

# Oklahoma Journal of Law and Technology

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Volume 5 | Number 1

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January 2009

## Do the Evolution: The Effect of KSR v. Teleflex on Biotechnology

Josh Harrison

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### Recommended Citation

Harrison, Josh (2009) "Do the Evolution: The Effect of KSR v. Teleflex on Biotechnology," *Oklahoma Journal of Law and Technology*. Vol. 5: No. 1, Article 1.

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5 OKLA. J.L. & Tech. 42 (2009)

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## DO THE EVOLUTION THE EFFECT OF KSR V. TELEFLEX ON BIOTECHNOLOGY

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### I. Introduction

In *KSR v. Teleflex*, the Supreme Court issued one of the most significant decisions dealt to intellectual property law in decades.<sup>1</sup> The ruling effectively restructures the approach used by courts to determine whether a claimed invention is “non-obvious,” a historically ambiguous and ill-defined condition to obtaining a patent.<sup>2</sup>

Biotechnology, or biotech, represents the forefront, both present and future, of modern medicine, agriculture, and energy.<sup>3</sup> Its growth and evolution as a science and as a technology is essential to the enrichment and increased well-being of humanity as a whole.<sup>4</sup> Because its funding stems primarily from private investors, biotechnology relies on consistent and dependable patent protection to sustain its progress and development.<sup>5</sup>

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<sup>1</sup> See, e.g., Harold C. Wegner, *Making Sense of KSR and Other Recent Patent Cases*, 106 MICH. L. REV. FIRST IMPRESSIONS 39, 39 (2007), <http://www.michiganlawreview.org/firstimpressions/vol106/wegner.pdf> (“For long-range importance in patent law, *KSR* stands alone as the single most important Supreme Court patent decision on the bread and butter standard of ‘obviousness’ in the more than forty years since the 1966 *Graham v. John Deere*.”).

<sup>2</sup> Clara R. Cottrell, Note, *The Supreme Court Brings a Sea Change with KSR International Co. v. Teleflex, Inc.*, 42 WAKE FOREST L. REV. 595, 596 (2007) (“[A] patent attorney can spend five minutes describing the first three patent requirements, but the next five days defining and explaining the obviousness requirement.”).

<sup>3</sup> See, e.g., BIOTECHNOLOGY INDUSTRY ORGANIZATION, *NEW BIOTECH TOOLS FOR A CLEANER ENVIRONMENT* (June 2004) (discussing the evolution and potential for industrial biotechnology); BIOTECHNOLOGY INDUSTRY ORGANIZATION, *BIOTECHNOLOGY’S IMPACT ON DISEASES OF THE ELDERLY: A WHITE PAPER* (Sept. 2000) (discussing the current impact and promise of biotech medicines and foods in treating a range of age-related diseases).

<sup>4</sup> See, e.g., Deval Patrick & Therese Murray, *The Promise of Biotech*, BOSTON GLOBE, May 9, 2007, [http://www.boston.com/news/globe/editorial\\_opinion/oped/articles/2007/05/09/the\\_promise\\_of\\_biotech](http://www.boston.com/news/globe/editorial_opinion/oped/articles/2007/05/09/the_promise_of_biotech) (“You cannot be in the company of someone you love, powerless to help them, without appreciating the vital importance of stem cell research and other biomedical breakthroughs. In many ways, the health of this industry and the health of our society are closely linked.”); Florence Wambugu, *Why Africa Needs*

This note analyzes *KSR v. Teleflex* and the effects the Court's holding is likely to have on the biotech industry. Part II begins the discussion with a brief overview of biotechnology's current and anticipated impact on human life. Part III addresses the intimate relationship between biotech and patent law, exploring what is needed and why for the field to prosper. Part IV outlines the general principles of the U.S. patent law system and succinctly delineates the progression of the “non-obvious” doctrine from the Supreme Court’s *Graham* framework to the Federal Circuit’s TSM test. In so doing, particular emphasis is deservedly paid to the troubling issue of hindsight bias and to the pervasive consequences it poses to proper patent analysis. Part V provides an introduction to the case, *KSR v. Teleflex*, and discusses its facts, its procedural history, and the Supreme Court’s ruling and rationale. Part VI examines the decision and explores its likely impact on the future of biotechnology in America. Part VII discusses procedural alternatives available to better address hindsight bias and concerns regarding patent over-issuance. Part VIII concludes this note.

## **II. Biotech and Our Needs**

The prevalence of biotechnology, or biotech, in modern society is so extensive that it is difficult to overstate. Indeed, few fields offer the breadth of promise, potential for revolution, and current depth of accomplishments that biotech enjoys. In strictly economic terms, the industry represents one of the most extensive and fastest growing

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*Agricultural Biotech*, NATURE, July 1, 1999, at 15-16 (arguing that agricultural biotechnology is essential to eliminating hunger and poverty in third world countries).

<sup>5</sup> Brief of Biotechnology Industry Organization as Amicus Curiae in Support of Respondents at 9, *KSR Int’l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350) [hereinafter Brief of Biotechnology Industry Organization].

markets in the world.<sup>6</sup> It accounts for over 20 billion dollars of research investment per year, and it provides employment to hundreds of thousands of people worldwide.<sup>7</sup>

Nonetheless, the scientific value biotechnology offers far overshadows its contribution to the world or national economy. It has literally revolutionized agriculture to the point that today over 252 million acres of the world's crops are genetically modified or selectively bred.<sup>8</sup> It has provided larger and improved global harvests through higher yield, nutritionally enhanced, and pest/herbicide resistant crops.<sup>9</sup> It has likewise revolutionized modern medicine, pioneering breakthrough technologies such as bone marrow transplants, viral inoculations, and pharmaceuticals.<sup>10</sup> It has paved the way for production of new therapies that treat an astounding and ever-growing range of medical disorders—including heart disease, AIDS, cancer, diabetes, anemia, and multiple sclerosis.<sup>11</sup>

The field is still very much in its infancy, however, and the true brunt of its weight will surely be felt in the coming decades. As the world population continues to grow and stretch its natural resources, more dependence on genetically modified, pesticide resistant, and nutritionally enhanced food sources will inevitably be invoked.<sup>12</sup>

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<sup>6</sup> See generally Joseph Cortright & Heike Mayer, *Signs of Life: The Growth of Biotechnology Centers in the U.S.*, BROOKINGS INST. CENTER ON URBAN AND METROPOLITAN POLICY (2002) (examining the growth trends of the biotech industry in America); Press Release, Ernst & Young, Global Biotechnology Makes Historic Advances (Apr. 16, 2007), [http://www.ey.com/global/content.nsf/International/Media\\_-\\_Press\\_Release\\_-\\_Beyond\\_Borders\\_2007](http://www.ey.com/global/content.nsf/International/Media_-_Press_Release_-_Beyond_Borders_2007) (discussing the strong and sustained progress of the global biotech industry).

<sup>7</sup> Brief of Biotechnology Industry Organization, *supra* note 5, at 9.

<sup>8</sup> Clive James, *Global Status of Commercialized Biotech/GM Crops: 2006*, ISAAA BRIEFS NO. 35, 2006, at 1.

<sup>9</sup> Brief of Biotechnology Industry Organization, *supra* note 5, at 8.

<sup>10</sup> U.S. Department of State International Information Programs Frequently Asked Questions About Biotechnology, [http://usinfo.state.gov/ei/economic\\_issues/biotechnology/biotech\\_faq.html](http://usinfo.state.gov/ei/economic_issues/biotechnology/biotech_faq.html) (last visited Feb. 9, 2008).

<sup>11</sup> Brief of Biotechnology Industry Organization, *supra* note 5, at 8-9.

<sup>12</sup> See, e.g., Anatole Krattiger, Executive Director, ISAAA, Keynote Address at the ABIC '98 Conference: The Importance of Ag-Biotech to Global Prosperity (June 9-12, 1998), in ISAAA BRIEFS NO. 6, 1998.

Stem cell research could potentially lead to cures to an untold array of ailments, from cancer<sup>13</sup> and diabetes<sup>14</sup> to blindness<sup>15</sup> and paralysis.<sup>16</sup> In addition, developments in bio-fuels, such as ethanol and bio-diesel, could ultimately free us from dependence on inefficient, costly, and environmentally harmful fossil fuels.<sup>17</sup>

### III. Biotech and Intellectual Property Law

While significant advances in biotechnology have already been realized, the road ahead remains arduous, and many milestones must be met before its full potential reaches fruition. Research and development (R&D) in the field is exceptionally high-risk.<sup>18</sup> Millions of dollars and years of research may be exhausted on projects which have only a low probability of success starting out. For example, the investment necessary to drive development of a single therapy can require over \$800 million and 14 years of work.<sup>19</sup> According to the Biotechnology Industry Organization, “[f]or every successful pharmaceutical product, thousands of candidates are designed, screened, and rejected after large investments have been made.”<sup>20</sup> Indeed, only a small minority of drug designs successful enough to advance to human clinical trials are approved by the FDA.<sup>21</sup> The

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Krattiger notes that the next two generations’ food consumption will double that of the entire history of mankind, *id.* at 1, then emphasizes the necessary role of agricultural biotechnology in meeting this extraordinary demand, *id.* at 2-10.

<sup>13</sup> *E.g.*, David Shaffer, *Stem Cells Fight Cancer Tumors in U Research; By Boosting the Body's Natural Killer Cells, the Researchers Hope Eventually to Find New Ways to Treat Cancer Cells*, MINNEAPOLIS STAR TRIB., Oct. 12, 2005, <http://www.stemcellnews.com/articles/stem-cells-fight-cancer.htm>.

<sup>14</sup> *E.g.*, Press Release, Am. Diabetes Ass'n, *Embryonic Stem Cell Research Offers Most Promise for Americans With Diabetes* (July 17, 2006) (on file with author).

<sup>15</sup> *E.g.*, Duncan Graham-Rowe, *Fetal Tissue Restores Lost Sight*, NEW SCIENTIST, Oct. 30, 2004, <http://www.medicalnewstoday.com/articles/15535.php>.

<sup>16</sup> *E.g.*, Roger Highfield, *Umbilical Cord Cells 'Allow Paralyzed Woman to Walk'*, DAILY TELEGRAPH, Nov. 11, 2004, <http://www.telegraph.co.uk/news/main.jhtml?xml=/news/2004/11/30/wcells30.xml>.

<sup>17</sup> Brief of Biotechnology Industry Organization, *supra* note 5, at 2 (“Research into plant-based fuels provides hope that the United States can lessen its dependence upon fossil fuels by making fuel alternatives, like ethanol and bio-diesel, more affordable.”).

<sup>18</sup> *Id.* at 9.

<sup>19</sup> *Id.*

<sup>20</sup> *Id.* at 10.

<sup>21</sup> *Id.*

chances, in fact, of a biopharmaceutical product achieving FDA approval are approximately one in 5,000.<sup>22</sup>

Complicating this is the fact that although some of the research and development in biotech is publicly funded, the overwhelming majority draws from private sources. Indeed, as much as ninety-eight percent of R&D investment stems from the private sector.<sup>23</sup> The high-risk nature of the industry therefore serves as a powerful deterrent to adequate funding, as the low likelihood of success is daunting to investors.<sup>24</sup> Nevertheless, when success is realized, the return can be staggering, providing the motivation necessary to keep investment in such endeavors alluring to private sponsors.<sup>25</sup> But for this to take effect, some guarantee must exist that, in the event such success is realized, the investors' interests in the resulting technology will be protected.<sup>26</sup>

The industry, therefore, relies heavily on stable, dependable protection from intellectual property laws to secure the fruits of its labor.<sup>27</sup> Without such reliable protection, potential investors would be without reasonable assurance that even successful ventures would result in an adequate return on investment. Tremendous resources could be devoted to the development of a technology that, once complete and marketable, is copied by a competitor and sold more cheaply because of that competitor's absence of R&D overhead expenses. The developing company, in debt as a result of the R&D costs and unable to compete with the prices of the infringing company, would go bankrupt. This could destroy any incentive for the private sector to invest, and

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<sup>22</sup> *Id.*

<sup>23</sup> *Id.* at 9.

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

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

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

<sup>27</sup> *Id.* (stating that investment "is predicated on an expected return . . . in the form of products or services that are protected by patents whose validity can be fairly determined").

biotechnology as a whole, which hinges so closely on private funding, could suffer immensely.

#### IV. Overview of Patent Law and Non-Obviousness

##### A. Patent Requirements

Because of the intimate relationship between biotechnology and legal protection, a basic grasp of patent law principles is in order. Essentially three requirements must be met for a discovery or invention to be considered patentable. These requirements, codified in Title 35 of the United States Code, include that the claim be new, that it be useful, and that it be non-obvious.<sup>28</sup> The most historically ambiguous of these three is the latter,<sup>29</sup> which will be the focus of this note. Broadly speaking, it insists that the claim seeking patent protection not be obvious to a “person having ordinary skill in the art,”<sup>30</sup> but the application of this standard has proven elusive over the years<sup>31</sup>—a fact perhaps unsurprising considering that neither the Patent Act, the Federal Circuit, nor the Supreme Court have defined the term “obvious.”<sup>32</sup> In addition to being the most ambiguous of the requirements, or conceivably because of this, non-obviousness is also the most significant and heavily relied-upon in the realm of patent litigation.<sup>33</sup> It is more commonly litigated than any other patent validity issue, and it is more likely than any other to result in the invalidation of a patent.<sup>34</sup>

##### B. *Graham’s* Clarification of Non-Obviousness

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<sup>28</sup> 35 U.S.C. §§ 101, 103 (2006).

<sup>29</sup> Cottrell, *supra* note 2, at 596.

<sup>30</sup> 35 U.S.C. § 103(a).

<sup>31</sup> JOHN KNIGHT, MOTIVATION FOR THE FEDERAL CIRCUIT TEST 5 (2006), <http://digital-law-online.info/papers/jk/tsm.pdf>.

<sup>32</sup> Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. 1391, 1399 (2006).

<sup>33</sup> *Id.* at 1398.

<sup>34</sup> *Id.*

In 1966, the Supreme Court attempted to clarify the meaning of “non-obvious,” outlining the relevant factors for a court to consider when determining the obviousness of a claim.<sup>35</sup> Those factors, referred to as the “*Graham* factors,” include: (1) the scope and content of the prior art, (2) the level of ordinary skill in the prior art, (3) the differences between the claimed invention and the prior art, and (4) the objective evidence of non-obviousness.<sup>36</sup> For this fourth factor, the court delineated examples of factors that could be used to demonstrate such objective evidence of non-obviousness, including (a) commercial success, (b) long-felt, but unresolved needs, and (c) the failure of others.<sup>37</sup>

### **C. The TSM Test and Hindsight Bias**

When the Court decided *Graham*, it recognized its approach would need further development at the lower court level, and, for over two decades, the Federal Circuit has developed such an approach.<sup>38</sup> Popularly known as the TSM test, it requires as part of the analysis that to hold invalid a combination patent—an invention that takes known and existing pieces of the prior art but combines them in a novel way—there must be some “teaching, suggestion or motivation to combine the pieces of art to arrive at the claimed invention as a whole.”<sup>39</sup> This teaching-suggestion-motivation, or TSM, analysis “informs the *Graham* analysis.”<sup>40</sup> According to the Federal Circuit, the teaching, suggestion, or motivation necessary need not be explicitly listed in the references, but may be “implicit from the prior art as a whole.”<sup>41</sup>

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<sup>35</sup> *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966).

<sup>36</sup> *Id.* at 17.

<sup>37</sup> *Id.* at 17-18.

<sup>38</sup> Brief of Biotechnology Industry Organization, *supra* note 5, at 15.

<sup>39</sup> *Id.* at 16.

<sup>40</sup> *In re Kahn*, 441 F.3d 977, 987 (Fed. Cir. 2006).

<sup>41</sup> *Id.* (quoting *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2002)).



The development and increased reliance on the TSM test over the years emerged largely to better account for what is known as hindsight bias—the tendency to regard past events as more predictable than they actually were before they occurred.<sup>42</sup> To put the principle in terms more readily applicable to patent law, it is the inclination to consider obvious, in hindsight, past combinations of then-existing parts in the creation of a new invention.<sup>43</sup> If this propensity is not adequately addressed, truly innovative and non-obvious advances may nonetheless be denied patent protection on grounds of obviousness.<sup>44</sup> Such susceptibility threatens not only the integrity of the intellectual property framework, it threatens—as discussed above—the progress of applied sciences, like biotechnology, which require consistent, dependable, and objective legal protection in order to facilitate adequate funding and encourage the free-flow of information.

The situation is complicated by the fact that hindsight bias is actually afforded *two* opportunities to influence the obviousness analysis. The first, more traditionally recognized of the two, involves the determination of whether or not the claimed invention was obvious at its conception.<sup>45</sup> Such a determination would ideally be free of the consideration that the invention was actually, in fact, successfully produced.<sup>46</sup> This requires, in essence, the decision-maker to mentally time-travel back to a period before the invention was known.<sup>47</sup> But people are not cognitively capable of ignoring what they know, so this is—in a pure sense—simply unachievable.<sup>48</sup> Studies exposing this inability illustrate the practical impossibility of effectively making a proper retrospective

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<sup>42</sup> KNIGHT, *supra* note 31, at 3.

<sup>43</sup> *Id.* at 12.

<sup>44</sup> *Id.* at 13.

<sup>45</sup> Mandel, *supra* note 32, at 1405.

<sup>46</sup> *Id.* at 1393.

<sup>47</sup> *Id.* at 1399.

<sup>48</sup> *Id.* at 1400.

evaluation of obviousness,<sup>49</sup> and the predisposition has unfortunately proven strikingly resistant to various techniques aimed at curtailing its effect.<sup>50</sup> Even when explicitly warned about hindsight bias or instructed to assume the position of a person unaware of the known outcome, individuals nonetheless unconsciously allow their awareness of that outcome to permeate their evaluation and bias their conclusions as to the obviousness or predictability of the outcome in the first instance.<sup>51</sup>

The second opportunity for hindsight bias to impact the obviousness analysis is in the determination of the past level of ordinary skill in the art.<sup>52</sup> Because the obviousness of an invention is considered in light of what a “person having ordinary skill in the art” (PHOSITA) would have known at the time,<sup>53</sup> it is again the obligation of the decision-maker to retreat in time to back before the invention was produced and evaluate the skill level present in the trade. But because the skill level of a given trade necessarily expands with time, hindsight bias can lead the decision-maker to regard the historic skill level of the trade as more sophisticated than it was in truth.<sup>54</sup> As a result, genuinely non-obvious inventions and insights hailing from that era’s misattributed skill level may improperly be considered obvious.<sup>55</sup>

The threat is most pronounced in relation to the so-called combination patents—those inventions that combine existing pieces of the prior art in novel ways. Because all the elements of such an invention are previously known, virtually every combination may seem obvious after the fact. This dilemma is especially poignant today considering that

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<sup>49</sup> *Id.* at 1393.

<sup>50</sup> *Id.* at 1403.

<sup>51</sup> *Id.* at 1393.

<sup>52</sup> *Id.* at 1405.

<sup>53</sup> 35 U.S.C. § 103(a) (2006).

<sup>54</sup> Mandel, *supra* note 32, at 1405.

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

most of, if not all, claimed inventions “almost of necessity [are] combinations of what, in some sense, is already known.”<sup>56</sup>

The courts have long since acknowledged the potentially devastating impact unchecked hindsight bias could have on the accurate evaluation of patents. The Supreme Court, in fact, identified the issue as early as 1881 in *Loom v. Higgins*.<sup>57</sup> But because hindsight bias appears to be an inevitable condition of the human cognitive process,<sup>58</sup> and because the nature of patent evaluation necessarily involves some level of subjective assessment, the only practical goal is to minimize, rather than entirely eradicate, the impact of the bias. An analytical framework with built-in objective criteria, as opposed to one more heavily weighted with subjective measures, would logically provide the best safeguard. By requiring either an explicit or an implicit teaching, suggestion, or motivation to combine elements of the prior art in order to invalidate a patent, therefore, the Federal Circuit’s TSM test, although not perfect, provided a layer of insulation to the *Graham* framework to guard against hindsight bias.

## V. *KSR*: The Facts, History, and Arguments

### A. The Background

The TSM test has encountered its share of opposition over the years—both from those who feel it is too rigid,<sup>59</sup> as well as from those who feel it is too lax.<sup>60</sup>

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<sup>56</sup> *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

<sup>57</sup> *Loom Co. v. Higgins*, 105 U.S. 580, 591 (1881) (“Now that [the invention] has succeeded, it may seem very plain to any one that he could have done it as well. This is often the case with inventions of the greatest merit.”).

<sup>58</sup> Mandel, *supra* note 32, at 1400.

<sup>59</sup> See Cottrell, *supra* note 2, at 604 (discussing the “inherent problems” of the TSM test and stating that the broadest concern is its inflexibility); Brief for the United States as Amicus Curiae Supporting Petitioner at 21, *KSR Int’l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350) (arguing how the test has led to problems of patent over-issuance).

<sup>60</sup> See Mandel, *supra* note 32, at 1414-18 (demonstrating how hindsight bias affects the decisions of juries, judges, and patent examiners).

Nevertheless, for over two decades, the Federal Circuit's approach served in tandem with the *Graham* analysis to form the standard of determining the obviousness or non-obviousness of a patent claim.<sup>61</sup>

In late spring of 2007, however, the Supreme Court struck down a Federal Circuit decision in *KSR v. Teleflex*, criticizing the appellate court's application of the TSM test as too stringent and inflexible.<sup>62</sup> Although stopping shy of explicitly discarding the test altogether, the Court made it abundantly clear it was no longer to be afforded anywhere near the degree of consequence it had accumulated over the years.<sup>63</sup>

*KSR* involved two competing manufacturers of automobile components. A brief mechanical background is necessary to fully appreciate the dispute, as the case hinged upon what was reasonably obvious, based on the prior art, to a person having ordinary skill in the art.

The 1990's brought many innovations to the world of automobile manufacturing, one of the most pronounced and far-reaching being an increased dependence on electronic signals to perform the duties traditionally carried out by physical mechanics.<sup>64</sup> From locks and windows to combustion and diagnostics, virtually every facet of the automobile transformed from mechanically-driven to computer-driven. Gas and brake pedals were no exception, and it became increasingly popular to replace the mechanical pivot on the pedals with electronic sensors that detected and communicated the pedals' position to the throttle.

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<sup>61</sup> KNIGHT, *supra* note 31, at 12.

<sup>62</sup> *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741-43 (2007).

<sup>63</sup> *Id.*

<sup>64</sup> *Id.* at 1735.

A situation that commonly arises involves drivers wishing to alter the position of the pedal in the footwell to account for differences in his or her height. For older automobile models, adjustable pedals were invented, patented, and made available.<sup>65</sup> The Asano patent encompasses one such invention. It discloses an adjustable pedal with a fixed pivot point, which allows the pedal's position to be adjusted in the footwell without changing the amount of force needed to depress the pedal.<sup>66</sup> The Redding patent also depicts an adjustable pedal, but with a different operating mechanism by which both the pedal and the pivot point are altered.<sup>67</sup>

As technology in the auto industry evolved towards electronic signaling, a number of patents emerged to amend the mechanical pedal constructs to the new computer-based model.<sup>68</sup> Designers began placing electronic sensors on the adjustable pedal kits, but questions surfaced regarding the sensors' ideal location on the assemblies to best account for wire-chafing and similar common limitations.<sup>69</sup> The Rixon patent, for instance, involves an adjustable pedal with an electronic sensor located in the pedal footpad, but it is prone to wire-chafing.<sup>70</sup> The Smith patent—issued five years prior to Rixon—recommends attaching the sensor to a fixed part of the assembly, rather than on the footpad, in order to sidestep this problem.<sup>71</sup> Though sensors were originally affixed to the pedal assembly, self-modulated ones were eventually developed. These sensors could

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<sup>65</sup> *Id.*

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

<sup>67</sup> *Id.*

<sup>68</sup> *Id.* at 1735-36.

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* at 1736.

<sup>71</sup> *Id.* at 1735-36.

be sold individually and joined with any mechanical pedal, making it compatible with a computer-driven throttle.<sup>72</sup>

## **B. The Parties**

In 2000, General Motors Corporation hired KSR, an auto part manufacturer and supplier, to supply adjustable pedal systems for its line of light trucks.<sup>73</sup> The trucks had engines with computer-controlled throttles.<sup>74</sup> KSR had previously designed and obtained a patent for an adjustable mechanical pedal, but the device was not equipped to function with a computer-controlled throttle.<sup>75</sup> So KSR took its design and added a modular sensor.<sup>76</sup>

Teleflex brought a patent infringement suit against KSR, claiming that this sensor-equipped KSR pedal violated Teleflex's so-called Engelgau patent, which essentially described how to attach such a sensor to such a pedal.<sup>77</sup> More specifically, the Engelgau patent disclosed a simpler, less expensive pedal that combined the principles taught by the Smith, Redding, and Asano patents.<sup>78</sup> KSR mounted a defense alleging Teleflex's patent invalid as obvious.<sup>79</sup> The district court granted summary judgment in favor of KSR, applying the framework from *Graham* and the TSM test to determine that the claim in question was indeed obvious in light of the prior art.<sup>80</sup>

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<sup>72</sup> *Id.* at 1736.

<sup>73</sup> *Id.*

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

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

<sup>76</sup> *Id.*

<sup>77</sup> *Id.* at 1737.

<sup>78</sup> *Id.* at 1738.

<sup>79</sup> *Id.* at 1737.

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

The Court of Appeals for the Federal Circuit reversed, relying primarily on the TSM test and holding that the lower court failed to apply the test stringently enough.<sup>81</sup> The trial court failed, according to the Court of Appeals, to make findings “as to the specific understanding or principle” that would have motivated a PHOSITA with no knowledge of the invention to attach to the Asano assembly an electronic sensor.<sup>82</sup> The Asano pedal was designed to address one dilemma, whereas the Engelgau claim sought to address another—how to make “a simpler, smaller, cheaper adjustable electronic pedal.”<sup>83</sup> Similarly, the Federal Circuit interpreted the other relevant prior art disclosures as not offering to a PHOSITA the requisite teaching, suggestion, or motivation to combine a sensor on the type of pedal depicted in Asano.<sup>84</sup> Rixon did not offer any helpful instruction to Engelgau, according to the Court of Appeals, and Smith did not necessarily provide motivation to attach the sensor as Engelgau did.<sup>85</sup> The nature of the problem Engelgau sought to remedy, in other words, would not in-and-of itself motivate or instruct an inventor to look to these specific instances of the prior art in achieving a solution.<sup>86</sup> The Court of Appeals reasoned that the Engelgau patent combined various elements of existing designs in an inventive way that was non-obvious to a skilled artisan at the time. Because there was no explicit or implicit references in the prior art teaching, suggesting, or motivating a PHOSITA to combine these elements in this manner, the Court of Appeals decided the district court had too leniently applied the TSM test.<sup>87</sup>

### **C. The Decision**

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<sup>81</sup> *Id.* at 1738.

<sup>82</sup> *Id.* (quoting lower court).

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

<sup>84</sup> *Id.* at 1738-39.

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> *Id.* at 1739.

The Supreme Court granted certiorari and, in November 2006, heard oral arguments.<sup>88</sup> The case generated substantial attention from various spheres, as many immediately recognized the potential consequences of the pending decision.<sup>89</sup> Both sides were well represented. Groups such as the Biotechnology Industry Organization, the American Intellectual Property Law Association, the American Bar Association, and the Business Software Alliance submitted Amicus Briefs.<sup>90</sup>

On April 30, 2007, the Supreme Court announced its unanimous decision, reversing the Federal Circuit and affirming the District Court's grant of summary judgment in KSR's favor.<sup>91</sup> Justice Kennedy, writing for the Court, rejected the Federal Circuit's "rigid approach" embodied in the TSM test, "in part because it depends on scientific literature and other forms of evidence that may not keep pace with fast-developing technologies."<sup>92</sup> The Court listed several specific errors and what it called "fundamental misunderstandings" in how the Federal Circuit analyzed the case.<sup>93</sup> In considering the Teleflex patent, for instance, the Court accused the appeals court of considering what a "pedal designer writing on a blank slate" would have done to solve

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<sup>88</sup> *Id.* at 1727.

<sup>89</sup> *See, e.g.*, S. Jafar Ali, *You Suggest What? How KSR Returned the Bite To Nonobviousness*, 16 FED. CIR. B.J. 247, 271 (2006) ("[KSR] presents an invaluable opportunity for the Court to clarify and restore uniformity to the law of nonobviousness."); Cottrell, *supra* note 2, at 626 (noting that "both sides of KSR believe the outcome of the case will cause a sea of change in the patent system").

<sup>90</sup> Brief of Biotechnology Industry Organization, *supra* note 5; Brief of American Intellectual Property Law Ass'n as Amicus Curiae in Support of Respondents, *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350); Brief of American Bar Ass'n as Amicus Curiae in Support of Respondents, *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350); Brief of Business Software Alliance as Amicus Curiae in Support of Petitioner, *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350).

<sup>91</sup> *KSR*, 127 S. Ct. at 1727.

<sup>92</sup> Tony Mauro, *Supreme Court Adopts New Standard on Patent Litigation*, LEGAL TIMES, May 1, 2007, <http://www.law.com/jsp/article.jsp?id=1177936770561>.

<sup>93</sup> *KSR*, 127 S. Ct. at 1739-44.



the problem Engelgau addressed.<sup>94</sup> This was an error, the Court suggested, as the slate was not blank.<sup>95</sup> Teleflex, instead, was simply upgrading the existing technology.<sup>96</sup>

The problem, according to the Court, was not the TSM test itself, or even the Federal Circuit's overall approach. Rather, it was the rigid manner in which the Federal Circuit applied the test.<sup>97</sup> Kennedy said the Federal Circuit's strict application of the TSM test led to a "constricted analysis" that gave too much deference to the inventor's motivation and too little deference to whether there "existed at the time of the invention a known problem for which there was an obvious solution."<sup>98</sup> According to the Court, the Engelgau patent fell under this banner.<sup>99</sup>

The Court warned that progress would be hindered and prior inventions could lose their value if patent protection was extended to developments that would occur in the "ordinary course without real innovation."<sup>100</sup> Instances of such "ordinary innovation" are not, and should not be, afforded exclusive rights under intellectual property laws.<sup>101</sup> "Were it otherwise," the Court cautioned, "patents might stifle, rather than promote, the progress of useful arts."<sup>102</sup> The Court's unanimous ruling was cordial, however, referring

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<sup>94</sup> *Id.* at 1744.

<sup>95</sup> *Id.*

<sup>96</sup> *Id.* at 1745. The Court suggested the Teleflex patent merely represented an upgrade of the Asano patent, stating that "[i]f Rixon's base pedal was not too flawed to upgrade, then Dr. Radcliffe's declaration does not show Asano was either." *Id.*

<sup>97</sup> *Id.* at 1741 ("There is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis. But when a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs.").

<sup>98</sup> *Id.* at 1742.

<sup>99</sup> *Id.* at 1746.

<sup>100</sup> *Id.* at 1741.

<sup>101</sup> *Id.* at 1746.

<sup>102</sup> *Id.*

to the TSM test as a “helpful insight” and noting that it should still play a role in a broader test for obviousness.<sup>103</sup>

## VI. What *KSR* Means for Biotechnology

Without question, the *KSR* decision is a major development in patent law. Indeed, the Washington Post hailed the decision as the Court’s furthest reaching ruling in the patent field for decades<sup>104</sup>—a strong sentiment echoed by many others in the days and months following the verdict.<sup>105</sup>

The “non-obvious” requirement, as previously mentioned, is easily both the most frequently litigated of issues relating to patent validity,<sup>106</sup> as well as the most historically ambiguous and ill-defined.<sup>107</sup> Rather than bestowing to the patent world some much-needed direction or sense of clarity in the matter, the Court’s decision in *KSR* does little but add to the already superfluous, muddled uncertainty that the test it chastised sought to improve. It essentially takes the thrust out of the TSM approach, reducing it to a shell of a test and giving it about as much muscle and authority as a non-binding regulation.

Worse, however, is that the Court, in criticizing but not discarding the Federal Circuit’s approach, offers in its place no substitute—no workable proxy or cohesive guiding light

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<sup>103</sup> *Id.* at 1741. The Court remarked that, in first establishing the TSM test, “the Court of Customs and Patent Appeals captured a helpful insight.” *Id.* The Court later added, “[h]elpful insights, however, need not become rigid and mandatory formulas.” *Id.*

<sup>104</sup> Robert Barnes & Alan Sipress, *Rulings Weaken Patents’ Power, High Court Decides on Two Key Cases*, WASH. POST, May 1, 2007, at D01.

<sup>105</sup> See, e.g., John F. Duffy, *KSR v. Teleflex: Predictable Reform of Patent Substance and Procedure in the Judiciary*, 106 MICH. L. REV. FIRST IMPRESSIONS 34, 34 (2007), <http://www.michiganlawreview.org/firstimpressions/vol106/duffy.pdf> (claiming the decision in *KSR* is “widely acknowledged in the bar and the academy to be the most significant patent case” in at least the last twenty-five years); Wegner, *supra* note 1, at 39 (“For long-range importance in patent law, *KSR* stands alone as the single most important Supreme Court patent decision on the bread and butter standard of ‘obviousness’ in the more than forty years since the 1966 *Graham v. John Deere.*”); Linda Greenhouse, *High Court Puts Limits on Patents*, N.Y. TIMES, May 1, 2007, <http://www.nytimes.com/2007/05/01/business/01bizcourt.html> (hailing the *KSR* decision as the Court’s “most important patent ruling in years”).

<sup>106</sup> Mandel, *supra* note 32, at 1398.

<sup>107</sup> Cottrell, *supra* note 2, at 596.

to inform the *Graham* analysis. Supporters of the ruling will no doubt contend that the Court voiced a problem, not with the TSM test itself, but rather with the Federal Circuit's rigid application of it. But this argument misses the point altogether—ambiguity, not rigidity, is the dilemma with respect to non-obviousness. The two approaches competing in *KSR* were flexibility and predictability, and the Court sided with flexibility.<sup>108</sup> Flexibility means subjectivity, which means more ambiguity, which means science and law will recede rather than progress in this regard.<sup>109</sup>

As a result, *KSR*'s outcome is likely to be broadly felt.<sup>110</sup> The impact will surface in two major ways: first, new patents will be more difficult to obtain; second, those that are obtained, as well as those already in existence, will be more prone to invalidation on grounds of obviousness. These added burdens, discussed below, will threaten the reputation and value of patent laws in the United States, make adequate funding for research and development substantially more difficult to procure, and, thus, render a crippling blow to the pace and welfare of scientific progress—the very advancements U.S. patent laws were intended to protect.<sup>111</sup>

#### **A. Effect on Future Patent Claims**

The TSM test developed to better account for hindsight bias, which, it was recognized, could label genuinely non-obvious inventions as obvious, thus unjustly barring them from patent protection. The quandary posed by this to fields such as

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<sup>108</sup> Barnes & Sipress, *supra* note 104.

<sup>109</sup> Brief of Biotechnology Industry Organization, *supra* note 5, at 1-3 (emphasizing the reliance of science on objective standards in patent laws and asserting that “[i]f those standards were to become less objective . . . increased uncertainty about the availability of patent rights would deter investment within the . . . industry”).

<sup>110</sup> See, e.g., Barnes & Sipress, *supra* note 104, at D01 (stating the *KSR* decision could “change the rules of the game from the way they’ve been for the last 20 years or so”).

<sup>111</sup> See U.S. CONST. art. I, § 8, cl. 8 (granting to Congress the power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”).

biotechnology is troubling and urgent, as it effectively undermines the purpose of the patent system by rendering its outcomes erratic and unpredictable. The TSM test, however, by requiring that a reference in the prior art provide some teaching, suggestion, or motivation to combine elements known in the art in order to establish the obviousness of a combination invention, afforded the patent system improved, though still imperfect, shelter from hindsight bias. *KSR* threatens this fabric, as it takes the wind out of the TSM sail and, in essence, opens the floodgates to subjectivity and hindsight with little but a fleeting warning that the courts be wary of their risk.<sup>112</sup>

As a result, judges and patent examiners will have much more discretion, and much less accountability, when weighing the obviousness of a patent claim. Psychology demonstrates the human inability to evade hindsight bias, even when explicitly reminded of its presence,<sup>113</sup> so without a built-in mechanism to neutralize its influence, it will undoubtedly play a larger roll in the patenting process. Many truly non-obvious claims will therefore be denied protection on grounds of hindsight-based “non-obviousness”—a situation the TSM test was far better equipped to forestall. Ultimately this means exactly what it appears to mean: it will be much harder to obtain patent protection, especially for combination patents.

Although a number of biotechnology patent experts initially predicted a gloomy forecast for *KSR*'s impact on biotech patents, others seemed unconcerned, as discoveries and inventions in the biotech domain tend to be extensively more complex than adding a

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<sup>112</sup> *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007) (“A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.”).

<sup>113</sup> Mandel, *supra* note 32, at 1403.

sensor to a car pedal.<sup>114</sup> This complexity, it was thought, would effectively shield much of the industry from the *KSR* decision.<sup>115</sup> But just a month after the Court announced its decision, the USPTO's Board of Patent Appeals and Interferences, relying on *KSR*, delivered a blow to this theory.<sup>116</sup> Reviewing a patent examiner's rejection of claims involving nucleic acid molecules, the Board upheld the rejection as obvious because the claims combined three references (a patent, a textbook, and a scientific report) and because, the Board decided, a PHOSITA would have (a) realized the use of isolating NAIL cDNA and (b) been motivated to utilize traditional techniques to do so.<sup>117</sup> The opinion seemingly discards the Federal Circuit's 1995 decision, *In re Deuel*, in which the appeals court held, "'Obvious to try' has long been held not to constitute obviousness."<sup>118</sup> Indeed, the Board pronounced, "Under *KSR*, it's now apparent 'obvious to try' may be an appropriate test in more situations than we previously contemplated."<sup>119</sup>

Practically, for biotechnology, all this translates into far greater risk for investors. Before *KSR*, the gamble involved in funding research and development was daunting enough—a lot of money was necessary and the odds of the science working out were poor. Now, after *KSR*, even if the science does work out and a successful, inventive product is developed, there is no longer assurance from the patent law that the product will be protected from pilfering competitors. Investors will be discouraged from investing in biotechnology, and without adequate funds, important advances in the field will be either delayed altogether or achieved overseas.

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<sup>114</sup> Phill Jones, *Cultivar Cultivates Disaster for Soybean Patent While Supremes Throttle Patent Test*, ISB NEWS REPORT, Sept. 2007, at 9.

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

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

<sup>117</sup> *Id.* at 10.

<sup>118</sup> *Id.* at 8-9.

<sup>119</sup> *Id.* at 10.

The detriment of this will fall disproportionately on smaller biotech firms, since these entities—as well as universities conducting research—do not possess the tremendous resources necessary to actually manufacture the biotech products, run sufficient clinical trials on them, and sell them on the market.<sup>120</sup> Only large biotech companies, then, will have the wherewithal to develop and produce such products.<sup>121</sup>

Even when financing issues are not present, however, *KSR* may still have widely felt implications. Because of the diminished predictability of the patenting analysis, companies that can afford to do so may forego the crapshoot altogether. It is important to keep in mind that patent laws benefit not more than merely the inventors themselves—they also benefit the scientific community as a whole by promoting the disclosure of discoveries and advances that may otherwise be kept secret. With flexible, but unpredictable patenting procedures in place, many companies may grow introverted, keeping the recipes to their achievements under wraps. Science will suffer as a result, as will the public interest.

## **B. Effect on Present Patents**

The Court's decision in *KSR*, adopting a more flexible standard, will likely weaken patent protection on another front as well. Not only will it be more difficult to get a patent issued, it will be more difficult to withstand obviousness challenges to existing patents. The new standard endorsed by the Court is likely to “weaken the protection given to patent holders, making it . . . easier to challenge existing” patents on grounds of obviousness.<sup>122</sup> Said differently, because the Court's decision applies to

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<sup>120</sup> Teodor Danielyan, *Obviousness and Biotechnology*, SCP J., Nov. 29, 2006.

<sup>121</sup> *Id.*

<sup>122</sup> Barnes & Sipress, *supra* note 104.

patent validity challenges concerning patents issued both before and after *KSR*, it may “subject existing patent-holders to fresh litigation over obviousness.”<sup>123</sup>

Specifically, it raises the standard “for obtaining patents on new products that combine elements of pre-existing inventions.”<sup>124</sup> As most inventions are merely new combinations of previously known parts, the approach endorsed by the Court in *KSR* for determining what combinations are too obvious for patent protection will have extensive application.<sup>125</sup> The result will be to make patents not only harder to obtain, but to defend. As one IP attorney in Pittsburgh explained, “Nearly every patent that contains a combination of prior ideas is at risk because the court has dramatically broadened the standard of obviousness.”<sup>126</sup> Michael Kreeger, one of the lawyers who prepared the Biotechnology Industry Organization's amicus brief in support of Teleflex, resonated this concern and warned that thousands of cases may emerge requesting the Patent Office to re-examine already-issued patents. “It doesn’t take a lot of resources to ask for a re-examination,” he mentioned.<sup>127</sup> He also pointed out that judges will now have more freedom to dismiss patent infringement suits without requiring a jury trial, and that patent examiners, who generally grant patent applications unless they find prior references to the same invention, will now have more leeway to deny claims.<sup>128</sup>

Monsanto Company, a multinational leader of agricultural biotechnology, encountered this reality only three months after *KSR* was handed down.<sup>129</sup> Upon petition by a nonprofit legal services group to reexamine four Monsanto patents involving

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<sup>123</sup> Mauro, *supra* note 92.

<sup>124</sup> Greenhouse, *supra* note 105.

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

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

<sup>128</sup> *Id.*

<sup>129</sup> Bette Hileman, *U.S. Patent Office Rejects Four Patents on Monsanto Crops*, CHEM. & ENG'G NEWS, July 30, 2007, at 15.

genetically modified crops, the U.S. Patent & Trademark Office (USPTO) rejected the patents on the grounds that the claims were not "non-obvious."<sup>130</sup> Monsanto believes no legitimate grounds for rejecting the patents exist, and it has already filed responses to three of the four rejections.<sup>131</sup> This mega-company, thanks to its size and control of the market share, can afford to fight back—a luxury not likely available to more modestly situated businesses which simply lack the resources required to win such a war of attrition.

Not all interested parties share these concerns, however. The Business Software Alliance, for instance, applauded the Court's decision. A spokesperson for the organization commented, "The ruling in the *KSR* case will improve patent quality by enabling examiners and the courts to deny patents to questionable applications."<sup>132</sup> But opponents disagree with this line of reasoning and fear the decision puts too much power in the subjective hands of individuals prone to hindsight bias. "This leaves patent litigation in a state of total disarray," according to *Legal Times*. "Judges are now permitted to use their own common sense rather than objective evidence or testimony."<sup>133</sup>

The vast freedom now afforded patent examiners to reject applications on obviousness grounds could raise not only the costs involved in litigation, but the costs of obtaining a patent in the first place as well.<sup>134</sup> According to John R. Thomas, a Georgetown University law professor, "The bottom-line effect is that interested parties have a greater ability to challenge patents and a greater possibility of prevailing."<sup>135</sup> This

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

<sup>131</sup> *Id.*

<sup>132</sup> Mauro, *supra* note 92.

<sup>133</sup> *Id.*

<sup>134</sup> *Id.*

<sup>135</sup> Barnes & Sipress, *supra* note 104.



makes existing patents, issued according to a standard the Supreme Court has now rejected, much more vulnerable to legal challenges.<sup>136</sup> In particular, Thomas predicts that generic drug makers will increase their number of lawsuits against pharmaceutical companies.<sup>137</sup>

## VII. Limitations and Resolutions

Apart from those criticizing the holding in *KSR* and those praising it, some commentators appear to more-or-less sympathize with the Court. *KSR* represented an opportunity to redress the issue of patent over-issuance, as well as that of hindsight bias, and the Court arguably failed in both regards.<sup>138</sup> Courts in general, however, may simply not be equipped to resolve such issues.<sup>139</sup> Reform, instead, may need to emerge from the ranks of Congress or the Patent and Trademark Office (PTO).<sup>140</sup> Congress, as opposed to the courts, has the necessary resources with which to balance these two troubles—hindsight and over-issuance—and the PTO has the expertise.<sup>141</sup>

A number of suggestions exist as to how such reform could take shape. One proposal calls for the PTO to conduct post-grant reviews, with reviewers selected based upon their personal expertise in the particular matter at issue.<sup>142</sup> Under this system, the obviousness determination of a claimed invention would be made separately by an

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<sup>136</sup> *Id.*

<sup>137</sup> *Id.*

<sup>138</sup> *See, e.g., The Supreme Court, 2006 Term—Leading Cases*, 121 HARV. L. REV. 375, 385 (2007) (stating that the Court, in *KSR*, "merely offered a solution unlikely to combat hindsight bias and unlikely to reduce patent overissuance problems in any systematic way").

<sup>139</sup> *Id.* at 376.

<sup>140</sup> *Id.* at 385 ("Real change addressing hindsight bias and overissuance problems in tandem will have to come from the efforts of Congress and the PTO, with the courts playing an oversight role only in extreme circumstances.").

<sup>141</sup> *Id.* at 382 ("Congress has more tools with which to craft a solution, including its delegation of authority to the PTO, an institution with expertise in the field.").

<sup>142</sup> *Id.* at 383.

experienced patent examiner and a panel of experts.<sup>143</sup> Such a structure could simultaneously confront over-issuance and hindsight bias.<sup>144</sup>

Another proposed format involves allowing third parties to submit their own evidence of prior art to the patent examiner.<sup>145</sup> Because patent applicants are not currently required by law to conduct and submit prior art searches, permitting interested third parties to do so would better insure the patent examiner has all the pertinent data on hand.<sup>146</sup> This adversarial process would add a coat of protection to address over-issuance concerns.<sup>147</sup>

A third option is to employ a bifurcated system of two patent examiners.<sup>148</sup> One examiner would conduct the traditional patent analysis, but without making an obviousness determination.<sup>149</sup> The second examiner, informed only of the problem to be solved and the level of ordinary skill in the art—but *not* informed of the actual claimed invention—would perform the obviousness analysis.<sup>150</sup> By separating out the obviousness finding from the rest of the patent examination procedure, hindsight bias may finally be adequately checked.<sup>151</sup> Combining this system with an adversarial process similar to the one discussed above would allow for a substantially enhanced defense mechanism against both hindsight bias and over-issuance.<sup>152</sup>

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

<sup>144</sup> *Id.* (stating that such a system could "serve not only to alleviate concerns about overissuance, but also to combat hindsight bias").

<sup>145</sup> *Id.* at 383-84.

<sup>146</sup> *Id.*

<sup>147</sup> *Id.* at 384 ("The test also could reduce overissuance, as it would cut into the pro-applicant stance typically attributed to the PTO.").

<sup>148</sup> *Id.* at 384-85; see also Gregory Mandel, *Patently Non-Obvious II: Experimental Study on the Hindsight Issue Before the Supreme Court in KSR v. Teleflex*, 9 *YALE J.L. & TECH.* 1, 35-39 (2007).

<sup>149</sup> *The Supreme Court, 2006 Term—Leading Cases*, *supra* note 138, at 384.

<sup>150</sup> *Id.* at 384-85.

<sup>151</sup> *Id.* at 385 ("[T]he bifurcated system would prevent hindsight bias on the part of the patent examiner.").

<sup>152</sup> *Id.*

These suggestions, of course, do not represent an exhaustive survey of possible remedies to the obviousness impasse. What they do demonstrate, however, is that conceivable solutions do exist and can be posited if ingenuity and innovation are put to proper use in the tackling of this persistent and plaguing problem. But whatever resolutions may arise in the future at the PTO level, their formal origins have seemingly yet to take root, as the PTO's post-*KSR* examination guidelines for determining obviousness, published in October 2007, essentially go no further than codifying the holding of that case.<sup>153</sup>

### VIII. Conclusion

Though the full impact of *KSR* on the biotechnology industry is impossible to predict, some things are certain. The flexible, subjective approach endorsed by the Court in *KSR* will make patents harder to get and harder to defend. This not only drives up the already-staggering legal costs associated with intellectual property protection, it essentially makes the likelihood of winning effective patent protection even more of a crapshoot. Investors funding technology R&D endeavors will necessarily be assuming a much higher risk in funding already high-risk/high-cost projects. Because biotechnology relies so heavily on private funding, and because such private funding is conditioned on the probability of profit, *KSR* could have profound, negative implications for the ability

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<sup>153</sup> 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 (Oct. 10, 2007). After summarizing the facts and holding of *KSR*, the Guidelines reemphasize the requirement that examiners search for relevant prior art and articulate their findings in light of the *Graham* analysis. *Id.* at 57,526-28. But the critical component of the Guidelines perhaps lies in the seven rationales for invalidating a pending patent claim on the basis of obviousness. *See id.* at 57,529. The failure of a claim to meet the TSM factors serves as one of these possible rationales, but as the Guidelines point out, examiners are not required to use the TSM test in making a proper rejection for obviousness. *Id.* at 57,528. Indeed, the Guidelines explain, even if a claimed invention passes muster under the TSM test, it can still be found obvious on other grounds. *Id.*

of biotech to secure adequate financing for its ambitions. Inventions require research and research requires money . . . money requires the opportunity to earn a profit. *KSR* severely diminishes this opportunity, and the trickle-down effect is immediately evident.

Not only will it be more difficult to get a patent issued, but once one is issued, it carries much less strength and security—as a challenge on grounds of obviousness will have a greater likelihood of success. In addition, existing patents may be re-opened for re-examination, leaving basically every issued patent in danger. Litigation costs associated with defending these patents could put a stranglehold on the corporations, as a larger percentage of what funds the companies do possess will necessarily be devoted to legal expenses rather than R&D.

Even setting financial issues aside, *KSR* could have a stifling effect on the biotech community, as companies will have less incentive to disclose their discoveries and inventions. Smaller companies will be hit disproportionately hard, as only their larger, multinational counterparts will control the resources sufficient to develop products, procure pricy—but priceless—patent protection, and afford the staggering costs involved in the increasingly likely event of litigation.

The patent law system was put in place to protect inventors' interests in effort to encourage the disclosure of technological advances that may otherwise be kept secret. This provides a substantial benefit to the scientific community, as well as society at large, by increasing the free-flow of information and spurring further progress. In order for the patent system to work effectively, however, it must provide reliable, dependable protection to new, non-obvious, and useful inventions. *KSR v. Teleflex* calls this into question by favoring flexibility over predictability and giving judges and patent

examiners excessive discretion to assess patent claims. Subjectivity and hindsight bias result in a watered-down and unreliable system that undermines the purpose and potential patent protection was intended to possess. Reform may be needed, but *KSR* suggests it is not likely to come from the Supreme Court. Ingenuity, wisdom, and resourcefulness, particularly at the congressional and PTO levels, may be the best hope. Perhaps *KSR*'s legacy, then, will not be in the changes it brought directly, but rather in the changes it stimulated others to make in response.