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Obvious to Try? The Slippery Slope of Biotechnology

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I. Introduction

One of the most significant hurdles in obtaining a patent is the requirement that an invention cannot be obvious to someone who possesses the ordinary level of skill in the technology area pertinent to the invention. The test has evolved throughout the history of patent law, with every change in technology creating new challenges for courts to determine what inventions deserve patent protection. Over the past several years, the analysis to determine whether an invention is obvious has undergone some seemingly dramatic changes through case law. One of the tests courts have implied may be used to analyze obviousness include the traditionally forbidden "obvious to try" analysis—meaning, if an invention would be "obvious to try" for a person of ordinary skill in the relevant art, it could be found obvious and the patent would be invalidated. Whether this test itself is valid is up for debate, but, if so, it would present particular challenges to fields like biotechnology. Due to the nature of biotechnology, there are only a select number of methods used to arrive at new and innovative discoveries in the field. Therefore, what may seem "obvious to try" on the surface is a larger universe than in other more "traditional" scientific fields. Biotechnology is a relatively immature science with incredible potential and the need to protect the ingenuity of these inventions are in the best interest of scientific development.

II. Obviousness

A. The Beginning

The nonobviousness requirement was first recognized by the Supreme Court in *Hotchkiss v. Greenwood*[1] in 1851, which predated the section of the U.S. codes that codifies the current obviousness requirement by over 100 years. *Hotchkiss* gave rise to a vague requirement that an invention must have some elusive quality that was beyond simple novelty. This case centered on an invention that claimed a mechanical combination of a doorknob, shank, and spindle, with a novel feature being that the knob was formed of clay or porcelain. The court stated that the invention, in order to be novel, should possess more ingenuity than would be conceived by the "ordinary mechanic acquainted with the business." This metaphor was the historical roots of the modern-day hypothetical *person having ordinary skill in the art*, which is reflected in 35 U.S.C. § 103. Ultimately, the court found that an ordinary mechanic would have had the foresight to use clay or porcelain in the door knob, rendering the patent invalid due to obviousness.

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35 U.S.C. Section 103 was created in 1952. Section 103 codified the language in *Hotchkiss* regarding the requirement that the invention not be obvious to a person with ordinary skill in the art ("POSA") in order to be patentable. Almost fifteen years after the enactment of section 103, the U.S. Supreme Court interpreted the obviousness codification by developing an analytical framework for determining the issue of nonobviousness in *Graham v. John Deere*.[2] They established four factors that are essential elements to a judicial obviousness determination: (1) determining the ordinary level of skill in the art; (2) scope and content of prior art; (3) differences between the claimed art and the prior art; and (4) secondary considerations, which include commercial success, long felt but unsolved needs, and/or failure of others to invent. Later, in evaluating differences between the claimed invention and the prior art, the U.S. Court of Appeals for the Federal Circuit has applied in certain cases, the teaching, suggestion, or motivation ("TSM") test. This test was devised by the Federal Circuit as a uniform method that involves asking whether there was specific reason at the time of the invention found either in the prior art or the knowledge of POSA to make a change to the prior art or to combine prior art to make the invention at issue. If there was no such teaching, suggestion, or motivation, then prima facie obviousness can be overcome. It was also developed to guard against hindsight bias that potentially occurs when evaluating prior art many years after the fact. Hindsight bias is essentially what it sounds like—using the knowledge of how a product was invented to demonstrate why it was obvious.

B. "Obvious to try"

Since Section 103 was enacted, the obviousness analysis has undergone several changes, with the TSM as the backbone of all analyses. The court has struggled to find the balance between allowing patents for inventions that are meaningful advances in science and weeding out the ones that do not contribute to scientific progress. The court has wavered in its view as to whether the "obvious to try" standard is sufficient to determine whether an invention deserves the right of patent protection. The standard was first tested in the Federal Circuit in 1988, in *In re O'Farrell* where the court stated: "[a]ny invention that would in fact have been obvious under § 103 would also have been, in a sense, obvious to try. The question is: when is an invention that was obvious to try nevertheless nonobvious?"[3] The court split the world of inventions that would seem as though they could be "obvious to try" on the surface into two categories. The first category contained a known method of discovering the invention, and the inventor varied all the possible parameters until a successful result included the claimed invention. In this scenario, no teaching, motivation, or suggestion was provided in the prior art. In these cases, inventions were clearly not obvious under § 103. The second universe of inventions involved inventions where the inventor was exploring a promising experimental area, where only general guidance as to the particular form of the invention was given in the prior art. In these cases, if there was no reasonable expectation of success for any particular part of the claimed invention, then the patent was not obvious. The court emphasized that the obviousness inquiry should focus on the *reasonable expectation* of success and not the *predictability* of success. For years after *O'Farrell*, the court was silent on whether "obvious to try" could be used in the obviousness inquiry.

In 1995, the Federal Circuit was faced with a classic biotechnology invention of isolating DNA molecules to encode proteins to repair or replace damaged tissue in the case *In re Deuel.* The prior art outlined the general method to isolate DNA

sequences; however, the prior art did not suggest the claimed compound. The court revisited "obvious to try" as a standard and clearly stated that, "'[o]bvious to try' has long been held not to constitute obviousness . . . [a] general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out."[4] It appeared "obvious to try" was no longer a potential measure of obviousness. The court resumed using only the TSM test to determine obviousness.

Twelve years later, the U.S. Supreme Court revisited this issue in *KSR v. Teleflex*[5] when they altered the long standing, formulaic tenants of obviousness by discarding "rigid or mandatory formulas" in obviousness analysis. *KSR* involved a vehicle pedal assembly including an electronic sensor for detection of the position of the pedal. The pedals and sensors were individually known in the art. The court believed that granting a patent for inventions that "would occur in the ordinary course without real innovation" would retard scientific progress. The Supreme Court reasoned that constricted analyses that do not allow courts to inquire whether an invention is "obvious to try" are an incorrect interpretation of the law. The court stated:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has a good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.[6]

KSR loosened the TSM test that was the central tenant of the obviousness analysis, creating a more flexible test in its wake. The question remained whether *KSR* resurrected the "obvious to try" standard.

After KSR, courts struggled to interpret the outer bounds of this flexible obviousness test to come up with their own language to bring definition to an amorphous inquiry. The "obvious to try" language began reappearing in biotechnology cases. In *Ortho-McNeil Pharmaceuticals v. Mylan*,[7] the court found the lower court did not apply the obviousness tests too strictly when they did not use an "obvious to try" standard. "KSR posits a situation with a finite, and in the context of the art, small or easily traversed, number of options that would convince an ordinarily skilled artisan of obviousness."[8] They reasoned when the Supreme Court decided to instill a less rigid analysis to determine obviousness, they meant to take all the evidence on the record as a whole and not single out any particular teaching, suggestion, or motivation as the deciding factor. A limited number of options to the inventor could lead to a conclusion that the invention was obvious to try.

In April of 2009, the Federal Circuit was once again faced with the classic biotechnology question of whether the isolation and sequencing of a human gene that encodes a particular domain of a protein is a patentable, nonbovious invention in the case *In re Kubin*. In light of KSR, it was apparent that "'obvious to try' may be an appropriate test in more situations than [they had] previously contemplated."[9] The court noted that KSR's "admonition against a formalistic approach to obviousness"[10] resurrected the "obvious to try" analysis in *O'Farrell*. The court

reiterated the two situations where "obvious to try" did not equate to obviousness. Obviousness is not a result of "throw[ing] metaphorical darts at a board filled with combinational prior art possibilities[.]"[11] Nor is it the result of general guidance in the prior art of a particular field, without an indication to examine the claimed compound. The court explicitly expressed that this type of analysis will not deem an entire body of inventions in a scientific field irrelevant because the nature of the field uses known methods to arrive at new inventions. They reiterated that each case should be analyzed on a factual basis, where the abilities of artisans of ordinary skill in the art will determine what is and is not a truly nonobvious invention.

In the cases since *KSR* and *Kubin*,[12] courts focus on whether the prior art identifies a finite number of identifiable, predictable solutions to determine obviousness. If general guidance is given in the prior art, then courts will focus on the reasonable expectation of success, as opposed to the predictability of success in their obviousness analysis.[13]

III. The Slippery Slope

Most recently, in March of 2010, the court in the U.S. District Court for the Southern District of New York found in *Association for Molecular Pathology v. USPTO* that isolated human genes in the form of DNA, and the comparison of their sequences, are not patentable under 35 U.S.C. § 101.[14] Although this case does not pertain directly to obviousness, it has potential to be used in a much wider context than intended by the court. The case centered around two genes that are used to analyze a woman's risk of getting breast or ovarian cancer. Because of the importance of this technology, this case drew attention from a wide variety of organizations, including companies that specialize in biotechnology products, scientific associations, physicians that use genetics to screen their patients from diseases, and various cancer organizations.

A long standing tenant of patent law is that a product of ordinary skill is not necessarily a product of invention.[15] The court in this case reasoned that for an invention to be patentable, the results in the creation of the invention should yield a fundamentally new product. The court's analysis turned on the test used in the Supreme Court case *Diamond v. Chakrabarty*,[16] where the court stated that a new product produced should have "markedly different characteristics from any found in nature and . . .[have] the potential for significant utility."[17] Prior case law found that purification of a product in nature does not create enough transformation to justify patent protection, because such a change is not sufficient to create the "markedly different characteristic" to deem it a true invention.[18] The court found that isolated DNA is not "markedly different" from native DNA as it exists in nature. They also found the method claims which were directed to the method for determining whether a patient carried the cancerous DNA mutations, were also not patentable under Section 101. Method claims are patentable if they are tied to a machine or apparatus; or, they transform an article to a different state or thing. The court found "analyzing" and "comparing" DNA sequences was not a meaningful transformation under the second part of this test. "[T]ransformation must be central to the purpose of the claimed process."[19]

Ultimately, the claims-in-suit were found invalid under Section 101 because they were not deemed to be patentable subject matter. Although the patenting of DNA

sequences found in nature was unpatentable, the decision did not necessarily preclude patenting DNA fragments with altered sequences, and left open the question whether adding start codons, promoters, or incorporating the DNA into a vector would be considered something beyond what is found in nature. This case will certainly find its way through the appeals process, as it is venturing into what some might characterize as new and unique applications of the law. Although the court firmly stated that the obviousness analysis is a separate and distinct requirement under patent law[20]; there is danger that some courts may read this holding more broadly to support obviousness opinions disguised under the "obvious to try" rhetoric, i.e., it is obvious to try to obtain biotechnology products found in nature regardless of the knowledge of its existence or the difficulty or motivation to obtain it. This is a danger that should be carefully avoided, as such an inappropriate determination would reduce the incentive to invest in this type of technology and perhaps hinder its ability to grow and flourish.

IV. Protecting Biotechnology Inventions

The question remains: "How do I best prepare myself for the rigors of *KSR* and the potential pitfalls of 'obvious to try' when dealing with biotechnology based inventions?" The test for obviousness is not easily defined and is even more difficult when considering the complexities of biotechnology. On the surface, it would seem difficult to successfully defend against allegations of obviousness in this field.

However, there are steps biotechnology practitioners can take to mitigate the chances of their patent being found invalid due to obviousness. As we have seen in the case law presented above, the court will take into account the entire process used to research and discover the invention when determining whether an invention is obvious. Therefore, clearly documenting all results leading to the invention, including those that ended unsuccessfully, is important in demonstrating that there was more than a single "obvious" solution to the problem addressed by the invention.

Another source of guidance could be the long standing secondary indicia of non-obviousness from the Supreme Court's *Graham v. John Deere.*[21] Documentation of failure of others, long felt unmet need, commercial success and how others in the art react to the invention can all be good sources of potential protection from the dangers of the elusive "obvious to try" concept. These are particularly useful in the biotechnology arena as they can be used to demonstrate the difficulties, complexities, and unpredictability of working in this field. And old standbys, such as teachings away in prior art can also be helpful. This again demonstrates that, as the saying goes, the more things change, the more they stay the same.

V. Conclusion

For any scientific field to progress and flourish, as is the case in biotechnology, intellectual advancements have to be protected through the patent system. *KSR* appeared to have changed the then currently accepted paradigm when it relieved courts of solely using the formulaic approach of the TSM test. Although there is no guaranteed procedure for protecting ones biotechnology invention from the potential dangers of *KSR*, it appears that the obviousness analysis has not changed as much as some might have feared. Based on the cases following *KSR*, "obvious to try" may

not be a sufficient test, by itself, to determine the obviousness of an invention. The cases after *KSR* give us insight as to what role the concept of "obvious to try" will play in the future. It is no longer simply TSM or "obvious to try," but an emerging test which uses the traditional TSM analysis with flexibility in view of all the facts on a case-by-case basis, using the whole record as guidance towards whether patentability is warranted. As biotechnology continues to grow and develop as a field, patent protection should ensure continued development in the art. To fail to do so would be to go against the U. S. Constitution's mandate to "promote the Progress of Science . . . by securing for limited Times to . . .Inventors the exclusive Right to their … Discoveries."[22]

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1 *Hotchkiss v. Greenwood*, *52 U.S. 248* (1850).
2 *Graham v. John Deere*, 383 U.S. 1 (1966).
3 *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).
4 *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995).
5 *KSR v. Teleflex*, *550 U.S. 398* (2007).
6 *KSR*, 550 US at 421.
7 *Ortho-McNeil v. Mylan*, 520 F.3d 1358 (Fed. Cir. 2008).
8 *Id.* at 1564.
9 *In re Kubin*, 561 F.3d 1351, 1358 (Fed. Cir. 2009).
10 *Id.* at 1359.
11 *Id.*
12 *See Alcon, Inc. v. Teva Pharms. USA, Inc.*, 664 F. Supp.2d 443 (D. Del. 2009) (where court found moxifloxacin was not "obvious to try" because prior art did not have a finite number of identifiable, predictable solutions); *see also Bayer v. Barr*, 575 F.3d 1341, 1346–50 (Fed. Cir. 2009) (where court found the election of micronized drospirenone in an oral contraception compound rendered the patent invalid due to obviousness, since the ordinary skilled artisans would be able to narrow the universe of possibilities to a small, finite number of possibilities to achieve the claimed compound from the prior art.)
13 *Bayer*, 575 F.3d at 1349.
14 *Ass'n for Molecular Pathology v. USPTO*, 2010 BL 68723 (S.D.N.Y. Mar. 29, 2010).
15 *See Funk Bros. v. Kalo Inoculant Co.*, 333 U.S. 127, 131–32 (1948) (finding the product claims covering strains of species of root-nodule bacteria were not patentable because they were a "discovery of some of the handiwork of nature" rather than innovation.)
16 *Diamond v. Chakraborty*, *447 U.S. 303* (1980).
17 *Id.* at 310.
18 *Id.*
19 *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008).
20 *Molecular Pathology*, 2010 BL 68723 at *100.
21 *Graham v. John Deere*, *383 U.S. 1*, *17–18* (1966).
22 U.S. Const., Art. I, sect. 8, cl. 8.