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**Three Years Post-KSR: A Practitioner's Guide to  
“Winning” Arguments on Obviousness and a  
Look at What May Lay Ahead**

*Katherine M. L. Hayes*



# Three Years Post-KSR: A Practitioner's Guide to "Winning" Arguments on Obviousness and a Look at What May Lay Ahead

By Katherine M. L. Hayes\*

¶1 In 2007, the United States Supreme Court decided *KSR International Company v. Teleflex Inc.*<sup>1</sup> Many called *KSR* the most important patent ruling in years.<sup>2</sup> Fried Frank hailed the decision as "greatly lowering the cost and uncertainty of patent litigation."<sup>3</sup> Akin Gump suggested a more limited effect: "[T]he justices wanted to make it harder to get a patent. What's not immediately clear is how far they want to go."<sup>4</sup> As some law firms offered their clients "Survival Guides" to the post-*KSR* world, a minority of lawyers suggested *KSR* would actually have a limited effect on patenting.<sup>5</sup>

¶2 In the three years since *KSR*, the patent bar, academia, and the lower courts have struggled to define the new boundaries of the obviousness test. In particular, because *KSR* invalidated a mechanical patent, its application to other arts, like chemistry and biology, has been less clear. As a result, the Federal Circuit has been cautious in its application of *KSR*.<sup>6</sup> Yet, scrutiny of post-*KSR* cases reveals some patterns. This article

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\* Northwestern Law, J.D. Candidate 2011. There were a variety of people who supported me while writing this piece. Particular thanks go to my mother, Eileen Larkin, who, in addition to being supportive, has been my lifetime editor and the first person I go to for an academic reality check. I also need to thank my sister, Kim Hayes, and partner, Jonathon Wong, for their patience and support when I had lost patience with myself.

<sup>1</sup> *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

<sup>2</sup> Linda Greenhouse, *High Court Puts Limits on Patents*, N.Y. TIMES, May 1, 2007, at C1, available at [http://www.nytimes.com/2007/05/01/business/01bizcourt.html?\\_r=2&ref=business&oref=slogin](http://www.nytimes.com/2007/05/01/business/01bizcourt.html?_r=2&ref=business&oref=slogin) (calling *KSR* the Court's "most important patent ruling in years"). See also Peter Lattman, *KSR v. Teleflex: The Supreme Court's Big Patent Ruling*, WALL STREET J. L. BLOG (May 1, 2007, 8:07 AM), <http://blogs.wsj.com/law/2007/05/01/ksr-v-teleflex-the-supreme-courts-big-patent-ruling/> (quoting Michael Barclay of Wilson Sonsini as saying, "thus this is the most important patent case of the last 20 years and perhaps since the passage of the 1952 Patent Act.").

<sup>3</sup> Lattman, *supra* note 2 (quoting James Dabney of Fried Frank, lawyer for *KSR*).

<sup>4</sup> *Id.* (quoting Thomas Goldstein of Akin Gump, lawyers for Teleflex). At the same time, Mr. Goldstein recognized the importance of *KSR*: "[O]bviousness is the most important legal gateway to patenting, and the future of the modern economy rests on intellectual property. So there are trillions of dollars at stake." *Id.* Some district courts also reflected on whether *KSR* constituted a major change in the law, albeit in the context of issue preclusion. See *Roche Palo Alto LLC v. Aptoex, Inc.*, 526 F. Supp. 2d 985, 996-97 (N.D. Cal. 2007) (discussing without deciding the effect of *KSR* on issue preclusion).

<sup>5</sup> See, e.g., Crowell Moring, *Post-KSR Patent Prosecution "Survival Guide,"* CROWELL MORING (May 16, 2007), <http://www.crowell.com/NewsEvents/Newsletter.aspx?id=407>; Gerald J. Mossinghoff, *KSR v. Teleflex: High Court's "Obviousness" Ruling No Sea Change in Patent Law*, WASH. LEGAL FOUND. LEGAL BACKGROUNDER (June 8, 2007), <http://www.wlf.org/upload/06-08-07mossing.pdf> (arguing that the practical realities (e.g. most patent examiners are recently graduated engineers) and restraints (e.g. time to process a patent) will mean *KSR* will have very little impact on the number of patents granted each year). In addition, Mossinghoff argues that the Court's reliance on prior precedent in establishing the new standard suggests that the new *KSR* standard is not actually "new." *Id.*

<sup>6</sup> *Shuffle Master, Inc. v. MP Games LLC*, 553 F. Supp. 2d 1202, 1222 (D. Nev. 2008) (noting the

reviews the Federal Circuit and some district court decisions since the Supreme Court changed the obviousness standard. In the process, successful methods of argument become apparent, providing a roadmap to the practitioner's post-*KSR* world. The analysis shows that *KSR*'s impact has differed based on the patented art. While *KSR* has only tweaked chemical patent inquiries, its effect on mechanical patent validity has been substantial.

¶3 Perhaps the most influential portion of the Supreme Court's *KSR* opinion has been the language concluding that a combination resulting from a "finite number of identifiable predictable solutions" is likely obvious.<sup>7</sup> That language has left litigators and lower courts grasping for what makes any number of solutions finite, identifiable, or predictable. The Court also held that a person of skill in the art ("POSA") is "one of ordinary creativity, not an automaton."<sup>8</sup> Because the POSA's creativity will vary with his skill level, *KSR* has also renewed emphasis on the importance of the POSA's level of skill. When carried to its extreme, emphasis on the POSA increases the likelihood of future procedural challenges to patent case law. Typically, parties agree on the definition of a POSA. If, however, the definition of a POSA becomes a larger issue post-*KSR*, the new question may be the sufficiency of evidence necessary for the court to determine the POSA's level of skill and then rule on obviousness on summary judgment.

¶4 This article proceeds in four parts. Part I provides an introduction to obviousness. Part II dissects the *KSR* decision, including the unanswered questions, which become the basis for a discussion of what practitioners should consider today. Part III analyzes how the lower courts have defined, changed, and extended *KSR*'s bounds. Cases are analyzed in two categories: chemical arts and mechanical/electrical arts. After *KSR*, many lawyers expected higher success rates for invalidating all patents. The reality, three years later, is different than many expected. While a valid mechanical patent is a rare exception, the effect of *KSR* on the chemical arts is significantly less pronounced. Part IV explains what arguments are most persuasive and how practitioners can exploit them most easily. The conclusion considers the road ahead. What arenas remain open for extension and what new arguments should be tested?

## I. INTRODUCTION TO OBVIOUSNESS

¶5 In 1952, Congress codified "obviousness" at 35 U.S.C. § 103:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title [35 U.S.C § 102], if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.<sup>9</sup>

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Federal Circuit has been "sensitive to the varying levels of relevance [of] the TSM test").

<sup>7</sup> *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007).

<sup>8</sup> *Id.* at 421.

<sup>9</sup> *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1353 (Fed. Cir. 2007).

Far from changing the law, the Supreme Court construed § 103 as “intended to codify judicial precedents” first announced in *Hotchkiss v. Greenwood* years earlier.<sup>10</sup>

¶16 In *Graham v. John Deere Co.*, the Court defined the obviousness test under Section 103. *Prima facie* obviousness depends on: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the difference between the claimed invention and the prior art, and (4) any evidence of secondary factors.<sup>11</sup> A court must consider secondary considerations if the challenger<sup>12</sup> demonstrates a *prima facie* case.<sup>13</sup> While obviousness is a question of law, the *Graham* factors are questions of fact.<sup>14</sup> Thus, a conflict over the appropriate level of ordinary skill in the art should be submitted to the jury, but the court makes the ultimate determination on obviousness.

¶17 The Federal Circuit extended *Graham* by adding the Teaching, Suggestion, or Motivation test (“the TSM test”).<sup>15</sup> The court held that, where the prior art offered the solution described in the patent, there must be a “teaching, suggestion, or motivation” to combine the prior art teachings.<sup>16</sup> The teaching, suggestion, or motivation can be found in the prior art, the nature of the problem, or the knowledge of a POSA.<sup>17</sup> The TSM test governed obviousness until the Supreme Court decided *KSR*.

## II. *KSR INTERNATIONAL CO. V. TELEFLEX INC.*

¶18 In *KSR*, the Court considered Teleflex-owned U.S. Patent No. 6,237,565 B1 (“the ‘565 patent”), which combined an adjustable automobile pedal with an electronic sensor that ultimately controlled the throttle.<sup>18</sup> The district court found the ‘565 patent obvious based on the Rixon and Smith patents. When combined, the two patents taught both the adjustable pedal and the electronic sensor for throttle control.<sup>19</sup> The district court applied

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<sup>10</sup> *Graham v. John Deere Co.*, 383 U.S. 1, 3 (1966). For further analysis of the Supreme Court’s obviousness jurisprudence see MATTHEW BENDER, PATENT LITIGATION: PROCEDURE & TACTICS Instruction 17 Obviousness (LexisNexis Group, 2009).

<sup>11</sup> *Graham*, 383 U.S. at 17–18. Secondary factors, also known as secondary considerations, include: commercial success, long felt but unsolved needs, and failure of others which “might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *Id.*

<sup>12</sup> Throughout this article, I use “challenger” to refer to the party challenging the validity of the patent regardless of whether they do so as a plaintiff or a defendant.

<sup>13</sup> *Graham*, 383 U.S. at 17–18. Indeed, the Federal Circuit has been more forceful in outlining the value of secondary considerations and one could read the court’s precedent as requiring a court to weigh secondary considerations as part of the *prima facie* test. See generally *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) (“Thus evidence rising out of the so-called ‘secondary considerations’ must always when present be considered en route to a determination of obviousness . . . . Indeed, evidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not.”); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 (Fed. Cir. 1985) (“Thus, the district court seemingly recognized the holdings of this court vis-a-vis secondary considerations, to wit, that all relevant evidence going to the issue of obviousness/nonobviousness, which includes properly presented evidence on secondary considerations, must have been considered prior to reaching a conclusion on obviousness/nonobviousness.”).

<sup>14</sup> *Graham*, 383 U.S. at 17–18.

<sup>15</sup> *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 399 (2007).

<sup>16</sup> *Id.* at 407 (citing *Al-Site Corp. v. VSI Int’l, Inc.*, 174 F.3d 1308, 1323–24 (Fed. Cir. 1999)).

<sup>17</sup> *Id.*

<sup>18</sup> *Id.* at 405.

<sup>19</sup> *Id.* at 413. The court found the Rixon patent provided a basis for the combination, and the Smith patent taught a solution to the wire chafing problems Rixon identified. *Id.*

the TSM test and found the POSA had sufficient motivation to combine the prior art based on the industry preference for adjustable pedals and electronic control of the throttle. The Federal Circuit reversed, finding the district court failed to make specific findings about what principle in the prior art would have motivated the POSA to combine the prior art teachings.<sup>20</sup>

¶9 The Supreme Court rejected the Federal Circuit’s “rigid” approach to the obviousness inquiry. The Court went on to make five observations which have been influential since:<sup>21</sup>

- (1) Combination patents must be treated with greater flexibility when considering obviousness.
- (2) The TSM test has value and the Court’s opinion should not be interpreted as a wholesale rejection of it.
- (3) Market demands or well-known and, as yet, unsolved problems in an industry may supply the POSA’s motivation to combine prior art.
- (4) The base of prior art from which a court makes an obviousness determination can be expansive and the court may look beyond the immediate field of the patent in suit.
- (5) “Obvious to try” may mean obvious.

Each of these observations is explored in greater detail below.

¶10 Combination Patents: The Court found the “rigid” TSM test particularly problematic when applied to combination patents.<sup>22</sup> While the Court recognized that “inventions . . . rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known,”<sup>23</sup> the Court rejected the Federal Circuit’s approach to the combination in *KSR*, holding that using known methods to combine familiar elements is likely to be obvious, particularly when the results are as expected.<sup>24</sup> A POSA confronted with a need and a limited number of solutions is expected to attempt the known solutions.<sup>25</sup> Thus, when the patent-in-suit teaches one of the potential solutions, it is likely the product of ordinary skill and common sense.<sup>26</sup> In particular, the successful combination of two elements where each

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<sup>20</sup> *Id.* at 413–14.

<sup>21</sup> See BENDER, *supra* note 10, at Instruction 17 Obviousness (offering one view on how these holdings translate to jury instructions). *But see* Joshua D. Sarnoff, Bilcare, *KSR*, *Presumptions of Validity, Preliminary Relief, and Obviousness in Patent Law*, 25 CARDOZO ARTS & ENT. L.J. 995, 1028–35 (2008) (Offering a competing view that in *KSR*, the Court laid the groundwork to alter the effect of the presumption of validity granted to patents issued by the PTO. Sarnoff argues that while the Court did not reach the issue explicitly, the Court’s analysis can be read as shifting the burdens of production and persuasion in the context of combination patents to the patent-holder.).

<sup>22</sup> *KSR*, 550 U.S. at 415–16 (“For over half a century, the Court has held that a ‘patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men.’”) (citing *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 152 (1950)).

<sup>23</sup> *Id.* at 418–19.

<sup>24</sup> *Id.* at 416.

<sup>25</sup> *Id.* at 421.

<sup>26</sup> *Id.*

still performs as it would have separately is obvious, unless the prior art also teaches away from using the claimed method.<sup>27</sup>

¶11 The Court foreclosed the argument that *KSR* is distinguishable based on the relative simplicity of the ‘565 patent when it recognized that many combination patents would be more complex than the one currently before it.<sup>28</sup> The Court suggested that more complex combination patents require that a court:

Look to the interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.<sup>29</sup>

Thus, the Court expanded the factors that the lower courts should address when considering an obviousness argument on a combination, in particular, elevating the importance of economic demands.

¶12 TSM Test Still Applicable: Despite overturning the Federal Circuit’s finding and describing the TSM test as “rigid,” the Court did not reject the TSM test in its entirety.<sup>30</sup> The TSM test “captured a helpful insight” that the presence of known elements in a patent is insufficient, on its own, to render the patent obvious.<sup>31</sup> Rather, a court must identify some motivation for the POSA to combine the known elements.<sup>32</sup> The test needed greater flexibility which the Court introduced by broadening the factors that might constitute motivation, placing a particular emphasis on economic demands in the marketplace.<sup>33</sup>

¶13 Market Approach: Where an invention solves a well-known market demand, the demand is sufficient to motivate the POSA to seek out and combine known solutions. The Court held, “Any need or problem known in the field of endeavor at the time of the invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.”<sup>34</sup> Thus, if the patent solves a known market problem (e.g. wire

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<sup>27</sup> *Id.* at 413, 416. “[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious.” *Id.* at 416. (citing *United States v. Adams*, 383 U.S. 39, 51–52 (1966)).

<sup>28</sup> *Id.* at 417 (“Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement.”).

<sup>29</sup> *Id.* at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

<sup>30</sup> Some lower courts struggle to see exactly what the Court endorsed about the TSM test. *See, e.g.*, *Shuffle Master, Inc. v. MP Games LLC*, 553 F. Supp. 2d 1202, 1221–22 (D. Nev. 2008) (offering a “summary of errors” the Supreme Court found with the TSM test).

<sup>31</sup> *KSR*, 550 U.S. at 418.

<sup>32</sup> *Id.*

<sup>33</sup> Gene Quinn, Editor of the IPWatchdog.com Blog, has opined (cleverly) on motivations for innovation by comparing them to the seven deadly sins. Among other things, Quinn suggests that “envy” of another’s products is one of the great motivators of patent innovation. Product envy is, arguably, a type of market-driven innovation. Gene Quinn, *Motivation for Success: The 7 Deadly Sins Patent Style*, IPWATCHDOG (Feb. 11, 2010, 3:05 PM), <http://www.ipwatchdog.com/2010/02/11/motivation-for-success-the-7-deadly-sins-patent-style/id=8835/>.

<sup>34</sup> *KSR*, 550 U.S. at 420.

chafing as a result of an adjustable pedal) and does so using a known solution (e.g., the Smith patent), then the patent is obvious.

¶14 Broad Base of Prior Art: The Court also increased the flexibility of the TSM test by broadening the scope of the POSA's search for a potential solution. A POSA is not limited to the art designed to solve the same problem, because a POSA "will be able to fit the teachings of multiple patents together like pieces of a puzzle."<sup>35</sup> Far from being limited to the most obvious solutions, "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton."<sup>36</sup> The POSA will be able to look beyond the known field, analogize to similar problems, and consider those solutions to the problem.<sup>37</sup>

¶15 Obvious to Try May Mean Obvious: Where the patent addresses a problem with a finite and predictable number of solutions which would be "obvious to try," the patent may be obvious. A POSA, operating against market pressures, would naturally pursue obvious options first.<sup>38</sup> If those options yield success, the combination was obvious to try.<sup>39</sup> In *KSR*, there was one easily identifiable solution which was obvious to try, therefore rendering the patent obvious.

### III. THE LOWER COURTS POST-*KSR*

¶16 Over the last three years, the lower courts have worked to define more exact bounds for *KSR*. Several recurring issues should be highlighted here. First, because the Supreme Court explicitly recognized the simplicity of the combination in the '565 patent, and the '565 patent combined two mechanical patents that offer less complexity than the variety of reactions that can occur when two chemicals are combined, lower courts have struggled to find the bounds of *KSR*'s application to other arts. Analogizing the "combination of known elements" analysis has been particularly problematic for chemical patents, where known elements were combined but were non-obvious based on the reaction from the combination. The solution has been to redefine *KSR*, particularly for chemical patents.

¶17 The Supreme Court also increased the flexibility of the test for the POSA's motivation. Lower courts have looked for bounds to a POSA's motivation and have found them in the POSA's level of skill in the art. The Court also emphasized the importance of a finite number of identifiable and predictable solutions which render a patent obvious. But what is a "finite" number? The Federal Circuit has offered some guidance.

¶18 This section examines how the lower courts have approached obviousness post-*KSR*. Selected cases are divided by the art: chemical and mechanical/electrical. As divided, lines of argument emerge and the reinterpreted bounds of *KSR* begin to take

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<sup>35</sup> *Id.* at 420.

<sup>36</sup> *Id.* at 421.

<sup>37</sup> Indeed the internet has simplified the task for an inventor who seeks a variety of potential solutions to any given problem. For example, Google Patents allows one to search over 7 million patents by performing a normal Google search. See GOOGLE PATENTS, <http://www.google.com/patents> (last visited Nov. 9, 2010). The PTO also offers access to its full text and full page image databases online. U.S. PATENT AND TRADEMARK OFFICE, *Patent Full Text and Full Page Image Databases*, <http://patft.uspto.gov/> (last visited Nov. 9, 2010).

<sup>38</sup> *KSR*, 550 U.S. at 421.

<sup>39</sup> *Id.*



some shape. *KSR*'s exact bounds, and how practitioners can use these lines of argument, will be examined in Part IV.

### A. Chemical Cases

¶19 Immediately after *KSR*, many predicted a major change in the patentability of pharmaceuticals.<sup>40</sup> Lending credence to the doomsday predictions was the Federal Circuit's first obviousness case following *KSR*, *Pfizer v. Apotex*.<sup>41</sup> Apotex filed an ANDA<sup>42</sup> application seeking approval to sell Pfizer's Norvasc which was covered by U.S. Patent No. 4,879,303 ("the '303 patent").<sup>43</sup> Pfizer filed a patent infringement suit; Apotex asserted the '303 patent was invalid for obviousness. The District Court entered final judgment for Pfizer finding the patent valid, and the Federal Circuit reversed.<sup>44</sup>

¶20 Pfizer developed and patented Norvasc, a besylate salt form of amlodipine, which is an active ingredient used to treat hypertension and certain types of angina.<sup>45</sup> Pfizer held the patent for amlodipine and claimed the '303 patent taught the most commercially viable delivery method for the drug because the besylate salt form of amlodipine resulted in the lowest incidence of side effects.<sup>46</sup> Apotex argued that the patent for the amlodipine, combined with a second patent by Berge ("the Berge patent") which identified the salt forms that were most pharmaceutically acceptable, offered a potential solution.<sup>47</sup> Commercial viability would have motivated the POSA to find the best salt, and through routine optimization tests, the POSA would have settled on the besylate salt.<sup>48</sup> Pfizer argued the besylate salt form was nonobvious because (1) the patent for amlodipine did not suggest the use of a salt with cyclic anions like a besylate salt, (2) that even combining the amlodipine patent with Berge did not render the besylate salt form

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<sup>40</sup> See, e.g., Mossinghoff, *supra* note 5; Janice M. Mueller, *Chemicals, Combinations, and "Common Sense": How the Supreme Court's KSR Decision is Changing Federal Circuit Obviousness Determinations in Pharmaceutical and Biotechnology Cases*, 35 N. KY. L. REV. 281, 281 (2008) ("By invoking ambiguous, non-statutory terms and circular statements, the Supreme Court's KSR decision injected greater uncertainty into an already complicated analysis."); Harold C. Wegner, *Chemical and Biotechnology Obviousness in a State of Flux*, BIOTECHNOLOGY L. REP., Oct. 2007, at 437, 437 ("KSR and *Pfizer v. Apotex* have provoked critical rethinking of long-standing principles of U.S. chemical patent law of great importance to the chemical, and particularly, the pharmaceutical industry, with sharp implications also for biotechnology."). Wegner's article also offers a good history of obviousness in the chemical compound context.

<sup>41</sup> *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007), *reconsideration denied*, 488 F.3d 1377 (Fed. Cir. 2007).

<sup>42</sup> ANDA stands for Abbreviated New Drug Application. Under the Hatch-Waxman Act, an ANDA application constitutes an "artificial" act of infringement which confers subject matter jurisdiction on the federal courts. See, e.g., *Novartis Pharm. Corp. v. Teva Pharm. USA, Inc.*, No. 05-1887, 2009 WL 3754170, at \*2 (D.N.J. Nov. 5, 2009) (order on motions in limine) (citing 35 U.S.C. § 271(e)(2) (2006)). If, however, the defendant proves the patent is invalid, the defendant may market the generic version of the drug.

<sup>43</sup> *Pfizer*, 480 F.3d at 1352.

<sup>44</sup> *Id.* at 1352–53.

<sup>45</sup> *Id.* at 1352.

<sup>46</sup> *Id.*

<sup>47</sup> *Id.* at 1363.

<sup>48</sup> *Id.* at 1361–62. For criticism of the court's optimization analysis, see Wegner, *supra* note 40, at 452–43 (arguing that the *Pfizer* decision improperly relegated therapeutic properties to secondary considerations when a court should consider all properties, including therapeutic properties, when determining chemical obviousness).

obvious because the Berge patent taught that besylate salt was rarely used (0.25%) in the pharmaceutical industry, and finally (3) that the references are irrelevant because the besylate salt form disclosed in Berge was never used with an active ingredient like amlodipine.<sup>49</sup>

¶21 The district court found the prior art did not offer the requisite motivation because the prior art did not disclose the use of besylate salt to treat hypertension or angina (the primary use of Norvasc).<sup>50</sup> The Federal Circuit held that to provide the requisite motivation, the prior art need not show that the salt's use with the active ingredient was known; it need only show that the salt was known and that it solved the problems a POSA would have been attempting to solve.<sup>51</sup>

¶22 The Federal Circuit decided *Pfizer v. Apotex* in March 2007, just before the April 2007 decision in *KSR*. But Pfizer filed a motion for reconsideration, making it one of the first cases before the Federal Circuit under the new *KSR* standard. Extensive amicus briefing on the importance of commercialization factors in determining obviousness did not sway the court, and it upheld its previous decision.<sup>52</sup> Judge Lourie's dissent emphasized his concern about the exceptional importance of obviousness to the pharmaceutical industries.<sup>53</sup>

¶23 The Federal Circuit next addressed obviousness in *Takeda Chemical Industries, LTD. v. Alphapharm Party, LTD.* Takeda owns U.S. Patent 4,687,777 ("the '777 patent") which discloses compounds of Thiazolidinediones ("TZDs") for use in controlling diabetes.<sup>54</sup> Takeda first discovered the class of drugs known as TZDs in the 1970's, but the '777 patent (similarly to Norvasc in *Pfizer v. Apotex*) covered a drug formulation with strong pharmacological effects and low side effects.<sup>55</sup> The district court relied on a pre-*KSR* test for chemical patent obviousness: the lead compound analysis.<sup>56</sup> The court affirmed that the lead compound analysis remained relevant post-*KSR*: "it remains necessary to identify [a lead compound and] some reason that would have led a chemist to modify a known compound in a particular manner."<sup>57</sup> The court reasoned that since chemical compound obviousness typically turns on structural similarities and differences between the patent and the prior art, post-*KSR*, the test still requires the challenger to select and then modify a known compound based on the prior art.<sup>58</sup> Alphapharm failed to prove a POSA's motivation to select the lead compound, "compound b."<sup>59</sup> The district court also credited Takeda's argument that the prior art actually taught away from the use

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<sup>49</sup> *Pfizer*, 480 F.3d at 1361–62.

<sup>50</sup> *Id.* at 1363.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 1378.

<sup>53</sup> *Id.* at 1383. Janice Mueller argues *Pfizer* can be read in one of three ways: (1) a decision that "radically alter[s] the landscape of chemical non-obviousness" by holding that "'obvious to try' evidence may indeed be probative of . . . obviousness" (2) a decision limited to its facts or (3) "another in a series of cases in which the Federal Circuit rejected a patentee's attempt to extend its period of exclusivity by obtaining a second patent on a derivative form of a compound." Mueller, *supra* note 400, at 288.

<sup>54</sup> *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1353 (Fed. Cir. 2007).

<sup>55</sup> *Id.* at 1352.

<sup>56</sup> *Id.* at 1356.

<sup>57</sup> *Id.* at 1357.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.* at 1353.

of compound b making it an unlikely starting point for the POSA.<sup>60</sup> Without a lead compound, Alphapharm failed to make out a *prima facie* case.<sup>61</sup>

¶24 The Federal Circuit upheld the ruling.<sup>62</sup> The court found that Alphapharm’s prior art citations disclosed “hundreds of millions” of TZD compounds which taught away from “compound b” and suggested other compounds were more likely to be successful.<sup>63</sup> Since Alphapharm’s argument depended on starting from “compound b”, the Federal Circuit upheld the patent’s validity.<sup>64</sup>

¶25 The Federal Circuit also distinguished its holding in *Pfizer v. Apotex*. *Pfizer* was based on prior art that “narrow[ed] the genus of fifty-three pharmaceutically-acceptable anions to a few *including* [the one ultimately chosen by Pfizer].”<sup>65</sup> By contrast, in *Takeda*, the POSA would have chosen from “over ninety” compounds and would have chosen one other than “compound b” which had known toxicity and side-effects.<sup>66</sup> *Takeda* demonstrates that the lead compound analysis remains relevant post-*KSR*, and the “number” of predictable identifiable solutions discussed in *KSR* should be “a few” and something less than fifty-three.<sup>67</sup>

¶26 In *McNeil-PPC, Inc. v. Perrigo Co*, another chemical compound case arising from an ANDA filing,<sup>68</sup> Perrigo alleged McNeil’s U.S. Patent No. 5, 817,340 (“the ‘340 patent”) was invalid for obviousness.<sup>69</sup> The ‘340 patent disclosed an impermeable coating to mask the bitter taste of the active ingredient in Pepcid AC.<sup>70</sup> The court found that all of the relevant limitations of the ‘340 patent—the combination to create the drug and the impermeable coating—were known in the prior art.<sup>71</sup> Moreover, under *KSR*, a POSA would have been motivated to combine the teachings to mask the bitter taste of the active ingredient and make the drug more marketable.<sup>72</sup>

¶27 The court also reaffirmed another pre-*KSR* holding. *McNeil* argued a POSA would have avoided the impermeable coating because of the costs of production.<sup>73</sup> The court rejected this argument and held that a business person’s reasons for rejecting a solution are not equivalent to a POSA’s.<sup>74</sup> Only the POSA’s reasoning is relevant in an

<sup>60</sup> *Id.*

<sup>61</sup> *Id.* The court also found that even if Alphaharm had made a *prima facie* case, it would be rebutted by the unexpected results of the ‘377 patent’s nontoxicity.

<sup>62</sup> *Id.*

<sup>63</sup> *Id.* at 1357–59.

<sup>64</sup> *Id.* at 1357–58.

<sup>65</sup> *Id.* at 1360 (emphasis added).

<sup>66</sup> *Id.*

<sup>67</sup> The “less than fifty-three” number can be assumed. The court distinguished *Pfizer* from *Takeda* because the fifty-three potential compounds had been narrowed to a “few” in *Pfizer*, suggesting that fifty-three would have been too many. For a litigator opposing a patent’s validity, *Aventis Pharma Deutschland v. Lupin Ltd.* offers a possible line of argument for limiting the number of solutions. Where the drug came from a large family of drugs known to treat blood pressure, a more purified form of the drug was obvious. *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1301 (Fed. Cir. 2007).

<sup>68</sup> For more information on ANDAs, see *supra* note 422.

<sup>69</sup> Merck markets McNeil’s patent as the over-the-counter drug, Pepcid Complete, which treats a variety of stomach acid disorders.

<sup>70</sup> *McNeil-PPC, Inc., v. Perrigo Co.*, 516 F. Supp. 2d 238, 244 (S.D.N.Y. 2007).

<sup>71</sup> *Id.* at 250.

<sup>72</sup> *Id.*

<sup>73</sup> *Id.* at 250–51.

<sup>74</sup> *Id.* at 251.

obviousness determination.<sup>75</sup> While the market may provide the motivation to solve a POSA's problem, it does not provide a similar restraint on the POSA's investigation. Thus, the market cannot limit the POSA's search for solutions.

¶28 In March 2008, the Federal Circuit, in *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, considered Ortho-McNeil's U.S. Patent No. 4,513,006 (the '006 patent), which teaches the formation of the anticonvulsive drug Topiramate.<sup>76</sup> The doctor who discovered Topiramate did so while testing for diabetes drugs but found one of the intermediates exhibited anticonvulsing properties. Ortho-McNeil then completed extensive testing to show the compound was safe and effective for treating seizure-related diseases.<sup>77</sup> Mylan asserted that Topiramate was obvious, because a POSA looking for a new diabetes drug would necessarily design a drug from the class of drugs Topiramate was in.<sup>78</sup> Citing *KSR*, Mylan argued that the class of drugs represented "a finite number of identified predictable solutions."<sup>79</sup>

¶29 The court held the record did not present "a finite . . . number of options easily traversed to show obviousness."<sup>80</sup> There were a number of motivational problems: (1) the POSA would be unlikely to start with the particular chemical formulation Dr. Maryanoff did, (2) the POSA "would have to have some reason to select (among several unpredictable alternatives) the exact route that produced Topiramate," and (3) the POSA would have had to stop and test the intermediate for properties related to epilepsy (without any idea about the value of Topiramate).<sup>81</sup> The court concluded, "this clearly is not the easily traversed, small and finite number of alternatives that *KSR* suggested might support an inference of obviousness."<sup>82</sup> Additionally, the court found Mylan relied on hindsight-driven analysis.<sup>83</sup> While the TSM test, flexibly applied, allows for a broad range of motivators, Mylan's expert ignored multiple paths to solutions and discounted the complexity of the alternatives.<sup>84</sup>

¶30 Next, in *Eisai Co. Ltd. v. Dr. Reddy's Laboratories, Ltd.*, the court considered Eisai's Rabeprazole.<sup>85</sup> In *Eisai*, the Federal Circuit explicitly analyzed how the lead compound analysis operated under the more flexible *KSR* standard. To maintain flexibility, "the requisite motivation can come from any number of sources and need not necessarily be explicit in the art."<sup>86</sup> The court explained:

The Supreme Court's analysis in *KSR* thus relies on several assumptions about the prior art landscape. First, *KSR* assumes a starting point or points in the art, prior to the time of invention, from which a skilled artisan might identify a

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<sup>75</sup> *Id.*

<sup>76</sup> *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1360 (Fed. Cir. 2008).

<sup>77</sup> *Id.*

<sup>78</sup> *Id.* at 1364.

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1356 (Fed. Cir. 2008). Rabeprazole is marketed as Aciphex.

<sup>86</sup> *Id.* at 1357 (citing *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1301 (Fed. Cir. 2007)).

problem and pursue potential solutions. Second, *KSR* presupposes that the record up to the time of invention would give some reasons, available within the knowledge of one of skill in the art, to make particular modifications to achieve the claimed compound. Third, the Supreme Court's analysis in *KSR* presumes that the record before the time of invention would supply some reasons for narrowing the prior art universe to a "finite number of identified predictable solutions."<sup>87</sup>

The court further explained, "To the extent an art is unpredictable, as the chemical arts often are, *KSR*'s focus on these 'identified, predictable solutions' may present a difficult hurdle because potential solutions are less likely to be genuinely predictable."<sup>88</sup> The court concluded that post-*KSR*, the obviousness inquiry for a chemical compound still begins with a lead compound.<sup>89</sup>

¶31 Teva claimed Lansoprazole as a lead compound. According to Teva, a POSA would have started by removing the fluorinated substituent from Lansoprazole to get to Rabeprazole.<sup>90</sup> The court, however, found no motivation to remove from Lansoprazole the fluorinated substituent which made it more effective.<sup>91</sup> Thus, in *Eisai*, while Teva chose an appropriate lead compound, it failed to logically explain what motivation the POSA would have had to take the first step necessary to arrive at the claimed compound.

¶32 March 2009 brought the consideration of *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.* In *Procter & Gamble*, the Federal Circuit considered a district court's holding that U.S. Patent 5,583,122 ("the '122 patent) was valid over obviousness defenses asserted by Teva. The '122 patent covers Risedronate, the active ingredient in Procter and Gamble's ("P & G") Actonel which treats osteoporosis.<sup>92</sup> The district court relied on arguments from *Takeda* and *Eisai*, finding that Teva's prior art citations would not have led a POSA to identify 2-pyr EHDP as the lead compound, a POSA would not have been "motivated to make the specific molecular modifications to make Risedronate," and secondary considerations supported these findings.<sup>93</sup>

¶33 In sum, the chemical patent cases have affirmed much of the pre-*KSR* precedent. Many feared that the "obvious to try" analysis in *KSR*, combined with the optimization language from *Pfizer v. Apotex*, meant chemical patents would be invalidated with ease on a theory that a POSA would find a combination obvious to try and then optimize to reach the specified chemical levels. But the Federal Circuit's interpretation of *KSR* has significantly limited its impact on chemical compounds. The lead compound analysis is still the test for invalidating chemical patents. The Federal Circuit further constrained the obvious to try analysis by suggesting that the number of options available to a POSA should be limited to "a few" and finding that more than fifty-three options are too many.<sup>94</sup> Finally, the optimization holding in *Pfizer v. Apotex* has simply not had the

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<sup>87</sup> *Id.* at 1359 (citations omitted).

<sup>88</sup> *Id.* (citing *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008)).

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> *Id.* at 1358.

<sup>92</sup> *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 992 (Fed. Cir. 2009).

<sup>93</sup> *Id.* at 993.

<sup>94</sup> *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1359–60 (Fed. Cir. 2007). Of course practitioners can always argue that a broader number of options is not as broad as an initial review

strength many feared in the immediate aftermath of *KSR*. These limitations suggest a less expansive obvious to try analysis than supporters of the pharmaceutical industry had feared.

¶34 Meanwhile, *KSR*'s instruction to survey market pressures has had an effect, as seen in *McNeil v. Perrigo*. The problem of bitter taste was known. The purpose of the impermeable coating was to make the drug more palatable. Because a method for creating an impermeable coating was known, the combination of the active drug and the coating was obvious. In short, *KSR*'s impact has been felt in the chemical patent context, but it has been less than the armageddon many had expected.

### B. District Courts and Chemical Cases

¶35 As the analysis below shows, district court decisions have followed the Federal Circuit's gloss on post-*KSR* analysis in the chemical context more closely than *KSR* itself. Probably the most distinctive feature of the district court opinions is the development of the secondary considerations analysis. Although secondary considerations operate primarily to negate a *prima facie* case of obviousness, many district courts, while finding against the challenger on the basis of the *prima facie* case, write lengthy opinions explaining why secondary considerations also support the initial finding of non-obviousness.<sup>95</sup>

¶36 Other district courts have considered *KSR*'s "obvious to try" standard in light of the clear and convincing burden a challenger faces when attempting to invalidate a patent.<sup>96</sup> The heightened burden has been most significant for a challenger to overcome where the patentee is able to cite pieces of prior art that teach away from the combination claimed by the patent-in-suit. Courts have noted that where prior art teaches away, the challenger simply cannot meet the clear and convincing burden placed on it as a result of the deference due to the PTO.<sup>97</sup>

¶37 The "obvious to try" analysis has also been affected in the district courts by the level of skill of the POSA. In *Alcon*, the court considered a patent for an antibacterial eye drop.<sup>98</sup> The court found the patent-in-suit was not obvious to try based, in part, on the POSA's *higher* level of skill in the art.<sup>99</sup> Because of the vast industry knowledge the

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might suggest based on the POSA's knowledge of the art. For example, if the "obvious to try" solution is within a family of pharmaceuticals but half of them have been ruled out for use in the industry due to side effects then, so long as the solution is within the other half of the drug family, the practitioner could argue that the number of solutions any POSA would have faced was actually smaller than the entire family.

<sup>95</sup> *Alcon, Inc. v. Teva Pharms. USA, Inc.*, 664 F. Supp. 2d 443, 464 (D. Del. 2009) (noting that there was a long-felt need in the industry for a replacement drug, experts were skeptical of the investigation of another quinolone, that the patent covered the unexpected result that moxifloxacin penetrated into and was retained by the eye, and that the commercial embodiment led to millions of dollars in sales). *See also In re Brimonidine Patent Litig.*, 666 F. Supp. 2d 429, 446 (D. Del. 2009) (Drug was a blockbuster, which was initially met by great skepticism, and others tried unsuccessfully to copy it.). This phenomenon may be largely attributed to the district court's interest in avoiding reversal and remand in the event the Federal Circuit believes the challenger actually made out a *prima facie* case for obviousness.

<sup>96</sup> *See Avia Group Int'l v. L.A. Gear Cal.*, 853 F.2d 1557, 1561 (Fed. Cir. 1988).

<sup>97</sup> *See, e.g., Brimonidine*, 666 F. Supp. 2d at 442; *Unigene Labs., Inc. v. Apotex Inc.*, No. 06 CV 5571, 2009 WL 2762706, at \*11, \*14 (S.D.N.Y. Aug. 31, 2009), *vacated on other grounds*, 2009 WL 3682179 (S.D.N.Y. Oct. 30, 2009), *reinstated in its entirety*, 2010 WL 2730471, at \*8 (S.D.N.Y. July 07, 2010).

<sup>98</sup> *Alcon*, 664 F. Supp. 2d at 447.

<sup>99</sup> *Id.* at 461–63.

POSA would have had, the court found that the POSA would have expected the patented drug to fail.<sup>100</sup> The court found that the POSA, based on its knowledge of toxicity and the industry's general distrust of Quinolones, would have tried a variety of other drugs before attempting a formulation with Quinolones.<sup>101</sup> If this type of argument becomes common, it may mean fewer obviousness cases are resolved on summary judgment, since parties will become less willing to concede the *Graham* factual question of the POSA's level of skill in the art, and the case will have to go to the jury to decide, at minimum, what the POSA's level of skill is.<sup>102</sup>

¶38 Other more creative arguments have come out of the district courts. For example, one party argued that *KSR*'s market pressures include the pressure felt by a pharmaceutical company at the "impending expiration of [its] patent" for a blockbuster drug.<sup>103</sup> That argument is an extension of the market pressure doctrine. It takes *KSR*'s holding that consumer demand is sufficient to motivate a POSA and applies it to a supplier's desire to continue its monopoly. Another court found that the process utilized to determine solubility for a drug, where different from all other references, may also establish non-obviousness.<sup>104</sup> This argument seems to be an extension of the "teaching away" doctrine, suggesting that a combination may not be obvious where the method or process utilized to find or test the pharmaceutical was itself unique, and other references taught away from the method of determining some part of the combination's makeup.<sup>105</sup>

¶39 Overall, chemical patents have been less affected than many initially expected, because the Federal Circuit's guidance post-*KSR* left in place many of the previous tests for obviousness in the chemical context. However, the reasoned path from a lead compound to the patent-in-suit offers an opportunity for structure around the obvious to try test. If not policed to ensure sufficient flexibility, the reasoned path may become too rigid and provide ground for a Supreme Court challenge that leaves chemical patents in a state not unlike mechanical patents are today.

### C. Mechanical and Electrical Patents

¶40 *KSR*'s effect on mechanical patents has been more pronounced, perhaps largely because the case dealt directly with mechanical arts, making it harder to distinguish.<sup>106</sup> In

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<sup>100</sup> *See id.*

<sup>101</sup> *Id.* at 462–63.

<sup>102</sup> *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

<sup>103</sup> *Alcon*, 664 F. Supp. 2d at 462–63.

<sup>104</sup> *In re Brimonidine Patent Litig.*, 666 F. Supp. 2d 429, 443 (D. Del. 2009). Note that this argument is different from process or methods claims which are affected by the recent Supreme Court decision *In re Bilski*. Whereas *Bilski* affects the patentability of method or process claims, this argument suggests that a unique method, process, or test for reaching the claimed patented material may demonstrate that the material itself is non-obvious. *See generally* *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

<sup>105</sup> *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 413, 416 (2007). In *KSR*, the court held that where prior art taught away from using a particular solution, the court may find the solution non-obvious, because the POSA was unlikely to try a solution that industry knowledge suggested would not work. *Brimonidine* suggests a litigator can look behind the elements to the methods used to test the combination or combine the elements. Even if those methods are not patented, they may be sufficient to make the combination non-obvious. *Brimonidine*, 666 F. Supp. 2d at 443.

<sup>106</sup> Judge Markey suggested long before *KSR* that all mechanical patents are inevitably combination patents. *See Stratoflex Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540 (Fed. Cir. 1983) ("Virtually all patents are 'combination patents' if by that label one intends to describe patents having claims to inventions

May 2007, the Federal Circuit considered *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.* Leapfrog appealed the district court's order holding that Fisher-Price's PowerTouch product (a reading tool for children) did not infringe Leapfrog's U.S. Patent 5,813,861 ("the '861 patent") and that the patent was invalid as obvious.<sup>107</sup>

¶41 After affirming the district court's non-infringement finding, the Federal Circuit turned to Leapfrog's obviousness argument. Leapfrog claimed there was inadequate evidence to support a finding of motivation to combine the prior art.<sup>108</sup> Fisher Price offered two patents that taught most of the elements of the Leapfrog product and argued the toy's final version was simply an electronic update of the prior art.<sup>109</sup> The Federal Circuit agreed. The court found that "accommodating a prior art mechanical device to modern electronics would have been reasonably obvious to one of ordinary skill in children's learning devices."<sup>110</sup> The POSA would have combined the prior art references to gain market-driven benefits like "decreased size, increased reliability, simplified operation, and reduced cost."<sup>111</sup> Leapfrog is an application of two *KSR* principles. First, a POSA is a person of ordinary creativity. A POSA would apply technological advances to older mechanical patents to meet new market trends.<sup>112</sup> Second, where market demands provide the POSA with motivation to combine the prior art, a patent is obvious.<sup>113</sup>

¶42 In August 2007, the Federal Circuit considered *In re Icon Health and Fitness*, an appeal from the Board of Patent Appeals and Inferences stemming from a reexamination of U.S. Patent No. 5,676,624 ("the '624 patent"), which taught a treadmill with a folding base supported by a gas spring.<sup>114</sup> The gas spring helped hold the treadmill base upright for easy storage.<sup>115</sup>

¶43 The Federal Circuit upheld the Board of Patent Appeals' obviousness finding that a treadmill advertisement and U.S. Patent No. 4,370,766 by Teague ("the '766 patent"), which disclosed a folding bed using a gas spring, rendered the patent obvious.<sup>116</sup> Icon argued that the '766 patent was irrelevant because it was outside the "treadmill art."<sup>117</sup> The Federal Circuit found a POSA would have sought to solve the problem of holding the base in a closed position. Relying on *KSR*, the court found that "[n]othing in Icon's folding mechanism requires any particular focus on treadmills; it generally addresses problems supporting the weight of such a mechanism and providing a stable resting position" and therefore the prior art "may come from any area describing [those issues]."<sup>118</sup> Since the '766 patent addresses the problem of holding a base in a closed

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formed of a combination of elements. It is difficult to visualize, at least in the mechanical-structural arts, a 'non-combination' invention; i.e. an invention consisting of a *single* element. Such inventions, if they exist, are rare indeed." (emphasis in the original).

<sup>107</sup> *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1158 (Fed. Cir. 2007).

<sup>108</sup> *Id.* at 1160.

<sup>109</sup> *Id.*

<sup>110</sup> *Id.* at 1160–61.

<sup>111</sup> *Id.* at 1162.

<sup>112</sup> *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

<sup>113</sup> *Id.*

<sup>114</sup> *In re Icon Health and Fitness, Inc.*, 496 F.3d 1374, 1377 (Fed. Cir. 2007).

<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

<sup>117</sup> *Id.* at 1379.

<sup>118</sup> *Id.* at 1380.



position, it offered a solution a POSA would have tried. Moreover, the court found a “striking similarity” between Icon’s application and the ‘766 patent, which further supported the idea that one skilled in the art would combine the two.<sup>119</sup>

¶144 In March 2008, the Federal Circuit looked at a “textbook case” of a combination by known methods to yield predictable results.<sup>120</sup> In *Agrizap, Inc. v. Woodstream Corp.*, the court considered U.S. Patent No. 5,949,636 (“the ‘636 patent”) which taught a method for building a rodent trap that electrocuted a pest when it came into contact with two electrodes: a high voltage electrode and a reference electrode.<sup>121</sup> The two electrodes trigger a generator that produces a current sufficient to kill the rodent.<sup>122</sup> The jury found the ‘636 patent non-obvious. Woodstream moved for judgment as a matter of law which the district court denied.<sup>123</sup> Woodstream appealed.

¶145 The PTO had initially rejected the ‘636 patent based on three references (Agrizap owned one, U.S. Patent No. 5,269,091 (“the ‘091 patent”)), because the sole change between the three patents and the ‘636 patent was the use of a mechanical switch instead of a resistive switch to complete the circuit.<sup>124</sup> Agrizap adjusted inventorship so that the ‘091 and the ‘636 patent had the same inventor.<sup>125</sup> Woodstream argued the PTO had been correct in the first place, because Agrizap had publicly revealed the commercial embodiment of the ‘091 patent at trade shows rendering the ‘636 patent obvious. The Federal Circuit agreed.<sup>126</sup> Moreover, the court upheld the obviousness determination over Agrizap’s secondary considerations including “the commercial success of the Rat Zapper, copying by Woodstream, and a long felt need in the market.”<sup>127</sup>

¶146 Despite the suggestion of the case law reported above, the Federal Circuit has not found all mechanical or electrical patents obvious since *KSR*.<sup>128</sup> But the court is not finding these patents non-obvious either. The court is finding unanswered factual questions and remanding the cases to the district courts. In *Commonwealth Scientific and Industrial Research Organisation v. Buffalo Technology (USA), Inc.*, the court held that “a genuine issue of material fact existed as to whether there was a motivation to combine prior art references.”<sup>129</sup> In *Commonwealth*, the court considered U.S. Patent No. 5,487,069 (“the ‘069 patent”) which taught a method for connecting wireless WLAN networks to avoid the problem of echo signals created when radio waves bounce off walls.<sup>130</sup> Prior to *KSR*, the district court held the ‘069 patent non-obvious based on

<sup>119</sup> *Id.* at 1381.

<sup>120</sup> *Agrizap, Inc. v. Woodstream Corp.*, 530 F.3d 1337, 1344 (Fed. Cir. 2008).

<sup>121</sup> *Id.* at 1339–40.

<sup>122</sup> *Id.* at 1340.

<sup>123</sup> *Id.* at 1341.

<sup>124</sup> *Id.* at 1343.

<sup>125</sup> *Id.* at 1344.

<sup>126</sup> *Id.* The Court of Federal Claims invalidated a patent for navy sonar buoys based on the same reasoning and an Engineering Change Proposal which the court found qualified as an offer for sale. *See Sparton Corp. v. United States*, No. 92-580 C, 2009 WL 2948555, at \*1 (Fed. Cl. Sept. 10, 2009).

<sup>127</sup> *Agrizap*, 530 F.3d at 1344.

<sup>128</sup> *See, e.g., Andersen Corp. v. Pella Corp.*, 300 F. App’x 893, 894 (Fed. Cir. 2008) (reversing the district court’s decision granting summary judgment on obviousness because there existed a genuine issue of material fact regarding whether a POSA would have even considered the prior art on which the challengers relied in their obviousness analysis).

<sup>129</sup> *Commonwealth Scientific and Indus. Research Org. v. Buffalo Tech. (USA), Inc.*, 542 F.3d 1363, 1374–75 (Fed. Cir. 2008).

<sup>130</sup> *Id.* at 1367.

CSIRO's argument that although the prior art contained all of the elements of the '069 patent, it dealt with a problem that was not directly analogous.<sup>131</sup> The Federal Circuit reversed and instructed the district court to apply *KSR*'s holding that any need or problem could supply a reason for combining known elements.<sup>132</sup>

¶47 *Commonwealth* suggests that *KSR*'s more flexible obviousness standard may be shifting the obviousness battle to the factual stage over the POSA's level of skill. A POSA with a higher level of skill can either see more complexity in a problem or recognize more easily the obviousness of a solution than a POSA with a lower skill level.<sup>133</sup> Similarly, a POSA with greater market experience may disregard potential solutions more quickly based on industry expectations that certain combinations will not work with one another.<sup>134</sup> In short, the definition of the POSA's level of skill in the art will have a significant effect on the outcome of the obviousness analysis, suggesting that the post-*KSR* obviousness analysis may generate more concern over the exact definition of the POSA. Regardless, these cases put practitioners on notice that they must consider whether and how the factual question of the POSA's level of skill will affect their legal analysis on obviousness.

¶48 Thus, in the mechanical arts, *KSR*'s impact has been significant.<sup>135</sup> While *Icon* is a clear extension of *KSR*'s admonition to broaden the base of the relevant prior art, *Leapfrog* suggests that mechanical patent lessons may be extended to the electronic arts, where the application of technological advances to known products will be treated as obvious. The electronic expansion could have far-reaching consequences for a wide variety of electronic patent applications. The rate of electronic expansion will depend on the Federal Circuit's willingness to expand its technological advancement ideas in *Leapfrog* and on the district courts' willingness to expand the doctrine at the lower level.

#### D. District Courts and Mechanical Patents

¶49 Mechanical patents have fared slightly better at the district court level than at the Federal Circuit. The biggest problem for mechanical patent holders is that there are fewer opportunities than in the chemical arts to complicate the path of the POSA from two previously known ideas to the ultimate combination. Moreover, the case law suggests that there are often fewer solutions to any given problem, which makes it easier to get to the "finite number of identified predictable solutions."<sup>136</sup>

<sup>131</sup> *Id.* at 1373–75.

<sup>132</sup> *Id.* at 1375 (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007)).

<sup>133</sup> *See, e.g., Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254, 1257–58 (Fed. Cir. 2007) (The Federal Circuit predicated error on the district court's finding that a POSA was less specialized than the Federal Circuit believed the evidence showed. Based on the heightened level of skill in the art, the court reversed the district court's holding of non-obviousness.).

<sup>134</sup> *See Commonwealth Scientific*, 542 F.3d at 1374–75.

<sup>135</sup> *See generally* Li Li & Shuba Ghosh, Analysis of the *KSR* Ruling's Impact on Electronics Patents (unpublished paper), available at [http://works.bepress.com/shubha\\_ghosh/4](http://works.bepress.com/shubha_ghosh/4) (documenting *KSR*'s effect on the electronics industry and suggesting a reversion to the TSM test for "cutting edge" electronics patents). Li and Ghosh are not alone in their argument for a reversion back to the TSM test. *See* Randall J. Hirsch, Note, *Well Duh: Obviousness, Gas Pedals, and the Teaching-Suggestion-Motivation Test*, 6 NW. J. TECH. & INTEL. PROP. 89 (2007). For a broader, but conflicting view *see* Emer Simic, *The TSM Test Is Dead! Long Live the TSM Test! The Aftermath of KSR, What Was All the Fuss About?*, 37 AIPLA Q.J. 227 (2009) (arguing *KSR* had little or no impact on patent litigation).

<sup>136</sup> *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007).

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Unlike chemical patents, where an analysis of sub-elements seems to offer some promising lines of argument, mechanical patents seem to survive an obviousness challenge one of two ways: either a perfect confluence of factors which render the patent non-obvious or a factual question which renders it procedurally impossible to decide obviousness on summary judgment. The perfect confluence of factors is well demonstrated by *Cimline, Inc. v. Crafcro*. At issue was U.S. patent 5,967,375 (the ‘375 patent) which taught the attachment of a mechanical conveyer belt leading to a box with flaps to concrete sealant melter trucks.<sup>137</sup> The conveyer belt facilitated easy transport of the sealant blocks which were dropped into the truck to melt.<sup>138</sup> The flaps prevented the 500 degree liquid from splashing and injuring workers below.<sup>139</sup> The ‘375 patent covered only the mechanical conveyer belt.<sup>140</sup> The challenger pointed to previous embodiments of the product to suggest the patent was obvious.<sup>141</sup> In rejecting the obviousness challenge, the court relied on four factors. First, the court relied on the challenger’s burden to prove by clear and convincing evidence that the patent was obvious.<sup>142</sup> Second, the court found that the burden, coupled with the fact that all of the relevant art was before the patent examiner, suggested the patent was non-obvious.<sup>143</sup> Third, the court noted that the arguably simple modification took a decade to complete, a secondary consideration suggesting the patent was not obvious.<sup>144</sup> Finally, the court found that the challenger failed to demonstrate that the POSA had a reasoned path to arrive at the patent in suit.<sup>145</sup> By contrast, in *Shuffle Master v. MP Games*, the court offered a long and well-reasoned decision explaining why U.S. Patent No. 5,781,647 was obvious, only to hold that factual questions about the scope of the prior art patent on which it relied prevented a summary judgment grant.<sup>146</sup>

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The district courts in mechanical cases also appear to be trying to integrate the Federal Circuit’s divergent application of *KSR* in the chemical and mechanical contexts. The court’s analysis in *Cimline* of the POSA’s reasoned path sounded more like a chemical case, because the court tracked the various choices the POSA had to make. In *Delta Frangible Ammunition v. Sinterfire*, by contrast, the court rejected a patentee’s arguments that a copper bullet would have required “undue experimentation” and was not obvious to try, because the prior art gave no direction toward choosing copper.<sup>147</sup> The court relied on *Proctor & Gamble v. Takeda*, a chemical case, holding “obviousness

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<sup>137</sup> *Cimline, Inc. v. Crafcro, Inc.*, 672 F. Supp. 2d 916, 918 (D. Minn. 2009).

<sup>138</sup> *Id.*

<sup>139</sup> *Id.*

<sup>140</sup> *Id.*

<sup>141</sup> *Id.* at 924–25.

<sup>142</sup> *Id.* at 923.

<sup>143</sup> *Id.* at 926.

<sup>144</sup> *Id.*

<sup>145</sup> *Id.* at 925–28. This deference suggests another strategy for litigants. If already litigating a re-exam, trial lawyers should make sure the prior art cited in a concurrent patent suit is before the examiner. Assuming the patent survives the re-exam, it will also be more likely to survive the suit.

<sup>146</sup> *Shuffle Master, Inc. v. MP Games LLC*, 553 F. Supp. 2d 1202, 1226 (D. Nev. 2008). Perhaps *Shuffle Master* suggests a new method for disposing of patent cases? Judge Reed’s opinion may have been intended as a signal to the parties that both faced significant risk if the case went to trial and they should consider settlement. Otherwise, the detailed explanation of obviousness makes little sense since Judge Reed could have disposed of the summary judgment issue on the factual question without ever reaching the obviousness analysis.

<sup>147</sup> *Delta Frangible Ammunition, LLC v. Sinterfire, Inc.*, 663 F. Supp. 2d 405, 412–13 (W.D. Pa. 2009).

cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success.”<sup>148</sup> Practitioners seeking to protect a mechanical patent should review the chemical cases and attempt to analogize the complication of the chemical patents to the mechanical one at issue in their case.

#### IV. EMERGING PATTERNS AND THE ROAD AHEAD

¶52 The analysis leaves one question unanswered. Post-*KSR*, what are the successful lines of argument and how can a practitioner best develop his or her case to take full advantage of them?

¶53 First, as the case review here demonstrates, the bar for proving nonobviousness of mechanical patents has been raised. *Leapfrog* suggests the same bar may apply to high-tech electronics and potentially, by extension, some forms of computer industry patents.<sup>149</sup> Meanwhile, the effect on the pharmaceutical industry is less pronounced than many first feared. That result is due, in large part, to the Federal Circuit. The Federal Circuit has emphasized the complexity and unpredictability of the chemical arts, which suggests for lower courts that they are different than the mechanical or electronic arts. Moreover, Federal Circuit decisions interpreting *KSR* have reduced the impact of the “obvious to try” doctrine by limiting what constitutes a number of “finite predictable” solutions in chemical cases to a “few.”

¶54 Practitioners seeking to protect a patent from an obviousness challenge should build a storyline that creates a number of decision points for a POSA and complicates, as much as possible, each decision so that the ultimate path the POSA must take to arrive at the patent-in-suit seems far from obvious. The chemical patent cases provide good examples of successful arguments that can and should be analogized to other areas.<sup>150</sup> The reverse is true for practitioners seeking to invalidate for obviousness. The path for the POSA must be simple and clear. In the chemical context, there must be a reasoned analysis for the POSA’s lead compound choice and then a clearly reasoned and relatively simple path to the final solution. The cases suggest that deluging the court with a large number of prior art references (a norm in patent cases) is less persuasive in a chemical arts case. More likely, it will offer the opposing side a citation to argue the prior art taught away from the suggested solution and suggest to the court that the path is unclear.

¶55 Once the POSA’s path is clear, motivating factors become most important. Motivating factors in particular provide an area where litigants need not be automatons. Like the POSA in *KSR*, the motivating factors litigants present may come from creative places. Litigants should look to market forces (e.g. *Alcon*), unsolved needs (e.g. *Perrigo*), and technological advancements (e.g. *Leapfrog*) that might apply to the patent. Practitioners should also look to differing but related fields (e.g. *Icon* or *Pfizer v. Apotex*) that might provide a POSA’s inspiration.

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<sup>148</sup> *Id.* at 414 (citing *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 996 (Fed. Cir. 2009)). In fact, the “case present[ed] a textbook example ‘where a skilled artisan merely pursued known options from a finite number of identified predictable solutions.’” *Id.* at 416.

<sup>149</sup> See also Li & Ghosh, *supra* note 1355, at 20.

<sup>150</sup> At least some district courts seem open to cross-citation to the chemical arts patent cases in the mechanical arts context. See, e.g., *Sensormatic Elecs. Corp. v. Tag Co. US, LLC*, 632 F. Supp. 2d 1147, 1175 (S.D. Fla. 2008) (citing *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008)).

¶56 Unfortunately for the litigator, much of what makes a strong case for validation occurs years before the litigation begins, at the prosecution stage. While claim construction allows for some variability in definition, the ability to say that a mechanical patent has complicated elements must be colorable based on the patent's original language. Patent prosecution attorneys will do well to include more rather than less prior art before the PTO, as one of the most successful arguments for validity arises out of the clear and convincing burden placed on a challenger. When all of the art the challenger cites is before the patent examiner, the challenger's task becomes significantly harder.<sup>151</sup>

¶57 Finally, litigators must consider potential procedural arguments. The importance of the POSA's level of skill in the art for determining what is obvious to try or within the POSA's creativity has already begun to place more emphasis on the *Graham* factors. The level of skill is certainly a material fact in the obviousness analysis and could push more patent cases to trial. Should this trend be pushed to its ultimate fruition, the Supreme Court may face a *Twombly*-like question at the summary judgment stage with patent law forming the substantive basis for the challenge.<sup>152</sup> In other words, the court may need to determine when a party has proven facts sufficient to set the level of the skill in the art. Exactly what such a challenge might look like is outside the scope of this article.

¶58 Another potential challenge to the law is a *KSR*-like challenge for chemical patents. In the event that the Federal Circuit's lead compound test continues to make it easier to protect chemical patents, practitioners could argue that the flexibility the Supreme Court infused into the TSM test has been lost on the chemical patent side. Such a challenge would most likely have to be framed as a question about the viability of the lead compound test but might follow the analysis in *KSR* as a guide. Again, a full exposition of what such a challenge might look like is outside the scope of this article.

## V. CONCLUSION: THE ROAD AHEAD

¶59 Thousands of pages have already been spent on how *KSR* altered patent litigation. There is no doubt that patents have become harder to secure in the post-*KSR* world. The question is how much has it really changed litigation? The answer varies based on which area of patentable science one analyzes.

¶60 Mechanical patents are simply harder to defend against an obviousness challenge in the post-*KSR* world. While the Federal Circuit has offered clarifying factors in the chemical context, none seem to be forthcoming for mechanical patents. Thus, litigators face an uncertain world. Chemical patents, while governed by a clearer test, are on a road that could result in a challenge similar to *KSR* that charges the lower courts with ignoring the flexibility requirement of *KSR* in the chemical context. Mechanical patentees, meanwhile, face a world where it seems that almost nothing mechanical is non-obvious.

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<sup>151</sup> If the patent is before the PTO on a reexamination anyway, it is worthwhile to make sure that all art and expert reports submitted in the litigation are before the PTO during the re-exam. If the patent survives, it makes the case against it much less strong. *See generally*, *Unigene Labs., Inc. v. Apotex Inc.*, No. 06 CV 5571, 2009 WL 2762706, at \*11, \*14 (S.D.N.Y. Aug. 31, 2009), *vacated on other grounds*, 2009 WL 3682179 (S.D.N.Y. Oct. 30, 2009), *reinstated in its entirety*, 2010 WL 2730471, at \*8 (S.D.N.Y. July 07, 2010)).

<sup>152</sup> *See generally* *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007).

¶61 The division based on the type of patent means litigators who defend interdisciplinary patents should emphasize the more complex art as much as possible. For example, medical device and process patents can have both mechanical and chemical or biological elements in them. If the litigator can increase the relevance of the non-mechanical portions of the patent, she will be in a more structured and harder-to-invalidate portion of the obviousness test. Perhaps the best opportunity to protect these patents from an obviousness challenge is at the prosecution stage. Patents covering interdisciplinary fields should integrate, to the extent possible, the more complex (e.g. chemical) arts into as many claims as possible.

¶62 The division between arts is likely to continue over the next several years and probably become more entrenched. There are some signs, however, that district courts are not applying the division between the arts as directly as the Federal Circuit and are borrowing concepts from the chemical cases for mechanical patents. Ultimately the analysis shows that practitioners live in a more stable world three years post-*KSR*, but many questions still remain open and unanswered.