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I. INTRODUCTION

Among the many objectives of the American patent system is the promotion of innovation, which is accomplished by providing inventors with an incentive to invent.[1] A patent provides this incentive by excluding anyone other than the patent holder from using the invention, among other things, for a limited period of time.[2] A patent provides pharmaceutical companies with motivation to invest considerably in research and development.[3] The grant of a patent, however, is subject to several statutory requirements, including that of "non-obviousness" under 35 U.S.C. § 103.[4] The purpose of the non-obviousness requirement is to prevent the issuance of a patent for something that is merely an obvious improvement on or variation of something already known.[5] Should inventor *B* receive a patent for making a metallic

1. The American patent system is a mix of incentives and restraints. Craig Allen Nard et al., The Law of Intellectual Property 655–66 (2d ed. 2008) [hereinafter Law of Intellectual Property]. The ultimate objective both "bestows benefits and impose[s] costs on society . . . ." *Id.* at 655. The requirement to disclose the invention to the world provides society with the knowledge and means to innovate beyond what was already invented. Patent law offers a potential financial reward as an incentive to invent, disclosure of technical data, incentive to invest in developing the invention, and a means to facilitate efficiency through licensing. *Id.* at 656.

2. A patent gives its owner a right to *exclude* others from "making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States." Craig Allen Nard, The Law of Patents 1 (2008) [hereinafter Law of Patents] (quoting 35 U.S.C. § 154 (2006)). A patent does not give its owner any *positive* rights, such as the right to make, use, or sell the invention. *Id.* The patent infringement statute states that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent." 35 U.S.C § 271(a). The term of the grant begins "on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed." 35 U.S.C § 154(a)(2).

3. *See* Law of Patents, *supra* note 2, at 2–3. The incentive offered by patent protection is relied on differently by various industries. Some industries rely more on copyright and trademark law to protect their intellectual property. However, the pharmaceutical industry relies heavily on patent protection. *Id.* The total estimated cost to develop a new drug was $897 million in May 2003. Am. Bar Ass'n, Biotechnology and the Law 204 (Eileen Smith Ewing & High B. Wellons eds., 2007).

4. 35 U.S.C. § 103. In addition, § 102 describes the statutory condition that the invention must be novel. *Id.* § 102. Section 112 is the specification statute, which restrains the claims to only what is disclosed and what the patent enables. *Id.* § 112. Section 101 pertains to the kinds of inventions that are eligible for patent protection, including the utility of the subject matter sought to be patented. *Id.* § 101. However, of all the statutory requirements, the most frequently litigated is non-obviousness. Non-obviousness is described in §103, as follows:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, 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. Patentability should not be negatived by the manner in which the invention was made.

Id. § 103.

5. The test for novelty under § 102 is confining in the sense that it requires that each and every limitation of the claimed invention be present in a single prior art source. Law of Intellectual Property, *supra* note 1, at 730. Non-obviousness under § 103, on the other hand, allows for the limitations to be present

doorknob when inventor *A* has already invented a clay doorknob? Clearly, the two are not the same invention because each is made of a different material.[6] However, under U.S. patent law, such a minor or "obvious" variation between inventor A's clay doorknob and inventor B's metallic doorknob makes the latter unworthy of patent protection.[7] When courts find that patent claims are invalid as obvious by improperly lowering the standard for non-obviousness under § 103, the incentive that the patent system attempts to promote is disturbed, and for pharmaceutical manufacturers in particular the motivation to innovate and develop new drugs is reduced.[8]

In *Bayer Schering Pharma AG v. Barr Laboratories, Inc.*, the U.S. Court of Appeals for the Federal Circuit considered the question of whether a pharmaceutical company's patent claims covering the invention of an oral contraceptive drug were invalid as obvious under § 103.[9] The court applied a test commonly known as the "obvious to try" test as a threshold matter in determining the patent's validity and affirmed the opinion of the U.S. District Court for the District of New Jersey. The district court found the patent's claims to be obvious under § 103 and therefore held that the patent was invalid.[10] The Federal Circuit found that the information available to the public at the time the patent was developed, also known as the "prior art,"[11] led the Plaintiff to reach a crossroads where the Plaintiff had to choose between two "viable options" that *might* work.[12] However, the court failed to find that any of the available viable options were predictable solutions with "anticipated success," as required by the U.S. Supreme

in multiple analogous sources which were available to a person having ordinary skill in the art at the time the invention was made. *Id.* at 745–46.

6. *See* Hotchkiss v. Greenwood, 52 U.S. 248, 265 (1850).

7. *Id.* The court in *Hotchkiss* held a doorknob patent invalid because, although it was a novel idea, "there was an absence of that degree of skill and ingenuity, which constitute essential elements of every invention." *Id.* at 267. However, the *Hotchkiss* test left great ambiguities. Law of Intellectual Property, *supra* note 1, at 746. The 1952 Patent Act, construing § 103, clarified the "invention" requirement by implementing the condition of non-obviousness. *Id.*

8. Of the many fields in which patents offer protection, the pharmaceutical industry is one where most experts believe that patent protection is necessary. John R. Thomas, Pharmaceutical Patent Law 4 (2005). It has been estimated that roughly 60% of the pharmaceuticals developed would not exist without the incentives provided by patent protection. Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 Mgmt. Sci. 173, 175 (1986).

9. 575 F.3d 1341 (Fed. Cir. 2009).

10. *Id.* at 1343. This analysis has typically required that "there is a design need or market pressure to solve a problem . . . there are a finite number of identified [and] predictable solutions, [and that] a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp." *Id.* at 1347 (citing KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 420 (2007)).

11. Courts have defined the scope of prior art for a non-obviousness inquiry to include all of the materials that could be considered relevant in determining novelty and statutory bar issues. However, for non-obviousness, the prior art must originate within an "analogous art." This includes a technical discipline relevant to the claimed invention. Thomas, *supra* note 8, 144–45.

12. The court held that "a person having ordinary skill in the art has reached a crossroads where he must choose between two known options: delivery of micronized drospirenone by a normal pill following the spirorenone analogy in the Krause series, or delivery of drospirenone by an enteric-coated pill following the Nickisch teaching that the drug needs to be protected from the stomach." *Bayer*, 575 F.3d at 1350.

Court's obvious to try test.[13] In *KSR International Co. v. Teleflex Inc.*, the Supreme Court held that an invention that is obvious to try can be unpatentable as obvious under § 103 when, through a combination of elements or a course of conduct, a person of ordinary skill in the art has available a "finite number of identified, predictable solutions," which would lead that person to "anticipated success."[14]

This case comment contends that the Federal Circuit erred in its obvious to try analysis by not properly applying the "predictable solutions" element of the obvious to try test. The Federal Circuit's predictable solutions analysis required only that prior art lead a person skilled-in-the-art[15] to viable options, instead of properly requiring that the prior art lead a person skilled-in-the-art to anticipated success.[16] The majority's analysis strays drastically from Supreme Court precedent, which requires a finding that the prior art would lead to anticipated success and not merely to viable options. The court's decision could have adverse consequences for future drug development because the incentive for drug manufacturers to invest in research and development will be reduced if the manufacturer is not confident that an issued patent will be upheld if challenged in court.[17]

A. Background of Bayer Schering Pharma AG v. Barr Laboratories, Inc.

Plaintiff Bayer Schering Pharma AG, a pharmaceutical company involved in drug research and development, produces the daily oral contraceptive Yasmin.[18] The active ingredient of Yasmin is drospirenone, which inhibits ovulation.[19] Drospirenone, however, also has the additional—and highly desirable—ability to reduce bloating and acne.[20] In formulating the appropriate use of drospirenone as an oral contraceptive, Bayer faced two critical challenges.[21] First, drospirenone is poorly water-soluble, which means that when taken orally, little drospirenone will be absorbed in the blood stream, where it is needed in order to be active on the body.[22] Second, drospirenone

13. *Id.* at 1349. In addition, the dissent reasoned that "[t]he district court stated that micronization was a 'viable' option, [h]owever, 'viability' is not the standard." *Id.* at 1351 (Newman, J., dissenting).

14. 550 U.S. 398, 421 (2007).

15. According to § 103, the assessment of non-obviousness must be from the perspective of a "person having ordinary skill in the art." 35 U.S.C. § 103(a) (2006). Courts have interpreted "person having ordinary skill in the art" to mean "what a hypothetical ordinary skilled artisan would have gleaned from the cited references at the time that the patent application leading to the . . . patent was filed." Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1364 (Fed. Cir. 2001).

16. *Bayer*, 575 F.3d at 1348.

17. The motivation for researchers to develop new drug formulations will be reduced if inventors will not be able to enforce the exclusion rights they were granted. Because the pharmaceutical industry relies heavily on patent protection, the result could be that the developers reduce funding for development.

18. *Bayer*, 575 F.3d at 1343.

19. *Id.*

20. *Id.* (citing these additional qualities as leading to the drug's success).

21. *Id.*

22. *Id.* The amount of active drug absorbed into the body's bloodstream is called the "bioavailability." *Id.*

is an acid-sensitive substance that undergoes a rapid molecular structure rearrangement process in the stomach, called isomerization,[23] resulting in the loss of the drug's desired anti-bloating qualities.[24] Prior art sources, however, disclosed several techniques for overcoming each of the individual challenges that Bayer faced, but none offered a solution for both challenges together.[25]

The De Castro reference, for example, is a prior art source that discloses a process called micronization, whereby the surface area of the drug is increased. This process can be used on poorly water-soluble drugs as a method to increase the amount of the drug that will be absorbed by the body.[26] But although this technique enables better absorption, it also makes the drug more sensitive to acid, which is problematic for substances such as drospirenone that are already acid-sensitive.[27] Additionally, another prior art source, known as the Nickisch reference, discloses that micronizing drospirenone would increase its exposure to the body's stomach acid, thereby increasing isomerization and causing the drug to lose the anti-bloating qualities.[28] Thus, although micronization may remedy the water solubility problem, it was known to further aggravate problems relating to acid sensitivity.

Another prior art source consisted of experiments performed by Dr. Werner Krause.[29] Krause disclosed the effects of both drospirenone and a similar compound called spirorenone.[30] Krause's experimentation with drospirenone was limited to *in vitro* studies—experiments which are conducted in a controlled setting without

23. Acid-sensitive compounds undergo a process called isomerization when they reach the stomach's acid, whereby the chemical's molecular structure rearranges. *Id.* During isomerization, the stomach's acid catalyzes a reaction that rearranges the molecular structure of the substance. *Id.* The resulting substance is called an isomer. *Id.*

24. During isomerization of drospirenone, the chemical's molecular structure is rearranged, causing a loss in the anti-bloating qualities and a reduction in the absorption rate of drospirenone into the blood stream. *Id.* After drospirenone goes through isomerization, the resulting isomer is non-antimineralocorticoidal. *Id.* The resulting effect leaves the substance without its desired anti-bloating diuretic qualities. *Id.* In designing methods to control this "isomerization" effect, Bayer scientists also were required to have the drug's bioavailability meet the standards required for oral contraceptives. *Id.* at 1344.

25. *See id.* at 1344–45.

26. "Micronization" is a technique commonly used by drug developers to combat similar poorly water-soluble compositions. *See id.* at 1343. Micronization increases the surface area of the drug, ensuring a faster dissolution rate so that all of the drug will dissolve, thus increasing the drug's bioavailability. *Id.* at 1344. Currently, all oral contraceptives use micronization to increase bioavailability. *Id.*

27. *Id.* at 1344.

28. During prosecution with the U.S. Patent and Trademark Office (USPTO), the patent examiner allowed the claims because the Nickisch reference "taught that micronizing drospirenone would increase its exposure to the highly acidic environment of the stomach, which would result in increased isomerization." *Id.* at 1345. The patent examiner considered this prior art reference to teach away from micronizing drospirenone because it would lead to undesired results. *See id.*

29. *Id.* at 1344.

30. Spirorenone metabolizes into drospirenone when consumed. *Id.*

living organisms.[31] Krause, however, experimented *in vivo,* on living organisms, with spirorenone.[32] Bayer scientist Dr. Johannes Tack decided that the Krause studies involving *in vivo* testing of spirorenone provided little information about the practice of drospirenone *in vivo*.[33] Thus, he conducted his own *in vitro* experiments of drospirenone, which yielded the undesired finding that drospirenone undergoes rapid isomerization.[34]

Prior art sources also disclose a technique called "enteric coating," which is used to control acid sensitivity.[35] When a drug is delivered via an enteric coating, it is surrounded by a pH-sensitive film that enables the drug to dissolve only while in the lower intestine, where it is less acidic than in the stomach.[36] Dissolving in a less acidic area of the body results in lower isomerization. This enables drospirenone to maintain its anti-bloating qualities, which would have been a concern according to the Nickisch reference and the Krause teaching.[37] Adding enteric coating to a drug, however, can lead to drawbacks, including: a possibly reduced ability to be absorbed into the bloodstream, delayed response of the drug on the body, and uncertain patient-to-patient outcomes.[38] Therefore, although enteric coating could have controlled drospirenone's acid sensitivity problems, it may have rendered the drug inactive in the body. Furthermore, a prior art source called the Hargrove reference concluded that not all acid-sensitive drugs require enteric coating.[39]

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31. *Id. In vitro* studies are not performed on living organisms. *See* Merriam-Webster's Dictionary (defining *in vitro* as "outside the living body and in an artificial environment"), *available at* http://www.merriam-webster.com/medlineplus/in%20vitro.

32. *Id. In vivo* studies are performed on living organisms. *See* Merriam-Webster's Dictionary (defining *in vivo* as "in the living body of a plant or animal"), *available at* http://www.merriam-webster.com/medlineplus/in%20vivo.

33. *Id.* Dr. Tack consulted the research conducted by Dr. Krause, a fellow Bayer scientist, to gain insight into the bioavailability of poorly water-soluble substances and acid sensitivity issues of a similar compound, spirorenone. *Id.* at 1343–45.

34. *Id.* at 1345. As a consequence of rapid isomerization, there was a "clear reduction of bioavailablity" of the substance to be absorbed by the body. *Id.* Tack's conclusion followed the standard known at the time to scientists who faced similar issues, and recommended that all further studies be performed by using drospirenone "with an enteric-coated formulation" so as to reduce the isomerization effect and increase the bioavailabilty of the drug. *Id.* These findings and conclusions were reconfirmed even five years later when Bayer conducted more *in vitro* studies. *Id.* at 1344–45.

35. *Id.* at 1344.

36. *Id.*

37. *Id.* at 1343–45.

38. *Id.* at 1344.

39. Hargrove was a study that included the use of progesterone. *Id.* at 1348. Progesterone, however, is not an acid-sensitive substance like drospirenone. *Id.*

Another available prior art source, called the Robert Aulton treatise, examines the relationship between *in vitro* experiments and *in vivo* experiments.[40] Aulton discloses that:

> dissolution rate data[,] when combined with solubility . . . provide an insight to the formulator into the potential in vivo absorption characteristics of a drug. However, in vitro tests only have significance if they can be related to in vivo results. Once such a relationship has been established, in vitro dissolution tests can be used as a quality control test.[41]

Additionally, Aulton agreed with the De Castro reference that micronization is an effective technique to be used with poorly water-soluble drugs, but makes no reference to acid-sensitive drugs and the problems that micronization can cause in further aggravating the acid sensitivity concern.[42]

In 1988, Bayer conducted *in vivo* experiments to determine the measurement and rate of the therapeutically active form of enteric-coated drospirenone on the body, or its "absolute bioavailability."[43] The company tested the effects of administering drospirenone through an intravenous injection, an enteric-coated pill, and a micronized pill.[44] The results unexpectedly showed that the micronized pill resulted in the same bioavailability as the enteric-coated pill.[45] Bayer filed an application for a patent where the application's claims were first rejected by the USPTO on grounds

40. *Id.* at 1349. The Federal Circuit in *Cross v. Iizuka* held that both *in vitro* and *in vivo* studies would satisfy the utility requirement set forth in § 101. 753 F.2d 1040 (Fed. Cir. 1985). If the data are reasonably correlated with the particular pharmacological or therapeutic utility requirement claimed in the patent application, then a satisfactory demonstration of patent utility is shown. U.S. Patent & Trademark Office, U.S. Dep't of Commerce, Manual of Patent Examining Procedure § 2107.03 (8th ed. 2001).

41. *Bayer*, 575 F.3d at 1348 (citing Robert Aulton, Pharmaceutics: The Science of Dosage Form Design 9 (1988)).

42. Aulton does not disclose the definite outcome when micronizing a poorly water-soluble substance that is also acid-sensitive. *Bayer,* 575 F.3d at 1348. In fact, Aulton teaches that the outcome would be uncertain. *Id.* Aulton also disclosed that micronizing a poorly water-soluble substance—such as drospirenone—may sometimes result in increased isomerization, but can also result in decreased isomerization. *Id.*

43. *Id.* at 1345. The "absolute bioavailability" would have been determined by comparing the results of the enteric-coated pill and the intravenous injection. *Id.*

44. *Id.* Experiments conducted to determine the absolute bioavailability of an enteric-coated substance routinely involve only comparing the results of the enteric-coated pill with the results of the intravenous injection. Tack chose to add the non-routine element of the normal micronized pill as well. *Id.*

45. *Id.* Tack, along with the rest of the Bayer scientists involved, expected the results to show that the enteric-coated tablet produced a lower bioavailability than the intravenous injection—which it did. *Id.* However, no one expected that the normal pill would deliver the same bioavailability as the enteric-coated pill. *Id.* It was expected, for good reason, that the enteric-coated pill would produce a higher bioavailability than the normal pill because the normal pill should have been dissolved more in the stomach where the acid would cause a higher rate of isomerization. *Id.* This finding was inconsistent with the Nickisch reference prior art, which indicated that there would be a clear reduction of the bioavailability of drospirenone when administered in a normal (micronized) pill because micronizing the compound would increase its exposure to the stomach's highly acidic environment. *Id.*

that the claims were obvious in view of the De Castro reference, which taught that poorly soluble drugs can be micronized in order to increase their absorption by the body.[46] However, Bayer responded by indicating that the Nickisch reference "teaches away"[47] from the micronizing of acid sensitive drugs and, therefore, the patent claims could not be obvious.[48] The USPTO considered Bayer's response and allowed the claims.[49] The USPTO issued Bayer U.S. Patent No. 6,787,531 ("Yasmin patent") for Yasmin on September 7, 2004.[50]

Defendant Barr Laboratories, Inc. is a generic pharmaceutical company[51] that filed an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA) seeking approval to market a generic form of Yasmin.[52] When Bayer learned of Barr's FDA application, it filed a patent infringement suit against Barr for infringing their Yasmin patent.[53] Barr argued that it should be permitted to

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46. *Id.*

47. According to the Federal Circuit, "[a] reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re* Kubin, 561 F.3d 1351, 1357 (Fed. Cir. 2009); *In re* Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994).

48. Nickisch taught that micronizing drospirenone would result in increased isomerization because of increased exposure to the stomach's acid. *Bayer*, 575 F.3d at 1345, 1349.

49. Upon allowing the claims, the examiner stated: "The micronized drospirenone will be degraded even more rapidly because the micronization of drospirenone expose[s] the drug particles in the stomach . . . . Therefore, to formulate an oral dosage form[] containing the drospirenone particles, which exposed to the gastric environment upon dissolution, would be un[o]bvious in view of the data presented . . . ." *Id.* at 1345.

50. *Id.* at 1343, 1345. The claims of the patent are covered by representative claim 1 which states:

> A pharmaceutical composition comprising[: a)] from about 2 mg to about 4 mg of micronized drospirenone particles, about 0.01 mg to about 0.05 mg of 17.alpha.-ethinyllestradiol, and one or more pharmaceutically acceptable carriers, [b)] the composition being in an oral dose form exposed to the gastric environment upon dissolution, [c)] and the composition being effective for oral contraception in a human female.

Id. at 1345–46.

51. *Id.* at 1346. Barr Laboratories is a subsidiary of Teva Pharmaceutical Industries. *Teva and Ortho McNeil-Janssen Settle Oral Contraceptive Lawsuit; Bayer Patent Declared Invalid*, World Generic Markets (ESPICOM Bus. Intelligence Ltd.), Aug. 21, 2009.

52. *Bayer*, 575 F.3d at 1346. It is very common for generic companies such as Barr to file ANDAs with the FDA to seek approval to market generic forms of patented drugs. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, contains provisions which enable generic manufacturers to obtain FDA approval to market a drug that is already patented by another pharmaceutical company. The Hatch-Waxman Act enabled generic manufacturers to begin developing a generic form of an approved drug during the life of a patent, as long as the development is in compliance with FDA regulations. ANDAs permit generic companies to use the safety and efficiency data, developed by the original manufacturer, for the purpose of FDA review. Thomas, *supra* note 8, at 12–15.

53. *Bayer*, 575 F.3d at 1346. The Hatch-Waxman Act requires the generic manufacturer applying for the ANDA to notify the patent holder that it has requested FDA approval to manufacture and market the new drug. Under § 271(e)(2), when a generic manufacturer files an ANDA they have performed a "somewhat artificial" act of patent infringement. Therefore, the patent holder may raise a patent infringement complaint in a federal district court. Thomas, *supra* note 8, at 16 (citing 35 U.S.C. § 271(e)(2) (2006)).

market a generic form of the drug Yasmin without infringing on Bayer's claims because the patent's claims are invalid due to obviousness or, in the alternative, were not infringed.[54]

B. The Bayer *Court's Legal Analysis*

The district court held the Yasmin patent claims to be invalid as obvious under § 103 after applying the obvious to try test.[55] The court concluded that "it would have been obvious to a person having ordinary skill in pharmaceutical formulation to try a normal [micronized] pill in formulating drospirenone as an oral contraceptive."[56] The court rejected Bayer's argument that Nickisch "teaches away" from micronizing drospirenone, and explained that a person skilled-in-the-art would recognize Nickisch's shortcomings because Aulton teaches to "verify whether drospirenone absorbed or isomerized with precise *in vivo* and *in vitro* testing."[57] Specifically, the court explained that Aulton teaches not to accept *in vitro* results without correlating the data with *in vivo* testing.[58] Thus, the court reasoned that Bayer should not have conclusively relied on the Nickisch and Krause *in vitro* disclosures, but rather should have conducted its own *in vivo* tests to verify the effects of micronizing drospirenone *in vivo*.[59] The court even acknowledged Aulton's silence regarding acid-sensitive drugs, but "concluded that a person having ordinary skill would have seen [micronization] as a viable option."[60] The court also determined that Krause should have led Bayer to believe that drospirenone—like spirorenone—may *absorb in vivo*, but *isomerize in vitro*, even though they are two different substances.[61] Furthermore, the court found that micronizing drospirenone was a viable option in light of Hargrove, even though Hargrove's test involved a different drug that is not acid-sensitive like drospirenone.[62]

On appeal, the Federal Circuit affirmed the district court's holding that Bayer's patent claims were obvious under § 103.[63] The Federal Circuit also applied the obvious

54. *Bayer*, 575 F.3d at 1346.

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*

59. *See id.*

60. *Id.* at 1348.

61. *Id.* at 1349.

62. *Id.* at 1348. On June 24, 2008, Barr entered into a licensing agreement with Bayer to distribute a generic form of Yasmin. Bayer supplied Barr with the generic form, which Barr marketed under the title "Ocella." Barr began distribution of Ocella in July 2008. *Teva and Ortho McNeil-Janssen Settle Oral Contraceptive Lawsuit; Bayer Patent Declared Invalid*, World Generic Markets (ESPICOM Bus. Intelligence Ltd.), Aug. 21, 2009; Elizabeth Jones, *Appeals Court Affirms Invalidity of Yasmin Patent*, Generic Line (FDA News), Aug. 19, 2009, Vol. 26 No. 16.

63. *Bayer*, 575 F.3d at 1350.

to try test and found that the "predictable solutions" element of the test was satisfied merely because Bayer had two known viable options to consider.[64] The court reasoned that the two known options available to Bayer were "delivery of micronized drospirenone by a normal pill following the spirorenone analogy in the Krause series, or delivery of drospirenone by enteric-coated pill following the Nickisch teaching that the drug needs to be protected from the stomach."[65] Thus, the court found that "[b]ecause the selection of micronized drospirenone in a normal pill led to the result anticipated by the Krause series, the invention would have been obvious."[66] However, in finding that the prior art would lead to viable options, neither the district court nor the Federal Circuit found that the prior art would lead a person skilled-in-the-art to "anticipated success."[67] In other words, the Federal Circuit failed to demonstrate the second element of the obvious to try test, which is that the solutions not only be of a "finite number" and "identified," but also that the solutions be "predictable," the latter being accomplished by a showing that the identified solutions will result in anticipated success if attempted.[68]

Judge Newman, in dissent, argued that the proper application of the obvious to try test requires a finding that the prior art lead to "predictable solutions," and that the "predictable solutions" standard is satisfied only when the prior art leads a person skilled-in-the-art to "anticipated success."[69] She further contended that the prior art "teaches away" from micronizing acid-sensitive chemicals because doing so will accelerate the degradation of the pill.[70] The dissent asserted the irrelevance of Krause, reasoning that Krause could not have led a person having ordinary skill in the art to anticipated success because Krause involved a chemical, which was not acid-sensitive.[71] According to the dissent's reasoning, nothing in the prior art suggests the likelihood of success from the ingestion of uncoated micronized drospirenone.[72] Instead, the dissent argued that the prior art taught of the likelihood of failure in such an experiment.[73] Judge Newman concluded that the proper application of the obvious to try test does not require that the prior art lead to merely viable options;[74]

64. *Id.*

65. *Id.*

66. *Id.*

67. *See id.* at 1347–48.

68. *See id.* at 1351.

69. Judge Newman argued, "The Court in *KSR* . . . explained that the standard for obvious to try is whether there was a 'reasonable expectation of success' at the time." *Id.* (Newman, J., dissenting).

70. *See id.* at 1350–51.

71. *See id.* at 1351.

72. *See id.*

73. *Id.* Judge Newman argued that "[n]othing in the prior art teaches the likelihood of success of ingestion of uncoated micronized drospirenone; what is taught is the likelihood of failure." *Id.*

74. *See id.* In dissent, Judge Newman stated that "'viability' is not the standard. 'Viability' implies that the experiment may or may not succeed. What the law requires is not guesswork, not dumb luck, but a reasonable degree of predictability of success." *Id.*

rather, it requires that the prior art lead to both viable options *and* anticipated success.[75] Furthermore, the dissent acknowledged that if the prior art "teaches away" from a result and there is no indication of a likelihood of success, then there cannot be anticipated success leading to predictable solutions.[76]

This case comment contends that the Federal Circuit incorrectly applied the obvious to try test in finding obviousness under § 103. Specifically, the Federal Circuit incorrectly applied the "predictable solutions" element of the test by requiring that the prior art lead a person skilled-in-the-art only to certain viable options that *might* work, instead of requiring that the prior art lead a person skilled-in-the-art to anticipated success, which is mandated by Supreme Court precedent.[77] Part II of this case comment discusses the origins of the obvious to try test and its elements. Part III of this case comment discusses the court's flawed application of the "predictable solutions" element of the obvious to try test and two ways in which it was inconsistent with Supreme Court precedent. Specifically, Part III.A analyzes how the Federal Circuit incorrectly devalued prior art that "taught away" from desired outcomes even in the absence of conflicting teachings. Part III.B of this case comment discusses how the Federal Circuit erroneously relied on prior art references that would only lead to experimentation with unknown results to find that the "predictable solutions" element of the obvious to try test was satisfied. Part IV concludes.

II. ORIGINS OF THE OBVIOUS TO TRY TEST

In *KSR International Co. v. Teleflex Inc.*, the Supreme Court articulated the obvious to try test to clarify certain circumstances in which a patent may be invalid as obvious under § 103 because the claims were obvious to try.[78] In *KSR*, the Supreme Court stated that:

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75. *Id.*

76. *See id.*

77. The court held that the predictable solution standard was satisfied because the prior art led Bayer to "reach a crossroad" where it would have to choose between two known viable options that might work. *Id.* at 1350. The two viable options were "delivery of micronized drospirenone by a normal [micronized] pill following the spirorenone analogy in the Krause series, or delivery of drospirenone by an enteric-coated pill following the Nickisch teaching that the drug needs to be protected from the stomach." *Id.* at 1350. However, the court failed to find that either viable option available to Bayer contained anticipated success. As Judge Newman argued in dissent, the Supreme Court requires that the viable options have a reasonable expectation of success. *Id.* at 1351 (Newman, J., dissenting).

78. 550 U.S. 398 (2007); 35 U.S.C. § 103(a) states that:

> [a] patent may not be obtained . . . 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. Patentability shall not be negatived by the manner in which the invention was made.

Id. In *KSR*, the Supreme Court interpreted the statute with regards to the obviousness of a patent claiming the use of an electronic sensor on an automobile pedal with a fixed pivot point. The Supreme Court held the patent invalid as obvious, reasoning that the patent was merely a combination of related prior art that anticipated predictable results. Specifically, the Court held that "[t]he combination of

> [w]hen 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 good reason to pursue the known options within his or her technical grasp. If this leads to the *anticipated success*, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.[79]

Thus, *KSR* provides that the obvious to try test may lead to a finding of obviousness under § 103 when two elements are satisfied.[80] First, there must be a finite number of identified solutions.[81] Second, those finite number of identified solutions must be "predictable solutions."[82] This second element is satisfied when the prior art leads a person skilled-in-the-art to anticipated success; in other words, there must be a reasonable expectation of success in order for the second element to be satisfied.[83] The Supreme Court did not articulate or endorse a standard under which obviousness may be based solely on the patentable alternative being merely a viable option—that is, an option that *might* work.[84]

The Supreme Court in *KSR* adopted its reasoning from the Federal Circuit decision of *In re O'Farrell,* where the Federal Circuit described two situations in which a finding that something is "obvious to try" is insufficient to establish obviousness under § 103.[85] The first situation explains KSR's first element that there be a "finite number of identified solutions," which was based on the holding in *O'Farrell* that § 103 obviousness is not found where

> what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.[86]

The other situation described in *O'Farrell* explains the second required element, specifically, that those "finite number of identified solutions" also be "predictable

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familiar elements according to known methods is likely to be obvious *when it does no more than yield predictable results*." 550 U.S. 398, 416 (2007) (emphasis added).

79. *KSR*, 550 U.S. at 421 (emphasis added).

80. *See id.*

81. *Id.*

82. *Id.*

83. *See id.*

84. *See* Brief of Amicus Curiae American Intellectual Property Law Association in Support of Neither Party at 4, Bayer Schering Pharma AG v. Barr Lab., Inc., 575 F.3d 1341 (Fed. Cir. 2009) (No. 2008-1282), 2009 WL 3393593 [hereinafter Brief for AIPLA].

85. *See KSR*, 550 U.S. 398, 415 (2007) (citing *In re* O'Farrell, 853 F.2d 894, 903 (1988)).

86. *Id.*

solutions."[87] As the majority in *Bayer* correctly pointed out, citing *O'Farrell*, § 103 obviousness is not found where "what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it."[88] Therefore, as the Federal Circuit acknowledged in *O'Farrell* and in *Bayer*, the Supreme Court's obvious to try standard—as expressed in *KSR*—is not met for purposes of finding obviousness under § 103 when the prior art supplies only "general guidance."[89]

III. THE COURT'S FLAWED APPLICATION OF THE OBVIOUS TO TRY STANDARD

The Federal Circuit incorrectly applied the "predictable solutions" element of the test by requiring that the prior art lead a person skilled-in-the-art to viable options, i.e., those that *might* work, instead of requiring that the prior art lead a person skilled-in-the-art to anticipated success. Its analysis of that element was flawed in two ways. First, the court incorrectly devalued prior art that "taught away" from the desired result without finding a conflicting prior art reference. Second, the court erroneously relied on prior art that would lead a person only to experimentation with unknown results. Each of these errors is discussed in turn.

A. Devalutation of Prior Art

The Federal Circuit's application of the predictable solution element of the obvious to try test was flawed because the court incorrectly devalued prior art that "taught away" without finding a conflicting prior art reference.[90] The Federal Circuit

87. *Bayer*, 575 F.3d at 1347 ("This expresses the same idea as the *KSR* requirement that the identified solutions be 'predictable.'" (quoting *O'Farrell*, 853 F.2d at 903)).

88. *Id.*; *O'Farrell*, 853 F.2d at 903.

89. *O'Farrell*, 853 F.2d at 903.

90. The "predictable solutions" element cannot be satisfied where the prior art "teaches away" from a particular solution because if it is "teaching away" then it cannot be supplying more than a "general guidance" as the particular form of the claimed invention or how to achieve it successfully. The Federal Circuit defined prior art that "teaches away" from a particular result in *In re Gurley* as "when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." 27 F.3d 551, 553 (Fed. Cir. 1994). Therefore, if a prior art reference is discouraging a person skilled-in-the-art from following a particular path, a person skilled-in-the-art cannot, at the same time, be provided more than a "general guidance" to a successful result unless there is some other prior art reference which is inconsistent with the reference that "teaches away" and does provide a correct guidance to the inventor. In *Gurley*, the court mentions that each prior art source can have a particular degree of teaching away. *Id.* In other words, in order for the identified solution to also be predictable where there are prior art references that are "teaching away," there must be another reference conflicting with the findings of the references that "teaches away" in order to provide sufficient guidance to a person skilled-in-the-art toward a successful outcome. *See In re* Young, 927 F.2d 588 (Fed. Cir. 1991). "When prior art contains apparently conflicting references, the Board must weigh each reference for its power to suggest solutions to an artisan of ordinary skill . . . . The Board, in weighing the suggestive power of each reference, must consider the degree to which one reference might accurately discredit another." *Id.* at 591. The importance of secondary considerations such as the presence of prior art that "teaches away" has been

acknowledged that Nickisch teaches that micronizing drospirenone would increase its exposure to the stomach's acid, thereby increasing isomerization and causing the drug to lose its anti-bloating qualities.[91] Therefore, if Bayer had followed Nickisch, it would have expected that delivery of drospirenone in a micronized form would provide an unsuccessful or undesired result. Nonetheless, the Federal Circuit disregarded the fact that Nickisch would lead Bayer away from the desired result and instead held that the predictable solution element was satisfied.[92]

In order for the Federal Circuit to have properly depreciated the value of the Nickisch teachings, the court would have had to simultaneously find an inconsistent teaching in another prior art source.[93] A proper application of the "predictable solutions" element under *KSR* would demonstrate that Nickisch "teaches away" from a successful result and therefore cannot satisfy the "predictable solutions" element because it cannot both lead a person toward a divergent path and, at the same time, offer more than a general guidance as to a successful result without another reference present to conflict with Nickisch. Therefore, because the Federal Circuit failed to find any prior art references that were inconsistent with Nickisch, the court incorrectly devalued Nickisch.[94]

B. Erroneous Reliance on Prior Art

The second way in which the Federal Circuit's application of the "predictable solutions" element was flawed was that the court erroneously relied on prior art that would lead a person only to experimentation with unknown results.[95] The court

long recognized by the Federal Circuit and was made explicit in *Stratoflex, Inc. v. Aeroquip Corp.,* 713 F.2d 1530 (Fed. Cir. 1983). In *Stratoflex*, the Federal Circuit stated that

> [i]t is jurisprudentially inappropriate to disregard any relevant evidence on any issue in any case, patent cases included. This evidence rising out of the so-called "secondary considerations" must always when present be considered en route to a determination of obviousness . . . . En route to a conclusion of obviousness, a court must not stop until all pieces of evidence on that issue have been fully considered and each has been given its appropriate weight . . . . It is an error to exclude that evidence from consideration.

Id. at 1538–39.

91. *Bayer*, 575 F.3d at 1346.

92. *See id.* at 1350.

93. *Id.* at 1346–47.

94. *Id.* at 1350.

95. Under the Federal Circuit's loose application of the "predictable solutions" requirement, certain patent claims will be rendered invalid as obvious if a challenging party can simply demonstrate that the prior art leads a person skilled-in-the-art to *viable known options to consider* without demonstrating that those identified viable options are also "predictable solutions." *Id.* at 1349–50. The problem with this standard is that it falls short of the Supreme Court's heightened requirement that the prior art lead a person skilled-in-the-art to anticipated success and enables the court to rely on prior art that only leads a person skilled-in-the-art to experimentation with unknown results. If the prior art only leads a person skilled-in-the-art to experimentation with unknown results, then it is difficult for a court to demonstrate that the prior art also provides more than a "general guidance" as required under the "predictable solutions" element. Judge Newman, in dissent, articulated this problem by stating "[t]he court rules that the

acknowledged, but improperly discredited, the fact that Krause leads only to experimentation in order to find the results of micronizing drospirenone because Krause uses a different substance with different qualities from drospirenone.[96] According to the majority's reasoning, the *in vivo* results of drospirenone are material in determining the proper delivery form of the substance.[97] The limited Krause *in vitro* experiments on drospirenone left Bayer scientists with uncertainty as to how drospirenone would react *in vivo*, and so further experimentation was necessary for Bayer to properly determine the behavior of drospirenone on the body.[98] When prior art teaches that a result is *unknown,* it is likely that it will not lead a person skilled-in-the-art to anticipated success because the prior art does not offer guidance toward a successful result. Krause only discloses information regarding the *in vivo* use of spirorenone, which provides little information about the proper delivery form of drospirenone *in vivo*.[99]

IV. CONCLUSION

The Federal Circuit's application of the *KSR* obvious to try test in *Bayer* was flawed because it only required that the prior art merely lead to viable options that *might* work as sufficient to satisfy the predictable solution element set forth in the test.[100] However, as the Supreme Court pointed out in *KSR,* a predictable solution under the test requires that the prior art lead not merely to viable options, but that it lead to anticipated success.[101] In *Bayer,* the Court held that because Bayer had two known viable options available, Bayer's patent was a "predictable solution," without

scientists should have 'tried' that which they believed would fail, and that when they eventually did try this unlikely formulation, and it succeeded, it was obvious to do so." *Id.* at 1351 (Newman, J., dissenting). If the outcome of experimentation was unknown at the time the invention was made, then it is difficult to find that there is a reasonable expectation of success. Finding that the patent is obvious under these circumstances is likely to condone the use of hindsight analysis by the courts. Brief for AIPLA, *supra* note 80, at 8–9; *see also Gurley*, 27 F.3d at 553.

96. Bayer argued that these two chemicals are so different that the former could isomerize at a rate of 40% faster than the latter. Yet still the court explained that in light of Krause, "a drug formulator having ordinary skill had a *viable known option to consider* with micronized, unprotected drospirenone." *Bayer*, 575 F.3d at 1349 (emphasis added).

97. According to the majority's own reasoning, Aulton teaches not to rely solely on *in vitro* results. *Id.* at 1348, 1350. Therefore, because Krause does not disclose any *in vitro* results for drospirenone, Bayer scientists should not have reasonably expected for it to be successful when delivered in a micronized form.

98. *Id.* at 1344–45, 1349. Therefore, although Krause may lead to a *known option to consider,* it does not necessarily provide more than a "general guidance" toward an *anticipation of success*—as required under the KSR predictable solution element—because experimentation is still required to resolve an uncertainty. The court, therefore, inappropriately assumed that a person skilled-in-the-art would rely on Krause as leading to a predictable solution because the court only required that Krause lead to *known options to consider* instead of properly requiring that Krause lead to anticipated success. *Id.* at 1349.

99. *See id.* at 1344–45, 49.

100. *See id.* at 1348; *see also KSR*, 550 U.S. 398, 415 (2007).

101. 550 U.S. at 421.

determining whether either viable option would lead to anticipated success.[102] Whether micronizing drospirenone was a viable option is not the end of the inquiry according to the Supreme Court's holding in *KSR*.[103] *KSR* requires more, which the Federal Circuit failed to find. In addition, the Supreme Court's obvious to try test requires that the viable options have a reasonable expectation of success, specifically, anticipated success.[104]

The court's failure to satisfy the second step in its application of the "predictable solutions" element of the obvious to try test strays drastically from the Supreme Court precedent. If such a loose analysis is followed, there could be drastic effects on the incentives that the patent system creates. Pharmaceutical manufacturers rely heavily on the patent system's incentive to invent when they invest considerable amounts of money in the research and development of new pharmaceuticals.[105] If courts continue to invalidate patents, as in *Bayer*, the incentive for pharmaceutical manufacturers to invest in research and development will be reduced, thus resulting in fewer drugs for the public.[106]

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102. 575 F.3d at 1347. In altering the standard to include viable options that might work, the Federal Circuit erroneously renders prior art that teaches away from an outcome irrelevant for an obvious to try analysis. *Id.* However, *KSR*, in establishing the test, required the courts to consider prior art that teaches away because it would likely demonstrate that the invention is not obvious. *KSR,* 550 U.S. at 416. Furthermore, the Federal Circuit inappropriately ignored clear errors made by the district court by holding that Hargrove provided Bayer with a predictable solution to the acid sensitivity problem, even though the majority acknowledged that the district court erroneously thought Hargrove taught a solution to acid sensitivity issues when, in fact, that prior art only teaches solutions for solubility. *Bayer,* 575 F.3d at 1348. By transforming the "predictable solutions" standard to include "viable options" that might work, the court is essentially considering situations where experimentation is required as sufficient to determine obviousness even though experimentation is required to determine an unknown outcome. *Id.*

103. Brief for AIPLA, *supra* note 80, at 4.

104. *Id.* at 4; *see also KSR*, 550 U.S. at 421.

105. *See* Thomas, *supra* note 8, at 2.

106. *Id.*