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David Tseng

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NOT ALL PATENTS ARE CREATED EQUAL: BIAS AGAINST PREDICTABLE ARTS PATENTS IN THE POST-KSR LANDSCAPE

David Tseng^{*}

INTRODUCTION

Investment in intellectual property is considered a shrewd business strategy.¹ However, companies that invest heavily in patenting the results of research and development may later be surprised by their inability to generate revenue from their patent portfolios. This is because those seeking to enforce patents in the predictable arts may find themselves stymied by recent developments in patent jurisprudence, especially with respect to the doctrine of obviousness. By encouraging a common sense perspective and rejecting rigid formulations, the Supreme Court in *KSR International Co. v. Teleflex, Inc.*² unintentionally injected a significant measure of subjectivity and irregularity into the obviousness analysis, which has led to an increase in the likelihood of a predictable arts patent being found obvious due to the wide array of rationales available to make such a conclusion. Another emerging trend in the post-*KSR* landscape is that the Supreme Court's flexible approach in determining obviousness has created a bias against patents in the predictable arts.

Part I of this paper defines the general contours between patents in the predictable arts and patents in the unpredictable arts. Parts II and III discuss how the holding of *KSR* and subsequent USPTO³ guidelines establish a bias against predictable art patents. In Part IV, this Article will examine two ways in which the bias against predictable arts patents manifests itself in patent invalidity

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¹ Elizabeth D. Ferrill, *Patent Investment Trusts: Let's Build a PIT to Catch Patent Trolls*, 6 N.C. J. L. & TECH. 367, 368 (2005) (“[I]ntellectual property portfolios (of which patents are a major part) have become valuable assets for businesses and important tools in attracting investment and venture capital. Modern patents have an intrinsic value beyond merely the right to exclude competitors—they serve as powerful marketing tools and can have the same influence on a corporation's bottom line as tangible property assets. In fact, today's intellectual property is a key corporate asset precisely because it may be the primary driver of revenue.”).

² *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).

³ “USPTO” refers to the United States Patent and Trademark Office.

jurisprudence: (1) the difficulty of proving secondary objective indicia of nonobviousness; and (2) the availability of a rigid test such as the Federal Circuit's "lead compound" analysis to inventions in the unpredictable arts but not the predictable arts. Further, Part IV will discuss the ways in which recent Federal Circuit decisions further confirm the bias resulting from the *KSR* decision. Finally, Part V proposes a revitalization of secondary considerations and the prohibition against the use of hindsight bias to offset this bias.

I. DEFINITION OF PREDICTABLE ARTS

In patent law jurisprudence, courts have traditionally differentiated between predictable and unpredictable arts.⁴ The distinction between predictable and unpredictable arises out of an enablement analysis, a statutory requirement to patentability.⁵ Under the enablement analysis, a patent disclosure needs to sufficiently enable one of ordinary skill in the art to make or use the invention without undue experimentation.⁶ The predictability of art is one of the factors that is used to assess the level of experimentation.⁷

A predictable art can be characterized as a technology field where one of ordinary skill has access to an extensive base of general knowledge. By contrast, a technological field is less predictable when a technology is nascent; therefore, the patent disclosure must include "specific and useful teaching," because enabling information is beyond the knowledge of an ordinary artisan.⁸ In other words, a predictable art is a field of art where, even when the patent disclosure is missing explanation of claimed technical details, one of ordinary skill can still

⁴ See Application of Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970).

⁵ The enablement requirement comes from 35 U.S.C. § 112 which requires the patent specification to describe "the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as 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 [invention]." 35 U.S.C. § 112 (2012).

⁶ *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

⁷ Known as one of eight *Wands* factual inquiries in determining the level of experimentation: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *See id.*

⁸ See, e.g., *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254 (Fed. Cir. 2004); *MacMillan v. Moffett*, 432 F.2d 1237, 1240 (C.C.P.A. 1970) ("In some unpredictable areas of chemistry and biology, there is no conception until the invention has been reduced to practice.").

use general knowledge to implement the claimed invention with reasonable expectation of success.⁹

Predictability of a particular art depends heavily on whether the existing knowledge base of one of ordinary skill in the art can be used to reliably achieve potentially patentable new results.¹⁰ As such, it has been observed that predictable arts include mechanical and electrical inventions, while unpredictable arts include chemical and physiological inventions.¹¹ Software is a technical discipline typically recognized as a predictable art due to its close association to electrical engineering, which generally requires very little to satisfy the written description requirement.¹² Regardless of its associated technological discipline, an invention directed towards novel configurations and arrangement of pre-existing technology infers a finding that the invention is directed towards the predictable arts.¹³

II. THE KSR DECISION CREATES A BIAS AGAINST PREDICTABLE ARTS

Issued patents are presumed to be valid, and challenges to patent validity must be proven by clear and convincing evidence,¹⁴ even for prior art references that were not examined by the USPTO during prosecution.¹⁵ The burden of

⁹ See *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003) (“[T]he artisan’s knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art.”).

¹⁰ See *Rothman v. Target Corp.*, 556 F.3d 1310, 1318 (Fed. Cir. 2009) (“In the predictable arts, a trial record may more readily show a motivation to combine known elements to yield a predictable result.”).

¹¹ *Application of Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970).

¹² Greg R. Vetter, *The Predictability Doctrine and the Software Arts*, 76 MO. L. REV. 763, 804–06 (2011) (arguing that software should not necessarily be considered as a predictable art despite conventional wisdom to the contrary because most software runs on a series of layers where vulnerability in each layer can lead to unpredictability); see also *In re Hayes Microcomputer Prod. Patent Litig.*, 982 F.2d 1527, 1533–36 (Fed. Cir. 1992).

¹³ See *Ex Parte Huppenthal*, No. 2009-010115, 2011 WL 1826813, at *3–4 (B.P.A.I. May 10, 2011) (affirming examiner finding of obviousness, noting that invention claiming cluster computer system covering a configuration of known components to be a predictable art).

¹⁴ The “‘clear and convincing’ standard is an intermediate standard which lies somewhere in between the ‘beyond a reasonable doubt’ and the ‘preponderance of the evidence’ standards of proof. Although an exact definition is elusive, ‘clear and convincing evidence’ has been described as evidence that ‘place[s] in the ultimate factfinder an abiding conviction that the truth of its factual contentions are highly probable.’” See *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359 n.5 (Fed. Cir. 2007) (citation omitted).

¹⁵ *Microsoft Corp. v. i4i Ltd. P’ship*, 132 S. Ct. 2238, 2252 (2011).

proof rests with the patent challenger.¹⁶ With respect to obviousness, the clear and convincing evidentiary standard is not satisfied by a mere showing that all of the claimed elements exist in the prior art.¹⁷ At a minimum, establishing obviousness under the clear and convincing evidentiary standard requires showing some likelihood of success in combining the prior art to meet the claim elements.¹⁸

On appeal, obviousness is a question of law receiving de novo review.¹⁹ It is important to note that “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”²⁰ As discussed in detail below, however, litigated patents in the predictable arts face an increased likelihood of obviousness invalidation in the post-*KSR* landscape.

KSR involved an infringement action over a patent directed to connecting an electronic throttle control to adjustable vehicle control pedals.²¹ Applying the obviousness factors articulated in *Graham v. John Deere*, the district court ruled on summary judgment that the relevant asserted patent claim was invalid due to obviousness, finding that there was little difference between the claim at issue and the prior art.²² The district court further stated that the Federal Circuit’s “teaching, suggestion, and motivation” (TSM) test was met because the claimed structure would have inevitably been derived in the industry based on teachings in the prior art.²³ The Federal Circuit reversed, holding that the district court failed to apply the TSM test strictly enough.²⁴ The Federal Circuit criticized the

¹⁶ “A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.” 35 U.S.C. § 282 (2012).

¹⁷ *See* *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1375 (Fed. Cir. 2011).

¹⁸ *See* *Celsis In Vitro, Inc. v. Cellzdirect, Inc.*, 664 F.3d 922, 928–29 (Fed. Cir. 2012).

¹⁹ *See* *Soverain Software LLC v. Newegg Inc.*, 705 F.3d 1333, 1336 (Fed. Cir. 2013).

²⁰ *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

²¹ *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 399 (2007).

²² *Id.* at 399–401 (finding that *Graham v. John Deere* set forth an “expansive and flexible approach to the obviousness question”). *Graham* sets forth the main factual inquiries to determine obviousness: (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue are to be ascertained; and (3) the level of ordinary skill in the pertinent art resolved. *Graham v. John Deere*, 383 U.S. 1, 17 (1966). Other factual factors may be relevant in determining, known as secondary considerations, include commercial success, long felt need, and failure of others. *Id.*

²³ *KSR Int'l Co.*, 550 U.S. at 399–400.

²⁴ *Id.*

inferences made based on the prior art because none of the references were directed to the precise problem that the invention sought to address.²⁵

On appeal, the Supreme Court reversed, reasoning that the Federal Circuit addressed the obviousness question in a narrow and rigid manner that is inconsistent with both 35 U.S.C. § 103 and the *Graham* decision.²⁶ One of the main takeaways from *KSR* is that, although the TSM test can provide a “helpful insight” regarding obviousness, the Federal Circuit improperly adopted this “helpful insight” as a “rigid and mandatory formula.”²⁷ Though the Supreme Court noted that there is no “necessary inconsistency” between the TSM test and *Graham*, it cautioned that an overly rigid adherence to the TSM test may lead to situations where common sense combinations of prior art are ignored.²⁸

The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advances that would occur in ***the ordinary course without real innovation retards progress*** and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.²⁹

The *KSR* decision eliminated the rigid application of the TSM test to show obviousness, and also made the *Graham* factors less restrictive. Under the traditional *Graham* analysis, a prior art reference cannot be considered in the obviousness analysis unless it can first be classified as an analogous art. Prior to *KSR*, the Federal Circuit followed a two-step analysis to determine whether a prior art reference is analogous: “(1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.”³⁰

The Supreme Court adopted a less restrictive approach, holding that all prior art can be considered for obviousness purposes as long as it addresses “any need or problem known in the field of endeavor at the time of invention and addressed by the patent.”³¹ The Supreme Court disapproved of the assumption that a person of ordinary skill attempting to solve a problem will be led only to

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.* at 418.

²⁸ *Id.* at 401.

²⁹ *Id.* at 419 (emphasis added).

³⁰ See, e.g., *In re Clay*, 966 F.2d 656, 658–59 (Fed. Cir. 1992) (citing *In re Deminski*, 96 F.2d 436, 442 (Fed. Cir. 1986)); *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004); *Innovation Toys, LLC v. MGA Entm’t, Inc.*, 637 F.3d 1314, 1321 (Fed. Cir. 2011).

³¹ *KSR Int’l Co.*, 550 U.S. at 420.

those elements of prior art designed to solve the same problem, noting that “familiar items may have obvious uses beyond their primary purposes.”³²

Once the threshold question of the scope of the relevant prior art has been determined, *Graham* requires the fact finder to consider whether the subject matter of a claim is obvious by analyzing the “objective reach of the claim.”³³ A guiding principle in this analysis requires courts to distinguish between “real innovation” versus “advances . . . in the ordinary course.”³⁴ In detailing a non-exhaustive list of rationales on which a conclusion of obviousness can be based, *KSR* heavily invoked the concepts of predictability and common sense. For instance, a rigid application of TSM analysis should not restrain a finding of obviousness when “[t]he combination of familiar elements according to known methods . . . does no more than yield predictable results.”³⁵ Likewise, an overly narrow application of the TSM test should not preclude a finding of obviousness when a claimed improvement was merely “the predictable use of prior art elements according to their functions.”³⁶

III. THE USPTO GUIDELINES INTERPRETING *KSR* FURTHER CEMENTS THE BIAS AGAINST PREDICTABLE ARTS

Approximately five months after the *KSR* decision, on October 10, 2007, the USPTO issued interim guidelines in response to the decision instructing examiners how to evaluate whether and how one of ordinary skill in the art would exercise ordinary creativity, common sense, and logic to determine obviousness.³⁷ The 2007 *KSR* Guidelines listed seven, non-mutually exclusive rationales discussed within the *KSR* decision that patent examiners may use to demonstrate obviousness.³⁸ Readily-apparent is the fact that virtually all the inquiries involve whether the elements were already “known” and whether the art is predictable:

³² *Id.* at 420; *see Wyers v. Master Lock Co.*, 616 F.3d 1231, 1237–38 (Fed. Cir. 2010) (finding prior art relating to sealing of padlocks to prevent contamination to be pertinent to asserted patents directed to sealing of trailer hitch locks for automobiles); *see also In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1380–82 (Fed. Cir. 2007) (finding patent claim directed to gas spring as means for retaining folding mechanism on treadmill as obvious).

³³ *KSR Int’l Co.*, 550 U.S. at 420.

³⁴ *Id.* at 402.

³⁵ *Id.* at 401; *U.S. v. Adams*, 383 U.S. 39, 50–52 (1966).

³⁶ *KSR Int’l Co.*, 550 U.S. at 401.

³⁷ *See Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57,526-01, 57,526–35 (Oct. 10, 2007) [hereinafter 2007 *KSR* Guidelines].

³⁸ *Id.* at 57,529.

- Combining prior art elements according to known methods to yield ***predictable results***
- Simple substitution according to known methods to yield ***predictable results***
- Use of known techniques to improve similar devices (methods, or products) in the similar way
- Applying a known technique to a known device (method, or product) ready for improvement to yield ***predictable results***
- "Obvious to Try" from a finite number of identified, ***predictable solutions***, with a reasonable expectation of success
- Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been ***predictable*** to one of ordinary skill in the art
- TSM test: Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention³⁹

The 2007 KSR Guidelines also provided the factual elements necessary to prove each of the seven rationales and utilized various pre-*KSR* Federal Circuit cases as examples. In lockstep with the *KSR* decision, the 2007 KSR Guidelines advised patent examiners to retreat from any structured approach to determine obviousness and support a flexible framework where the focus of the inquiry is on the predictability of prior art combinations or the application of known components or techniques.⁴⁰

Approximately three years later, the USPTO issued an updated guideline on September 1, 2010 to provide additional guidance based on an analysis of Federal Circuit jurisprudence on obviousness *after KSR*. The 2010 KSR Guidelines reaffirmed that “KSR did not place any limit on the particular approach to be taken to formulate the line of reasoning [and that] the KSR decision is not to be seen as replacing a single test for obviousness—e.g., the TSM test—with the seven rationales listed in the 2007 KSR Guidelines.”⁴¹ In addition, the 2010 KSR Guidelines further re-affirmed that although patent practitioners needed to shift the emphasis of nonobviousness arguments to a certain degree, the familiar lines of nonobviousness argument still apply,

³⁹ *Id.* (emphasis added).

⁴⁰ *Id.* at 57,534.

⁴¹ Examination Guidelines Update: Developments in the Obviousness Inquiry After *KSR v. Teleflex*, 75 Fed. Reg. 53,643-01, 53,645 (Sept. 1, 2010) [hereinafter 2010 KSR Guidelines].

including “teaching away from the claimed invention by the prior art, lack of a reasonable expectation of success, and unexpected results.”⁴²

These lines of argument, especially with respect to reasonable expectation of success and unexpected results, are influenced by the relative predictability of the art. The predictability of the technology affects the scope and content of the knowledge base for one of ordinary skill in the art. In unpredictable fields where pertinent references to a proposed claim invention are sparse, it may be more difficult to identify prior art that teaches away from the claimed invention. Moreover, it is often difficult to discern the advantages and innovation of predictable art inventions, making it easier for a potential patent infringer to present sufficient facts to establish a prima facie case of obviousness during prosecution. This has the effect of placing a heavier burden on the patentee, where the patentee must be prepared to demonstrate nonobviousness, “such as comparative test data showing that the claimed invention possesses improved properties not expected by the prior art,” in order to overcome likely obviousness rejections from the USPTO.⁴³

Whereas the 2007 KSR Guidelines provided explanations and case examples with respect to seven types of obviousness reasoning, the 2010 KSR Guidelines focused on Federal Circuit obviousness cases involving three rationales: combining prior art elements, substitution of known methods with another, and obvious to try.⁴⁴

The “combining prior art elements” case examples discussed by the USPTO in the 2010 KSR Guidelines demonstrate that the greater the complexity of the art, the easier it is to argue that the combination of known elements of

⁴² *Id.*

⁴³ See Manual of Patent Examining Procedure (MPEP) § 2142 (9th ed. Rev. 9, Aug. 2012). It is important to note that in the patent litigation context, there is no shifting of “the burden of proof to the patentee to rebut the asserted, but improper, prima facie case with the evidence of commercial success and copying. This is a distortion of the burden of proof, which never leaves the challenger.” *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1367 (Fed. Cir. 2012); *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1078 (Fed. Cir. 2012) (“[T]he Supreme Court has never imposed nor even contemplated a formal burden-shifting framework in the patent litigation context.”).

⁴⁴ The 2010 KSR Guidelines also discussed consideration of evidence, noting that all timely presented evidence, including evidence rebutting a prima facie case of obviousness, must be considered in an obviousness analysis; evidence of commercial success is pertinent where a nexus between the success of the product and the claimed invention has been demonstrated; and that evidence of secondary consideration may not overcome a strong prima facie case of obviousness. See, e.g., 2010 KSR Guidelines, *supra* note 41, at 53,658–59; *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007); *In re Sullivan*, 498 F.3d 1345, 1351–53 (Fed. Cir. 2007); *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1374–75 (Fed. Cir. 2010); *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310 (Fed. Cir. 2008).

prior art “teaches away” from the claimed invention. For example, the claimed technology in *In re Omeprazole Patent Litigation* involved coatings on a pill formulation.⁴⁵ The Federal Circuit found that one of ordinary skill would not have predictably arrived at the claimed modification from the prior art process due to the “multiple paths” available to address the problem.⁴⁶ Indeed, the benefits of the claimed modification over the known and successful prior formulation were not recognized at the time of patenting.⁴⁷

Likewise, with respect to a medical device patent directed to screws used in spinal surgery, the Federal Circuit preserved validity in finding that the presented prior art combination expressly taught away from the claimed configuration.⁴⁸ By contrast, obviousness-based “combining known elements” is more likely to be found in the predictable technical fields, such as mechanical covers, trailer locks, or methods of applying pesticide.⁴⁹

The case examples discussing obviousness by “substituting one known element for another” in the 2010 KSR Guidelines illustrate only examples of obviousness for predictable art inventions such as inventions directed to folding and stabilizing the base of a treadmill,⁵⁰ utilizing a resistive electrical switch in a stationary pest control device,⁵¹ and internet auction systems for municipal bonds.⁵²

The 2010 KSR Guidelines also discuss cases involving “obvious to try,” perhaps the most controversial expansion in the obviousness analytical framework.⁵³ In this particular analysis, the context of the subject matter must be

⁴⁵ *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1365 (Fed. Cir. 2008).

⁴⁶ *Id.* at 1380–81.

⁴⁷ *Id.*

⁴⁸ *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009).

⁴⁹ *See, e.g., Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1366–68 (Fed. Cir. 2008) (finding asserted patent claims directed to segmented and mechanical covers to be obvious); *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1349–50 (Fed. Cir. 2009) (finding method of sanitizing meat by spraying it with an antibacterial spray under conditions, including “at least 50 psi,” to be obvious); *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1237–38 (Fed. Cir. 2010) (finding patent covering hitch pin locks for trailers to be obvious); *Cf. Crocs, Inc. v. Int’l Trade Comm’n*, 598 F.3d 1294, 1308–11 (Fed. Cir. 2010) (finding patent covering footwear nonobvious because prior art expressly taught away from claimed feature of having foam straps riveted to a foam base).

⁵⁰ *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1380–82 (Fed. Cir. 2007).

⁵¹ *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1344 (Fed. Cir. 2008).

⁵² *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1327 (Fed. Cir. 2008).

⁵³ The Supreme Court in *KSR* identifies the elements of “obvious to try.” *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 402–03 (2007) (“When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.”).

considered, meaning that the “characteristics of the science of technology [and] its state of advance” are an explicit part of the analysis.⁵⁴ The “obvious to try” analysis, as with the other lines of obviousness reasoning discussed in the 2010 KSR Guidelines, hinges largely on whether one of ordinary skill in the art would be able to predictably combine or modify the prior art references to arrive at the claimed invention. This is exemplified with respect to the requirement that there only be a “finite number” of predictable solutions in the art.⁵⁵

As interpreted by the Federal Circuit, “finite” means a small or easily negotiable number, such as a claimed drug formulation that can be discovered by experimenting with one of two known techniques in the prior art.⁵⁶ For example, in the pharmaceutical industry, a claimed isolated nucleic acid molecule was found to be obvious when prior art identified “conventional methods” by which the claimed molecule can be isolated.⁵⁷ If the facts demonstrate that there are only a “finite number” of predictable solutions in the art, nonobviousness can be demonstrated if there is no reasonable expectation of success in combining or modifying the prior art references.⁵⁸ Again, it is more likely that a claimed invention is “obvious to try” for technologies in traditionally predictable fields of art, because a claimed combination is obvious to try when it makes common sense to do so.⁵⁹ As noted by *KSR*, common sense obviousness manifests when there are “finite number of identified, predictable solutions”⁶⁰

⁵⁴ See *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1352 (Fed. Cir. 2008) (affirming district court’s granting of preliminary injunction on extended release formulations of an antibiotic).

⁵⁵ See *Ortho-McNeil Pharm., Inc. v. Mylan Labs, Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008) (holding anti-convulsion drug nonobvious because it was unexpectedly discovered during research for new anti-diabetic drug).

⁵⁶ *Id.*; *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341, 1349 (Fed. Cir. 2009) (finding patent relating to drug coating for increasing bioavailability to be obvious because the prior art was not vague in pointing toward a general approach or area of exploration, but rather guided the formulator precisely to the use of one of two methods).

⁵⁷ *In re Kubin*, 561 F.3d 1351, 1360–61 (Fed. Cir. 2009).

⁵⁸ *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007); *Ortho-McNeil*, 520 F.3d at 1364; see also *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1087–89 (Fed. Cir. 2008) (finding patent relating to drug used to treat or prevent blood-thrombotic events, such as heart attacks and strokes, not obvious due to unpredictability and experimentation involved); *Rolls-Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1338–39 (Fed. Cir. 2010) (finding patent relating to swept fan blades used on turbofan jet engines nonobvious due the broad selection of choices for further investigation in the art, and the lack of motivation in prior art to create the claimed design).

⁵⁹ *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1328–29 (Fed. Cir. 2009).

⁶⁰ *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007).

Thus, the USPTO's post-KSR guidelines further confirm the existence of a bias against the predictable arts.

IV. CURRENT BIAS AGAINST THE PREDICTABLE ARTS IN PATENT OBVIOUSNESS FRAMEWORK

The expansion of the obviousness doctrine to include "common sense" combinations of prior art shifts the focus of an obviousness analysis from what is disclosed in the prior art to the level of predictability in the art and the level of knowledge of one of ordinary skill in the art. Although the USPTO guidelines have emphasized that evaluations of invalidity should always be evaluated on a case-by-case basis, there are indicators in patent jurisprudence to strongly suggest that there is a bias against patents in the predictable art fields. For one, the predictability of the art has entrenched many of the secondary considerations of nonobviousness. Second, the Federal Circuit's lead compound analysis is an example of the rigid analysis needed to analyze obviousness in unpredictable arts. Finally, Federal Circuit decisions after issuance of the post-KSR guideline confirm the existence of this bias.

A. The Objective Indicia of Secondary Considerations Incorporates Analysis of Technology Predictability

Secondary considerations are court-recognized contextual considerations used to assist judges in determining obviousness with the most prominent categories being commercial success, long felt need, failure of others, and copying by others.⁶¹ Created to serve as "objective indicia" of whether an invention should be afforded a patent, secondary considerations are based upon "economic and motivational" reasons, divorced from the technology claimed in the patent at issue.⁶²

A study of cases after *KSR* shows that secondary considerations, rarely, if ever, override a prima facie showing of obviousness.⁶³ Indeed, there is criticism that the doctrine of secondary considerations is substantially underdeveloped.⁶⁴ In addition, it has been suggested that the *KSR* decision implicitly downplays the role of secondary analysis by holding that where "the content of the prior art, the

⁶¹ See *Perfect Web*, 587 F.3d at 1328–29 (for a discussion of other secondary consideration analyzed by courts); *Graham v. John Deere*, 383 U.S. 1, 17–18 (1966).

⁶² *Graham*, 383 U.S. at 36.

⁶³ See, e.g., Natalie A. Thomas, *Secondary Considerations in Nonobviousness Analysis: The Use of Objective Indicia Following KSR v. Teleflex*, 86 N.Y.U. L. REV. 2070, 2077 (2011); Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. 1391, 1404 (2006).

⁶⁴ Jonathan J. Darrow, *Secondary Considerations: A Structured Framework for Patent Analysis*, 74 ALB. L. REV. 47, 50 (2010).

scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors, summary judgment is appropriate.”⁶⁵

Further, issues regarding predictability and technological complexity invariably become a part of the discussion in a secondary analysis. Proof of secondary considerations of nonobviousness must demonstrate a nexus between the objective indicia and the patented invention.⁶⁶ For example, with respect to the indicia of commercial success, the patentee is required to show a “legally and factually sufficient connection” between proven success and the patented invention to establish the requisite nexus.⁶⁷

This standard is applied to require the patentee to demonstrate that the inventive features of the patent are the reason for the commercial success.⁶⁸ On the other hand, if the commercial success is “due to an element in the prior art, no nexus exists.”⁶⁹ Moreover, to the extent that the commercial success and the patented invention are not co-extensive, the patentee must demonstrate a relationship between the patent and the commercial product sufficient to support an inference of nexus.⁷⁰ Even if an inference of nexus has been established, it can be rebutted by showing that the commercial success is due to non-technical factors, such as advertising, business acumen, capital resources, or superior workmanship.⁷¹

The secondary indicia of long-felt need requires a technical discussion, as the technical merits of the invention at issue must represent a solution to the problem identified in the prior art.⁷² In addition, a failure of others analysis requires a technological discussion, as relevant factors include the acknowledgement of a need in the art, and that artisans were attempting to find a

⁶⁵ *KSR Int’l Co.*, 550 U.S. at 426; Eli M. Sheets, *Arguing Secondary Considerations After KSR: Proceed with Caution*, 21 FED. CIRCUIT B.J. 1, 14–15 (2011).

⁶⁶ *See, e.g., In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011); *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010); *Tokai Corp. v. Easton Enter., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011).

⁶⁷ *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988); *Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1027 (Fed. Cir. 1985).

⁶⁸ *In re Kao*, 639 F.3d at 1069–70.

⁶⁹ *See Tokai*, 632 F.3d at 1369–70.

⁷⁰ *Demaco*, 851 F.2d at 1392.

⁷¹ *J.T. Eaton & Co., Inc. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997).

⁷² *See Demaco*, 851 F.2d at 1392–93; *Hughes Tool Co. v. Dresser Indus., Inc.*, 816 F.2d 1549, 1556 (Fed. Cir. 1987).

solution to the art over a long duration of time.⁷³ Similarly, relying on copying by others to show nonobviousness requires a showing that competitors are specifically copying the patented features to give rise to an inference of a nexus.⁷⁴

When it comes to patents in the predictable arts, the patentee faces a higher burden in establishing the nexus for commercial success. Since most technical elements will be already known in a predictable art, the patentee may find it difficult to identify the inventive elements that link the commercial success to the proposed invention. Hypothetically, even if an invention proposes a new configuration of previously known prior art elements not readily discoverable by one of ordinary skill in the art, there may still be insufficient factual basis for commercial success because the reason for said success is “due to an element in the prior art.”⁷⁵ Even if competitors in the industry copied the patented product, in fields of predictable art, it will be difficult to prove that competitors actually copied the inventive aspects of the invention, as opposed to merely copying marketing methods or workmanship quality. By contrast, it will be far easier to prove a nexus between commercial success and a new pharmaceutical product that serves as a more effective treatment for a particular illness. The fact that the new product is more effective than already existing medications serves as a strong inference of such a nexus.

As is the case with proving the nexus to commercial success, proving the other secondary indicia in predictable art patents is similarly difficult. Fields of predictable art, such as simple mechanical devices, are far less likely to generate scholarly articles articulating a particular need in the industry, as opposed to unpredictable fields such as biochemistry. Furthermore, fields of predictable arts are less likely to generate breakthrough technologies that impact the marketplace. These technological breakthroughs occur more frequently in unpredictable arts such as biochemistry and physiology, where long-thought incompatible reactions and combinations of compounds ultimately prove to be useful. On the other hand, publications on more predictable fields, such as software, slant more heavily towards using the broad base of known technologies and techniques. In this environment, it will be more difficult to discern specific declarations of long-felt need from those of ordinary skill in the relevant industry. As such, despite the fact that secondary considerations are meant to be non-technical in nature, demonstrating nonobviousness through secondary considerations in the predictable arts is not an easy task, since

⁷³ *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1583 (Fed. Cir. 1996) (“only a brief time period” found unpersuasive); *Intel Corp. v. U.S. Int’l Trade Comm’n*, 946 F.2d 821, 835 (Fed. Cir. 1991); *Minnesota Min. & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1574–75 (Fed. Cir. 1992); *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1285 (Fed. Cir. 2000).

⁷⁴ *Cable Elec. Prods, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1028 (Fed. Cir. 1985).

⁷⁵ *See Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369–70 (Fed. Cir. 2011).

proving the relevant objective indicia requires well-developed discussion regarding the technical merits.

B. The Federal Circuit's "Lead Compound" Analysis of Chemical Compounds Exemplifies a Bias Against Predictable Arts

The "lead compound" cases further demonstrate the technological sophistication in an obviousness analysis.⁷⁶ The "lead compound" cases involve a two-factor test for determining the obviousness of a claimed compound: that one of ordinary skill in the art (1) would have selected a certain chemical compound as a lead compound; and (2) would have had motivation to modify the lead compound to arrive at the claimed compound.⁷⁷ This stringent and intensive analysis is meant to specifically help the courts determine obviousness in the unpredictable field of biological compounds. The relatively rigorous application of this test by the courts raises the burden of proving obviousness for an unpredictable art beyond the *KSR* baseline. This serves as yet another instance of bias against predictable arts.

On its face, the categorical application of this two-factor test for chemical compounds appears to be the type of "rigid" analysis, akin to the TSM test, that *KSR* frowned upon.⁷⁸ Yet, it has persevered and thrived post-*KSR*. The 2010 *KSR* Guidelines note that the lead compound cases "form an important subgroup of the obviousness cases that are based on substitution."⁷⁹ This, however, left unanswered the question of whether it is proper to follow the "lead compound" analysis *per se* in determining the patentability of chemical compounds. In response, the Federal Circuit has indicated that the flexibility in determining the "lead compound" factors is consistent with the *KSR* principles, though they failed to reconcile the categorical application of an obviousness rule to the principles of *KSR*.⁸⁰

⁷⁶ See *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1343 (Fed. Cir. 2000) ("At the heart of this validity dispute is whether one of skill in this art would have found motivation to combine pieces from one compound in a prior art patent with a piece of another compound in the second prior art patent through a series of manipulations."); see also *In re Lalu*, 747 F.2d 703, 707 (Fed. Cir. 1984).

⁷⁷ See *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1354 (Fed. Cir. 2007).

⁷⁸ Other problems with the lead compound analysis include district court confusion over the application of this test, and the failure to factor in the realities of drug development, such as patents covering combination drugs and formulations. See Briana Barron, *Structural Uncertainty: Understanding the Federal Circuit's Lead Compound Analysis*, 16 MARQ. INTELL. PROP. L. REV. 401, 417–20 (2012).

⁷⁹ 2010 *KSR* Guidelines, *supra* note 41, at 53,651.

⁸⁰ *Eisai Co. v. Dr. Reddy's Labs. Ltd.*, 533 F.3d 1353, 1357–59 (Fed. Cir. 2008) ("[P]ost-*KSR*, a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound.").

The heart of the matter is that the flexibility inherent within the lead compound analysis gives patentees more leeway to argue nonobviousness of their invention. For example, any known compound can serve as a lead compound as long as there is some motivation by one of ordinary skill in the art to select that compound.⁸¹ But demonstrating a suitable lead compound is no easy task, and instead presents an additional element in the nonobviousness analysis that must be determined. The 2010 KSR Guidelines instruct that examiners can select compounds that “pharmaceutical chemists would not select as lead compounds due to expense, handling issues, or other business considerations.”⁸² Nevertheless, the examiner must still present adequate reasons to justify the selection of a particular lead compound.

It is difficult to reconcile the difference between how pharmaceutical chemists and one of ordinary skill in the art would select a lead compound. In addition, the Federal Circuit has said that the selection of a lead compound should be guided by the compound’s pertinent properties as assessed by one of ordinary skill in the art, such as activity, potency, toxicity, and other chemical properties.⁸³

Assuming that a suitable lead compound even exists, then there must be motivation to modify the chemical compound, but such motivation need not be explicitly found in the prior art, and more than one compound may be selected as a lead compound.⁸⁴ However, the mere structural similarity between the claimed compounds and any other prior art lead compound is insufficient motivation.⁸⁵ Instead, the patent challenger must demonstrate “a sufficiently close relationship” to create an expectation that the claimed compound will have “similar properties” to the prior art compound.⁸⁶ Moreover, even if there is a motivation to select and modify the claimed compound, obviousness can be found only if there is a “reasonable expectation of success” that modifying the prior art lead compound will yield the claimed compound.⁸⁷ Accordingly, sorting through this myriad of technological issues gives the patentee plenty of latitude to make nonobviousness arguments. The lead compound analysis appears to be in stark contradiction to the Supreme Court’s disapproval of the rigid application of rules to determine obviousness. By comparison, the same

⁸¹ *Id.* at 1359.

⁸² 2010 KSR Guidelines, *supra* note 41, at 53,652.

⁸³ *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1292 (Fed. Cir. 2012).

⁸⁴ *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1007 (Fed. Cir. 2009) (“The requisite motivation [to modify] can come from any number of sources and need not necessarily be explicit in the art.”); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1352 (Fed. Cir. 2007).

⁸⁵ *Eisai Co.*, 533 F.3d at 1357.

⁸⁶ *Id.*

⁸⁷ *See Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 996–97 (Fed. Cir. 2009).

elevated burden of proof to show obviousness is not afforded to patentees in predictable fields of art, demonstrating a tangible bias against predictable arts.

C. Recent Federal Circuit Decisions Further Demonstrate the Bias in the Analysis of Obviousness Against Patents in the Predictable Arts

As discussed earlier, prime examples of unpredictable arts usually involve biochemistry and physiology, such as pharmaceuticals compounds for human use. Pharmaceutical compound patents are more likely to be nonobvious due to extensive amounts of research and development involved in their discovery. This research will have probative value in demonstrating that the claimed invention is more than the “common sense” combination of known elements. For example, *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation* involved patents covering a modified-release dosage form of skeletal muscle relaxants and a method of relieving muscle spasms with the said formulation.⁸⁸ The technical field involved pharmacokinetics, the study of how a person reacts to medication after administration.⁸⁹ The inventors conducted experiments to ascertain the correct pharmacokinetic/pharmacodynamic (PK/PD) profile for the extended release of cyclobenzaprine hydrochloride.⁹⁰ The prior art did not disclose PK/PD values, and the district court premised a finding of obviousness based on bioequivalence of PK values upon immediate release of the compound.⁹¹

The Federal Circuit disagreed and noted that without known PK/PD relationship, immediate-release PK values were of little use in calculating extended-release values, because there was no proof that a skilled artisan would expect the extended release values to produce a therapeutic effect solely because they are drawn from immediate-release values.⁹² The patent expressly disclosed the PK/PD data generated by experimentation.⁹³ Here, due to the unpredictability of measuring the physiological effectiveness of medication, there was tangible research that was disclosed in the patent that the prior art failed to disclose.

The unpredictability of the technological field at issue is also likely to lead to the availability of evidence that the prior art teaches away from the claimed invention. In *Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, the patent-in-suit involved intervertebral implants that have an upper side and lower side each containing a “single anchor” to affix the implant into the

⁸⁸ *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1071 (Fed. Cir. 2012).

⁸⁹ *Id.* at 1067.

⁹⁰ *Id.* at 1071.

⁹¹ *Id.*

⁹² *Id.* at 1073.

⁹³ *Id.*

vertebrae.⁹⁴ The parties agreed that a prior art reference from a common inventor disclosed all of the elements of the only independent claim asserted but for the “single anchor” element.⁹⁵ The Federal Circuit also found that the “single anchor” design was present in the prior art.⁹⁶ Nevertheless, although the prior art references met all of the elements of the claimed invention, the Federal Circuit affirmed the jury’s finding of nonobviousness because the record showed that single anchors were previously thought to be unsafe and unsuitable for use in implants.⁹⁷

Whether a field of art is predictable may not always be superficially apparent,⁹⁸ as illustrated in *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*⁹⁹ There, the patent was directed towards a specific method to cure tobacco leaves to prevent TSNA, a known carcinogen, from forming.¹⁰⁰ The court observed that although methods of curing tobacco have long been known, the patent-in-suit observed that tobacco-curing procedures required a careful controlling of conditions such as humidity, temperature, airflow, and carbon dioxide levels that is “more of an art than a science,” interjecting unpredictability into the field of art.¹⁰¹ The patented method claimed a very specific set of curing conditions and procedures that substantially prevented TSNA from forming.¹⁰² Because the two main prior art references presented failed to make the key observation that TSNAs may be prevented in an aerobic curing condition, which is the condition specifically claimed by the asserted patent to prevent TSNAs from forming, the Federal Circuit affirmed a finding of nonobviousness.¹⁰³

As indicated above, the unpredictability of the “lead compound” sub-class of cases makes it easier to show nonobviousness, especially in regard to proving that one of ordinary skill would be able to modify the prior art to obtain the claimed compound. For example, the Federal Circuit affirmed summary judgment of nonobviousness in *Unigene Laboratories, Inc. v. Apotex, Inc.*,

⁹⁴ *Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1311–12 (Fed. Cir. 2010).

⁹⁵ *Id.* at 1311.

⁹⁶ *Id.*

⁹⁷ *Id.* at 1312.

⁹⁸ For instance, in a recent reexamination appeal, the Board of Patent Appeals and Interferences considered the opinion of a retained expert to help decide whether the design of golf balls is a predictable art in determining issues of obviousness. *See Acushnet Co. Requester v. Patents of Callaway Golf Co. Patent Owner*, Nos. 2010-012258, 2011-001247, 2011-001248, 2011-001255, 2011 WL 841207, at *4–6 (B.P.A.I. Mar. 9, 2011).

⁹⁹ *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1375–76 (Fed. Cir. 2011).

¹⁰⁰ *Id.*

¹⁰¹ *Id.* at 1368.

¹⁰² *Id.* at 1369.

¹⁰³ *Id.* at 1376.

where the asserted claim at issue involved specific formulations for nasal sprays.¹⁰⁴ The claim at issue involved the use of citric acid as an absorption and stabilizing agent in lieu of the prior art agent BZK that does not contain citric acid.¹⁰⁵ This, in combination with the fact that the prior art references discussed minimalized the role of citric acid as an absorption/stabilizing agent, led the Federal Circuit to conclude that the asserted patent claim was nonobvious.¹⁰⁶ Even though all of the elements of the claimed compound were known in the prior art, the analytical framework still required a suggestion to modify the prior art to obtain the claimed compound.

Indeed, one of the challenges of proving obviousness in “lead compound” cases is the selection of the lead compound itself. In *Daiichi Sankyo Co. v. Matrix Laboratories, Ltd.*, the patent-in-suit covered angiotensin receptor blockers (ARBs) used in the treatment of high blood pressure.¹⁰⁷ The Federal Circuit affirmed the district court’s rejection of the selection of the prior art ARB as a lead compound based solely on the structural similarity of the claimed compound, explaining that selecting “a compound as a lead compound depends on more than just structural similarity, but also knowledge in the art of the functional properties and limitations of the prior art compounds.”¹⁰⁸ The Federal Circuit additionally affirmed the finding that the prior art teaches away from the claimed compound, indicating that the prior art expressed a preference for lipophilic groups at a certain point in the compound, whereas the claimed compound used hydrophilic substitutes instead.¹⁰⁹ Given the unpredictability in the field, the mere structural resemblance alone is an insufficient reason for a compound to be selected as a lead compound.¹¹⁰

The difficulty in selecting a suitable lead compound is further examined in *Otsuka Pharmaceutical Co., Ltd. v. Sandoz, Inc.*, which involved a patent for the antipsychotic compound aripiprazole, the active ingredient in the brand name drug Abilify.¹¹¹ In *Otsuka*, the Federal Circuit affirmed the district court’s rejection of the defendants’ three proposed compounds as lead compounds due to the fact that the proposed compounds lacked sufficient potency, were of an overbroad genus of compounds, and exhibited far too toxic effects for one of ordinary skill to select any of the proposed compounds as a starting point.¹¹² The

¹⁰⁴ *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1362–64 (Fed. Cir. 2011).

¹⁰⁵ *Id.* at 1363.

¹⁰⁶ *Id.* at 1364.

¹⁰⁷ *Daiichi Sankyo Co., Ltd. v. Matrix Labs., Ltd.*, 619 F.3d 1346, 1348 (Fed. Cir. 2010).

¹⁰⁸ *Id.* at 1354; *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369, 1377–79 (Fed. Cir. 2006).

¹⁰⁹ *Daiichi Sankyo Co.*, 619 F.3d at 1354–55.

¹¹⁰ *Id.*

¹¹¹ *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1285 (Fed. Cir. 2012).

¹¹² *Id.* at 1293–96.

Otsuka case demonstrates that the negative effects or characteristics associated with a compound can weigh against its selection as a lead compound.¹¹³

One distinction impacting obviousness may be whether the claims are directed towards a compound versus the application or efficacy of a compound. The creation of a new compound is likely to be deemed unpredictable whereas an invention claiming the dosage of a known compound for improved efficacy is likely to be deemed predictable.¹¹⁴ For example, a recent case found a patent claim covering the administration of a chemotherapy cancer drug in a solution to be obvious.¹¹⁵ Regarding patents relating to dosage of drug compounds already known, the Federal Circuit noted that “where there is a range disclosed in the prior art, and the claimed invention falls within that range, there is a presumption of obviousness.”¹¹⁶ For instance, in *Tyco Healthcare Group LP v. Mutual Pharmaceutical Co., Inc.*, the patented formulation for a sleep-inducing drug fell within the range of prior art, and there was no record that the patented formulation had a particular impact on the efficacy of the drug.¹¹⁷ As such, the district court’s finding of obviousness was affirmed.¹¹⁸ Likewise, a patent on a chewing gum formulation with improved cooling effects was found to be obvious when the elements of the formulations were known, and the combination did not achieve an unexpected cooling effect.¹¹⁹

Demonstrating nonobviousness is a far more difficult task in the predictable arts, as it typically requires an explicit showing that the prior art references teach away from the claimed combination.¹²⁰ In the predictable arts, there is a far greater likelihood that most of the claimed elements are already well-known, and that the art is characterized by marginal and incremental

¹¹³ See Barron, *supra* note 78, at 410.

¹¹⁴ See Frederick G. Vogt, *Unexpected Results: The Current Status of Obviousness Determinations for Pharmaceutical and Biotechnology Patents*, 29 TEMP. J. SCI. TECH. & ENVTL. L. 305, 325 (2010) (discussing the unpredictability of polymorphic compounds—the different crystalline states of the same drug molecule that may have different properties).

¹¹⁵ *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1332 (Fed. Cir. 2012).

¹¹⁶ *Tyco Healthcare Group LP v. Mutual Pharm. Co., Inc.*, 642 F.3d 1370, 1372–73 (Fed. Cir. 2011); see also *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1331–32 (Fed. Cir. 2008) (invalidating asserted claims to methods and apparatuses for generating a particular pulse sequence for recording information to a rewritable optical disc for obviousness because the desired range for rotation of apparatus overlaps with prior art).

¹¹⁷ *Tyco Healthcare*, 642 F.3d at 1376.

¹¹⁸ *Id.* at 1377.

¹¹⁹ *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1363–64 (Fed. Cir. 2012).

¹²⁰ See *In re Suong-Hyu Hyon*, 679 F.3d 1363, 1468–72 (Fed. Cir. 2012) (affirming method for making ultra high molecular weight polyethylene block for artificial joints to be obvious).

improvements.¹²¹ In addition, in cases where “the technology is easily understandable,” expert testimony is not required,¹²² further reducing the overall burden of proof in demonstrating obviousness for predictable arts.

For instance, in *Spectralytics, Inc. v. Cordis Corp.*, the patented inventions relate to the relatively predictable art of machines that make stainless steel stents cut into a lace-like pattern to permit expansion and retention after insertion into the artery.¹²³ Specifically, the claimed machines affixed laser cutters in a way that embraced the machine vibrations, as opposed to prior art methods that attempted to suppress or deaden the vibrations.¹²⁴ Here, the Federal Circuit found sufficient facts on record that the prior art taught away from the claimed invention, but noted that there was some level of flexibility in applying the concept of teaching away because it did “not require that the prior art fores[ee] the specific invention that was later made, and warned against taking that path.”¹²⁵ Instead, to demonstrate that the references teach away, there must be sufficient facts showing that prior art methods contradict the claimed invention so that a reasonable jury could conclude nonobviousness.¹²⁶

In *Media Technologies Licensing, LLC v. Upper Deck Co.*, the patent-in-suit was titled “Memorabilia Card” and was directed towards attaching a small portion of authentic sports memorabilia to a related article (i.e., baseball trading card).¹²⁷ The Federal Circuit found that the characteristics of trading cards were predictable in both content and presentation.¹²⁸ As such, the only question with respect to obviousness is whether it would have been obvious to one skilled in the art to attach a sports-related item to a trading card, as opposed to other types of authentic memorabilia items shown in the prior art.¹²⁹ Despite a well-reasoned

¹²¹ See FED TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 2, at 25–26 (2003), available at <http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf> [hereinafter FTC REPORT] (“[T]echnology developed in industries such as semiconductors, computer hardware, and software can contain a large number of incremental innovations.”).

¹²² *Meyer Intellectual Props. Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1379 (Fed. Cir. 2010); *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1242 (Fed. Cir. 2010); *Centricut, LLC v. Esab Group, Inc.*, 390 F.3d 1361, 1369 (Fed. Cir. 2004).

¹²³ *Spectralytics, Inc. v. Cordis Corp.*, 649 F.3d 1336, 1343 (Fed. Cir. 2011).

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.* at 1344.

¹²⁷ *Media Techs. Licensing, LLC v. Upper Deck Co.*, 596 F.3d 1334, 1340 (Fed. Cir. 2010).

¹²⁸ *Id.* at 1338.

¹²⁹ *Id.*

policy dissent from Judge Rader, the Federal Circuit affirmed the district court's finding of obviousness.¹³⁰

Another predictable technological field that relies heavily on well-known elements is in the mechanical arts. In *In re Construction Equipment Co.*, the Federal Circuit affirmed the USPTO's finding of obviousness for a patent directed to a vehicle for screening rocks and plant matter based on or from an area of soil or dirt.¹³¹ In that case, the court concluded that the alleged invention, while possibly new, was nevertheless obvious because it consisted entirely of known elements combined into a machine.¹³² There, the record showed that the basic concepts of sifting and sorting through materials, carrying materials via conveyors, and positing the machine for use were not new.¹³³

Similarly, in *Tokai Corp. v. Easton Enterprises, Inc.*, claims of the asserted patents directed to utility lighters with automatic child safety mechanisms for preventing accidental ignition were affirmed to be obvious.¹³⁴ The Federal Circuit noted that the prior art taught all of the claimed elements, and that there was no unpredictability in combining the elements, particularly in light of the fact that one of ordinary skill in the art was defined as "an individual showing aptitude in high school shop class, or someone who builds, takes apart, or repairs basic mechanical toys/devices."¹³⁵

Internet transaction patents are also typically considered to be predictable as they frequently claim "routine modifications" to the prior art. This is especially true with respect to the commonplace application of "computer and internet technology to replace older electronics."¹³⁶ In *Western Union Co. v. MoneyGram Payment Systems, Inc.*, the invention was a method for performing "formless" money transfer transactions using an electronic transaction fulfillment device (EFTD) over the Internet.¹³⁷ The prior art system implemented a fax machine over a phone line to conduct the same transaction.¹³⁸ Dismissing the fact that the patentee spent considerable resources towards the commercial embodiment of the EFTD system as unrelated to any "inventive aspects

¹³⁰ Judge Rader criticized the lack of rigor in weighing the evidence and applying the obviousness standards, asking rhetorically, "[i]s this an indication that this court views this field of art and this invention as unworthy of the full processes of the law?" *Id.* at 1342.

¹³¹ *In re Constr. Equip. Co.*, 665 F.3d 1254, 1254–55 (Fed. Cir. 2011).

¹³² *Id.*

¹³³ *Id.*; see also *Cimline, Inc. v. Crafcro, Inc.*, 413 Fed. Appx. 240, 245–46 (Fed. Cir. Mar. 2, 2011) (invalidating patent disclosing a sealant melter having a manual, gravity powered conveyor and a splash guard box as being obvious).

¹³⁴ *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1372 (Fed. Cir. 2011).

¹³⁵ *Id.* at 1369–71.

¹³⁶ *W. Union Co. v. MoneyGram Payment Sys., Inc.*, 626 F.3d 1361, 1370 (Fed. Cir. 2010).

¹³⁷ *Id.* at 1366.

¹³⁸ *Id.* at 1370.

claimed,” the Federal Circuit held the substitution of fax machines over phone lines to EFTDs over the Internet to be predictable.¹³⁹

More recently, *Soverain Software LLC v. Newegg Inc.* employed similar reasoning to the *Western Union* case.¹⁴⁰ In *Soverain*, the patents-in-suit were directed towards an online commerce system where a merchant’s product could be offered and purchased.¹⁴¹ During trial, the district court removed the question of obviousness from the jury based on insufficiency of testimony.¹⁴² The Federal Circuit reversed and found the patents-in-suit to be obvious upon de novo review.¹⁴³ Specifically, the Federal Circuit analyzed three separate sets of claims at issue and found each set to be obvious in view of a prior art system labeled as “CompuServe Mall.”¹⁴⁴ The Federal Circuit based its analysis primarily on the fact that all of the claimed elements were generally well-known in the prior art.¹⁴⁵ Moreover, even though the claimed system may have had superior features and the CompuServe Mall was created for pre-Internet systems, one of ordinary skill would have been able to readily adapt the available prior art to render the asserted claims obvious.¹⁴⁶ Moreover, the Federal Circuit noted that plaintiff, *Soverain*, failed to establish a nexus between the commercial software and the patents-in-suit.¹⁴⁷

Telecommunications is a related, but separate, technological field characterized by incremental improvements.¹⁴⁸ For example, in *In re Katz Interactive Call Processing Patent Litigation*, the asserted patents covered telephone systems and interfaces for transactions, call routing, and handling of both digital and voice signals from callers.¹⁴⁹ Here, the Federal Circuit affirmed the district court’s grant of summary judgment for obviousness, finding that the proposed prior art combinations covered the claimed elements and that there was no unpredictability for one of ordinary skill to combine the elements.¹⁵⁰ As the cases above illustrate, whether a patent is likely to be found invalid due to obviousness can be heavily inferred from whether the field of art can be characterized as predicable. In the post-*KSR* “common-sense” obviousness

¹³⁹ *Id.*

¹⁴⁰ *See Soverain Software LLC v. Newegg Inc.*, 705 F.3d 1333, 1335 (Fed. Cir. 2013).

¹⁴¹ *Id.*

¹⁴² *Id.* at 1336.

¹⁴³ *Id.* at 1336–37.

¹⁴⁴ *Id.* at 1338–46.

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* at 1346–47.

¹⁴⁸ Computer hardware and integrated circuits provide the foundation for the telecommunications industry. *See* FTC REPORT, *supra* note 121, ch. 3, at 30.

¹⁴⁹ *See In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1308–09 (Fed. Cir. 2011).

¹⁵⁰ *Id.* at 1322–23.

landscape, the patentee faces significant difficulties in rebutting a prima facie presentation of obviousness in fields of predictable arts.¹⁵¹

V. PROPOSED SOLUTIONS FOR BALANCING AGAINST THE BIAS

Although obviousness remains a bedrock eligibility requirement to patents in the United States, the task of sifting through complicated issues of fact and law for obviousness may have become too overbearing for some. Recently, those alleged of patent infringement have been increasingly resorting to utility arguments under 35 U.S.C. § 101 as a basis to attack patentability.¹⁵² Many have observed that this trend is an attempt to avoid engaging in an obviousness analysis altogether.¹⁵³ In comparison to the myriad of factors and considerations in an obviousness argument, the utility invalidity argument requires the validity challenger to demonstrate that the invention lacks any “specific, substantial, and credible” use.¹⁵⁴ The vagueness of the utility invalidity argument allows the USPTO to project standards of what qualifies as a “useful” art, an approach criticized by Judge Rader precisely “because it lacks any standard for assessing the state of the prior art and the contributions of the claimed advance.”¹⁵⁵ This trend further reflects a growing discontent with the legal framework of obviousness.

The frustration regarding the inconsistent application of the obviousness standard is palpable. For example, Judge Dyk of the Federal Circuit noted in an infringement action involving patents directed towards the frothing of milk for coffee beverages that “one cannot help but conclude that this case is an example

¹⁵¹ See Michael R. Dzwonczyk, Implementing a “Predictable” Obviousness Standard Post-KSR 5, 8 (2009) (unpublished manuscript), available at <http://www.sughrue.com/files/Publication/c184ddaf-8489-4b7c-84a9-061409df7037/Presentation/PublicationAttachment/35de691e-b34e-4e83-9ce6-092161dca7d8/Implementingapredictable.pdf> (“[I]n the first four months following KSR, affirmances [of final office action rejections] in technology center 1600 (biotechnology) rose to almost 80%. . . . [A]ffirmances in technology center 3700 (mechanical engineering) rose from less than 50% to over 60% in the same time period.”).

¹⁵² Imran Khaliq, *Expect More Rulings Invalidating Patents Under Section 101*, LAW360 (Nov. 25, 2013, 1:13 PM), <http://www.law360.com/articles/488905/expect-more-rulings-invalidating-patents-under-section-101>.

¹⁵³ See Benjamin H. Graf, *Prognosis Indeterminable: How Patent Non-Obviousness Outcomes Depend Too Much on Decision-Makers*, 9 CARDOZO PUB. L. POL’Y & ETHICS J. 567, 590–91 (2011).

¹⁵⁴ The substantial utility requirement requires showing that the claimed invention has a “significant and presently available benefit to the public.” *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). Under the specific utility requirement, an application must “disclose a use which is not so vague as to be meaningless.” *Id.* Both substantial and specific utility must be considered credible by a person of ordinary skill in the art. See Utility Examination Guidelines, 66 Fed. Reg. 1092-02, 1098 (Jan. 5, 2001).

¹⁵⁵ *In re Fisher*, 421 F.3d at 1382.

of what is wrong with our patent system.”¹⁵⁶ Specifically, Judge Dyk provided additional strong language criticizing the application of the current obviousness framework:

[Under *KSR*], it would be reasonable to expect that the claims would have been rejected as obvious by the examiner, and, if not, that they would have been found obvious on summary judgment by the district court. But no such thing. The parties have spent hundreds of thousands of dollars and several years litigating this issue, and are invited by us to have another go of it in a second trial. Such wasteful litigation does not serve the interests of the inventorship community, nor does it fulfill the purposes of the patent system.¹⁵⁷

However, the courts should not be so rash in dismissing inventions on the sole basis of art predictability alone. In the dissenting opinion of the *Media Technologies* case, Judge Rader expressly cautioned against the discrimination against patents in the predictable arts, stating that courts “cannot overlook that many individuals invest vast energies, efforts, and earnings to advance these nontechnical fields of human endeavor,” and that the “incentives for improvement and the protection of invention apply as well to the creator of a new hair-extension design as to a researcher pursuing a cure for cancer.”¹⁵⁸

The question then becomes what should the courts do to counterbalance the bias against predictable art patents in the current obviousness analytical framework. There are two potential solutions: (1) strengthen the secondary consideration analysis, and (2) revitalize the prohibition against the use of hindsight bias in an obviousness analysis. The revitalization of the prohibition against the use of hindsight is crucial since *KSR* disavowed the rigorous application of the TSM test.¹⁵⁹ The TSM test was noted to be the best defense against the use of hindsight bias.¹⁶⁰

D. Strengthening of Secondary Considerations

As mentioned earlier, one of the consequences of the *KSR* decision is the diminished role of secondary considerations in obviousness considerations.¹⁶¹ This diminished role is reflected in *Leapfrog Enterprises, Inc. v. Fisher Price, Inc.*, where the Federal Circuit held that “substantial evidence” of commercial success, praise in the industry, and long-felt need were insufficient to overcome

¹⁵⁶ See *Meyer Intellectual Props. Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1379 (Fed. Cir. 2012) (Dyk, J., concurring).

¹⁵⁷ *Id.* at 1380.

¹⁵⁸ See *Media Techs. Licensing, LLC v. Upper Deck Co.*, 596 F.3d 1334, 1340 (Fed. Cir. 2010) (Rader, J., dissenting).

¹⁵⁹ *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 402–03 (2007).

¹⁶⁰ *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999).

¹⁶¹ See *supra* Part IV.A.

the strength of a prima facie finding of obviousness (though the *Leapfrog* case is ambiguous regarding whether “substantial evidence” of secondary consideration will always be insufficient to overcome a prima facie finding of obviousness).¹⁶² As a corrective measure, a rigorous analysis of the secondary consideration factors should be permitted to overcome a “common sense” prima facie case of obviousness.¹⁶³ Given the relative ease that *KSR* allows one to establish a prima facie showing of obviousness, an equitable counterbalance would be to presumptively give more weight to the secondary consideration elements.

To further revitalize the secondary considerations, there should be a less stringent standard for evaluating the nexus between the factual indicia and the claimed invention. For example, with respect to commercial success, as long as there is evidence that a commercial embodiment of an invention is actually being successfully sold, an inference of nonobviousness should be given if it is more likely than not that the inventive features caused the commercial success. Similarly, allowing the patentee to prove the secondary factors with circumstantial evidence, or through a totality of the circumstances approach, may otherwise help preserve validity of a patent in the predictable arts. For example, strong sales of a product with patented features in combination with copying by others in the industry should be strong indicators that the patent is nonobvious. Moreover, proof of significant expenditure in the research and development leading to the claimed invention should also be probative evidence in favor of nonobviousness.

The Federal Circuit or the USPTO may also help raise the relevance of secondary considerations by issuing a comprehensive framework for secondary considerations, something that the Federal Circuit has so far declined to take on.¹⁶⁴ Having a more workable and well-defined framework may improve the form and substance of secondary consideration arguments presented before judges. Recognizing the need to preserve the incentive to innovate in the predictable arts, Congress may also pass legislation to ensure that patents in all fields are entitled to equal protection.

E. Prohibit the Use of Hindsight

Another way to balance the obviousness inquiry is to revitalize the prohibition against the use of hindsight. Generally, this prohibition is based on the observation that obviousness “cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the

¹⁶² See *Leapfrog Enters., Inc. v. Fisher Price, Inc.*, 485 F.3d 1157, 1161–62 (Fed. Cir. 2007).

¹⁶³ *Id.*; See Amanda Wieker, *Secondary Considerations Should Be Given Increased Weight in Obviousness Inquiries Under 35 U.S.C. § 103 in the Post-KSR v. Teleflex World*, 17 FED. CIR. B.J., 665, 680 (2008).

¹⁶⁴ See Darrow, *supra* note 64, at 53–54.

patented invention.”¹⁶⁵ Similar to the application of the secondary considerations, there has been no consistent framework of applying the hindsight bias prohibition. The *KSR* decision preserved the prohibition against the use of hindsight bias but gave little guidance with respect to how to identify the bias: “the distortion caused by hindsight bias” and the need to “be cautious of arguments reliant upon *ex post* reasoning,” and at the same time rejecting the need for a teaching, suggestion, or motivation as an absolute prerequisite for finding the obviousness of a given combination of prior art elements.¹⁶⁶

Indeed, the improper use of hindsight appears precisely to be the concern obviated by a rigorous application of the TSM test.¹⁶⁷ Prior to *KSR*, the Federal Circuit found that “[t]he best defense against the subtle but powerful attraction of hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.”¹⁶⁸ In the post-*KSR* landscape, a set of more predictable guidelines for analyzing hindsight bias in an obviousness analysis could provide much needed clarity for practitioners, and also strike a balance against the expansive scope of *KSR*.¹⁶⁹ Without further guidance, the hindsight bias consideration runs the risk of either becoming a complete afterthought in an obviousness inquiry or a purely subjective determination by a judge or patent examiner.

Finally, post-*KSR*, courts should exercise more caution to ensure that their exercise of a “common sense” approach to obviousness invalidity is based on the state of the art at the time of patenting. This awareness should be heightened in the predictable arts, a field dominated by common knowledge and incremental improvements. To avoid falling into the hindsight bias trap, courts should recognize the need to preserve the incentive to innovate in the predictable arts and not overlook innovative combinations or configurations of known technologies and methods. Ironically, perhaps a cursory application of the TSM test as performed by the district court in the *KSR* decision can prevent against improper applications of hindsight.

CONCLUSION

The current state of the patent obviousness inquiry poses a significant bias against patents in the predictable arts. The doctrines of secondary consideration and hindsight bias have been significantly weakened by the *KSR*

¹⁶⁵ See *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed.Cir.1998).

¹⁶⁶ See *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421–23 (2007).

¹⁶⁷ Joseph Scott Miller, *Remixing Obviousness*, 16 TEX. INTELL. PROP. L.J. 237, 240–44 (2008).

¹⁶⁸ See *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999).

¹⁶⁹ The hindsight bias analysis has been criticized as “irrational” based upon empirical research of experimental scenarios, concluding that “once individuals are aware of an outcome, they are cognitively unable to discount or ignore that knowledge; they no longer view prior events objectively.” See Mandel, *supra* note 63, at 1403.

decision and have long been criticized as esoteric and unpredictable. The current state of the obviousness analysis in awarding patents in the predictable arts has the potential to deprive inventors of incentives to innovate in certain technological fields altogether. Indeed, many technical arts can be characterized as predictable because of the heavy utilization of pre-existing and predictable techniques and technologies. From a policy viewpoint, revitalization measures should be taken to ensure that the broad lines of reasoning for obviousness in *KSR* do not become an insurmountable bottleneck against those who innovate in predictable technologies.

Legislative and/or judicial measures should be taken to set more definitive and uniform guidelines on how obviousness is to be evaluated (regardless of the predictability of the art) to provide more certainty to innovators and patent practitioners. These measures should be carefully crafted to give equal consideration to the value and potential of the claimed inventions, regardless of technological complexity.