1356 (Fed. Cir. 2007)).

\textsuperscript{164} Procter & Gamble Co. v. Teva Pharm. USA, Inc., 566 F.3d 989, 999 (Fed. Cir. 2009).

\textsuperscript{165} \textit{id}. at 992.

\textsuperscript{166} \textit{id}.

\textsuperscript{167} \textit{id}. at 992–93.

\textsuperscript{168} See \textit{id}.
would not have been obvious to one skilled in the art at the time of the invention to modify it to create risedronate (3-pyr EHDP).\(^ {169}\) The court found that despite the fact that 2-pyr EHDP and risedronate are positional isomers with highly similar structures, the SAR in the evidence did not show, and Teva failed to establish, sufficient motivation for a skilled artisan to make such modification.\(^ {170}\)

E. Altana Pharma v. Teva

In May 2009, the CAFC affirmed the decision by the U.S. District Court for the District of New Jersey denying Altana Pharma’s motion for preliminary injunction to prevent Teva Pharmaceuticals from marketing a generic version of pantoprazole (trade name: Protonix\(^ {6}\) in the U.S.) for treatment of erosion and ulceration of the esophagus.\(^ {171}\)

Altana Pharma’s pantoprazole, a proton pump inhibitor (PPI), is covered by its U.S. Patent No. 4,758,579 (the “’579 patent”).\(^ {172}\) After Teva filed an ANDA seeking FDA approval of a generic version of pantoprazole, Altana Pharma filed an infringement suit and a motion for preliminary injunction.\(^ {173}\) While it conceded infringement, Teva maintained that the ’579 patent was invalid due to obviousness in light of several prior art teachings, especially compound 12 from Altana Pharma’s earlier patent (U.S. Patent No. 4,555,518, the “’518 patent”), as shown in Table 7.\(^ {174}\) Upon hearing Altana Pharma’s motion for preliminary injunction, the District Court found that the defendants had demonstrated a substantial question of invalidity.\(^ {175}\) “In particular, the court found that one of skill in the art would have selected compound 12 as a lead compound for modification.”\(^ {176}\)

Table 7. Comparison of the prior art and pantoprazole:

\(^{169}\) Id. at 994–95.
\(^{170}\) Id. at 995–96.
\(^{171}\) Altana Pharma AG v. Teva Pharm. USA, Inc., 566 F.3d 999, 1000, 1002–04, 1011 (Fed. Cir. 2009).
\(^{172}\) Id. at 1002.
\(^{173}\) Id. at 1004.
\(^{174}\) Id.
\(^{175}\) Id.
\(^{176}\) Id. at 1004–05.
In the portion of the Altana Pharma court’s opinion on likelihood of success on the merits, the court pointed out several pieces of evidence supporting the finding that a skilled artisan would have selected compounds disclosed in the ’518 patent, especially compound 12, as a lead compound for further development.177 First of all, the ’518 patent claimed that its compounds were improvements over the prior art, specifically omeprazole (the first successful PPI).178 Second, compound 12 was “one of the more potent of the eighteen compounds of the ’518 patent for which data was provided during prosecution.”179 As stated by the court, “[a]lthough potency is not dispositive, the district court believed—not unreasonably—that the potency of the compound was a factor that would have led one of skill in the art to select compound 12 from the group for further study.”180

Despite the limited precedential value of Altana Pharma due to its procedural posture,181 one teaching from the case is that to establish a prima facie case of obviousness the prior art need not identify a sole lead compound.182 The CAFC panel clearly rejected Altana Pharma’s suggestion that “the prior art must point to only a single lead compound for further development efforts.”183 In CAFC’s opinion, this “restrictive view of the lead compound test would present a rigid test similar to the teaching-suggestion-motivation test that the Supreme Court explicitly rejected in KSR.”184

While Altana Pharma is one of the closest cases where the CAFC may hold a chemical compound patent invalid due to obviousness, it is important to note that an “appellant carries a heavier burden when

<table>
<thead>
<tr>
<th>Prior art</th>
<th>Claimed invention</th>
</tr>
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<tbody>
<tr>
<td><img src="image" alt="compound 12 in ’518 patent" /></td>
<td><img src="image" alt="pantoprazole" /></td>
</tr>
</tbody>
</table>

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177 Id.
178 Id. at 1007.
179 Id. at 1007–08.
180 Id. at 1008.
181 When appealing a denial of a preliminary injunction, the appellant must show that part of the decision of denial was based on a clearly erroneous finding, and that the trial court’s denial of the injunction constituted an abuse of discretion.
182 See Altana Pharma 566 F.3d at 1007–08.
183 See id. at 1008.
184 Id.
seeking to reverse the denial of a preliminary injunction than seeking
to reverse the grant of a preliminary injunction.” 185 Moreover, this
decision also heavily hinged on the fact that discretionary weight must
be given to a district court's decision. As noted in Judge Newman’s
concurring opinion, “[a]lthough the evidence presented to the district
court does not . . . establish invalidity of the patent on the
pharmaceutical product pantoprazole, at this preliminary stage
decree is warranted to the district court's weighing of the
conflicting expert opinions interpreting the evidence.” 186 This
comment highlights the possibility that the outcome of this case could
have been completely different had the review been solely based on
the determination of obviousness for the patent-at-issue.

F. Daiichi v. Matrix Labs

In 2010, the CAFC affirmed the decision of the U.S. District Court
for the District of New Jersey that Matrix Labs failed to establish a
prima facie case of obviousness and upheld the validity of U.S. Patent
No. 5,616,599 (the “’599 patent”)187 for olmesartan medoxomil (trade
name: Benicar® in the U.S.), an angiotensin receptor blocker (ARB)
approved by the FDA for treatment of high blood pressure
(hypertension). 188

The discovery of olmesartan medoxomil as an effective ARB for
hypertension was built on years of research beginning in the 1970s. 189
More than 200 structurally-related ARBs were disclosed in the
losartan patent (U.S. Patent No. 5,138,069, the “’069 patent”) and
DuPont’s U.S. Patent No. 5,137,902 (the “’902 patent”). 190 The
compound bearing the highest structural similarity to olmesartan is
example 6 from the ’902 patent, as shown in Table 8, differing by only
a single oxygen atom at the 4-position of the imidazole ring. 191 Based
on this structural similarity, Matrix Labs and other defendants
challenged the validity of the olmesartan patent asserting that it was
obvious to a skilled artisan in light of the prior art known at the time of

185 Id. at 1005.
186 Id. at 1011 (Newman, J., concurring) (citation omitted).
188 Id. at 1347.
189 Id. at 1348–49 (stating losartan was developed by DuPont and disclosed “in
U.S. Patent 5,138,069 (the ’069 patent’) along with more than four hundred
structurally related ARBs.”).
190 See id. at 1349–50.
191 Id. at 1350–51.
the invention.\textsuperscript{192}

\textbf{Table 8.} Comparison of the prior art and the claimed invention:

<table>
<thead>
<tr>
<th>The closest prior art</th>
<th>Claimed invention</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Example 6" /></td>
<td><img src="image2.png" alt="Olmesartan" /></td>
</tr>
</tbody>
</table>

Applying the lead compound theory to olmesartan, the CAFC panel agreed with the trial court that the SAR for all ARBs in the prior art did not make it obvious for a skilled artisan to select one of the compounds in the '902 patent bearing high similarity with olmesartan as a lead compound.\textsuperscript{193} In selecting a lead compound for further development, a skilled artisan depends on not only structural similarity, but also knowledge of SARs among prior art compounds.\textsuperscript{194} According to the CAFC panel, based on SARs disclosed in the prior art and a rich collection of testing data, compounds in the '902 patent did not stand out as an obvious choice of a lead compound.\textsuperscript{195}

\textsuperscript{192} See id. at 1351 (One of the defendants, Mylan, alleged in a counterclaim that: (1) one of skill in the art would have been motivated to select ARBs in DuPont’s '902 patent as lead compounds; (2) Example 118 in DuPont’s '069 patent would have motivated one of skill in the art to modify the '902 compounds’ lipophilic alkyl groups at the 4-position with olmesartan’s hydrophilic hydroxyalkyl group; and (3) the use of medoxomil as a prodrug was well-known.).

\textsuperscript{193} See id. at 1353 (“[A] medicinal chemist of ordinary skill would not have been motivated to select the '902 compounds over other second-generation ARBs, including L-158,809, DuP 532, the Eisai compounds, and valsartan, because many of the latter ARBs demonstrated greater potency and all had been more thoroughly studied than the '902 ARBs.”).

\textsuperscript{194} See id. at 1354 (“[P]roving a reason to select a compound as a lead compound depends on more than just structural similarity, but also knowledge in the art of the functional properties and limitations of the prior art compounds. Potent and promising activity in the prior art trumps mere structural relationships.” (citation omitted)).

\textsuperscript{195} See id. at 1353–54 (The CAFC pointed out not only oral activity, but also continued . . .
CAFC stated, “[p]otent and promising activity in the prior art trumps mere structural relationships.”\textsuperscript{196} The court also relied on the SAR to decide whether a skilled artisan would have had a motivation to modify the structure to olmesartan from the lead compound asserted by the defendant.\textsuperscript{197} Specifically, the SAR indicated that at the 4-position of the imidazole ring, a lipophilic group was preferred.\textsuperscript{198} This SAR led away from olmesartan, which has a hydrophilic group at this position.\textsuperscript{199} Therefore, the CAFC panel concluded that structures and activity data in the prior art “counter any notion that one of skill in the art would have been motivated to modify the ’902 compounds’ lipophilic alkyl groups to a hydrophilic group. Such a holding would have been based on hindsight.”\textsuperscript{200}

\textbf{G. Otsuka v. Sandoz}

The latest case from the CAFC regarding the obviousness standard of a chemical compound claim is \textit{Otsuka Pharm. Co. v. Sandoz, Inc.} Decided on May 7, 2012, the CAFC affirmed the district court’s finding of validity, holding that the compound at issue, aripiprazole, was not obvious to a skilled artisan in light of prior art compounds, as shown in Table 9.\textsuperscript{201} Aripiprazole (trade name: Abilify®) is an atypical antipsychotic and antidepressant approved by the FDA for the treatment of schizophrenia.\textsuperscript{202} Unlike “typical” antipsychotics that only treat positive symptoms of schizophrenia, those that treat both positive and negative symptoms are referred to as “atypical” antipsychotics.\textsuperscript{203} Since the approval of clozapine in 1990 and risperidone in 1994, seven other atypical antipsychotics have been approved, among which aripiprazole is the only compound that is not structurally related to either clozapine or risperidone.\textsuperscript{204}

\begin{flushleft}
\begin{footnotesize}
\textsuperscript{196} Id. at 1354. \\
\textsuperscript{197} Id. \\
\textsuperscript{198} Id. at 1355. \\
\textsuperscript{199} Id. at 1354. \\
\textsuperscript{200} Id. \\
\textsuperscript{201} Otsuka Pharm. Co. v. Sandoz, Inc., 678 F.3d 1280, 1280, 1285-86, 1288-89 (Fed. Cir. 2012). \\
\textsuperscript{202} Id. at 1284. \\
\textsuperscript{203} Id. \\
\textsuperscript{204} Id. \\
\end{footnotesize}
\end{flushleft}
Table 9. Comparison of the prior art and aripiprazole:

<table>
<thead>
<tr>
<th>Prior art</th>
<th>Claimed invention</th>
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<tbody>
<tr>
<td><img src="image1" alt="Prior art 1" /> unsubstituted butoxy</td>
<td><img src="image2" alt="Claimed invention" /> aripiprazole</td>
</tr>
<tr>
<td><img src="image3" alt="Prior art 2" /> 2,3-dichloro propoxy</td>
<td></td>
</tr>
<tr>
<td><img src="image4" alt="Prior art 3" /> OPC-4392</td>
<td></td>
</tr>
</tbody>
</table>

As shown in Table 9, various aspects of aripiprazole existed in prior art compounds that have the same scaffold. The structure of prior art 1 is identical to aripiprazole, except that it is missing the dichloro substitution on the phenyl ring, which is exhibited in prior art 2. Prior art 3 has a similar structure to aripiprazole but with a shorter linker (proproxy instead of butoxy) and two methyl substitutions in lieu of two chloro substitutions on the phenyl ring.

Closely following the two-step inquiry in the lead compound theory, the court analyzed the SAR of prior art compounds. The CAFC panel recognized that the trial record provided nine compounds with either proproxy linker (3 carbons) or butoxy linker (4 carbons). The court noted that “[o]f the nine carbostyril test compounds for which the Nakagawa declaration supplied mouse jumping data, the unsubstituted butoxy was inferior to four other test compounds and thus ‘was only of middling potency.’” Therefore, the court agreed with the expert that “if a skilled artisan were to select any compound from the Nakagawa declaration, it would be Compound 44,” the one

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205 See id. at 1285–86.
206 See id. at 1290.
207 See id. at 1288–89.
208 See id. at 1287–88.
209 Id. at 1294.
with propoxy instead of a butoxy linker. Therefore, the SAR did not provide a reason or motivation for a skilled artisan to select a compound with a butoxy linker as a lead compound or modify a propoxy linker in a lead compound to a butoxy linker. Without such reason or motivation, the CAFC panel held no prima facie case of obviousness had been established.

As shown in this section, some cases introduced prior art compounds bearing very high structural similarity to the claimed invention, such as a methyl substitution in olanzapine versus an ethyl substitution at the same location in a prior art compound, 3-pyridine in risedronate versus 2-pyridine in the prior art, and a butoxy linker in aripiprazole versus a propoxy linker in the prior art. Notwithstanding such high structural similarity, none of these were able to establish a prima facie case of obviousness. Underlining this seemingly insurmountable obstacle is the assumed unpredictability of chemical compounds.

VI. THE PREDICTABILITY OF CHEMICAL COMPOUNDS

As shown in previous sections, the modern obviousness analysis for chemical arts and the lead compound theory are largely based on the assumption that properties of chemical art are unpredictable. Accordingly, similar structures do not necessarily lead to similar properties and a minor structural modification may cause a significant and unpredictable change in properties. As will be discussed in this section, however, not all properties of chemical art are equally unpredictable. Certain properties are more predictable than others and various technologies are available to make such predictions.

A. Some Properties of Chemical Compounds Can Be Predicted Based on Physical Chemical Principles

Although properties of chemical arts are not as predictable as mechanical arts, some properties can still be predicted with reasonable accuracy. This subsection will review some popular approaches to predict properties of chemical compounds based on physical chemical principles and the applications of such predictions in pharmaceutical development.

Many molecular properties including 3D molecular structures can

210 See id.
211 See id. at 1292–93.
212 See id. at 1296.

Similarly, various molecular properties can be calculated using the molecular mechanics force field method.\footnote{See id. at 923.} “Force field calculations rest on the fundamental concept that a ball-and-spring model may be used to approximate a molecule.”\footnote{Id.} In this model, the positions of atoms in a molecule are “a function of through-bond and through-space interactions, which may be described by relatively simple mathematical relationships.”\footnote{Id.} Based on this mathematical relationship, a geometry optimization can be carried out to calculate 3D structures of a molecule with different conformations.\footnote{See id. at 929–33.} Also, based on this mathematical relationship, molecular dynamics simulations can be carried out to study molecular motions and predict macroscopic properties of a molecule.\footnote{See id. at 933–35.}

Modern chemistry is largely based on rules and predictability of chemical properties. For example, reaction rates and equilibrium constants of certain classes of organic reactions can be calculated using the famous Hammett equation, which holds true for hundreds of
chemical reactions.\textsuperscript{225} By using only two constants, one can predict the relative $K_{eq}$ value or the relative reaction rate of a chemical reaction.\textsuperscript{226}

Another example is the Hückel $4n + 2$ rule, which states that “to be aromatic a compound must have a molecule that contains cyclic clouds of delocalized $\pi$ electrons above and below the plane of the molecule; further, the $\pi$ clouds must contain a total of $(4n + 2)$ $\pi$ elections.”\textsuperscript{227} Aromatic compounds generally have a high degree of unsaturation, and yet are resistant to addition reactions generally characteristic of unsaturated compounds.\textsuperscript{228} Purely based on molecular structures, the Hückel rule can be used to predict whether a compound has aromatic properties and whether a compound can undergo certain chemical reactions.\textsuperscript{229}

In some cases, the intermolecular interaction between a drug molecule and the drug target can be predicted using a structure-based drug design approach. In one of the earlier examples that predate the use of modern computers and sophisticated software, Beddel and coworkers successfully predicted compounds that bind to the binding site of the human deoxyhaemoglobin tetramer.\textsuperscript{230} The haemoglobin tetramer consists of two $\alpha$ and two $\beta$ subunits.\textsuperscript{231} Based on a wire model of the tetramer, molecules were selected based on their likelihood to fit into the model.\textsuperscript{232} The selected molecule was proven to be able to bind with deoxyhemoglobin tetramer with enhanced binding affinity and thus it went into further pharmaceutical development.\textsuperscript{233}

Dorzolamide was the first marketed drug resulting from structure-based drug design.\textsuperscript{234} Dorzolamide (trade name Trusopt\textsuperscript{®}) decreases the production of aqueous humor by inhibiting carbonic anhydrase, thus lowering elevated intraocular pressure in open-angle glaucoma.

\textsuperscript{226} Id.
\textsuperscript{227} Id. at 504 (emphasis in original).
\textsuperscript{228} Id.
\textsuperscript{229} See, e.g., id.
\textsuperscript{230} Id. at 904.
\textsuperscript{231} C. R. Beddel et al., Compounds Designed to Fit a Site of Known Structure in Human Hemoglobin, 57 Brit. J. Pharmacology 201, 201 (1976).
\textsuperscript{232} See id. at 201-08 (1976) (Reporting that three 2,3-diphosphoglycerate analogs, e.g. 4,4'-diformyl-2-bibenzyl-oxyacetic acid, bound to human deoxyhemoglobin at the I-binding site. They promoted oxygen liberation in the predicted sequence as assessed by sigmoidal dose-response curves).
\textsuperscript{233} See id. at 207.
\textsuperscript{234} Bowen, supra note 219, at 943.
and ocular hypertension. X-ray studies and molecular models were used to predict the interaction between dorzolamide and its drug target, carbonic anhydrase, which catalyzes a reversible reaction interconverting carbon dioxide and water to and from bicarbonates. Based on the predicted interaction between the drug target and potential inhibitors, suitable molecules were selected for further evaluation, one of which was dorzolamide.

Another example of rational drug design is the research for viral neuraminidase inhibitors, which led to the discovery of Relenza® and Tamiflu®. Viral neuraminidase is a type of enzyme found on the surface of influenza viruses.

When influenza viruses replicate, they bind to sialic acid groups of glycoproteins on the host cell surface. To be released from the host cell, the viral neuraminidase enzymatically cleaves sialic acid groups from host glycoproteins. Because the cleavage of sialic acid groups is an integral step of the influenza virus replication cycle, inhibiting the enzymatic function of viral neuraminidase is an effective way to control the replication of influenza viruses.

Table 10. Structures of the lead compound, zanamivir and oseltamivir:

![Lead compound](image1)
![zanamivir](image2)
![oseltamivir](image3)

235 See Bowen, supra note 219, at 943.
237 Id. (reporting that X-ray crystallographic studies with human carbonic anhydrase II-inhibitor complexes provided a basis for rationalizing the potency difference by establishing that the binding of the S isomer within the enzymic active site was clearly different from that of its R-antipode).
238 See Joseph N. Varghese et al., The Structure of the Complex Between Influenza Virus Neuraminidase and Sialic Acid, the Viral Receptor, 14 PROTEINS: STRUCTURE, FUNCTION, & GENETICS 327, 327 (1992).
239 See I-Chueh Huang et al., Influenza A Virus Neuraminidase Limits Viral Superinfection, 82 J. VIROLOGY 4834, 4834 (2008).
240 See id.
To guide the inhibitor design, von Itzstein and coworkers at Monash University used a structure-based drug design program, GRID, to search the surface of neuraminidase for active binding sites and predicted the nature of the interaction between neuraminidase and potential inhibitors.\textsuperscript{242} GRID predicted that replacing the hydroxyl group at the 4-position of the lead compound, as shown in Figure 1, with a larger and more basic group would enhance the interaction between the inhibitor and the enzyme.\textsuperscript{243} Following this prediction, a guanidinyl group (larger and more basic than hydroxyl) was introduced at the 4-position, which resulted in a 5,000-fold increase in binding affinity.\textsuperscript{244} This new compound with a guanidinyl group, zanamivir, was the first sialidase-targeting anti-influenza drug, subsequently marketed by GlaxoSmithKline under the trade name Relenza.\textsuperscript{245}

The search for more neuraminidase inhibitors with properties superior to zanamivir continued under the guidance of rational drug design. Zanamivir is a very polar molecule and was delivered by means of dry-powder inhalation. Scientists at Gilead Pharmaceuticals designed a new generation of neuraminidase inhibitors by replacing the guanidinyl group with a less polar amino group and by replacing the hydrophilic glycerol chain with a lipophilic ethylpropoxy group.\textsuperscript{246} This new design maintained all critical interactions between the inhibitor and the enzyme while significantly decreasing the polarity of the inhibitor, which was predicted to improve pharmacokinetic properties, especially absorption. Just as predicted, the modified compound had a significantly improved gastrointestinal bioavailability, which made it possible to deliver the inhibitor orally.\textsuperscript{247} This compound, oseltamivir, was the first oral anti-influenza drug, Tamiflu.\textsuperscript{248}

In summary, many properties of chemical art can be calculated

\textsuperscript{242} See id. at 420.
\textsuperscript{243} See id.
\textsuperscript{244} See id.
\textsuperscript{245} See Mark von Itzstein, The War Against Influenza: Discovery and Development of Sialidase Inhibitors, 6 NATURE REVIEWS: DRUG DISCOVERY 967, 970–71 (2007).
\textsuperscript{247} See id.
\textsuperscript{248} Andrew M. Davis et al., Application and limitations of X-ray Crystallographic Data in Structure-Based Ligand and Drug Design, 42 ANGEWANDTE CHEMIE INT. ED. 2718, 2722 (2003).
based on physical chemical principles and rules. Some calculations are based on fundamental physical principles, such as the Schrödinger equation in quantum mechanics. Many other calculations are based on both physical chemical principles and empirically derived parameters, such as molecular mechanics calculations and structure-based design software.

B. Some Properties of Chemical Compounds Can Be Predicted Through SARs

In some cases, properties of chemical compounds cannot be reliably calculated based on fundamental physical chemical principles, but can be estimated based on intrinsic SARs of related compounds, which is the goal of quantitative structure activity relationship (“QSAR”) models.

One of the most successful pioneers in the field of QSAR is Corwin Hansch who developed the Hansch equation that correlated biological activities with measurable physical chemical properties:

\[
\log \frac{1}{C} = -a(\log P)^2 + b \log P + p\sigma + c
\]

where activity is expressed as \(1/C\); \(C\) is the concentration of the drug compound required to elicit a given biological response; \(P\) is the octanol/water partition coefficient that reflects the hydrophobicity of the molecule; \(p\) is a constant featuring the molecular type of the given molecule; and \(\sigma\) is the Hammett substituent constant which measures the electronic effect on the rate of reaction.\(^{249}\)

QSAR is widely used in computer assisted drug design. One of the most popular 3D QSAR software packages commercially available is Comparative Molecular Field Analysis (“CoMFA”) developed by Richard Cramer and coworker.\(^ {250}\) In CoMFA, each molecule is represented by its steric field and electrostatic field in a grid box.\(^ {251}\) The strength of each field at each grid point can be calculated using the molecular mechanics method.\(^ {252}\) Therefore, each molecule can be reduced to a list of molecular descriptors.\(^ {253}\) This 3D QSAR model


\(^{251}\) See id.

\(^{252}\) See id.

\(^{253}\) See id. at 5959–60.
can then be used to predict biological activities of other molecules.\textsuperscript{254}

Many other QSAR programs have been developed, most of which involve various novel approaches to generate molecular descriptors used in the QSAR equation. For example, Molecular Shape Analysis ("MSA") combines the conventional Hansch QSAR approach with systematic conformation search to include conformational flexibility in the QSAR equation.\textsuperscript{255} Comparative Molecular Similarity Indices Analysis ("CoMSIA") was developed to overcome limitations of CoMFA by including hydrophobic and hydrogen-bonding properties in the analysis.\textsuperscript{256} Additionally, molecular descriptors were calculated by comparing similarities to a set of pre-defined molecular probes.\textsuperscript{257} Comparative Molecular Surface Analysis ("CoMSA") is a non-grid 3D QSAR method that uses molecular surface to define molecular descriptors in the QSAR equation.\textsuperscript{258} Adaptation of Fields for Molecular Comparison ("AFMoC") generates molecular descriptors using the protein environment with which training molecules interact, often called reversed CoMFA.\textsuperscript{259} Comparative Molecular Moment Analysis ("CoMMA") is an alignment-independent 3D-QSAR method, which derives molecular descriptors based on spatial moments of molecular mass and charge distribution.\textsuperscript{260}

The reliability of the QSAR prediction is critically important for its application. It is especially important to be able to estimate how well the model predicts properties of molecules outside the training set instead of how well the model reproduces properties of molecules

\textsuperscript{254} Id. at 5959, 5967.
\textsuperscript{255} See A. J. Hopfinger, A QSAR Investigation of Dihydrofolate Reductase Inhibition by Baker Triazines Based Upon Molecular Shape Analysis, 102 J. AM. CHEMICAL SOC’Y 7196, 7196, 7205–06 (1980).
\textsuperscript{256} T.J. Hou et al., Three-Dimensional Quantitative Structure—Activity Relationship Analysis of the New Potent Sulfonylureas Using Comparative Molecular Similarity Indices Analysis, 40 J. CHEMICAL INFO. & COMPUTER SCI. 1002, 1003 (2000).
\textsuperscript{257} Yong-Qiang Zhu et al., 3D QSAR Studies of Boron-Containing Dipeptides as Proteasome Inhibitors with CoMFA and CoMSIA Methods, 44 EUR. J. MED. CHEMISTRY 1486, 1486–87, 1494 (2009).
\textsuperscript{259} See Holger Gohlke & Gerhard Klebe, DrugScore Meets CoMFA: Adaptation of Fields for Molecular Comparison (AFMoC) or How to Tailor Knowledge-Based Pair-Potentials to a Particular Protein, 45 J. MED. CHEMISTRY 4153, 4154, 4168 (2002).
inside the training set. Various methods have been developed for this purpose. Cross-validation\(^2\) is one the most often used methods for this purpose. It divides the whole data set into a training set and a validation set.\(^2\) A QSAR model, constructed only based on the training set, is used to predict properties of the validation set.\(^3\) Because molecules in the validation set were never used in the model construction, this comparison can be used to estimate how well the model can predict, rather than reproduce, molecular properties.\(^4\)

Bootstrapping is another technique that can be used to evaluate the statistical confidence and robustness of QSAR models.\(^5\) In bootstrapping, a large number of new datasets are constructed by randomly selecting molecules from the original set. Because redundancy is allowed during the selection process, some molecules are excluded for each new dataset. A QSAR model is built based on each new dataset. The statistical stability of all QSAR models built on all newly-generated datasets can be used to estimate the robustness of the QSAR model.\(^6\)

In summary, certain molecular properties, including biological activities, can be predicted through SAR and QSAR methods. Numerous approaches have been developed and applied in drug discovery—especially in computer-aided drug design—and met with various successes. While the predictability of SAR and QSAR methods depends on the nature of compounds involved, especially their conformational flexibility, cross-validation techniques are available to estimate the reliability and applicability of the SAR/QSAR approach for a given project.

**C. The Most Desirable Compound May Also Be Identified Through an Exhaustive Search of a Finite Number of Possible Solutions**

While certain physical chemical properties can be calculated with reasonable accuracy, some other properties are predictively unpredictable. For example, in pharmaceutical research and

\(^{263}\) See id.
\(^{265}\) See id.
development ("R&D"), it is rather difficult to reliably predict many in vivo properties (properties typically observed in animal studies), such as in vivo activities, in vivo pharmacokinetics properties, toxicities, and drug-drug interactions. In fact, even for those semi-predictable properties, the accuracy and reliability of predictions are limited in some cases, especially when determining the subtle differences between highly analogous structures.

Knowing this limitation, it is an ordinary practice during compound optimization in pharmaceutical R&D to expand and explore the SAR around the lead compound by synthesizing and testing analogues with similar structures. At the final stage of the compound optimization, this SAR expansion is typically done exhaustively. For example, during the course of the compound optimization of pitavastatin, a cholesterol lowering agent, a list of compounds were synthesized and tested for their inhibitory potency against HMG-CoA reductase, as shown in Table 11.267 As recognized by the project team, the SAR suggested that "a lipophilic interaction in this region is essential in inhibiting the target enzyme."268 Additionally, it was also recognized that the carbon length of the substitution was preferred to be around two carbon atoms.269

With this SAR knowledge, the project team exhaustively explored all small lipophilic groups commonly used in medicinal chemistry.270 Although the authors could not predict which of those compounds would be the best candidate for further development, it was foreseeable that the best candidate must be among the compounds shown in the table because there was only a finite number of possible compounds with a small (around two carbons) lipophilic substitution at that position, all of which were included in the table. As predicted, one of those compounds with a small lipophilic substitution (c-propyl, 17jj in Table 11) showed a five-fold increase in the IC50 against HMG-CoA reductase and was further developed into a marketed drug, pitavastatin.271

268 Id. at 2730.
269 See id. (stating that “inhibitory potency increased with length of the 2-substituent from methyl (17bb) through ethyl (17cc), with the greatest effect shown with isopropyl (17ee),” and that “increasing the length of the substituent to three carbons, n-propyl (17dd) resulted in loss of activity and showed a length limitation of the 2-substituent.” (emphasis in original)).
270 See id. at 2730–31.
271 See id. at 2731.
Table 11. SAR table of pitavastatin:

<table>
<thead>
<tr>
<th>No.</th>
<th>R&lt;sup&gt;1&lt;/sup&gt;</th>
<th>IC&lt;sub&gt;50&lt;/sub&gt; (nM)&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>17aa</td>
<td>H</td>
<td>&gt;1000</td>
</tr>
<tr>
<td>17bb</td>
<td>methyl</td>
<td>241</td>
</tr>
<tr>
<td>17cc</td>
<td>ethyl</td>
<td>44</td>
</tr>
<tr>
<td>17dd</td>
<td>n-propyl</td>
<td>76</td>
</tr>
<tr>
<td>17ee</td>
<td>i-propyl</td>
<td>19</td>
</tr>
<tr>
<td>17ff</td>
<td>n-butyl</td>
<td>618</td>
</tr>
<tr>
<td>17gg</td>
<td>CH&lt;sub&gt;2&lt;/sub&gt;CHMe&lt;sub&gt;2&lt;/sub&gt;</td>
<td>71</td>
</tr>
<tr>
<td>17hh</td>
<td>CHMeEt</td>
<td>74</td>
</tr>
<tr>
<td>17ii</td>
<td>t-butyl</td>
<td>343</td>
</tr>
<tr>
<td>17jj</td>
<td>c-propyl</td>
<td>4.1</td>
</tr>
<tr>
<td>17kk</td>
<td>c-hexyl</td>
<td>67</td>
</tr>
<tr>
<td>17ll</td>
<td>phenyl</td>
<td>377</td>
</tr>
<tr>
<td>17mm</td>
<td>CF&lt;sub&gt;3&lt;/sub&gt;</td>
<td>140</td>
</tr>
<tr>
<td>17nn</td>
<td>OMe</td>
<td>124</td>
</tr>
<tr>
<td>17oo</td>
<td>SMe</td>
<td>484</td>
</tr>
<tr>
<td>17pp</td>
<td>NMe&lt;sub&gt;2&lt;/sub&gt;</td>
<td>184</td>
</tr>
<tr>
<td>17qq</td>
<td>NMeEt</td>
<td>209</td>
</tr>
</tbody>
</table>

Hypothetically speaking, if compound 17aa to 17ff were available in the prior art at the time of the invention and compound 17jj was the claimed invention, would there have been a prima facie case of obviousness based on the structural similarity and the SAR? Pursuant to the Supreme Court opinion in *KSR*,

[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to
try might show that it was obvious under § 103.272

In the hypothetical case of pitavastatin, there was certainly a design need to further improve the potency of the lead compound. Because the SAR limited the size of the substitution to be shorter than three carbon lengths and the nature of the substituents to be lipophilic, only a finite number of possible functional groups (as exhibited in Table 11) can satisfy this requirement. Although it was unpredictable as to which of those small lipophilic groups would have the best substituent, the identities and structures of all possible substituents were known (predictable). Moreover, because there was no technical innovation involved to pursue each and every one of those substituents, the fact that one of the substituents was identified to be the best is arguably “not of innovation but of ordinary skill and common sense,”273 and is thus obvious under § 103, according to KSR.

D. The Obviousness Analysis Based on the Lead Compound Theory Should Reflect the (Un?)predictability of Chemical Compounds

As discussed above, properties of chemical compounds are not always unpredictable. With the advancement of science and technology, more properties of more chemical compounds can be predicted more reliably, which could significantly change the obviousness analysis based on the lead compound theory. The above-mentioned technologies and approaches used to predict properties of chemical compounds have grown out of the ivory tower of theoretical chemistry and become more and more accepted by the general scientific community. As evidence of how widespread those technologies are, a key word search was carried out at the website of the Journal of Medicinal Chemistry, one of the leading scientific journals in the field of drug discovery. Various key words related to those predicting technologies were used to search the database for any article published in the Journal between January 2000 and December 2011, inclusive. The number of articles containing those key words is summarized in Table 12. Several generic key words, such as “drug,” “compound,” and “molecule,” were also used to serve as a baseline comparison.

273 Id.
Table 12. Summary of key word search on the Journal of Medicinal Chemistry between January 2000 and December 2011:

<table>
<thead>
<tr>
<th>Key word</th>
<th>#Articles containing the key word</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;rational design&quot;</td>
<td>571</td>
</tr>
<tr>
<td>&quot;rational drug design&quot;</td>
<td>187</td>
</tr>
<tr>
<td>“SAR”</td>
<td>3726</td>
</tr>
<tr>
<td>“QSAR”</td>
<td>745</td>
</tr>
<tr>
<td>“structure based drug design”</td>
<td>347</td>
</tr>
<tr>
<td>&quot;molecular modeling&quot;</td>
<td>2127</td>
</tr>
<tr>
<td>&quot;X-ray&quot;</td>
<td>3219</td>
</tr>
<tr>
<td>“docking”</td>
<td>2145</td>
</tr>
<tr>
<td>&quot;homology model&quot;</td>
<td>484</td>
</tr>
<tr>
<td>“drug”</td>
<td>6778</td>
</tr>
<tr>
<td>“compound”</td>
<td>8314</td>
</tr>
<tr>
<td>“molecule”</td>
<td>5494</td>
</tr>
</tbody>
</table>

As shown in the table, a significant percentage of those relevant articles (defined as those hitting one of the baseline key words), mentioned the technology used to predict properties of chemical compounds. It is fair to conclude that these predictive technologies are firmly rooted in the knowledge of people having ordinary skill in the art and are often applied in their research. Are properties of chemical compounds predictable or unpredictable? The answer may depend on both the type of the compound and the type of the property. While scientists working in the field are embracing technologies that can predict properties of chemical compounds, perhaps, the court should do the same, especially when it is possible to estimate the predictability of chemical compounds.

VII. CONCLUSION

The lead compound theory established in the 1990s, and reaffirmed after KSR, is the prevailing law for patent validity analysis based on obviousness for chemical compounds. As exhibited by recent decisions in the CAFC, a prima facie case of obviousness for a compound claim could be established by structural similarity between the claimed compound and the compound(s) in the prior art, if the prior art gave reason or motivation for a person having ordinary skill in the art to make the claimed compound. This is a very high standard, which has not been met by any CAFC case challenging the validity of a compound claim. Structural similarity alone does not suffice, according to the CAFC, because the court assumed that properties of
chemical compounds are unpredictable and that similar structures do not always lead to similar properties.

Recent progress in chemistry, especially in medicinal chemistry, demonstrates that certain properties of chemical compounds can be predicted. Some properties can be calculated based on fundamental physical chemical principles and other properties can be predicted through SARs and QSARs. While some properties are difficult to predict accurately, based on a reliable SAR, one can narrow the scope to a finite number of possible solutions among which the best compound can be identified through an exhaustive search. While not all compounds with similar structures have similar properties, some of them do. Cross-validation methods are available to identify compounds and properties for which reliable predictions can be made. Therefore, at least for those compounds, if the claimed utility can be directly derived from those predictable properties, it may be plausible to argue that the prima facie case of obviousness can be established based on the structural similarity between the prior art compound and the claimed compound because the predicted properties could be used to support the reason and motivation required in the lead compound theory.
PAYING THE OPPOSITION’S LEGAL FEES: DID POSNER
AND THE SEVENTH CIRCUIT FORMULATE THE
CORRECT STANDARD IN THEIR ATTEMPT AT
UNIFORMITY?

Christopher N. Hewitt†

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them.
I. INTRODUCTION

The Lanham Act provides for the award of attorney fees at the court’s discretion.¹ The statute, however, does not provide concrete guidance for courts that are attempting to determine whether attorney fees should be awarded in a trademark dispute. Instead, the statute merely grants attorney fees in “exceptional cases.”² But what circumstances qualify as exceptional? What standards are the courts to use to determine whether the case just argued was exceptional enough for the imposition of paying the other party’s attorney fees?

The circuit courts have attempted to answer this question for more than a decade.³ As a result, multiple standards that vary substantially have developed throughout the circuits. The variation is not simply a difference in the articulation of what is exceptional. In some circuits a different standard is applied to a prevailing plaintiff than is applied to a prevailing defendant.⁴ Late in 2010, Judge Posner and the Seventh Circuit recognized the disparity in tests throughout the nation and attempted to unify the circuits by espousing a new test and calling for its sister circuits to adopt the test.⁵

Given the importance of maintaining and protecting one’s business trademark and the vast reach of businesses in our interdependent economy, it is essential that the circuits develop a uniform standard for the award of attorney fees under the Lanham Act. Such a standard would provide national corporations with greater ability to predict the outcome of legal disputes and protect their trademarks.

Part II of this Comment briefly examines the “English Rule” on attorney fees, the history and adoption of the “American Rule,” and the various exceptions to the American Rule, including the award of attorney fees in other intellectual property arenas. Part III introduces the statutory language of the Lanham Act that provides for the award of attorney fees, briefly explores the legislative history of the

² Id.
³ See Nightingale Home Healthcare, Inc. v. Anodyne Therapy, LLC, 626 F.3d 958 (7th Cir. 2010); Retail Servs. Inc. v. Freebies Publ’g, 364 F.3d 535 (4th Cir. 2004); Eagles, Ltd. v. Am. Eagle Found., 356 F.3d 724 (6th Cir. 2004); Patsy’s Brand, Inc. v. I.O.B. Realty, Inc., 317 F.3d 209 (2d Cir. 2003); Procter & Gamble Co. v. Amway Corp., 280 F.3d 519 (5th Cir. 2002); Lipscher v. LRP Publ’ns, Inc., 266 F.3d 1305 (11th Cir. 2001); Tire Kingdom, Inc. v. Morgan Tire & Auto, Inc., 253 F.3d 1332 (11th Cir. 2001); Reader’s Digest Ass’n v. Conservative Digest, Inc., 821 F.2d 800 (D.C. Cir. 1987).
⁴ See Retail Servs., 364 F.3d at 550; Reader’s Digest, 821 F.2d at 808-09; Eagles, 356 F.3d at 728-29.
⁵ Nightingale, 626 F.3d at 963-64.
II. THE AMERICAN RULE: ITS HISTORY AND EXCEPTIONS

A. The English Rule

To understand the American Rule regarding the award of attorney fees, it is important to see how the rule originated and developed. Much of the American legal system is a carryover from the English legal system, such as the recognition of claims that were derived in equity versus those that were originally claims at law. A part of the English system that did not last long in Colonial America is the English Rule for awarding attorney fees.6 The English Rule is also known as the “loser pays’ rule.”7 The English Rule formulates a two-way, fee-shifting system that results in the losing party paying the attorney fees of the prevailing party.8 This fee shifting, however, is not automatic, as English courts retain broad discretion in determining the actual amount of the award.9

Proponents of the English Rule argue that a major benefit is that prevailing parties receive “the full compensation to which they are entitled.”10 Specifically, a prevailing defendant will be reimbursed for the costs of his or her defense.11 Likewise, a prevailing plaintiff gets his or her attorney’s fees reimbursed in addition to any damages

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7 Id. at 369.
8 Id.
9 Id.
10 Id.
11 Id.
awarded at trial, thus making the plaintiff truly whole. Another benefit is that the risk of having to pay another’s legal fees deters the filing of frivolous suits. Lastly, it is widely claimed that the English Rule fosters settlement because of the threat of paying the opposing party’s legal fees. Despite these benefits, the United States has rejected this approach for one of its own.

B. The Advent of the American Rule

Originally, the American colonies and a young United States followed the English rule. This rule, however, began to lose favor with the public as attorneys started charging more for their services. The public began to view awarding attorney fees as an unjust penalty imposed on the losing party.

The Supreme Court first faced the issue of awarding attorney fees in *Arcambel v. Wiseman* in 1796. The Court overturned an award of $1,600 for attorney fees, reasoning that the English Rule was against the “general practice of the United States.” The Court further stated that the American Rule is entitled to respect from the courts until it is changed by statute, thereby crafting a judicially defined standard of not awarding attorney fees.

The American Rule, unlike the English Rule, provides that parties pay their own litigation costs regardless of the outcome of the dispute. There are two policy reasons for this rule. First, the underlying rationale is that parties should not be punished for merely bringing a suit. Second, adding a dispute over what constitutes reasonable attorney fees places an additional burden on courts and presumably wastes judicial resources. Several exceptions to the

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12 *Id.*
13 *Id.* at 369-70.
14 *Id.* at 370.
16 McLennan, *supra* note 6, at 366.
17 *Id.*
19 *Id.*
21 *Id.* at 695.
22 *Id.* at 693.
23 *Id.* at 695.
24 *Id.*
25 *Id.* at 696.
American Rule, which have developed over time, will be examined next.

C. Exceptions to the American Rule

Federal courts have always recognized numerous exceptions to the American Rule. 26 Statutory exceptions began to emerge during the twentieth century. 27 There are three major areas of exceptions to the American Rule: (1) sanctions for bad faith; (2) contractual agreements that provide for fee shifting; and (3) statutory exceptions based on the underlying claim. 28 A brief examination of these exceptions will be of assistance later when formulating a workable standard for awarding attorney fees under the Lanham Act.

First, the Supreme Court has long recognized the bad faith exception for awarding attorney fees to plaintiffs or defendants that have been the victims of bad faith conduct. 29 Qualifying bad faith conduct includes circumstances in which a party denies his or her opponent’s legal rights prior to the inception of the litigation or where a party to the litigation attempts to avoid jurisdiction by selling relevant property and then proceeding to file meritless motions in an attempt to delay the litigation. 30 The exception is broader and covers more conduct than Rule 11 of the Federal Rules of Civil Procedure, which only covers pleadings and other papers offered to the court for an improper purpose. 31 The bad faith exception was crafted by courts in an attempt to ensure that plaintiffs would be made completely whole when they were successful in their suit. 32 Thus, the exception is meant to further justice. 33 The bad faith exception, in addition to making the plaintiff whole, is meant to deter illegitimate behavior of litigants both inside and outside of the courtroom. 34

The bad faith exception awards attorney fees for bad faith conduct

26 Id. at 693.
27 McLennan, supra note 6, at 366.
28 Id.
29 Vargo, supra note 18, at 1584.
30 Singer, supra note 15, at 703-04.
31 Id. at 699. Specifically, the author argues that Rule 11 is narrower in that the sanctions do not cover acts that “degrade the judicial system,” such as attempts to avoid jurisdiction by fraud or other conduct that would occur outside of court. Id. Secondly, it only applies to papers offered to the court by the attorney. Id. The bad faith exception, on the other hand, applies to all conduct involved, whether it was prior to or concurrent with the litigation. Id.
32 Id. at 696.
33 Id. at 693.
34 Id. at 696-97.
that occurs in three circumstances. The first circumstance pertains to the prelitigation period. This period includes bad faith conduct that occurs during the actions that are the basis for the cause of action, as well as bad faith conduct that occurs when the injured party is attempting to assert its legal right. Prelitigation conduct that rises to the necessary level of bad faith to result in awarding attorney fees to the prevailing parties includes: fraud; failure to follow the results of arbitration; breach of a fiduciary duty; failure to abide by the law; or multiple attempts to bring suits barred by res judicata. Second, attorney fees can be awarded for bad faith conduct that occurs during the litigation, which is malicious or attempts to “unnecessarily prolong[] or delay[] the litigation.” Lastly, a party can be awarded attorney fees when his opponent refuses to recognize a clear legal right that he had prior to trial.

A second exception to the American Rule that the courts have recognized is the ability to contract for a fee shifting between the parties, such that one party will pay the legal fees of the opposing party. This occurs when a contract provides that one of the contracting parties will pay for the other’s attorney fees should a dispute arise over the contract itself. Though such provisions are disfavored, they are generally allowed unless the provisions are found to be contrary to public policy.

The last major exception to the American Rule is statutory fee shifting. “There are over 200 federal statutes and almost 2,000 state statutes that provide for the shifting of attorney’s fees” in certain types of disputes. Such provisions commonly involve public interest litigation, such as suits under the Civil Rights Act. These provisions, however, are also found in other areas, such as trademarks and copyrights. Thus, the very issue that this Comment explores is a product of the statutory exception to the American Rule.

A specific example of a statutory exception to the American Rule

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35 Id. at 700.
36 Id.
37 Id. at 700-01.
38 Vargo, supra note 18, at 1585.
39 Singer, supra note 15, at 700.
40 Vargo, supra note 18, at 1586.
41 Singer, supra note 15, at 700.
42 Vargo, supra note 18, at 1578.
43 Id.
44 Id. at 1579.
45 Id. at 1587.
46 Id. at 1588.
47 Id.
is found in the realm of copyrights. Section 505 of the Copyright Act provides that courts can award reasonable attorney fees to the prevailing party in a civil copyright suit. In determining whether attorney fees should be awarded under this statute, courts look at the following factors: the frivolousness of the claim, the reasonableness of the claim, the motivation of the plaintiff, and the goal of deterring frivolous claims. These factors are very similar to some of the factors courts use in determining whether fees should be awarded under the Lanham Act.

III. SECTION 1117(A), ITS HISTORY, AND COURTS’ INTERPRETATIONS

A. Statutory Language of §1117

Section 1117 of the Lanham Act governs the recovery for violation of rights under the Lanham Act. In addition to governing the award of attorney fees, Section 1117 provides for treble damages and the ability to recover wrongful profits and sustained damages. Section 1117(a) specifically gives courts the following power in civil suits under the act: “The court in exceptional cases may award reasonable attorney fees to the prevailing party.” The statute fails to provide any further guidance for courts in determining whether to award attorney fees to the prevailing party because of its failure to define what an “exceptional” case is. Thus, a look into the legislative history of the provision is necessary.

B. Legislative History of § 1117(a)

One of the main purposes of H.R. 8981, a bill that resulted in the amendment of the Lanham Act, was to allow the award of attorney fees to prevailing parties in trademark disputes when equitable considerations dictated such an award. This was to be the sole substantive addition to the statute.

The Senate Report examines the history of the American Rule,

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50 Fogerty v. MGM Grp. Holdings Corp., Inc., 379 F.3d 348, 357 (6th Cir. 2004).
52 Id.
53 Id.
55 Id.
discussing the fact that early in the United States there was a fear that awarding attorney fees would result in discouraging individuals from bringing suits.\textsuperscript{56} The report then recognizes that exceptions began to develop as people began to realize that judges were fully capable of determining what constituted reasonable attorney fees and when they should be awarded.\textsuperscript{57}

The amendment allowing the award of attorney fees was in direct response to \textit{Fleischmann Distilling Corp. v. Maier Brewing Co.}\textsuperscript{58} Prior to that case, the courts had formulated an equitable doctrine allowing the imposition of attorney fees for successful plaintiffs in trademark infringement and unfair competition cases.\textsuperscript{59} The Supreme Court, however, overruled that tradition in \textit{Fleischmann}.\textsuperscript{60} \textit{Fleischmann} specifically held that Congress intended to limit the awards available under the Lanham Act to those specifically enumerated in the Act.\textsuperscript{61} Therefore, the Court found that the judiciary could not craft a compensatory remedy in addition to those delineated under the Lanham Act.\textsuperscript{62}

The Senate saw a compelling need to provide for awarding attorney fees under trademark and unfair competition suits.\textsuperscript{63} Trademarks are important to both the businesses that own and distribute the goods as well as consumers.\textsuperscript{64} This is especially true as mass demand, advertising, and distribution has resulted in an exponential number of goods released into the nation.\textsuperscript{65} The Senate found a need to protect trademark owners against “deliberate and flagrant infringement” by “unethical competitors” looking to get an advantage in any way possible.\textsuperscript{66}

Given that trademark enforcement is left to the trademark owners, those owners should be encouraged to bring suit to protect their trademarks.\textsuperscript{67} For the Senate, this encouragement was to take the form of an award of attorney fees that would make plaintiffs whole in cases

\textsuperscript{56} Id.
\textsuperscript{57} Id.
\textsuperscript{58} Id.
\textsuperscript{59} Id.
\textsuperscript{60} Fleischmann Distillery Corp. v. Maier Brewing Co., 386 U.S. 714, 714 (1967).
\textsuperscript{61} Id. at 721.
\textsuperscript{62} Id.
\textsuperscript{63} Id.
\textsuperscript{65} Id.
\textsuperscript{66} Id.
\textsuperscript{67} Id.
where acts could be described as “malicious, fraudulent, deliberate, and willful.” 68 Furthermore, the legislative history makes clear that treble damages awarded under the Act are not a substitute for attorney fees, especially in suits that seek only injunctive relief instead of monetary relief. 69 The bill was also meant to provide defendants with the ability to recover attorney fees in exceptional cases. 70 Thus, defendants are protected against harassing and unfounded suits brought by trademark owners. 71

Despite what appears to be a clear intent on the behalf of Congress, the various circuits have been unable to develop a consensus on the proper test to use for awarding fees under Section 1117(a) of the Lanham Act.

C. Dual Standards of the Fourth, D.C., and Sixth Circuits

The Fourth Circuit interpreted Section 1117(a) in Retail Services, Inc. v. Freebies Publishing in 2004. 72 The case involved claims and counterclaims alleging cybersquatting violations and trademark infringement under the Lanham Act. 73 In holding that the case was not “exceptional,” 74 the court defined an exceptional case as one in which the defendant’s conduct could be described as “malicious, fraudulent, willful or deliberate in nature.” 75 The Fourth Circuit, which imposes a dual standard for plaintiffs and defendants, allows for a prevailing plaintiff to show that the defendant acted in bad faith, while allowing a prevailing defendant to make a showing of something less than bad faith. 76 Pertinent considerations for a prevailing plaintiff’s (or a counterclaim plaintiff’s) conduct when looking at the defendant’s attorney fees claim include: “economic coercion, groundless arguments, and failure to cite controlling law.” 77 Specifically, the court looked into whether the defendants’ counterclaims were so lacking that it made the case exceptional, but determined that the defendants had a good faith belief that their claims were viable and the plaintiff (counterclaim defendant) could not meet

68 Id.
69 Id.
70 Id.
71 Id.
72 See Retail Servs., Inc. v. Freebies Publ’g, 364 F.3d 535 (4th. Cir. 2004).
73 Id. at 537.
74 Id. at 551.
75 Id. at 550 (quoting People for the Ethical Treatment of Animals v. Doughney, 263 F.3d 359, 370 (4th Cir. 2001)).
76 Id.
77 Id.
the lesser standard.\textsuperscript{78}

The D.C. Circuit examined the issue in \textit{Reader’s Digest Association v. Conservative Digest, Inc.}\textsuperscript{79} The plaintiff brought various claims under the Lanham Act after the defendant revised its magazine cover to strongly resemble the cover that the plaintiff used.\textsuperscript{80} Two of the individual defendants requested attorney fees under section 1117(a).\textsuperscript{81} After applying the same test used by the Fourth Circuit, the court found the suit was not exceptional because the defendants’ positions at the infringing magazine made them “natural targets” of a lawsuit.\textsuperscript{82}

The Sixth Circuit interpreted Section 1117(a) in \textit{Eagles, Ltd. v. American Eagle Foundation}.\textsuperscript{83} The plaintiff filed suit for trademark infringement and dilution, among other Lanham Act causes of action.\textsuperscript{84} The plaintiff subsequently filed for a voluntary dismissal, which was granted, because many of its key witnesses were on tour overseas.\textsuperscript{85} In finding that the case was not exceptional and affirming the district court’s decision denying the defendant’s motion for attorney fees,\textsuperscript{86} the court applied a dual standard test similar to the Fourth Circuit test discussed above.\textsuperscript{87} The court found that a prevailing plaintiff can recover attorney fees when “the infringement is malicious, fraudulent, willful, or deliberate.”\textsuperscript{88} A prevailing defendant, on the other hand, can recover by showing that the plaintiff’s suit is oppressive.\textsuperscript{89} Thus, unlike the Fourth Circuit, which allows a defendant to show “something less than bad faith,”\textsuperscript{90} the Sixth Circuit does not provide a more lenient standard for defendants. Instead, the Sixth Circuit simply provides a different substantive articulation for the qualifying conduct for a defendant. This oppressiveness test requires the court to make an objective inquiry into

\textsuperscript{78} \textit{Id.} at 551.

\textsuperscript{79} \textit{See} Reader’s Digest Ass’n v. Conservative Digest, Inc., 821 F.2d 800 (D.C. Cir. 1987).

\textsuperscript{80} \textit{Id.} at 802-03.

\textsuperscript{81} \textit{Id.} at 808.

\textsuperscript{82} \textit{Id.} at 808-09.

\textsuperscript{83} \textit{See} Eagles, Ltd. v. Am. Eagle Found., 356 F.3d 724 (6th Cir. 2004).

\textsuperscript{84} \textit{Id.} at 726.

\textsuperscript{85} \textit{Id.}

\textsuperscript{86} \textit{Id.} at 729-30.

\textsuperscript{87} \textit{Id.} at 729.

\textsuperscript{88} \textit{Id.} at 728 (citing Hindu Incense v. Meadows, 692 F.2d 1048, 1051 (6th Cir. 1982)).

\textsuperscript{89} \textit{Id.} at 728-29.

\textsuperscript{90} Nightingale Home Healthcare, Inc. v. Anodyne Therapy, LLC, 626 F.3d 958, 960 (7th Cir. 2010) (citing Retail Servs., Inc. v. Freebies Pub’g, 364 F.3d 535, 550 (4th Cir. 2004)).
whether the suit was founded when filed and a subjective inquiry in the plaintiff’s conduct during the course of the litigation. The court ultimately refused to award attorney fees to the defendant, concluding that the plaintiffs had “colorable” legal arguments and a good reason for seeking dismissal of the case.

D. The Second, Fifth, and Eleventh Circuits’ Test

The Second, Fifth, and Eleventh Circuits do not apply a dual standard for plaintiffs and defendants, but instead apply one standard to both. Each circuit articulates a similar substantive standard that it uses to establish whether a prevailing party will recover attorney fees. The Second Circuit interpreted Section 1117(a) in Patsy’s Brand, Inc. v. I.O.B. Realty, Inc. The plaintiff brought suit for trademark infringement and was granted summary judgment on its claim. The plaintiff was also granted attorney fees because the defendants presented fraudulent documents during the dispute in an attempt to show prior usage of the trademark.

In upholding the award of attorney fees, the court defined an exceptional case as one in which there is fraud or bad faith, and held that fraudulent conduct during the course of litigation can render a case “exceptional.”

The Fifth Circuit crafted its standard in Procter & Gamble Co. v. Amway Corp. The plaintiff filed a Lanham Act claim based on allegations that the defendant created and spread rumors that the plaintiff had links to Satanism. In reversing the district court’s award of fees to the defendant and remanding for further proceedings, the court found that the district court must determine if the plaintiff acted in good faith. The court also explained that plaintiffs must show bad faith on the part of the defendants in order to recover attorney fees.

The Eleventh Circuit examined the issue in Lipscher v. LRP

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91 Eagles, Ltd. V. Am. Eagle Found., 356 F.3d 724, 729 (6th Cir. 2004).
92 Id. at 729-30.
94 Id. at 212.
95 Id. at 221.
96 Id. at 221-22.
97 See Procter & Gamble Co. v. Amway Corp., 280 F.3d 519, 525 (5th Cir. 2002).
98 Id. at 522-23.
99 Id. at 527-28.
100 Id.
Publications, Inc. The district court entered a directed verdict in favor of the defendant on the Lanham Act claims and denied the defendant’s request for attorney fees. Like the Second and Fifth Circuits, the court determined that the correct standard for the recovery of attorney fees is a showing of fraud or bad faith. The court found that the plaintiff’s claim was not meritless and was able to survive multiple motions to dismiss. Thus, the court held that the plaintiff did not act fraudulently or in bad faith in bringing the suit.

E. The Seventh Circuit’s Attempted Solution

In Nightingale Home Healthcare, Inc. v. Anodyne Therapy, LLC, the Seventh Circuit reviewed the grant of attorney fees to a defendant. Judge Posner began by observing an occurrence he called “circuit drift,” whereby each circuit develops its own “circuit law,” which the courts then follow instead of acting as if each circuit is one part of a single national judicial system. After examining the various formulations of the circuits’ tests, Posner conceded that it is unclear whether the different tests result in inconsistent outcomes because of the circuits’ use of vague terms and catchall provisions.

The Seventh Circuit attempted to follow legislative intent and examined issues other circuits failed to consider in interpreting Section 1117(a). Posner examined the legislative history of Section 1117(a) and found the threat of a plaintiff using a Lanham Act cause of action to drive a new entrant out of the market to be quite serious. The court likened this to the concept of abuse of process, which uses litigation to serve an improper purpose. Posner said that the equivalent of a plaintiff bringing a frivolous suit would be a defendant insisting on mounting a costly defense when his infringement is blatant. Thus, to Posner, an exceptional case (one in which attorney fees are warranted), is one in which the plaintiff has used litigation for an oppressive purpose or where the defendant had no defense yet

101 See Lipscher v. LRP Publ’ns, Inc., 266 F.3d 1305, 1309 (11th Cir. 2001).
102 Id.
103 Id. at 1320.
104 Id.
105 Id.
106 Nightingale Home Healthcare, Inc. v. Anodyne Therapy, LLC, 626 F.3d 958, 959-60 (7th Cir. 2010).
107 Id. at 962.
108 Id.
109 Id.
110 Id. at 963.
111 Id.
persisted in his action to impose litigation costs on the plaintiff.\textsuperscript{112} This is different from the other circuit tests, such as the one espoused by the Sixth Circuit, in that it looks into the purpose behind the suit and not just the underlying infringement.

The court did not opt for a general rule favoring one party over the other, reasoning that parties to a Lanham Act suit are “symmetrically situated” in that they are businesses, even if they are businesses of different sizes.\textsuperscript{113} Disparity of size, Posner said, is a factor to be considered in determining whether the suit or defense is legitimate, but not a reason to favor one party over the other.\textsuperscript{114} Furthermore, the court favored an objective inquiry over a subjective one.\textsuperscript{115} Thus it would be sufficient for the purposes of Section 1117(a) to show that the opposing party’s claim or defense was objectively unreasonable or, in other words, one that a rational litigant would pursue only for the purpose of imposing litigation costs on the other party.\textsuperscript{116}

In applying this test to the case at bar, the court found that the plaintiff’s Lanham Act claim did not have any possible merit.\textsuperscript{117} The court concluded that the plaintiff made the claim in an attempt to coerce the defendant to reduce its prices.\textsuperscript{118} Consequently, the defendant’s motion for attorney fees was granted.\textsuperscript{119}

\textbf{IV. THE FORMULATION OF A NEW STANDARD}

It is evident from the preceding background that the circuits are not in agreement over the precise test to use for awarding attorney fees to a prevailing party. The dispute goes even further than the correct standard to apply, with some circuits applying different standards depending on which party is requesting attorney fees.

Even though it is unclear whether this variance in tests actually results in different outcomes, it is imperative that the courts develop a uniform national standard. The uncertainty as to whether different results occur is mostly due to the catchall phrases that many circuits use, such as the Tenth Circuit’s use of the phrase “perhaps for other reasons as well” in its “test.”\textsuperscript{120} Providing a catchall provision at the end of a specific test results in no test at all. Instead, it invites courts

\textsuperscript{112} \textit{Id.} at 963-64.
\textsuperscript{113} \textit{Id.} at 964.
\textsuperscript{114} \textit{Id.}
\textsuperscript{115} \textit{Id.} at 965.
\textsuperscript{116} \textit{Id.}
\textsuperscript{117} \textit{Id.}
\textsuperscript{118} \textit{Id.}
\textsuperscript{119} \textit{Id.} at 966.
\textsuperscript{120} \textit{Id.} at 962.
to decide the issues on a case-by-case basis, which wastes judicial resources and fails to provide litigants with a clear substantive standard. Though the test should depend on the facts of each case, there should still be a set standard for what qualifies as an exceptional case under Section 1117(a). The various tests discussed above fail to do this. Furthermore, not even a remote possibility of different outcomes should exist among the circuits when the guiding principle is a federal statute applicable in all circuits. Posner’s “unifying test” will be discussed and critiqued at a later point.

The courts should adopt an interpretation of Section 1117(a) that would allow the award of attorney fees to the prevailing party when the opposing party has acted in bad faith, thereby avoiding a dual standard approach that provides a more lenient test for one of the parties. It is necessary for courts to examine the conduct surrounding the action that caused the initiation of the suit (i.e., the trademark infringement, the infringement of trade dress, etc.). Courts must also examine the conduct of the parties once the litigation has begun, to determine if they have acted in bad faith during the course of the suit. Thus, the test combines the tests of all of the various circuits while remaining faithful to the legislative purpose underlying Section 1117(a). Furthermore, courts should look at the conduct from an objective viewpoint. This test and its various parts are discussed in further detail below.

A. Reasoning Behind Attorney Fees

As previously discussed, courts and legislatures carved out exceptions to the American Rule to ensure that plaintiffs were made completely whole on their claim or that defendants were made whole when a plaintiff brought an unnecessary suit against them. That is the very reasoning behind Section 1117(a) that the Senate espoused in its report. Congress wanted to ensure that individuals or companies, who are left to enforce trademarks themselves, could effectively protect their trademarks without being placed in a worse position financially because of litigation costs.

Posner spends a significant portion of his opinion in Nightingale discussing the threat of companies using Lanham Act suits to drive new business entities out of the market. In the same vein, he discusses that the equivalent for a defendant would be to persist in defending an action for which he has no defense for the sole purpose of forcing

121 See Singer, supra note 15, at 696.
litigation costs on the plaintiff. He seems to focus almost entirely on improper use of the legal system for business purposes as a reason to award attorney fees to the prevailing party. Whereas such an abuse of process is a very important consideration, it neglects to take into account the underlying infringement. Posner only mentions the necessity of remedying a willful and purposeful infringement by awarding attorney fees in passing.\textsuperscript{123} A willful or bad faith infringement was one of the concerns that Congress specifically discussed in enacting Section 1117(a) to allow for the award of attorney fees.\textsuperscript{124} Posner’s formulation and discussion, however, barely regard this as an issue.

Protecting against a blatant and willful infringement (i.e., a bad faith infringement) should be at the forefront of reasons supporting the award of attorney fees under Section 1117(a) instead of being afforded secondary treatment. The Lanham Act was intended to govern trademarks and allow individuals to protect their trademarks.\textsuperscript{125} Having to prosecute a suit against a defendant that has purposefully and blatantly infringed on a trademark will not make the plaintiff whole unless he is able to recover the attorney fees incurred in the prosecution of his claim. After all, were it not for the bad faith conduct of the opposing party, the innocent party would not have incurred significant litigation costs.

In sum, when an opposing party has acted in bad faith, the innocent party should be restored to the position he was in prior to the suit, regardless of whether the bad faith conduct occurred prior to, or during the litigation. Thus, a suit brought for an improper purpose and a blatant underlying infringement will result in the award of attorney fees.

B. A Uniform Standard for Plaintiffs and Defendants

As previously discussed, the Fourth, Sixth, and D.C. Circuits all have interpretations of Section 1117(a) that vary depending on whether it is the plaintiff or the defendant requesting attorney fees.\textsuperscript{126} In contrast, the Second, Fifth, Seventh, and Eleventh Circuits currently

\begin{itemize}
  \item \textsuperscript{123} Nightingale Home Healthcare, Inc. v. Anodyne Therapy, LLC, 626 F.3d 958, 965 (7th Cir. 2010).
  \item \textsuperscript{125} See Retail Servs., Inc. v. Freebies Pub’l’g, 364 F.3d 535, 538-39 (4th Cir. 2004).
  \item \textsuperscript{126} See id.; Eagles, Ltd. v. Am. Eagle Found., 356 F.3d 724, 728 (6th Cir. 2004); Reader’s Digest Ass’n v. Conservative Digest, Inc., 821 F.2d 800, 808-09 (D.C. Cir. 1987).
\end{itemize}
all apply a uniform test for both a prevailing plaintiff and a prevailing defendant. These tests are distinctly different, as those Circuits that apply differing tests often provide a higher standard for one of the parties.

An interpretation offering differing tests that upholds a dual standard is diametrically opposed to the underlying principals and concerns discussed in the legislative history of Section 1117(a). The Senate made clear that it was attempting to protect both plaintiffs and defendants when it discussed its reasons behind Section 1117(a). In its discussion, Congress never mentions that it should be easier for one party to recover attorney fees than another. Instead, Congress intended to equally protect both parties from the bad faith conduct of competitors: including willful infringements, and abuses of the judicial system aimed at imposing burdensome litigation costs on an opponent. Thus, it is apparent that Congress did not intend for the courts to apply separate tests to different parties.

Posner refused to adopt a test that would provide a more lenient standard to one of the parties. As previously discussed, Posner reasoned that the parties to a Lanham Act suit are similarly situated in that they are businesses, regardless of the fact that the business may be different sizes. Although it is true that business are similarly situated and a discrepancy in sophistication does exist between individuals and businesses, this reasoning undermines his previous argument and ignores congressional reasoning. Posner’s opinion is concerned with large, established businesses using litigation to force new entrants out of the market. This concern lends itself to the belief that defendants should be better protected than plaintiffs and subject to a lesser standard. Posner, however, skirts this result by providing that variations in size should be taken into account when determining the objective reasonableness of the suit in analyzing the conduct of the parties.

127 See Nightingale, 626 F.3d at 964 (7th Cir. 2010); Patsy’s Brand, Inc. v. I.O.B. Realty, Inc., 317 F.3d 209, 222 (2d Cir. 2003); Procter & Gamble Co. v. Amway Corp., 280 F.3d 519, 527 (5th Cir. 2002); Lipscher v. LRP Publ’ns, Inc., 266 F.3d 1305, 1320 (11th Cir. 2001).


129 See id.

130 See id.

131 See id.

132 Nightingale, 626 F.3d at 964.

133 Id.

134 Id. at 963.

135 Id. at 964.
The result of having one party better protected than the other through the imposition of a dual standard can be avoided by acknowledging congressional intent and the fact that both plaintiffs and defendants should be protected equally. Both are subject to an abuse of process in suits and other instances of bad faith conduct that cause unnecessary litigation and associated expenses.\textsuperscript{136} Thus, both should be afforded the same protection and the same opportunity to recover attorney fees so that they are restored as closely as possible to their pre-litigation position.

C. Why the Standard Should be Bad Faith Conduct

One of the first exceptions to the American Rule at common law was for bad faith conduct of the litigants.\textsuperscript{137} The bad faith exception has sought to perform both punitive and restorative functions.\textsuperscript{138} This long history of the common law bad faith exception is what makes a bad faith standard the perfect formulation for the Section 1117(a) test.

The history surrounding the bad faith exception provides much precedent for attorneys and litigants to rely on in determining what conduct would suffice under Section 1117(a) for an award of attorney fees. Furthermore, the bad faith exception covers both conduct that is involved in the act that initiates the lawsuit as well as conduct that occurs during litigation.\textsuperscript{139} Thus a willful, purposeful, or fraudulent infringement as well as oppressive litigious conduct would suffice for attorney fees under the bad faith standard.\textsuperscript{140}

The bad faith standard for awarding attorney fees would also better protect litigants than the sanctions of Rule 11 of the Federal Rules of Civil Procedure. As previously discussed, Rule 11 is defined much more narrowly than bad faith conduct and only applies to documents produced to the court for an improper purpose.\textsuperscript{141} Furthermore, courts are often reluctant to impose Rule 11 sanctions. The bad faith standard would serve to protect litigants from conduct motivated by an improper purpose, as well as from willful and blatant trademark infringements that occur prior to litigation. Thus, the bad faith standard would give courts another method to deter improper conduct in litigation without having to resort to Rule 11 sanctions.

Under this standard, a prevailing plaintiff can recover when the

\textsuperscript{136} Id. at 963-64.
\textsuperscript{137} Vargo, supra note 18, at 1584.
\textsuperscript{138} See Singer, supra note 15, at 698.
\textsuperscript{139} Id. at 700.
\textsuperscript{140} Vargo, supra note 18, at 1584-85.
\textsuperscript{141} Singer, supra note 15, at 699.
defendant has acted in bad faith. This occurs either when the defendant has willfully and blatantly infringed on the plaintiff’s trademark or where the defendant has insisted on defending a claim for the purpose of subjecting the plaintiff to increased litigation expenses. Likewise, a prevailing defendant can be awarded attorney fees when the plaintiff has acted in bad faith. This is likely to occur when the plaintiff has brought a baseless suit for the sole purpose of imposing litigation costs on the defendant. This test combines the Second, Fifth, and Eleventh Circuits’ bad faith standard with the concern shared by the Fourth, Sixth, and Seventh Circuits that plaintiffs will bring suits for oppressive and improper purposes.

This standard compiles the concerns of many jurisdictions into a simple test with enough precedent to provide guidance for practitioners and their clients. This solution resolves the issue that was presented by the existence of multiple tests. With a bad faith standard, not only will there be one simple test, but precedent will provide answers to the question of what conduct suffices for bad faith conduct.

D. An Objective Approach is Critical

The law is riddled with tests, the majority of which are objective tests. An objective test serves many purposes. It ensures that the judiciary remains efficient because judges compare the acts of litigants to the objective reasonable man rather than conducting a subjective inquiry into the inner motivations of the litigant. Furthermore, it establishes a standard that can be applied to all instead of one that is formulated for each given circumstance.

An objective standard is the one thing the circuits seem to agree on. It is much more efficient to determine how one should have objectively conducted himself instead of determining what subjectively drove him to act the way that he did. Posner is in agreement that an objective approach is absolutely necessary.\(^\text{142}\)

It may seem strange to use an objective approach for a test that is in part meant to protect defendants from plaintiffs that have brought a Lanham Act suit for an improper purpose. Instead it appears that a subjective approach would be necessitated by such an inquiry. As Posner discusses, however, an objective inquiry can be applied to determine the intent of the parties in Lanham Act suits.\(^\text{143}\) This can be done by looking at the objective reasonableness of the suit or the

\(^\text{142}\) Nightingale Home Healthcare, Inc. v. Anodyne Therapy, LLC, 626 F.3d 958, 965 (7th Cir. 2010).

\(^\text{143}\) Id.
defense.\textsuperscript{144} If the claim has no merit, and thus no likelihood of prevailing, then it would objectively appear that the suit had no purpose but to impose litigation costs on the defendant. Likewise, if a defendant has blatantly infringed on a plaintiff’s trademark, yet persists in levying a baseless defense, then objectively, a court could find that the defendant was conducting his defense for an improper purpose.

Thus, an objective approach suffices to protect all the parties from unnecessary and abusive litigation while preserving judicial efficiency by avoiding subjective inquiries.

\textbf{E. The Proposed Test Compared with the Copyright Regime}

Unlike Section 1117(a) of the Lanham Act, Section 505 of the Copyright Act does not include the phrase “exceptional cases” so the courts have not struggled in interpreting this term.\textsuperscript{145} Section 505, however, does not give clear guidance on when to award attorney fees, but simply states that a court may award attorney fees to a prevailing party.\textsuperscript{146} Thus, courts formulated a test that took into account the motivation of the plaintiff, the reasonableness of the claim, and the frivolousness of the claim.\textsuperscript{147}

Those factors cover the very concerns that have been expounded throughout this Comment. The proposed bad faith standard encompasses those worries, but in a more concise manner. Furthermore, having a unified test for all courts to apply that is similar to the copyright standard will give courts even more guidance since they would be able to compare trademark claims to their copyright counterparts. Additionally, it would make cases that cover trademark and copyright infringement more simple, as courts would be applying a very similar standard in both statutes.

\textbf{V. CONCLUSION}

The circuit drift that the federal circuit courts have experienced has resulted in varying standards for when attorney fees can be awarded under Section 1117(a). Consequently, litigants are left without a clearly formulated test to gauge the potential success of their claims. Though Posner and the Seventh Circuit attempted to formulate a

\begin{itemize}
  \item \textsuperscript{144} \textit{Id.}
  \item \textsuperscript{145} See 17 U.S.C. § 505 (2006).
  \item \textsuperscript{146} \textit{Id.}
  \item \textsuperscript{147} See, e.g., Fogerty v. MGM Grp. Holdings Corp., 379 F.3d 348, 357 (6th Cir. 2004).
\end{itemize}
unifying test, that proposal still does not completely embody the legislative intent surrounding Section 1117(a) and the history of the awarding attorney fees.

The proper interpretation of an “exceptional case” under Section 1117(a) encompasses a test that awards attorney fees when either party to the litigation has acted in bad faith. This includes bad faith conduct that occurred during the act underlying the litigation and during the litigation itself. The standard should be the same whether the party requesting attorney fees is the plaintiff or the defendant. Furthermore, the inquiry should be an objective one. This formulation provides a judicially efficient test with a plethora of precedent available to guide courts when deciding whether to award attorney fees.
NOTE: PATENT TROLL OR PROPERTY DEFENDER? A DEFENSE OF LITIGATION AS A DOMESTIC INDUSTRY

W. Pierce Haar†

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I. INTRODUCTION

Imagine that Alpha, Inc. is a small business with a patent on some newly invented product. Despite an optimistic view of the patent’s revenue potential, Alpha is unable to secure immediate licensing agreements with others. A peer corporation, Beta, Inc., has a recognized licensing scheme for its own patented product. Then a foreign company begins importing products into the United States that infringe upon the patents of both Alpha and Beta. Currently, only Beta would be eligible for relief under the jurisdiction of the United States International Trade Commission (“ITC”), despite both patent holders having taken steps to protect their inventions. This is how intellectual property rights enforcement is currently handled under 19 U.S.C. § 1337 (“§ 1337”) and is unsurprisingly the source of some frustration.1

Section 1337 provides a relatively quick resolution compared to the lengthy litigation process in U.S. district court, and is particularly effective given its in rem jurisdiction and the ability for intellectual property holders to prevent the importation of infringing products.2 This makes it a valuable tool for domestic producers to protect their products and investments through the enforcement of intellectual property rights. All one needs is an intellectual property right in a given product and a “domestic industry” involving that right in order to utilize the protections of § 1337.3 However, as the previous example illustrated, its current use can lead to both divergent and unfair outcomes for differently situated intellectual property right holders depending upon their maintenance of a “domestic industry.”

In 1988 Congress expanded the definition of a “domestic industry” to include the licensing and exploitation of an intellectual property right in the United States.4 Since this amendment, non-practicing entities (“NPEs”), or organizations that hold patents but do not use them in production, have increased their usage of the ITC, due to their newfound qualification as intellectual property right holders.5 The introduction of the new requirement for a domestic industry and the increased presence of “patent trolls” have led to some interesting

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questions surrounding the use, purpose, and future of § 1337. While many are quick to decry “patent trolls” no matter the circumstances, there may be some merit in adopting a more modern and equitable approach to the usage of § 1337 and the ITC.

This note will address the usage of § 1337 and the domestic industry requirement, as well as where utilization of the statute and the ITC’s jurisdiction could or should go in the future. Part II will look at the inspiration and history of both § 1337 and the Tariff Act as a whole, paying particular attention to the changing domestic industry requirement. Additionally, Part II will look at the emergence and prominence of NPEs. Part III will examine how the Tariff Act and intellectual property rights function in today’s business environment, paying particular attention to the issue of patents as property. Part IV will then address the issue of how § 1337—in particular the domestic industry requirement—should be employed to best suit the needs of both the United States and businesses, arguing for the inclusion of intellectual property litigation in the definition of a domestic industry.

II. BACKGROUND

A. History of § 1337

A precursor of § 1337 first appeared in Section 316 of the Tariff Act of 1922, which made it illegal for importers to engage in methods of unfair competition.6 As part of a broader protectionist act, this particular section empowered the President to use a variety of tools to prevent unfair competition by those importing into the United States.7 The President could impose duties or tariffs on importers who violated the provisions of the act.8 Additionally, in “extreme cases,” the President could altogether ban any imports that violated the provisions.9 In its inception, § 1337 was a very strong “sword” of both protectionism and competitive practices, despite the inherent conflict between the two.

In 1930, the protections found in § 316 of the Tariff Act of 1922 were relocated into § 337 of the Smoot-Hawley Tariff Act.10 This new section tracked the language of the old section. The Smoot-Hawley Tariff Act was protectionist in nature and failed to provide a formal

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7 Id.
8 Id.
9 Id.
process for resolving issues of intellectual property infringement. Instead, one would have to complete a difficult multi-step process for relief. First, a complainant would have to prove their case to the ITC predecessor: the Tariff Commission. Then, if successful, the complainant would then have to take that result to the President and convince the President to either block the infringing import or place a duty on it.

By the 1970s, proponents of free trade had made inroads against the historical protectionism of the United States, creating a tension with domestic unions. As a result of this tension Congress passed the Trade Act of 1974. In addition to removing many trade constraints, the Trade Act of 1974 formally replaced the Tariff Commission with the ITC. Congress granted the ITC broad powers for protecting U.S. interests against unfair trade practices, including intellectual property right infringement. The ITC was also brought under the Administrative Procedures Act, giving its procedures more formality and authority. This change made the ITC a more popular destination for intellectual property right holders to protect their property, given the greater legitimacy of the ITC’s procedures. Among the most important provisions of the Trade Act of 1974 was the creation of 12-month deadlines on investigations and 18-month deadlines for exceptionally complicated deadlines. In juxtaposition to the typical length of proceedings in federal district court, these deadlines helped facilitate much speedier trials.

Despite this new forum available to intellectual property holders in their fight against infringement, intellectual property holders still found some barriers to success. In particular, the domestic industry requirement—a vestige of the earlier protectionist laws passed during more industrial times—was sometimes difficult to satisfy. In reality, the domestic industry requirement necessitated proof of operations and sales that was often difficult to produce or involved sensitive

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11 Allison, supra note 2, at 875.  
12 Id.  
13 Id.  
14 Id.  
15 Id.  
16 Id.  
17 Id.  
18 Id.  
19 Id. at 876.  
20 Id.  
21 Id.  
22 Id.
information. In 1988 Congress passed the Omnibus Trade and Competitiveness Act of 1988 ("Omnibus") to help address this issue. The first change that Omnibus made was to remove the requirement of a complainant showing that the importation of infringing products would be a substantial cause of serious injury to their industry. The second change that Omnibus made was to expand the definition of a domestic industry to include: "(A) significant investment in plant and equipment; (B) significant employment of labor or capital; or (C) substantial investment in [a patent's] exploitation, including engineering, research and development, or licensing." Besides its protectionist roots, this would prove to be the most contested provision of § 1337.

Section 1337 would not undergo any more significant changes after Congress passed Omnibus in 1988. In 1994 Congress passed the Uruguay Round Agreements Act ("URA") in order to harmonize its existing ITC law with the requirements of the General Agreement on Tariffs and Trade. This law was primarily passed to rectify issues of bias against foreign respondents under ITC jurisdiction. The URA required that imports be treated “no less favorably than domestic products.” The “aggressive schedules, absence of counterclaims for respondents, and potential for concurrent district court litigation” were among some of the examples of bias against foreign respondents. The URA eliminated the old statutory limits on investigations, which were then replaced with adjustable time limits by the ITC. Respondents can now file counterclaims, which will promptly be removed to federal district court. Lastly, under the URA, respondents can order a stay on any litigation in federal district court while awaiting the resolution of similar issues in ITC proceedings.

NPEs, commonly referred to as patent trolls, are patent owning entities that “do not actively innovate, develop or manufacture patented material but instead seek to profit from patent ownership through licensing agreements and litigation. “Within the last decade,
there have been significant developments in the number and sophistication of non-practicing entities . . . . These entities typically do not practice their patents, but rather, base patent ownership on collecting licensing fees or pursuing litigation based on infringement.”

Typically, NPEs do not file for any of the patents that they hold. Rather, they will purchase unused patents from firms that are not actively using them or they will purchase patents at a bankruptcy auction. The use of financial leverage by NPEs against smaller and/or struggling firms helps lend to their poor public image. It is argued that once NPEs have patents, they will then wait for someone in the market to infringe upon those patents. Then the NPE will swoop in to either negotiate a licensing scheme, or, if that fails, initiate litigation against the infringing party. Since NPEs do not actively use their patents or otherwise produce goods, they are virtually never subject to the threat of litigation. Given the costs of patent litigation defense and the unknown of jury awards, it is no surprise that “infringers” are often willing to settle with NPEs. These incentives and costs create a system where organizations will try to collect as many patents as possible in order to convert their newfound intellectual property rights into a moneymaking machine, or as some might refer to it, a tool to extort money from the real producers.

Despite the “patent troll” moniker, the emergence of NPEs and their practice of collecting patents have some supporters. Among the benefits of NPEs is the creation of a secondary market for technologies. Currently, if a company engages in research and is unable to incorporate the fruits of their labor into a new product, they are relegated to not receiving adequate, or any, compensation for their investment. However, with a secondary market, they may sell the rights to whatever they have worked on. This secondary market would help create better incentives for research, as organizations would face a reduced risk of “financial bust” as a result of innovative

Recent Judicial Activity on Non-Practicing Entities, 12 U. PITT. J. TECH. L. & POL’Y, Fall 2011, no. 4, at 1, 1.

34 Id.
36 Id.
37 Id.
38 Id.
39 Id.
40 Id.
41 Id.
research.42 Additionally, the emergence of such markets would help out the “little guys”—small companies and individuals—by allowing them to focus on research and development, without the specter of futility.43

However, the weight of the public falls on the other side of the “patent troll” debate.44 While the secondary market approach to NPEs and the benefits that some organizations might reap from such a market are undeniable, it is also undeniable that NPEs impose burdensome costs on “true producers” through their litigation and licensing efforts.45 From an economic standpoint, opponents of NPEs argue that any benefits realized by both legitimate and “illegitimate” NPEs are insufficient to balance out the costs to technological innovators that actually produce goods and are subject to harassing litigation.46

Given the importance that innovation and new technology have in our economy, the harassing litigation of NPEs is certainly troublesome. It is no surprise then that patent reform in recent years has focused on the issues facing innovators, in particular the looming threat of patent infringement litigation by NPEs.47 In fact, Congress passed and signed the Leahy-Smith America Invents Act (“AIA”) into law in 2011.48 Among the AIA’s changes to intellectual property law was a section governing joinder in intellectual property litigation.49 Now, joinder of parties is only proper when both:

(1) any right to relief is asserted against the parties jointly, severally, or in the alternative with respect to or arising out of the same transaction, occurrence, or series of transactions or occurrences relating to making, using, importing into the United States, offering for sale, or selling of the same accused product or process; and

(2) questions of fact are common to all defendants or counterclaim defendants will arise in the action.50

Previously, plaintiffs in an intellectual property lawsuit could join

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42 Id. at 94-95.
43 Id. at 94.
44 Id.
45 Id.
46 Id. at 93-94.
47 Forsberg, supra note 33, at 3.
50 Id.
alleged defendants simply based on their common infringement of the same patent. This change to the procedure of intellectual property litigation aims to reduce the ease with which “patent trolls” are able to employ harassing litigation against organizations that actually use their patents and produce goods.


On October 4, 2011 the United States Court of Appeals for the Federal Circuit decided a case of first impression concerning the potential use of intellectual property litigation as a means of satisfying the domestic industry requirement under § 1337 in John Mezzalingua Associates, Inc. v. International Trade Comm’n (“Mezzalingua”). In Mezzalingua, a cable connector manufacturer, PPC, filed a complaint with the ITC, claiming that certain cable connector imports infringed upon four of PPC’s patents. PPC claimed that “expenses . . . incurred in asserting and defending the validity of that patent constituted a ‘substantial investment in exploitation’ of the ’539 design patent through licensing.” Based on PPC’s expenditures in a series of lawsuits that resulted in a licensing agreement, an administrative law judge held that PPC had satisfied the domestic industry requirement of § 1337. The ITC then reviewed the administrative law judge’s determination and reversed it, holding that PPC had not met the domestic industry requirement of § 1337. While admitting that enforcement-related litigation expenses and licensing might satisfy the domestic industry requirement, the ITC found PPC had not satisfactorily shown that its litigation expenses were related to licensing. The ITC enumerated several factors to consider in the determination of whether or not the domestic industry requirement is satisfied. The nature of the industry and the size of the complaining party should be considered.

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51 Forsberg, supra note 33, at 4.
52 660 F.3d 1322, 1336 (Fed. Cir. 2011).
53 Id. at 1324.
54 Id. at 1324-25.
55 Id. at 1325.
56 Id.
57 Id.
58 Id. at 1326.
59 Id.
invention or bring patented technology to the market.”60 The ITC remanded the case to give PPC an opportunity to show that its enforcement-related expenses were related to licensing and that it had substantially invested in licensing.61

On remand, the administrative law judge held that PPC had not satisfied either prong of the test for the domestic industry requirement.62 The judge admitted that the issue was “close,” but emphasized that PPC had only received one license, partially related to ’539 patent design, had no established licensing program, and had not made any other efforts to license the design in question.63 The ITC adopted the judge’s decision in making its final order.64

On appeal, the Federal Circuit affirmed the lower decision.65 After determining that PPC had standing, the court then addressed the domestic industry requirement issue, using the substantial evidence test.66

The court “agree[d] with the Commission that expenditures on patent litigation do not automatically constitute evidence of the existence of an industry in the United States established by substantial investment in the exploitation of a patent.”67

In affirming the lower decision the Court of Appeals for the Federal Circuit emphasized the “administrative law judge’s thorough review of the pertinent evidence, adopted in full by the Commission.”68 The appellate court agreed that PPC, lacking a formal licensing program or scheme, did not have enough licensing related litigation expenditures, despite their extensive litigation of the ’539 design patent.69

In dissent, Judge Reyna first looked at the legislative history of § 1337. “The owner of the property right must be actively engaged in steps leading to the exploitation of the intellectual property, including application engineering, design work, or other such activities.”70 Judge Reyna noted that Congress did not exclude litigation activities as evidence of a substantial investment in domestic industry.71 He found the majority’s construction of the statute to be “unduly narrow”

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60 Id.  
61 Id.  
62 Id.  
63 Id.  
64 Id.  
65 Id. at 1331.  
66 Id. at 1327.  
67 Id. at 1328.  
68 Id. at 1330.  
69 Id.  
70 Id. at 1338.  
71 Id.
and “a departure from the plain meaning of the statutory language.”\textsuperscript{72} He then went on to dispute the majority’s contention that the ITC was primarily a forum for trade disputes, rather than intellectual property disputes.\textsuperscript{73} Citing the legislative history, Judge Reyna claimed that § 1337 made the ITC a forum for the enforcement of intellectual property rights.\textsuperscript{74} Noting the benefits that litigated patents can provide, Judge Reyna argued that patent litigation leads to a substantial investment in the exploitation of an intellectual property right.\textsuperscript{75} Judge Reyna concluded:

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When faced with a flood of infringing “copy-cat” imports able to undercut their prices, it is unreasonable that entities like PPC be discouraged from first enforcing a patent in litigation in lieu of producing the patented article to compete in the marketplace while at a clear economic disadvantage. Likewise, when an industry is highly reluctant to license patents in the relevant technological field, a patentee should be able to pursue litigation as an alternative or precursor to licensing negotiations without diluting its patent rights. Litigation in these contexts constitutes an investment in exploitation. Entities that are or can become market participants in the field of the patented technology should not be deemed to lack standing for a section 337 action if those entities have substantially staked out their claim to the technology via infringement litigation.

Litigation undertaken to enforce patent rights and enhance the value of a patent or pave the way for a stronger competitive advantage constitutes an investment in exploitation under section 337(a)(3)(C), regardless of that activity's relationship to licensing, engineering, research, or production. Here, the ITC's determination to exclude litigation costs untethered to licensing from consideration has impermissibly and arbitrarily limited the reach of section 337 for patent owners.\textsuperscript{76}
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III. PATENTS AS PROPERTY

A. The Tariff Act

The United States Constitution states that “The Congress shall have power to lay and collect taxes, duties, imposts, and excises, to pay the debts and provide for the common defence and general welfare of the United States…” 77 Tariffs were the most used source of revenue for the federal government until the Civil War. 78 In fact, tariffs were a significant contributor to the federal coffers until the passage of the Sixteenth Amendment in 1913 and the introduction of the personal income tax. 79 The first Congress passed tariff legislation for the purpose of the “encouragement and protection of manufactures.” 80

While the protection of domestic manufacturing via tariffs is probably the most recognizable purpose of the Tariff Act of 1930, the encouragement of domestic manufacturing and industry is also an established and integral purpose of the Act. Protection and encouragement of domestic manufacturing and industries, while potentially detrimental to international trade and economies, are desirable goals for a nation. While the Constitution explicitly mentions the use of taxes and tariffs for the payment of debts, one must look to the practices of Congress to determine how the implementation of constitutional powers interfaces with the demands of running a nation. As mentioned above, Congress created the original tariff legislation for the purpose of protecting and encouraging domestic manufacturing and industry. While this most obviously may be accomplished through the use of tariffs, additional measures, such as those of § 1337, amplify the federal government’s ability to protect domestic industry, as well as their legal rights. Section 1337 of the Tariff Act of 1930 is a viable and appropriate means of securing the dual purposes of tariffs as originally envisioned by the first Congress, as well as protecting and ensuring individual and organizational property rights. Individuals or organizations will take their business elsewhere if they believe that their patents and products are threatened in the United States.

77 U.S. CONST. art. I, § 8, cl. 1.
79 Id.
80 See Ch. 2, 1 Stat. 24, 24 (1789) (emphasis added).
B. Property Rights in Patents

While seeking a patent is one method of protecting a given invention, patents themselves are not merely the fruits of an invention. Rather, they are a prospective means of ownership rights over the material, process, etc. that has been invented and patented. A patent grants the owner the right to a limited monopoly of the production, use, and sale of a material, process, etc. in order to benefit the public. “Protection for progress in the useful arts is through the patent process, and a patent is the grant of a special privilege to promote the progress of science and the useful arts, and is an exception to the general rule against monopolies.” “The patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology in return for an exclusive monopoly for a limited period of time.” “A patentee is generally entitled to determine how it wishes to commercialize its invention in order to optimize its economic benefit from the patent grant.”

The right to prevent others from using or creating a certain material, process etc. is the same as the “right to exclude” that traditionally defines many forms of property. Furthermore, inventors are free to assign patents, just like other forms of property, without restriction. Patent owners are free to contract with others desiring to take advantage of their patent and create licensing or royalty schemes.

It is true that patents do require innovation and hard work on the part of inventors. One of the main purposes of patents is to encourage and reward innovation by protecting new discoveries. However, once a patent is established, it creates a property right for the establishing party. This property right is quite similar to the various other types of property rights that an individual may hold under the law. The inventor may arrange for a licensing agreement or may prevent anyone else from taking advantage of the subject of the patent. Patents not only reward innovation, but they also protect, as well as create, economic interests. A patentee may decide that a patent’s market

82 See id. at § 12.
83 Id.
84 Id.
87 Id. at § 6.
88 Id.
value is appropriate or even above the intrinsic value of the patent and sell the patent. The buyer of the patent will have determined that the patent was worth more than the selling price. In this case, the ability of patents to change hands as property will have not only rewarded the inventor’s hard work, but also created the opportunity for economic and innovative development by others. The treatment of patents as property, despite their inception through the innovation of one party, helps to create an efficient system where innovation is stimulated and then directed towards those who find a given material, process, etc., valuable enough to purchase the patent from the original inventor or holder. In the current global economic climate, where innovation and new technologies help to drive society as well as economies, such an established system as that of patents in the United States is integral to continuing economic growth and development.

IV. PATENT LITIGATION AS LICENSING

A. The Majority Approach in *Mezzalingua*

One of the strongest arguments of the majority position in *Mezzalingua* is:

The Commission ruled that to permit litigation costs not shown to be licensing-related to satisfy the domestic industry requirement would effectively render the domestic industry requirement a nullity for patentees who choose to enforce their patent rights in the district courts. The consequence of so doing, the Commission stated, would be to dilute the Commission's role as a forum for resolving trade disputes.\(^{89}\)

While it is true that permitting litigation costs related to patent enforcement “would effectively render the domestic industry requirement a nullity,” the outcome is not nearly as dire or drastic as the majority’s language suggests. First, Congress has previously relaxed the standards under § 1337 for the domestic industry requirement.\(^{90}\) By changing the standard from requiring actual domestic production to licensing, Congress shifted the paradigm from the protection of actual goods and production to the protection of legal rights and ideas. To suggest that a further extension of the domestic

\(^{89}\) John Mezzalingua Ass’n, Inc. v. Int’l Trade Comm’n, 660 F.3d 1322, 1325-26 (Fed. Cir. 2011).

\(^{90}\) See *supra* Part II.A.
industry requirement under § 1337 to patent litigation would completely water down the requirement is extreme. If anything, such an extension would merely serve to fully extend the previous shift in law to its natural conclusion: that patents are a property right and have a place in international trade. Rather than diluting the ITC’s role as a “forum for resolving trade disputes,” allowing patent litigation to qualify as a domestic industry would allow for more resolution of legitimate trade disputes by the ITC.

Under the current requirement, a patent holder that is not actively engaging in the trade of goods or services, such as the hypothetical large company Beta, may nevertheless employ the jurisdiction of the ITC if they are licensing their patent. The only actual trade that would be occurring in that case is the importation of infringing goods. If the domestic industry requirement were expanded, a patent holder that is not actively engaging in the trade of goods or services, such as the hypothetical small company Alpha, could use the jurisdiction of the ITC to enforce its patent so long as Alpha was litigating its patents. In both scenarios neither company is actually producing anything or engaging in trade. Rather, they are both protecting and exploiting their property rights in their respective patents. If an expansion of the domestic industry requirement of § 1337 as described in this Note would completely water down the ITC as a forum for trade disputes, then the ITC is already fully dissolved.

Additionally, the majority in Mezzalingua also stated that “[w]e agree with the Commission that expenditures on patent litigation do not automatically constitute evidence of the existence of an industry in the United States established by substantial investment in the exploitation of a patent.”91 While the original domestic industry requirement actually required physical industry or production, the newer requirement allows for substantial investment in the exploitation of a patent. A licensing scheme in the United States related to a patent clearly satisfies such a requirement and purpose for the revised domestic industry requirement. One of the principal ways in which a patent holder may exploit a patent is by licensing it to others for royalty fees. However, this is not the only way that a patent holder may exploit their patent. In order to exploit a patent, the patent owner must be able to ensure the value of the patent and then extract that value financially from others who wish to employ the patented subject matter. In the absence of a licensing agreement, a patent owner must protect its property rights through litigation. If infringing products enter and remain in the market, then the value of the patent

91 Mezzalingua, 660 F.3d at 1328.
suffers. In this respect, a patent is only valuable to a patent holder if it is properly protected. Furthermore, given that the right to exclude is inherent in the property rights of a patent, a patent holder must be able to extract financial value from any other entity using its patent, with or without its permission. Therefore, patent litigation is a necessary and unavoidable reality for patent holders. This does not, however, detract from its purpose of patent exploitation. Patent licensing and patent litigation both revolve around the economic use of a patent and, despite their differences in timing and implementation, are not easily fully distinguished with respect to the exploitation of a patent.

The majority in *Mezzalingua* does make some facially valid points in its discussion of the domestic industry requirement and patent litigation. However, upon closer review, their distinctions between patent licensing and patent litigation do not hold up.

B. Using Patent Litigation as a Form of Licensing Under § 1337

First and foremost, it is worth noting that Congress left the list of activities that could qualify as exploitation of a patent “open-ended to provide flexibility for what may be deemed to constitute exploitation, expressing that criteria other than the examples would appropriately qualify for consideration.”92 Therefore, the ITC is not bound to follow only the examples set out in the statute. Rather, the ITC should consider all activities related to the exploitation of an intellectual property right when trying to determine whether or not a significant investment in such exploitation of an intellectual property right has been made in a given case.

As previously mentioned, the ITC is primarily a forum for trade disputes, particularly imports.93 However, with the introduction of intellectual property issues in § 1337, the ITC, for better or worse, has become more than just a means of trade dispute resolution. The ITC has become an arbiter of intellectual property issues as they relate to imports and trade. Given that patent rights are useless without enforcement and “[b]y permitting patent rights to be more effectively enforced at the border, Congress [has] advanced the axiom that enforceable patent rights are good for innovation and the economy.”94 Given the importance of technological innovation to the current global economy and the means that Congress has put at the disposal of the ITC, the ITC should embrace its role as an arbiter of issues at the intersection of intellectual property law and trade disputes.

92 *Id.* at 1338.
93 *See supra* Part II.C.
94 *Mezzalingua*, 660 F.3d at 1340.
When considering whether patent litigation qualifies as a substantial investment in the exploitation of a patent, it is appropriate to frame the issue against the majority’s opinion in *Mezzalingua*. As previously discussed in the critique of the majority’s opinion, patent litigation is no less exploitation of a patent than patent licensing is. First, both patent litigation and patent licensing seek to protect the patent at issue and extract financial value from the patent. Just because one method involves activity primarily before the use of the patent and the other involves activity primarily after the use of the patent does not render patent licensing as the only means of exploitation. Rather, this difference shows the varying experiences that a patent holder may have depending upon the circumstances. While a huge corporation might be able to secure licensing for its patents, a small business may be unable to exert itself enough to secure licensing for its patents. Should the small business be punished for its lack of clout? Is the small business less deserving of patent protection? Assuming that the small business is pursuing patent litigation, it is no less of a patent exploiter than a huge corporation or other patent holder who manages to secure a licensing agreement before the use of its patents. Restricting patent exploitation to just licensing potentially creates several scenarios where patent holders are unable to protect their rights through the ITC’s jurisdiction. If the patent holder seeks to establish an actual domestic industry in the face of infringing imports, they risk diluting and losing their patent. If industry competitors to a patent holder are unwilling to agree to a licensing agreement, then the patent holder is left high and dry without the protections of the ITC against infringing imports. From a practical standpoint, patent licensing is not always a viable option for patent holders, particularly smaller businesses or individuals. In light of the realities of the circumstances of our global economy and the rights and incentives concerning patents, the ITC should allow patent litigation to qualify as a form of exploitation of an intellectual property right under § 1337.

V. CONCLUSION

Returning to the hypothetical in the introduction, both Alpha and Beta have worked hard and created something patentable, or they have purchased a patent from an inventor or another patent holder. In either scenario, both companies have made a conscious effort to procure a property right in an invention. Patents are an important component of the increasingly technological domestic and global economy. It is vital that patent holders be able to protect their rights. Without such protection, their patents lose value. When patents lose value,
innovation loses value and the overall economy suffers.

The differing treatment of patent litigation and patent licensing by the ITC under § 1337 is irreconcilable with the purpose of the ITC, the purpose of § 1337, and present business realities. Patent holders should not be penalized for failure to license their patents before infringement. Rather, patent litigation should be viewed as “licensing after the fact.” Patent litigation shares many of the same “exploitative” qualities that patent licensing has. Patent holders should be rewarded for protecting and strengthening their property rights. Whether patents are being actively used or passively held, their intrinsic value is helping to drive the technology-focused economy, as well as innovation. Failing to reward patent litigation would risk the invitation of the devaluation of patents and their function as vital property. Whether the ITC admits it or not, they are now a forum for both trade disputes and intellectual property issues. The ITC should embrace its role at the intersection of international trade and intellectual property and realize its responsibility to domestic patent holders that succeed in licensing their patents, as well as those that “merely” succeed in litigating their patents. If the ITC fails to fully embrace its role, then it risks diminishing the power and value of patents in the United States.