

IRRATIONAL BEHAVIOR, HINDSIGHT, AND PATENTABILITY: BALANCING THE “OBVIOUS TO TRY” TEST WITH UNEXPECTED RESULTS

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I. INTRODUCTION

Pharmaceutical and other high tech science industries require patent protection to justify the risks of expensive research. Without protection a copycat could bring the same product to market without the expense of research, enabling them to undercut price. This might benefit the consumer in the short term with lower prices, but it will destroy incentives to innovate. Ultimately this would lead to no new pharmaceutical and other research-intensive products.

There is a delicate balance between allowing patent protection for something truly innovative and denying it for a pedestrian advancement. It is the patentability standard of obviousness—the legal framework upon which courts and the Patent Office interpret whether the proposed invention would have been obvious to a person of ordinary skill in the art—that controls this balance. The difficulty for courts in determining obviousness, and thus patentability, is hindsight bias. When someone already knows how an invention works it is all too easy to consider it obvious, yet before learning about the invention, the same person would not have been able to envision the invention.

The Supreme Court has recently reasserted that a prima facie case of obviousness¹ may be determined by the analytical framework set forth in *Gra-*

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¹ *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1360 (Fed. Cir. 2007).

*ham v. John Deere Co.*² Under this framework, one must: (1) determine the scope and contents of the prior art; (2) compare the differences between the prior art and the claims; (3) determine the level or ordinary skill in the pertinent art; and (4) determine whether the claims as a whole would have been obvious to one of ordinary skill at the time of the invention.³ *Graham* also indicated that “obvious to try” may be an acceptable standard for determining obviousness.⁴ The “obvious to try” test attempts to determine whether the approach to create the invention would have been “obvious to try” by a person of ordinary skill.

In unpredictable fields such as chemistry or biotechnology, inventors will try to solve problems using an approach that has the greatest chance of success. The danger with the “obvious to try” test is that it is especially susceptible to hindsight bias because it uses the inventor’s own reasoned approach to solve a problem against him. The effect of extensive use of the “obvious to try” test will be to deny patent protection for logically guided research, while rewarding patent protection for inventions obtained through irrational behavior or luck. This will upset the balance of patent protection for innovative inventions by denying protection to those inventions derived through good research and lead to a decline in new research-intensive products.

Due to the problem of hindsight bias, where an invention may look obvious after one knows about it but not before, courts may evaluate secondary considerations and unexpected results to rebut the prima facie case of obviousness.⁵ The secondary considerations that a court will often consider are commercial success, long-felt need, failure by others, copying, teaching away, licensing, and initial disbelief and subsequent acclaim by experts.⁶ The problem with many of these secondary considerations is that some are duplicative, some are not necessarily indicative of non-obviousness, and some are so difficult to apply that they are meaningless. Consequently, there must be a reasonable factor to rebut obviousness found through the “obvious to try” test. This factor should focus on significant unexpected results of the invention because if a result is truly unexpected, then the invention could not have been obvious.

² 383 U.S. 1 (1966).

³ *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (citing *Graham*, 383 U.S. at 17–18).

⁴ *Id.* at 421.

⁵ *Id.* at 406, 415–18.

⁶ Jay Jongjitirat, Note, *Leapfrog Enterprises v. Fisher-Price: Secondary Considerations in Nonobviousness Determinations*, 42 U.C. DAVIS L. REV. 599, 611–16 (2008).

II. BACKGROUND OF THE PATENT SYSTEM AND OBVIOUSNESS**A. Patent System****1. History**

Promotion of science and the useful arts for the good of the general population was the reason the Constitution granted Congress an enumerated power to secure limited rights for inventors.⁷ Acting under this power, Congress enacted the Patent Act in 1790.⁸ However, the difficulty in determining what is deserving of patent protection led Congress to modify the conditions of patentability, culminating in the 1952 Patent Act, which set out several requirements for patentability: utility, novelty, and non-obviousness.⁹

2. Requirements for Patentability

The utility requirement is satisfied when “the invention [is] operable to achieve useful results.”¹⁰ An example of a purported invention that lacks utility is a perpetual motion machine that supposedly generates more energy than it uses.¹¹ Boundless energy would be useful; the problem is that no perpetual motion machines actually work because they would violate the first law of thermodynamics.¹²

An invention is anticipated, or lacks novelty, when it has been published anywhere, in public use, or offered for sale before the date of the invention (known as “prior art”).¹³ For example, a patent that disclosed a polycarbonate resin with a metal salt, which lists many metal salts including cadmium laurate, will anticipate a later claim to an invention for a polycarbonate resin with cad-

⁷ U.S. CONST. art. I, § 8, cl. 8; *Graham*, 383 U.S. at 6. *But see* Kenneth J. Burchfiel, *Revising the “Original” Patent Clause: Pseudohistory in Constitutional Construction*, 2 HARV. J.L. & TECH. 155, 165–66 (1989) (“The absence of any evidence indicating the intentions or identities of the actual framers of the intellectual property clause did not prevent an imaginative reconstruction based principally upon the letters of Thomas Jefferson.”) (footnotes omitted).

⁸ *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966).

⁹ 35 U.S.C. §§ 101–103, 112 (2006).

¹⁰ *In re Swartz*, 232 F.3d 862, 863 (Fed. Cir. 2000).

¹¹ *Newman v. Quigg*, 877 F.2d 1575, 1577 (Fed. Cir. 1989).

¹² *Id.*

¹³ 35 U.S.C. § 102.

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mium laurate.¹⁴ Even though the invention was listed with many alternatives, it was still specifically disclosed and so anticipates the later claim.¹⁵

The non-obviousness requirement is a higher barrier to patentability than novelty. It guards against patenting something which may in fact be new, yet is not a significant enough improvement over the prior art to warrant patent protection.¹⁶ An obviousness determination allows combining multiple pieces of prior art to show that the invention was merely a substitution of one part for another known part, provided there is a reason to do so.¹⁷ For example, in an early Supreme Court case, a patent claimed a doorknob made from clay with the same shape as previously made knobs made from metal or wood.¹⁸ The clay knobs were fitted to a metal shank, where previously only metal or wood knobs were used.¹⁹ The substitution of clay for metal or wood may have made a better or cheaper doorknob, but the change only required the skills of a mechanic, not an inventor.²⁰ Consequently, the invention was found to be obvious and not patentable.²¹

3. Policy for a Patent System

The patent system is an ingenious way to give a benefit to both an inventor and society by creating an incentive for time and money to be invested in research.²² The inventor receives protection for his invention, allowing him to prevent others from practicing his invention for a limited time.²³ This protection allows the inventor to create new products without fears that a copycat will sell a similar product without investing in research.²⁴ Without the protection, there is little incentive to conduct expensive research because a knock-off product made without the expense of research may be sold for less than the original

¹⁴ *In re Parameswar Sivaramakrishnan*, 673 F.2d 1383, 1384–85 (C.C.P.A. 1982).

¹⁵ *Id.* at 1385.

¹⁶ *Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966).

¹⁷ *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418–19 (2007).

¹⁸ *Hotchkiss v. Greenwood*, 52 U.S. 248, 266–67 (1851).

¹⁹ *Id.*

²⁰ *Id.* at 267.

²¹ *Id.*

²² Jeanne C. Fromer, *The Layers of Obviousness in Patent Law*, 22 HARV. J.L. & TECH. 75, 77 (2008).

²³ U.S. CONST. art. I, § 8, cl. 8.

²⁴ Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 508 (2009).

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product, which must recoup research costs.²⁵ In exchange for this protection, the inventor must satisfy the various requirements of patentability.²⁶ The two requirements of novelty and non-obviousness demand that the inventor actually create something new;²⁷ this entails investing time and money in research.²⁸ The utility condition simply requires that the invention be useful.²⁹ Additionally, the inventor must provide a written description of the invention in enough detail to enable a person of ordinary skill in the art to make and use it.³⁰

The benefits to society are several. First, it receives the benefits of new products, many of which require investment of research.³¹ Second, due to the limitations of the protection, after a limited time, the invention becomes part of the public domain so anyone may freely practice the invention.³² This might be a hollow promise without the third benefit; as part of the requirements for an invention the inventor must provide enough details to allow others to make and use the invention.³³ This disclosure also assists further innovation.³⁴

While society receives a benefit for new products, it does not receive a significant benefit for "discovery" of slight improvements over what exists in the public domain.³⁵ Whether an invention is patentable is mainly determined by novelty and non-obviousness determinations.³⁶ The novelty requirement can typically be determined by directly comparing the invention to what is in the public literature, patents, and in public use.³⁷ It is the non-obviousness determi-

²⁵ *Id.*

²⁶ 35 U.S.C. §§ 102–103, 112 (2006).

²⁷ *Id.* §§ 102–103.

²⁸ Roin, *supra* note 24, at 508.

²⁹ *See* 35 U.S.C. § 101.

³⁰ *Id.* § 112.

³¹ Roin, *supra* note 24, at 508.

³² 35 U.S.C. § 154.

³³ *Id.* § 112.

³⁴ Carl E. Gulbrandsen et al., *Patent Reform Should Not Leave Innovation Behind*, 8 J. MARSHALL REV. INTELL. PROP. L. 328, 335 (2009).

³⁵ *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415–16 (2007) (quoting *Great Atlantic & Pacific Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 152–53 (1950)). Although a patent covering what is part of the public domain may allow someone to produce a new product where otherwise there would be no incentive because there would be no guaranteed for a large enough profit margin to cover the development costs.

³⁶ *See* 35 U.S.C. §§ 102–103.

³⁷ *Id.* § 102.

nation which is the more difficult to evaluate and is the most often litigated.³⁸ The non-obviousness standard is not clearly defined and requires that the Patent Office or the courts attempt to judge what was obvious before the invention was made.³⁹

B. Obviousness

1. *Graham v. John Deere Co.*

Congress set the statutory framework for obviousness in § 103, stating that a patent will not be granted when 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.”⁴⁰ To evaluate obviousness under § 103, the Supreme Court set out the factual analysis to determine obviousness in *Graham v. John Deere Co.*⁴¹ First, “the scope and content of the prior art are to be determined;” second, “differences between the prior art and the claims at issue are to be ascertained;” and third “the level of ordinary skill in the pertinent art resolved.”⁴² With this background, the obviousness determination is evaluated.⁴³ Additionally, secondary considerations may be considered to help determine obviousness or non-obviousness.⁴⁴

The first *Graham* factor, the scope and content of the prior art, is the knowledge that was publicly available to a person of ordinary skill in the art at the time of the invention. In general, what constitutes prior art is anything that is in a published document accessible to the public.⁴⁵ Multiple references may be combined when they both teach that something is useful for the same purpose,⁴⁶ or to substitute one thing for something that is equivalent.⁴⁷ The next

³⁸ Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. 1391, 1398 (2006) (citing John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 208–09 (1998)).

³⁹ Gregory Mandel, *The Non-Obvious Problem: How the Indeterminate Nonobviousness Standard Produces Excessive Patent Grants*, 42 U.C. DAVIS L. REV. 57, 59 (2008).

⁴⁰ 35 U.S.C. § 103.

⁴¹ *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.* at 17–18.

⁴⁵ *See In re Wyer*, 655 F.2d 221, 225 (C.C.P.A. 1981).

⁴⁶ *In re Kerkhoven*, 626 F.2d 846, 850 (C.C.P.A. 1980).

⁴⁷ *In re Ruff*, 256 F.2d 590, 592 (C.C.P.A. 1958).

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step is to note the differences between the prior art, and what the inventor is claiming.⁴⁸

The last step is to ascertain the level of ordinary skill in the pertinent art.⁴⁹ The courts have used several factors to determine the hypothetical "person having ordinary skill in the art" ("PHOSITA").⁵⁰ They include: "(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field."⁵¹ These factors create an image of the PHOSITA, which is used to determine if a PHOSITA could bridge the gap between the prior art and the claimed invention.⁵² If so, then the invention is obvious and not patentable.⁵³ The test is whether this invention would have been obvious to this hypothetical PHOSITA "not to the judge, or to a layman, or to those skilled in remote arts, or to geniuses in the art at hand."⁵⁴

Secondary considerations, such as "commercial success, long felt but unsolved needs, failure of others, etc."⁵⁵ may be used to aid in the analysis of obviousness. Unexpected results have also been used to show non-obviousness.⁵⁶ These considerations may help determine that an invention that appears to be obvious is actually not.⁵⁷

2. *KSR International Co. v. Teleflex Inc.*

a. *Hindsight, TSM, & "Obvious to Try"*

The courts have recognized that hindsight may influence the obviousness determination.⁵⁸ People often consider something to be obvious after learn-

⁴⁸ *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

⁴⁹ *Id.*

⁵⁰ *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983).

⁵¹ *Id.* (citing *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1382 (Fed. Cir. 1983)).

⁵² *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007).

⁵³ *Id.*

⁵⁴ *Envtl. Designs*, 713 F.2d at 697.

⁵⁵ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

⁵⁶ *United States v. Adams*, 383 U.S. 39, 51 (1966).

⁵⁷ *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 315 (Fed. Cir. 1985) (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983)).

⁵⁸ *Graham*, 383 U.S. at 36 (quoting *Monroe Auto Equip. Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (1964)).

ing about it, when if questioned about it before, they would not have realized it.⁵⁹ Guarding against this has proven to be extremely difficult.⁶⁰ There is a tendency to use what is taught by the invention as a guide to reconstruct it from the prior art.⁶¹

To combat hindsight bias the Court of Appeals for the Federal Circuit had used a test known as the teaching, suggestion, motivation (TSM) test for determining obviousness.⁶² The TSM test was used “[t]o reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references.”⁶³ Under the TSM test, the factfinder must determine if there was any teaching, suggestion, or motivation for combining or modifying prior art references to arrive at the claimed invention with an expectation of success.⁶⁴ The focus is a determination based upon evidence, not conjecture.⁶⁵ However, this does not mean that prior art must explicitly teach, suggest, or provide motivation to combine or modify references, it may be implied.⁶⁶ Determinations of obviousness “cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”⁶⁷

In their preference to using the TSM test, the Court of Appeals for the Federal Circuit held that “obvious to try” does not constitute obviousness.⁶⁸ It is not an adequate basis to modify or combine references.⁶⁹ The fact that something was “obvious to try” does not create any expectation of success that would

⁵⁹ KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007); W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1553 (Fed. Cir. 1983).

⁶⁰ Jun Wu, Note, *Rewinding Time: Advances in Mitigating Hindsight Bias in Patent Obviousness Analysis*, 97 KY. L.J. 565, 569 (2008–2009); Mandel, *supra* note 38, at 1393.

⁶¹ Mandel, *supra* note 38, at 1394.

⁶² Dystar Textilfarben GmbH v. C.H. Patrick Co., 464 F.3d 1356, 1360 (Fed. Cir. 2006).

⁶³ Alza Corp. v. Mylan Labs., Inc., 464 F.3d 1286, 1290 (Fed. Cir. 2006) (quoting *In re Kahn*, 441 F.3d 977, 987 (Fed. Cir. 2006)).

⁶⁴ *Id.*

⁶⁵ *Id.* at 1289–90.

⁶⁶ *Id.* at 1291 (citing *Kahn*, 441 F.3d at 988).

⁶⁷ *Id.* (citing *Kahn*, 441 F.3d at 987–88).

⁶⁸ *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995) (citing *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)).

⁶⁹ *O'Farrell*, 853 F.2d at 902.

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lead to an invention.⁷⁰ “Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant’s disclosure.”⁷¹

b. Rejection of a Rigid Approach

In *KSR International Co. v. Teleflex Inc.* the Supreme Court considered the TSM test.⁷² At issue was a patent that covered an adjustable gas pedal system that would allow the gas pedal’s position to be adjusted for smaller people.⁷³ An electronic sensor was located at the pivot point in the pedal assembly.⁷⁴ The court found that one reference, Asano (U.S. Patent No. 5,010,782), disclosed everything in the patent except the electronic sensor.⁷⁵ The electronic sensor was disclosed in another patent, the ’068 patent (U.S. Patent No. 5,385,068).⁷⁶ The Court of Appeals for the Federal Circuit applied the TSM test and found that there was no teaching, suggestion, or motivation for a PHOSITA to combine Asano and the ’068 patent.⁷⁷ Whether it was “obvious to try” to combine the two references was irrelevant because “[o]bvious to try” has long been held not to constitute obviousness.⁷⁸

The Supreme Court rejected the rigid approach used by the Court of Appeals.⁷⁹ Instead it made clear that a court may take in to account the creativity of a PHOSITA.⁸⁰ In addition, one motivation to combine references may come from a showing that it was “obvious to try.”⁸¹ “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 good reason to

⁷⁰ See *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988) (citing *Burlington Indus. v. Quigg*, 822 F.2d 1581, 1583 (Fed. Cir. 1987); *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986); *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1013 (Fed. Cir. 1983); *In re Rinehart*, 531 F.2d 1048, 1053–54 (C.C.P.A. 1976)).

⁷¹ *Dow*, 837 F.2d at 473.

⁷² 550 U.S. 398 (2007).

⁷³ *Id.* at 408.

⁷⁴ *Id.* at 409.

⁷⁵ *Id.* at 413.

⁷⁶ *Id.*

⁷⁷ *Id.* at 413–14.

⁷⁸ *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 414 (2007) (quoting *Teleflex, Inc. v. KSR Int’l Co.*, 119 F. App’x 282, 289 (Fed. Cir. 2005)).

⁷⁹ *Id.* at 415.

⁸⁰ *Id.* at 418.

⁸¹ *Id.* at 421.

pursue the known options within his or her technical grasp.”⁸² If these options produce the expected result then it was not innovation, but ordinary skill, and consequently obvious.⁸³ The Supreme Court cautioned against hindsight bias, but “[r]igid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.”⁸⁴

c. Rebutting a Finding of Obviousness

In *KSR* the Supreme Court separately reaffirmed both the use of secondary considerations, and unexpected results.⁸⁵ Secondary considerations are not absolute indicators of non-obviousness but they may rebut a prima facie case of obviousness.⁸⁶ The most commonly cited secondary considerations are commercial success, long felt but unsolved needs, and failure of others.⁸⁷ The other important consideration for rebutting obviousness is when the invention produces unexpected results.⁸⁸ In general, unexpected results are used in unpredictable fields, such as chemistry and biotechnology, instead of the more predictable fields such as the mechanical arts.⁸⁹ To make an effective showing of unexpected results, they must be established by factual evidence.⁹⁰ Some courts have treated unexpected results as a secondary consideration and not necessarily recognized the importance of unexpected results.⁹¹ “Obvious to try” and unexpected results jurisprudence will be discussed in more detail in the next sections.

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *KSR*, 550 U.S. at 421.

⁸⁵ *Id.* at 415–16.

⁸⁶ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966) (citing Richard L. Robbins, Note, *Subtests of “Nonobviousness”: A Nontechnical Approach to Patent Validity*, 112 U. PA. L. REV. 1169 (1964)); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007) (citing *Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988)).

⁸⁷ *See Graham*, 383 U.S. at 17.

⁸⁸ *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995).

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *See* Rebecca S. Eisenberg, *Business Law Forum: Nonobviousness—The Shape of Things to Come: Pharma’s Nonobvious Problem*, 12 LEWIS & CLARK L. REV. 375, 418 (2008).

III. "OBVIOUS TO TRY"

A. History of "Obvious to Try"

1. Early History

Since its inception, the "obvious to try" test has been an ill-defined test causing it to be applied without consistency.⁹² The test has alternately been embraced, rejected, and most recently affirmed as a test for non-obviousness.⁹³ Prior to the 1952 Patent Act, several cases applied what could be considered "obvious to try" tests.⁹⁴ In *Mandel Bros.* a patent for an antiperspirant was found invalid for obviousness using "obvious to try" analysis but with different terminology.⁹⁵ At the time, many antiperspirants contained acid salts that retard perspiration, but would sometimes irritate the skin or rot clothing.⁹⁶ Alkaline could be used to neutralize the acid, which would reduce skin irritation and cloth rotting, but it would also reduce the effectiveness of the antiperspirant.⁹⁷ The patentees found that the use of certain types of amines, such as urea, would reduce the problems but still maintain the antiperspirant's effectiveness.⁹⁸ The prior art taught that urea had been previously used to reduce the corrosive effects of acids on clothing.⁹⁹ The court decided that "the patentees promptly turned to urea," resulting in immediate success.¹⁰⁰ The term "promptly turned to" is simply another way of saying "obvious to try," but without the court formulating any sort of a test.¹⁰¹

In a case that actually mentioned the term "obvious to try," the court affirmed the Patent Office's rejection of a patent application relating to the production of toluene from a mixture of benzene, polyalkylated hydrocarbons, and

⁹² See Andrew V. Trask, Note, "Obvious to Try": A Proper Patentability Standard in the Pharmaceutical Arts?, 76 *Fordam L. Rev.* 2625, 2643–44 (2008) (providing a history of inconsistent judicial application of the "obvious to try" test).

⁹³ See e.g., *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

⁹⁴ E.g., *Mandel Bros., Inc. v. Wallace*, 335 U.S. 291, 296 (1948); *In re Ruscetta*, 255 F.2d 687, 692 (C.C.P.A. 1958); *In re Leum*, 158 F.2d 311, 312 (C.C.P.A. 1946).

⁹⁵ See *Mandel Bros.*, 335 U.S. at 295.

⁹⁶ *Id.* at 292.

⁹⁷ *Id.*

⁹⁸ *Id.* at 293.

⁹⁹ *Id.* at 294.

¹⁰⁰ *Id.* at 295 (emphasis added).

¹⁰¹ *Gillette Co. v. S.C. Johnson & Son, Inc.*, 12 U.S.P.Q.2d (BNA) 1929, 1954 (D. Mass. 1989).

AlCl_3 , by heating it in a closed container.¹⁰² The applicants conceded that the heating of the mixture in a closed container, above the boiling point of benzene, was the only aspect that could create patentability in the claims.¹⁰³ The patent examiner rejected the application because it was common practice to use a closed container when the reaction temperature was high enough to cause one of the reactants to boil away.¹⁰⁴ The court decided that if it were within the skill of the art to use a closed container then “there can be no invention;” it would be “obvious to try” the reaction in either an open or closed container.¹⁰⁵

In another case the Court of Customs and Patent Appeals (CCPA) decided that an etching method that could etch tantalum, a difficult to etch metal, would be “obvious to try” on other difficult to etch metals.¹⁰⁶ Consequently, “mere proof that it worked would not make it patentable.”¹⁰⁷

In these three cases, the patents were found to be obvious because they were “obvious to try.”¹⁰⁸ The courts recognized that there was an “obvious to try” rationale, but did not define it, nor state when it could be used.¹⁰⁹

2. Rejection of “Obvious to Try” as a Test for Non-Obviousness

The “obvious to try” test fell out of favor after the 1952 Patent Act when the CCPA began to reject it.¹¹⁰ In *In re Huellmantel*, a patent applicant challenged the Patent Office’s rejection of his application that claimed a therapeutic comprising salicylate and either prednisone or prednisolone.¹¹¹ The Patent Office argued that the prior art contained references showing a therapy that combined salicylate and cortisone, and other references that showed that prednisone or prednisolone were more effective than cortisone.¹¹² The Patent Office

¹⁰² *In re Leum*, 158 F.2d 311, 312 (C.C.P.A. 1946).

¹⁰³ *Id.* at 311.

¹⁰⁴ *Id.* at 312.

¹⁰⁵ *Id.*

¹⁰⁶ *In re Ruscetta*, 255 F.2d 687, 692 (C.C.P.A. 1958).

¹⁰⁷ *Id.*

¹⁰⁸ *Mandel Bros., Inc. v. Wallace*, 335 U.S. 291, 296 (1948); *Ruscetta*, 255 F.2d at 692; *In re Leum*, 158 F.2d 311, 312 (C.C.P.A. 1946).

¹⁰⁹ *E.g.*, *Mandel Bros.*, 335 U.S. at 296; *Ruscetta*, 255 F.2d at 692; *Leum*, 158 F.2d at 312.

¹¹⁰ *See, e.g.*, *In re Tomlinson*, 363 F.2d 928, 933 (C.C.P.A. 1966); *In re Henderson*, 348 F.2d 550, 554 (C.C.P.A. 1965); *In re Huellmantel*, 324 F.2d 998, 1001 n.3 (C.C.P.A. 1963).

¹¹¹ *Huellmantel*, 324 F.2d at 998.

¹¹² *Id.* at 1000.

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stated that it would have been "obvious to try" to substitute prednisone or prednisolone for cortisone.¹¹³ The CCPA affirmed the rejection because they found that there was nothing unexpected about the synergism of the combination, but rejected the "obvious to try" test because nothing was said about it in § 103 of the Patent Act.¹¹⁴

a. Reason to Combine

The CCPA better explained its move away from the "obvious to try" test in *In re Tomlinson*.¹¹⁵ In *Tomlinson*, the applicants sought to patent stabilizers (nickel and cobalt dialkyldithiocarbamates) for polypropylene to prevent its breakdown upon exposure to ultraviolet light.¹¹⁶ The Patent Office argued that nickel stabilizers were known for polyethylene, a polymer similar to polypropylene.¹¹⁷ "[I]t would be obvious for a skilled chemist to try to stabilize polypropylene with a known stabilizer for polyethylene," and "that obviousness does not require absolute predictability."¹¹⁸ The court rejected the "obvious to try" test because research

[I]s not undertaken with complete blindness but rather with some semblance of a chance of success, and that patentability determinations based on that as the test would not only be contrary to statute but result in a marked deterioration of the entire patent system as an incentive to invest in those efforts and attempts which go by the name of "research."¹¹⁹

The obviousness question relates to compositions and methods, not the direction to be taken in research.¹²⁰ Consequently, the court found that the very general claims that encompassed both nickel and cobalt compounds were obvious because the nickel compounds were used to stabilize polyethylene, but claims for specific cobalt compounds were patentable.¹²¹ The dissent agreed that the invention must be considered as a whole, but disagreed with the allowance of any of the claims.¹²² The problem of selecting a stabilizer was not from a

¹¹³ *Id.*

¹¹⁴ *Id.* at 1001 n.3.

¹¹⁵ *Tomlinson*, 363 F.2d at 931.

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Tomlinson*, 363 F.2d at 934.

¹²² *Id.* at 935 (Smith, J., dissenting).

universe of choices, but only a few.¹²³ This case illustrates that a suggestion for research in a general direction does not create a presumption of obviousness when an invention was found in the suggested direction.¹²⁴

Not only was a general suggestion for research not enough to create obviousness, neither was the combination of an unsatisfactory process and an incentive to seek an improvement.¹²⁵ In *In re Dien*, the applicants filed a patent application for a process to make quinacridones by a process of double ring-closure.¹²⁶ The applicants found that using polyphosphoric acid (“PPA”) as a reagent for the ring closure produced high yields of the desired quinacridones.¹²⁷ There were two main references found to be prior art.¹²⁸ The Liebermann reference showed the basic ring-closure process for quinacridones using phosphorous pentoxide but with much lower yields and other problems.¹²⁹ The Uhlig reference claimed that PPA could be used for ring closures generally with better yields than other reagents, such as phosphorous pentoxide.¹³⁰ The Patent Office rejected the application, reasoning that a chemist would follow the Uhlig reference’s suggestion of using PPA in place of other ring closure reagents, such as the phosphorous pentoxide used in Liebermann.¹³¹ The court disagreed and allowed the patent to be granted because the Patent Office relied too strongly on Uhlig’s enthusiastic report.¹³² In a concurring opinion, Judge Smith noted that the patent examiner analyzed the patentability in terms of “obvious to try,” which is not the test for obviousness.¹³³

b. Two Main Errors Inherent in “Obvious to Try”

The Court of Appeals for the Federal Circuit explained that “obvious to try” is not the standard for obviousness, but that logically, something that was obvious may have also been “obvious to try.”¹³⁴ The arguments against “ob-

¹²³ *Id.* at 935–36.

¹²⁴ *See id.* at 932 (majority opinion).

¹²⁵ *In re Dien*, 371 F.2d 886, 888 (C.C.P.A. 1967).

¹²⁶ *Id.* at 886.

¹²⁷ *Id.*

¹²⁸ *Id.* at 887.

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Dien*, 371 F.2d at 887–88.

¹³² *Id.* at 888.

¹³³ *Id.* at 889 (Smith, J., concurring).

¹³⁴ *In re O’Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).

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vious to try” have focused on two main errors.¹³⁵ First, the Federal Circuit has reasoned that it would not have been obvious to “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.”¹³⁶ Second, that court has ruled that it was not obvious to explore a promising field of research, “where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.”¹³⁷ However, when neither of these situations exist, it would be reasonable to apply an “obvious to try” test.¹³⁸

c. Disavowed Standard

In some cases the Federal Circuit simply states that “obvious to try” was not a proper method for determining obviousness and did not focus on its two criticisms.¹³⁹ Instead, the court focused on its TSM test to determine whether references could be combined to determine obviousness.¹⁴⁰ The evolution of the “obvious to try” test has progressed from a new rationale, but which slowly fell out of favor after the passing of the 1952 Patent Act.¹⁴¹ The court continued to argue against the test because it did not consider the invention as a whole as required by § 103,¹⁴² and because it could not be used when the prior art did not indicate which combinations would be successful, nor when the prior art only

¹³⁵ *Id.*; see *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1365–66 (Fed. Cir. 2007); *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006).

¹³⁶ *O’Farrell*, 853 F.2d at 903 (citing *In re Geiger*, 815 F.2d 686, 688 (Fed. Cir. 1987); *Novo Industri A/S v. Travenol Labs., Inc.*, 677 F.2d 1202, 1208 (7th Cir. 1982); *In re Yates*, 663 F.2d 1054, 1057 (C.C.P.A. 1981); *In re Antonie*, 559 F.2d 618, 621 (C.C.P.A. 1977)).

¹³⁷ *Id.* (citing *In re Dow Chemical Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); *In re Tomlinson*, 363 F.2d 928, 931 (C.C.P.A. 1966))..

¹³⁸ *See id.* at 904.

¹³⁹ *Geiger*, 815 F.2d at 688; *Hybritech*, 802 F.2d at 1380 (citing *Jones v. Hardy*, 727 F.2d 1524, 1530 (Fed. Cir. 1984)).

¹⁴⁰ *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988).

¹⁴¹ *See Gillette Co. v. S.C. Johnson & Son, Inc.*, 12 U.S.P.Q.2d (BNA) 1929, 1953–54 (D. Mass. 1989); *Trask*, *supra* note 92, at 2645.

¹⁴² *Hardy*, 727 F.2d at 1530 (citing *In re Antonie*, 559 F.2d 618, 620 (C.C.P.A. 1977)).

suggested a promising field of research.¹⁴³ Eventually, the court simply explained that “obvious to try” was not an indication of obviousness.¹⁴⁴

3. Affirmation of “Obvious to Try” Test

In the 2007 *KSR* decision, the Supreme Court found several errors that were the result of the Federal Circuit’s TSM test being too narrow for determining obviousness.¹⁴⁵ While the focus of the decision was on the error of the rigid approach of the TSM test, the court affirmed the “obvious to try” test.¹⁴⁶ With little detail, the court explained that the Federal Circuit erroneously concluded that “obvious to try” is not a test for obviousness.¹⁴⁷ “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 good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success,” the claim is likely obvious.¹⁴⁸

KSR involved a patent in the mechanical arts for an adjustable gas pedal system.¹⁴⁹ At the outset, it was not clear whether an “obvious to try” test should be applied only to mechanical arts, or if it should also be applied to unpredictable arts such as chemistry and biotechnology.¹⁵⁰ However, subsequent Federal Circuit cases have made clear that it will apply the *KSR* ruling to the unpredictable arts.¹⁵¹

B. Elements of the “Obvious to Try” Test

In *KSR* the Supreme Court provided some guidance for the “obvious to try” test.¹⁵² The elements of the test require at least a reason to solve a problem,

¹⁴³ *In re O’Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).

¹⁴⁴ *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995) (citing *O’Farrell*, 853 F.2d at 903); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 725 (Fed. Cir. 1990) (citing *O’Farrell*, 853 F.2d at 903); *Hybritech*, 802 F.2d at 1380 (citing *Jones*, 727 F.2d at 1530).

¹⁴⁵ *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007).

¹⁴⁶ *Id.* at 419, 421.

¹⁴⁷ *Id.* at 421.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.* at 405.

¹⁵⁰ *See In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009).

¹⁵¹ *E.g.*, *Kubin*, 561 F.3d at 1360; *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1351 (Fed. Cir. 2008).

¹⁵² *KSR Int’l Co.*, 550 U.S. at 421.

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where there are (1) a finite number of identified solutions, (2) there is a reason to pursue the options, and (3) the success was anticipated.¹⁵³

1. Finite Number of Identified, Predictable Solutions

The first element for the “obvious to try” test is that there were a finite number of identified, predictable potential solutions.¹⁵⁴ Knowledge of a general approach,¹⁵⁵ or the recognition of a problem, does not mean there are a limited number of possible solutions.¹⁵⁶ This is highlighted in *Sandoz*, where Abbott sued Sandoz for a preliminary injunction for patent infringement, and Sandoz claimed the patents were invalid for obviousness.¹⁵⁷ The Federal Circuit decided that the district court did not make an error in determining that Abbott was likely to show the patents were not obvious.¹⁵⁸ At issue was an extended release pharmaceutical containing clarithromycin.¹⁵⁹ The patents claimed clarithromycin with a pharmaceutically acceptable polymer, which exhibited specific drug bioavailability after ingestion.¹⁶⁰ Sandoz argued that the combination of multiple patent references would show that it was merely routine experimentation to derive the claimed formulation with the desired bioavailability.¹⁶¹ Abbott countered that one of the references discussed “over a dozen possible drug delivery modes . . . each containing sub-classes and variations.”¹⁶² In support of its holding, the court quoted the words of *KSR* that there must be “finite, identified, and predictable” solutions before the invention, not solutions that are found with hindsight knowledge afterwards.¹⁶³ “The Court in *KSR* did not create a presumption that all experimentation in fields where there is already a background of useful knowledge is ‘obvious to try.’”¹⁶⁴ It even went so far as to say that

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1366 (Fed. Cir. 2007) (citing *In re O’Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)).

¹⁵⁶ *Abbott*, 544 F.3d at 1348.

¹⁵⁷ *Id.* at 1344.

¹⁵⁸ *Id.* at 1352–53.

¹⁵⁹ *Id.* at 1343.

¹⁶⁰ *Id.* at 1344.

¹⁶¹ *Id.* at 1347.

¹⁶² *Abbott*, 544 F.3d at 1351.

¹⁶³ *Id.*

¹⁶⁴ *Id.* at 1352.

where FDA regulations state the requirements for approval “knowledge of the goal does not render its achievement obvious.”¹⁶⁵

2. Reason to Pursue the Options

The second element of the test, that there had been a reason to pursue the options to solve a problem, first requires that the options be recognized.¹⁶⁶ This had been an early criticism of the “obvious to try” test.¹⁶⁷ It would not necessarily have been obvious to vary a particular parameter to achieve the desired result, unless it was recognized that the parameter had an effect on the problem.¹⁶⁸

This element is shown in *In re Omeprazole Patent Litigation*¹⁶⁹ where Apotex challenged the validity of Astrazeneca’s patents that involved omeprazole, a pharmaceutical used to treat acid-related gastrointestinal problems.¹⁷⁰ The patents at issue claimed an oral pharmaceutical with a core of omeprazole, an inert subcoating, and an outer enteric coating.¹⁷¹ Omeprazole decomposes when exposed to acid, such as in the stomach.¹⁷² This problem could have been solved by using an enteric coating to protect the omeprazole until the pill is in the small intestine.¹⁷³ It was later found that enteric coatings, which contain acidic compounds, also caused some decomposition during storage.¹⁷⁴ The district court decided that a person of ordinary skill in the art would not necessarily have recognized the relationship between the problem and a solution of using a subcoating.¹⁷⁵ The Federal Circuit agreed with the district court’s finding that “a person of skill in the art would not have seen a reason to insert a subcoating in the prior art formulation.”¹⁷⁶ The court’s analysis affirms the requirement that

¹⁶⁵ *Id.* *But cf.* Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1366 (Fed. Cir. 2007) (deciding that fifty-three FDA approved anions was a finite number of predictable solutions).

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

¹⁶⁷ *In re Antonie*, 559 F.2d 618, 620 (C.C.P.A. 1977).

¹⁶⁸ *Id.*

¹⁶⁹ 536 F.3d 1361 (Fed. Cir. 2008).

¹⁷⁰ *Id.* at 1364, 1366.

¹⁷¹ *Id.* An enteric coating is one that prevents the release of a pharmaceutical ingredient until it reaches the small intestine. *Id.* at 1365.

¹⁷² *Id.* at 1365.

¹⁷³ *Id.*

¹⁷⁴ *Id.*

¹⁷⁵ Astrazeneca AB v. Mylan Labs., Inc., 490 F. Supp. 2d 381, 526 (S.D.N.Y. 2007).

¹⁷⁶ *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1381 (Fed. Cir. 2008).

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there must be recognition of a potential benefit before obviousness may be determined under the "obvious to try" test.¹⁷⁷

3. Reasonable Expectation of Success

The third element for the "obvious to try" test is that the success could have been anticipated.¹⁷⁸ It is well settled in obviousness determination that anticipated success is when there is a reasonable, but not guaranteed, expectation of success.¹⁷⁹ In a case that was decided before *KSR*, but appeared to predict its affirmation of the "obvious to try" test, the Federal Circuit based its decision on a reasonable expectation of success.¹⁸⁰ In *Pfizer*, Apotex challenged a patent owned by Pfizer, which claimed the uncommon besylate salt of the previously known amlodipine, a pharmaceutical active ingredient.¹⁸¹ The Federal Circuit determined, based on expert testimony, that a person of ordinary skill in the art would have had a reasonable expectation of success in solving the problems of the prior art compound, amlodipine maleate, by making amlodipine besylate.¹⁸²

While a reasonable expectation of success may be enough to show obviousness, mere contemplation of future success is not.¹⁸³ Nor is motivation 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."¹⁸⁴ Syngenta Seeds, in an appeal to reverse a finding of obviousness, argued that there was no reasonable basis for the jury to have found there was a reasonable expectation of success.¹⁸⁵ The Federal Circuit agreed that contemplated future success was not sufficient, but it distin-

¹⁷⁷ *Id.*; *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1351 (Fed. Cir. 2008).

¹⁷⁸ *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

¹⁷⁹ *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) (citing *In re O'Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988)).

¹⁸⁰ *Id.* at 1369.

¹⁸¹ *Id.* at 1353.

¹⁸² *Id.* at 1364–65, 1369.

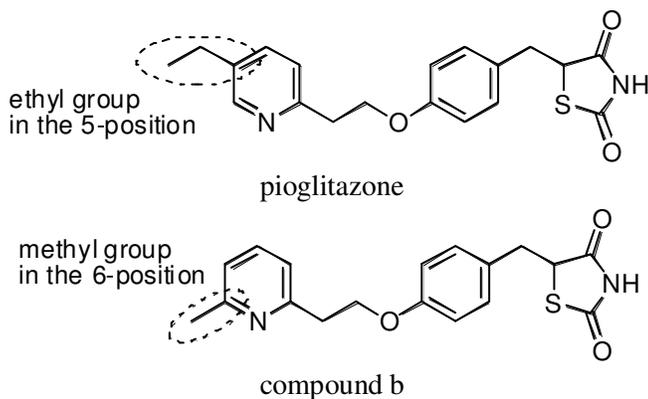
¹⁸³ *Syngenta Seeds, Inc. v. Monsanto Co.*, 231 F. App'x 954, 958 (Fed. Cir. 2007) (citing *Adang v. Fischhoff*, 286 F.3d 1346 (Fed. Cir. 2002)).

¹⁸⁴ *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (quoting *O'Farrell*, 853 F.2d at 903).

¹⁸⁵ *Syngenta*, 231 F. App'x at 958.

guished the facts in this case because there was substantial supporting evidence that a jury could reasonably find an expectation of success.¹⁸⁶

Another way a reasonable expectation of success may be lacking is when the prior art teaches away from the invention.¹⁸⁷ In *Takeda*, Alphapharm appealed a decision that Takeda's patent was valid based on a decision that the prior art did not make the claims obvious.¹⁸⁸ The patent claimed pioglitazone, which is used to activate insulin receptors to treat diabetics.¹⁸⁹ Alphapharm argued that pioglitazone was obvious because compound b was structurally similar and the most effective compound in the prior art.¹⁹⁰ Two supposedly obvious chemical changes would have been made to compound b to lead to pioglitazone: "first, homologation, i.e., replacing the methyl group with an ethyl group, which would have resulted in a 6-ethyl compound; and second, 'ring-walking,' or moving the ethyl substituent to another position on the ring, the 5-position."¹⁹¹



The district court and Federal Circuit disagreed with Alphapharm, because a person of ordinary skill in the art would not have chosen compound b to begin their research.¹⁹² The reference that disclosed compound b, specifically identified fifty-four compounds, and generally hundreds of millions of com-

¹⁸⁶ *Id.* at 958–59.

¹⁸⁷ *Takeda Chem. Indus. v. Alphapharm Proprietary, Ltd.*, 492 F.3d 1350, 1359 (Fed. Cir. 2007).

¹⁸⁸ *Id.* at 1352.

¹⁸⁹ *Id.* at 1352–54.

¹⁹⁰ *Id.* at 1355.

¹⁹¹ *Id.* at 1357.

¹⁹² *Id.*

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pounds.¹⁹³ Of the fifty-four compounds specified, only nine had test results reported, but there was no data indicating that any of the nine were the best performing compounds.¹⁹⁴ A later reference disclosed compound b with considerably more data.¹⁹⁵ Not only was compound b not one of the three best compounds, it also had an undesirable trait of causing an increase in body weight, which would be detrimental in a long-term treatment for diabetes.¹⁹⁶ In effect, the later reference taught away from compound b and a person of ordinary skill in the art would have chosen one of the other more promising compounds.¹⁹⁷ The Federal Circuit held that in light of this, the invention was not "obvious to try."¹⁹⁸

IV. UNEXPECTED RESULTS

A. Countering Obviousness

After the Patent Office has made a prima face case of obviousness, the patent applicant has an opportunity to rebut that presumption of obviousness.¹⁹⁹ The applicant may use secondary considerations, such as "commercial success, long felt but unsolved needs, failure of others, etc." to rebut this presumption.²⁰⁰ However, many of these secondary considerations suffer from the difficulty that they are not good indicators of non-obviousness.²⁰¹ Another stronger method to rebut the prima face case of obviousness is by showing that the claimed inven-

¹⁹³ *Takeda*, 492 F.3d at 1357.

¹⁹⁴ *Id.*

¹⁹⁵ *Id.* at 1358.

¹⁹⁶ *Id.*

¹⁹⁷ *Id.* at 1358–59.

¹⁹⁸ *Id.* at 1359.

¹⁹⁹ *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990).

²⁰⁰ *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966); *Süd-Chemie, Inc. v. Multisorb Techs.*, 554 F.3d 1001, 1008 (Fed. Cir. 2009) ("[E]vidence relating to secondary considerations 'constitutes independent evidence of nonobviousness' and can be quite instructive in the obviousness inquiry." (quoting *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008))).

²⁰¹ Dorothy Whelan, Note, *A Critique of the Use of Secondary Considerations in Applying the Section 103 Nonobviousness Test for Patentability*, 28 B.C. L. REV. 357, 374–75 (1987). But see Amanda Wieker, *Secondary Considerations Should Be Given Increased Weight in Obviousness Inquiries Under 35 U.S.C. § 103 in the Post-KSR v. Teleflex World*, 17 FED. CIR. B.J. 665, 666 (2008–2009).

tion exhibits unexpected results over the prior art.²⁰² This approach has mainly been applied to unpredictable fields, “where minor changes in a product or process may yield substantially different results.”²⁰³ An apparently obvious invention, which had unexpected results, “was in law nonobvious” and thus patentable.²⁰⁴

B. Requirements for Unexpected Results

There are several requirements that must be met to show unexpected results: the results must be (1) unexpected²⁰⁵ when (2) compared to the closest prior art,²⁰⁶ and (3) commensurate in scope with the claims.²⁰⁷ These unexpected results must be shown by factual evidence, not merely arguments.²⁰⁸

1. Unexpected

There are two main ways to show a property of the claimed invention is unexpected: first, when the prior art teaches away from the claimed invention,²⁰⁹ and second, when the invention has a new²¹⁰ or superior²¹¹ property, or is lacking

²⁰² *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004) (citing *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990)).

²⁰³ *In re Mayne*, 104 F.3d 1339, 1343 (Fed. Cir. 1997) (quoting *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995)).

²⁰⁴ *In re O’Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988) (citing *In re Merck & Co.*, 800 F.2d 1091, 1098 (Fed. Cir. 1986); *Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1461 (Fed. Cir. 1984); *In re Papesch*, 315 F.2d 381, 386–87 (C.C.P.A. 1963)).

²⁰⁵ *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 808 (Fed. Cir. 1989).

²⁰⁶ *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1370 (Fed. Cir. 2007) (citing *In re Baxter Travelnol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991)).

²⁰⁷ *In re Peterson*, 315 F.3d 1325, 1330–31 (Fed. Cir. 2003); *In re Lindner*, 457 F.2d 506, 508 (C.C.P.A. 1972).

²⁰⁸ *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997) (quoting *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1994)).

²⁰⁹ *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) (citing *United States v. Adams*, 383 U.S. 39, 48 (1966)); *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1331 (Fed. Cir. 2008) (quoting *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006)).

²¹⁰ *In re Papesch*, 315 F.2d 381, 387 (C.C.P.A. 1963).

²¹¹ *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987).

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an expected undesirable property.²¹² It is the property of the invention that must be unexpected, not merely an unexpected use of the invention.²¹³

A superior property may be one that is simply better than what was described in the prior art,²¹⁴ or it may be more than the expected sum of improvements by a combination of what was described in the prior art (i.e. synergistic effect).²¹⁵ In *United States v Adams*,²¹⁶ the patentee invented a battery that used magnesium and cuprous chloride.²¹⁷ The U.S. government claimed the patent was not valid because it was obvious to substitute magnesium for zinc and cuprous chloride for silver chloride, which were known in the prior art.²¹⁸ The Supreme Court decided that the Adams battery was not obvious because the battery had operating advantages that far exceeded the existing batteries.²¹⁹ It was the fact that the battery had a superior property that made it patentable, despite the fact that all the elements used in the battery were already known.²²⁰

The determination of whether a result is actually unexpected depends upon what a person of ordinary skill in the art would predict based upon the prior art.²²¹ Determining what is unexpected based upon a layperson's opinion can lead to the wrong result.²²² As an example, the Federal Circuit reversed and remanded a case involving the manufacture of salty fishing lures, where the district court determined it would be obvious for a lay person to add salt to the plastic used to make the fishing lure.²²³ The Federal Circuit decided that a person of ordinary skill in the art would not have expected the addition of salt to work because salt would change the surface properties of the lure, weaken the plastic, and potentially cause an explosion during the mixing of the salt into the

²¹² See *Ex parte Mead Johnson & Co.*, 227 U.S.P.Q. 78, 79 (B.P.A.I. 1985) (deciding that the claimed compounds have an absence of beta-blocking property which is an unexpected property and therefore are unobvious).

²¹³ *In re Sullivan*, 498 F.3d 1345, 1353 (Fed. Cir. 2007).

²¹⁴ *In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997) (quoting *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995)).

²¹⁵ *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 808 (Fed. Cir. 1989) (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)).

²¹⁶ 383 U.S. 39 (1966).

²¹⁷ *Id.* at 48.

²¹⁸ *Id.*

²¹⁹ *Id.* at 51.

²²⁰ *Id.* at 51–52.

²²¹ *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 997–98 (Fed. Cir. 2009); see *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1367 (Fed. Cir. 2007).

²²² See *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957–58 (Fed. Cir. 1997).

²²³ *Id.*

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plastic.²²⁴ In cases that appear to use simple technology, a layperson may not appreciate enough of the technical details to truly determine what is an expected result.²²⁵

When there are not new properties, or an absence of undesirable properties, the question becomes, how much improvement is enough to show that the results are unexpected? Clearly the degree of improvement in the properties showing the unexpected results must be more than what one would expect.²²⁶ If a patentee argues that a combination has an unexpected effect, the improvement should be greater than the sum of the effects of each of the individual components.²²⁷ For example, a patentee's water flush system was claimed to have a synergistic effect to wash animal wastes from a barn.²²⁸ The Supreme Court decided that the arrangement of old elements, while producing a striking result, did no more than produce the sum of the functions of each of the old elements.²²⁹ Consequently there was no synergism between the elements to produce an unexpected result, and the patent was not valid.²³⁰

In contrast, resedronate, a pharmaceutical, was found to have unexpected results in a case involving treatment for osteoporosis.²³¹ Experts testified that researchers did not predict that resedronate would "outperform 2-pyr EHDP by a substantial margin."²³² They also noted that the toxic effect for resedronate required more than 0.75 mg P/kg/day while 2-pyr EHDP only needed at 0.25 mg P/kg/day.²³³ The court determined that these unexpected results were enough to rebut obviousness.²³⁴

But not every property of the invention must be improved—in fact, only a single property needs to be improved.²³⁵ In *Chupp*, a patent for an herbicide

²²⁴ *Id.*

²²⁵ *See id.* at 957.

²²⁶ *See Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1302 (Fed. Cir. 2007).

²²⁷ *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 808 (Fed. Cir. 1989) (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)).

²²⁸ *Sakraida*, 425 U.S. at 281–82.

²²⁹ *Id.* at 282.

²³⁰ *Id.*

²³¹ *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 992, 997–98 (Fed. Cir. 2009).

²³² *Id.* at 997.

²³³ *Id.*

²³⁴ *Id.* at 998.

²³⁵ *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987) (citing *In re Ackermann*, 444 F.2d 1172, 1176 (C.C.P.A. 1971)).

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was rejected by the Patent Office because it was only slightly different from a prior art herbicide.²³⁶ The patentee presented evidence of unexpected results where the herbicide clearly showed superior control of two weeds for two crops.²³⁷ The Patent Office still rejected the claims because tests on only two weeds for two crops were not enough.²³⁸ The Federal Circuit reversed, finding that there is no set number of superior properties that must be shown.²³⁹

When the patentee claims a range that overlaps the range of a prior art reference, it is not enough to merely discover an optimum range through routine experimentation.²⁴⁰ Yet the claims may be patentable if the optimized variable produces "unexpectedly good" results.²⁴¹ In a case involving a reflective article with a protective coating, the unexpected results of the thickness of the protective coating was in dispute.²⁴² The claims were rejected based on prior art that showed a thickness not less than about 100 angstroms.²⁴³ The patentee argued that a thickness of 50 to 100 angstroms had an unexpected property of being more wear resistant.²⁴⁴ The Federal Circuit upheld the rejection because the selection of a thinner layer was not surprising as there was only a twenty-six percent improvement, which the court compared to another case that showed a fifty-fold improvement.²⁴⁵

2. Compared to the Closest Prior Art

The invention must be compared against the closest prior art.²⁴⁶ The comparison may be done through direct or indirect testing.²⁴⁷ The test need not

²³⁶ *Id.* at 644.

²³⁷ *Id.*

²³⁸ *Id.* at 645.

²³⁹ *See id.* at 647 (holding that the two superior properties of the claimed compound are sufficient to rebut a prima facie case of obviousness).

²⁴⁰ *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997) (quoting *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955)).

²⁴¹ *Id.* at 1470 (citing *In re Antonie*, 559 F.2d 618, 620 (C.C.P.A. 1977); *In re Dillon*, 919 F.2d 688, 692–93 (Fed. Cir. 1990) (en banc)).

²⁴² *Id.* at 1467.

²⁴³ *Id.* at 1467–68.

²⁴⁴ *Id.* at 1468.

²⁴⁵ *Id.* at 1470.

²⁴⁶ *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1370 (Fed. Cir. 2007) (quoting *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991)).

²⁴⁷ *In re Payne*, 606 F.2d 303, 316 (C.C.P.A. 1979) (citing *In re Merchant*, 575 F.2d 865, 869 (C.C.P.A. 1978); *In re Blondel*, 499 F.2d 1311, 1317 (C.C.P.A. 1974)).

compare every compound in the prior art,²⁴⁸ but should be enough to allow a determination of the effectiveness of the claimed invention, compared to the closest prior art.²⁴⁹ Yet when the prior art requires the combination of two or more references to produce the claimed invention, the patentee need not compare to non-existent prior art, i.e. the product of the suggested combination of references.²⁵⁰ To do so “would amount to requiring comparison of the results of the invention with the results of the invention”²⁵¹

3. Commensurate in Scope with the Claims

The “objective evidence of non-obviousness must be commensurate in scope with the claims.”²⁵² Otherwise there is little basis for determining that the unexpected result extends across the entire scope of the claim.²⁵³ In many cases a single species may not be enough for a broad claim,²⁵⁴ yet a narrow range may be enough if there is reason to believe that the results will extend across the scope of the claim.²⁵⁵

In *Kollman*, the Patent Office rejected a patentee’s claim for a ratio of two herbicides because there was no evidence of synergism over the entire claimed range of ratios of the two herbicides, 1:10 to 20:1.²⁵⁶ The evidence supplied by the patentee did not cover the entire scope of the claim, but it indicated a trend of increasing or decreasing effectiveness in the untested scope.²⁵⁷ For claim six, the patentee claimed a ratio of 1:1 to 4:1 of FENAC and a particular ether.²⁵⁸ The data provided only covered the ratio of 1:1 to 2:1, which showed a trend of decreased effectiveness as the ratio approached 2:1, and no data for the

²⁴⁸ *Id.* (citing *In re Holladay*, 584 F.2d 384, 386 (C.C.P.A. 1978)).

²⁴⁹ *Id.* (citing *Holladay*, 584 F.2d at 386; *Merchant*, 575 F.2d at 869).

²⁵⁰ See *In re Chapman*, 357 F.2d 418, 422 (C.C.P.A. 1966).

²⁵¹ *Id.*

²⁵² *In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003) (quoting *In re Greenfield*, 571 F.2d 1185, 1189 (C.C.P.A. 1978) (quoting *In re Tiffin*, 448 F.2d 791, 792 (C.C.P.A. 1971))).

²⁵³ *In re Lindner*, 457 F.2d 506, 508 (C.C.P.A. 1972); cf. *In re Saunders*, 444 F.2d 599, 605 (1971) (deciding that the appellants showed unexpected results even though they did not isolate every possible variable and demonstrate that substitution of their surfactants invariably led to a superior result).

²⁵⁴ *Lindner*, 457 F.2d at 508.

²⁵⁵ *In re Kollman*, 595 F.2d 48, 56 (C.C.P.A. 1979).

²⁵⁶ *Id.* at 53.

²⁵⁷ *Id.* at 56–57.

²⁵⁸ *Id.* at 49–50.

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ratios between 2:1 and 4:1.²⁵⁹ The court affirmed that this claim was obvious because the effectiveness of the herbicides approached the expected effectiveness in the untested range.²⁶⁰ Claims seven and eight covered a ratio of 1:1 to 4:1 of FENAC and two different ethers.²⁶¹ In contrast to the data for claim six, this data showed a trend of increased effectiveness as the ratio approached the untested ratios.²⁶² The court reversed the Patent Office's holding for these claims, and allowed them because it was reasonable to extend the unexpected result across the remaining scope of the claim.²⁶³

4. Disclosed Advantage

Typically the patentee discloses the unexpectedly superior results of the invention in the patent application, however sometimes advantages are realized after the application has been filed. The failure of a patentee to recognize all the advantages of their invention at the time of filing does not prevent them from using subsequently found unexpected results to argue against a determination of obviousness.²⁶⁴ The unexpected results are properties of the invention whether discovered before or after filing.²⁶⁵ Yet, if the patentee claims a different use of the invention, or makes no mention at all of the utility, the court may not consider the results.²⁶⁶

V. BALANCING "OBVIOUS TO TRY" WITH UNEXPECTED RESULTS

After a *prima facie* determination of obviousness, the courts must always consider secondary considerations and unexpected results. However, secondary considerations are considered to only be helpful in determining obvious-

²⁵⁹ *Id.* at 57.

²⁶⁰ *Id.*

²⁶¹ *Kollman*, 595 F.2d at 49–50.

²⁶² *Id.* at 56–57.

²⁶³ *Id.*; *cf. Ex parte Winters*, 11 U.S.P.Q.2d 1387, 1388 (B.P.A.I. 1989) (“[A]ppellant is not required to test each and every species within the scope of the appealed claims and compare same with the closest prior art species.”).

²⁶⁴ *Knoll Pharm. Co. v. Teva Pharms. USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 2004); *In re Zenitz*, 333 F.2d 924, 927 (C.C.P.A. 1964) (quoting *Westmoreland Specialty Co. v. Hogan*, 167 F. 327, 328 (3d Cir. 1909)).

²⁶⁵ *Knoll*, 367 F.3d at 1385.

²⁶⁶ *Zenitz*, 333 F.2d at 927–28 (distinguishing *In re Herr*, 304 F.2d 906 (C.C.P.A. 1962)).

ness; they are not determinative of non-obviousness.²⁶⁷ Unexpected results have often been considered a secondary consideration and likewise only helpful in determining obviousness.²⁶⁸ This approach is inconsistent with the importance of unexpected results in determining non-obviousness. A finding of unexpected results should always overcome a prima facie case of obviousness made through the “obvious to try” test.²⁶⁹ Secondary considerations, however, need not necessarily overcome a strong prima facie case of obviousness.²⁷⁰ The fact that an invention has unexpectedly superior results shows that it would not have been obvious.²⁷¹

There are several rationales for combining prior art references:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try”—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art

²⁶⁷ *Süd-Chemie, Inc. v. Multisorb Techs.*, 554 F.3d 1001, 1009 (Fed. Cir. 2009) (citing *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007)).

²⁶⁸ *Id.* (citing *Pfizer*, 480 F.3d at 1372).

²⁶⁹ It may be argued that unexpected results should overcome all prima facie cases of obviousness not just those made using the “obvious to try” test.

²⁷⁰ *Id.* (citing *Pfizer*, 480 F.3d at 1372).

²⁷¹ *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995).

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reference or to combine prior art reference teachings to arrive at the claimed invention.²⁷²

Of these rationales, the "obvious to try" test is the most tenuous way to create a prima facie case of obviousness. Accordingly, a showing of unexpectedly superior results should always negate it. This is not to say, however, that any showings of unexpected results should result in a finding of unexpectedly superior results that rebut obviousness.

A. Extent of "Obvious to Try"

The Federal Circuit has reasonably declined to limit the "obvious to try" test to the predictable arts, so it may be used in evaluating the unpredictable arts, such as chemistry and biotechnology.²⁷³ But application of the "obvious to try" test to unpredictable arts involves risks similar to hindsight bias. There is a possibility that a patent may be found obvious by circular reasoning. The fact that a scientist tried a reasonable approach to solving a problem and was successful could create the presumption that the inventive result was "obvious to try."²⁷⁴

Slight reflection suggests, we think, that there is usually an element of "obviousness to try" in any research endeavor, that it is not undertaken with complete blindness but rather with some semblance of a chance of success, and that patentability determinations based on that as the test would not only be contrary to statute but result in a marked deterioration of the entire patent system as an incentive to invest in those efforts and attempts which go by the name of "research."²⁷⁵

Productive research typically involves exploration of the most reasonable approaches. To expect otherwise is lunacy because the possibilities for experiments in the unpredictable arts is limitless. To only allow patents for research that use less than the most reasonable approaches in solving problems, is to reward irrational behavior.

Each of the elements of the "obvious to try" test ultimately depend upon the person of ordinary skill in the art either implicitly or explicitly. Whether there are a finite number of identified solutions depends on whether a PHOSITA

²⁷² 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. 57526, 57529 (Oct. 10, 2007).

²⁷³ *In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009).

²⁷⁴ *In re Merck & Co.*, 800 F.2d 1091, 1100 (Fed. Cir. 1986).

²⁷⁵ *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1352 (Fed. Cir. 2008) (quoting *In re Tomlinson*, 363 F.2d 928, 931 (C.C.P.A. 1966)).

would have identified a finite number of solutions. Whether there is a reason to pursue the different options depends upon whether a PHOSITA would have thought it would have been reasonable. Whether there was a reasonable expectation of success depends upon what the PHOSITA would have thought. The closer the PHOSITA resembles the actual inventor, the more a PHOSITA would mimic the decisions of the inventor, assuming that the inventor acts in a reasonable way. The “obvious to try” test then is a comparison on how closely the PHOSITA resembles the inventor, whether the inventor acted in a reasonable way, or if the inventor had a “flash of genius.” It would be absurd to decide patentability upon how closely the PHOSITA resembles the inventor.²⁷⁶ Whether the inventor acted in a reasonable way is not a measure of patentability. To make it one suggests that § 103 should reward illogical or unreasonable behavior by an inventor. A “flash of genius” is not the standard of patentability because under § 103, “[p]atentability shall not be negated by the manner in which the invention was made,” which was intended to abolish the flash of genius test.²⁷⁷ Consequently, the “obvious to try” test can potentially be a poor determinant of obviousness.

The elements of the *KSR* “obvious to try” test should prevent a superficial “obvious to try” determination based on what may be a mere offhand suggestion to combine elements to solve a problem.²⁷⁸ Nonetheless the fact that a problem has been solved by a method that was “obvious to try” does not mean that the invention does not solve the problem in a way that is superior to what could have been expected.

B. Extent of Unexpected Results

While unexpected results are the harbinger of an invention, it is possible that they may be abused by claims of unexpected results that have no impact on the invention (i.e. a pharmaceutical drug that is unexpectedly colored green). In some cases, unexpected results are merely recognition of an unknown property of the prior art and are at best creations of ordinary skill and common sense, not a patentable invention.²⁷⁹ For example, in *Ricoh*, a patentee argued that increas-

²⁷⁶ *But see* *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983) (explaining that one of the factors for determining the PHOSITA is the education level of the inventor).

²⁷⁷ 35 U.S.C. § 103 (2006); *Graham v. John Deere Co.*, 383 U.S. 1, 15 (1966).

²⁷⁸ *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

²⁷⁹ *Ricoh Co., Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325, 1333 (Fed. Cir. 2008) (citing *KSR*, 550 U.S. at 398).

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ing the speed that a laser could write to an optical disc (such as a rewritable CD or DVD) was an unexpected superior result.²⁸⁰ The speed at which a laser can write to an optical disc depends upon the physical characteristics of the material of the optical disc and the writing method of laser pulses.²⁸¹ A laser writes to an optical disc by causing a phase change in the media, making it more or less crystalline.²⁸² The patentee argued that using the same method of laser pulses to write the disc, but at a higher speed is an unexpected result.²⁸³ The court decided that claiming a previously disclosed method of writing a disc performed at a higher speed, is merely recognition of an unknown property of prior art, and consequently obvious.²⁸⁴

Care must be taken when evaluating whether a property may create patentability. A new property or use of a known composition "can not impart patentability to claims to the known *composition*,"²⁸⁵ but that may not prevent patenting the *use* of the composition. Likewise, the use of known compositions in a known process may be patentable because of the unexpectedly superior results obtained,²⁸⁶ provided of course that the compositions had not been actually used in the process in the prior art.²⁸⁷

C. Balance

Balancing obviousness through an "obvious to try" test with non-obviousness due to unexpected results may be best done through the various elements of the two tests. Initially, for this conflict to even arise, a claim must have first been found *prima facie* obvious under the "obvious to try" test described in *KSR*; i.e. that there is a reason to solve a problem, where there are (1) a finite number of identified solutions, (2) there is a reason to pursue the options, and (3) the success was anticipated.²⁸⁸ Upon a *prima facie* case of obviousness, a showing of unexpectedly superior results should always determine

²⁸⁰ *Id.*

²⁸¹ *Id.* at 1332.

²⁸² *Id.* at 1327–28.

²⁸³ *Id.* at 1332–33.

²⁸⁴ *Id.* at 1333.

²⁸⁵ *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) (emphasis added) (citing *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 782 (Fed. Cir. 1985); *In re Pearson*, 494 F.2d 1399, 1403 (C.C.P.A. 1974); *In re Lemin*, 326 F.2d 437, 440 (C.C.P.A. 1964)).

²⁸⁶ *In re Eli Lilly & Co.*, 902 F.2d 943, 947 (Fed. Cir. 1990) (citing *In re Orfeo*, 440 F.2d 439, 442 (C.C.P.A. 1971)).

²⁸⁷ Here, the process would lack novelty. See 35 U.S.C. § 102 (2006).

²⁸⁸ *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

patentability. An absolute determination of patentability eliminates a subjective balancing of whether a result is unexpected enough to overcome the prima facie case of obviousness. Instead, the court would engage in an easier factual determination of whether a result was actually unexpected or not.²⁸⁹ If unexpectedly superior results have not been shown, then the other secondary considerations will be considered.²⁹⁰

Treating unexpectedly superior results differently than other secondary considerations is logical to do. The other secondary considerations are arguably flawed to some extent,²⁹¹ and are really a best guess at obviousness based upon extrinsic evidence.²⁹² In general they have been treated by courts as something that must be considered, but may not necessarily carry much weight.²⁹³ While courts have listed unexpected results as one of the secondary considerations while citing the Supreme Court's *Graham* opinion, *Graham* does not even mention unexpected results.²⁹⁴ The Supreme Court's recent *KSR* opinion addresses separately unexpected results and secondary considerations.²⁹⁵ Instead of treating unexpectedly superior results as a secondary consideration, courts should treat them as carrying substantially more weight because they are central to the determination of obviousness.²⁹⁶ "[T]hat which would have been surprising to a person of ordinary skill in a particular art would not have been obvious."²⁹⁷

²⁸⁹ *Pfizer, Inc. v. Apotex, Inc.*, 488 F.3d 1377, 1383 (Fed. Cir. 2007) (Rader, J., dissenting) (recognizing that the trial court made the factual determination of unexpected superior properties); *In re Inland Steel Co.*, 265 F.3d 1354, 1366 (Fed. Cir. 2001) (citing *In re Mayne*, 104 F.3d 1339, 1343 (Fed. Cir. 1997)).

²⁹⁰ *Süd-Chemie, Inc. v. Multisorb Techs.*, 554 F.3d 1001, 1008 (Fed. Cir. 2009) (citing *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008)) ("[S]econdary considerations 'constitutes independent evidence of nonobviousness' and can be quite instructive in the obviousness inquiry.").

²⁹¹ Whelan, *supra* note 201, at 377–80. *But see* Wieker, *supra* note 201, at 682–83.

²⁹² *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

²⁹³ *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986); 2 DONALD S. CHISUM, CHISUM ON PATENTS § 5.05 (2005); Rebecca S. Eisenberg, *Business Law Forum: Nonobviousness—The Shape of Things to Come: Pharma's Nonobvious Problem*, 12 LEWIS & CLARK L. REV. 375, 418 (2008) (citing *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007)).

²⁹⁴ *See Graham*, 383 U.S. at 17–18.

²⁹⁵ *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406, 415–18 (2007); *see also* *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 997–98 (Fed. Cir. 2009) (treating unexpected results separately from secondary considerations).

²⁹⁶ *In re Papesch*, 315 F.2d 381, 386–87 (C.C.P.A. 1963) ("If that which appears, at first blush, to be obvious though new is shown by evidence not to be obvious, then the evidence prevails over surmise or unsupported contention and a rejection based on obviousness must fall.").

²⁹⁷ *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995).

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1. What are the Unexpected Results to be Compared Against?

While unexpectedly superior results should always overcome a determination of obviousness, that does not mean that any unexpected result is sufficient.²⁹⁸ The first step is to determine a standard against which the results of the invention are to be compared. Clearly it is the closest prior art suggested by the "obvious to try" test, which should be compared to the claimed invention.²⁹⁹ However, when the results of the claimed invention are to be compared with the results of something that has not been made before, but which may have been "obvious to try," it is not exactly clear what the comparison results should be.

The claimed invention should be compared with the results of what actually exists in the prior art.³⁰⁰ This is reasonable as one would expect that an "obvious to try" combination would produce the same result as that in the prior art. It would be unreasonable to compare to something that does not actually exist.³⁰¹ To do otherwise would "requir[e] comparison of the results of the invention with the results of the invention."³⁰²

When the prior art teaches away from making a combination, that in itself strongly suggests that almost any beneficial result would be unexpected. In *Adams*,³⁰³ there were indications in the prior art that the use of magnesium as an electrode would result in a battery that was both dangerous and inoperable.³⁰⁴ Yet the patentee used magnesium and developed a superior battery.³⁰⁵ In situations such as this, unexpected results should be relatively easy to achieve. In fact, it is questionable whether a court should even proceed to this analysis because under the "obvious to try" test there would not likely be a reason to pursue this option, nor would success be anticipated.

²⁹⁸ *Id.* at 751.

²⁹⁹ *In re Baxter Travenol Labs*, 952 F.2d 388, 392 (Fed. Cir. 1991) (citing *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984)).

³⁰⁰ *In re Geiger*, 815 F.2d 686, 689–90 (Fed. Cir. 1987) (Newman, J., concurring).

³⁰¹ *Id.* at 690.

³⁰² *In re Chapman*, 357 F.2d 418, 422 (C.C.P.A. 1966).

³⁰³ 383 U.S. 39 (1966).

³⁰⁴ *Id.* at 50.

³⁰⁵ *Id.* at 50–51.

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2. Improvement

Once a standard has been determined, the improvement must be evaluated to see if it was substantial enough to make the results unexpectedly superior. There may be two types of improvement: degree and kind. An improvement in degree is simply an improvement of a known property, or the decrease of an undesirable property.

The expectation of a person of ordinary skill in the art plays a part in the evaluation of the improvement. When there are indications in the prior art that the “obvious to try” combination of two components would result in an improvement, or a deterioration, this must be taken into consideration. Determinations of this sort have been done before by the courts through witness testimony.³⁰⁶

a. Degree of Improvement

An improvement in degree should always be sufficient if the improvement is substantial enough to enable a new use of the invention that was not possible with the prior art. For example, *Pfizer, Inc. v. Apotex, Inc.* involved a composition using a different acid addition salt that enables a pharmaceutical to be formulated as a direct compression tablet instead of the prior art capsule.³⁰⁷ An active drug molecule (amlodipine) is typically made into an acid addition salt to improve its bioavailability.³⁰⁸ The maleate addition salt of amlodipine was known in the prior art to produce excellent capsules.³⁰⁹ The besylate addition salt was one of fifty-three FDA approved addition salts at the time of the invention.³¹⁰ The Federal Circuit reasonably found that it would have been “obvious to try” to make the amlodipine besylate.³¹¹ But it did not consider the improvements of good solubility and processability, which enabled a compression tablet to be made, superior enough to rebut the prima facie case of obviousness.³¹² Instead, the court based its opinion on a lack of evidence of what the

³⁰⁶ *E.g.*, *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 998 (Fed. Cir. 2009) (determining that unexpected results, as shown by expert witnesses, were sufficient to rebut obviousness despite the fact that a prima facie case of obviousness had not been established).

³⁰⁷ *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1353–54 (Fed. Cir. 2007).

³⁰⁸ *Id.* at 1353.

³⁰⁹ *Id.*

³¹⁰ *Id.* at 1355.

³¹¹ *Id.* at 1369.

³¹² *Id.* at 1371.

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expected properties were,³¹³ and that the properties of amlodipine besylate were not sufficient to be considered unexpectedly superior results.³¹⁴ The court explained that “[c]reating a ‘product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient . . . to enhance commercial opportunities . . . is universal—and even common-sensical.’”³¹⁵ While this may be common sense, it is not a logical consequence that the way to produce a more desirable product or process is part of the public domain or obvious. If it truly were, then that more desirable product or process would actually be in use. An improvement that enables a new use, such as producing a compression tablet, which is not a trivial new use, that could not have been performed by the prior art shows unexpectedly superior results, which in turn indicate patentability.

An improvement that does not result in a new use, but only improves a product may be sufficient if the improvement is substantial enough according to a person of ordinary skill in the art.³¹⁶

b. Kind of Improvement

An improvement where the claimed invention possesses properties that were not part of the prior art can also be an indication of non-obviousness.³¹⁷ Likewise, absence of an undesirable property is also an indication of non-obviousness. A new property is one that exists in the claimed invention, but not in the prior art. Recognition by the patentee of an unknown property in the claimed compound when the prior art inherently also has the property, is not a new property conferring patentability.

For example, in a 1963 Court of Customs and Patent Appeals case, a new chemical compound was found obvious by the U.S. Patent Office because it was structurally similar to a prior art compound.³¹⁸ The court overturned the decision because the new compound, despite the structural similarities, had the

³¹³ As discussed above, the expected results should have been the results of the closest prior art, amlodipine maleate. The fact that the experts asserted the results were not predictable, and some salts would have superior and others inferior properties to amlodipine maleate does not support the idea that any of the acid addition salts would be significantly better than amlodipine maleate. *See supra* Part IV.B.2.

³¹⁴ *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1371 (Fed. Cir. 2007).

³¹⁵ *Id.* (quoting *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1368 (Fed. Cir. 2006)).

³¹⁶ *See supra* Part IV.B.1.

³¹⁷ *In re Sullivan*, 498 F.3d 1345, 1353 (Fed. Cir. 2007).

³¹⁸ *In re Papesch*, 315 F.2d 381, 382, 385–86 (C.C.P.A. 1963).

unexpected beneficial property of being an anti-inflammatory agent.³¹⁹ The prior art compound had no anti-inflammatory activity.³²⁰ Because the claimed compound had a new property that did not exist in the closest prior art, the compound was not obvious.

c. Not Reasonable Expectation of Success

One of the elements in the “obvious to try” test is that there be a reasonable expectation of success.³²¹ A reasonable expectation of success exists when there is an expectation that combining two references will solve the recognized problem. This expectation of success is different than an unexpectedly superior result. When a combination is successful the recognized problem has a working solution. In contrast, unexpected results depend upon how well the problem is solved. For example, a problem may be solved by combining two references to produce a new pharmaceutical. Yet the solution may be so successful that instead of requiring ten milligrams of the compound for a dose, only ten micrograms is required.³²² This could be an unexpectedly superior result. Alternatively, if the compound treats a disease which the prior art compounds do not, that could also be an unexpectedly superior result.

D. Policy

There are at least two reasons that unexpectedly superior results should always rebut a prima facie case of obviousness. First, the policy behind the patent system is to reward inventors for advancing science and creating new benefits for society. The crux of whether to reward an inventor with a patent depends upon whether the invention was a significant enough advance. The height of the non-obviousness barrier determines the commercial impact of the patent system.³²³ A high barrier necessitates that an invention be more significant, potentially creating a greater commercial impact than a lower barrier. Yet, a barrier that is too high, such as requiring a “flash of genius,”³²⁴ will stifle re-

³¹⁹ *Id.* at 391.

³²⁰ *Id.* at 383.

³²¹ *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

³²² Ten milligrams is 0.01 grams; ten micrograms is 0.00001 grams.

³²³ Mandel, *supra* note 39, at 80–81.

³²⁴ 35 U.S.C. § 103 (2006) (“Patentability shall not be negated by the manner in which the invention was made.”); *Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966) (interpreting § 103 to prevent a so-called “flash of genius” test).

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search because a patent will be too difficult to obtain. Alternatively, a barrier that is too low will stifle commercialization because too many patents may be granted preventing commercialization of new products. Thus, the non-obviousness barrier must be intermediate between a "flash of genius" and the pre-1952 Patent Act "obvious to try" rationale. The barrier should be high enough to give patent protection only to inventions that give sufficient benefit to society. Measuring the benefit of an invention to society is not the sort of evaluation that courts typically engage in, so a suitable proxy must be used. Unexpectedly superior results, since they are the result of the invention, are more likely to reflect the benefit that society will receive from the invention. They are more central to the benefit society receives than a comparison of evidence of obviousness with unexpected results.

Second, it is difficult to compare the evidence of a prima facie case of obviousness with a showing of unexpected results. They are two unrelated factors. A better comparison is between the expected results and the actual results. Determining whether the difference is unexpected is much easier and likely to result in a more accurate outcome. This is especially true when using the "obvious to try" test because it is inherently a poor determinant of obviousness.³²⁵ Results that are surprising to a person of ordinary skill in the art indicate non-obviousness.³²⁶ Consequently, unexpectedly superior results should always rebut a prima facie obviousness determination under the "obvious to try" test.

VI. CONCLUSION

The renewal of the "obvious to try" test is a reasonable way to prevent patents that "discover" something that marginally advances what was part of the public domain. *In re Kubin* showed that the courts will apply this test to the unpredictable sciences.³²⁷ However, courts must be careful that they examine each element of the test so as not to hold an invention obvious that had the misfortune of being discovered by the most promising avenue of research.³²⁸ Each of the elements serve to help prevent a finding of obviousness simply because a court can reconstruct the invention from selected prior art guided by hindsight.

³²⁵ See *supra* Part V.A.

³²⁶ *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995).

³²⁷ *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009).

³²⁸ Cf. *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341 (Fed. Cir. 2009) (Newman, J., dissenting) (arguing that the majority failed to consider that there must be a reasonable expectation of success).

The patent system exists to benefit society through the promotion of progress in the scientific arts. A showing of unexpected results clearly shows that the inventor has made a significant advance that is likely to result in a substantial benefit to society. The “obvious to try” test creates the most tenuous prima facie case of obviousness because to some extent it is a comparison on how closely the PHOSITA resembles the inventor, whether the inventor acted in a reasonable way, or if the inventor had a “flash of genius.” Unexpected results are the most certain way to rebut obviousness because “that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious.”³²⁹ Consequently, the measurement of the benefit to society and the certainty of the patentability of an invention are best served when unexpectedly superior results are a definitive showing of patentability.

³²⁹ *Soni*, 54 F.3d at 750.