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Teleflex, Secondary Patents, and Products Liability

Abstract

The recent patent decision *KSR International v. Teleflex* increased the rigor of the obviousness inquiry. This Note joins the deluge of articles exploring the impacts of this fundamental change to the patentability requirements. After *Teleflex*, the patent obviousness inquiry became equally (if not more) rigorous relative to the state products liability test for a foreseeable alternative design.

What should state courts now do when a plaintiff seeks to argue that a non-obvious patent was a foreseeable alternative design? The new legal equivalence should encourage state policymakers to rethink their law on subsequent remedial measures. Subsequent remedial measures doctrine is a rule-like determination of the probative-prejudicial inquiry. After *Teleflex*, the argument that a secondary patent was not obvious under federal law, yet was foreseeable under state law, becomes especially tenuous. The evidence has become less probative, more prejudicial, and more confusing. States that do not already deem secondary patents inadmissible should consider doing so in light of *Teleflex*.

If a state does not independently follow the policy wisdom of banning secondary patents as subsequent remedial measures, it may be forced to do so by federal preemption. A state that replaces the federal obviousness test with its own, more demanding, state alternative design foreseeability test deters innovation and deters disclosure of new inventions. This frustrates patent policy goals, and is therefore preempted by conflict.

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I. Introduction

Secondary patents are patents on small improvements to an already effective invention. Where a secondary improvement relates to product safety, there are a variety of potential tensions between patent law and products liability law. This Note specifically addresses the tensions that arise when secondary patents are used as evidence in products liability suits for earlier iterations of the invention.

The existence of a superior alternative design is critical to proving a design defect in products liability lawsuits. Consider a company that makes and sells invention 1.0 for several years before replacing it with invention 2.0. A plaintiff injured by invention 1.0 may point to invention 2.0 as an example of the superior alternative design. Because invention 2.0 did not exist at the time she was injured, the plaintiff's expert will attempt to convince the jury that invention 2.0 was a foreseeable alternative well before it was actually invented. However, the patent office has already reached an opposite conclusion from the plaintiff's expert. By granting a patent for invention 2.0, the patent office determines that invention 2.0 was "non-obvious" to an inventor of ordinary skill.

The patent office's obviousness inquiry became more demanding in 2007 after *KSR v. Teleflex*. Under the *Teleflex* test, a finding of non-obviousness indicates that the invention would not be apparent to a person in the field with perfect knowledge, ordinary creativity, and common sense. A state court that admits a later-developed secondary patent as a foreseeable available alternative to an injuring invention reaches a conclusion directly opposed to the determination of the federal patent office. These conclusions have only become irreconcilable post-*Teleflex*.

Despite the logical failures of using later-developed secondary patents as an example of an alternative design, plaintiffs seek to do so for two reasons. First, in order to overcome the *Teleflex* obviousness standard, applications are increasingly required to make disparaging

comments about earlier inventions. Second, even if it is difficult to prove the secondary patent was foreseeable, tangible real-world examples of alternatives are especially impactful to juries.

This Note explores this new state court v. federal patent office conflict. Part II lays out products liability basics, identifies important shifts patent law, and explains the mechanics of the conflict that arises when secondary patents are deemed available alternatives. Part III explains why admission as evidence may be undesirable under state law as a policy matter. Part IV explains why admission as state court evidence may be impermissible under Constitutional frustration preemption.

II. Tension between products liability & patent obviousness

A. Products liability & the reasonable alternative design

Products liability seeks to "address the consequences of modern science and technology gone awry."[1] Carrying underlying ideas of responsibility and wrongdoing, many state laws on products liability may be described as "negligence stripped of scienter."[2]

There are three critical elements to a products liability claim: identifying a defect, proving causation, and quantifying harm.[3] "Defectiveness lies at the center of products liability law."[4] The idea that something is "wrong" with the product is the core moral justification for the producer's liability.[5] Proving a defect often relies upon experts to explain the dangers, how to remove said dangers, and possible alternatives.[6] The issue discussed in this Note is concerned

[1] DAVID G. OWEN, PRODUCTS LIABILITY LAW 6–7 (2d. ed. 2008).
[2] *Id.* at 547 ((("The simplest and easiest way [to define defectiveness] is to assume that the defendant knew of the dangerous condition of the product and ask whether he was then negligent in putting it on the market") (quoting John Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L. J. 825, 834–35 (1973))). This idea of constructive knowledge is strikingly similar to patent law's obviousness inquiry. This author has found no use for this comparison, though it may be noteworthy to future thinkers.
[3] RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 1 (AM. LAW INST. 1998) (a seller of a defective product "is subject to liability for harm . . . caused by the defect.").
[4] OWEN, *supra* note 1 at 342; See also Prentis v. Yale Mfg. Co., 365 N.W.2d 176, 181–82 (Mich. 1984) ("the plaintiff must, in every case, in every jurisdiction, show that the product was defective.").
[5] David G. Owen, *The Moral Foundations of Products Liability Law: Towards First Principles*, 68 NOTRE DAME L. REV 427, 461 (1993). Products liability law must be distinguished from product safety law, such as which operates *ex ante* to prevent accidents from ever occurring.
[6] Owen, *supra* note 1 at 34–35.

with claims that the product was defectively designed, though there are other types of products liability claim, including manufacturing defects and warning defects.[7]

Arguing that a design is defective necessarily implies that there is some better design out there. The "alternative design," as it is known in the field, is functionally a required element of a design defect claim.[8] Comparison of the accused product and the alternative is typically done though the risk-utility inquiry, which imports the Hand Formula. Design defects exist wherever the "the probability and seriousness of harm" exceed the "costs of taking precaution."[9] Phrased another way, the risk-utility approach requires producers to undertake a precaution if the safety benefits foreseeably exceed the diminished usefulness.[10]

Proof of defectiveness typically "boils down to a battle of experts."[11] While expert evidence has been widely criticized for its manipulability,[12] it is typically required for a

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[7] RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 2 (AM. LAW INST. 1998)

> A product:
> (a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;
> (b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;
> (c) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.

See also OWEN, *supra* note 1 at 34 ("Virtually every American jurisdiction now divides product defect cases into [these] three categories.").

[8] See, e.g. Jones v. NordicTrack, Inc., 550 S.E.2d 101, 103 (Ga. 2001) ("The heart of a design defect is the reasonableness of selecting from among alternative designs and adopting the safest one.").

[9] Raney v. Honeywell Inc., 540 F.2d 932, 935 (8th Cir. 1976) (explaining the risk-utility test in Iowa's products liability law); United States v. Carroll Towing, 159 F.2d 169, 173 (2d Cir. 1947) (Hand, J.) (creating the Hand Formula of negligence by balancing "(1) The probability [of malfunction]; (2) the gravity of the resulting injury [and]; (3) the burden of adequate precautions.").

[10] David G. Owen, *Toward a Proper Test for Design Defectiveness: Micro-Balancing Costs and Benefits*, 75 TEX. L. REV. 1661, 1690 (1997).

[11] Jenkins v. General Motor Corp., 466 F.2d 377, 380 (5th Cir. 1971); see also Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1535 (D.C. Cir. 1984) ("The case was thus a classic battle of the experts, a battle in which the jury must decide the victor."); Forrest v. Beloit Corp, 424 F.3d 344, 360 n.11 (3d Cir 2005) ("design defect cases governed by Pennsylvania law generally boil down to a battle between competing expert witnesses.").

[12] *See, e.g.*, Black et. al., *Science and the Law in the Wake of Daubert: A New Search for Scientific Knowledge*, 72 TEX. L. REV. 715, 789 (1994) ("ostensibly scientific testimony may sway a jury even when as science it is palpably wrong.").

successful products liability case.[13] If an expert's opinion is scientific in nature, the underlying basis of that opinion may be initially scrutinized by the administering judge to ensure the opinion is sufficiently "scientific."[14] In design defect cases, alternatives are typically identified and explained by experts. They may point to existing alternatives in the market or their own proposed alternatives.

B. Patent law, obviousness & *Teleflex*

The fundamental goal of the patent system is to incentivize production of socially useful inventions.[15] Without a patent system, second-movers could leverage their lack of research costs to copy and sell inventions at a much lower price, rendering innovation unprofitable. The patent system protects the profitability of innovation by granting a limited monopoly to the inventor. In exchange for her monopoly, the inventor discloses all of the details of her invention.[16] When the patent monopoly expires, everyone is free to make, use, build and improve the publicly disclosed invention.

The disclosure-for-monopoly bargain is not available to everyone. Instead, the Patent Act and federal common law go about "the difficult business of drawing a line between the things which are worth the public embarrassment of an exclusive patent and those which are not."[17] The tools used to identify sufficiently "inventive" inventions are the three requirements of utility, novelty, and non-obviousness. [18]

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[13] *See* OWEN, *supra* note 1 at 365 & nn. 11, 21 (observing eight jurisdictions granting summary judgement against plaintiffs that failed to provide an expert). *But see* Faryniarz v. Nike Inc., 2002 WL 530997 (S.D.N.Y. 2002) (holding an expert is not required to contemplate the appropriate length of a shoelace).
[14] Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579, 592–93 (1993).
[15] *See, e.g.*, Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 150–51 (1989) ("The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.").
[16] 35 U.S.C. § 112(a) (2016) (requiring patent applications to "to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same").
[17] Bonita Boats v. Thunder Craft Boats, 489 U.S. 141, 148 (1989) (citing 13 WRITINGS OF THOMAS JEFFERSON 335 (MEMORIAL ED. 1904)).
[18] 35 U.S.C. § 101 (2016) ("whoever invents or discovers any **new** and **useful** [patentable subject matter] or any new and useful improvement thereof, may obtain a patent therefor."); 35 U.S.C. § 103 (2016) ("A patent for a claimed

The utility test is divided into substantial utility and specific utility. The specific utility requirement ensures adequate disclosure and is quite removed from the issues of this Note. The substantial utility requirement demands a presently available utility.[19] The substantial utility requirement ensures that the patent system deals in "the world of commerce rather than the realm of philosophy."[20]

Novelty and non-obviousness are closely related concepts. Because patents grant monopolistic rights, these doctrines ensure patents do not mistakenly take publicly available information out of the public domain. Savvy patent attorneys rarely tread upon the novelty requirement, which is violated only if a *single* piece of "prior art"[21] contemplates every feature of the invention they are attempting to patent (as dictated by the claims).[22]

Non-obviousness is patent law's closest proxy for "inventiveness," which is why many consider it the most important criteria for patentability.[23] It seeks to ensure that the technical achievement underlying the claimed invention is "nontrivial" before rewarding the applicant with a quasi-monopoly.[24] This policy approach is known as the "inducement theory" – some inventions are simply the inevitable next step and therefore do not require the patent system's incentives.[25]

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invention may not be obtained . . . [if] the claimed invention as a whole would have been **obvious** . . . to a person having ordinary skill in the art.") (Emphasis added).

[19] *In re* Fisher, 421 F.3d 1365, 1371 (2005) (finding substantial utility where "one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public.") (quoting Nelson v. Bowler, 626 F.2d 853 (C.C.P.A 1980)).

[20] Brenner v. Manson, 383 U.S. 519, 536 (1966).

[21] Identifying what information is publicly available, aka "prior art," is a complex and frequently contested issue, the details of which are beyond the scope of this Note. It shall suffice to say that prior art includes scientific journals, other patents, and products for sale. 35 U.S.C. § 102 (prior art includes anything "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public" before the patent's effective filing date).

[22] *See, e.g.*, *In re* Robertson, 169 F.3d 743 (Fed. Cir. 1999) (finding the patent for a diaper is novel because one element of the claimed invention differs from a pre-existing patent).

[23] *See generally*, JOHN F. WITHERSPOON, NONOBVIOUSNESS – THE ULTIMATE CONDITION OF PATENTABILITY (1980).

[24] ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW & POLICY: CASES & MATERIALS 606 (6th ed. 2013).

[25] Graham v. John Deere Co., 383 U.S. 1, 11 (1966) (describing a need to identify " those inventions which would not be disclosed or devised but for the inducement of a patent."); *See also* Michael Abromowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L. J. 1590 (2011).

When patent examiners and courts consider the technical obviousness of an innovation, they are confronted with a difficult question – if the invention is obvious, why hadn't anyone else done it? This question is answered from the perspective of a hypothetical "person having ordinary skill in the art" or PHOSITA.[26]

Prior to 2007, the Federal Circuit had assumed the PHOSITA had no creativity, requiring that the prior art itself "motivate" the inventor to make the new innovation before rejecting a patent for obviousness.[27] This lenient test did not provide much of a challenge for savvy secondary patent applicants.

To avoid such situations, the landmark 2007 *Teleflex* decision promoted this hypothetical "person having ordinary skill in the art" to an inventor in the same field with perfect knowledge of all publicly available information *and* ordinary creativity.[28] By instructing the patent office to consider creativity and common sense, the new obviousness standard casts doubt upon inventions that are "obvious to try" to those in the inventor's field.[29] The *Teleflex* decision has made the obviousness inquiry more demanding.

Hindsight bias has always plagued the obviousness inquiry.[30] The Court has given gave several tools the help "guard against slipping into the use of hindsight."[31] These "*Graham* factors" include commercial success, long felt but unsolved needs, failure of others, and prior art that "teaches away" (aka discourages) the path taken.[32] Demonstrating these "objective factors"

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[26] 35 U.S.C. § 103 (2016) ("A patent for a claimed invention may not be obtained . . . [if] the claimed invention as a whole would have been obvious . . . to a person having ordinary skill in the art.").
[27] *See, e.g.*, Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1361-1365 (Fed. Cir. 2007) (explaining the pre-*Teleflex* rule that obviousness required "clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.").
[28] KSR International v. Teleflex, 550 U.S. 398 (2007).
[29] *Id.* at 413.
[30] Loom Co. v. Higgins, 105 U.S. 580, 591 (1881) ("Now that it has succeeded, it may seem very plain to any one that he could have done it as well. This is often the case with inventions of the greatest merit.").
[31] *Teleflex*, 550 U.S. at 421 (citing Graham v. John Deere Co., 383 U.S. 1, 36 (1966)).
[32] *Id.* at 406 (citing *Graham*, 383 U.S. at 17–18) (establishing commercial success, long-felt need, and failure of others as "objective factors" of non-obviousness); Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1165 (Fed. Cir. 2006) (establishing discouragement or "teaching away" as a *Graham* factor).

helps patent applicants prove that their invention was non-obvious. The *Graham* factors are becoming increasingly important in the face of *Teleflex*'s stricter obviousness test.[33]

C. Use of secondary patents as evidence in products liability

To re-state the Note's goal, we are especially concerned with the use of patents that do not cover the injury-causing invention, but a later-developed improvement of the injury-causing invention. Consider the following timeline:

- T_0: Pharma Co. discovers and patents the active ingredient "drugamine." It is administered in a pure form by a shot as "drug 1.0." Phama Co. knows and warns against the risk of heart disease as a side-effect and immediately begins working on ways to mitigate the side-effect.
- T_1: Plaintiff takes drug 1.0, develops heart disease.
- T_2: Pharma Co. discovers and patents a new form of drugamine that can be taken as an oral pill. The new pill form reduces risk of heart disease as a side-effect. Pharma Co. patents the new formula and sells the pills as "drug 2.0."
- T_3: Plaintiff sues Pharma Co. over injuries from drug 1.0.

Here, plaintiff never used drug 2.0, the secondary innovation. Nonetheless, she seeks to use the drug 2.0 patent as relevant evidence.

The existence of an alternative design is a de-facto necessary element for a design defect claim.[34] In a design defect claim, the plaintiff will argue that drug 2.0 was an available alternative to drug 1.0, and the inventing company was therefore negligent for making and selling drug 1.0. Drug 2.0 is almost certainly a superior alternative at T_2 because it accomplishes the same utility with less risk of heart disease, but the core legal question remains – was it an alternative *available* at T_1, when the plaintiff actually took drug 1.0?

The patent office has already concluded that drug 2.0 was not a foreseeable or available alternative at T_1. By granting a patent on drug 2.0, the Patent Office necessarily determines that

[33] *See, e.g.*, Forest Labs v. Ivax Pharmaceuticals, 501 F.3d 1263, 1269–70 (Fed. Cir. 2007) (difficult to execute and unexpected results); Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075, 1088–89 (Fed. Cir. 2008) (difficult to execute); Ortho-McNeil Pharmaceutical v. Barr Laboratories, 2009 WL 2182665 at *5 (D.N.J. 2009) (unexpected results); Depomed, Inc. v. Ivax Corp., 532 F. Supp. 2d 1170, 1185 (N.D. Cal. 2007) (no reasonable expectation of success).

[34] See, e.g. Jones v. NordicTrack, Inc., 550 S.E.2d 101, 103 (Ga. 2001) ("The heart of a design defect is the reasonableness of selecting from among alternative designs and adopting the safest one.").

the discovery of drug 2.0 was new, useful, and non-obvious, even at the time of invention (T_2). A state court treating the secondary innovation (drug 2.0) as a foreseeable alternative at the time of injury (T_1) disregards this federal finding and replaces it with its own factual determination.

Differing treatment at the federal and state level could be conceptually valid based on differing standards, but that cannot be the case here. The patent office's post-*Teleflex* obviousness inquiry is more demanding, or at least equally demanding, than the state court's foreseeability inquiry.

The state court could not possibly be holding the defendant to a higher standard of research or diligence. The patent office asks whether the invention was obvious to an *omniscient* inventor in the field – one with knowledge of every single piece of relevant publicly available information.[35] And the patent office's inquiry looks at all of the information available at the time of filing (T_2), which is later than the time of the plaintiff's injury (T_1).[36] The state court therefore cannot justify an opposite finding from the patent office on the basis of previously unconsidered facts.

Nor should the state court be holding the defendant to a higher standard of sensibility. In *Teleflex*, the Court explained that the patent office must undertake the obviousness inquiry from the perspective of a person with ordinary creativity and common sense.[37] The state court almost certainly does not intend to burden the defendant to possess above-average creativity or super-common sense.[38] This would exceed the reasonable person standard.

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[35] 35 U.S.C. § 102(a) ("a person shall be entitled to a patent unless the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.").
[36] 35 U.S.C. § 102 (considering all prior art that existed "before the effective filing date of the claimed invention."); 35 U.S.C. § 100(i) (defining "effective filing date" as "the filing date of the earliest application for which the patent or application is entitled" or "the actual filing date of the patent or application.").
[37] KSR International v. Teleflex, 550 U.S. 398, 421 (2007)("Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.").
[38] However, for patents granted before the new *Teleflex* obviousness standard (pre-2007), a state court's conclusion of foreseeability may be explained as an additional state duty to have common sense & creativity.

In light of the *Teleflex* obviousness test, a state court conclusion that a later-developed secondary patent embodies a foreseeable available alternative directly conflicts with the patent office's conclusion that the secondary patent was non-obvious. This logically tenuous evidence is valuable to the plaintiff's attorney for two reasons.

First, a tangible example is much more persuasive to jurors than an expert's hypothetical proposal. A juror will be especially swayed by the secondary patent application's diagram of a superior alternative.[39] While the juror is holding that diagram, the defense attorney can undermine the evidence by explaining to the jury that the patent office disagrees with the plaintiff's expert, and the expert will attempt to convince the jury that the patent office was wrong. This is a complex and lengthy process. In a survey of federal judges, most thought even simple patent cases required seven to fourteen days of trial to resolve.[40]

Second, the secondary patent application may contain disparaging statements against the defendant's earlier invention. Using the *Graham* factors to help prove its own non-obviousness, the secondary patent applicant laments the failures and flaws of earlier inventions. The plaintiff seeks admit these criticisms of the defendant. The defense attorney can explain that these statements were made at a later time, with hindsight knowledge, and actually reflect the secondary applicant's view that the state of the art, not the defendant, are to blame for the defendant's failures. To understand this, the jury will require a crash course on patent law.

In the Part III, we explain the weak relevance of secondary patents as proof of defect, and counsel state courts that admission is not worth the risks of prejudice and confusion.

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[39] *See, e.g.*, Forrest v. Beloit Corp., 424 F.3d 344 n.11 (3d Cir. 2005) ("any testimony that leaves the ethereal realm of expert opinion and discusses real-world prior experience is likely to have an especially profound impact upon the jury, particularly when the time comes to apply the trial testimony to complex and abstract legal concepts such as 'defect' and 'proximate cause.'").

[40] 1 Size Doesn't Fit All in Patent Trials LAW360 (October 28, 2010), https://www.law360.com/articles/203660/1-size-doesn-t-fit-all-in-patent-trials

If state courts make their own policy decision to reject the advice in Part III, they essentially create a design defect foreseeability standard that exceeds the federal obviousness standard. Part IV explores whether that inconsistency is preempted by patent law.

III. Admissibility of secondary patents as an alternative design

A. The secondary patent as a subsequent remedial measure

A secondary improvement that improves the safety of an earlier invention is a "measure ... that would have made an earlier injury or harm less likely to occur."[41] The use of secondary patents in products liability should therefore implicate all of the legal concerns surrounding subsequent remedial measures.

Many jurisdictions, including federal courts, do not allow use of subsequent remedial measures as proof of negligence or culpability.[42] Since 1997, the federal rules of evidence expressly prevents the use of subsequent remedial measures as proof of defect.[43] In these jurisdictions, state legislatures and courts have already made policy determinations that secondary patents are not sufficiently relevant to warrant the negative costs of their admission.

However, a net eighteen states allow evidence of subsequent remedial measures as proof of defect: six by statute,[44] two by committee notes,[45] and ten by court decision.[46] Eighteen more states mirror the pre-1997 FRE language, which does not expressly prevent use for proof of defect, without judicial or legislative comment on the issue of proof-of-defect.[47] This means anywhere from eighteen states (31% of the population) to thirty-six states (53% of the

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[41] FED. R. EVID. 407.
[42] *Id.*
[43] *Id.* ("When measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove . . . a defect in a product or its design; or a need for a warning or instruction.").
[44] 4 JONES ON EVIDENCE § 21:7 SUBSEQUENT REMEDIAL MEASURES: APPLICABILITY IN PRODUCTS LIABILITY LITIGATION (7th ed. 2017) (Alaska, Conn., Hawaii, Iowa, Maine, Texas).
[45] 4 *id.* § 21:7 (Ind., Wyo.).
[46] 4 *id.* § 21:7 (Colo., Ga., Ky., Minn., Mo., Nev., Ohio, S.D., Utah, Wis.).
[47] 4 *id.* § 21:3 (Ala., Ark., Del., Md., Mich., Miss., Mont., Nev., N.H., N.M., N.C., N.D., Okla., Ore., S.C., Vt., Wash., W.V.).

population) are open to the use of secondary patents, as subsequent remedial measures, as proof of defect.

There are two core justifications to the ban on using subsequent remedial measures as evidence. First, as a policy matter, the risks resulting from admission as evidence might discourage people from adding safety features.[48] Second, there is high risk that the subsequent remedial measure will unfairly prejudice the defendant.[49] The jurisdictions that refuse to apply the subsequent remedial measure doctrine to design defect products liability cases doubt that the stated policy goal applies to big businesses, which are already incentivized to make improvements by the free market.[50]

The anti-deterrence rationale to the ban on subsequent remedial measures as evidence is generally applicable, and has no unique force in the specific case of using of secondary patents as evidence in products liability cases. Law-and-economics Professor Keith Hylton has suggested that the risk of erroneous products liability findings will cause companies to abandon efforts to innovate even where the social utility actually outweighs the risk.[51]

The Supreme Court recognized the prejudicial effect of subsequent remedial measures in one of its first cases on the issue in 1892, noting that the evidence "has no legitimate tendency to prove that the defendant had been negligent before the accident happened, and is calculated to distract the minds of the jury from the real issue, and to create a prejudice against the

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[48] 1973 Advisory Report for the Federal Rules of Evidence, 56 F.R.D. 183, 225–26 (1973) ("exclusion rests on a social policy of encouraging people to take, or at least not discouraging them from taking, steps in furtherance of added safety.").

[49] Grenada Steel Industries v. Alabama Oxygen, 695 F.2d 883, 888 (5th Cir. 1983) ("The introduction of evidence about subsequent changes in the product or its design threatens to confuse the jury by diverting its attention from whether the product was defective at the relevant time to what was done later.").

[50] *See, e.g.*, Ault v. International Harvester Co., 528 P.2d 1148, 1152 (Cal. 1974) ("The contemporary corporate mass producer of goods, the normal products liability defendant, manufactures tens of thousands of units of goods; it is manifestly unrealistic to suggest that such a producer will forego making improvements in its product, and risk innumerable additional lawsuits and the attendant adverse effect upon its public image, simply because evidence of adoption of such improvement may be admitted in an action founded on strict liability for recovery on an injury that preceded the improvement.").

[51] Keith N. Hylton, *The Law and Economics of Products Liability*, 88 NOTRE DAME L. REV. 2457, 2497.

defendant."[52] Using secondary patents is especially problematic. Patents are confusing and at times arcane, written by experts, for experts, with the goal of satisfying the patentability requirements.[53] Federal patent law has already deemed jurors incapable of interpreting the claims of a patent.[54]

The ban on admission of subsequent remedial measures is a rule-like decision on a probative-prejudicial inquiry. The legal impacts of *Teleflex* make secondary patents both less probative and more prejudicial if used as proof of defect. In light of *Teleflex*, state legislatures should re-think the scope of their subsequent remedial measures rule. Furthermore, the rule-like operation of the subsequent remedial measure ban does not prohibit courts from undertaking an independent probative-prejudicial inquiry under their FRE 403 equivalent.[55]

Under the *Teleflex* obviousness test, approval of the secondary patent amounts to a patent office conclusion that the subsequent remedial measure could not have been easily made at the earlier time of injury. This makes the evidence non-probative towards the existence of a design defect. This differs from the pre-*Teleflex* use of the patent, when the obviousness-foreseeability difference was easily explained on the basis of different requirements of creativity & common sense.

In order to overcome the heightened scrutiny of the *Teleflex* obviousness test, patent applicants are forced to make increasingly prejudicial statements. To convince the patent office that the secondary innovation was not apparent to another inventor of ordinary creativity, secondary patents have increasingly relied on "*Graham* factors" of commercial success, long felt

[52] Columbia & P.S.R. Co v. Hawthorne, 144 U.S. 202, 207 (1892).
[53] *See* 35 U.S.C. § 112(a) (2016) (patent applications must be informative to a person skilled in the art).
[54] Markman v. Westview Instruments, 517 U.S. 370, 372 (1996).
[55] *See, e.g.*, 1997 Advisory Report for the Federal Rules of Evidence ("Evidence of subsequent measures that is not barred by Rule 407 may still be subject to exclusion on Rule 403 grounds when the dangers of prejudice or confusion substantially outweigh the probative value of the evidence.").

but unsolved needs, failure of others, and prior art that teaches away from the path taken.[56] To demonstrate the existence of a "long felt need," the secondary inventor acknowledges that the original invention did not satisfy that need. To demonstrate unexpected benefits, secondary applications discuss the failures of the original invention. To demonstrate that the field "taught away" from the secondary innovation, secondary applications may identify the members of the mistaken majority.

Products liability litigators want to use these statements, criticizing the injury-causing invention, against the defendant. The *Graham* factor statements themselves are incriminating, but do not go towards the core issue under products liability – identifying available alternatives. Statements explaining that the original invention is outdated in light of the new secondary invention, at T_2, are not helpful in determining whether the invention was negligently designed at T_1. Instead, as predicted by the Court 200 years ago, they "distract the minds of the jury from the real issue, and [] create a prejudice against the defendant."[57]

Where the secondary patent was written by a third party, the prejudice factor remains. Secondary patent applicants that do not hold primary patents are not exposing themselves to liability, and therefore do not require the anti-deterrence policy protections of this rule.[58] While there is no risk of the jury mis-construing the secondary patent as an admission of fault by the defendant, the prejudicial impacts of the *Graham* statements remain. The third party patent applicant has a self-interest in criticizing the defendant's product in order to establish her own non-obviousness. While those criticisms will enflame the jury into thinking the defendant's

[56] Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966); Elaborated at *supra* notes 31–32 and accompanying text.
[57] Columbia & P.S.R. Co v. Hawthorne, 144 U.S. 202, 207 (1892).
[58] *See, e.g.*, Diehl v. Blaw-Knox, 360 F.3d 426, 430 (3d. Cir. 2004) ("The admission of remedial measures by a non-party necessarily will not expose that non-party to liability, and therefore will not discourage the non-party from taking the remedial measures in the first place.").

application was dangerous, they do not contain probative value about whether the third party's invention should have been foreseeable to the defendant.

The use of secondary patents as an argued alternative design are especially likely to confuse the jury as well. A defense attorney could refute a plaintiff's expert's claim that the secondary patent was foreseeable by explaining the *Teleflex* obviousness test. But in order to do so, she would be required to give the jury a crash course on patent law. Ultimately, the attorneys would delve into a debate over whether the patent office was right or wrong about obviousness. Even assuming the state is competent and capable of "correcting" the patent office,[59] this is needlessly complex for what is ultimately a very weak point the plaintiff's expert.

The Supreme Court has counseled federal courts to avoid invoking complex patent inquiries wherever possible. In *Federal Trade Commission v. Actavis*, a generic manufacturer, hoping to enter the market under the Hatch-Waxman Act, challenged the validity of a branded manufacturer's secondary patent, claiming the secondary patent was obvious.[60] The branded manufacturer paid a multi-million dollar settlement on the invalid-for-obviousness case, leaving the patent unchallenged and preventing the generic from entering the market.[61] The FTC claimed the settlement was an anti-competitive deal to maintain an otherwise invalid patent monopoly. The Court acknowledged that the reasonableness of the settlement was informed by the validity of the patent.[62] Nonetheless, it concluded that an examination of the patent's validity was unnecessary to answer the ultimate antitrust question, instead suggesting that the mere existence

[59] An assumption that is relaxed in Part IV's preemption discussion.
[60] Federal Trade Commission v. Actavis, 133 S.Ct. 2223 (2013). FTC v. Watson Pharmaceuticals, 677 F.3d 1298, 1304 (2012) ("A prior patent covering the [active ingredient] had expired decades earlier, but [the patent challenged] sought patent protection for a particular gel formulation of it."); Second Amended Complaint for Plaintiff at 88, FTC v. Watson Pharmaceuticals, 677 F.3d 1298 (2012) (No. 109-CV-000955), 2009 WL 1952661 ("[The generics] also argued that the formulation patent was invalid. Among other things, these firms developed evidence that . . . [t]he patent was invalid as obvious under 35 U.S.C. § 103 because the gel formulations and related methods covered by the patent were obvious variations of existing products and methods.").
[61] *Actavis*, 133 S.Ct at 2229.
[62] *Id.* at 2230–31 ("A *valid* patent excludes all except its owner from the use of the protected process or product . . . [b]ut an *invalidated* patent carries with it no such right.").

of a large payment may be sufficient to show the patent was invalid.[63] The examination of patent validity was too costly and specialized to justify.[64]

Even where the obviousness of the patent was outcome determinative, the Court refused to participate in an earnest analysis of the patent's obviousness.[65] State courts deciding products liability cases are not bound by this policy decision, but should be swayed by it. *Actavis* involved an outcome-determinative question decided by federal judges with repeat-player expertize. Even then, the obviousness inquiry was too complex to be valuable. State judges should hesitate before taking on an equally complex question, with lower stakes, determined by less confident state jurors.

Ultimately, the states that ban use of secondary patents as subsequent remedial measures have made the correct policy decision. In light of *Teleflex*, states should update their FRE 407 equivalent, or at least prevent the use of secondary patents as an alternative design under their FRE 403 equivalent. The evidence is minimally probative, and contains prejudicial and confusing information.

Where states disagree with this policy argument, the secondary patent's foreseeability will almost certainly be explained by an expert. The following sub-part explains why that expert testimony should be viewed as questionable.

B. The secondary patent as a basis of expert testimony

Products liability suits live and die by the expert.[66] Rule 702 instructs whether or not an expert can reasonably rely upon a secondary patent by demanding that expert testimony be

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[63] *Id.* at 2236–37 ("The size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.").
[64] *Id.* at 2236 (citing administrative feasibility).
[65] *Id.* at 2239–40 (Roberts, C.J., dissenting) (accusing the majority of avoiding patent law policy considerations by shifting the focus to antitrust).
[66] Jenkins v. General Motor Corp., 466 F.2d 377, 380 (5th Cir. 1971); *see also* Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1535 (D.C. Cir. 1984) ("The case was thus a classic battle of the experts, a battle in which the jury must decide the victor."); Forrest v. Beloit Corp, 424 F.3d 344, 360 n.11 (3d Cir 2005) ("design defect cases governed by Pennsylvania law generally boil down to a battle between competing expert witnesses.").

"scientific" and well-founded. An expert's use of a secondary patent to propose a foreseeable available alternative should not be viewed as scientific and well-founded.

The scientific and well-founded inquiry is commonly understood through the application of the *Daubert* test which seeks "to improve the legitimacy of judicial determinations involving science and technology by forcing courts to rigorously scrutinize the foundations of an expert's scientific or technological opinions."[67] This is accomplished through five factors that inform the reliability of an expert's underlying opinion: testability, peer review, error rate, control standards, and general acceptance.[68] This rule was endorsed by Congress in 2000, when it amended Rule 702 to demand that expert testimony be "the product of reliable principles and methods."[69] Thirteen states, however, have refused to implement a *Daubert*-type analysis into their state evidentiary rules.[70]

Daubert itself was a drug products liability case over a drug with a "vast body" of peer-reviewed human studies concluding no causation between the drug and the plaintiff's injury. The Court refused to allow testimony of an expert that willfully ignored the established body of research in favor of her own un-reviewed "reanalysis" of the situation.[71] While the Court expressed general optimism about the ability of juries to understand scientific evidence with guidance of the adversarial system,[72] *Daubert* review interposes a judicial first-look to prevent courts from "simply pass[ing] along to juries the principle task of determining the validity of expert testimony on difficult questions of science and engineering."[73]

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[67] OWEN, *supra* note 1 at 389.
[68] Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579, 593–94; FED. R. EVID. 702, advisory committee's note to the 2000 Amendment; see also Capra, *The Daubert Puzzle*, 32 GA. L. REV. 699, 702 (1998).
[69] FED. R. EVID. 702.
[70] OWEN, *supra* note 1 at 387 n.131 (Ala., Ariz., Cali., Fla., Ill., Kansas, Md., Minn., N.Y., N.C., N.D., Penn., Wash.).
[71] *Daubert*, 509 U.S. at 582–83.
[72] *Id.* at 595–96 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").
[73] OWEN, supra note 1 at 389.

Patents are correctly viewed as evidence within the realm of experts. After all, patent applications are legally required to contain a "full, clear, concise and exact" written description of the invention.[74] This description is targeted at people having ordinary skill in the art, which should include experts. But the true question under *Daubert* is the "analytical gap" between the expert's use of the patent and the conclusion offered – that, even though this patent document says the opposite, the secondary innovation was foreseeable at the time of injury.[75] This analytical gap is too large to even present the question to the jury.

Courts have already confronted the use of patents as the foundation of an expert's proposed alternative reasonable design. In *Colon ex rel. Molina v. BIC USA,* a six year old found his mother's cigarette lighter and set his own clothes on fire.[76] His mother asserted that the lighter was insufficiently child-proofed and sued on the basis of a design defect.[77] The plaintiff's expert reviewed ten lighter design patents held by the defendant and concluded that BIC could have established safer alternatives by mixing-and-matching features from several of those patents.[78] Even with a "flexible" application of *Daubert*, the court refused to admit the expert's opinion.

Because alternative designs are scientific and technical "by definition," the feasibility of the alternative design needs to be tested.[79] The expert's hypothesized alternative design, the mixed-and-matched lighter, was never tested, which offended a *Daubert* factor.[80] The idea, cooked up in the expert's mind for the purposes of litigation, also never had an opportunity to be considered by the scientific community for peer review or error rate analysis, much less for

[74] 35 U.S.C. § 112(a) (2016).
[75] General Electric v. Joiner, 522 US 136, 146 (1997).
[76] Colon ex rel. Molina v. BIC USA, 199 F.Supp.2d 53, 63–64 (S.D.N.Y. 2001).
[77] *Id.* at 63–64.
[78] *Id.* at 74–75.
[79] *Id.* at 76 (citing eight cases with similar reasoning).
[80] *Id.* at 75–78.

general acceptance or rejection.[81] Because the expert's assertion depended on modifications and adaptations of the BIC patents, the granting of the patents did not amount to acceptance either.[82] For these reasons, the court concluded that the *Daubert* test required exclusion of the expert's testimony about potential alternative designs extrapolated form the defendant's other patents. The logical jump from the patents to the argued alternative was too large.

These same flaws apply to the use of later-developed secondary patents as evidence of a foreseeable alternative design. When an expert attempts to use the secondary patent as an alternative, they are either explicitly or implicitly arguing that the alternative could have been discovered sooner. Much like in *Colon*, the patents alone are not sufficient to support that claim. The "it could have been done faster" assertion is made by the expert for the purposes of litigation. It is not tested, peer-reviewed, generally accepted, or subject to an error-rate analysis. Because of this, such an assertion is not be sufficiently "scientific" to be treated as expert testimony.

The patent office's approval of the secondary patent as non-obvious should itself militate the *Daubert* test against the expert's conclusion that the secondary patent was foreseeable. The expert is doing exactly what the *Daubert* court criticized – ignoring the patent office's obviousness conclusion for her own "re-analysis" of the patent's foreseeability.[83] The obviousness inquiry is a peer review. The patent office assumes the mindset of a "person having reasonable skill in the art" and asks whether the invention is truly inventive. By granting the patent, the patent office concludes that the inventor's peers would *not* have viewed the secondary patent as an inevitable or foreseeable invention. The *Graham* factors test obviousness against the

[81] *Id.* at 78–79.
[82] *Id.* at 79.
[83] *Daubert*, 509 U.S. at 582–83.

free market. By granting a patent, the patent office concludes that the market has tested and rejected the plaintiff's expert's claim that the secondary invention was foreseeable.

IV. Preemption of conflicting state & federal conclusions

The state government may, for its own policy reasons, choose to ignore the arguments in Part III and allow secondary patents as proof of a foreseeable alternative. In doing so, the state would establish a products liability foreseeability standard that exceeds the patent law obviousness standard. This Part explores whether such a state rule should be preempted by federal patent law.

The Supremacy Clause allows federal patent law to preempt inconsistent state law.[84] The preemptive reach of patent law can be fundamentally understood through two seminal cases. *Bonito Boats v. Thunder Craft Boats* serves to address the "easy" cases – state laws that distort the fundamental "bargain" of patent law.[85] *Aronson v. Quick Point Pencil* addresses the harder cases – those that do not directly interact with patent law, but may still frustrate patent policy.[86]

Products liability attorneys are no stranger to federal preemption arguments.[87] These arguments, however, are invariably connected to federal safety standards.[88] There is a separate abundance of writing on the potential disincentives that products liability may have upon innovation.[89] It is therefore surprising that this Author was unable to locate a single federal court

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[84] U.S. CONST. art. VI, cl 2.
[85] Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 150–51 (1989) ("The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.").
[86] Aronson v. Quick Point Pencil, 440 U.S. 257 (1979); *see also* Ultra-Precision Mfg. v. Ford Motor Co., 411 F.3d 1369 (Fed. Cir. 2005) (a modern revitalization of the *Aronson* test).
[87] See OWEN, *supra* note 1 at 941 (describing federal preemption as "inscrutable . . . formless and elusive," but functionally "one of the most powerful defenses in all of products liability law").
[88] *Id.* at 938–70 & n. 2 (thoroughly exploring federal safety preemption across industries and citing over twenty articles doing the same).
[89] *See, e.g.*, A. Mitchell Polinsky & Steven Shavell, *The Uneasy Case for Product Liability*, 123 HARV. L. REV. 1437 (2010); Keith N. Hylton, *The Law and Economics of Products Liability*, 88 NOTRE DAME L. REV. 2457 (2009).

case, and only one article,[90] that earnestly engages with the preemptive interactions of patent law and products liability law.

It is understandable why *field* preemption of products liability is never discussed – the field is not preempted. A core purpose of the Congressional "bargain" is to allow the market to determine the success or failure of an innovation.[91] Product liability is plainly a mechanism by which the market comments on the merits of an innovation. The Federal Circuit has acknowledged that "conflict preemption is a more precise means of determining which state laws are preempted than the blunt tool of field preemption" and encouraged "as-applied" review of potential conflicts.[92] Therefore, the remainder of this section will apply conflict preemption ideas to the narrow practice of using secondary patents as evidence in products liability.

Bonito Boats holds that federal patent law preempts state laws that grant patent-like protection. The Court waxes poetic about the history and requirements of patentability to conclude that "the federal patent system embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and non-obvious advances in technology."[93] A state's decision to give protection even after a patent's expiration plainly "renders[s] the [Congressionally contemplated] exchange fruitless," and is therefore preempted.[94] State laws that directly and intentionally adjust the benefits of discovery and disclosure are clearly preempted for frustrating the "bargain." The *Aronson* test explores when laws unintentionally or indirectly frustrate the bargain.

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[90] Louis M. Bograad & Andre M. Mura, Buckman *Stops Here! Limits on Preemption of State Tort Claims Involving Allegations of Fraud on the PTO or the FDA*, 41 RUTGERS L.J. 309 (2009) (attempting to reconcile Court doctrine that state law claims based upon fraud on the Patent Office was not preempted, but similar claims for fraud upon the FDA are preempted).
[91] Lowell v. Lewis, 15 F.Cas. 1018, 1019 (C.C.D. Mass. 1817) (finding that patentable utility only requires the invention to be "substantially different," and that patents that lack market value will simply "sink into contempt and disregard.").
[92] Hunter Douglas v. Harmonic Design, 153 F.3d 1318, 1334–35 (Fed. Cir. 1998).
[93] Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 146–52 (1989).
[94] *Id.* at 152 ("Where the public has paid the congressionally mandated price for disclosure, the States may not render the exchange fruitless by offering patent-like protection to the subject matter of the expired patent.").

The *Aronson* test identifies conflict preemption where state law "frustrates" the three "aims" and "purposes" of the federal patent system: (1) fostering and rewarding invention; (2) promoting disclosure of inventions to stimulate further innovation and to permit the public to practice the invention once the patent expires; (3) assuring that ideas in the public domain remain there for the free use of the public.[95] A mere relationship to intellectual property is not sufficient to cause preemption – states are free to regulate the use of intellectual property so long as those regulations are not inconsistent with federal patent policy.[96] State actions that mix areas of traditional state law policy with the encouragement of invention and disclosure are also less likely to be preempted.[97]

For a sense of when "frustration" is met, we may look to a couple examples. In *Aronson* itself, the inventor sold, for a royalty, the exclusive right to produce an invention she had not patented.[98] State law enforcement of that commercial agreement was not inconsistent with the three federal purposes, so there was no preemption. Where a pair of doctors sued another doctor for stealing and selling their discovery, unjust enrichment liability actually enhanced incentives to innovate by ensuring the benefits inure to the true inventor, and thus there was no preemption.[99]

Biotechnology Industry Organization v. District of Columbia found that price control mechanisms may frustrate the patent bargain.[100] Washington D.C.'s "Excessive Pricing Act" prohibited sale of patented drugs at an "excessive price" in order to protect the health and welfare of its citizens.[101] The city argued that because the Patent Act does not include right to

[95] *Aronson*, 440 U.S. at 262; Ultra-Precision Mfg. v. Ford Motor Co., 411 F.3d 1369, 1377 (Fed. Cir. 2005).
[96] *Aronson*, 440 U.S. at 262.
[97] *Bonito Boats*, 489 U.S. at 155 ("There was no indication that Congress had considered this [non-economic privacy] interest in the balance struck by the patent laws, or that state protection for [said interest] would interfere with the policies behind the patent system.").
[98] *Aronson*, 440 U.S. at 256–60.
[99] University of Colorado Foundation v. American Cyanimid, 342 F.3d 1298, 1306–07 (Fed. Cir. 2003).
[100] Biotechnology Industry Organization v. District of Columbia, 496 F.3d 1362 (Fed. Cir. 2007).
[101] *Id.* at 1365.

practice the patented invention, the city should be free to place a price cap.[102] The court disagreed, stating that limiting the profits derived from the monopoly frustrated both the development and disclosure of invention.[103] The law's exclusive targeting of patented products was especially offensive.[104] Even the non-economic considerations of the city's police power, a mitigating factor under *Bonita Boats*, was not sufficient to overcome the frustration of the federal bargain.

A state court's determination that a later-developed secondary patent is a foreseeable alternative design should be preempted under the *Aronson* frustration idea. It frustrates two of the *Aronson* purposes of patent law: (1) fostering and rewarding invention; and (2) promoting disclosure of inventions to stimulate further innovation and to permit the public to practice the invention once the patent expires.

At its core, using secondary patents as proof of defect is a subsequent remedial measure issue.[105] In its passage of FRE 407, Congress explicitly stated that it expects admission of secondary patents as evidence of a design defect to deter future innovation.[106] FRE 407 is not independently binding upon state courts. However, when the subsequent remedial measure is a patent, the anti-deterrence policy values of FRE 407 align with patent law's purpose of fostering and rewarding innovation. This implicates the *Aronson* test and suggests conflict preemption.

By only preempting an evidentiary tactic, we achieve the "precise" and narrow preemption sought by the Federal Circuit.[107] Subsequent remedial measures policy explains that

[102] *Id.* at 1372.
[103] *Id.* at 1372–74 ("By penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—the District has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs.").
[104] *Id.* at 1374.
[105] *Supra* Section III.A.
[106] 1973 Advisory Report for the Federal Rules of Evidence, 56 F.R.D. 183, 225–26 (1973).
[107] Hunter Douglas v. Harmonic Design, 153 F.3d 1318, 1334–35 (Fed. Cir. 1998).

the true deterrent effect comes from confused and prejudiced juries.[108] Where misguided juries are what truly frustrate innovation, limiting the tools available to plaintiffs' attorneys is a targeted way to eliminate that frustrating effect. Preemption does not require a broad imposition on state jurisdiction to set its own rules on subsequent remedial measures. Deterrence of non-patentable subsequent remedial measures would have no impact on the federal bargain, and be of no concern to the *Aronson* test. Preemption would only ban the use specific use of secondary patents as subsequent remedial measures.

An "as-applied" examination also eliminates the *Bonito Boats* mitigating factors. The evidentiary treatment of documents in state court does not implicate billion dollar industries or the general welfare, and should therefore not be assumed to catch the eye of Congress, eliminating the "congressional silence" justification for non-preemption. While state evidentiary rules are a traditional and non-economic state issue, they are not nearly as compelling of a state interest as *Bonita Boats*' privacy rights, *Aronson*'s business relationships or *BIO*'s health and welfare considerations. *BIO* teaches that the fact that products liability law's goal of protecting the health and safety of state citizens alone may be insufficient to overcome frustration preemption. Even then, evidentiary practice is not fundamentally tied to product liability's purpose.

Preempting the use of secondary patents as a proof of defect is a narrowly tailored mechanism to prevent frustration of the first *Aronson* factor, the fostering and reward of innovation.

A state conclusion that the secondary invention was a foreseeable alternative frustrates the second *Aronson* purpose of promoting disclosure to stimulate further innovation. If the state

[108] Columbia & P.S.R. Co v. Hawthorne, 144 U.S. 202, 207 (1892) (Explaining that the use of subsequent remedial measures "has no legitimate tendency to prove that the defendant had been negligent before the accident happened, and is calculated to distract the minds of the jury from the real issue, and to create a prejudice against the defendant.").

court treats a secondary patent as a foreseeable alternative, design defect liability essentially concludes that that the defendant should have never sold invention 1.0, but instead waited until invention 2.0 (which was, by the state court's conclusion, foreseeable) was ready to hit the market.[109] And each state court might develop its own test for "foreseeability." Rather than face the inconsistent judgements of dozens of state courts that render tool 1.0 unprofitable, the inventor of tool 1.0 may be encouraged to never disclose or sell tool 1.0, holding onto it in secret until she can make an improved tool 2.0.[110] Instead of applying for a patent as soon as she reaches federal non-obviousness, the inventor is encouraged to delay her patent application until she meets the state products liability foreseeability requirements. This would frustrate Congress's "carefully crafted bargain," which already has mechanisms that reflect a congressional determination on the optimal time for disclosure.[111]

The patent doctrines of novelty, non-obviousness, and utility both indicate a Congressional desire for prompt applications and disclosure. Novelty and non-obvious encourage prompt applications because applicants want to compete with the least possible amount of prior art. The low threshold of utility also shows a federal policy desire to see prompt patent applications. There are three proposed justifications for the federal policy in favor of early patenting. The "prospect theory" notes that granting an early patent heavily incentivizes additional investment in the right.[112] The waste-limiting theory suggests that early patents reduce

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[109] Although the federal government has been generally permissive of state products liability law, this "stop-selling" idea has been one of the rare instances of preemption found by the Supreme Court. In *Mutual Pharmaceutical v. Bartlett*, a generic pharmaceutical company noted that federal law prevented it from using the label sought by a plaintiff in a failure to warn claim. 133 S. Ct. 2466 (2013). The injured plaintiff argued that a generic drug manufacturer could have avoided both state and federal liability by simply pulling its drug from the market. *Id.* at 2470. The Supreme Court rejected this argument, using law and economics to express distaste for the state court ruling's effect of "require[ing] a manufacturer to choose between leaving the market and accepting the consequences of its actions." *Id.* at 2479 (citing Calabresi & Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089 (1972) (discussing the law's responsibility to allocate entitlements)).
[110] If the inventor never sells, uses or discloses tool 1.0, her own tool 1.0 will not count against the patentability of tool 2.0. *See, e.g.*, Moleculon Research v. CBS, 793 F.2d 1261, 1266 (Fed. Cir. 1986) (secretly keeping and working on a prototype toy for many years does not destroy novelty).
[111] Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 146–52 (1989).
[112] Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J. L. & ECON. 265 (1977).

the amount wasted effort by competitors.[113] The most pragmatic theory is that earlier patents lead to earlier expiration.[114]

The three requirements of obviousness, novelty, and utility are carefully tailored to calibrate the ideal *timing* of disclosure for an invention. When a state court overrides obviousness with its own foreseeability inquiry, it encourages inventors to hold invention 1.0 secret and unused, until the foreseeable, but not obvious, invention 2.0 is ready. This delay frustrates the federal patent aim of "promoting disclosure of inventions" and the secrecy prevents the collaborative "stimulat[ion of] further innovation."[115] This offends the *Aronson* test.

This frustration is easily and narrowly corrected by conflict preemption. Binding state courts to federal determinations of non-obviousness would prevent state courts from weaponizing 2.0 against the inventor of tool 1.0. Preventing the state "foreseeability" test from exceeding the federal obviousness test provides the requisite certainty to ensure successful disclosure of inventions.

V. Conclusion

Prior to 2007, the patent obviousness inquiry assumed no creativity on the part of the inventor. This meant that a secondary invention that was "foreseeable" to a person with common sense was not necessarily "obvious" under the patent inquiry. Under pre-2007 law, it was therefore feasible that a secondary patent, even though it was non-obvious to the patent office, could embody a foreseeable alternative design in state products liability suits. The 2007 *Teleflex* decision changed the patent obviousness inquiry. Once the patent office began considering common sense and creativity, the patent obviousness inquiry became equivalent to, if not more demanding than, the state alternative design foreseeability inquiry.

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[113] Mark Grady & Jay Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305 (1992).
[114] John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439 (2003).
[115] Aronson v. Quick Point Pencil, 440 U.S. 257, 262 (1979).

This change to federal patent law changes the patent document's interactions with state products liability law. Many states had already reached the correct policy decision before *Teleflex* – preventing the use of secondary patents as proof of defect under the subsequent remedial measures doctrine. This Note encourages state governments that previously allowed secondary patents as subsequent remedial measures to reconsider their treatment of secondary patents as products liability evidence in a post-*Teleflex* world.

Because the new obviousness test includes common sense and creativity, it is much harder for plaintiff's experts to explain why the secondary would be non-obvious, yet still constitute a foreseeable alternative design. Using secondary patents as evidence will invite a needlessly complex and confusing inquiry into the courtroom.

The rigor of the new *Teleflex* obviousness inquiry encourages secondary patent applicants to disparage earlier inventions in order to demonstrate their own non-obviousness. State courts can expect to see more and more secondary patents submitted as evidence for this reason. However, those criticisms of the defendant are of tenuous relevance and typically prejudicial.

When an expert seeks to use a secondary patent as an example of an available alternative, she actually asks the jury to reach the opposite conclusion from the document she offers. This is a suspect use of expert testimony, subject to *Daubert* scrutiny.

Where a state court ignores this Note's policy suggestion and admits a secondary patent as a foreseeable alternative, it necessarily establishes an alternative design foreseeability standard that is more demanding than the patent obviousness standard. This should be preempted by federal patent law. The *Aronson* test preempts state laws that frustrate the federal aims of promoting innovation and promoting disclosure. A state foreseeability standard that exceeds the patent obviousness standard does both.

The federal stance of use of secondary patents as a foreseeable alternative explicitly states that Congress expects such an evidentiary tactic to deter future innovation. And the threat of being financially punished by state courts would encourage inventors to withhold their discoveries until they met the state standard – distorting the federal calculation of the optimal time to disclose inventions.

In conclusion. *Teleflex* raised the federal patent obviousness standard to be at least equivalent to state alternative design foreseeability standards. Subsequent remedial measure doctrine should have prevented use of secondary patents as an alternative design even before *Teleflex*. After *Teleflex*, states that previously chose not to extend subsequent remedial measure rules to secondary patents should now do so. If they do not do so by their own policy decision, they may be forced to do so by federal preemption.