

Preliminary Injunctive Relief in Patent Cases: Repairing Irreparable Harm

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Abstract.....	64
Introduction	65
I.Preliminary Injunctive Relief	68
A. The Winter Test.....	68
B. Preliminary Versus Permanent Injunctive Relief	70
C. Preliminary Injunction Grant Rates	71
II.Importance of Irreparable Harm	74
A. Federal Circuit Law.....	74
B. District Court Law	75
III.Proving Irreparable Harm.....	81
A. Federal Circuit Law.....	81
1. Output Harms	82
2. Input Harms	83
3. Indicia of Harm.....	83
B. District Court Law	84
IV.Problems With Irreparable Harm	87
A. Categorical Statements	89
1. Free Riding	90
2. Right to Exclude	90
3. Compulsory License	91
4. Diminished Patent Value	92
B. Broad Statements.....	93
1. Direct Competition	93

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2. Consequential Harm	95
3. Reputational Harm.....	95
4. Expiring Patent Rights.....	96
5. Level of Harm.....	97
C. Proof of Irreparable Harm	98
V.Solving Irreparable Harm	100
A. Economic Framework	101
B. Economic Test.....	102
1. Preservation of Status Quo	102
2. Likelihood of Harm	104
a. Reasonable Probability of Harm	105
b. Imminence.....	105
c. Delay in Suing.....	106
d. Willingness to License	108
3. Causation (Causal Nexus).....	109
4. Award of Adequate Compensation.....	114
a. But-For World Uncertainties.....	115
b. Future World Uncertainties.....	118
c. Measurement Uncertainties.....	121
d. Collectability.....	128
VI.Conclusion.....	129

Abstract

Unlike a permanent injunction, which is an equitable remedy awarded to an injured party, a preliminary injunction is a form of interlocutory relief that is imposed by a court to preserve the status quo during litigation. In patent cases decided since (and often before) the Supreme Court’s 2006 decision in *eBay v. MercExchange*, courts have applied a four-factor test when considering the issuance of a permanent injunction. A similar test has evolved for preliminary injunctions, following the Court’s decision in *Winter v. NRDC*. Both the *eBay* and *Winter* tests rely heavily on whether the patentee is likely to suffer “irreparable” harm if an injunction is not granted. Yet despite the very different statutory bases and underlying reasoning for preliminary versus permanent injunctions, almost no scholarly attention or judicial reasoning has been devoted to an analysis of the meaning of irreparable harm in the context of preliminary injunctions. In order to gain a better understanding of the information that courts consider when deciding motions for preliminary injunctions, we collected data from 211 published district court opinions in patent cases decided between 2013 and 2020 in which a preliminary injunction was sought. Based on our research, as well as recent opinions of the Federal Circuit, we find that much of the uncertainty and lack of clarity surrounding preliminary injunctive relief can be reduced, or eliminated, by explicit recognition that irreparable harm has (or should

have) a certain meaning, and that meaning is not the same as harm. We propose a new four-factor test for irreparable harm when assessing the issuance of preliminary injunctions in patent cases. That test provides that to be considered irreparable, harm should be that which, in the absence of an injunction, 1) would unduly disrupt the status quo, 2) is imminent and likely to occur, 3) is causally linked to the alleged infringement, and 4) is unlikely to result in payment of adequate compensation. We believe that the application of this new test will make the preliminary injunction analysis more certain, economically sensible, and better fitted to achieve its stated statutory goals.

Introduction

A permanent injunction is an equitable remedy that is authorized in patent cases by statute. Section 283 of the U.S. Patent Act provides that courts may “grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.”¹ In 2006, the U.S. Supreme Court in *eBay v. MercExchange*² established a four-factor test³ to be applied by courts considering the issuance of permanent injunctions in patent cases.⁴

A preliminary injunction, on the other hand, is a form of interlocutory relief that is imposed by a court to preserve the status quo during litigation.⁵ Preliminary injunctions are authorized under Federal Rule of Civil Procedure 65(a) to prevent irreparable injury to a party until the court renders a decision on the merits.⁶ They are granted in patent cases, when appropriate, to halt potentially infringing activity until the court renders a decision on the merits.⁷ The Court of Appeals for the Federal Circuit has explained that preserving the status quo “is of particular relevance for patent property, for the patent term continues to run during litigation, and a loss of patent-supported exclusivity during the years of litigation may exhaust not only the life of the patent but also the value of the invention to its creator.”⁸ Two years after *eBay*, the U.S. Supreme Court articulated a similar four-factor test for preliminary injunctive relief in *Winter v. National Resources Defense Council, Inc.*⁹

¹ 35 U.S.C. § 283.

² *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

³ *eBay*, 547 U.S. at 391. The factors are 1) irreparable injury, 2) adequacy of monetary damages, 3) balance of the hardships, and 4) public interest. *See infra* Section I.A.

⁴ The so-called *eBay* test has since been extended to numerous other types of litigation. *See* Mark P. Gergen, John M. Golden & Henry E. Smith, *The Supreme Court’s Accidental Revolution? The Test for Permanent Injunctions*, 112 COLUM. L. REV. 203, 215 (2012) (“federal courts now commonly accept the *eBay* test as *the* test for injunctions in virtually all types of cases”).

⁵ *See, e.g.*, *United Mine Workers v. Int’l Union, United Mine Workers*, 412 F.2d 165, 168 (D.C. Cir. 1969); *Quon v. Stans*, 309 F. Supp. 604, 607 (N.D. Cal. 1970); *Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859, 863 (Fed. Cir. 1987).

⁶ *See* *United States v. Criminal Sheriff*, 19 F.3d 238, 239 (5th Cir. 1994).

⁷ *See id.*

⁸ *Kimberly-Clark Worldwide, Inc. v. First Quality Baby Prods., LLC*, 660 F.3d 1293, 1299 (Fed. Cir. 2011) (Newman, J., dissenting) (per curiam).

⁹ *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The factors in preliminary injunction

If granted, preliminary injunctions are drastic remedies.¹⁰ They can effectively end a case before a decision is reached on the merits.¹¹

Despite the differing purposes behind, and the statutory basis for, permanent and preliminary injunctive relief, both depend on a finding of irreparable harm. The meaning of irreparable harm in the context of permanent injunctions has attracted significant attention from commentators, is analyzed in numerous scholarly articles and treatises,¹² and even forms the basis of a book by noted remedies scholar Douglas Laycock.¹³ In most of these analyses, however, the term “irreparable harm” in the context of preliminary injunctions is given short shrift—essentially tracking the analysis of irreparable harm in permanent injunction cases with little recognition of their different contexts and purposes.¹⁴ Only a handful of scholarly articles address preliminary injunction (and the significance of irreparable harm to it) as a unique form of remedy¹⁵ rather than as a poor, and more transient, cousin of the permanent injunction. Courts have largely done the same.¹⁶

The limited attention and sometimes economically questionable guidance about irreparable harm in preliminary injunction cases was illustrated by the four-year legal

cases are 1) the likelihood of the patentee’s success on the merits, 2) irreparable harm, 3) balance of the equities, and 4) public interest. *See infra* Section I.A.

¹⁰ *See* KIRSTIN STOLL-DEBELL, NANCY L. DEMPSEY & BRADFORD E. DEMPSEY, *INJUNCTIVE RELIEF: TEMPORARY RESTRAINING ORDERS AND PRELIMINARY INJUNCTIONS* 3 (2009) (“Nearly every judicial opinion addressing a request for preliminary injunctive relief recognizes the historic principle that such relief is a drastic remedy to be granted sparingly and only in cases of urgent necessity.”); Jean O. Lanjouw & Josh Lerner, *Tilting the Table? The Use of Preliminary Injunctions*, 44 J.L. & ECON. 573, 573–74 (2001) (collecting examples); *Leary v. Daeschner*, 228 F.3d 729, 739 (6th Cir. 2000) (“[A] preliminary injunction is an extraordinary remedy involving the exercise of a very far-reaching power, which is to be applied only in [the] limited circumstances which clearly demand it.”) (internal citation and quotation omitted).

¹¹ *See* John G. Mills, *The Developing Standard for Irreparable Harm in Preliminary Injunctions to Prevent Patent Infringement*, 81 J. PAT. & TRADEMARK OFF. SOC’Y 51, 57 (1999) (“An order for a preliminary injunction may effectively end the case because such an early decision that the patent was infringed places substantial pressure on the defendant to abandon the market or to negotiate a license for the patented technology.”).

¹² *See, e.g.*, J. Gregory Sidak, *Irreparable Harm from Patent Infringement*, 2 CRITERION J. INNOVATION 1, 2 (2017); Stevan D. Porter, Jr., *Post-eBay Economic Standards for Assessing Irreparable Harm*, 94 J. PAT. & TRADEMARK OFF. SOC’Y 250 (2012); Ronald T. Coleman Jr. et al., *Applicability of the Presumption of Irreparable Harm After eBay*, 32 FRANCHISE L.J. 3, 3 (2012); Stacy Streur, *The eBay Effect: Tougher Standards but Courts Return to the Prior Practice of Granting Injunctions for Patent Infringement*, 8 N.W. J. TECH. & INTELL. PROP. 67, 68–69, 71 (2009); George M. Newcombe et al., *Prospective Relief for Patent Infringement in a Post-eBay World*, 4 N.Y.U. J.L. & BUS. 549, 550 (2008).

¹³ *See* DOUGLAS LAYCOCK, *THE DEATH OF THE IRREPARABLE INJURY RULE* (1991).

¹⁴ *See, e.g., id.* at 110–32 (dedicating 23 out of 283 pages to preliminary injunctions); 7 DONALD S. CHISUM, *CHISUM ON PATENTS* § 20.04 (discussing permanent injunctions at nearly twice the length of the section on preliminary injunctions).

¹⁵ *See* Lanjouw & Lerner, *supra* note 10, at 573 (stating that preliminary judgment actions “have garnered almost no attention in the law and economics literature”).

¹⁶ *See, e.g., Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 681 (Fed. Cir. 1990) (referring to a preliminary injunction motion as “only the first round, involving only a preliminary injunction”).

battle between Olaplex and L’Oréal covering a patented method for bleaching hair.¹⁷ Though the precise contours of the competitive market in the case were in dispute, there was no question that the two parties would be direct, head-to-head competitors in the bleach business if entry were allowed.¹⁸ Almost immediately after filing its complaint alleging infringement by L’Oréal and its affiliates, Olaplex sought preliminary injunctive relief. The district court found that the defendants, the primary distributors of Olaplex’s products, were Olaplex’s direct competitors in a “two-player national market.”¹⁹ If market entry by the defendants were allowed, Olaplex was likely to face significant price pressure and declining revenue. As a result, the court found that the “irreparable harm [factor] weighs in favor of plaintiffs.”²⁰ Nevertheless, because Olaplex was unlikely to succeed at trial on the merits of its infringement claim, the court denied its motion for a preliminary injunction.²¹

On appeal, the Court of Appeals for the Federal Circuit (Federal Circuit) vacated the district court’s ruling on Olaplex’s likelihood of success on the merits.²² However, it found no reversible error in the court’s finding of a “two-player national market” that would lead to Olaplex likely suffering irreparable harm.²³ On remand, the district court reconsidered Olaplex’s motion for preliminary injunction and granted it. As to irreparable harm, the entirety of its opinion stated that “Olaplex presented evidence showing actual monetary harm, and reputational harm, and L’Oréal did not submit sufficient evidence of a substantial change in the market [since the lower court’s initial decision], so as to change the initial finding of irreparable harm.”²⁴

The hair bleach business appears to be well worth fighting over, but the court’s guidance as to whether likely market entry will lead to irreparable harm justifying the issuance of a preliminary injunction is, at best, unclear. Without a doubt, there was very little discussion about irreparable harm. This is in stark contrast to the extensive discussion of likelihood of success on the merits at both the district court and Federal Circuit level. Moreover, simply identifying and documenting likely harm (i.e., monetary and reputational) appeared to be sufficient. The question was neither asked nor answered as to whether any of that harm was, in fact, irreparable. An “extraordinary remedy” was thus granted with little discussion, and perhaps consideration, of whether a later damages trial could make Olaplex whole if infringement were actually found.

In order to gain a better understanding of the information that courts analyze and

¹⁷ *Liqwd, Inc. v. L’Oréal USA, Inc.*, No. 17-14-SLR, 2017 U.S. Dist. LEXIS 104123, at *19 (D. Del. July 6, 2017), *vacated*, 720 F. App’x 623 (Fed. Cir. 2018).

¹⁸ *Liqwd*, 720 F. App’x at 628–29.

¹⁹ *Liqwd*, 2017 U.S. Dist. LEXIS 104123, at *19.

²⁰ *Id.* at *20.

²¹ *Id.* at *22.

²² *Liqwd*, 720 F. App’x at 628–29.

²³ *Id.* at 633.

²⁴ *Liqwd, Inc. v. L’Oréal USA, Inc.*, No. 17-14-JFB-SRF, 2019 U.S. Dist. LEXIS 70749, at *12 (D. Del. Apr. 25, 2019).

the direction that they provide to potential litigants when considering motions for preliminary injunctions in patent cases, we collected data from 211 published district court opinions in cases decided between 2013 and 2020 in which a preliminary injunction was sought. Based on these decisions, as well as recent opinions of the Federal Circuit, we find that much uncertainty and lack of clarity surrounding preliminary injunctive relief can be reduced, or eliminated, by explicit recognition that *irreparable harm* has (or should have) a certain meaning, and that meaning is not the same as *harm*. We propose a new test for irreparable harm when assessing the issuance of preliminary injunctions in patent cases. As we discuss below, to be considered irreparable, harm should be that which, in the absence of an injunction, (1) would unduly disrupt the status quo, (2) is imminent and likely to occur, (3) is causally linked to the alleged infringement, and (4) is unlikely to result in payment of adequate compensation. We believe that the application of this new test will make the preliminary injunction analysis more certain and economically sensible, and better fitted to achieve its stated statutory goals.

The remainder of this article proceeds as follows. In Part I, we describe the current law pertaining to preliminary injunctions in patent cases. There, we describe the trend in outcomes at the district court level. In short, preliminary injunctions are not often granted—they are often viewed as (perhaps overly) drastic remedies. In Part II, we describe the significance of the irreparable harm factor. The language from our collected cases and an empirical analysis of the results reveal that irreparable harm is one of the two most critical factors in determining whether an injunction should be entered. To prevail, patent owners must prove this factor. In Part III, we identify the factors that courts have considered in their evaluation of irreparable harm. Some of the factors are measures of patent owner outputs. Some are measures of patent owner inputs. Some are not forms of harm at all. In Part IV, we discuss the problems associated with the evaluation of irreparable harm. The current law often provides either analytically confusing guideposts or no guideposts at all. This limited or conflicting guidance has resulted in a lack of clarity regarding what is and what is not irreparable harm. Finally, in Part V, we introduce and describe a new four-part test for assessing irreparable harm in preliminary injunction cases. The test is grounded in economics and is intended to add more certainty and predictability for litigating parties.

I. Preliminary Injunctive Relief

A. The Winter Test

Courts adjudicating patent cases largely have adopted the four-factor test laid out in 2008 by the U.S. Supreme Court in *Winter v. NRDC*²⁵ to assess whether a moving party is entitled to a preliminary injunction. Under that test, the moving party must establish

- (1) it is likely to succeed on the merits;

²⁵ *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7 (2008).

- (2) it is likely to suffer irreparable harm in the absence of a preliminary injunction;
- (3) the balance of the equities tips in its favor; and
- (4) a preliminary injunction is in the public interest.²⁶

Unfortunately, there does not appear to be uniform application of the four-factor test across causes of action, whether patent or not.²⁷ Courts have implemented the *Winter* test in one of three ways.²⁸

- The “Sequential Test” is a step-by-step approach requiring that each factor be fulfilled before the other factors are considered.²⁹ Ultimately, the moving party must prevail on each of the four *Winter* factors. Failure to prove any one of the factors bars entry of a preliminary injunction.
- The “Sliding Scale Test” balances all four of the factors.³⁰ A weak showing on one factor can be overcome by a strong showing on another. But all four factors are evaluated in every case.
- The “Gateway Factor Test” considers certain factors to be threshold elements that must be satisfied before consideration of the other factors.³¹ These factors are likelihood of success and irreparable harm. Once the gating factors are satisfied, the other factors are evaluated. The Gateway Factor Test can be thought of as a variant of the Sequential Test.

The *Winter* four-factor test for preliminary injunctions mirrors—though is not identical to—the test applied in patent cases considering requests for permanent

²⁶ *Id.* at 20; *See* *Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1352 (Fed. Cir. 2016) (citing *Winter*, 555 U.S. at 20); *Apple Inc. v. Samsung Elecs. Co. (Apple I)*, 678 F.3d 1314, 1323 (Fed. Cir. 2012) (citing *Winter*, 555 U.S. at 20); *Celsis In Vitro, Inc. v. Cellzdirect, Inc.*, 664 F.3d 922, 926 (Fed. Cir. 2012) (citing *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1344 (Fed. Cir. 2008)).

²⁷ Richard R.W. Brooks & Warren F. Schwartz, *Legal Uncertainty, Economic Efficiency, and the Preliminary Injunction Doctrine*, 58 STAN. L. REV. 381, 390 (2005).

²⁸ *See generally* Taylor Payne, *Now is the Winter of Ginsburg’s Dissent: Unifying the Circuit Split as to Preliminary Injunctions and Establishing a Sliding Scale Test*, 13 TENN. J.L. & POL’Y 15, 18 (2013).

²⁹ *See, e.g.*, *Dine Citizens Against Ruining Our Env’t v. Jewell*, 839 F.3d 1276, 1281 (10th Cir. 2016) (“[E]ach of these elements is a prerequisite for obtaining a preliminary injunction . . .”).

³⁰ *See, e.g.*, *Hoosier Energy Rural Elec. Coop., Inc. v. John Hancock Life Ins. Co.*, 582 F.3d 721, 725 (7th Cir. 2009) (“How strong a claim on the merits is enough depends on the balance of harms: the more net harm an injunction can prevent, the weaker the plaintiff’s claim on the merits can be while still supporting some preliminary relief.”). In her dissent in *Winter*, Justice Ginsburg wrote that various courts, including the U.S. Supreme Court, historically have applied the Sliding Scale Test and that *Winter* does not abrogate previous holdings that have applied that test. *Winter*, 555 U.S. at 51 (Ginsburg, J., dissenting).

³¹ *See, e.g.*, *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017) (“[A] movant for preliminary equitable relief must meet the threshold for the first two ‘most critical’ factors: it must demonstrate that it can win on the merits . . . and that it is more likely than not to suffer irreparable harm in the absence of preliminary relief. If these gateway factors are met, a court then considers the remaining two factors . . .”).

injunctions. The *eBay* test was described by the U.S. Supreme Court in its 2006 opinion in *eBay, Inc. v. MercExchange*.³² In *eBay*, the Court held that to obtain a permanent injunction, a patent owner must establish that:

- (1) it has suffered irreparable injury;
- (2) remedies available at law, such as monetary damages, are inadequate to compensate for that injury;
- (3) considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and
- (4) the public interest would not be disserved by a permanent injunction.³³

B. Preliminary Versus Permanent Injunctive Relief

The judicial tests governing preliminary and permanent injunctions are different in several important ways. First, as noted in the Introduction, preliminary injunctions are authorized under Federal Rule of Civil Procedure 65(a) to prevent irreparable injury to a party until the court renders a decision on the merits.³⁴ Thus, in a preliminary injunction case, preservation of the status quo is paramount. Whether the alleged infringing entry has occurred by then or not, courts have defined the status quo to be that which existed immediately prior to the alleged infringement. In a permanent injunction case, preservation of the status quo is of no moment; market entry already has occurred.

Second, in a request for a preliminary injunction, the moving party needs to show that it is likely to succeed on the merits.³⁵ In a permanent injunction case, success on the merits already has been established.³⁶ A moving party has weaker rights in the first case, where liability has yet to be established, compared with the second case, where liability already has been found.³⁷ This weakens the moving party's case for any kind of relief, including a "drastic" preliminary injunction.

Third, as noted by Laycock, the "injury that counts [for a preliminary injunction] is injury that cannot be prevented after a more complete hearing at the next stage of

³² *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

³³ *Id.*

³⁴ *See United States v. Crim. Sheriff*, 19 F.3d 238, 239 (5th Cir. 1994).

³⁵ *Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 546 n.12 (1987).

³⁶ In any case, whether patent or not, a district court's opinion is not necessarily the final word. In concept, an appeal is always available. In their empirical study of the results of permanent injunction rulings on appeal, Ryan Holte and Christopher Seaman found that approximately 9 out of 10 times, grants of permanent injunction were affirmed on appeal. However, approximately 5 out of 10 times, denials of permanent injunction were overturned. Ryan T. Holte & Christopher B. Seaman, *Patent Injunctions on Appeal: An Empirical Study of the Federal Circuit's Application of eBay*, 92 WASH. L. REV. 145, 187–88 (2017).

³⁷ For purposes of determining entitlement to injunctive relief, however, there is currently no reason to think that grants of preliminary injunction are affirmed or overturned (or settled) at a rate that is much different than that for permanent injunctions. *Id.*

the litigation.”³⁸ In other words, because there is a later point in time at which a moving party can be made whole or where permanent injunctive relief can be granted (after the merits trial), there is less of a need for the early relief associated with a preliminary injunction versus the later relief associated with a permanent injunction.

Fourth, a request for a preliminary injunction focuses on harm that will likely occur and whether that harm can be repaired. In a permanent injunction case, the effects of improper (infringing) competition have usually been felt for some period. Though the future has yet to play out, for certain effects, the past can sometimes provide a useful basis for measuring the probability, nature, and degree of future harm. Compared with situations involving permanent injunctions, the need for a preliminary injunction may be less clear because the impact of competition may be less clear.

Finally, the public interest must not be disserved in a permanent injunction case but must be served in a preliminary injunction case. To the extent that enforcement of duly issued patent rights favors a patent owner, that argument is less strong in a preliminary injunction case because the liability issues have not yet been resolved (i.e., the patent owner may not, in fact, hold a valid, enforceable, and infringed patent).

C. Preliminary Injunction Grant Rates

In assessing the impacts of *eBay*, various empirical studies have found that the permanent injunction grant rate after 2006 in patent cases has ranged from 66%–80%.³⁹ When parties have been deemed to be direct competitors, the grant rate has been even higher, ranging from 84%–92%.⁴⁰

³⁸ LAYCOCK, *supra* note 13, at 113.

³⁹ Jorge L. Contreras & Jessica Maupin, *Unenjoined Infringement and Compulsory Licensing*, BERKELEY TECH. L.J. (forthcoming) (finding 72% grant rate for permanent injunctions between *eBay* decision and 2020); Holte & Seaman, *supra* note 36, at 163 n.91 (compiling studies); Christopher B. Seaman, *Permanent Injunctions in Patent Litigation After eBay: An Empirical Study*, 101 IOWA L. REV. 1949, 1988 fig.3 (2016); Kirti Gupta & Jay P. Kesan, *Studying the Impact of eBay on Injunctive Relief in Patent Cases* 12–13 tbl. 2 (Hoover Institution Working Group on Intell. Prop., Innovation, and Prosperity, Stanford U., Working Paper No. 17004, 2017) (finding a grant rate of approximately 66% from May 2006 through end of 2012); Colleen V. Chien & Mark A. Lemley, *Patent Holdup, the ITC, and the Public Interest*, 98 CORNELL L. REV. 1, 9–10 (2012) (finding a grant rate of about 75% from July 2006–August 2011); Ernest Grumbles III et al., *The Three Year Anniversary of eBay v. MercExchange: A Statistical Analysis of Permanent Injunctions*, INTELL. PROP. TODAY 25, 26 (2009) (finding a grant rate of 72% from May 2006 through May 2009); Benjamin Peterson, Note, *Injunctive Relief in the Post-eBay World*, 23 BERKELEY TECH. L.J. 193, 196–97 (2008) (finding a grant rate of 73% from May 2006 through February 2008); Douglas Ellis et al., *The Economic Implications (and Uncertainties) of Obtaining Permanent Injunctive Relief After eBay v. MercExchange*, 17 FED. CIR. B.J. 437, 441 (2008) (finding a grant rate of 80% from May 2006 through 2007).

⁴⁰ Seaman, *supra* note 39, at 1990 fig.4 (finding a grant rate of 84% between May 2006 and December 2013 when the parties were competitors); FED. TRADE COMM’N, *THE EVOLVING IP MARKETPLACE: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION* 259 (2011), <https://www.ftc.gov/sites/default/files/documents/reports/evolving-ip-marketplace-aligning-patent-notice-and-remedies-competition-report-federal-trade/110307patentreport.pdf> (finding a grant rate

However, there have been relatively few empirical studies analyzing the grant rate of preliminary injunctions in patent cases.⁴¹ We are aware of one 2001 study of cases that was conducted before the *eBay* decision.⁴² In an unpublished study, Kirti Gupta and Jay Kesan analyzed all district court patent cases filed from 2000 through 2012 where there was a motion for a preliminary or a permanent injunction.⁴³ According to the study, after *eBay*, fewer parties sought preliminary injunctions given the higher hurdles to obtaining them and fewer preliminary injunctions were granted.⁴⁴

Partly to evaluate the hypothesis that preliminary injunctions are harder to obtain than permanent injunctions, we constructed a database containing the results of all 211 published district court opinions in utility patent cases over the years 2013 through 2020 in which a patent owner requested a preliminary injunction.⁴⁵ The database we constructed contains information from the published opinions in patent cases that were reported over the 2013 through 2020 period in *DocketNavigator*.⁴⁶ We did not include opinions where the motion for preliminary injunction was deferred, denied as moot, or the result of a request for modification. We focused on data from cases in which there was a substantive ruling associated with the *Winter* factors. The information that we collected included the venue, whether a preliminary injunction was granted, which of the *Winter* factors the court considered, whether the court found each of the factors to favor the patent owner or the alleged infringer, and what specifically the court considered for each of the *Winter* factors and which party the individual considerations were found to favor.

Our data shows that motions for preliminary injunctive relief in patent cases were denied far more than they were granted, even with the wide variation of facts, parties, litigators, and judges across cases.⁴⁷ Over the period studied, preliminary

of 87% between May 2006 and December 2008 when the parties were competitors); Ellis et al., *supra* note 39, at 442–43 (finding that “with two exceptions, permanent injunctions issued in all twenty-six cases where courts found direct competition between a plaintiff and the infringer” from May 2006 through January 2008).

⁴¹ We have limited our analysis here to patent cases. Of course, preliminary injunctive relief is available and sought in a wide variety of cases, even in a wide variety of intellectual property cases. We do not know whether our results and observations can be extrapolated to a larger set of cases.

⁴² Lanjouw & Lerner, *supra* note 10.

⁴³ Gupta & Kesan, *supra* note 39.

⁴⁴ *Id.* at 12–13 tbl. 2, 36–37 tbl. 10. The authors reached a similar conclusion regarding permanent injunction rates. *Id.*

⁴⁵ Our empirical analysis excludes sixty-one design patent opinions. A significant number of these opinions resulted from injunction requests from the same patent owners. In 2020 alone, there were thirty-nine design patent opinions—twenty-eight of which were related to injunction requests filed by just two patent owners, Deckers Outdoor Corporation and Oakley, Inc. Patent holder success rates from design patent opinions are higher, though it is not clear if these rates are representative of those from a large group of litigants. For those two patent owners, roughly, the same arguments were made and the same opinions issued across different alleged infringers. The opinions were issued by a single court, the US District Court for the Northern District of Illinois.

⁴⁶ Access to the database is available from the authors upon request.

⁴⁷ We have not noted the timing of a preliminary injunction (or its denial) during the life cycle of a

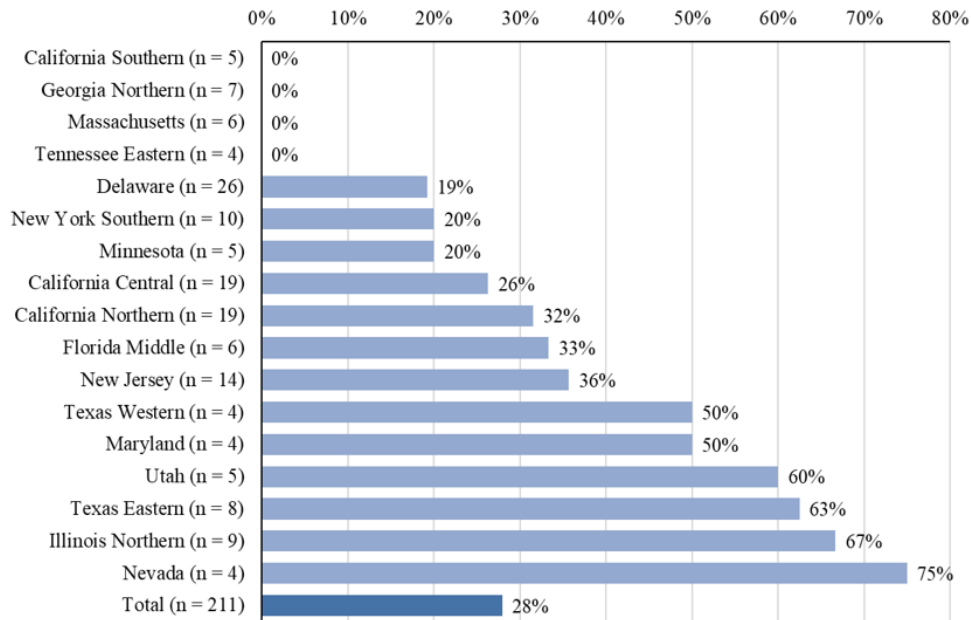
injunctions were granted in 28.0% of the utility patent cases in which they were requested, ranging from a low of 17.4% in 2013 to a high of 33.3% in 2020, though there does not appear to be an upward trend over time.⁴⁸ While preliminary injunctions were requested in 211 cases, they were granted in only fifty-nine cases and denied in 152 cases.⁴⁹ Arguably, low grant rates could scare off cases, even meritorious ones, and high grant rates could encourage cases, even questionable ones. It is virtually impossible, however, for us to discern from the published opinion data whether there is a perception of whether grant rates have been or are high or low. Moreover, there appears to be no discernable trend in grant rates over time that can be used to comment on either hypothesis.

case. Moreover, we have not noted the industry or technology. There were, however, twenty opinions in pharmaceutical cases, with most of those being Hatch-Waxman cases. In those twenty cases, a preliminary injunction was granted eight times, or 40 percent of the time it was requested.

⁴⁸ In a recent article, Marie McKiernan summarized and commented on the results of motions for preliminary injunction in patent cases as reported by *Lex Machina* over the 2013 through 2020 period. Marie McKiernan, *An Exercise in Restraint: Seeking and Combatting Injunctive Relief*, IPWATCHDOG (Aug. 23, 2022, 8:46 AM), <https://ipwatchdog.com/2022/08/23/exercise-restraint-seeking-combatting-injunctive-relief/id=151016/>. She found that, associated with 490 motions, preliminary injunctive relief was granted 41 percent of the time. The rate is higher than we found, but perhaps this is not surprising. She did not limit her data to cases involving utility patents and to cases in which there was a substantive published opinion. Our data show that there were many design patent cases pursued by a limited set of patent owners making very similar motions across a wide set of small, alleged infringers. Moreover, there were many motions filed that resulted in a consent or default judgment and/or no published opinion.

⁴⁹ Over this period, there were likely about forty thousand patent cases filed in the U.S. See James C. Yoon, *IP Litigation in United States*, Wilson Sonsini Goodrich & Rosati, <https://law.stanford.edu/wp-content/uploads/2016/07/Revised-Stanford-August-4-2016-Class-Presentation.pdf>. Out of these cases, 211, or 0.5 percent, resulted in an opinion being issued on the question of preliminary injunctive relief.

Figure 1
Motions for Preliminary Injunction
Success Rate by District⁵⁰
(2013-2020)



The probability of success varied dramatically from court to court. Though the sample sizes are small, Figure 1 shows that over the 2013 to 2020 period requests were granted 60% or more of the time in Utah, the Eastern District of Texas, the Northern District of Illinois, and Nevada. On the other hand, no requests for preliminary injunctions were granted in the Southern District of California, the Northern District of Georgia, Massachusetts, or the Eastern District of Tennessee over that same period. In the busiest patent court during this period, the District of Delaware, a preliminary injunction was granted only 19.2% of the time requested.

II. Importance of Irreparable Harm

Our data also provide useful insights as to the significance of each *Winter* factor by courts considering preliminary injunctive relief. In this Part, we focus on the most poorly understood of these factors: irreparable harm.

A. Federal Circuit Law

The Federal Circuit largely has applied the Sequential Test when evaluating requests for preliminary injunctive relief in patent cases. That is, like many other circuit

⁵⁰ Includes districts with four or more opinions.

courts,⁵¹ it has determined that the moving party must prevail on each of the four *Winter* factors, including irreparable harm. Because each factor is conjunctive, or necessary to satisfy the test, failure of any one factor will preclude entry of an injunction.⁵²

By way of example, in its 2012 opinion in *Sciele Pharma, Inc. v. Lupin Ltd.*, the Federal Circuit wrote, “Because the district court incorrectly concluded that Lupin failed to raise a substantial question of validity regarding the asserted claims . . . it abused its discretion by issuing a preliminary injunction.”⁵³ In other words, because the alleged infringer was able to raise substantial questions about the patent owner’s likelihood of success on the merits, the other factors (including irreparable harm) were not addressed, and a preliminary injunction was deemed to be improper.

Similarly, in 2020, the Federal Circuit wrote in *LEGO v. ZURU, Inc.* that there was no dispute about the patent owner’s likelihood of succeeding on the merits, but there was dispute about irreparable harm.⁵⁴ The Court ultimately vacated the issuance of a preliminary injunction because LEGO failed to prove that it would suffer irreparable harm.⁵⁵

Failure on just one of the *Winter* factors, according to the Federal Circuit, is fatal to a party bringing a motion for preliminary injunctive relief.

B. District Court Law

Though they appear to, at times, pay lip service to the Sequential Test, district courts employ the Gateway Factor Test in practice when considering the issuance of preliminary injunctions in patent cases.⁵⁶ That is, like courts in a variety of circuits,⁵⁷ district courts in patent cases have evaluated whether the moving party prevails on the first two *Winter* factors—likelihood of success on the merits and irreparable

⁵¹ See Payne, *supra* note 28, at 18.

⁵² See, e.g., Jack Guttman, Inc. v. Kopykake Enters., 302 F.3d 1352, 1356 (Fed. Cir. 2002) (“While granting a preliminary injunction requires analysis of all four factors, a trial court may, as the court did here, deny a motion based on a patentee’s failure to show any one of the four factors—especially either of the first two—without analyzing the others.”).

⁵³ *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1263 (Fed. Cir. 2012).

⁵⁴ *LEGO A/S v. ZURU Inc.*, 799 F. App’x 823, 833 (Fed. Cir. 2020).

⁵⁵ *Id.* at 837; see also *Celgard, LLC v. LG Chem, Ltd.*, 624 F. App’x 748, 755 (Fed. Cir. 2015).

⁵⁶ See, e.g., *Antares Pharma, Inc. v. Medac Pharma, Inc.*, 55 F. Supp. 3d 526, 529 (D. Del. 2014); *Everett Labs. v. Acella Pharm., LLC*, No. 13-3470, 2013 U.S. Dist. LEXIS 131086, at *5 (D.N.J. 2013); *Briggs & Stratton Corp. v. Chongqing RATO Power Co.*, No. 5:13-CV-0316 (LEK/ATB), 2013 U.S. Dist. LEXIS 111766, at *6–7 (N.D.N.Y. 2013). Though citing Seventh Circuit law rather than Federal Circuit law, the Northern District of Illinois has written recently that there is a two-step process to determine whether a preliminary injunction should issue in a patent case. *Peng v. The Partnerships*, No. 21-CV-1344, 2021 U.S. Dist. LEXIS 174254, at *5 (N.D. Ill. Sep. 14, 2021). The first step is the “threshold” phase in which the court needs to assess whether there is a likelihood of success on the merits and irreparable harm. The second step is the “balancing” phase in which the court determines balance of the harms and public interest, but only if the threshold requirement has been satisfied.

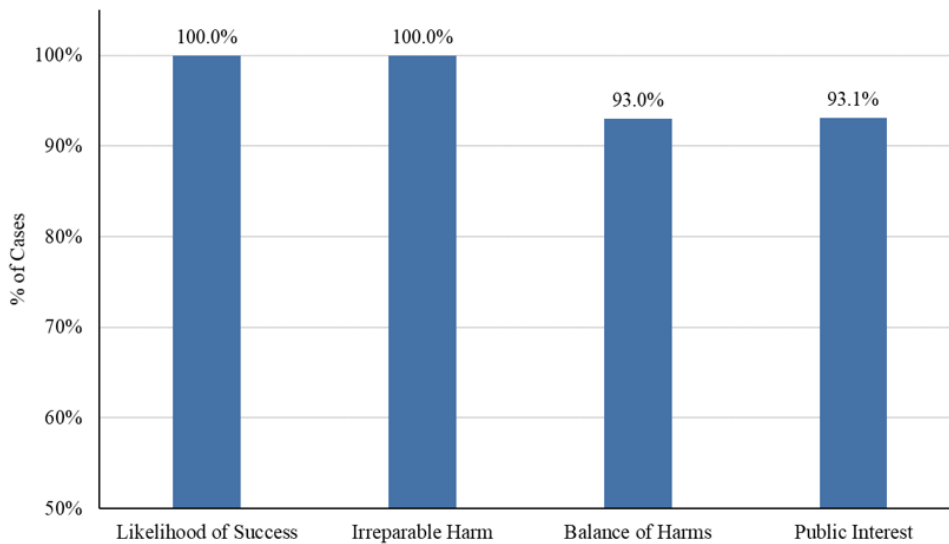
⁵⁷ See Payne, *supra* note 28, at 19.

harm—in every case. If the patent holder loses on either of those factors, an injunction will not issue. Many of the district courts have not gone on to evaluate the second two *Winter* factors—balance of the equities and public interest—often leaving an incomplete record for appeal purposes. In fact, of the 211 cases that we examined over the 2013 through 2020 period, the court offered an opinion on all four *Winter* factors in only 108 of those cases. For the other 103 cases, the court did not provide an opinion on all four factors, almost entirely because the patent owner did not prevail on the first two *Winter* factors.

Our data show that when a motion for preliminary injunction was granted in a patent case, consistent with *Winter*'s requirement, a finding was made 100% of the time (59 out of 59 cases) that the patent owner had shown that it was likely to succeed on the merits. Similarly, a successful showing was made 100% of the time that the patent owner would suffer irreparable harm without an injunction. In other words, prevailing on the first two *Winter* factors was in fact necessary or required for a preliminary injunction to be granted.

Our findings are reflected below in Figure 2.

Figure 2
Preliminary Injunction Granted
Factors Found to Favor Plaintiff⁵⁸
(2013-2020)



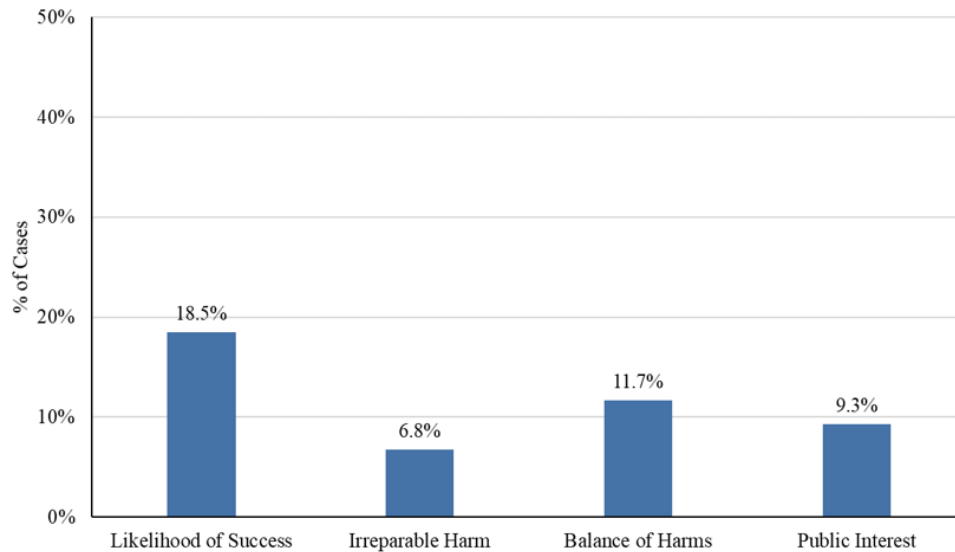
Though the balance of the equities and public interest factors almost always were found to favor the patent owner, this was not always the case. In 10 cases, the court

⁵⁸ Excludes cases where the court has no explicit ruling nor opinion for the factor.

granted a preliminary injunction but did not find balance of the equities or public interest factors to favor the plaintiff. In other words, prevailing on the third or fourth *Winter* factors is not strictly required for a preliminary injunction to be granted, although there appears to be a high correlation between prevailing on these factors and the likelihood of obtaining a preliminary injunction.

Our data also show that winning on the first two *Winter* factors does not guarantee issuance of a preliminary injunction. For example, in patent cases in which a motion for preliminary injunction was denied and all factors were considered, a finding was made 18.5% of the time that the patent owner had prevailed on likelihood of success but was still not granted preliminary relief. A finding was made 6.8% of the time (8 out of 118 cases) that the patent owner had prevailed on showing irreparable harm but was still not granted preliminary relief. That is reflected in Figure 3 below.

Figure 3
Preliminary Injunction Denied
Factors Found to Favor Plaintiff⁵⁹
(2013-2020)

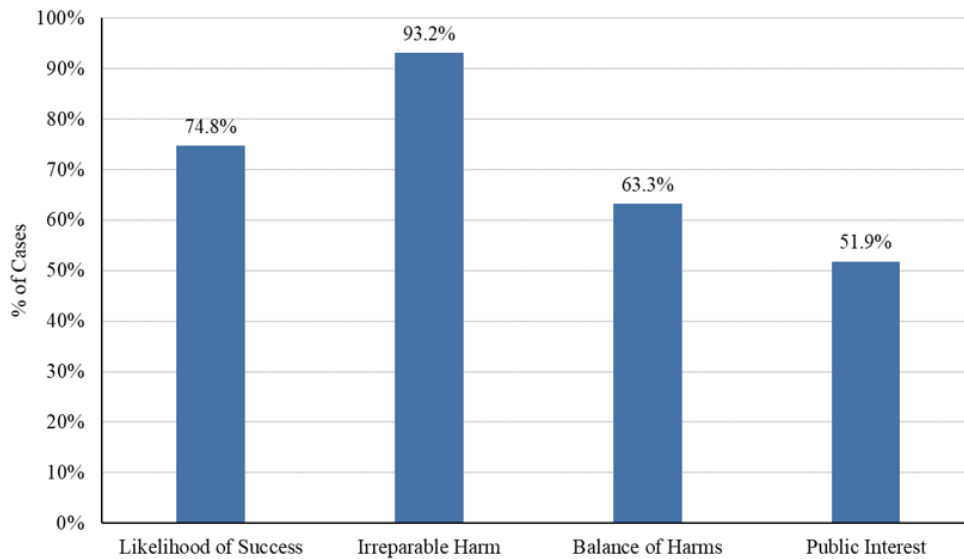


Finally, our data show that when a preliminary injunction is denied and all factors are considered, alleged infringers tend to prevail on the first two *Winter* factors. In fact, the irreparable harm factor was found to favor the alleged infringer 93.2% of the time when an injunction was denied and the likelihood of success on the merits factor was found to favor the alleged infringer 74.8% of the time. The results are

⁵⁹ Excludes cases where the court has no explicit ruling nor opinion for the factor.

reflected in Figure 4 below.

Figure 4
Preliminary Injunction Denied
Factors Found to Favor Defendant⁶⁰
(2013-2020)



Among the cases in which an injunction was denied, the sum of percentages does not add up to 100 percent (compare Figure 3 and Figure 4). For example, the sum of percentages for likelihood of success equals roughly 93.3%. This is because, in certain cases, courts did not find a factor to be in favor of either side. Courts may not even analyze a factor at all; for example, some courts might have started analyzing irreparable harm first, subsequently finding it in favor of the alleged infringer and deciding not to analyze likelihood of success. This observation reinforces different implications that the Gateway Factor test has for the patent owner and for the alleged infringer. The patent owner must prevail on both the irreparable harm and likelihood of success factors. The alleged infringer needs to prevail on only one factor, and irreparable harm is the factor that has proven to be most fruitful for alleged infringers.

To test the strength of each *Winter* factor more rigorously, we assessed the relative importance of each factor to the probability of a preliminary injunction being granted. Although Figure 2 is instructive, to accurately establish how each *Winter* factor affects the granting of preliminary injunctions, one needs to control for the effects of each of the other *Winter* factors.

⁶⁰ Excludes cases where the court has no explicit ruling nor opinion for the factor.

Figure 5
Relationship Between Preliminary Injunction Grant
and the Four *Winter* Factors⁶¹

(2013-2020)

Coefficients from Firth Logistic Regression⁶²

Variables	Odds Ratios (Z-statistic)	
	(1)	(2)
	Considering All Four <i>Winter</i> Factors	Considering Only Last Two <i>Winter</i> Factors
Finding of Likelihood of Success	422.420*** (3.067)	
Finding of Irreparable Harm	385.677*** (2.686)	
Finding of Balance of Harms	3.127 (0.391)	15.211*** (3.646)
Finding of Public Interest	1.742 (0.185)	26.338*** (4.478)
Constant	0.000*** (-4.062)	0.042*** (-4.747)

The estimates of the odds ratios in Figure 5 suggest that, all else equal, when a patent owner is able to prove that the likelihood of success factor is satisfied, there is a much higher likelihood of the patent owner succeeding in its request for a preliminary injunction. That is, it appears to be the most important factor.⁶³ The model also shows that the irreparable harm factor matters. All else equal, when a patent owner can prove that factor is satisfied, there is a very high likelihood that the patent owner will succeed.

These results are consistent with a much simpler observation—when preliminary injunctions are granted, the first two *Winter* “gateway” factors must be satisfied. However, although the third and fourth *Winter* factors are often satisfied, the full Firth model predicts that these factors have no discernable impact upon the likelihood of issuance of a preliminary injunction.⁶⁴

Another way to compare the relative importance of the four factors is to evaluate how much real estate (or the number of words) in each court ruling is devoted to

⁶¹ Excludes cases where the court has no explicit ruling nor opinion for the factor.

⁶² A standard logistic regression may produce biased or no results when individual variables predict outcomes perfectly or nearly perfectly. This often occurs when data are sparse (e.g., when indicator variables have a high percentage of ones or zeros), as here. The Firth logistic regression can mitigate these issues and produce results when a standard logistic regression would fail to do so.

⁶³ See *Luminara Worldwide, LLC v. Liown Elecs. Co.*, No. 14-CV-3103 (SRN/FLN), 2015 U.S. Dist. LEXIS 57370 (D. Minn. Apr. 20, 2015) (“While ‘no single factor is determinative,’ the likelihood of success factor is the most important.” (citations omitted)).

⁶⁴ Our analysis does show that courts’ rulings on Factors 1 and 2 are positively correlated with their rulings on Factors 3 and 4. But, this phenomenon could be partially, but not entirely, a mechanical result of motions that fail under a Gateway Factor Test.

discussing each factor. We call this a measure of each factor’s “intensity,” and define it as the count of words used to discuss each factor.⁶⁵ Our hypothesis is that this measure is somewhat informative of the relative weight that the court assigns to each of the four factors.

Figure 6 shows the results of our intensity analysis. It provides a boxplot summary for each factor’s intensity, separately for cases with granted and denied injunctions.⁶⁶

Figure 6
Intensity Boxplot Summary (Based on Number of Words Discussing Each Factor)

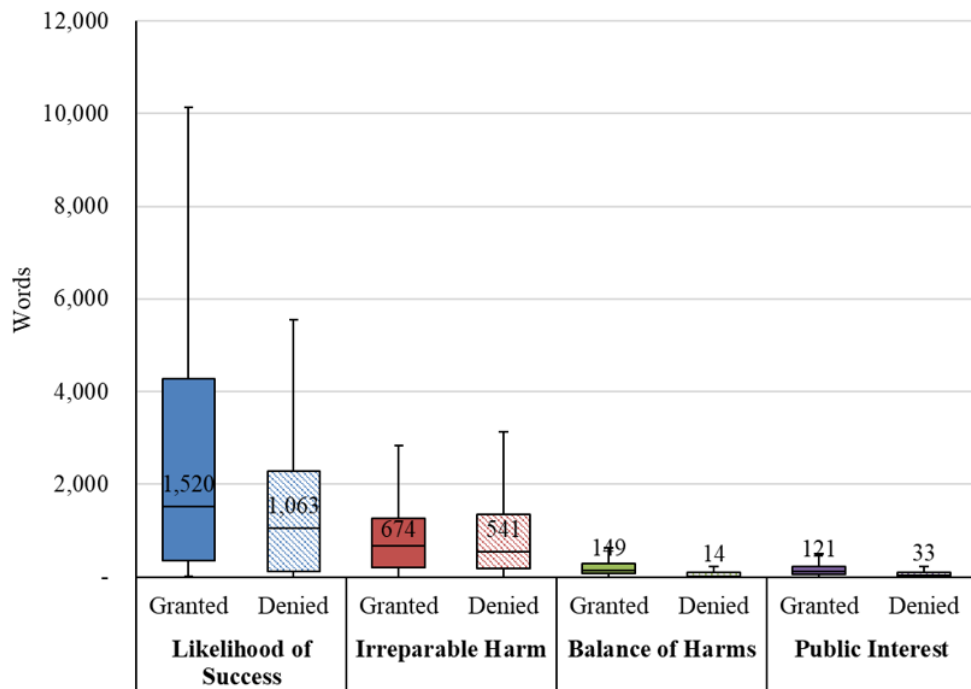


Figure 6 demonstrates that the four *Winter* factors ranked by intensity are (1) likelihood of success, (2) irreparable harm, (3) balance of harms, and (4) public

⁶⁵ We collect measures of intensity by counting the number of words dedicated to a court’s analysis—defined as a series of non-space characters, bounded by empty spaces—of each factor. We consider a given word as specific to a court’s analysis of a certain factor if it is placed after the factor’s heading and before the beginning of a new factor’s analysis. For example, any word following the section header “Likelihood of Success on the Merits” or “Likely to Succeed on the Merits,” and preceding the next section “Irreparable Harm,” is considered to be pertaining to court’s analysis of the Likelihood of Success. Our analysis was conducted in R using R base functions for regular expression and user-package “pdftools” for text extraction.

⁶⁶ For each boxplot, a box is drawn between the first and third quartiles, with a line drawn along the second quartile to mark the median.

interest. When a preliminary injunction is granted, the median number of words devoted to the discussion of the likelihood of success is 1,520. This represents something on the order of ten paragraphs per opinion. The median number of irreparable harm words is 674, or less than half of the median number of words devoted to the discussion of the likelihood of success. The balance of harms discussion covers 149 words, and the public interest discussion covers 121 words, with roughly one paragraph devoted to each of these latter two factors. This ranking is generally consistent with the relative effect of the four factors on the granting of injunctions described above.

Each factor's average intensity for the cases with granted injunctions is higher than for the cases with denied injunctions. In other words, courts find it necessary to be more expansive when substantiating factor-specific rulings in favor of patent owners. When a preliminary injunction is denied, the median number of words devoted to discussion of each of the factors is: 1,063 words for likelihood of success, 541 words for irreparable harm, 14 words for balance of the hardships, and 33 words for public interest.

In sum, as it relates to irreparable harm, several observations can be made. First, irreparable harm needs to be proven by the patent owner in every preliminary injunction case. Effectively rebutting this factor, or any other, defeats a request for preliminary injunction.

Second, when alleged infringers prevail in defeating a motion for preliminary injunction, the factor on which they most often prevail is irreparable harm. Courts show particular attention in addressing irreparable harm issues versus likelihood of success issues when the infringer prevails in defeating a motion for preliminary injunction.

Third, courts hearing patent cases appear to devote much more attention to the likelihood of success factor than they do to irreparable harm. Perhaps this is due to litigator and court comfort with technical issues, the complexity of the technical issues, or litigator and court discomfort, and perhaps confusion, associated with economic issues like irreparable harm.

III. Proving Irreparable Harm

A. Federal Circuit Law

The Federal Circuit has not defined irreparable harm. On occasion, it has identified forms of harm that ultimately may be deemed irreparable depending on the facts of each case.

Patent infringement damages are authorized under 35 U.S.C. § 284, which provides that “upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable

royalty for the use made of the invention by the infringer.”⁶⁷

Patent damages trials (and any resulting appeals) often focus on the impacts, or harms, of alleged infringement on a patent holder’s sales volumes, prices, and profits. Lost revenues, which consolidate the bottom-line impacts of volumes and prices, and the corresponding lost profits, which also include the patent owner’s incremental costs, as well as reasonable royalty damages are the types of harms that economists frequently evaluate and quantify in patent cases. Virtually all of these evaluations are backward-looking. Occasionally, claims are made for damages that may occur in the future because of the Federal Circuit’s professed willingness to have those damages considered.⁶⁸ Most of the focus of damages trials, however, is on the impacts of infringement between the point of first infringement and the point of trial.

In determining whether a preliminary injunction should be granted in advance of a full merits trial, the Federal Circuit has considered several factors. We classify these factors into three groups. One set of factors is possible “Output Harms.” Those represent the direct marketplace impacts on the patent owner of potential infringing activity. A second set of factors is possible “Input Harms.” Those represent the internal impacts of potential infringing activity on the operations of the patent owner’s business that ultimately may translate to output or marketplace harms. The third set is not harms at all, but “Indicia of Harm.”

I. Output Harms

The Federal Circuit has identified several forms of potential irreparable harm to a patent holder’s success in the marketplace, all of which are explained and illustrated more fully below. Those are harms to:

- Sales, market share, or market position;⁶⁹
- Ecosystem or follow-on sales;⁷⁰
- direct competition;⁷¹ and
- prices.⁷²

⁶⁷ 35 U.S.C. § 284 (1952).

⁶⁸ See *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1581 (Fed. Cir. 1992) (acknowledging that “projected future losses may be recovered when sufficiently supported”).

⁶⁹ See, e.g., *Genband US LLC v. Metaswitch Networks Corp.*, 861 F.3d 1378, 1383 (Fed. Cir. 2017); *Apple Inc. v. Samsung Elecs. Co. (Apple III)*, 735 F.3d 1352, 1360 (Fed. Cir. 2013); *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012); *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1153–54 (Fed. Cir. 2011); *Abbott Lab’ys. v. Sandoz, Inc.*, 544 F.3d 1341, 1361–62 (Fed. Cir. 2008); *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001); *Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1566 (Fed. Cir. 1996).

⁷⁰ See, e.g., *Metalcraft of Mayville v. Toro Co.*, 848 F.3d 1358, 1368 (Fed. Cir. 2017); *Apple Inc. v. Samsung Elecs. Co. (Apple IV)*, 809 F.3d 633, 641 (Fed. Cir. 2015).

⁷¹ See, e.g., *Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1171 (Fed. Cir. 2014); *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1348 (Fed. Cir. 2013); *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1363 (Fed. Cir. 2012).

⁷² See, e.g., *Celsis*, 664 F.3d at 930; *Abbott Lab’ys.*, 544 F.3d at 1361–62; *Boehringer*, 237 F.3d at

2. *Input Harms*

The Federal Circuit has identified several forms of potential irreparable harm to the patent owner's ability to succeed, also explained and illustrated more fully below. Those are harms to:

- Reputation or goodwill;⁷³
- research and development (R&D);⁷⁴
- employment;⁷⁵
- business opportunities or partnerships;⁷⁶
- first mover advantage;⁷⁷
- exclusivity;⁷⁸ and
- value of the patent.⁷⁹

3. *Indicia of Harm*

The Federal Circuit has further identified several other factors to consider in determining the existence of irreparable harm, which are more fully explained and illustrated below. Those are:

- willingness to license;⁸⁰
- delay in suing;⁸¹ and
- ability to pay a judgment.⁸²

1368.

⁷³ See, e.g., *Genband*, 861 F.3d at 1383; *Trebro Mfg.*, 748 F.3d at 1170; *Celsis*, 664 F.3d at 930; *Astrazeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1062 (Fed. Cir. 2010); *Abbott Lab 'ys.*, 544 F.3d at 1361–62; *Genentech, Inc.*, 80 F.3d at 1566.

⁷⁴ See, e.g., *Abbott Lab 'ys.*, 544 F.3d at 1362; *Genentech, Inc.*, 80 F.3d at 1566.

⁷⁵ See, e.g., *Celgard, LLC v. LG Chem, Ltd.*, 624 F. App'x 748, 749 (Fed. Cir. 2015); *Trebro Mfg.*, 748 F.3d at 1170; *Astrazeneca LP*, 633 F.3d at 1062.

⁷⁶ See, e.g., *Celsis*, 664 F.3d at 930; *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 975–76 (Fed. Cir. 1996).

⁷⁷ See, e.g., *Bio-Rad Labs., Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1378 (Fed. Cir. 2020).

⁷⁸ See, e.g., *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1149 (Fed. Cir. 2011); *Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1328 (Fed. Cir. 2008).

⁷⁹ See, e.g., *Trebro Mfg.*, 748 F.3d at 1172; *Celsis*, 664 F.3d at 931.

⁸⁰ See, e.g., *Apple Inc. v. Samsung Elecs. Co. (Apple III)*, 735 F.3d 1352, 1368–69 (Fed. Cir. 2013); *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1381 (Fed. Cir. 2005); *Polymer Techs., Inc.*, 103 F.3d at 976; *Illinois Tool Works, Inc.*, 906 F.2d at 683.

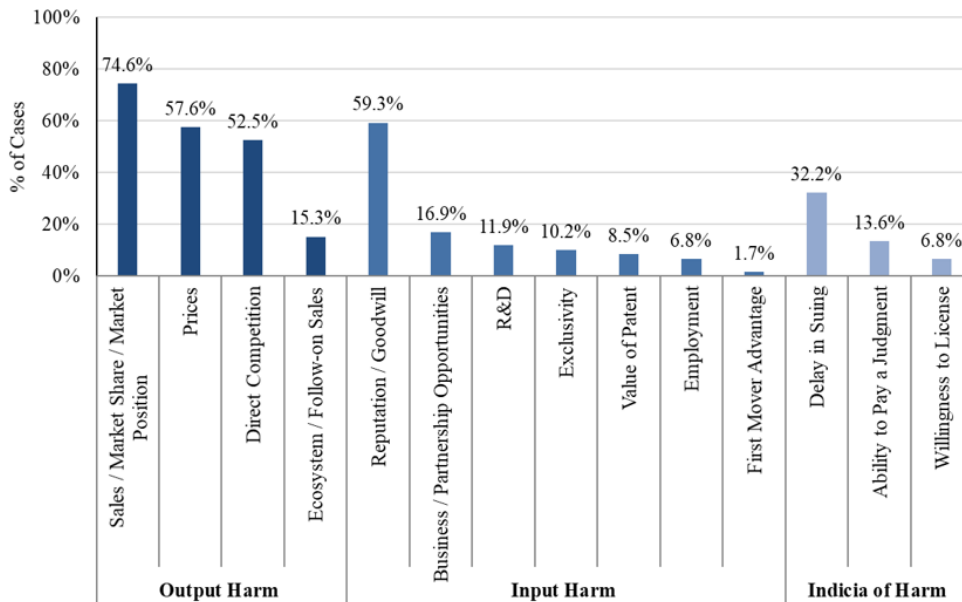
⁸¹ See, e.g., *Apple v. Samsung Elecs. Co. (Apple I)*, 678 F.3d 1314, 1325 (Fed. Cir. 2012); *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995); *Nutrition 21 v. United States*, 930 F.2d 867, 872 (Fed. Cir. 1991).

⁸² See, e.g., *Apple III*, 735 F.3d at 1369; *Robert Bosch LLC*, 659 F.3d at 1154–55.

B. District Court Law

In Figure 7 **Error! Reference source not found.**, we have shown the importance of each of the factors identified above as reflected in the 211 district court opinions that we examined.

Figure 7
Preliminary Injunction Granted
Irreparable Harm Considerations
Categories of Harm Found to Favor Plaintiff
(2013-2020)



On the Output Harm side, a prevailing patent owner in a motion for preliminary injunction proved irreparable impact to sales, market share, or market position 74.6% of the time, irreparable impact on prices 57.6% of the time, and irreparable impact because of direct competition 52.5% of the time. On the Input Harm side, when a patent owner was granted a preliminary injunction, it prevailed on its claim of irreparable harm to reputation 59.3% of the time. Other Input Harms had much less of an impact on the patent owner's probability of obtaining injunctive relief. For Indicia of Harm, delay in bringing suit mattered and favored the patent owner 32.2% of the time, while the other factors had a positive impact less than 15% of the time.

As shown in Figure 8, when defendants prevail in opposing a preliminary injunction and the court makes a finding on irreparable harm, the same factors matter, although their impacts are less pronounced. On the Output Harm side, a successful

defendant prevailed on irreparable impact to sales, market share, or market position 53.3% of the time (i.e., the patent owner was unable to prove irreparable impact on sales, market share, or market position 53.3% of the time), irreparable impact on prices 31.6% of the time, and irreparable impact because of direct competition 16.4% of the time. On the Input Harm side, a successful defendant prevailed on claimed irreparable harm to reputation 40.1% of the time. Other Input Harms had much less of an impact on the defendant’s probability of succeeding. For Indicia of Harm, delay in bringing suit mattered and favored the defendant 19.1% of the time, while the other factors had a positive impact less than 15% of the time. Important to note is that in these cases, the defendant prevailed in showing that the patent owner had not met its burden of proving irreparable harm. It did not necessarily prevail, for instance, in proving that there was *no* irreparable harm to market share.

Figure 8
 Factors Found to Favor Defendant when a Preliminary Injunction was Denied
 (2013-2020)

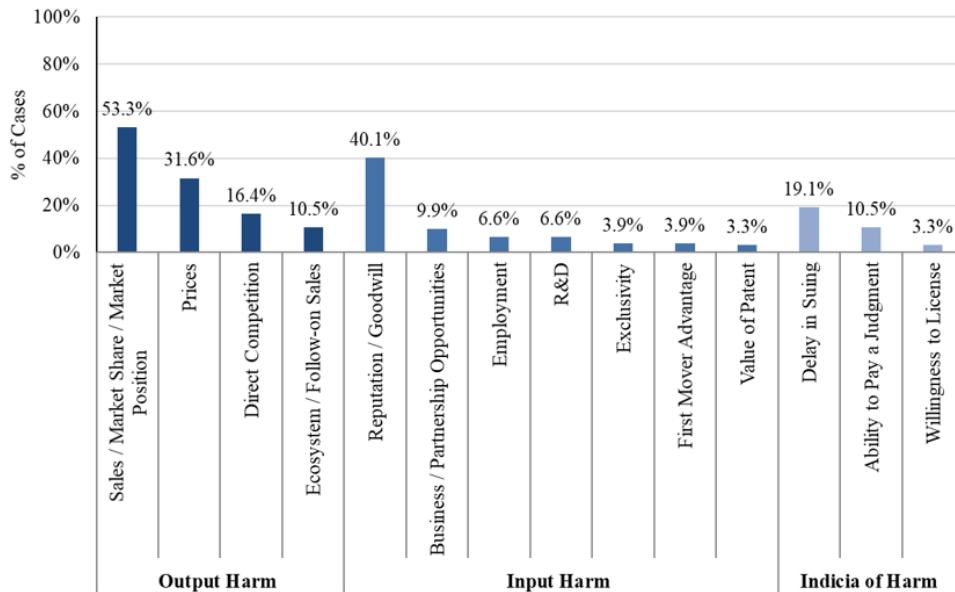


Figure 9 represents a more thorough economic evaluation of the underlying data at the district court level, accounting for patent owner wins and losses, and controlling for all categories of harm and indicia of harm. It shows that, all else equal, the likelihood of proving irreparable harm is 118.2 times higher when the patent owner successfully proves an irreparable impact on prices versus when it does not, 20.7 times higher when it shows an irreparable impact on sales, market share, or market position, 19.6 times higher when the patent owner successfully proves an irreparable impact on reputation, and 19.8 times higher when the patent owner successfully proves that

there was no unacceptable delay in bringing suit.

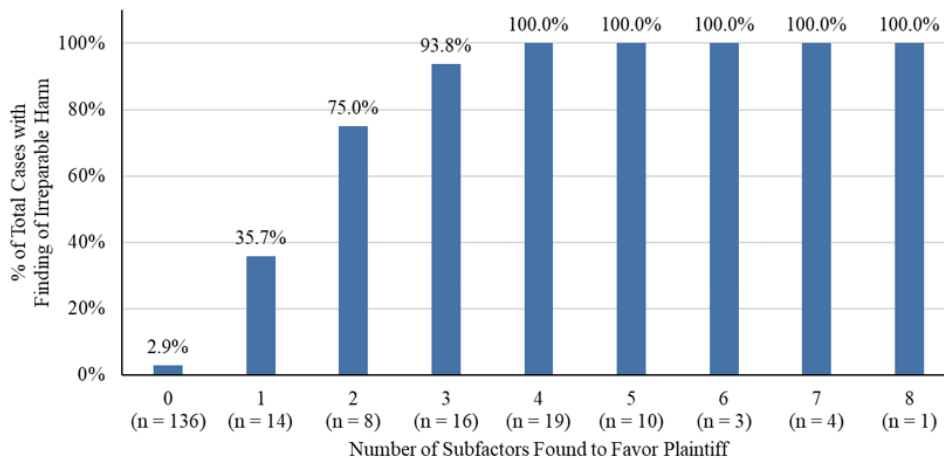
Figure 9
Relationship Between Finding of Irreparable Harm
and Irreparable Harm Considerations
(2013-2020)
Coefficients from Firth Logistic Regression

Variables	Odds Ratios (Z-statistic)
Output Harm	
Prices	118.155*** (3.663)
Sales / Market Share / Market Position	20.656* (1.865)
Ecosystem / Follow-on Sales	0.989 (-0.006)
Direct Competition	0.327 (-0.540)
Input Harm	
Reputation / Goodwill	19.609** (2.459)
R&D	3.380 (0.548)
Business / Partnership Opportunities	0.675 (-0.219)
Exclusivity	0.620 (-0.222)
Value of Patent	0.255 (-0.298)
Employment	0.173 (-0.729)
First Mover Advantage	0.000** (-2.285)
Indicia of Harm	
Ability to Pay a Judgment	35.766 (1.009)
Delay in Suing	19.826*** (3.488)
Willingness to License	9.281 (1.544)
Constant	0.032*** (-7.220)

Our data also show that a patent owner's reliance on only one category of considerations is likely to be unsuccessful. Figure 10 below shows that prevailing patent owners are much more likely to succeed when they show proof of two or more forms of irreparable harm.⁸³ By way of example, in 15 cases in which only one form of harm was found to be irreparable, the patent owner succeeded in showing irreparable harm only 33% of the time. In the 19 cases in which four forms of harm were found to favor the patent owner, a finding of irreparable harm was found 100% of the time. In short, district courts appear to require that there be fairly broad impacts of the alleged infringement in order to support a finding of irreparable harm, or, at least, those courts have chosen to write about the very broad impacts of infringement.

⁸³ See, e.g., Parah, LLC v. Mojack Distributions, LLC, No. 18-1208-EFM-TJJ, 2018 U.S. Dist. LEXIS 142217, at *9-10 (D. Kan. Aug. 22, 2018); Veeco Instruments Inc. v. SGL Carbon, LLC, No. 17-CV-2217 (PKC), 2017 U.S. Dist. LEXIS 181935, at *26 (E.D.N.Y. Nov. 2, 2017).

Figure 10
Number of Harms Found to Favor Plaintiff
(2013-2020)



IV. Problems With Irreparable Harm

There is no doubt that assessing irreparable harm is far from straightforward. Thirty years ago, long before the Supreme Court’s decisions in *eBay* and *Winter*, Steven Shapiro wrote:

Irreparable injury is the most difficult factor to comprehend conceptually and is the most susceptible to conflicting opinions from the courts. The courts have indicated that “[t]he focus on the irreparable injury inquiry is harm that is impossible to measure in monetary terms.” However, all patent cases concern money. Patent holders obtain patents for the very purpose of making money. As one trial court wrote:

I am frequently at a loss to understand in civil cases what is meant by irreparable injury. In criminal cases it is clear. You serve time in jail, and that time is gone; it can not be brought back. . . . If an error is made, we can award money and repair the harm. So I am not quite sure what irreparable injury means in this context, but it must mean something.⁸⁴

The Federal Circuit has provided some guidance. It has written that irreparable harm is not the same as harm.⁸⁵ That is sensible. Further, it has written that harm

⁸⁴ *Hybritech Inc v. Abbott Lab’ys*, No. CV 86-7461/AK (PX), 1987 WL 123997 (C.D. Cal. July 14, 1987), *aff’d*, *Hybritech Inc. v. Abbott Lab’ys*, 849 F.2d 1446 (Fed. Cir. 1988); Steven E. Shapiro, *Preliminary Injunction Motions in Patent Litigation*, 33 IDEA 323, 336 (1993) (alteration in original) (citing *Drexelbrook Controls, Inc. v. Magnetrol Int’l, Inc.*, 720 F. Supp. 397, 408 (D. Del. 1989)).

⁸⁵ *See, e.g., Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) (citing *Sampson v. Murray*, 415 U.S. 61, 90 (1974) (“The key word in this consideration is irreparable.

which can be repaired via a later damages trial is not irreparable.⁸⁶ That is sensible. It has not, however, provided clear guideposts as to the bounds of what is to be deemed irreparable harm.

Uncertainties (and errors) with evaluation of any of the *Winter* factors, including irreparable harm, can and do lead to (1) a likely increase in the costs of litigation as litigants attempt to satisfy unclear, and perhaps inconsistent, standards, (2) an increased likelihood that certain meritorious requests will not prevail and certain non-meritorious requests will prevail, and (3) an increased likelihood that certain meritorious cases will not be pursued and certain non-meritorious cases will be pursued.

Many problems in claims for and decisions about irreparable harm arise from false positive errors; others arise from false negative errors. False positives occur when there actually is no underlying harm, much less irreparable harm, yet there are non-fact-based claims of harm that are offered and accepted. Many times, those claims are categorical or overly broad—that is, they would hold in every case and provide no real filter for truly meritorious cases.

False negatives occur when it is too costly for the patent owner to provide adequate proof of irreparable harm. In most preliminary injunction cases, little to no discovery has occurred, hampering the patent holder's ability to assess the extent and level of the infringer's likely competitive impacts. Further, harm in a preliminary injunction matter is almost always future-looking, and the future is always uncertain. While irreparable harm may exist, proving it to a reasonable degree of certainty, and the associated costs of doing that are exceptionally, perhaps prohibitively, high.

False positive errors result in too many cases being brought. False negative errors result in too few cases being brought. They both can result in confusing law, uncertain standards, and costly and protracted litigation.⁸⁷

To some, after-the-fact damages estimation is wildly speculative or at least highly uncertain.⁸⁸ Some commentators hold the view that many litigants in patent

Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay, are not enough.”); *Robert Bosch LLC*, 659 F.3d at 1152 (“An injury is either of the irreparable sort, or it is not.”).

⁸⁶ See, e.g., *Canon, Inc. v. GCC Int'l*, 263 F. App'x 57, 62 (Fed. Cir. 2008) (“[I]rreparable harm consists of harm that could not be sufficiently compensated by monetary damages or avoided by a later decision on the merits.”).

⁸⁷ We do not mean to suggest that there are no laudable (precedential or policy) purposes for the categorical or broadly applicable arguments. We do believe that many of those arguments, however, often conflict with basic economic principles, often leading to litigation unpredictability and uncertainty, and much too frequently resulting in economically undesirable outcomes.

⁸⁸ See, e.g., Daralyn J. Durie & Mark A. Lemley, *A Structured Approach to Calculating Reasonable Royalties*, 14 LEWIS & CLARK L. REV. 627, 628 (2010) (noting that “lawyers can make an argument that some combination of factors will support virtually any number that an expert (or jury) might come up with” during damages calculations); Mark A. Lemley, *Distinguishing Lost Profits from Reasonable Royalties*, 51 WM. & MARY L. REV. 655, 666 (2009) (noting accepted use of discretionary increases of reasonable royalties awards by courts due to concerns of potential undercompensation of plaintiffs).

litigation are significantly overcompensated while many others are significantly undercompensated.⁸⁹ According to this argument, the primary value of preliminary injunctive relief is to reduce the risk of either significant over- or under-compensation after the fact. As long as there is a robust balance of hardships analysis, the generous granting of preliminary injunctive relief, regardless of the false positive and false negative errors noted, may reduce aggregate error costs. In short, according to that argument, arguably there is no real need to clean up the analysis of preliminary injunctions.

Though the above argument has some facial appeal, it suffers from several problems. First, there is no consensus that after-the-fact damages estimation is wildly speculative or highly uncertain. Second, it is not at all clear that error costs from damages estimations exceed error costs from preliminary injunctions. Third, preliminary injunction error costs can be greatly reduced by cleaning up the problems associated with irreparable harm. Why not try to reduce all error costs, including those associated with assessing irreparable harm in preliminary injunction cases?

A. Categorical Statements

Many of the cases that we reviewed contained self-serving categorical statements by the patent owner as to the likely irreparable harm that would flow from continued infringement. These arguments are categorical because they would seemingly apply in every patent infringement case. In many instances, courts found these arguments to be compelling. In those cases, the facts at hand did not appear to matter.

Despite these arguments by patent holders and their acceptance by district courts, it is unlikely that they would satisfy the Supreme Court. As the Court wrote in *eBay*, “traditional equitable principles do not permit such broad classifications.”⁹⁰ Categorical rules for granting or denying injunctive relief “cannot be squared with the principles of equity adopted by Congress” in the Patent Act.⁹¹

Moreover, categorical allegations of harm make the likelihood-of-success factor virtually the sole criterion for issuing a preliminary injunction. As the Supreme Court noted in *Winter*, an injunction “does not follow from success on the merits as a matter

⁸⁹ See, e.g., William F. Lee & A. Douglas Melamed, *Breaking the Vicious Cycle of Patent Damages*, 101 CORNELL L. REV. 385, 411–12, 415–16 (2016) (arguing that ex post considerations in damages calculations result in overcompensation, while noting arguments from courts and other commentators that purely ex ante considerations would result in undercompensation); J. Gregory Sidak, *Holdup, Royalty Stacking, and the Presumption of Injunctive Relief for Patent Infringement: A Reply to Lemley and Shapiro*, 92 MINN. L. REV. 714, 737 (2008) (arguing that lost-profits measure of damages undercompensates patent holders, while noting other’s arguments that lesser remedy of reasonable royalties overcompensates patent holders); Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 2017–25 (2007) (noting that assumptions made by hypothetical negotiation test encourage patentee undercompensation, but arguing that practical problems with court-determined royalty rates ultimately result in overcompensation).

⁹⁰ *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393 (2006).

⁹¹ *Id.*

of course.”⁹² Rather, all factors, including the balance of equities and the public interest, are “pertinent in assessing the propriety of any injunctive relief, preliminary or permanent.”⁹³

Below we discuss the various species of categorical arguments about irreparable harm that we identified from our review of the preliminary injunction cases.

1. *Free Riding*

In many cases, an argument is made that harm is irreparable because an alleged infringer will be free riding off the investment and development efforts of the patent owner if it is allowed to continue infringing.⁹⁴ In short, as the argument goes, the patent owner invested in establishing the technology or business and the infringer is able to ride those coattails without making concomitant investments.

Patent laws, just like competition laws, do not prohibit free riding. They prohibit only certain forms of free riding. Nor do they prohibit competition. They prohibit only certain forms of competition. Likewise, patent laws do not guarantee the patent owner a positive return on its investment and development efforts. All investment and development efforts are risky endeavors.

Moreover, as the district court in *DMF v. AMP Plus* wrote, investment in developing and promoting a technology “may very well constitute harm,” but “this harm is quantifiable and can be addressed through money damages.”⁹⁵

Finally, it is rarely the case that an infringer has made no investments of its own. In fact, in cases of non-intentional infringement, the infringer arguably has not avoided any investment costs. For all of these reasons, arguments as to free riding appear categorical and thus unpersuasive in preliminary injunction cases.

2. *Right to Exclude*

In many cases, a patent owner argues that infringement causes irreparable harm because it eliminates the patent owner’s “right to exclude” under the Patent Act.⁹⁶ That argument was presented in, among other cases, *Whirlpool v. DeltaFill*, where the plaintiff successfully demonstrated that it would suffer irreparable injury in the form of “the loss of [its] *exclusive patent rights*, and harm to [its] goodwill and

⁹² *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 32 (2008).

⁹³ *Id.*

⁹⁴ *See, e.g., Abbott Cardiovascular Sys. v. Edwards Lifesciences Corp.*, No. 19-149 (MN), 2019 U.S. Dist. LEXIS 104628, at *73 (D. Del. June 6, 2019); *Precision Med., Inc. v. Genstar Techs. Co.*, No. 10-5161, 2011 U.S. Dist. LEXIS 48406, at *39 (E.D. Pa. May 3, 2011).

⁹⁵ *DMF, Inc. v. Amp Plus, Inc.*, No. 2:18-CV-07090-CAS-GJSx, 2019 U.S. Dist. LEXIS 37831, at *40 (C.D. Cal. Mar. 7, 2019).

⁹⁶ *See, e.g., Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (noting that the patent system “provides incentive to the innovative drug companies to continue costly development efforts”); *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985) (“The encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.”).

reputation as the creator and *only authorized provider*” of its patented products.⁹⁷

Yet the right to exclude is threatened in every patent infringement matter. Categorical statements of harm like this can be unsatisfying. According to the district court in *ATLeisure*, this is a “circular and conclusory argument” that provides little assistance in determining irreparable harm because “[t]he ‘existence of a likely infringer’ is essentially the same as saying there is a likelihood of success on the merits of a patent infringement claim, and the court has already held such a finding *cannot* give rise to a presumption of irreparable harm.”⁹⁸ While the loss of the right to exclude may constitute actual harm, the mere existence of this harm does not address the fundamental question of whether it can be measured and repaired.

The right to exclude argument was of substantial significance in Judge Reyna’s concurring opinion in *Apple v. Samsung (Apple IV)*.⁹⁹ According to Judge Reyna, though the loss of the right to exclude does not automatically entitle a moving party to injunctive relief, that right cannot be ignored.¹⁰⁰ As with free riding, while patent laws do, in fact, protect a party’s right to exclude, that right is uncertain prior to a finding of infringement, which is the circumstance under which a preliminary injunction is sought.¹⁰¹

Moreover, patent laws do not grant an unlimited and unfettered right to exclude—only the right to exclude infringement of the patent at issue. Assessing entitlement to a preliminary injunction is an attempt to set the bounds of that entitlement.

3. *Compulsory License*

A variant of the right to exclude argument is that, by not being granted a preliminary injunction, a moving party is forced into a compulsory license. That is, though

⁹⁷ *Whirlpool Corp. v. DeltaFill Inc.*, No. 2:17-CV-00520-JRG, at 2 (E.D. Tex. Sept. 20, 2017) (emphasis added).

⁹⁸ *Atleisure, Inc. v. Ace Evert Inc.*, No. 1:12-CV-1260-CAP, 2013 WL 12099363, at *7 (N.D. Ga. June 6, 2013).

⁹⁹ *Apple Inc. v. Samsung Elecs. Co. (Apple IV)*, 809 F.3d 633, 649 (Fed. Cir. 2015) (Reyna, J., concurring) (citing *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1149 (Fed. Cir. 2011)) (“Though we read *eBay* to overrule our presumption of irreparable injury, we cautioned that courts should not necessarily ‘ignore the fundamental nature of patents as property rights granting the owner the right to exclude.’” see Matthew C. Darch, Note, *The Presumption of Irreparable Harm in Patent Infringement Litigation: A Critique of Robert Bosch LLC v. Pylon Manufacturing Corp.*, 11 NW. J. TECH. & INTELL. PROP. 103, 103 (2013) (arguing that the loss of exclusivity cause by infringement should create a rebuttable presumption of irreparable harm).

¹⁰⁰ *Apple IV*, 809 F.3d at 649. See also Darch, *supra* note 99, at 103 (“[T]he loss of exclusivity caused by continued infringement should create a rebuttable presumption of irreparable harm.”); *Smith Int’l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1581 (Fed. Cir. 1983) (“Once the patentee’s patents have been held to be valid and infringed, he should be entitled to the full enjoyment and protection of his patent rights. . . . [W]here validity and continuing infringement have been clearly established . . . immediate irreparable harm is presumed.”).

¹⁰¹ It is important to note that the loss of the right to exclude does not necessarily amount to irreparable harm even in cases in which infringement is found and a permanent injunction is sought. If this were the case, permanent injunctions would always be issued after a finding of infringement.

the patent owner opposes competitive entry, not granting an injunction would force it to allow such entry. For example, that argument was presented in *OMIX-ADA*, where the patent owner argued that infringing competition would irreparably injure it because it would lose “control over its valuable intellectual property right.”¹⁰²

Assuming liability, a compulsory license is virtually always the outcome when an injunction, whether permanent or preliminary, is denied in patent cases and the alleged infringer intends to continue to participate in the business.¹⁰³ Further, while having to grant a compulsory license may constitute harm to the patent owner, it does not address the fundamental question of whether that harm is irreparable.

As noted by the Federal Circuit in *LEGO v. ZURU*, “the compulsory license argument is circular, because the result of not being enjoined necessarily entails allowing the alleged infringer to continue selling their accused products in every case.”¹⁰⁴ Moreover, the impact of denying a preliminary injunction to the patent holder, even if the patent is infringed, is somewhat different than the impact of denying a permanent injunction. If a compulsory license is granted after a preliminary injunction is denied, then the duration of that license typically extends to the end of the litigation when the court will make a decision regarding the entry of a permanent injunction. If the patent holder experiences an irreparable injury from such a compulsory license, then it would seem to arise primarily from the much more important permanent injunction decision, rather than the injury associated with the denial of a preliminary injunction.

4. *Diminished Patent Value*

In some cases, an argument is made that the value of an owner’s patent would be diminished because of the infringing activity and that diminishment is necessarily irreparable.¹⁰⁵ For example, in *Anderson v. TOL*, the patent owner successfully argued that the poor quality and low profit margins of the infringing products “threatened to degrade the value of [the patents] to such a degree that other companies might not do business with [the patent owner] at all.”¹⁰⁶

Market entry may diminish the position of the incumbent. The question in a patent infringement case is whether that entry *improperly* diminishes the position of the incumbent. Even if it does, that does not address the fundamental question of whether the patent owner could be made whole with monetary damages for that harm.

¹⁰² *Omix-Ada, Inc. v. Qingdao Hairunkaiyuan Auto Parts Co.*, No. 2:17-CV-02748-MMD-PAL, at *1 (D. Nev. Nov. 22, 2017).

¹⁰³ See Contreras & Maupin, *supra* note 39, at 35.

¹⁰⁴ *LEGO A/S v. ZURU Inc.*, 799 F. App’x 823, 834 (Fed. Cir. 2020); see also *Atlas Powder Co. v. Ireco Chems.*, 773 F.2d 1230, 1233 (Fed. Cir. 1985) (“If monetary relief were the sole relief afforded by the patent statute then injunctions would be unnecessary and infringers could become compulsory licensees for as long as the litigation lasts.”).

¹⁰⁵ *Juicero, Inc. v. iTaste Co.*, No. 17-CV-01921-BLF, 2017 U.S. Dist. LEXIS 171947, at *4–5 (N.D. Cal. Oct. 5, 2017).

¹⁰⁶ *Anderson v. TOL, Inc.*, 927 F. Supp. 2d 475, 488 (M.D. Tenn. 2013).

Moreover, as noted above, many forms of infringement may actually enhance the patent owner's market position and future prospects. Broader use of a patented invention, through network effects or credibility enhancement, may legitimize and even enhance the desirability of a patented invention and the products that embody it.

As the Federal Circuit wrote in *Illinois Tool Works v. Grip-Pak*, “[a]pplication of a concept that every patentee is always irreparably harmed by an alleged infringer’s pretrial sales would . . . disserve the patent system.”¹⁰⁷ Virtually every patentee in every case could make that argument. It should prevail, however, only if that diminished value is truly irreparable.

B. Broad Statements

Many of the cases that we reviewed contained broad statements by the patent owner as to the likely irreparable harm that would flow from continued infringement. In many instances, courts found those arguments to be compelling. Some of those arguments may, in fact, be tenable. Others, however, were not tied to the facts at hand. Rarely was there proof, or even argument, that the resulting harm could not be repaired through monetary damages at a later damages trial.

The factors considered in this section cannot be criticized as being unsupported, categorical assertions of harm that are argued in every case. These factors do apply in some cases but only if the facts of the case lend themselves to a finding of harm.

More critically, however, these factors, if shown to apply, do not by definition mean that the underlying harm has been or will be irreparable. Again, the facts of the case at hand must lend themselves to a finding of irreparability.

If shown to be real, but not irreparable, these harms cannot and should not be discarded as irrelevant to a determination of entitlement to a preliminary injunction. Recall, the third *Winter* factor asks the trier of fact to balance the equities. That often results in courts balancing the hardships, or harms, to the patent owner of no injunction against the hardships, or harms, to the alleged infringer of an injunction. For that determination, harms are relevant, even if not deemed to be irreparable.

1. Direct Competition

An impact of infringement in many, though not all, cases is new and unwanted direct competition.¹⁰⁸ As noted above, according to the Federal Circuit in *Liqwd, Inc. v. L’Oréal*, “[w]e conclude that the district court did not err when it determined that the bond-builder market is a ‘two player national market’ and that Olaplex would likely suffer irreparable harm from L’Oréal’s ‘direct competition in [its] primary market.’”¹⁰⁹

¹⁰⁷ *Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683 (Fed. Cir. 1990).

¹⁰⁸ *See, e.g.*, *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1348 (Fed. Cir. 2013); *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1360–63 (Fed. Cir. 2012).

¹⁰⁹ *Liqwd, Inc. v. L’Oréal USA, Inc.*, 720 F. App’x 623, 633 (Fed. Cir. 2018) (alteration in original)

In *Trebro v. Firefly*, the Federal Circuit observed that the relevant market was quite small (comprised of three suppliers) and the infringer's sales would naturally displace those of the patent owner.¹¹⁰ It went on to conclude that because “the record shows that a loss of market share and customers is a loss that Trebro is not likely to recover[,] . . . money damages are likely inadequate in this market.”¹¹¹ Direct competition appears to have been virtually dispositive as to irreparable harm.¹¹²

Direct competition arising from patent infringement will often lead to harm to the incumbent (except, of course, in cases involving a non-practicing entity). Harm is almost always difficult to quantify. But, as noted by Ellis, Jarosz, Chapman, and Oliver,

Normal business losses, however, are not per se incalculable. In fact, there is a whole industry of economists, financial analysts and accountants who regularly calculate damages associated with lost sales, loss of market share and lost profits, for example. And courts regularly accept these calculations. Many of these same calculations are used in the business world to forecast or predict various performance metrics and to value assets, liabilities, projects and other potential investment opportunities—billions of dollars are spent on the basis of these types of calculations. Done carefully, these calculations can be reliable. The fact that the impact of the loss of an asset may be challenging to estimate does not mean it is impossible.¹¹³

There can be little doubt, as noted by Laycock, that commercial damages are “notoriously difficult” to measure, including damages in patent infringement actions,¹¹⁴ but damages are the usual remedy in those cases for past harm.¹¹⁵ Evaluation of harm in patent cases is almost backward-looking. The harm that is envisioned under the four-factor test, whether past or future, is that which is shown to be irreparable. As the Federal Circuit has noted, irreparable harm is not the same as harm.¹¹⁶

Though direct competition may lead to harm, that harm, though often challenging to prove, is not inherently irreparable. Proof needs to be provided that there is harm beyond that which economists, financial analysts, and accountants normally calculate.

(quoting *Douglas Dynamics*, 717 F.3d at 1345). See also *Douglas Dynamics*, 717 F.3d at 1345 (“Where two companies are in competition against one another, the patentee suffers the harm—often irreparable—of being forced to compete against products that incorporate and infringe its own patented inventions.”); *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1151 (Fed. Cir. 2011) (dictum) (“[T]he existence of a two-player market may well serve as a substantial ground for granting an injunction.”).

¹¹⁰ *Trebro Mfg., Inc. v. Firefly Equipment, LLC*, 748 F.3d 1159, 1170–72 (Fed. Cir. 2014).

¹¹¹ *Id.* at 1170–71.

¹¹² See *id.* This was in spite of the fact that the patent owner did not practice the patent in suit.

¹¹³ Ellis et al., *supra* note 39, at 446.

¹¹⁴ Laycock, *supra* note 13, at 47.

¹¹⁵ *Id.*

¹¹⁶ See, e.g., *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) (citing *Sampson v. Murray*, 415 U.S. 61, 90 (1974) (“The key word in this consideration is irreparable. Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay, are not enough.”)); *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1152 (Fed. Cir. 2011) (“An injury is either of the irreparable sort, or it is not.”).

2. Consequential Harm

Harm that is likely to have either a lasting or derivative effect is sometimes argued, and often is presumed to be, irreparable. According to the Federal Circuit in *Metalcraft of Mayville, Inc. v. Toro Co.*:

[T]he loss by Scag of customers may have far-reaching, long-term impact on its future revenues, and the sales lost by Scag are difficult to quantify due to “‘ecosystem’ effects, where one company’s customers will continue to buy that company’s products and recommend them to others.” Because of its variable and uncertain nature, this loss is very difficult to calculate. Therefore, the district court did not abuse its discretion in holding that Scag is likely to suffer irreparable harm in the absence of an injunction.¹¹⁷

In *Apple v. Samsung* (Apple I), the Federal Circuit similarly wrote,

As the district court correctly noted, Apple could lose sales of tag-along products including apps, other Apple devices, and future models of its products. Although the district court discussed downstream implications in the context of the smartphone patents, these concerns apply to all of Apple’s iconic products, including the iPad. Because the loss of customers and the loss of future downstream purchases are difficult to quantify, these considerations support a finding that monetary damages would be insufficient to compensate Apple.¹¹⁸

Harm can be long-lasting and can extend to products and services other than those directly implicated by the infringement. Evidence of that in any particular case can be convincing—bald allegations much less so. The fact that there may be long-lasting and derivative harm does not make it irreparable. In fact, economists often estimate these types of damages. Estimates are done in virtually all breach of contract damages cases and in most tort cases.¹¹⁹ Again, proof needs to be provided that there is harm beyond that which economists, financial analysts, and accountants normally calculate.

3. Reputational Harm

Harm to reputation can occur along several dimensions. In patent cases, it is often asserted to be harm to the patent owner’s reputation as an innovator or harm to the reputation of the patent owner’s product due to an inferior product offering.¹²⁰ Such harm is often argued and deemed to be irreparable. That appears to have been the case in the eyes of Judge Reyna in his concurrence in *Apple v. Samsung* (Apple IV).¹²¹ He wrote that the majority failed to reach the issue of reputational injury to

¹¹⁷ *Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1368–69 (Fed. Cir. 2017) (internal citations omitted) (citing *Apple Inc. v. Samsung Elecs. Co.* (Apple IV), 809 F.3d 633, 641 (Fed. Cir. 2015)).

¹¹⁸ *Apple, Inc. v. Samsung Electronics Co.* (Apple I), 678 F.3d 1314, 1337 (Fed. Cir. 2012).

¹¹⁹ See John C. Jarosz, Robert L. Vigil, and Michael J. Chapman, *Introduction to Lost Profits*, in *LOST PROFITS DAMAGES: PRINCIPLES, METHODS, AND APPLICATIONS* 31, 33–34 (Everett P. Harry, III & Jeffrey H. Kinrich eds., 2d ed. 2022); 8 AM. JUR. 2D *Proof of Facts* § 1 (2022) (discussing the discount rate for future damages).

¹²⁰ See, e.g., *Tinnus Enters., LLC v. Telebrands Corp.*, 846 F.3d 1190, 1207–08 (Fed. Cir. 2017); *Apple Inc. v. Samsung Elecs. Co.* (Apple IV), 809 F.3d 633, 655 (Fed. Cir. 2015) (Reyna, J., concurring); *Reebok Int’l, Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1558 (Fed. Cir. 1994).

¹²¹ *Apple IV*, 809 F.3d at 655; see also *Eyeticket Corp. v. Unisys Corp.*, 155 F. Supp. 2d 527, 548 (E.D. Va. 2001) (“Money damages alone cannot restore the technological lead-time that the Plaintiff would

Apple. Relying on a prior Federal Circuit ruling in *Douglas Dynamics, LLC v. Buyers Prods. Co.*, Judge Reyna explained that “when customers find the patentee’s innovations appearing in a competitor’s products, the patentee’s reputation as an innovator will ‘certainly’ be damaged.”¹²² This is particularly true when the patentee and the infringer compete toe-to-toe in a two-competitor marketplace, as Apple and Samsung do, and therefore, “the loss of reputation caused by infringement marks a gain of reputation of the infringer as an innovator.”¹²³ Judge Reyna also noted that Apple’s reputation as an innovator was “critical to its ability to compete against Samsung” given the nature of the smartphone and tablet market:

Apple’s reputational injury is all the more important here because of the nature of Apple’s reputation, i.e., one of an *innovator* (as opposed to, e.g., a producer of low-cost goods). Consumers in the smartphone and tablet market seek out innovative features and are willing to pay a premium for them. Sometimes consumers in this market will even prioritize innovation over utility. A reputation as an innovator creates excitement for product launches and engenders brand loyalty.¹²⁴

Reputational harm, if proven to apply in a given case, is particularly difficult to quantify. In large part that is because the economic value of reputation is difficult to measure in the first place and difficult to disentangle from other factors. But economists can and do measure it in cases ranging from defamation to patent infringement.¹²⁵ Again, proof is required that there is harm beyond that which a whole industry of economists, financial analysts, and accountants normally calculate.

4. *Expiring Patent Rights*

Another argument pursued in some cases is that a patent owner’s rights may expire in short order.¹²⁶ That is, a patent owner has a right to exclude over a defined number of years, and infringement measurably shortens that period of protection. That argument was presented in *H.H. Robertson, Co. v. United Steel Deck, Inc.*, where the Federal Circuit observed that the patent at issue “[did] not have many more years to run” and accordingly affirmed the grant of a preliminary injunction.¹²⁷ The court noted the “finite term of the patent grant,” explaining that “patent expiration is not suspended during litigation, and the passage of time can work irremediable harm.”¹²⁸

have enjoyed,” during which it could build its “reputation for expertise and advanced products.”).

¹²² *Apple IV*, 809 F.3d at 654.

¹²³ *Id.* at 653.

¹²⁴ *Id.* at 654–55 (emphasis in original).

¹²⁵ See, e.g., *Jordan v. Wonderful Citrus Packing LLC*, No. 1:18-CV-00401-AWI-SAB, 2020 U.S. Dist. LEXIS 178235 (E.D. Cal. Sep. 28, 2020) (affirming jury award in a defamation case of \$1,958,957 for reputational damages proposed in testimony from plaintiff’s expert economist). See generally Thomas F. Cotter, *Damages for Noneconomic Harm in Intellectual Property Law*, 72 HASTINGS L.J. 1055, 1097–98 (2021).

¹²⁶ See, e.g., *H.H. Robertson, Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 390 (Fed. Cir. 1987); *Atlas Powder Co. v. Ireco Chems.*, 773 F.2d 1230, 1234 (Fed. Cir. 1985).

¹²⁷ *H.H. Robertson, Co.*, 820 F.2d at 391 (quoting *H.H. Robertson Co. v. United Steel Deck, Inc.*, No. 84–5357, slip op. at 24 (D.N.J. Mar. 31, 1986)).

¹²⁸ *Id.* at 390. *But see* *Woodard v. Sage Prods.*, 818 F.2d 841, 854 (Fed. Cir. 1987) (“We do not, however, accept the remainder of [plaintiff’s] argument, that the need for injunctive relief necessarily is

Yet infringement that is not enjoined always leads to an effective truncation of the term of patent protection. In some cases, it may have a significant impact on the patent owner's future prospects. In many cases, it does not. Technology lives are often limited and short. Proof of an economically significant impact is required. Importantly, the fact that there may be a loss of patent rights during the period of infringement does not address the fundamental question of whether that loss is measurable and repairable.

5. *Level of Harm*

In some cases, infringers have argued that the irreparable harm arising from infringement is harm that will likely put the patent owner out of business prior to a merits trial.¹²⁹ If it is not so devastating, according to that argument, the patent owner can wait for a merits determination and the chance to seek a permanent injunction.¹³⁰ Such an argument was presented in *QBAS v. C Walters Intercoastal*, where the court granted a preliminary injunction and explained that “[g]iven the relatively small size of Plaintiff QBAS, losses [due to alleged infringement] can be devastating and even put QBAS out of business altogether, certainly a factor that must be considered when determining whether irreparable harm will result.”¹³¹

On the other hand, to some courts, evaluation of the harm must consider the infringer's ability to pay a judgment. That is reflected in the Ability to Pay statistics in Figure 7 above. In *LifeScan v. Shasta*, for example, the court granted a preliminary injunction where the alleged infringer had “no income stream from anything other than the sale of [the infringing product]” and had only “minimal cash on hand.”¹³² According to the court, “without revenues from other sources, it will be impossible for Defendants to satisfy a judgment covering the entirety of Plaintiffs' damages.”¹³³

Irreparable, however, does not mean “grave” or “fatal.”¹³⁴ Defining irreparable harm as being grave or fatal would mean that a large company would rarely be entitled to a preliminary injunction while a small company often would, in spite of the fact that the nature and level of harm may be equivalent in those two cases. Patent laws, like competition laws, are meant to protect certain forms of activity, not certain

more imperative as the end of the patent term approaches.”).

¹²⁹ See, e.g., *QBAS Co. v. C Walters Intercoastal Corp.*, No. SACV 10-406 AG (MLGx), 2010 U.S. Dist. LEXIS 143945, at *34 (C.D. Cal. Dec. 16, 2010); *Schawbel Corp. v. Conair Corp.*, 122 F. Supp. 2d 71, 84 (D. Mass. 2000).

¹³⁰ See, e.g., *Am. Cyanamid Co. v. United States Surgical Corp.*, 833 F. Supp. 92, 123–24 (D. Conn. 1992).

¹³¹ *QBAS*, 2010 U.S. Dist. LEXIS 143945, at *34.

¹³² *LifeScan, Inc. v. Shasta Techs., LLC*, 933 F. Supp. 2d 1243, 1262–63 (N.D. Cal. 2013), *rev'd on other grounds sub nom.* *LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361, 1377 (Fed. Cir. 2013).

¹³³ *Id.* at 1263.

¹³⁴ See, e.g., *Eisai Co. v. Teva Pharm. USA, Inc.*, Nos. 05-5727 (HAA) (ES), 07-5489 (HAA) (ES), 2008 U.S. Dist. LEXIS 33747, at *32 (D.N.J. Mar. 28, 2008) (“[T]he question of irreparable harm does not ask whether the patentee will go out of business, but instead asks whether the patentee will be harmed in such a manner that the damage cannot be undone.”).

forms of competitors. Apple may not prevail in defeating a motion for preliminary injunction when a two-person start-up would prevail even if both, hypothetically, held the same patent rights and were injured in identical fashions.

C. Proof of Irreparable Harm

In trademark cases, the need to prove irreparable harm effectively has been eliminated. In 2020, Congress passed the Trademark Modernization Act.¹³⁵ A critical aspect of the new law was adoption of a presumption of irreparable injury when likelihood of confusion has been found.¹³⁶ Several arguments were provided in support of the presumption. One is that trademark law is rooted in consumer protection, unlike patent and copyright law, and injunctions are critical to protect both the trademark owner and the public.¹³⁷ Another argument is the belief that it is difficult to obtain monetary relief in Lanham Act cases, unlike in patent cases, where it is routinely granted.¹³⁸ Much of that may be due to a perception that it is virtually impossible to determine whether a given amount of money can undo the cost of confusion.¹³⁹ Another argument is that the Lanham Act is intended to protect goodwill and reputation, unlike patent law, and those assets are virtually unquantifiable.¹⁴⁰ A final argument was that once a trademark plaintiff demonstrates consumer confusion or loss of control over its brand, it is unclear what additional evidence is needed to establish irreparable harm.¹⁴¹ In short, it appears that injunctive relief is deemed a much more adequate remedy than monetary damages in trademark cases, resulting in a lower bar—not needing to prove irreparable harm—to obtaining an injunction.

In patent cases prior to *eBay*, the Federal Circuit essentially presumed irreparable harm when infringement was shown in permanent injunction cases.¹⁴² That presumption was effectively eliminated with the decision in *eBay*. However, some commentators have argued that a presumption of irreparable harm should be reinstated in

¹³⁵ See Consolidated Appropriations Act, 2021, Pub. L. No. 116–260, Div. Q, Title II, Subtitle B, § 221, 134 Stat. 1182, 2200–2211 (2020) (incorporating the Trademark Modernization Act of 2020).

¹³⁶ H.R. Rep. No. 116–645, at 16–19 (2020); see, e.g., *Harley’s Hope Found. v. Harley’s Dream*, No. 22-CV-0136-WJM-STV, 2022 WL 1154526, at *3 (D. Colo. Apr. 19, 2022) (rebutting the irreparable injury presumption when the plaintiff delayed bringing suit for three years after learning of the activity at issue and eight months after sending a cease and desist letter).

¹³⁷ H.R. Rep. No. 116–645, at 9, 18–19; Mark A. Lemley, *Did eBay Irreparably Injure Trademark Law?*, 92 NOTRE DAME L. REV. 1795, 1809 (2017).

¹³⁸ H.R. Rep. No. 116–645, at 17; Lemley, *supra* note 137, at 1806.

¹³⁹ Lemley, *supra* note 137, at 1803.

¹⁴⁰ H.R. Rep. No. 116–645, at 16 (citing Anne Gilson LaLonde & Jerome Gilson, *Adios! To the Irreparable Harm Presumption in Trademark Law*, 107 Trademark Rep. 913, 921 (2017)); see also Lemley, *supra* note 137, at 1803.

¹⁴¹ H.R. Rep. No. 116–645, at 19.

¹⁴² *H.H. Robertson, Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 390 (Fed. Cir. 1987) (“In matters involving patent rights, irreparable harm has been presumed when a clear showing has been made of patent validity and infringement.”); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1246–47 (Fed. Cir. 1989) (“Infringement having been established, it is contrary to the laws of property, of which the patent law partakes, to deny the patentee’s right to exclude others from use of his property.”).

patent cases when there has been adequate proof of likelihood of success on the merits.¹⁴³ Those arguments are based on the theory that the fundamental patent right of exclusivity is granted only for a limited term and any infringement of that right is not compensable by damages, thus automatically causing irreparable harm.¹⁴⁴

There certainly are differences and similarities between trademark law and patent law, and the motivations underlying each. But the stated and (presumably congressionally accepted) differences between the two, as noted above, suggest that the bar for irreparable harm is and should be higher in patent cases than trademark cases.

According to some courts adjudicating patent cases, proving the nature and level of harm arising from infringement is exceptionally difficult, thereby supporting a conclusion that the harm is presumably irreparable. The Federal Circuit’s opinion in *Celsis In Vitro, Inc. v. CellzDirect, Inc.* noted that:

There is no effective way to measure the loss of sales or potential growth—to ascertain the people who do not knock on the door or to identify the specific persons who do not reorder because of the existence of the infringer.¹⁴⁵

The existence and magnitude of many kinds of harm are difficult to evaluate, but that does not mean that they are inherently unmeasurable or, by extension, irreparable. Examples include lost earnings, lost business opportunities, and investor losses due to financial misrepresentation. Economists often evaluate claims of harm that may occur sometime in the future.¹⁴⁶ On occasion, those evaluations are found to be overly speculative, but often, they are not.

Some have argued that the Federal Circuit in *Celsis* erected a strawman: “irreparable harm” is that which “no damages payment, however great, could address.”¹⁴⁷ That view of irreparable harm, however, cannot be sustained. There are very few patent owners that would not feel whole upon receipt of a damages payment of sufficiently great magnitude. As the court noted in *Apple IV*, “‘irreparable’ does not mean that the injury cannot be remedied at all. If that were the case, the plaintiff would not have standing to sue.”¹⁴⁸

¹⁴³ See, e.g., Kenneth C. Louis, *Reports of Its Death Are Greatly Exaggerated: eBay, Bosch, and the Presumption of Irreparable Harm in Hatch-Waxman Litigation*, 4 PACE. INTELL. PROP. SPORTS & ENT. L.F. 33, 49, 70–71 (2014) (suggesting that the Hatch-Waxman Act be amended to permit the irreparable harm presumption in pharmaceutical patent infringement actions); Darch, *supra* note 99, at 118.

¹⁴⁴ See, e.g., Louis, *supra* note 143, at 49 (“[I]n the absence of the presumption, courts can still reach similar results by examining the patent holder’s right to exclude”); Darch, *supra* note 99, at 118 (“[I]t follows that any continued infringement would be irreparable harm, as the holder of the right has lost the ability to exclude”); Mitchell G. Stockwell, *Implementing Ebay: New Problems in Guiding Judicial Discretion and Enforcing Patent Rights*, 88 J. Pat. & Trademark Off. Soc’y 747, 749 (2006) (“This reasoning would seem to argue in favor of retaining the presumption, which is, at heart, simply a useful procedural device.”).

¹⁴⁵ *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012).

¹⁴⁶ See Jarosz et al., *supra* note 119, at 32; Ellis et al., *supra* note 39, at 446.

¹⁴⁷ *Celsis In Vitro*, 664 F.3d at 930.

¹⁴⁸ *Apple Inc. v. Samsung Elecs. Co. (Apple IV)*, 809 F.3d 633, 650 (Fed. Cir. 2015) (Reyna, J.,

Moreover, some courts have written that it is the alleged infringer's burden to show that the harm is quantifiable and thus not irreparable.¹⁴⁹ Under this reasoning, the patent owner has virtually no burden to prove irreparability. However, a long line of case law has held consistently that it is the moving party's burden to prove each of the four *Winter* factors.¹⁵⁰ There does not appear to be a presumption that the test has been satisfied absent contrary proof. In fact, in *Apple v. Samsung (Apple II)*, the Federal Circuit wrote that "[i]t is well established that . . . the party seeking emergency relief . . . must make a clear showing that it is at risk of irreparable harm, which entails showing a likelihood of substantial and irreparable injury."¹⁵¹ In *Takeda v. Mylan*, Takeda argued that each sale by Mylan would reduce Takeda's units sold and likely cause irreversible price erosion and long-term loss of market share.¹⁵² However, the Federal Circuit held that though those forms of harm might be deemed irreparable in certain cases, Takeda's "nonspecific and unsupported assertion" of likely irreparable harm "falls far short of establishing that irreparable harm has occurred, or will likely occur, absent a preliminary injunction."¹⁵³

As noted above, the fact that a harm is shown to be real but not shown to be irreparable does not make that harm irrelevant to a determination of entitlement to injunctive relief. It just means that such a harm should be considered in evaluation of the third *Winter* factor: balance of the equities and hardships.

V. Solving Irreparable Harm

The problems associated with evaluating irreparable harm in patent cases are not insurmountable. One approach that could overcome the issues noted above involves marrying basic and sensible economic principles with a large swath of judicial decisions. We propose a four-part test for irreparable harm that should lead to economically sensible outcomes and provide consistent guidance to future litigants. The four-part test can be summarized as follows. First, is an injunction halting infringement necessary to preserve the status quo?¹⁵⁴ Second, is the patent holder likely to suffer

concurring) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561(1992)).

¹⁴⁹ *Celsis In Vitro*, 664 F.3d at 930 (first citing *Abbott Lab'ys v. Sandoz, Inc.*, 544 F.3d 1341, 1361–62 (Fed. Cir. 2008); and then citing *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006)) ("[T]he mere possibility of future monetary damages does not defeat a motion for preliminary injunction.").

¹⁵⁰ *See, e.g., Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555 (Fed. Cir. 1994) ("The burden is always on the movant to show entitlement to a preliminary injunction."); *Sofamor Danek Grp., Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1219 (Fed. Cir. 1996) ("The movant bears the burden of proving entitlement to relief.").

¹⁵¹ *Apple, Inc. v. Samsung Elecs. Co. (Apple II)*, 695 F.3d 1370, 1374 (Fed. Cir. 2012) (quoting *Apple, Inc. v. Samsung Elecs. Co., (Apple I)*, 678 F.3d 1314, 1325 (Fed. Cir. 2012)).

¹⁵² *Takeda Pharms. U.S.A., Inc. v. Mylan Pharms. Inc.*, 967 F.3d 1339, 1349 (Fed. Cir. 2020).

¹⁵³ *Id.* at 1349–50.

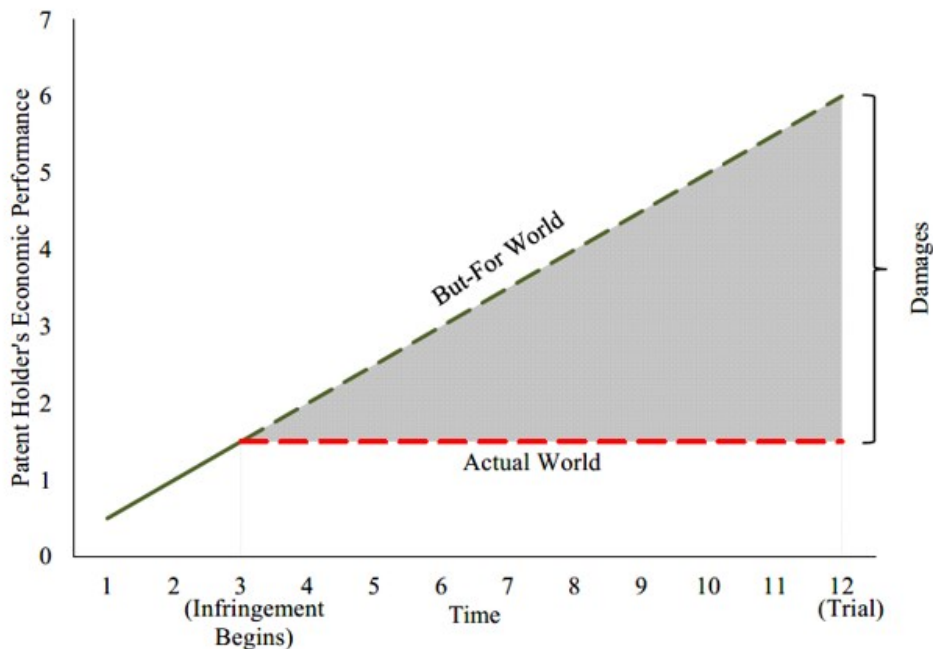
¹⁵⁴ It is important to note that preservation of the status quo may impact other factors under the *Winter* framework in addition to irreparable harm. For example, in *Tiber Lab'ys*, a pediatric drug was available to patients for two to three years prior to the request for an injunction. *Tiber Lab'ys, LLC v. Hawthorn Pharms., Inc.*, 527 F. Supp. 2d 1373, 1383 (N.D. Ga. 2007). As a result, the court, in analyzing the public interest factor under *Winter*, found that "the public interest favors maintaining

imminent harm from continued infringement? Third, does the harm flow from the infringement? Fourth, is the patent owner likely to be adequately compensated for the harm? Like the *eBay* and *Winter* four-factor tests for injunctive relief, the proposed four-part test for irreparable harm is conjunctive, meaning that each of the four elements must be satisfied in order for an injunction to issue.

A. Economic Framework

Assessment of economic harm to an injured party, whether in a patent case or not, involves a comparison of two worlds.¹⁵⁵ The first is the “But-For World,” which is one that would have existed but for the actions at issue. The second is the “Actual World,” which embodies the alleged unlawful actions at issue. Any difference in the injured party’s condition between those two worlds represents the injured party’s harm attributable to the allegedly unlawful actions, holding all else constant. Graphically, economic harm is illustrated as the shaded area in Figure 11 below.

Figure 11
Calculation of Past Damages



To be awarded monetary damages for any harm that is incurred, the injured party

the *status quo* in the supply of those medications to pediatric patients, and weighs strongly against disrupting that supply and potentially misinforming pharmaceutical consumers concerning their use of prescription medication.” *Id.*

¹⁵⁵ Jarosz et al., *supra* note 119, at 31–32.

must show that the harm is quantifiable, i.e., reducible to monetary value, with a reasonable degree of accuracy and certainty such that the magnitude of the difference between the But-For World and the Actual World is not speculative. If such a calculation cannot be made for any portion of the actual harm suffered by the injured party, then the injured party will not be able to receive adequate monetary damages for that harm.

As noted above, typically, the but-for performance of an injured party in a patent infringement suit is measured in output terms: volumes, prices, and profits. Those metrics are often impacted by alleged infringement and typically are reasonably straightforward to measure.

Input metrics, like R&D, employment, business opportunities or partnerships, first mover advantage, exclusivity, and the presumed value of the patent, may not be as easy to quantify. Most inputs, such as lost business opportunities or partnerships and first mover advantage, can be much more difficult to measure than outputs. Many inputs, like employment, commonly benefit a variety of product lines beyond just those at issue in a patent infringement suit. Almost all inputs, such as R&D, exclusivity, and value of the patent, have potentially long-term benefits, like future sales, that can be very difficult to measure. Despite the measurement difficulties, input harms often do occur because of infringement. Those harms, as with any others, are assessed by comparing the But-For World with the Actual World.

B. Economic Test

This Section lays out our proposed four-part test for irreparable harm in preliminary injunction cases.

1. *Preservation of Status Quo*

Unlike a permanent injunction, which is an equitable remedy awarded to an injured patentee, a preliminary injunction is a form of relief that is imposed by a court to preserve the status quo during litigation.¹⁵⁶ The Federal Circuit has explained:

[Preserving] the relative positions of the parties . . . is of particular relevance for patent property, for the patent term continues to run during litigation, and a loss of patent-supported exclusivity during the years of litigation may exhaust not only the life of the patent, but also the value of the invention to its creator.¹⁵⁷

The rationale behind preservation of the status quo is to “ensure that the judicial process is not rendered futile”¹⁵⁸ by “protecting the respective rights of the parties pending final disposition of the litigation.”¹⁵⁹ The perceived need to maintain the

¹⁵⁶ See *Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859, 863 (Fed. Cir. 1987); *Atlas Powder Co. v. Ireco Chems.*, 773 F.2d 1230, 1231 (Fed. Cir. 1985).

¹⁵⁷ *Kimberly-Clark Worldwide, Inc v. First Quality Baby Prods., LLC*, 660 F.3d 1293, 1299 (Fed. Cir. 2011) (internal citations omitted).

¹⁵⁸ *Conair Corp. v. Barbar, Inc.*, No. 6:14-CV-831-ORL-31TBS, 2014 U.S. Dist. LEXIS 90869, at *6 (M.D. Fla. July 3, 2014).

¹⁵⁹ *Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1578 (Fed. Cir. 1983).

status quo has been recognized by numerous courts in patent infringement matters.¹⁶⁰

Though, as noted above, the concept of irreparable harm in preliminary injunction cases often is equated with the notion of irreparable harm in permanent injunction cases. The overriding aim of preliminary actions as mechanisms to preserve the status quo, rather than to provide a remedy to patent holders, distinguishes these two forms of relief and thus the manner in which irreparable harm must be assessed in them.

Preserving the status quo is reasonably straightforward to assess in a case in which alleged infringement has not yet begun. According to the court in *Impax v. Aventis*, an alleged infringer who has not yet entered the market “would only be delayed in doing so for the duration of this litigation” and would be “in the same position as it was in before the injunction was granted, i.e., excluded from the . . . market.”¹⁶¹ Thus, the status quo of no infringement would be preserved by the issuance of a preliminary injunction.

Preserving the status quo is less straightforward in a case in which infringement has already begun. In those cases, is status quo meant to represent the state of the world before the alleged infringement began, at the time litigation is brought, or when the motion for preliminary injunction is filed? According to the Federal Circuit in *Litton Sys v. Sundstrand*, status quo refers to “the last uncontested status which preceded the pending controversy.”¹⁶² In *Atlas Powder Co. v. Ireco Chemicals*, the Federal Circuit further clarified that *Litton* should not be read as “allowing [the defendant] to continue the alleged infringements at the rate they occurred when the suit was filed.”¹⁶³ According to the court, “authorizing the wrongdoer to continue the wrong, only not at an increased rate, is in no realistic sense maintaining the status quo.”¹⁶⁴

In *Won-Door Corp v. Cornell Iron Works*, the court found that “the last uncontested status” between the parties preceded the defendant’s infringement and that the

¹⁶⁰ See, e.g., *Trebro Mfg., Inc. v. Firefly Equip., LLC*, No. CV 13-36-BLG-RFC, 2013 U.S. Dist. LEXIS 55891, at *4 (D. Mont. Apr. 17, 2013); *Bird-B-Gone, Inc. v. Bird Barrier Am., Inc.*, No. 8:12-CV-00178-AG-RNB, 2013 U.S. Dist. LEXIS 191316, at *3 (C.D. Cal. Mar. 20, 2013); *Smith Int’l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1578 (Fed. Cir. 1983); *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981). At least one scholar in a non-U.S. common law jurisdiction has argued that preservation of the status quo should not carry much, if any, weight beyond the traditional preliminary injunction considerations in certain other jurisdictions. That is, consideration of the strength of the patent holder’s liability case trumps blind preservation of the status quo. See generally Gang Mei, *Interlocutory Injunctions in IP Infringement Actions in England and Wales and in Ireland – American Cyanamid Revisited*, 46 INT’L REV. INTELL. PROP. & COMPETITION L. 175, 175–202 (2015).

¹⁶¹ *Impax Lab’ys, Inc. v. Aventis Pharms., Inc.*, 235 F. Supp. 2d 390, 396 (D. Del. 2002). *But see* *Feit Elec. Co. v. Cree, Inc.*, No. 1:15CV535, 2016 U.S. Dist. LEXIS 32083, at *8 (M.D.N.C. Mar. 14, 2016) (“Plaintiff’s requested relief would not preserve the status quo so much as it would simply freeze Defendant’s ability to expand its market presence. In contrast, the status quo prior to this suit being brought was one of free market competition, where Defendant was free to expand its customer base and maneuver in the market at will.”).

¹⁶² *Litton Sys., Inc. v. Sundstrand Corp.*, 750 F.2d 952, 961 (Fed. Cir. 1984).

¹⁶³ *Atlas Powder Co. v. Ireco Chems.*, 773 F.2d 1230, 1231 (Fed. Cir. 1985).

¹⁶⁴ *Id.*

patentee “contested Defendant’s use of the [infringing product] as soon as Plaintiff became aware of it, even if Plaintiff did not file a complaint at that time.”¹⁶⁵ On those grounds, the court granted a preliminary injunction barring all sales of any product infringing the patent.¹⁶⁶ In contrast, the court in *Waters Corp. v. Agilent Technologies* denied a preliminary injunction where the accused product already held a 20-25 % market share, finding that a preliminary injunction would actually “alter the status quo – essentially decreasing the [accused product’s] share to zero pending trial.”¹⁶⁷ Thus, the goal of preserving the status quo in cases where infringement already has begun at the time of trial should weigh against the issuance of a preliminary injunction.

Of course, the direction in which this factor weighs may depend upon the amount of time that the infringer has been on the market and the extent of sales by the infringer. An infringer who has been on the market for a short period of time or who has made only nominal sales at the time the preliminary injunction is sought may not have sufficiently altered the marketplace compared to before infringement began in order for the status quo to be considered materially different than prior to the time of first infringement.

As described below, many courts have denied a request for preliminary injunction when the patent holder has unduly delayed bringing suit or seeking an injunction. Although assessment of delay rarely falls under the explicit rubric of preserving the status quo, it arguably belongs there. A patent holder’s urgency or lack of urgency provides strong, though certainly not dispositive, evidence of the perceived need to preserve the pre-infringement status quo.

2. *Likelihood of Harm*¹⁶⁸

The second element of the proposed framework for preliminary injunctions is that harm to the patent holder is reasonably probable and imminent. As is true in any damages analysis, an allegedly injured patent owner must prove with a reasonable degree of certainty that harm has occurred or will occur.¹⁶⁹ While both the existence

¹⁶⁵ *Won-Door Corp. v. Cornell Iron Works, Inc.*, 981 F. Supp. 2d 1070, 1079 (D. Utah 2013).

¹⁶⁶ *Id.*

¹⁶⁷ *Waters Corp. v. Agilent Techs. Inc.*, 410 F. Supp. 3d 702, 717 (D. Del. 2019).

¹⁶⁸ The Likelihood of Harm here focuses on the impact of infringing activity assuming, with 100 percent probability, that the patent owner has been able to prove that the activity is likely to be infringing. That is, the focus here is just on the nature and magnitude of the harm, not taking into account the court’s assessment as to the patent owner’s entitlement to remedy for that harm. Separately, there is an economic model put forward by Prof. Leusdorf and refined by Judge Posner that provides a framework for determining whether a preliminary injunction should be granted, providing an alternative to the *Winter* four-factor test. The economic model allows for the grant of a preliminary injunction if the probability of the patent owner succeeding on the merits times the patent owner’s irreparable harm exceeds the probability of the alleged infringer succeeding on the merits times the alleged infringer’s irreparable harm. John Leusdorf, *The Standard for Preliminary Injunctions*, 91 Harv. L. Rev. 525, 542 (1978); *Am. Hosp. Supply Corp. v. Hosp. Prods. Ltd.*, 780 F.2d 589, 593–94 (7th Cir. 1986).

¹⁶⁹ *LEGO A/S v. ZURU Inc.*, 799 F. App’x 823, 834, 836 (Fed. Cir. 2020).

and amount of harm must be proven at trial, the standards of proof are different. Numerous courts have long held that the existence of harm is held to a higher standard of proof than is the level of harm.¹⁷⁰

a. Reasonable Probability of Harm

To prove irreparable harm, a patent owner must show that there is a reasonable likelihood of harm. Some courts have required a “clear showing” of a risk of irreparable harm.¹⁷¹ Mere speculation as to what might occur is not enough.¹⁷² Citing *Winter*, the Federal Circuit has held that the moving party must show that “irreparable injury is *likely* in the absence of an injunction.”¹⁷³ Its reasoning was that “a possibility of irreparable harm is inconsistent with [the] characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.”¹⁷⁴

The Federal Circuit recently reiterated its position in *Koninklijke Philips N.V. v. Thales*, writing that the “mere possibility or speculation of harm is insufficient.”¹⁷⁵ It found there that “Thales did not present any evidence that it lost customers, had customers delay purchases, or struggled to acquire new business” because of the threat of improper action.¹⁷⁶ It further wrote that conclusory statements alleging living under a “cloud” of alleged harm or the potential of lost business are not evidence of likely irreparable harm.¹⁷⁷

b. Imminence

Moreover, to support a preliminary injunction, the harm must be imminent.¹⁷⁸ Preliminary injunctive relief is drastic. The court is being asked to move with all due haste because of that imminency. Harm that may occur far in the future, or may never occur, is not likely to be deemed irreparable. Likewise, if the infringer has discontinued the alleged infringement with no intention to renew it or if the infringer is merely experimenting with a patented invention with no immediate plans to deploy it

¹⁷⁰ *Story Parchment Co. v. Patterson Parchment Paper Co.*, 282 U.S. 555, 562 (1931) (“[T]here is a clear distinction between the measure of proof necessary to establish the fact that petitioner had sustained some damage, and the measure of proof necessary to enable the jury to fix the amount.”); *Alphamed Pharms. Corp. v. Arriva Pharms., Inc.*, 432 F. Supp. 2d 1319, 1342 (S.D. Fla. 2006) (noting that “a relaxed burden of proof should apply to the ascertainment of the amount of damage, the plaintiff retains the burden of proof to a reasonable certainty that some damage occurred,” in surveying cases addressing this point), *aff’d per curiam*, 294 F. App’x 501 (11th Cir. 2008).

¹⁷¹ *Apple Inc. v. Samsung Elecs. Co. (Apple I)*, 678 F.3d 1314, 1325 (Fed. Cir. 2012).

¹⁷² *See, e.g., id.* at 1325–26.

¹⁷³ *IGT v. Aristocrat Techs., Inc.*, 646 F. App’x 1015, 1018 (Fed. Cir. 2016) (emphasis in original) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008)).

¹⁷⁴ *Id.* (alteration in original).

¹⁷⁵ *Koninklijke Philips N.V. v. Thales DIS AIS USA LLC*, 39 F.4th 1377, 1380 (Fed. Cir. 2022).

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ *See, e.g., Apple Inc. v. Samsung Elecs. Co. (Apple II)*, 695 F.3d 1370, 1374 (Fed. Cir. 2012); *Zeller Plastik, Koehn, Grabner & Co. v. Joyce Molding Corp.*, 698 F. Supp. 1204, 1227 (D.N.J. 1988).

commercially, the harm may not be considered imminent.¹⁷⁹

The classic example of imminent harm occurs in Abbreviated New Drug Application (ANDA) cases. In those settings, typically, generic drug manufacturers are attempting to enter a branded drug market as quickly as possible, usually at the point at which they receive U.S. Food and Drug Administration (FDA) approval. The impact on the patent holder will occur almost immediately absent the imposition of an injunction.¹⁸⁰ The imminency of harm to the patent holder often weighs in favor of granting a preliminary injunction.

c. Delay in Suing

Another consideration bearing on the likelihood of harm is whether the patent owner has delayed in bringing its request for injunctive relief, which falls in the category of Indicia of Harm, as described above.¹⁸¹ Many courts have concluded that irreparable harm is not imminent when the patent holder unduly delays in bringing suit or seeking an injunction. In *High Tech Medical Instrumentation v. New Image*, for example, the court found that seventeen months was a “substantial period of delay that militates against the issuance of a preliminary injunction by demonstrating that there is no apparent urgency to the request for injunctive relief.”¹⁸² According to this argument, the harm must not have been severe, and certainly not irreparable, because the patent owner did not deem it an imminent threat to its business. A similar result obtained in *Tiber v. Hawthorn Pharms.*, in which the patentee, Tiber, delayed six months between filing its request for injunctive relief and specifying the nature of the remedy it desired.¹⁸³

¹⁷⁹ Shapiro, *supra* note 84, at 338.

¹⁸⁰ *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig.*, No. 09–MD–2118–SLR, 2011 WL 1980610, at *3 (D.Del. May 20, 2011) (“In every ANDA case there is a likelihood of irreparable harm . . . as the generics have a ready-made market to flood as soon as they receive approval . . .”).

¹⁸¹ See, e.g., *Apple Inc. v. Samsung Elecs. Co.*, (*Apple I*), 678 F.3d 1314, 1321 (Fed. Cir. 2012) (“The [district] court noted that Apple had alleged in its complaint that Samsung had been copying its designs and trade dress since 2007; the court found that Apple’s failure to file suit until April 2011 and to seek an injunction until July 2011 undermined its claim of irreparable harm. The court rejected Apple’s argument that its delay should be excused on the ground that the parties were engaged in negotiations, because the negotiations only covered part of the period of delay.”); *Nutrition 21 v. United States*, 930 F.2d 867, 872 (Fed. Cir. 1991) (stating that delaying “for a substantial period of time before seeking a preliminary injunction at least suggests that the status quo does not irreparably damage” the patent owner).

¹⁸² *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995). See also *Vertigo Media, Inc. v. Earbuds Inc.*, No. 21-120 (MN), 2021 U.S. Dist. LEXIS 198045, at *14 (D. Del. Oct. 14, 2021) (“Although the Court commends Plaintiffs for trying to settle the present matter without litigation,” an eleven month delay between sending a cease and desist letter and seeking a preliminary injunction demonstrated that “Plaintiffs have not acted with an urgency that suggests they will suffer irreparable harm in the absence of an injunction.”).

¹⁸³ *Tiber Lab’s, LLC v. Hawthorn Pharms., Inc.*, 527 F. Supp. 2d 1373, 1383 (N.D. Ga. 2007) (stating that patentee’s “apparent lack of urgency in detailing the nature of the preliminary relief it has requested further undercuts [patentee]’s case for injunctive relief and is at odds with a finding of irreparable harm”).

Though fact patterns may often support such an inference, they do not always. The Federal District Court for the Northern District of New York has reasoned that “[a]lthough it is true that an excessive delay, without any reasonable explanation, can tip the scales in favor of finding that there is no irreparable harm, a showing of delay does not, as a matter of law, preclude a determination of irreparable harm.”¹⁸⁴

There can be many reasons for delay in bringing suit. One reason may be uncertainty about the existence of infringement. Another is hesitation about the cost of bringing suit. One more is reluctance to undermine existing customer and competitor relationships. If present, these considerations tend to rebut any presumption that the patent holder’s delay in bringing suit is indicative of a lack of irreparable harm.

Moreover, at issue is whether there has been *undue* delay in bringing suit. Discovering and evaluating a potential infringement takes time. Bringing suit two days after infringing competition has emerged is quite different from bringing suit two years after infringing competition has emerged.¹⁸⁵ Nevertheless, when analyzing the likelihood of harm in the context of a preliminary injunction determination, the patentee’s delay in bringing suit should weigh against the issuance of a preliminary injunction, absent there being reasonable explanations for the delay and assuming something more than a nominal amount of delay.

Courts in trademark cases, at least prior to the Trademark Modernization Act’s 2020 statutory presumption of irreparable harm,¹⁸⁶ regularly denied preliminary injunctions in cases in which there had been even a short delay in bringing suit or requesting injunctive relief.¹⁸⁷ This trend in trademark cases may be due to the perception that detection of trademark infringement may be easier than detection of patent infringement and also due to the imminency and depth of the likely harm. In any event, the presumption of irreparable harm under the Trademark Modernization Act

¹⁸⁴ *MacDermid Enthone, Inc. v. BASF Corp.*, No. 1:15-CV-00233-TJM-DEP, at 47 (N.D.N.Y. Feb. 26, 2018), https://www.govinfo.gov/content/pkg/USCOURTS-nynd-1_15-cv-00233/pdf/USCOURTS-nynd-1_15-cv-00233-1.pdf.

¹⁸⁵ *See, e.g.*, *Smith & Nephew, Inc. v. Biomet, Inc.*, No. 05-611-KI, 2005 U.S. Dist. LEXIS 31723, at *51 (D. Or. Nov. 21, 2005) (“At most a six-month delay, Smith & Nephew did not unduly drag its feet in bringing this lawsuit.”); *Peng v. The P’ships*, No. 21-CV-1344, 2021 U.S. Dist. LEXIS 174254, at *8–9 (N.D. Ill. Sep. 14, 2021) (holding a delay of six months, which is only one factor to consider, not viewed to be “extreme” in light of the facts of the case).

¹⁸⁶ *See supra* notes 134–140 and accompanying text.

¹⁸⁷ *See, e.g.*, Sandra Edelman & Fara S. Sunderji, *Delay in Filing Preliminary Injunction Motions: 2015 Edition*, 105 TRADEMARK REP. 1012, 1015 (2015) (finding that, in trademark cases decided between 2009–2015, “a delay of three months or fewer will not impede the grant of a preliminary injunction motion; many cases with a delay of four to six months resulted in a denial of relief, sometimes on grounds relating to the likelihood of success on the merits, rather than delay . . . [and in] the seven-to twelve-month time period, there were about as many cases granting the motion as denying it”); *Wreal, LLC v. Amazon.com*, 840 F.3d 1244, 1248 (11th Cir. 2016) (holding five-month delay “fatally undermined any showing of irreparable injury”); *Smart Vent Prods. v. Crawl Space Door Sys.*, No. 13-5691 (JBS/KMW), 2016 U.S. Dist. LEXIS 108052, at *35–36 (D.N.J. Aug. 16, 2016) (holding delay of two to seven months “knocks the bottom out of any claim of immediate and irreparable harm”).

does not apply in patent cases.

d. Willingness to License

A final consideration bearing on the likelihood of harm is the willingness of the patent owner to grant licenses to its patents in exchange for monetary compensation, which also falls in the category of Indicia of Harm, as described above.¹⁸⁸ If the patent owner has willingly allowed, even encouraged, market entry in the past, some courts have deemed this as evidence of a lack of competitive harm, or certainly the lack of irreparable harm. These patents may not be “priceless.”¹⁸⁹ Such evidence is sometimes deemed to be particularly relevant when the moving party is primarily in the licensing business.¹⁹⁰

While not directly relevant to the analysis of preliminary injunctions, commentators analyzing issuances of permanent injunctions have concluded that the first and second *eBay* factors—irreparable harm and the adequacy of monetary damages to remedy the harm—have effectively merged into a single factor. That is, irreparable harm in the permanent injunction context is often equated with the inadequacy of monetary damages.¹⁹¹ Courts have not gone so far in the context of preliminary injunctions. As noted above, the willingness of a patentee to license its patents in exchange for monetary compensation has been found to indicate that harm may not be irreparable, but this fact is not dispositive.

The fact that a patent owner has willingly granted licenses in the past does not mean that all forms of licenses are acceptable to it in the future or that all licenses would lead to the same amount of harm. Infringement has caused the patent owner to lose control over its licensing program.¹⁹² Moreover, the patent owner may never have

¹⁸⁸ See, e.g., *Celgard, LLC v. LG Chem, Ltd.*, 624 F. App'x 748, 754 (Fed. Cir. 2015); *Apple Inc. v. Samsung Elecs. Co. (Apple III)*, 735 F.3d 1352, 1368–69 (Fed. Cir. 2013); *Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683 (Fed. Cir. 1990). But see, e.g., *Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1328 (Fed. Cir. 2008) (upholding the grant of a permanent injunction on grounds that “[t]he fact of the grant of previous licenses, the identity of the past licensees, the experience in the market since the licenses were granted, and the identity of the new infringer all may affect the district court’s discretionary decision concerning whether a reasonable royalty from an infringer constitutes damages adequate to compensate for the infringement. The district court here weighed these factors and determined, . . . that money damages constituted adequate compensation only for Stryker’s past infringement and that no adequate remedy at law existed for Stryker’s future infringement”)

¹⁸⁹ *Apple III*, 735 F.3d at 1369–70.

¹⁹⁰ See, e.g., *Apple Inc. v. Samsung Elecs. Co. (Apple IV)*, 809 F.3d 633, 650 (Fed. Cir. 2015).

¹⁹¹ See *Gergen et al.*, *supra* note 4, at 209 (“The *eBay* test omits success as a factor and instead doubles up on irreparable injury. The test’s requirements of (1) irreparable injury and (2) inadequacy of legal remedies are redundant as these are, traditionally speg, one and the same.”); *Lemley*, *supra* note 137, at 1802 (“An ‘irreparable’ injury is one that cannot be undone or uncompensated for. If money damages are an adequate legal remedy, the injury is not irreparable—it can be repaired. . . . [I]n practice the two factors tend to stand or fall together . . .”).

¹⁹² See, e.g., *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1381 (Fed. Cir. 2005) (granting a narrow, exclusive license did not require the district court to find that any harm would not be irreparable); *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 976 (Fed. Cir. 1996) (“By entering into an exclusive license agreement, Polymer has manifested a strong interest in maintaining an exclusive

wanted to license the alleged infringer, or any similarly-situated entity.

In fact, in *eBay*, the Supreme Court wrote that a patent owner may have willingly licensed its patents in the past, but “traditional equitable principles do not permit” broadly classifying that as defeating a claim for irreparable harm.¹⁹³ According to the Court, “some patent holders, such as university researchers or self-made inventors, might reasonably prefer to license their patents . . . Such patent holders may be able to satisfy the traditional four factor test and we see no basis for categorically denying them the opportunity to do so.”¹⁹⁴

Hovenkamp and Cotter have argued that, as reflected in the Federal Circuit’s opinion in *Trebro*, the inability of a patent holder to exclude competition by deliberately idling its patent should be viewed as a cognizable harm.¹⁹⁵ In a preliminary injunction analysis, on balance, a patent holder’s willingness to license its patents for monetary compensation in the past should weigh against the issuance of a preliminary injunction unless the patent holder can show why the infringer should be treated differently than prior licensees. A patent holder’s unwillingness to license the alleged infringer, much less any party, should weigh in favor of a preliminary injunction.

3. Causation (Causal Nexus)

The third prong of our proposed irreparable harm test is a determination of whether the alleged harm flows from, or is causally linked to, the alleged infringement. To show irreparable harm, it is necessary to show that the infringement, and not exclusively other events or factors, will cause the harm.¹⁹⁶ That is, a connection or “causal nexus” must exist between the infringing behavior and the harm to the patent holder.

For many years, this inquiry was of minimal significance in requests for preliminary injunctive relief. Some of that limited attention is likely due to the fact that, for generations, patents either have been, or have been presumed to be, at the core of practicing products. Only in recent years has patent litigation centered on multi-component and multi-feature products, in which the infringing element may make only a small or negligible contribution to the whole.¹⁹⁷

position in the relevant market.”); *Jacobson v. Cox Paving Co.*, No. 89-1786 PHX PGR, 1991 U.S. Dist. LEXIS 17787, at *44 (D. Ariz. May 16, 1991) (noting that infringement may “interfere with the plaintiff’s ability to control the use and licensing of the patented technology”), *aff’d*, 949 F.2d 404 (Fed. Cir. 1991).

¹⁹³ *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393 (2006).

¹⁹⁴ *Id.*

¹⁹⁵ Erik Hovenkamp & Thomas Cotter, *Anticompetitive Patent Injunctions*, 100 MINN. L. REV. 871, 906–09 (2016).

¹⁹⁶ *Apple Inc. v. Samsung Electronics Co. (Apple I)*, 678 F.3d 1314, 1324 (Fed. Cir. 2012).

¹⁹⁷ *See, e.g., Apple Inc. v. Samsung Elecs. Co. (Apple III)*, 735 F.3d 1352, 1362 (Fed. Cir. 2013) (“[S]ome of the cases involved relatively simple products—at least in the sense that they had a small number of features when compared to the complex, multi-featured smartphones and tablets at issue in this case. Those products included windshield wiper blades (*Bosch*), orthopedic nails used to treat fractures of the upper arm bone (*Acumed*), and broadband capacitors used in electrical systems

But in the patent infringement cases between Apple and Samsung, the Federal Circuit established that in order to prove irreparable harm, a patent owner must show a sufficiently strong nexus between the alleged infringement and the alleged harm.¹⁹⁸ The Federal Circuit explained that “it is necessary [in order prove the existence of irreparable harm] to show that infringement caused harm in the first place. Sales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature.”¹⁹⁹ Recoverable harm does not exist, much less harm that is irreparable, if “sales would be lost even if the offending feature were absent from the accused product.”²⁰⁰ If “the accused product would sell almost as well without incorporating the patented feature,” the infringement injures the patentee only insubstantially even if the accused product’s sales cause substantial damage commercially.²⁰¹

The Federal Circuit in the *Apple v. Samsung* cases may have had in mind the concurrence of Justice Kennedy in *eBay*.²⁰² He wrote that,

When the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest.²⁰³

In its decisions in *Apple v. Samsung*, and since then, the Federal Circuit has imposed the requirement in assessing irreparable harm that the patented feature be shown to drive consumer demand for the practicing product.²⁰⁴ Some commentators have concluded, however, that the level of necessary proof has been left somewhat ill-defined by the Federal Circuit.²⁰⁵

In *Apple I*, the court wrote that “[a] mere showing that Apple might lose some insubstantial market share as a result of Samsung’s infringement is not enough.”²⁰⁶ The court wrote that evidence that Samsung believed it important to incorporate the

(*Presidio*). In those cases, the impact that the infringing features had on demand for the products may never have been in doubt.”)

¹⁹⁸ See generally *Apple Inc. v. Samsung Elecs. Co. (Apple IV)*, 809 F.3d 633 (Fed. Cir. 2015); *Apple Inc. v. Samsung Elecs. Co. (Apple III)*, 735 F.3d 1352 (Fed. Cir. 2013); *Apple, Inc. v. Samsung Elecs. Co. (Apple II)*, 695 F.3d 1370 (Fed. Cir. 2012); *Apple Inc. v. Samsung Elecs. Co. (Apple I)*, 678 F.3d 1314 (Fed. Cir. 2012).

¹⁹⁹ *Apple I*, 678 F.3d at 1324.

²⁰⁰ *Id.*

²⁰¹ *Apple II*, 695 F.3d at 1374–75; see also *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 873 (Fed. Cir. 2017).

²⁰² *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 395–97 (2006) (Kennedy, J., concurring).

²⁰³ *Id.* at 396–97.

²⁰⁴ See, e.g., *Genband US LLC v. Metaswitch Networks Corp.*, 861 F.3d 1378, 1383 (Fed. Cir. 2017).

²⁰⁵ See, e.g., Steven M. Amundson, *Federal Circuit Decisions Concerning Smartphones Have Created Uncertainty Regarding the Evidence Needed to Prove Irreparable Harm and Establish Entitlement to Injunctive Relief*, 42 RUTGERS COMPUTER & TECH. L.J. 231, 243–44 (2016).

²⁰⁶ *Apple Inc. v. Samsung Elecs. Co. (Apple I)*, 678 F.3d 1314, 1324–25 (Fed. Cir. 2012) (addressing Apple’s request for a preliminary injunction in a case involving infringement claims covering Apple design patents).

patented feature was “relevant” but “not dispositive . . . because the relevant inquiry focuses on the objective reasons as to why the patentee lost sales, not on the infringer’s subjective beliefs as to why it gained them (or would be likely to gain them).”²⁰⁷

In *Apple II*, the Federal Circuit explained that the causal nexus analysis “is not a true or false inquiry,” but should assess the extent to which “the harm resulting from selling the accused product can be ascribed to the infringement.”²⁰⁸ It went on to write that “it is not enough for the patentee to establish some insubstantial connection,” but instead it must demonstrate “that a sufficiently strong causal nexus relates the alleged harm to the alleged infringement.”²⁰⁹ The court then noted that the “causal nexus requirement is not satisfied simply because removing an allegedly infringing component would leave a particular feature, application, or device less valued or inoperable.”²¹⁰ “The patentee must . . . show that the infringing feature drives consumer demand for the accused product.”²¹¹

In *Apple III*, the Federal Circuit wrote that “[t]he reasoning in *Apple I* and *Apple II* reflects general tort principles of causation and applies equally to the preliminary and permanent injunction contexts.”²¹² The court was explicit in writing that “the causal nexus requirement is part of the irreparable harm factor,” and that “[w]ithout a showing of causal nexus, there is no relevant irreparable harm.”²¹³ The court noted that without a causal nexus, “it is reasonable to conclude that a patentee will suffer the same harm with or without an injunction.”²¹⁴ According to the court, the harm caused by infringement is “the only harm that should count.”²¹⁵

The Federal Circuit criticized the district court for “appear[ing] to have required” that Apple prove that a patented feature is the “sole” reason why consumers purchase the infringing devices.²¹⁶ It explained that a patentee may establish a causal nexus without evidence that a patented feature is the “exclusive” or “one and only” reason for consumer demand.²¹⁷ Instead, a patentee only needs to show “some connection” between a patented feature and consumer demand.²¹⁸

According to the Federal Circuit in *Apple III*, a patentee can satisfy the causal

²⁰⁷ *Id.* at 1328.

²⁰⁸ *Apple Inc. v. Samsung Elecs. Co. (Apple II)*, 695 F.3d 1370, 1375 (Fed. Cir. 2012) (addressing Samsung’s appeal from the grant of a preliminary injunction).

²⁰⁹ *Id.* at 1374–75.

²¹⁰ *Id.* at 1376.

²¹¹ *Id.* at 1375.

²¹² *Apple Inc. v. Samsung Elecs. Co. (Apple III)*, 735 F.3d 1352, 1361 (Fed. Cir. 2013) (addressing Apple’s appeal from the lower court’s refusal to grant a permanent injunction).

²¹³ *Id.* at 1363.

²¹⁴ *Id.*

²¹⁵ *Id.* at 1361 (quoting *Apple II*, 693 F.3d at 1375).

²¹⁶ *Id.* at 1364.

²¹⁷ *Id.*

²¹⁸ *Id.*

nexus requirement in “a variety of ways,” including showing:

- “a patented feature is one of several features that cause consumers to make their purchasing decisions”;
- “the inclusion of a patented feature makes a product significantly more desirable”; or
- “the absence of a patented feature would make a product significantly less desirable.”²¹⁹

In *Apple IV*, the Federal Circuit wrote that the causal nexus requirement must be satisfied by the moving party regardless of whether the requested injunction covers an entire product or is narrowly limited to particular features.²²⁰ Moreover, the court found that it was error for the district court to require proof that the infringement was the “sole,” “exclusive,” or “predominant” reason for the harm.²²¹ A showing of “some connection” is all that is required,²²² including proof that the patents were important or that customers sought out the patented features.²²³

The Federal Circuit’s conclusions as to the importance of a showing of causal nexus make eminent economic sense. In fact, causal nexus should be treated here just as it is treated in patent damages cases.²²⁴ It is at the core of determining whether there has been harm due to the infringement and the degree of that harm. It should be treated similarly in determining whether there has been irreparable harm in injunction cases. Harm that should be evaluated here, as in a damages case, is harm that flows from the alleged infringement. It is not harm from competition.

In some cases, proving (or disproving) causal nexus is fairly straightforward. The Federal Circuit in *Celgard, LLC v. LG Chem, Ltd.* (2015) found that the harm asserted clearly did not flow from the alleged infringement. It flowed from the alleged infringer’s decision to no longer purchase products from the patent owner for reasons unrelated to the patent.²²⁵

In most cases, proving (or disproving) causal nexus is much more difficult. In *Genband US LLC v. Metaswitch Networks Corp.* (2017), the Federal Circuit reiterated that in the context of a large product or system, it is not necessary for the

²¹⁹ *Id.*

²²⁰ *Apple Inc. v. Samsung Elecs. Co. (Apple IV)*, 809 F.3d 633, 640 (Fed. Cir. 2015) (addressing Apple’s appeal from the lower court’s refusal to grant it a permanent injunction).

²²¹ *Id.* at 641–42.

²²² *Id.*

²²³ *Id.*

²²⁴ 1 IP STRATEGY, VALUATION, AND DAMAGES § 4.02 (2021) (analyzing that patent damages requires “evaluation of the causal nexus between infringement and any economic harm”); *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869 (Fed. Cir. 2010) (“At all times, the damages inquiry must concentrate on compensation for the economic harm *caused by infringement* of the claimed invention.” (emphasis added)).

²²⁵ *Celgard, LLC v. LG Chem, Ltd.*, 624 F. App’x 748, 752–53 (Fed. Cir. 2015).

infringing feature to be the sole driver of demand to prove entitlement to injunctive relief.²²⁶ When the patentee relies on lost sales to show irreparable harm, the causal nexus can be established by showing the infringing features significantly increased the product’s desirability, or that they impact purchasing decisions.²²⁷ It found unconvincing, however, three forms of lost sales evidence offered by the moving party: (1) a won-loss report, (2) correlations between the infringer’s press releases and the decline in the moving party’s market share, and (3) infringer marketing materials and the moving party’s executive opinion testimony.²²⁸ It went on, “[i]f all but an insignificant number of purchases from the infringer would have been made even without the infringing feature, the causal connection to the asserted lost-sale-based injury is missing.”²²⁹ It wrote,

The standard prescribed by *Apple III* and *Apple IV*, as appropriate to the multi-purchaser, multi-component context, lies between the unduly stringent “sole reason” standard we rejected in *Apple III* and *Apple IV* and the unduly lax “insubstantial connection” standard we rejected in *Apple II*.²³⁰

But it wrote that it was for the district court to properly apply that “test.”²³¹

Patent damages law provides, at best, uncertain guidance as to the Federal Circuit’s views on causal nexus. In reasonable royalty cases, it appears that the selling price of the end product can be used as the royalty base if the patent is shown to create the basis for customer demand or substantially create the value of the component parts.²³² In lost profits cases, however, it appears that recovery is allowed when a patent reading on a component causes the patentee to lose sales even though the patent does not confer the end product’s entire market value.²³³

The Federal Circuit’s guidance as to what constitutes sufficient causal nexus in preliminary injunction cases, and perhaps damages cases, likely demands further clarification. While there may be an abundance of factual disputes in cases up until that point, and very likely even after, these disputes are worth analyzing.²³⁴ Disputes surrounding the right issues (here, the causal nexus requirement) are certainly more productive and lead to better and more certain law than do disputes surrounding what the required issues are.

In spite of the challenges of proving causal nexus, there is little dispute as to its significance, particularly of late. As shown in Figure 12 below, our data reveal that,

²²⁶ *Genband US LLC v. Metaswitch Networks Corp.*, 861 F.3d 1378, 1383–85 (Fed. Cir. 2017).

²²⁷ *Id.*

²²⁸ *Id.* at 1380–81.

²²⁹ *Id.* at 1384.

²³⁰ *Id.*

²³¹ *Id.* at 1385.

²³² *See Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1318 (Fed. Cir. 2011).

²³³ *See, e.g., Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275 (Fed. Cir. 2017) (allowing recovery so long as the patentee establishes the four factors of the Panduit test).

²³⁴ *See Celgard, LLC v. LG Chem, Ltd.*, 624 F. App’x 748, 752–53 (Fed. Cir. 2015) (analyzing three of the four fact-based factors required to receive a preliminary injunction).

from 2013 through 2020, when a court granted a preliminary injunction in a patent case and made a finding on causal nexus, the patent owner proved causal nexus 100% of the time (17 out of 17 cases).²³⁵ Conversely, when an injunction was denied, the patent owner failed to prove causal nexus 87.5% of the time (35 cases out of 40 cases).²³⁶ Because there were many cases in which no explicit finding on causal nexus was made, it is hard to conclude that the consideration is dispositive, but it is certainly critical to many courts.

Figure 12
Causal Nexus Rulings and Motion Outcomes

Causal Nexus Ruling	Denied Motions								
	2013	2014	2015	2016	2017	2018	2019	2020	Total
Finding of Causal Nexus	-	-	-	2	1	1	1	-	5
No Finding of Causal Nexus	4	4	6	3	4	8	4	2	35
Neutral	-	1	-	1	-	-	-	-	2
N/A	15	22	12	12	16	16	11	6	110
Total	19	27	18	18	21	25	16	8	152

Causal Nexus Ruling	Granted Motions								
	2013	2014	2015	2016	2017	2018	2019	2020	Total
Finding of Causal Nexus	2	4	2	-	2	1	4	2	17
No Finding of Causal Nexus	-	-	-	-	-	-	-	-	-
Neutral	-	-	-	-	-	-	-	-	-
N/A	2	7	7	8	6	7	3	2	42
Total	4	11	9	8	8	8	7	4	59

4. Award of Adequate Compensation

While a sensible and practical economic test for a preliminary injunction requires that the patent owner prove the existence and imminency of harm and its causal nexus to the alleged infringement, it also requires proof that those harms, or some subset of them, not be adequately quantifiable and recoverable.²³⁷ In other words, an assessment must be made of the reliability or unreliability of adequately assessing the difference between the patent owner's But-For World and its Actual World and the practicalities of payment.

²³⁵ See, e.g., *Veeco Instruments Inc. v. SGL Carbon, LLC*, No. 17-CV-2217 (PKC), 2017 U.S. Dist. LEXIS 181935, at *83 (E.D.N.Y. Nov. 2, 2017); *Cordelia Lighting, Inc. v. Zhejiang Yankon Grp. Co. Ltd.*, No. EDCV 14-881 JGB (SPx), 2015 U.S. Dist. LEXIS 189725, at *27 (C.D. Cal. Apr. 27, 2015).

²³⁶ See, e.g., *Ethicon Endo-Surgery, Inc. v. Covidien LP*, No. 16-12556-LTS, 2017 U.S. Dist. LEXIS 163269, at *22–23 (D. Mass. Oct. 2, 2017); *TeleSign Corp. v. Twilio, Inc.*, No. CV 15-3240 PSG (SSx), 2015 U.S. Dist. LEXIS 193355, at *18, *22 (C.D. Cal. Oct. 19, 2015).

²³⁷ *LEGO v. ZURU Inc.*, 799 F. App'x 823, 833 (Fed. Cir. 2020) (“Where the injury cannot be quantified, no amount of money damages is calculable, and therefore the harm cannot be adequately compensated and is irreparable.” (citing *Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358 (Fed. Cir. 2017))); *Broadcom Corp. v. Qualcomm, Inc.*, 543 F.3d 683, 703 (Fed. Cir. 2008) (“[D]ifficulty in estimating monetary damages reinforces the inadequacy of a remedy at law.”).

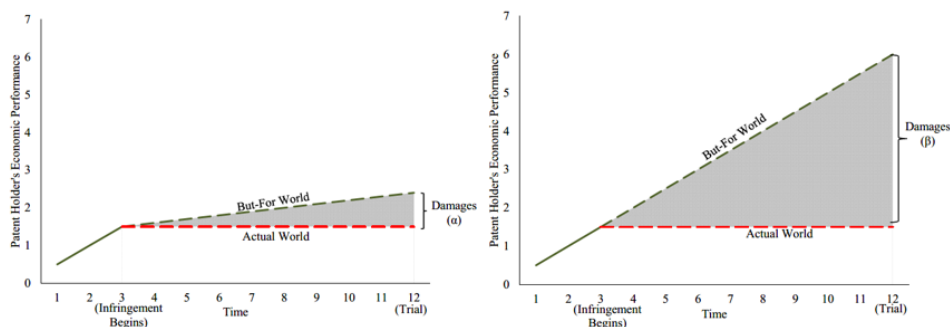
There are at least three potential impediments to adequately assessing the potential harm associated with patent infringement: (1) determining whether the But-For World can be reasonably estimated; (2) determining whether, and the extent to which, future harms may occur; and (3) determining whether the harm in the case at hand is a type that can be reasonably quantified. Though these impediments certainly do not exist in every case, one or more of them, depending on the facts of any individual case, may make the harm not adequately quantifiable.

It is important to note that, as of the point of a merits trial, it will be known how the patent owner performed in the face of infringement. Referring to Figure 11, at the point of a merits trial, the Actual World will be known. Whether the Actual World slope is upward-pointing after the point of the first alleged infringement (perhaps because of aggressive efforts by the patent owner to retain and expand its business in the face of infringing activity) or is downward-sloping (perhaps because of the impacts of the COVID-19 pandemic), the Actual World up to the point of trial is taken as given. The challenge is to assess the degree to which the But-For World would have differed from the Actual World only owing to the impacts of infringement. The degree of difficulty in assessing that difference determines whether the infringement harm can be quantified, which subsequently affects whether that harm may be repairable at a later trial or not.

a. But-For World Uncertainties

Assessing the contours of the But-For World can be challenging. As reflected in Figure 13, though the Actual World will be known as of the point of trial, the But-For World may fall within a wide range. The wider the range, the less precise the estimate of and confidence in any quantification of damages.

Figure 13
Uncertainties in But-For Calculations



Sometimes the patent owner's product that will be harmed is a new product in a new area. Modeling the success that this product would have had, absent the

introduction of the infringing product, can be quite difficult. Often, there is no appreciable history or analog upon which to base a model. Uber is emblematic of this phenomenon. Though some estimates projected 2013 revenues of around \$125 million,²³⁸ Uber's annualized 2013 revenues were \$1 billion.²³⁹ It is no surprise that courts sometimes hesitate to award damages to new or unestablished businesses.²⁴⁰ But sometimes they do.²⁴¹

Sometimes the product that will be harmed is a new product in an existing area. Modeling the likely, or but-for, success of this kind of product can also be challenging. The Apple iPhone is a good example, as it transformed the cell phone marketplace.²⁴² Prior to its introduction in 2007, the securities analysis firm American Technology Research estimated that iPhone unit sales would top out at \$250,000 in year one. Credit Suisse estimated that iPhone unit sales would reach \$1.7 million in year one.²⁴³ Actual sales in 2007 were \$1.4 million and in 2018 were \$217.7 million.²⁴⁴ As with Uber, many predictions about the iPhone were, *ex ante*, very wrong. It is no surprise that courts sometimes hesitate to award damages for new products in existing businesses (and improved products in existing businesses).²⁴⁵ But sometimes they

²³⁸ Kara Swisher, *Uber Filing in Delaware Shows TPG Investment at \$3.5 Billion Valuation; Google Ventures Also In*, ALLTHINGS (Aug. 22, 2013, 2:43 PM), <http://allthingsd.com/20130822/uber-filing-in-delaware-shows-tpg-investment-at-3-5-billion-valuation-google-ventures-also-in/>.

²³⁹ Alyson Shontell, *Leaked: Internal Uber Deck Reveals Staggering Revenue and Growth Metrics*, BUSINESS INSIDER, (November 20, 2014, 4:58 PM), <https://www.businessinsider.com/uber-revenue-rides-drivers-and-fares-2014-11>.

²⁴⁰ See, e.g., Bernadette J. Bollas, *The New Business Rule and the Denial of Lost Profits*, 48 OHIO ST. L.J. 855, 855 (1987) (discussing the New Business Rule, which did not allow new or unestablished businesses to recover lost profits “because absent a history of past profits, future profits are too ‘uncertain, contingent, and speculative’”).

²⁴¹ See generally Todd R. Smyth, Annotation, *Recovery of Anticipated Lost Profits of New Business: Post-1965 Cases*, 55 A.L.R. 4th 507 (1987); 11 CORBIN ON CONTRACTS § 56.17, n.2 (2022) (“Recent cases have eroded the once generally accepted rule against awarding damages for lost profits to a new business. The modern trend is to allow recovery for such lost profits if they can be proven with reasonable certainty.”).

²⁴² Kif Leswing, *The iPhone Decade: How Apple's Phone Created and Destroyed Industries and Changed the World*, CNBC (December 16, 2019, 8:09 AM), <https://www.cnbc.com/2019/12/16/apples-iphone-created-industries-and-changed-the-world-this-decade.html>.

²⁴³ See *Analysts' Estimates for Apple iPhone Unit Sales for 2007 and 2008 Run Wide Gamut*, MACDAILYNEWS, (June 25, 2007), https://macdailynews.com/2007/06/25/analysts_estimates_for_apple_iphone_unit_sales_for_2007_and_2008/.

²⁴⁴ See *Unit Sales of the Apple iPhone Worldwide from 2007 to 2018*, STATISTA (Jul 27, 2022), <https://www.statista.com/statistics/276306/global-apple-iphone-sales-since-fiscal-year-2007/>.

²⁴⁵ See, e.g., *Kinesoft Development Corp. v. Softbank Holdings Inc.*, 139 F. Supp. 2d 869, 908 (N.D. Ill. 2001) (“[A] new business, or an existing business with a new product, cannot recover lost profits because the future profits of a new business cannot be ascertained with any degree of certainty.”); *Scheduled Airlines Traffic Offices, Inc. v. Objective, Inc.*, 180 F.3d 583, 588 (4th Cir. 1999) (“The software product was newly developed, so there was no predecessor product on which to predicate a reasonably certain estimate of lost profits.”); *Apple Inc. v. Samsung Elecs. Co.*, No. 12-CV-0630-LHK (PSG), 2013 U.S. Dist. LEXIS 116493, at *31 (N.D. Cal. 2013) (“Different generations of iPhone products . . . are almost guaranteed to have different profit margins.”); *Dictiomatic, Inc. v.*

do.²⁴⁶

Whether dealing with a new product in a new area or a new product in an existing area, estimating product success can be a subject of great uncertainty. It often takes significant effort to commercialize a new technology.²⁴⁷ The dynamics of changes in technology, combined with shifting consumer sentiment, can make predicting marketplace outcomes extremely difficult.²⁴⁸ A study conducted by McKinsey & Co. in 2013 found that, of the 1,700 analyst forecasts of new drug launches between 2002 and 2011, more than 60% were off by more than 40%.²⁴⁹ Once drugs were launched, sales forecast errors remained as high as 45% even six years after launch.²⁵⁰ While courts sometimes hesitate to award damages for improved products in existing businesses,²⁵¹ they sometimes do.²⁵² Likewise, while courts sometimes hesitate to award

United States Fid. & Guar. Co., 958 F. Supp. 594, 606 (S.D. Fla. 1997) (finding that a history of successful sales of hand-held electronic translators did not establish lost profits for subsequent models “because the latter products were not sufficiently similar and did not attract a comparable market”).

²⁴⁶ See, e.g., *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1063 (Fed. Cir. 2016); *Astrazeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1338–40 (Fed. Cir. 2015) (finding damages proper when “product was previously unknown in the art and was novel in its own right”); *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, No. 4-86-359, 1991 U.S. Dist. LEXIS 11451, at *204 (D. Minn. Apr. 30, 1991) (damages warranted for new product in synthetic cast industry); *i4i Ltd. P’ship v. Microsoft Corp.*, 598 F.3d 831, 839 (Fed. Cir. 2010); *Bose Corp. v. JBL, Inc.*, 274 F.3d 1354, 1361 (Fed. Cir. 2001).

²⁴⁷ Gina Colarelli O’Connor & Mark P. Rice, *New Market Creation for Breakthrough Innovations: Enabling and Constraining Mechanisms*, 30 J. PRODUCT INNOVATION MANAGEMENT 209, 210 (2013).

²⁴⁸ Jan-Michael Ross & Jan Hendrik Fisch, *How to Launch Products in Uncertain Markets*, 60 MIT SLOAN MANAGEMENT REV. 61, 61 (2018).

²⁴⁹ Myoung Cha et al., *Pharmaceutical Forecasting: Throwing Darts?*, 12 NATURE REVIEWS DRUG DISCOVERY 737, 737 (2013).

²⁵⁰ *Id.*

²⁵¹ See, e.g., *Apple Inc. v. Samsung Elecs. Co.*, No. 12-CV-0630-LHK (PSG), 2013 U.S. Dist. LEXIS 116493, at *31 (N.D. Cal. Aug. 14, 2013) (“Different generations of iPhone products . . . are almost guaranteed to have different profit margins.”); *Dictionomatic, Inc. v. United States Fid. & Guar. Co.*, 958 F. Supp. 594, 606 (finding that a history of successful sales of hand-held electronic translators did not establish lost profits for subsequent models “because the latter products were not sufficiently similar and did not attract a comparable market”).

²⁵² See, e.g., *Astrazeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1340 (Fed. Cir. 2015) (“The district court permissibly found no reason to exclude the value of the active ingredient when calculating damages in this case.”); *i4i Ltd. P’ship v. Microsoft Corp.*, 598 F.3d 831, 839 (Fed. Cir. 2010) (“The district court . . . awarded \$40 million in enhanced damages.”); *Bose Corp. v. JBL, Inc.*, 274 F.3d 1354, 1361 (Fed. Cir. 2001) (affirming the judgment of the district court for enhanced damages based on the new patent).

damages in new technology cases,²⁵³ they sometimes do.²⁵⁴

Sometimes the product that will be harmed is an existing product in an existing area where the product involves very good, but not disruptive, technology. Even in these situations, new and emboldened competition can make modeling the likely but-for success of a product challenging. Many firms, such as those in industries with intensified product life cycles or technological expansion, can be described as being in a hypercompetitive state, which is characterized by turbulence and volatility.²⁵⁵ Advantages that companies can create are often fleeting, and marketplaces can change quickly.²⁵⁶ The advantages that new companies and new products gain often sweep away the advantages that older companies and products formerly held but not always at a predictable pace.

In the end, even though a merits trial may occur years after the first alleged infringement, the difficulties in modeling new marketplaces, new products, new technologies, and new competition can make estimating an infringement But-For World challenging. Those problems are particularly acute in situations where the patent owner is new to the market, or the alleged infringer has substantially upended the market. Impediments to but-for estimation are, by definition, impediments to reasonably quantifying damages due to alleged infringement, but that does not mean that new marketplaces, new products, new technologies, and new competition are inherently incapable of being valued. In short, they are not presumptively subject, or not subject to reasonably accurate quantification.

b. Future World Uncertainties

Assessing the contours of the future world can be challenging. For many years, patent damages analyses rarely focused on the impact of alleged infringement on the future (i.e., post damages trial) But-For World. There usually was an explicit or

²⁵³ See, e.g., *Pharmanetics, Inc. v. Aventis Pharm., Inc.*, 182 F. App'x 267, 273 (4th Cir. 2006) (finding “no clear error in ruling the new technology’s lost sales to be too speculative”); *Trademark Rsch. Corp. v. Maxwell Online, Inc.*, 995 F.2d 326, 333 (2d Cir. 1993) (noting that CD-ROMs were a new product in a transforming market and therefore subject to stricter evidentiary standard for damages); *Hunters Int’l Mfg. Corp. v. Christiana Metals Corp.*, 561 F. Supp. 614, 616 (E.D. Mich. 1982) (noting the challenges in determining lost profits for an “enterprise venturing into a new industry or method”).

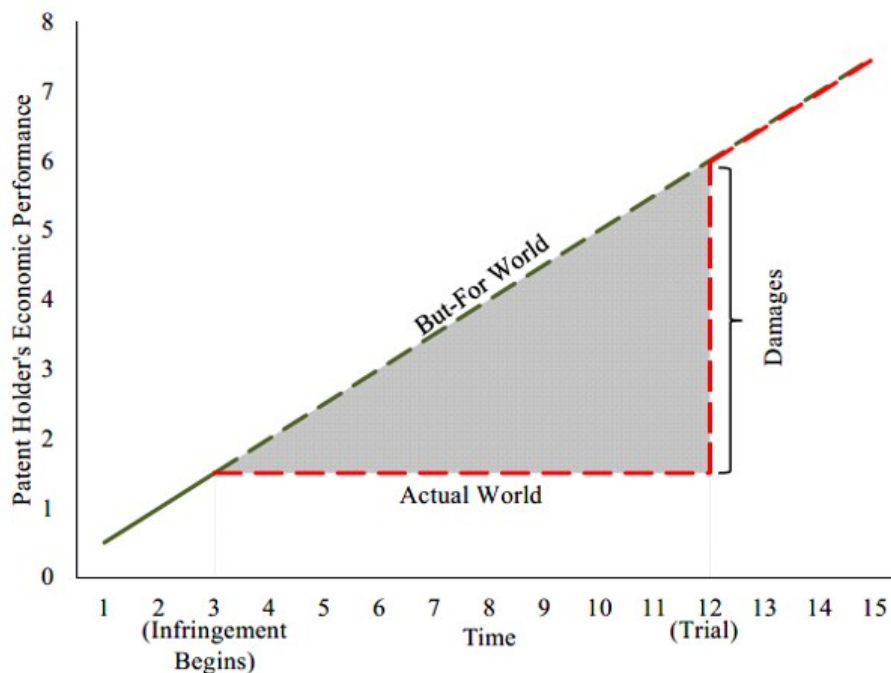
²⁵⁴ See, e.g., *EagleView Techs., Inc. v. Xactware Sols., Inc.*, 485 F. Supp. 3d 505, 511–12, 537 (D.N.J. 2020) (affirming damages award where plaintiff’s invention was “groundbreaking”); *Spectralytics, Inc. v. Cordis Corp.*, 650 F. Supp. 2d 900, 918 (D. Minn. 2009) (“In every new industry, someone has to be the first to demand a use-based royalty.”); *DSC Communic. Corp. v. Next Level Communic.*, 107 F.3d 322, 329 (5th Cir. 1997) (affirming award of profits where plaintiff’s “history of strong performance is indicative of the likely success of this revolutionary new product”); *Polaroid Corp. v. Eastman Kodak Co.*, No. 76-1634-MA, 1990 U.S. Dist. LEXIS 17968, at *1 (D. Mass. 1990) (holding damages proper for novel Polaroid instant camera technology).

²⁵⁵ Alexandra Kriz et al., *The Dynamic Capability of Ambidexterity in Hypercompetition: Qualitative Insights*, 22 J. STRATEGIC MKTG. 287, 288 (2014).

²⁵⁶ Richard A. D’Aveni, *Coping with Hypercompetition: Utilizing the New 7S’s Framework*, 9 ACAD. MGMT. EXEC. 45, 45 (1995); Richard A. D’Aveni, *The Age of Temporary Advantage*, 32 STRATEGIC MGMT. J. 1371, 1371 (2010).

implicit assumption that, upon a finding of liability, an injunction will issue and that, following the injunction, the patent owner's world would, in short order, return to what it would have been had there been no infringement.²⁵⁷ In other words, there often was an assumption that, almost immediately following an injunction, the Actual World and But-For World would be the same and, as a result, there are no future damages. This is illustrated in Figure 14.

Figure 14
Calculation of Past and Future Damages



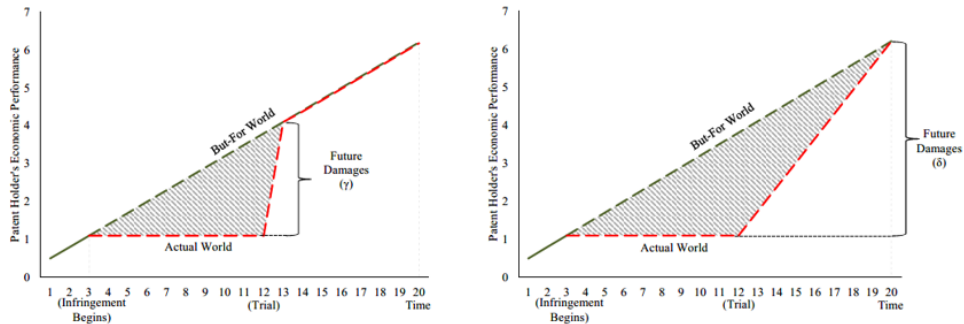
Not only can a permanent injunction no longer be assumed after *eBay*,²⁵⁸ the impacts of infringement on the Actual World, even with a permanent injunction, may linger well beyond the point of trial. As reflected in Figure 15, though the past Actual World will be known as of the point of trial, even assuming a permanent injunction is granted, there can still be some uncertainty regarding whether and how quickly the future Actual World will bounce back from the effects of the infringement. In some

²⁵⁷ See Richard A. D'Aveni, *Coping with Hypercompetition: Utilizing the New 7S's Framework*, 9 ACAD. OF MGMT. EXEC. 45, 48 (1995) (assuming valid patents create a monopoly); see generally Richard A. D'Aveni, *The Age of Temporary Advantage*, 31 STRATEGIC MGMT. J. 1371, 1371–85 (2010) (implying most competitive advantages are temporary, leaving room for sustainable advantages such as patents).

²⁵⁸ See *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391–92 (2006).

cases, the future Actual World could fall within a wide range. The wider the range, the less precise the estimate of and confidence in any quantification of damages.

Figure 15
Uncertainties in Future Actual Calculations



How quickly the Actual World returns to the But-For World following an injunction depends on the type and severity of distortion caused by the infringement and the resulting competition. Some distortions, such as those related to pricing, may continue well beyond the end of the alleged infringement. Depending upon the nature of the market, it may take an extended period for an injured patent holder to be able to return to the but-for trajectory that it would have been on absent the infringement, assuming such a return is even possible. Sometimes such a return may never be possible.

In fact, the Federal Circuit in *Aria Diagnostics, Inc. v. Sequenom* held that, when infringement ends, it is not appropriate to assume that the harm ends.²⁵⁹ It wrote that, while “the facts may show that the damages may be reparable,” an “assumption” as to reparability “is not sufficient.”²⁶⁰

²⁵⁹ *Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1304 (Fed. Cir. 2013).

²⁶⁰ *Id.* (emphasis in original).

c. Measurement Uncertainties

A final impediment to assessing the contours of the infringement But-For World, and ultimately damages, is that many forms of harm can be exceptionally difficult to assess, whether in patent cases or not. That is primarily true for the Input Harms noted above, including harms to reputation, goodwill, R&D, employment, business opportunities, first mover advantage, exclusivity, and perceived value of the patent.

i. Reputation

Harm to reputation can be caused when there is confusion between a patent owner's product and an infringing product.²⁶¹ Such reputational harm was found in *Tinnus Enterprises, LLC v. Telebrands Corp.*²⁶² In that case, the Federal Circuit found "persisting harm" to the patentee's reputation because confusion between the patented product and the infringing product caused the patented product to be "diluted in the minds of the consuming public," and because the infringer's product received better ratings.²⁶³ However, harm to reputation can occur even in the absence of confusion. For example, a company's reputation as an innovator can be damaged if consumers find "the same 'innovations' appearing in competitors' [products], particularly products considered less prestigious and innovative."²⁶⁴

Harm to reputation can be especially devastating in the early stages of a company or a product, as noted by the Federal Circuit in *Celsis In Vitro, Inc. v. CellzDirect, Inc.*²⁶⁵ The court explained that during the growth stages, it is "particularly crucial to be able to distinguish oneself from competitors."²⁶⁶ "This includes building the brand, expanding the customer base, and establishing one's reputation and leadership in the market."²⁶⁷ A preliminary injunction was therefore warranted when the infringement precluded the patentee from marketing itself as the exclusive market leader to potential and existing customers.²⁶⁸

The value of a company's reputation can take many forms. Most notably, a company's reputation may impact how many products the company is able to sell and the prices it is able to charge. These kinds of reputational effects can be difficult to disentangle from the many other factors that affect a company's sales and pricing capabilities. Because quantifying the value of reputation is far from straightforward, quantifying its diminution in value as a result of infringement can be very difficult.

²⁶¹ See, e.g., *Tinnus Enters., LLC v. Telebrands Corp.*, 846 F.3d 1190, 1208 (Fed. Cir. 2017); *Reebok Int'l, Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1558 (Fed. Cir. 1994).

²⁶² *Tinnus Enters.*, 846 F.3d at 1208.

²⁶³ *Id.*; see also *id.* at 1201 ("Bunch O Balloons product had 'been diluted in the minds of the consuming public.' Aside from the consumer confusion, the false association between the products harmed Tinnus because Bunch O Balloons received better ratings than Balloon Bonanza on Amazon.com and ToysRUs.com.").

²⁶⁴ *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344–45 (Fed. Cir. 2013).

²⁶⁵ *Celsis In Vitro, Inc. v. Cellzdirect, Inc.*, 664 F.3d 922, 931 (Fed. Cir. 2012).

²⁶⁶ *Id.*

²⁶⁷ *Id.*

²⁶⁸ *Id.*

ii. *Goodwill*

In patent cases, harm to goodwill frequently is used interchangeably with harm to reputation²⁶⁹ and is almost always used in an informal sense. In *AstraZeneca LP v. Apotex, Inc.*, for example, the Federal Circuit affirmed the grant of a preliminary injunction, finding that AstraZeneca would “suffer incalculable harm to its goodwill” from the launch of defendant’s generic drug.²⁷⁰ The court explained that if the defendant “began distributing its generic drug and was subsequently forced to remove the drug from the market, the resulting confusion among physicians and patients, as well as price changes, would cause unquantifiable harm to AstraZeneca’s goodwill.”²⁷¹

Though formally valuing goodwill can be difficult, valuing it in an informal sense can be even more complicated, as there are not always adequate measures for the types of things that contribute to or reflect goodwill. Moreover, goodwill usually is measured at the corporate level. Quantifiable goodwill rarely is attached to a product line, and a product line often is what is at issue in a patent case.

Because quantifying goodwill is far from straightforward, quantifying its diminution in value as a result of the infringement can be very difficult.

iii. *Research & Development*

Research and development refers to innovative activities undertaken by a company in developing new products or services and improving existing ones.²⁷² Harm to R&D activities was addressed in *Eisai Co., Ltd v. Teva Pharmaceuticals USA, Inc.*, where the defendant was preliminarily enjoined from launching a generic version of the plaintiff’s treatment for Alzheimer’s disease.²⁷³ The district court explained that the patent owner had “organized its business plans in reliance on patent exclusivity” through the patent expiration date.²⁷⁴ Therefore, “research and development projects dependent on [the patented product’s] profits for continued viability are at risk of

²⁶⁹ Laura A. Heymann, *The Law of Reputation and the Interest of the Audience*, 52 B.C. L. REV. 1341, 1355 (2011) (“[R]eputation is often equated to the concept of ‘goodwill,’ although commentators are not agreed on whether this is a precise overlap.”); see also *BlackBerry Ltd. v. Typo Prods. LLC*, No. 14-CV-00023-WHO, 2014 U.S. Dist. LEXIS 42702, at *35 (N.D. Cal. Mar. 28, 2014) (discussing an argument advanced by the patent owner that “because the Typo keyboard is allegedly inferior to the BlackBerry keyboard, the ‘distribution of such an inferior product with the unique design cues intrinsic to BlackBerry will indelibly harm BlackBerry’s goodwill with its customers’”).

²⁷⁰ *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1062 (Fed. Cir. 2010).

²⁷¹ *Id.*; see also *Edge Sys. LLC v. Aguila*, 186 F. Supp. 3d 1330, 1360 (S.D. Fla. 2016) (granting a preliminary injunction and subsequently a permanent injunction, finding that the plaintiff’s goodwill was harmed when it received multiple complaints from potential customers who purchased the defendant’s infringing product on the belief that it was the plaintiff’s skin care device).

²⁷² See Will Kenton, *Research and Development (R&D)*, INVESTOPEDIA (June 19, 2022), <https://www.investopedia.com/terms/r/randd.asp> (“R&D represents the activities companies undertake to innovate and introduce new products and services or to improve their existing offerings.”).

²⁷³ *Eisai Co. v. Teva Pharmaceuticals USA, Inc.*, Nos. 05-5727 (HAA) (ES), 07-5489 (HAA) (ES), 2008 U.S. Dist. LEXIS 33747, *32–33 (D.N.J. Mar. 28, 2008).

²⁷⁴ *Id.*

being short circuited or shut down altogether” if Teva launches a generic version before the patent’s expiration.²⁷⁵ The court further noted that “if there is a reasonable likelihood that research on future drugs . . . will be eliminated, or even reduced or delayed, then the harm is irreparable.”²⁷⁶

Universities and research groups are similarly susceptible to R&D harms, as explained in *Commonwealth Sci. & Indus. Research Organisation v. Buffalo Tech. Inc.*, where the court granted a permanent injunction in large part on grounds of irreparable harm to a Commonwealth Scientific and Industrial Research Organisation (CSIRO) research program:

Having its patents challenged via the courts not only impugns CSIRO’s reputation as a leading scientific research entity but forces it to divert millions of dollars away from research and into litigation costs. Delays in funding result in lost research capabilities, lost opportunities to develop additional research capabilities, and lost opportunities to accelerate existing projects or begin new projects. Once those opportunities have passed, they are often lost for good, as another entity takes advantage of the opportunity. Delays in research are likely to result in important knowledge not being developed at all or CSIRO being pushed out of valuable fields as other research groups achieve critical intellectual property positions.²⁷⁷

Infringing activities or products may have impacts on the patent owner’s R&D activities and its long-run ability to benefit from those activities.²⁷⁸ The value of R&D, separate from the out-of-pocket investments in R&D activities, is rarely undertaken and almost never reported. As a result, it can be difficult to measure the harm associated with forgone R&D projects.²⁷⁹

iv. Employment

Employment refers to a company’s workforce. Infringing activity may lead patent owners to take measures that increase the likelihood that incumbent employees will be demotivated or leave (i.e., benefit cuts or layoffs, among other things) or decrease the likelihood of attracting new employees.

Harm to employment was prominent in *Endo Pharm., Inc. v. Amneal Pharm.*²⁸⁰ There, the district court granted a permanent injunction upon finding that the plaintiff needed to lay off 25% of its pain medication sales force due to infringement of a pain

²⁷⁵ *Id.*

²⁷⁶ *Id.* at *33.

²⁷⁷ *Commonwealth Sci. & Indus. Rsch. Org. v. Buffalo Tech. Inc.*, 492 F. Supp. 2d 600, 604 (E.D. Tex. 2007).

²⁷⁸ *See, e.g., Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1566 (Fed. Cir. 1996). *But see* *Eli Lilly and Co. v. American Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996) (“If a claim of lost opportunity to conduct research were sufficient to compel a finding of irreparable harm, it is hard to imagine any manufacturer with a research and development program that could not make the same claim and thus be equally entitled to preliminary injunctive relief.”).

²⁷⁹ Maria Salgado, *Economics of Irreparable Harm in Pharma Patent Litigation*, LAW360 (November 18, 2013); *see also* Lisa J. Cameron, *Preliminary Injunctions in Pharmaceutical Litigation*, Brattle Group Discussion Paper (2011).

²⁸⁰ *Endo Pharm., Inc. v. Amneal Pharm., LLC*, 2016 U.S. Dist. LEXIS 57420, at *29 (S.D.N.Y. Apr. 29, 2016), *aff’d*, 731 F. App’x 962 (Fed. Cir. 2018).

medication patent.²⁸¹ The Federal Circuit agreed, noting that the layoffs “may damage Endo’s reputation in its market segment and have also made the company less attractive to potential new hires.”²⁸²

Measuring the value of a company’s workforce can be difficult. Moreover, infringement may have a differential impact across the workforce. Some of that impact may be straightforward to counteract upon cessation of infringing activity. Some may have much longer-term impacts.

v. *Business Opportunities/Partnerships*

Harm to business opportunities or partnerships refers to impediments to the creation or further development of projects that otherwise would have grown. In *Veeco Instruments Inc. v. SGL Carbon, LLC*, a manufacturer of semiconductor components argued that the defendant’s infringement would cause a decrease in customer feedback about Veeco’s products, “which will hamper Veeco’s ability to make improvements and modifications that are desired by its customer base.”²⁸³ The court granted a preliminary injunction, agreeing with Veeco that “loss of customer feedback will hamper its ability to continue innovating its . . . designs to remain competitive in the . . . market.”²⁸⁴

Business opportunities or partnerships are rarely monetized. That is because such “assets” are often unknown and sometimes virtually unknowable. In the real world, companies are not valued based on hypothesized opportunities or partnerships that might occur in the future. Because quantifying business opportunities or partnerships is far from straightforward, quantifying their diminution in value can be very difficult.

vi. *First Mover Advantage*

A first mover advantage can be thought of as a firm’s benefits from being the first to market a new product or service.²⁸⁵ Among other things, the advantage flows from perceptions of technology leadership, the ability to control strategic and scarce resources, and the existence of buyer switching costs.²⁸⁶ A patented invention can

²⁸¹ *Id.*

²⁸² *Id.* at *32; *see also* *Trebro Mfg., Inc. v. Firefly Equipment, LLC*, 748 F.3d 1159, 1170 (Fed. Cir. 2014) (finding irreparable harm and granting a preliminary injunction where the loss of sales would lead to layoffs for the patentee, a company with 18 employees).

²⁸³ *Veeco Instruments Inc. v. SGL Carbon, LLC*, No. 17-CV-2217 (PKC), 2017 U.S. Dist. LEXIS 181935, at *36 (E.D.N.Y. Nov. 2, 2017).

²⁸⁴ *Id.* at *80; *see also* *TruePosition Inc. v. Andrew Corp.*, 568 F. Supp. 2d 500, 532 (D. Del. 2008) (noting the infringing acts impacted plaintiff’s “recognition of being a technology innovator and the first global supplier of the patented technology, and an unquantifiable amount of business opportunities flowing therefrom”).

²⁸⁵ Fernando F. Suarez & Gianvito Lanzolla, *The Half-Truth of First-Mover Advantage*, HARV. BUS. REV. (2005), <https://hbr.org/2005/04/the-half-truth-of-first-mover-advantage>.

²⁸⁶ *Id.*; *see also* *First Mover Advantage*, CORP. FIN. INST. (Oct. 27, 2022), <https://corporatefinanceinstitute.com/resources/knowledge/strategy/first-mover-advantage/>.

result in its owner having a first mover advantage because the patent can and often does discourage competition. Loss of a first mover advantage was prominent in *Bio-Rad v. 10X Genomix*. There, the Federal Circuit upheld the lower court’s grant of a permanent injunction,²⁸⁷ finding that the plaintiff was irreparably harmed by losing its first mover advantage to the alleged infringer:

It is undeniable that Bio-Rad has suffered harm from 10X’s first mover advantage and “sticky” customer relationships. . . . Bio-Rad is being forced to compete with 10X’s products that incorporate the infringing technology. Based on its willful infringement—a finding 10X does not challenge on appeal—10X has established a strong market lead over Bio-Rad. The court also found that, based on 10X’s first mover advantage, Bio-Rad had to increase its marketing costs. Money damages will not be able to compensate Bio-Rad for the harms stemming from 10X’s first mover advantage.²⁸⁸

Besides noting possible harm associated with loss of a first mover advantage, the *Bio-Rad* decision references possible harm related to the loss of “sticky” customer relationships. Sometimes those relationships arise from a first mover advantage; sometimes they do not. Regardless, those harms can be real and long-lasting. But the existence and degree of “stickiness” cannot be presumed.

Because it is difficult to assess whether a particular market or product lends itself to a first mover advantage or “sticky” relationships, and it is difficult to assess the degree and length of those advantages, assessing the costs of the loss of those advantages can be difficult.

vii. Exclusivity

A patent allows its owner to exclude any other party from practicing the claimed invention for a defined period of time. Exclusivity is a powerful right. This was recognized in *Gonza v. Mission Competition Fitness Equipment*, where the court explained that the right to exclude embodies “an ability to protect one’s product and establish a controlling market share” and granted a preliminary injunction to the patent holder.²⁸⁹ Keeping competition out of a market typically enhances the owner’s probability and degree of success. Exclusivity, therefore, is a powerful “incentive to engage in the toils of scientific and technological research.”²⁹⁰

It is important to recognize, however, that a patent does not confer exclusivity as to a market or a product, or even a technology. Exclusivity is granted as to the claims of the patent. The extent to which that right can preclude competition is fact-specific. Exclusivity does not mean that a patent owner is a lawful monopolist in a given product or service market.

²⁸⁷ *Bio-Rad Lab’sys., Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1380 (Fed. Cir. 2020).

²⁸⁸ *Id.* at 1378.

²⁸⁹ *Gonza LLC v. Mission Competition Fitness Equip. LLC*, No. W-21-CV-00771-ADA, 2021 U.S. Dist. LEXIS 229632, at *21 (W.D. Tex. Dec. 1, 2021).

²⁹⁰ *Id.* at *24 (quoting *Smith Int’l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1578 (Fed. Cir. 1983)); *see also* *Novozymes A/S v. Genencor Int’l, Inc.*, 474 F. Supp. 2d 592, 613 (D. Del. 2007) (noting a patentee “has a right, granted by Congress, not to assist its rival with the use of proprietary technology”).

Though exclusivity has its benefits, it may also have drawbacks. A single supplier of a patent-covered product may not be able to develop a market at the rate and to the extent that multiple suppliers might develop the market. Measuring the benefits of exclusivity can be a very difficult task.

viii. *Perceived Value*

Losing the perceived value of a patent can also be a substantial harm to a patent owner. Determining whether that loss is irreparable is driven by specific facts and circumstances. The court in *Anderson v. TOL*, for example, concluded that the plaintiff would suffer “multiple forms of irreparable harm” where the value of the patents was diminished by the infringing products’ poor quality and lower prices of the alleged infringer, and the plaintiff would suffer irreparable harm where continuing infringement “threatened to degrade the value of those Patents to such a degree that other companies might not do business with [the plaintiff] at all.”²⁹¹ In contrast, the court in *Juicero v. iTaste* declined to find irreparable harm where the plaintiff expected to sell its company and claimed that infringement would diminish the value of its patent to a prospective buyer; however, the plaintiff offered no evidence of prospective buyers who wished to practice the patent.²⁹² Furthermore, the fact that the plaintiff’s company was up for sale indicated that monetary damages would be a sufficient remedy.²⁹³

Even without infringement, valuing a patent is not an easy task. There is no agreed-upon method for patent valuation, and assessing the value of a patent is a highly contextual analysis that requires economic, legal, and technical knowledge.²⁹⁴

²⁹¹ *Anderson v. TOL, Inc.*, 927 F. Supp. 2d 475, 487–88 (M.D. Tenn. 2013).

²⁹² *Juicero, Inc. v. iTaste Co.*, No. 17-CV-01921-BLF, 2017 U.S. Dist. LEXIS 171947, at *4–5 (N.D. Cal. Oct. 5, 2017).

²⁹³ *See id.* at *11; *see also* *Finjan, Inc. v. Blue Coat Sys., LLC*, No. 15-CV-03295-BLF, 2016 U.S. Dist. LEXIS 162881, at *19 (N.D. Cal. Nov. 22, 2016) (finding no irreparable harm where patentee “has not offered any specific evidence that the value of its patents have declined (e.g., potential licensees have been less willing to pay the same price for license)”).

²⁹⁴ *See* *Commonwealth Sci. & Indus. Rsch. Org. v. Cisco Sys.*, 809 F.3d 1295, 1301 (Fed. Cir. 2015) (observing that there is “inherent imprecision in patent valuation”); *see also* Dov Solomon and Miriam Bitton, *Intellectual Property Securitization*, 33 *CARDOZO ARTS & ENT L.J.* 125, 171–72 (2015) (“There exist many challenges regarding valuation of IP Despite the growing field of monetization of patents in the form of licensing, litigation, sale, and other methods, there is no agreed-upon method for valuation of patents.”); Andrew J. Maas, *Valuation & Assessment of Intangible Assets, and How the America Invents Act Will Affect Patent Valuations*, 94 *J. PAT. & TRADEMARK OFF. SOC’Y* 300, 328 (2012) (“To derive a meaningful value on intellectual property assets, a full complement of knowledge is required in the technical, legal, and business areas.”); Malcolm T. Meeks & Charles A. Eldering, *Patent Valuation: Aren’t We Forgetting Something? Making the Case for Claims Analysis in Patent Valuation by Proposing a Patent Valuation Method and a Patent-Specific Discount Rate Using the CAPM*, 9 *NW. J. TECH. & INTELL. PROP.* 194, 195–196 (2010) (“No agreed-upon patent valuation technique currently exists. . . . Proper valuation of a patent requires the combination of three specialized disciplines: patent law, technology, and finance.”).

ix. Ecosystem Harms

Though many Output Harms, like lost sales, customers, and market share, may be fairly straightforward to assess and monetize, some forms of Output Harm are more difficult to assess. Arguments about ecosystem harms were prominent in *Apple IV*, where the Federal Circuit recognized that a patentee may suffer harm due to the “ecosystem effect,” where “one company’s customers will continue to buy that company’s products and recommend them to others.”²⁹⁵ In general, an ecosystem can be thought of as a group of interconnected elements.²⁹⁶ In a business setting, it can be thought of as a set of products or business activities that are complementary, or mutually reinforcing. In *Apple IV*, the Federal Circuit explained that in the smartphone and tablet market, “the sale of a single product can have [an effect] on downstream sales of accessories, computers, software applications, and future smartphones and tablets.”²⁹⁷ Furthermore, individual customers within the Apple ecosystem have a “‘network effect,’ by which they advertise Apple’s product to their friends, family, and colleagues.”²⁹⁸ The loss of a single smartphone or tablet customer may therefore have a “far-reaching impact” on Apple’s future revenues, which is difficult to calculate due to its “variable and uncertain nature.” Finding that this difficulty in quantifying ecosystem harms weighed strongly in favor of Apple, the Federal Circuit overturned the district court’s denial of a permanent injunction.²⁹⁹

Identifying the contours of a firm’s ecosystem is difficult and is subject to substantial dispute and change. Because quantifying the ecosystem “asset” is far from straightforward, quantifying its diminution in value can be very difficult.

As noted above, whether considering alleged Output Harms or alleged Input Harms, measuring the value of a patent owner’s assets that may have been impacted by infringement often is not easy. That might suggest that all such harms are inherently irreparable. The measurement difficulties might also suggest, however, that harms to those assets may not be real enough to be cognizable, supporting denial of a preliminary injunction.

Categorical acceptance or rejection of claims of harms that are difficult to

²⁹⁵ *Apple Inc. v. Samsung Elecs. Co. (Apple IV)*, 809 F.3d 633, 641 (Fed. Cir. 2015); *see also* *Simo Holdings, Inc. v. H.K. uCloudlink Network Tech. Ltd.*, 396 F. Supp. 3d 323, 345 (S.D.N.Y. 2019) (“A consumer who has already bought into uCloudlink’s ecosystem, therefore, is unlikely to switch to Skyroam’s, because they would have to buy another hotspot device. Thus, lost customers are likely to stay lost.”); *Metalcraft of Mayville v. Toro Co.*, 848 F.3d 1358, 1368 (Fed. Cir. 2017) (noting that some customers “prefer to purchase an entire line of products from the same manufacturer for consistency”).

²⁹⁶ *See* James F. Moore, *Predators and Prey: A New Ecology of Competition*, 71 HARV. BUS. REV. 75, 76 (1993), <https://hbr.org/1993/05/predators-and-prey-a-new-ecology-of-competition> (“A business ecosystem, like its biological counterpart, gradually moves from a random collection of elements to a more structured community.”).

²⁹⁷ *Apple IV*, 809 F.3d at 645.

²⁹⁸ *Id.*

²⁹⁹ *Id.* at 645, 647.

measure as irreparable is not justified under legal or economic principles. The question to be answered in a preliminary injunction case is not whether there might be harm, not whether the harm might be severe, and not whether the harm could be long-lasting. The question is whether the likely harms are irreparable. Only facts, specifically facts tied to the infringement, can answer that question.

As Figure 7 shows, irreparable harm is often found in those instances in which there is harm to sales, market shares, and prices. Those, not coincidentally, are the types of harms that are often the subject of damages awards. The fact that damages historically have centered on a certain set of harms does not mean that those are the only ways in which infringement can harm a patent holder. In fact, the Federal Circuit has emphasized that patent infringement is a tort,³⁰⁰ and there are many potential forms of recoverable harm that may flow from infringement.³⁰¹ Harm certainly can exist beyond the traditional bounds of calculation and presentation, but facts as to irreparability must be presented and established.

d. Collectability

Even if the harm to an injured patentee can be quantified sufficiently, the patent owner will not be made whole if it is unable to recover a judgment from the infringer. In other words, a paper victory may be no victory at all.

There are several reasons why a future, non-speculative damages award may not make an injured patent owner whole.

i. Timing

Some number of patent owners are either new business ventures or struggling business ventures. For those patent owners who are barely financially viable and will not survive the trial and appeal process, an award of damages at a later merits trial, and subsequent appeal, may simply be too late.

In *BlephEx v. Myco*, for example, the plaintiff successfully argued that it was a small company that had only sold 118 of its patented devices prior to the alleged infringer's market entry and that it would not survive until the scheduled trial date due to losses in sales and price erosion from the infringing product.³⁰² The court granted a preliminary injunction, agreeing that the "[p]laintiff's small business is threatened with extinction if Defendants do not stop their infringing acts because the

³⁰⁰ See, e.g., *Wordtech Sys. v. Integrated Networks Sols., Inc.*, 609 F.3d 1308, 1313 (Fed. Cir. 2010); *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1365 (Fed. Cir. 2008); *Trintec Indus. v. Pedre Promotional Prods.*, 395 F.3d 1275, 1280 (Fed. Cir. 2005).

³⁰¹ See, e.g., *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 2013 U.S. Dist. LEXIS 74243, at *16 (D.N.J. May 14, 2013) ("[T]here are no strict limits as to how the patentee can prove its harm."); *Mars*, 527 F.3d at 1366 ("Despite the broad damages language of § 284, patentees tend to try to fit their damages cases into the 'lost profits' framework or else fall back on the statutory grant of a reasonable royalty.").

³⁰² *BlephEx v. Myco Indus.*, No. 19-13089, 2020 U.S. Dist. LEXIS 186914, at *8, *23 (E.D. Mich. Oct. 8, 2020).

[patented product’s] sales prices will remain depressed.”³⁰³ In *Blackberry v. Typo*, the alleged infringer argued that Blackberry was not irreparably harmed because “it is already struggling and losing market share” for reasons unrelated to the infringement.³⁰⁴ The district court found that argument unconvincing, holding that a finding of no irreparable harm “would prevent struggling companies from obtaining injunctions at the time when they may be the most vulnerable to harm from infringing conduct.”³⁰⁵

ii. *Infringer Creditworthiness*

Sometimes the alleged infringer is not or will not be viable enough to satisfy a judgment.³⁰⁶ That may be particularly true for a new-to-the-business entity that has yet to accumulate sufficient operating funds. As noted by Laycock, “damages are no remedy at all if they cannot be collected”³⁰⁷

In *QBAS v. C Walters Intercoastal*, for example, the court found that the defendant’s financial condition warranted a preliminary injunction to prevent irreparable harm, noting that defendants “have been unable to pay Plaintiffs for past purchases of the patented product, and have made representations to this Court explaining their precarious financial position.”³⁰⁸ The court noted that plaintiffs “would likely be unable to recover an adequate monetary award” and “any potential trial victory by Plaintiffs would be an empty one when remedies are considered”³⁰⁹

The court in *Peng v. The Partnerships* found that a monetary judgment is “likely uncollectable” because the defendants are “individuals and businesses who, upon information and belief, reside in the People’s Republic of China”³¹⁰ The court did not explain either its logic or any of the underlying facts. Nevertheless, harm was found to be irreparable.

VI. Conclusion

The *Winter* four-factor test is the *sine qua non* for obtaining preliminary injunctive relief in patent cases. The first two factors—likelihood of success on the merits and likely irreparable harm—have proven to be the most important of the four essential factors.

³⁰³ *Id.* at *22.

³⁰⁴ *BlackBerry Ltd. v. Typo Prods. LLC*, No. 14-CV-00023-WHO, 2014 U.S. Dist. LEXIS 42702, at *39 (N.D. Cal. Mar. 28, 2014).

³⁰⁵ *Id.*

³⁰⁶ *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1153–55 (Fed Cir. 2011).

³⁰⁷ LAYCOCK, *supra* note 13, at 75.

³⁰⁸ *QBAS Co. v. C Walters Intercoastal Corp.*, No. SACV 10-406 AG (MLGx), 2010 U.S. Dist. LEXIS 143945, at *35–36 (C.D. Cal. Dec 16, 2010).

³⁰⁹ *Id.* at *36 (failing to provide information about its creditworthiness leaned in favor granting a preliminary injunction against the Defendant); *see Kimberly-Clark Worldwide, Inc. v. First Quality Baby Prods., LLC*, 714 F. Supp. 2d 919, 936 (E.D. Wis. 2010).

³¹⁰ *Peng v. The P’ships*, No. 21-CV-1344, 2021 U.S. Dist. LEXIS 174254, at *8 (N.D. Ill. Sep. 14, 2021).

In spite of the importance of proving irreparable harm, courts have provided limited and sometimes confusing or unpersuasive guidance as to what qualifies as irreparable harm. In some cases, that guidance appears to be at odds with core economic principles. Clearly, irreparable harm is something beyond mere harm. Sensible judicial guidance and established economic principles suggest that there is a four-factor test that should be used in determining whether there is likely irreparable harm associated with likely continued infringement, meriting the issuance of a preliminary injunction. That test provides that to be considered irreparable, harm should be that which, in the absence of an injunction, (1) would unduly disrupt the status quo, (2) is imminent and likely to occur, (3) is causally linked to the alleged infringement, and (4) is unlikely to result in payment of adequate compensation. While each of these factors can involve the consideration of multiple sub-factors and facts, we believe that the complexity of the irreparable harm analysis, and the significance of a possible preliminary injunction, justifies this degree of detailed analysis.

The proposed approach is structured to answer systematically the core question: will harm occur to a patent owner that disrupts the status quo and leads, with reasonable economic certainty, to a loss to the patent owner for which the patent owner either cannot or will not be fully compensated? Even though a later trial on the merits may occur, that later trial may be too late in time for the patent owner to realize the benefits of the patent to which it is entitled.