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What About Know-How: Heightened Obviousness and Lowered Disclosure is Not a Panacea to the American Patent System for Biotechnology Medication and Pharmaceutical Inventions in the Post-KSR Era

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WHAT ABOUT KNOW-HOW: HEIGHTENED OBVIOUSNESS AND LOWERED DISCLOSURE IS NOT A PANACEA TO THE AMERICAN PATENT SYSTEM FOR BIOTECHNOLOGY MEDICATION AND PHARMACEUTICAL INVENTIONS IN THE POST-*KSR* ERA

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ABSTRACT

In *KSR International Co. v. Teleflex, Inc.*, the Supreme Court rejected the Federal Circuit's rigid application of the "teaching, suggestion, or motivation" test (TSM test), and replaced it with an "expansive and flexible" approach, in determining the question of obviousness. Nevertheless, an expansive and flexible approach to obviousness may not be consistent with the international norms of practice if it is applied literally. The U.S. Patent and Trademark Office's literal application of the *KSR* decision has essentially created another set of inflexible rules, which is contrary to the Supreme Court's intent.

The Federal Circuit's recent decision in *In re Kubin* cautiously revived "obvious to try" in its obviousness jurisprudence. However, *In re Kubin* may not represent a clear precedent for determining obviousness in the biotechnological context. Certain key technological factual issues were unclear when the court was making its judgment.

Commentators have suggested that "a fairly high obviousness threshold coupled with a fairly low disclosure requirement will produce a few very powerful patents in uncertain industries." Nevertheless, lowering the disclosure requirement in the biotechnological context would provide inventors incentives to retain more know-how and thus frustrate the purposes of the existing statutory exemptions, namely the "medical practice exemption" under 35 U.S.C. § 287(c) and the so called "FDA exemption" under 35 U.S.C. § 271(e)(1). Therefore, this Article suggests that the high disclosure requirement for biotechnological patent applications should not be sacrificed as a tradeoff for a heightened obviousness standard.

I. INTRODUCTION

Since the United States Supreme Court issued its opinion in *KSR International Co. v. Teleflex, Inc*. in 2007,[1] the decision has created legal uncertainty concerning obviousness from at least three perspectives. First, the application of the obviousness doctrine between the Federal Circuit Court of Appeals and the U.S. Patent and Trademark Office

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

(PTO) are inconsistent. Second, the PTO's practice regarding the standard of obviousness before and after *KSR* lacks consistency. Third, the obviousness standard in a re-examination proceeding after *KSR* for a patent issued before that decision is uncertain.

Though the *KSR* court revered *Graham v. John Deere Co.*[2] as the highest principle in making obviousness determinations, the *KSR* decision has essentially created the same problem that the *Graham* court sought to resolve—that is, the inconsistency among the courts and the Patent Office.

In *KSR*, the Supreme Court rejected the Federal Circuit's rigid application of "teaching, suggestion, or motivation" test (TSM test), and replaced it with an "expansive and flexible" approach, in determining the question of obviousness.[3] Before *KSR*, the Federal Circuit had developed a more rigid approach, the TSM test. In rejecting the rigid application of the TSM test, the Supreme Court replaced it with an expansive and flexible approach by stating that, "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."[4]

Nevertheless, an expansive and flexible approach to obviousness may not be consistent with the international norms of practice if it is applied literally. Moreover, even if an expansive and flexible approach to obviousness is favorable and can be justified, the PTO's literal application of the *KSR* decision has essentially created another set of inflexible rules for the determination of obviousness, which is contrary to the Supreme Court's intent.

The Federal Circuit's recent decision in *In re Kubin* cautiously revived "obvious to try" in its obviousness jurisprudence.[5] The decision has narrowed the gaps between the court and the PTO after *KSR* to some extent. However, *In re Kubin* may not represent a clear precedent for determining obviousness in the biotechnological context because certain key technological factual issues were unclear and unanswered when the court was making its judgment.[6]

Commentators have suggested that a judge-made industry-specific standard of patentability tailored for each industry in which certain common characteristics can be found is preferable. Commentators also

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2. Graham v. John Deere Co., 383 U.S. 1 (1966).
3. *KSR Int'l Co.*, 550 U.S. at 415.
4. *Id*. at 416.
5. *In re* Kubin, 561 F.3d 1351 (C.A. Fed. 2009).
6. *Id.*

suggested that "a fairly high obviousness threshold coupled with a fairly low disclosure requirement will produce a few very powerful patents in uncertain industries."[7] Nevertheless, lowering the disclosure requirement in the biotechnological context would provide inventors incentives to retain more know-how and thus frustrate the purposes of the existing statutory exemptions, namely the "medical practice exemption" under 35 U.S.C. § 287(c)[8] and the so called "FDA exemption" under 35 U.S.C. § 271(e)(1).[9]

This Article starts with the introduction of the historical background of obviousness as a requirement of patentability in various countries in Part II. Part III further examines why biotechnology invention is especially vulnerable to the challenge on the ground of obviousness. Part IV examines how the European Patent Office ("EPO") and other major patent systems, such as Germany, the United Kingdom, Canada, Japan, and China have approached the issue of obviousness, especially in the biotechnological and pharmaceutical contexts.

Then the focus of this Article turns to the American patent system. Part V begins with the examination of the application of the Federal Circuit's TSM test in biotechnological and pharmaceutical contexts before *KSR*, followed by the Supreme Court's *KSR* test, and the Federal Circuit's interpretation and application of obviousness test in the pharmaceutical context after *KSR*. In addition, this Part examines and compares the obviousness tests and their application in biotechnology cases in the PTO's practice before and after *KSR*. A discussion of the Federal Circuit's decision in *In re Kubin* follows, which may be deemed as a step in filling the gaps between the court and the PTO on the disagreement of obviousness standard in the

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7. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1682 (2003).

8. 35 U.S.C. § 287(c)(1) provides that:

> With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

9. 35 U.S.C. § 271(e)(1) provides that:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

biotechnological context.

This Article suggests that a judge-made industry-specific standard of obviousness in biotechnological and pharmaceutical contexts is consistent with the Supreme Court's teaching in *KSR* that the evaluation of obviousness should remain flexible. Nevertheless, the current high disclosure requirement for biotechnological patent applications should not be sacrificed as a tradeoff for a heightened obviousness standard.

II. HISTORICAL BACKGROUND OF OBVIOUSNESS

"Non-obviousness," "inventive step," or "inventive level" is a relatively new requirement of patentability compared to novelty and utility.[10] Novelty and utility were regarded as common law prerequisites for the issuance of a privilege and the predecessors of patentability requirements.[11] Unlike novelty or utility, non-obviousness is a product of modern patent law and was not developed until the middle of the nineteenth century and the early twentieth century.[12]

Section 103 of the present American Patent Act provides that obviousness shall be tested by reference to the differences between the invention and the prior art.[13] The non-obviousness criterion was codified in the 1952 American Patent Act as a requirement that the claimed invention taken as a whole not be obvious to one of ordinary skill in the art at the time the invention was made.[14]

The new provision was intended by Congress to abolish the "flash of genius" test set by the Supreme Court and to instigate a milder standard of inventiveness.[15] However, there was no case law or literature about the meaning of the new provision until 1966 in the Supreme Court's opinion, *Graham v. John Deere Co.*[16]

Across the Atlantic Ocean, it was not until the British Patent Act of 1977, the inventive step, which was the European counterpart of obviousness, was fully introduced into the British patent statute as a separate patentability requirement.[17] In England, though the

10. Friedrich-Karl Beier, *The Inventive Step in Its Historical Development*, 3 I.I.C. 301, 301–03 (1986).

11. *Id*. at 302–03.

12. *Id*. at 303.

13. 35 U.S.C. § 103(a) (2000).

14. Burk & Lemley, *supra* note 7, at 1648–49; 35 U.S.C. § 103 (2000).

15. Beier, *supra* note 10, at 309.

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

17. Beier, *supra* note 10, at 313.

requirement of an inventive step was first introduced in 1932 into the British patent statute,[18] it was initially only as a ground for revocation of issued patents.[19]

It was recognized in England, earlier than elsewhere, that a small step may advance the art.[20] Contrary to the United States' patent system, as Friedrich-Karl Beier has stated, the primary emphasis of the introduction of inventive step to the British patent system was the technical and economic importance of the differences between the prior art and the claimed invention, rather than "the kind of creative criteria or the more or less ingenious abilities of the inventor."[21]

As commentators have observed, in the United States, much of the case law concerning the person having ordinary skill in the art arises out of the consideration of the obviousness standard in § 103 of the Patent Act.[22] It contributes to the result that the application of the person-having-ordinary-skill-in-the-art standard varies by industry, which led to, for example, fewer but broader software patents, and more but narrower biotechnology patents.[23]

The development of a higher patentability requirement in Germany has its unique historical background. In Friedrich-Karl Beier's opinion, it was the creation of the protection of utility models for smaller technical improvements that freed the hands of the German patent system and German courts to demand additional prerequisites for patent protection and higher standards for the originality or works of applied arts.[24]

The German Utility Model Act of 1891 introduced a new form of protection which came into force with the amended Patent Act.[25] Under the utility model system, in addition to the protection of examined patents, a simpler and faster protection could be obtained without previous examination.[26] The protection of utility model, which still exists today, allowed the German patent system and courts to apply stricter standards for the longer lasting and better protected patents.[27]

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18. *Id*.
19. *Id*.
20. *Id*. at 312.
21. *Id*.
22. Burk & Lemley, *supra* note 7, at 1648.
23. *Id*. at 1650.
24. Beier, *supra* note 10, at 319.
25. *Id*.
26. *Id*.
27. *Id*.

Nevertheless, the requirement of patentability in Germany has changed in the process of harmonizing European patent law since the 1960's.[28] The prerequisite of inventive step was introduced into the German patent statute.[29] In addition, the advance in art, or technical progress, as a separate patentability requirement for seeking German patent protection was entirely dismissed.[30]

Though obviousness is a relatively new concept compared to other patentability requirements, the advance of technology has continuously challenged and forced the relevant authority to re-examine the feasibility of such a standard. Specifically, the diversity of technologies today has raised the question whether a standard created before a specific industry emerging can be feasibly employed without modification to determine the inventiveness of an invention in such an industry. Biotechnology is simply one among many examples.

III. THE NATURE OF BIOTECHNOLOGY MEDICATION AND PHARMACEUTICALS

Both traditional and modern definitions of biotechnology acknowledge that sharing techniques and experiment procedures are essential to the development of biotechnology. Biotechnology has been generally defined as "the use of biology or biological process to develop helpful products and services."[31] A modern definition of biotechnology is "the set of biological techniques originally resulting from basic research, specifically molecular biology and genetic engineering, and now used for research and product development."[32] Popular examples of biotechnology techniques and processes include recombinant DNA, polymerase chain reaction (PCR) technology, DNA sequencing instruments, and expressed sequence tags (EST).[33] These technologies and processes are all useful research tools which have greatly enhanced the progress of biotechnology.[34]

Though building-block technologies have enhanced the progress of biotechnology, in the mean time, they also have served as prior art to

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28. *Id*. at 323.

29. *Id*.

30. *Id*.

31. U.S. Dep't of Agric., Biotechnology & Genomics, http://www.csrees.usda.gov/nea/biotech/biotech_all.html (last visited Apr. 16, 2009).

32. *Id*.

33. Tanuja V. Garde, *Supporting Innovation in Targeted Treatments: Licenses of Right to NIH-Funded Research Tools*, 11 MICH. TELECOMM. & TECH. L. REV. 249, 273 (2005).

34. *Id*.

block certain valuable inventions from attaining patent protection on the ground of obviousness. In turn, these potentially valuable inventions may not be able to attract sufficient financial funding to move forward. Without patent protection, potential funders for the inventions may withhold their funding for fear that the inventions would be copied by free-riders easily when the inventions become matured.

In addition, "[t]he ready availability of tools for finding a new biotechnology product does not change the high cost and uncertainty entailed in developing a marketable product using those tools."[35] Many patentable inventions in biotechnology spring from known components and methodologies found in the prior art. Such combinations of prior art may be logical to try, but the advances "are only won through trial and error, at great effort and expense, and with only a low probability of success in achieving the claimed invention."[36] As the Biotechnology Industry Organization has argued in the amicus brief in *KSR International Co. v. Teleflex, Inc.*,[37] "[r]esearch and development in the biotechnology industry is particularly expensive, time-consuming, and presents an unusually high-risk investment that relies on an objective and predictable application of obviousness law."[38]

Nevertheless, 35 U.S.C. § 103(a) provides that "[p]atentability shall not be negatived by the manner in which the invention was made."[39] It is true that research tools, such as bioinformatics and DNA databases, have enhanced biotechnology research. However, if the ease of a research process is taken into account in a negative sense to counteract the finding of non-obviousness, then the length of time, the amount of money, or the quality and quantity of human resources devoted to a certain invention should be taken into account in a positive sense for the finding of non-obviousness.

Biotechnology shares the common characteristics of pharmaceutical industry and DNA research. The long development and testing lead time characteristic of pharmaceuticals can also be found in DNA-related innovation.[40] As commentators have observed, "[i]f any technology fits the criteria of high-cost, high-risk innovation, it is

35. Burk & Lemley, *supra* note 7, at 1678.

36. Brief for Biotechnology Industry Organization as Amicus Curiae Supporting Respondents at 2, *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007) (No. 04–1350).

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

38. Amicus Curiae Brief for Biotechnology Industry Organization at 8, KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398 (2007) (No. 04-1350).

39. 35 U.S.C. § 103(a) (2000).

40. Burk & Lemley, *supra* note 7, at 1624–25.

certainly biotechnology."[41]

The patent law has been perceived by some as conflicting with the traditional norms of sharing in the field of biotechnology research.[42] Nevertheless, the norm may be changing or has been changed when modern biotechnology in general is no longer confined in basic research but focusing on how to reduce to practice and benefit the public. "[I]nnovation in the biomedical fields, while critical to human health, also poses concerns for health and safety until the long-term effects of new drugs can be determined."[43] The underlying policy is best illustrated in the statement made by the Legal Board of Appeal of the EPO in *T1020/03*, which reads:

> It is the very responsible task of physicians to treat their patients according to the best method known to the physician, and the more well-established the method is the more certain the physician can be of its success. However the knowledge as to the best treatments has to be gained somehow, from *in vitro* tests, *in vivo* tests on cells and animals, and clinical trials under specially supervised conditions. This needs to be financed.[44]

Inventing a new drug or a biomedical product is only the beginning of the process, not the end.[45] Industries that must spend more time and money in research and development ("R&D") generally have a greater need for patent protection.[46] For instance, the R&D, drug design, and testing of a new drug in the pharmaceutical industry can take a decade or more and cost hundreds of millions of dollars.[47] Moreover, the Food and Drug Administration (FDA) requires a lengthy and rigorous set of tests before companies can release drugs or biotechnology medications to the market.[48] It makes the already expensive process even more costly.

As Professor Merges has proposed, obviousness or non-obviousness

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41. *Id*. at 1676.

42. Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 184–85 (1987).

43. Burk & Lemley, *supra* note 7, at 1588.

44. *T1020/03 Genentech Inc./Method of Administration of IGF-I* [EPO (Legal Bd. App.)], [2006] E.P.O.R. 9: 67, 93.

45. Burk & Lemley, *supra* note 7, at 1616.

46. *Id*. at 1583.

47. *Id*. at 1581.

48. *Id*. at 1616.

should be viewed as a function of uncertainty.[49] Where uncertainty is high, courts should moderately lower the standard of patentability to compensate for the risk of failure.[50] Under the theory, uncertain and high-cost innovation, especially for those which are very expensive in the early stages, should more likely be entitled to a determination of non-obviousness.[51]

The Federal Circuit has concluded that chemistry, pharmaceutical research, and biotechnology are inherently uncertain disciplines.[52] In addition to Professor Merges's uncertainty-based view of obviousness,[53] commentators have also suggested that, if patents are to drive innovation in biotechnology, rather than merely invention, courts must take account of the cost and uncertainty of post-invention testing and development.[54] "Where commonalities within an industry can be identified, tailoring may sometimes be best accomplished via judicial application of a bright-line rule."[55] This led to the proposal of judge-made industry-specific standards of patentability.[56]

Though commentators suggested that "a fairly high obviousness threshold coupled with a fairly low disclosure requirement will produce a few very powerful patents in uncertain industries,"[57] a lower disclosure requirement may impede biotechnology research and use to a greater extent than the benefit brought about by granting fewer patents. Specifically, lowering the disclosure requirement for biotechnology inventions would frustrate non-infringing use, such as the "medical practice exemption" under 35 U.S.C. § 287(c)[58] and the so-called "FDA

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49. *See* Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1 (1992).

50. *Id*. at 4.

51. *Id*. at 69.

52. *See, e.g.*, Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1208–09 (Fed. Cir. 1991) (finding that biotechnology is an uncertain discipline); Burk & Lemley, *supra* note 7, at 1655.

53. Merges, *supra* note 49, at 3.

54. Burk & Lemley, *supra* note 7, at 1678.

55. *Id*. at 1639.

56. *Id*. at 1696.

57. *Id*. at 1682.

58. 35 U.S.C. § 287(c)(1) provides that:

> With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

exemption" under 35 U.S.C. § 271(e)(1).[59]

Lowering the high disclosure requirement would increase the burden of a non-infringing user in acquiring additional information, namely the know-how,[60] for an effective use regardless of whether the patent for that invention is granted. Biotechnology research, as well as the use of biotechnology, requires a high demand of precision. High precision in operating such technology generally relies on a high disclosure requirement in the prior art. Lowering the disclosure requirement would provide inventors incentive to retain more "know-how." Without first acquiring such information from the inventor, non-infringing use would be unlikely if the high disclosure requirement is removed. It would essentially grant inventors more leverage to hinder legitimate use by others.

As evidenced by the study of point mutation[61] or single mutation,[62] one single nucleotide or amino acid missing or misplaced at a critical site may cause reading-frame shifting, drastic loss of specificity, or change of characteristic in the resulting DNA, RNA, or protein. When a non-infringing use becomes too burdensome, it essentially renders the statutory exemption meaningless. Thus, lowering the disclosure requirement, even just exempting one single nucleotide or amino acid from disclosure, would be enough to cripple the existing statutory exemptions.

Moreover, unlike "obvious to try" as an indicator of "obviousness"

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59. 35 U.S.C. § 271(e)(1) provides that:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

60. *See* BRIAN G. BRUNSVOLD ET AL., DRAFTING PATENT LICENSE AGREEMENTS 193 (BNA Books 2008) (1971).

61. Point mutation is defined as "[a] single nucleotide base change in the DNA. A point mutation may consist of the loss of a nucleotide, the insertion of an additional nucleotide, or the substitution of one nucleotide for another." MedicineNet.com, *Definition of Point Mutation*, http://www.medterms.com/script/main/art.asp?articlekey=4968 (last visited Feb. 17, 2009). A classical example of human diseases caused by a point mutation is sickle cell anemia. *See id*.

62. For example, a single amino acid substitution in N1 nuraminidase of human influenza virus confers the virus high level drug resistance to oseltamivir. World Health Org., *Influenza A (H1N1) Virus Resistance to Oseltamivir*, *available at* http://74.125.47.132/search?q=cache:VXLj600kE1oJ:www.who.int/csr/disease/influenza/oseltamivir_summary/en/index.html+single+mutation&hl=en&ct=clnk&cd=4&gl=us (last visited Feb. 17, 2009).

in other disciplines, "obvious to try" is an anomaly in the biotechnological and pharmaceutical contexts. Because of the high costs of biotechnology and pharmaceutical research, a research proposal is unlikely to receive grants or any sort of financial support without the projection of a "reasonable expectation of success." Nevertheless, a documented "reasonable expectation of success" would render an invention "obvious to try" under a "one-size-for-all" obviousness standard. As a result, only very few, if any, biotechnology or pharmaceutical inventions can escape from the suspicion of "obvious to try" if the nature of the industry and the characteristic of the technology is not taken into consideration.

As a result, the judge-made industry-specific obviousness standard for biotechnology medication and pharmaceutical inventions suggested in the thesis is referred to as a lower obviousness threshold coupled with a high disclosure requirement. Before turning the focus of this Article to the American patent system, Part IV first examines how other major patent systems have approached the issue of obviousness, especially in the biotechnological and pharmaceutical contexts. Specifically, the Canadian system may be deemed as an example of the judge-made industry-specific approach, though this approach is traceable to English case law.

IV. OBVIOUSNESS IN OTHER PATENT SYSTEMS

The Federal Circuit Court of Appeals has extensive jurisdiction over patent-law claims in which district courts would have jurisdiction under 28 U.S.C. § 1338(a).[63] Because of the lack of competing circuits in adjudicating patent issues, including obviousness, a comparative study among other major patent systems may have some value before discussing the obviousness jurisprudence in the United States.

The obviousness examinations in major patent systems may be sorted into three basic categories. The first category is a rigid step-by-step analysis, as exemplified by the EPO practice. The second type is a judge-made industry-specific approach, as exemplified by the Canadian common law. The third approach is a higher obviousness standard supplemented with a less stringent utility model protection as a safety net, as represented by the German patent system.

Nevertheless, some patent systems choose to adopt certain features

63. *E.g.*, Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc., 535 U.S. 826, 834 (2002); 28 U.S.C. § 1338(a)(2007) (providing "[t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patent").

from different models and thus signify the compromise among different models. The obviousness tests adopted in the United Kingdom and Japan are step-by-step analysis but they are not as rigid as the EPO approach. It is interesting to note that the Chinese patent system has adopted an agency-generated industry-specific obviousness standard for chemical compounds and biotechnology inventions, although judges are not allowed to make law under its current political and legal system. In addition to China, Japan represents another civil law system that has adopted industry-specific inventive-step rules for biotechnology inventions.

A. The Practice of the European Patent Office

The analysis of obviousness in the EPO's practice is a rigid step-by-step approach.[64] It is called the problem-and-solution approach.[65] This approach is a means to show that an invention is lacking an inventive step "by demonstrating the existence of an obvious route" between the closest prior art and the claimed invention.[66] The goal of this approach is to assess inventive step in an objective and predictable manner.[67]

"Inventive step" is the European equivalent of "non-obviousness." Article 56 of the European Patent Convention provides that "[a]n invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art."[68] As non-obviousness, inventive step is a requirement of patentability.

The problem-and-solution approach is essentially comprised of three steps:[69] (i) determining the "closest prior art";[70] (ii) establishing the "objective technical problem" to be solved;[71] and (iii) considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the

64. *See* George S.A. Szabo, *The Problem and Solution Approach in the European Patent Office*, 4 I.I.C. 457, 458 (1995).

65. Guidelines for Examination in the European Patent Office, pt. C, ch. IV, § 11.7. (European Patent Office, Dec. 2007).

66. Szabo, *supra* note 64, at 458.

67. Guidelines for Examination in the European Patent Office, *supra* note 65, pt. C, ch. IV, § 11.7.

68. European Patent Convention art. 56, Oct. 10, 1973, revised Dec. 13, 2007.

69. Guidelines for Examination in the European Patent Office, *supra* note 65, pt. C, ch. IV, § 11.7.

70. *Id*.

71. *Id*.

skilled person.[72]

First, the closest prior art is a single reference, which constitutes the most promising starting point for an obvious development leading to the claimed invention.[73] Contrary to the doctrine of inherency in U.S. practice, as George S.A. Szabo has explained, the recognizable content of the closest prior art should not include hidden properties which the skilled person cannot be aware of.[74] In practice, the closest prior art is selected from references which correspond to a similar use and require the minimum of structural and functional modifications to arrive at the claimed invention.[75] The closest prior art being selected may be different from the prior art of which the applicant was actually aware at the time the application was filed.[76]

Combination of other references with the closest prior art is permissible.[77] However, "the fact that more than one disclosure must be combined with the closest prior art in order to arrive at a combination of features may be the sign of the presence of an inventive step."[78]

Second, the objective technical problem in the problem-and-solution approach context "means the aim and task of modifying or adapting the closest prior art to provide the technical effects that the invention provides over the closest prior art."[79] In formulating the problem, one should study the patent application, the closest prior art, and identify their difference.[80] The difference is also called "the distinguishing features" of the invention.[81] The distinguishing features between the invention and the closest prior art can be either structural or functional.[82]

In order to avoid hindsight judgment, the objective technical problem must not contain any pointer to the technical solution offered

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72. *Id*.

73. Guidelines for Examination in the European Patent Office, *supra* note 65, pt. C, ch. IV, § 11.7.1. The single reference being selected "should be directed to a similar purpose or effect as the invention or at least belong to the same or a closely related technical field as the claimed invention." *Id*.

74. Szabo, *supra* note 64, at 463.

75. Guidelines for Examination in the European Patent Office, *supra* note 65, pt. C, ch. IV, § 11.7.1.

76. *Id*. § 11.7.2.

77. *Id*. § 11.8.

78. *Id*.

79. *Id*. § 11.7.2.

80. *Id*.

81. *Id*.

82. *Id*.

by the invention.[83] In addition, the term "technical problem" does not suggest that the technical solution must be a technical improvement over the prior art.[84] Thus, as George S.A. Szabo has explained, "all quantitative and qualitative characteristics of the result, attributable to the modifications of the prior art in question, should be given credit."[85] On the other hand, where no problem at all can be recognized in the closest prior art, the consequence is that the claimed invention is necessarily non-obvious with respect to the closest prior art.[86]

In the final stage of analysis, it is specifically called the "could-would approach."[87] This is another measure to avoid hindsight judgment in the analysis. The key is to ask whether there is any teaching in the prior art as a whole that "would," rather than just "could," have prompted the skilled person, "faced with the objective technical problem, to modify or adapt the closest prior art while taking account of that teaching, thereby arriving at something falling within the terms of the claims, and thus achieving what the invention achieves."[88] It is irrelevant to the analysis whether a skilled person "could" have done the same thing as the applicant.

In practice, the burden is on the EPO or with the opponent to prove that "a skilled person would have done so" and to refute the presumption of patent validity.[89] As George S.A. Szabo has observed, this is contrary to the practice in the United States.[90] In the United States, the possibility of "could" usually evokes a prima facie obviousness objection leaving the applicants with the difficult task of proving that "a skilled person would not have done the same."[91]

The inventive-step test in the EPO practice is a rigid step-by-step analysis. It is carefully crafted to avoid hindsight judgment, which is often stated as "a skilled person could have done the same." Though Germany is a signatory state of the European Patent Convention (EPC), some have observed that the inventive-step standard in the

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83. *Id*.

84. *Id*. "[T]he problem could be simply to seek an alternative to a known device or process providing the same or similar effects or which is more cost-effective." *Id*.

85. Szabo, *supra* note 64, at 466.

86. *Id*.

87. Guidelines for Examination in the European Patent Office, *supra* note 65, pt. C, ch. IV, § 11.7.3.

88. *Id*.

89. Szabo, *supra* note 64, at 475.

90. *Id*.

91. Szabo, *supra* note 64, at 475.

German patent system may be higher than the EPO practice due to procedural reasons. Nevertheless, the German utility model system has provided sufficient protection to inventions which possess relatively minor inventive steps.

B. Obviousness in Germany

Germany had abandoned the requirement of "technical progress," which was considered a higher standard of obviousness, after its harmonization with the European patent system.[92] However, some have observed that the concept of "technical progress" continued to affect the German courts' determination of inventive step or obviousness at least in certain cases.[93] Alternatively, others have suggested that the difference of inventive step between the German patent system and the EPO practice, if any, is due to the accessibility and the different weight given to evidence such as prior art[94] or secondary consideration.[95] Nevertheless, a higher standard of obviousness can be justified under the German patent system because in difficult cases, such as the second medical indication of a pharmaceutical, the utility model protection may be available.[96]

Though "technical progress" is no longer a prerequisite of patentability under the German patent system, the German Federal Supreme Court in *Trigonellin* stressed that, it should not be the purpose of patent law to protect and encourage nonsense.[97] Under the European patent system, national courts are bound by the EPO and the Implementation Regulation but not the Examination Guidelines.[98] As Alfred Keukenschrijver has observed, the German Federal Patent Court is often dissatisfied with the level of inventive step that the EPO

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92. Beier, *supra* note 10, at 323.

93. Alfred Keukenschrijver, *European Patents with Effect for Germany in the Light of Recent Federal Supreme Court Decisions*, 7 I.I.C. 711, 720 (2003).

94. *See, e.g., id*. at 711; Rüdiger Rogge, *The Revocation of European Patents in Germany*, 2 I.I.C. 217 (1996).

95. *See* Jochen Pagenberg, *Different Level of Inventive Step for German and European Patents? The Present Practice of Nullity Proceedings in Germany*, 6 I.I.C. 763 (1991) [hereinafter Pagenberg, *Different Level*].

96. Dieter R. Schneider, *Patenting of Pharmaceuticals—Still a Challenge?*, 5 I.I.C. 511, 518–19 (2008).

97. Keukenschrijver, *supra* note 93, at 720. The German Federal Supreme Court's *Trigonellin* decision was issued in 2001. *Id*. at 719; Bundesgerichtshof [BGH] [Federal Court of Justice] 2001, 147 Gewerblicher Rechtsschutz und Urheberrecht [GRUR] 730 (F.R.G).

98. *Id*. at 714.

applies.[99] However, after examination of twenty-nine decisions rendered by the German Federal Supreme Court from 1996 to 2000, he concluded that, at least statistically, there is no proof that the German Federal Supreme Court has a hostile attitude towards European patents.[100] If the German courts evaluate the inventive step differently from the EPO, it was suggested that it may arise from two possibilities, namely the admissibility of evidence[101] and the different weight given to secondary considerations.[102]

First, the German procedural law has adopted "the principle of the unrestricted assessment of evidence," while only documented and published evidence is admissible in the EPO practice.[103] Therefore, the discrepancy between the German courts and the EPO concerning the problem-and-solution-approach may arise from the definition of the person skilled in the art resulting from different sources of evidence.[104] For instance, the EPO has criticized the German Federal Supreme Court for imposing a high level of specialist skills without citing any published evidence in certain cases.[105]

Second, it was suggested that the weight given to secondary considerations may have affected the determination of inventive step in the German patent system, but it was inconclusive. It has long been debated that various German courts have weighed secondary considerations differently.[106] However, it is inconclusive whether this factor, if it exists, has affected the inventive-step standard in the German patent system.

Though the German patent system has arguably adopted a higher inventive-step standard compared to the EPO practice, the German utility model system has served as a safety net providing sufficient

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99. *Id*. at 713.

100. *Id*.

101. *See, e.g., id*. at 711 (2003); Rogge, *supra* note 94.

102. *See, e.g*., Jochen Pagenberg, *Examination for Nonobviousness—A Critical Comment on German Patent Practice*, 1 I.I.C. 1 (1981) [hereinafter Pagenberg, *A Critical Comment*]; Ernst K. Pakuscher, *Examination for Nonobviousness—A Response*, 6 I.I.C. 816 (1981); Jochen Pagenberg, *Examination for Nonobviousness—Concluding Observations*, 6 I.I.C. 824 (1981) [hereinafter Pagenberg, *Concluding Observations*]; Pagenberg, *Different Level, supra* note 95.

103. Keukenschrijver, *supra* note 93, at 715.

104. *Id*.

105. *Id*. at 718.

106. *See, e.g.,* Pagenberg, *A Critical Comment*, *supra* note 102; Pakuscher *supra* note 102; Pagenberg, *Concluding Observations*, *supra* note 102; Pagenberg, *Different Level*, *supra* note 95, at 763.

protection to inventions which possess relatively minor inventive step. For instance, under German law, processes are generally excluded from utility model protection and "uses" are regarded as a form of processes.[107] Nevertheless, in difficult cases, such as the second medical indication of a pharmaceutical, the German Federal Supreme Court in *Arzneimittelgebrauchsmuster* stated that the use of a pharmaceutical is more closely linked to a substance than to a process.[108] Therefore utility model protection is possible.[109]

A higher obviousness standard under the German patent system can be justified because the utility model protection has served as a safety net for inventions in which the inventive step is difficult to evaluate. Like Germany, the United Kingdom is under an obligation to harmonize its patent system with its European counterparts. However, unlike Germany, the United Kingdom has its common law tradition, which is distinct from the civil law systems on the European continent. Under a common law system, the evolution of law primarily rests in the courts.

C. Obviousness in the United Kingdom

The inventive-step analysis in the United Kingdom is flexible in that it has taken specific categories of inventions, such as chemical class claim, and the high-tech nature of an invention into account. In a recent case reviewed by the English House of Lords, Lord Walker of Gestingthorpe has stated that a precedent decided more than four decades ago may not be applicable to a case concerning modern technology which did not even exist when the precedent was decided. Specifically, an "obvious to try" rationale stemming from a low-tech process may not be applicable to a high-tech context.

The English Court of Appeal first established its inventive-step test in *Windsurfing International, Inc. v. Tabur Marine, Ltd.*[110] In 2007, the

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107. Schneider, *supra* note 96, at 519.

108. *Id.* at 518; Bundesgerichtshof [BGH] [Federal Court of Justice] Oct. 5, 2005, Gewerblicher Rechtsschutz and Urheberrecht [GRUR] 135, 136 (F.R.G.).

109. *Id.* at 519.

110. Windsurfing Int'l, Inc. v. Tabur Marine, Ltd., [1985] R.P.C. 59, 73–74 (C.A.) (Civ. Div.). The original test includes four steps:

> The first is to identify the inventive concept embodied in the patent in suit. Thereafter, the court has to assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and to impute to him what was, at that date, common general knowledge in the art in question. The third step is to identify what, if any, differences exist between the matter cited as being "known or used" and the alleged invention. Finally, the court has to ask itself whether,

English Court of Appeal modified and restated the *Windsurfing* test in *Pozzoli SPA v. BDMO SA*.[111] The court summarized the restated *Windsurfing* test as the following:

> (1) (a) Identify the notional "person skilled in the art"
> (b) Identify the relevant common general knowledge of that person;
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
> (3) Identify what, if any, differences exist between the matter cited as forming part of the 'state of the art' and the inventive concept of the claim or the claim as construed;
> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?[112]

Before indentifying the inventive concept of a claim, there should be claim construction to find out what the claim means.[113] In principle, the inventive concept should be derived from the claim in question, rather than some generalized concept derived from the specification as a whole.[114] However, the principle is not so wooden.[115] The *Pozzoli* court acknowledged that it may be impractical to identify the inventive concept in certain cases, such as a chemical class claims.[116] After all, "[i]n the end what matters is/are the difference(s) between what is claimed and the prior art."[117]

In 2008, the House of Lords reaffirmed that the question of obviousness should be determined by reference to the claim in issue, rather than some vague paraphrase based upon the extent of the disclosure in the description.[118] In *Conor Medsystems, Inc. v. Angiotech*

> viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they require any degree of invention.

Id.

111. Pozzoli SPA v. BDMO SA, [2007] EWCA Civ 588.
112. *Id.* ¶ 23.
113. *Id.* ¶ 17.
114. *Id*.
115. *Id*.
116. *Id.* ¶ 20.
117. *Id.* ¶ 19.
118. Conor Medsystems, Inc. v. Angiotech Pharms., Inc., [2008] UKHL 49, ¶ 19.

Pharmaceuticals, Inc., Lord Hoffmann rebuffed the challenger's argument as "watering down the claimed invention by reference to what [the challenger] said were inadequacies in the specification."[119]

The English patent system has long recognized that an "obvious to try" test can be relevant in an obviousness inquiry. However, the House of Lords also recognized that the "obvious to try" test has its limitation. In *Conor Medsystems*, Lord Walker of Gestingthorpe cautioned about being trapped into the anomaly of "obvious to try" in his separate opinion.[120] Lord Walker of Gestingthorpe restated the observation made by the EPO concerning obvious to try:

> If the reward for finding a solution to a problem and securing a monopoly for that solution is very high, then it may well be worthwhile for large players to examine all potential avenues to see if one gives the right result, even though the prospects of any one of them succeeding are much less than 50/50. What makes something worth trying is the outcome of a simple risk to reward calculation. Yet, if the reward is very large, the avenues worth trying will be expanded accordingly. So, the more commercially attractive the solution and the more pressing the public clamour for it, the harder it will be to avoid an obviousness attack.[121]

As Lord Walker of Gestingthorpe has stated, the English precedent[122] establishing the rationale of "obvious to try" was decided more than four decades ago, and that case was concerned with a fairly low-tech process.[123] During the last forty years, the volume of biotechnology and pharmaceutical research has increased enormously.[124] The potential rewards in worldwide markets are great and the competition is fierce.[125] "In this climate 'obvious to try' has tended to take on a life of its own as an important weapon in the armory of those challenging the validity of a patent."[126] Quoting from Sir Hugh Laddie, Lord Walker of Gestingthorpe restated that "as technology advances rapidly, this is a serious and growing problem."[127]

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119. *Id.*
120. *Id.* ¶¶ 45–48.
121. *Id.* ¶ 48.
122. *Johns-Manville Corporation's Patent*, [1967] R.P.C. 479.
123. *Conor Medsystems, Inc*., UKHL 49, ¶ 47.
124. *Id*.
125. *Id*.
126. *Id*.
127. *Id.* ¶ 48.

Recent opinions of the English courts have suggested a trend of an industry-specific obviousness analysis for the biotechnology medications or pharmaceuticals, though the underlying reason may be, at least in part, due to the English patent system's obligation as a signatory state of the EPC in harmonizing with its European counterparts. As technology advances, Lord Walker of Gestingthorpe in the English House of Lords has opined that a precedent decided more than four decades ago may not be applicable to a case concerning modern technology which did not even exist when the precedent was decided.[128] Moreover, an "obvious to try" rationale stemming from a low-tech process may not be applicable to a high-tech context. On the other hand, the Canadian patent system is an example which has elected an industry-specific approach without a mandate to harmonize with other patent systems.

D. Obviousness in Canada

The Canadian patent system has essentially adopted a judge-made industry-specific obviousness standard, at least for pharmaceutical inventions. This approach, as exemplified by the selection patent doctrine, has a root traceable to the English case law. In a recent case reviewed by the Canadian Supreme Court, the Court further interpreted "obvious to try" as a high burden of proof if a challenger chooses to argue on this ground.

The Canadian obviousness jurisprudence was first enunciated by the Federal Court of Canada, Appellate Division, in *Beloit Canada Ltd. v. Valmet Oy*.[129] It was later adopted by the Canadian Supreme Court in *Whirlpool Corp. v. Camco, Inc.*[130]

The *Beloit* court started its analysis by defining what a technician skilled in the art would possess.[131] In the *Beloit* court's view, for the purpose of determining obviousness, a technician skilled in the art should possess "no scintilla of inventiveness or imagination."[132] In other words, the hypothetical technician skilled in the art must be unimaginative.[133]

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128. Conor Medsystems, Inc. UKHL 49, ¶ 47.

129. Beloit Canada, Ltd. v. Valmet Oy, [1986], 8 C.P.R. (3d) 289 (Fed. C.A.).

130. Whirlpool Corp. v. Camco, Inc., [2000] 9 C.P.R. (4th) 129, ¶ 49 (S.C.C.); *see also, e.g.* Procter & Gamble Pharms. Canada, Inc. v. Canada, [2004], 37 C.P.R. (4th) 289, ¶ 45 (Fed. C.A.).

131. *Beloit Canada*, 8 C.P.R. (3d) 289, ¶ 17.

132. *Id.*

133. Apotex, Inc. v. Wellcome Found., Ltd., [2000], 10 C.P.R. (4th) 65, ¶ 63 (Fed. C.A.).

The court stressed that non-obviousness is "a very difficult test to satisfy."[134] The question in an obviousness analysis to be asked is whether a technician skilled in the art "would, in the light of the state of the art and of common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent."[135]

In addition, the *Beloit* court expressed its caution about the adoption of expert testimony in the determination of obviousness. In the court's view, expert testimony is admissible even on "an 'ultimate issue' question such as obviousness."[136] However, it must be treated with extreme care,[137] because "[e]very invention is obvious after it has been made, and to no one more so than an expert in the field."[138] "Where the expert has been hired for the purpose of testifying, his infallible hindsight is even more suspect."[139] Therefore, before an expert's assertion can be given any weight, the expert must have a satisfactory answer to the question, "Why didn't you do it if it is so easy?"[140]

It is worth noting that the Canadian Federal Court of Appeal has extended the selection patent doctrine to the selection between two isomers of a racemate[141] in *Sanofi-Synthelabo Canada, Inc. v. Apotex,*

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134. *Beloit Canada*, 8 C.P.R. (3d) 289, ¶ 17.

> The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right. The question to be asked is whether this mythical creature (the man in the Clapham omnibus of patent law) would, in the light of the state of the art and of common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent. It is a very difficult test to satisfy.

Id.

135. *Id*.

136. *Id.* ¶ 20.

137. *Id*.

138. *Id.* ¶ 21.

> Every invention is obvious after it has been made, and to no one more so than an expert in the field. Where the expert has been hired for the purpose of testifying, his infallible hindsight is even more suspect. It is so easy, once the teaching of a patent is known, to say, "I could have done that"; before the assertion can be given any weight, one must have a satisfactory answer to the question, "Why didn't you?"

Id.

139. *Id*.

140. *Id*.

141. A racemate is a substance containing equal amounts of two optical isomers, known as the dextro-rotatory isomer (also known as the *d* enantiomer, and represented by

Inc.[142] in 2006. The selection patent rationale was established in *Pfizer Canada, Inc. v. Canada*[143] in the same year.

The court in *Pfizer Canada, Inc*. identified two general classes of chemical patents.[144] They are the originating patent and selection patent.[145] The former is referring to "an originating invention involving the discovery of a new reaction or a new compound."[146] The latter is referring to "a selection from related compounds derived from the original compound and which have been described in general terms and claimed in the originating patent."[147]

It is immaterial whether a selection patent is claimed for a selection from a class of thousands or for a selection of one out of two.[148] The Canadian Federal Court of Appeal referred to English case law and stated that "the 'inventive step in a selection patent lies in the discovery that one or more members of a previously known class of products possess some special advantage for a particular purpose which could not be predicted before the discovery was made.'"[149] The policy behind the selection patent doctrine is "to encourage researchers to further use their inventive skills so as to discover new advantages for compounds within the known class."[150]

However, "[a]ll claimed members of the known class must have the advantage and the advantage must not be one that those skilled in the art would expect to find in a large number of the previously disclosed class."[151] The Canadian Federal Court of Appeal in a later case rephrased the requirement that "the validity of [a selection patent] depends on it having unexpected advantages over the class from which it is selected."[152] In other words, "[n]o one can claim a selection patent merely for ascertaining the properties of a known substance."[153]

The Canadian Federal Court of Appeal in *Sanofi-Synthelabo*

[+]) and the levo-rotatory isomer (also known as the *l* enantiomer, and represented by [-]). Sanofi-Synthelabo Canada, Inc. v. Apotex, Inc. [2006], 59 C.P.R. (4th) 46, ¶ 4 (Fed. C.A.).

142. *Id.*

143. Pfizer Canada, Inc. v. Canada, [2006], 52 C.P.R. (4th) 241 (Fed. C.A.).

144. *Id*. ¶ 3.

145. *Id*.

146. *Id*.

147. *Id*.

148. *Id*. ¶ 5.

149. *Id*. ¶ 4.

150. *Id*. ¶ 5.

151. *Id*. ¶ 4.

152. *Id.* ¶ 69.

153. *Id.* ¶ 24.

Canada, Inc. affirmed the trial judge's finding that a selection patent claimed for a selection of one isomer out of two may meet the threshold of non-obviousness.[154] In *Sanofi-Synthelabo Canada, Inc.*, the prior-art patent specifically identified twenty-one individual racemates, including the racemate from which the separated isomers were obtained in the patent at issue.[155] However, the court agreed with the trial judge's finding that

> there is no teaching on how to separate the racemates into their isomers, and no mention or suggestion [in the prior art] that there are any pharmaceutical or toxicological differences between the isomers of the disclosed racemates with respect to activity or tolerability.[156]

Though the separation technique was well-known, it "had to be tried with uncertainty as to which would actually result in a successful separation."[157] Therefore, a selection patent claimed for a selection of one isomer out of two may satisfy the requirement of non-obviousness.[158]

On appeal to the Canadian Supreme Court, the Court again affirmed the appellate court judge's finding and stated that the finding was unaffected by the lower court's rejection of the "obvious to try" test.[159] The Canadian Supreme Court sought advice from the English *Windsurfing* test,[160] as restated by the English Court of Appeal in 2007,[161] in analyzing a potential "obvious to try" situation where the Canadian *Beloit* test[162] would not accommodate.[163] The question to be asked in the fourth step of the *Windsurfing* test is that "[v]iewed without any knowledge of the alleged invention as claimed, do those differences

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154. *See Sanofi-Synthelabo Canada, Inc.*, 59 C.P.R. (4th) 46, ¶ 44.

155. *Id.* ¶ 9.

156. *Id*. ¶ 10.

157. *Id*. ¶ 42.

158. *See id*. ¶ 44.

159. Sanofi-Synthelabo Canada, Inc. v. Apotex, Inc., [2008] 69 C.P.R. (4th) 251, ¶ 72 (Can.).

160. Windsurfing Int'l, Inc. v. Tabur Marine, Ltd., [1985] R.P.C. 59, 73–74 (C.A.) (Civ. Div.).

161. Pozzoli SPA v. BDMO SA, [2007] EWCA Civ. 588, ¶ 23.

162. Beloit Canada, Ltd. v. Valmet Oy, [1986], 8 C.P.R. (3d) 289, ¶ 17 (Fed. C.A.).

163. *Sanofi-Synthelabo Canada, Inc.*, 69 C.P.R. (4th) 251, ¶¶ 52, 60, 67.

constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?"[164] In applying the test, the Canadian Supreme Court stated that it is "the fourth step of the *Windsurfing/Pozzoli* approach to obviousness that the issue of 'obvious to try' will arise."[165]

Before conducting an "obvious to try" analysis, a court needs to determine whether the analysis is warranted in such a situation.[166] In situations where an "obvious to try" analysis is warranted, the Canadian Supreme Court suggested a list of factors that a court should take into consideration at the fourth step of the obviousness inquiry.[167]

In particular, unlike the American approach,[168] the Canadian Supreme Court stated that there should be "no reason to exclude evidence of the history of the invention, particularly where the knowledge of those involved in finding the invention is no lower than what would be expected of the skilled person."[169] "[W]here those involved including the inventor and his or her team were highly skilled in the particular technology involved, the evidence may suggest that the skilled person would have done a lot worse and would not likely have managed to find the invention."[170] In such a situation, the inventors' course of conduct would suggest that it would not have been obvious for a skilled person to try the course that led to the invention.[171]

Moreover, the Canadian Supreme Court has noted that "obvious to

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164. *Id.* ¶ 67.

165. *Id*.

166. *Id*. ¶ 68. An "obvious to try" analysis might be appropriate in areas where advances are often won by experimentation. *Id*. A pharmaceutical invention might warrant an "obvious to try" analysis where "there may be many chemically similar structures that can elicit different biological responses and offer the potential for significant therapeutic advances." *Id*.

167. *Id.* ¶ 69. The Court cautioned that this is not an exhaustive list:

> (1) Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?
>
> (2) What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
>
> (3) Is there a motive provided in the prior art to find the solution the patent addresses?

Id.

168. *See* 35 U.S.C. § 103(a).

169. *Sanofi-Synthelabo Canada, Inc.*, 69 C.P.R. (4th) 251, ¶ 70.

170. *Id.* ¶ 71.

171. *Id.*

try" is not a mandatory test.[172] Whether it is a factor to be considered depends on the context and the nature of the invention.[173] Most importantly, "obvious to try" "is not a panacea for alleged infringers."[174] As the Court has stated, "[t]he patent system is intended to provide an economic encouragement for research and development."[175] "It is well known that this is particularly important in the field of pharmaceuticals and biotechnology."[176]

Before finding an invention "obvious to try," "there must be evidence to convince a judge on a balance of probabilities that it was more or less self-evident to try to obtain the invention."[177] As a result, the Canadian Supreme Court has interpreted the "obvious to try" test as a high standard to meet if the challenger of patent validity chooses to argue on this ground.

The Canadian obviousness jurisprudence represents an industry-specific approach, which has taken the specific characteristic of the biotechnology and pharmaceutical industries into account, specifically the adoption of the selection patent doctrine and the expansion of such doctrine to the selection between two isomers. Though the Canadian Supreme Court has adopted the "obvious to try" rationale from English case law, the Court has interpreted "obvious to try" as a high standard. Unlike Canada or the United Kingdom, judges in countries which have a civil law tradition cannot make law. Alternatively, certain countries provide industry-specific obviousness standard in their Patent Examination Guidelines. China and Japan are two examples.

E. Obviousness in China

The obviousness analysis under the Chinese patent system possesses two distinct features. On the one hand, the Chinese patent system has adopted the European problem-and-solution approach in general. On the other hand, the Chinese patent office provides special obviousness rules for chemical compound and biotechnology inventions. Therefore, its obviousness standard retains certain industry-specific features as seen in the Canadian or English patent system, though judges cannot make law under the Chinese legal and political system.

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172. *Id.* ¶ 62.

173. *Id.*

174. *Id.* ¶¶ 62, 64.

175. *Id.* ¶ 64.

176. *Id.*

177. *Id.* ¶ 66. The mere possibility that something might turn up is not enough to find "obvious to try." *Id.*

Inventiveness is one of the patentability requirements in addition to novelty and practical applicability under Chinese Patent Law.[178] The inventiveness requirement applies to both the invention[179] and utility models,[180] although the definitions of inventiveness differ.[181] For the purposes of patent application, inventiveness means that, as compared with the technology existing before the date of filing, the invention has "prominent substantive features" and represents a "notable progress."[182] For the purposes of utility-model application, the utility model should possess "substantive features" and represent "progress."[183]

The so called "prominent substantive features" is the Chinese equivalent of "non-obviousness."[184] All inventions that have prominent substantive features would automatically fall into one of the four circumstances listed in the Guideline for Examination, and therefore meet the "notable progress" requirement.[185] No additional inquiry is needed. Moreover, despite the differences in statutory language, the Chinese patent system has essentially adopted the same problem-and-

178. Patent Law of the People's Republic of China, ch. II, art. 22 (2000).

179. "Invention" in the Chinese Patent Law means any new technical solution relating to a product, a process or improvement. Implementing Regulations of the Patent Law of the People's Republic of China, ch.1, rule 2 (promulgated by the State Council of the People's Republic of China on June 15, 2001, and effective as of July 1, 2001), *available at* http://www.sipo.gov.cn/sipo_English/laws/lawsregulations/200203/t20020327_33871.htm (last visited Feb. 12, 2009).

180. "Utility model" in the Chinese Patent Law means any new technical solution relating to the shape, the structure, or their combination, of a product, which is fit for practical use. Implementing Regulations of the Patent Law of the People's Republic of China, ch.1, rule 2 (promulgated by the State Council of the People's Republic of China on June 15, 2001, and effective as of July 1, 2001), *available at* http://www.sipo.gov.cn/sipo_English/laws/lawsregulations/200203/t20020327_33871.htm (last visited Feb. 12, 2009).

181. Patent Law of the People's Republic of China, *supra* note 177.

182. *Id*.

183. *Id*.

184. Guanle Wu, *How to Get a Patent in China*, MANAGING INTELLECTUAL PROPERTY, *available at* http://www.managingip.com/Article/1321548/How%20to%20get%20a%20patent%20in%20China.html (last visited Feb. 12, 2009).

185. *Id*. The four circumstances are (1) the invention produces a better technical effect compared with the prior art; (2) the invention provides a technical solution which has a different technical concept but has a technical effect substantially the same level as in the prior art; (3) the invention represents a new trend in the development of new technology; and (4) in certain aspects, the invention has some negative effects, but it has outstanding positive technical effect in other respects. Guideline for Examination, pt. II, ch. 4, §3.2.2 (State Intellectual Property Office of the People's Republic of China, July 2006) (hereinafter Chinese Guideline for Examination).

solution approach in determining obviousness as the EPO.[186]

Unlike common law systems as exemplified by the United Kingdom or Canada, a judge-made industry-specific obviousness standard is unlikely to occur in China.[187] Alternatively, the Chinese patent system has provided industry-specific obviousness standards for specific industries, such as chemistry and biotechnology, in the Guideline for Examination.[188]

As specifically provided in the Guideline, the inventive step of a compound should not be denied simply on the ground of structural similarity,[189] unless it does not possess unexpected use or effect.[190] Before an examiner makes such a rejection, "[i]t is necessary to further explain that its use or effect can be expected or is predictable, or that a person skilled in the art is able to produce or use that compound by logical analysis, inference or limited experiment on the basis of the prior art."[191]

In addition to chemical compounds, the Chinese Examination Guideline provides in great length the special rules for determining the inventive step of inventions relating to genetic engineering[192] or microorganism.[193] Under the category of inventions relating to genetic engineering, specific rules are provided for patent applications in which the claimed subject matter is gene, recombinant vector, transformant, fused cell, or monoclonal antibody respectively.[194]

Generally, "a person skilled in the art cannot expect" or "unexpected technical effects compared with the prior art" is required for a finding of inventive step for an invention relating to genetic engineering.[195] Specifically, where the protein or the amino acid

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186. Chinese Guideline for Examination § 3.2.1.1. As provided in the Guideline for Examination, three steps are followed to determine whether a claimed invention is obvious as compared with the prior art: first, determining the closest prior art; second, determining the distinguishing features of the invention and the technical problem actually solved by the invention; and third, determining whether or not the claimed invention is obvious to a person skilled in the art. *Id*.

187. Under the Chinese Constitution, judicial decisions are subject to interference by legislatures, which exercise a supervisory function over the courts. Stanley Lubman, *Looking for Law in China*, 20 COLUM. J. ASIAN L. 1, 30 (2006).

188. Chinese Guideline for Examination, *supra* note 184, ch. 10.

189. *Id*. § 6.1(4).

190. *Id*. § 6.1(2).

191. *Id*. § 6.1(4).

192. *Id*. § 9.4.2.1.

193. *Id*. § 9.4.2.2.

194. *Id*. § 9.4.2.1(1)(5).

195. *Id*.

sequence of the protein is known, if a claimed gene has a specific base sequence and has technical effects compared with other genes having a different base sequence encoding the same protein, which a person skilled in the art cannot expect, then the invention of the claimed gene involves an inventive step.[196] The invention of a monoclonal antibody generally does not involve an inventive step, unless "the invention is further defined by other features, and hence has unexpected technical effects," then the invention of that monoclonal antibody involves an inventive step.[197]

In patenting a microorganism itself, the minimal requirement is that, so long as the microorganism produces technical effects that cannot be expected by a person skilled in the art, it involves an inventive step.[198] An invention relating to the use of a microorganism involves an inventive step if the microorganism used in the invention is remarkably different from a microorganism of known species with taxonomic characteristics, even if the use is the same as the prior art.[199] Otherwise, there is no inventive step unless unexpected technical effects are found.[200]

Under the current Chinese political and legal system, it is unlikely for the courts to develop a judge-made industry-specific obviousness standard. Though the Chinese patent system has generally adopted the European problem-and-solution approach in determining obviousness, the patent office has employed special obviousness rules for chemical compound and biotechnology inventions. In addition to China, the Japanese patent system is another example which has expressly provided an industry-specific obviousness standard in its Examination Guidelines.

F. Obviousness in Japan

The determination of inventive step under the Japanese patent system is generally based on the comparison between the claimed invention and one of the cited references which is considered the most suitable for the reasoning.[201] One single cited reference is selected for

196. *Id.* § 9.4.2.1(1).
197. *Id.* § 9.4.2.1(5).
198. *Id.* § 9.4.2.2(1).
199. *Id.* § 9.4.2.2(2).
200. *Id.*
201. Examination Guidelines for Patent and Utility Model in Japan, pt. II, ch. 2, § 2.4(2) (Japan Patent Office, June 2006) (hereinafter Japanese Examination Guidelines).

this purpose.[202] However, the Examination Guidelines do not exclude examiners from taking other cited inventions or even general common knowledge into account as the basis of comparison.[203] Similar to Germany, the Japanese patent system also provides utility model protection.[204]

As provided in the Examination Guidelines, the Japanese inventive-step test is basically comprised of four steps: first, finding of the claimed invention and one or more cited inventions; second, selecting one cited invention most suitable for the reasoning; third, comparing the claimed invention with the most suitable prior art; fourth, clarifying the identicalness and the difference in matters defining the inventions.[205] If reasoning can be made based on the contents of the most suitable prior art, other cited inventions, and the common general knowledge, then the claimed invention lacks an inventive step.[206] On the other hand, if the reasoning cannot be made, the claimed invention cannot be denied its involvement of an inventive step.[207]

Similar to the selection of the closest prior art in the EPO problem-and-solution approach, the Japanese inventive-step test includes the step of selecting the most suitable prior art.[208] This step is deemed as a means to reduce the effects of hindsight on the decision of obviousness.[209]

The Japanese Examination Guidelines also provide a method in handling selection inventions, which involves the finding of advantageous effects.[210] A selection invention involves an inventive step when it generates an advantageous effect, which is not disclosed in a cited reference.[211] An advantageous effect is defined as an effect which is advantageous in comparison with an effect of a cited invention, among the effects derived from the matters defining a claimed invention.[212] An advantageous effect can be found when the invention is

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202. *Id*.

203. *Id*.

204. *Id*. pt. X, ch. 1–2.

205. *Id*. pt. II, ch. 2, § 2.4(2).

206. *Id*.

207. *Id*.

208. *Id*.

209. Tomotaka Homma, *Comparing Japanese and U.S. Standards of Obviousness: Providing Meaningful Guidance After* KSR, 48 IDEA 449, 483 (2008).

210. Japanese Examination Guidelines, *supra* note 200, § 2.5(3).

211. *Id*.

212. *Id*.

qualitatively different, or qualitatively the same but quantitatively prominent, in comparison with that of a cited invention disclosing a generic concept, provided that neither of the effect can be foreseen by a person skilled in the art from the state of the art.[213] However, regardless of the finding of advantageous effects, inventive step may be denied if a person skilled in the art could have easily arrived at a claimed invention.[214] Basically, an "advantageous effect" is the Japanese equivalent of the "unexpected technical effects compared with the prior art" under the Chinese patent system.

The Japanese patent system is another example, which has provided industry-specific obviousness standards for biological inventions expressly in its Examination Guidelines. For instance, the inventive step of inventions involving genetic engineering and microorganisms are treated differently than other subject matter.[215] Inventions resulting from genetic engineering are further divided into five basic categories.[216] They are genes, recombinant vectors, transformants, fused cells, and monoclonal antibodies.[217] Nevertheless, unlike biological inventions, the Examination Guidelines state that the inventive step analysis regarding medicinal inventions is not different from the general test though the Guidelines have devoted great length in explaining what constitutes a concrete practice of the judgment.[218]

The Japanese patent system has arguably adopted a higher obviousness standard because it allows patent examiners more leeway in considering prior art or evidence compared to the EPO's problem-and-solution approach. However, similar to the German patent system, a higher obviousness standard in Japan can be justified because the system provides utility model protection to inventions with relatively minor inventiveness, in addition to an agency-made biotechnology-specific obviousness standard.

In the United States, the Federal Circuit Court of Appeals had developed a more rigid and arguably restrictive obviousness test, until the Supreme Court rendered its *KSR* decision in 2007. To some extent, the American patent system may be deemed as the fourth type of obviousness approach after *KSR*. That is, a higher obviousness standard

213. *Id.*
214. *Id.*
215. *Id.* pt. VII, ch. 2, § 1–2.
216. *Id.* § 1.3.3.
217. *Id.*
218. *Id.* ch. 3, § 2.3.

without a safety-net provision comparable to the utility model system.

V. OBVIOUSNESS IN THE AMERICAN PATENT SYSTEM

The "consistency, uniformity, and familiarity with the extensive and relevant body of patent jurisprudence" is the underlying policy for the creation of the Federal Circuit.[219] As Justice Stevens stated in his dissenting opinion in *Florida Prepaid Postsecondary Education Board v. College Saving Bank,*[220] which cited *Graham*,[221] "[t]here is, . . . a strong federal interest in an interpretation of the patent statutes that is both uniform and faithful to the constitutional goals of stimulating invention and rewarding the disclosure of novel and useful advances in technology."[222]

The Federal Circuit's experiment in developing a more rigid obviousness test was halted by the Supreme Court's *KSR* decision. Nevertheless, another experiment in developing a judge-made industry-specific obviousness standard was somehow undisturbed.

Though the *KSR* court revered *Graham* as the highest principle in making obviousness determinations, the *KSR* decision has essentially created the same problem that the *Graham* court sought to resolve. That is, the inconsistency among the courts and the Patent Office.

A. TSM Test

Before *KSR*, the Federal Circuit Court of Appeal and its predecessor had developed a teaching-suggestion-motivation (TSM) test.[223] Similar to the EPO's problem-and-solution approach, the TSM test was designed to guard against hindsight judgment especially in the situation where more than one reference needs to be considered.[224] The European problem-and-solution approach does not have the same problem because of its selection of one single closest prior art, rather than multiple references, as the basis of comparison with the claimed invention.

The TSM test is part of the Federal Circuit and its predecessor's anti-hindsight jurisprudence, as well as the "motivation to combine"

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219. Florida Prepaid Postsecondary Educ. Bd. v. College Saving Bank, 527 U.S. 627, 650–52 (1999) (Stevens, J., dissenting).

220. *Id.* at 650 (Stevens, J., dissenting).

221. Graham v. John Deere Co., 383 U.S. 1 (1966).

222. *Florida Prepaid Postsecondary Educ. Bd.*, 527 U.S. at 650 (Stevens, J., dissenting).

223. Alza Corp. v. Mylan Labs., Inc., 464 F.3d 1286, 1290 (C.A. Fed. 2006).

224. *See id.*

requirement.[225] Under the TSM test, "a court must ask 'whether a person of ordinary skill in the art, possessed with the understandings and knowledge reflected in the prior art, and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims.'"[226] The legal determination of obviousness "should be based on evidence rather than mere speculation or conjecture."[227] Such evidence includes expert testimony regarding the knowledge that a person of ordinary skill in the art would have possessed at a given time.[228]

Under the Federal Circuit's obviousness jurisprudence, "motivation to combine" alone is not sufficient to find obviousness. In addition to the "motivation to combine" the prior art, it is a predicate to the finding of obviousness that the motivation of a person of ordinary skill in the art needs to be coupled with a "reasonable expectation of success" in doing so.[229]

Prior to *KSR*, the Federal Circuit stated in *Alza Corp. v. Mylan Laboratories, Inc.* that the teaching, suggestion, or motivation to combine the relevant prior art teachings "does not have to be found explicitly in the prior art."[230] "[T]he teaching, motivation, or suggestion may be implicit from the prior art as a whole."[231] However, implicit teaching, suggestion, or motivation is subject to a limitation. That is, "rejections on obviousness grounds cannot be sustained by mere conclusory statements."[232] "[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."[233]

Like other patent systems, the Federal Circuit had cautioned about the use of "obvious to try." However, unlike the Canadian Supreme Court, which has interpreted "obvious to try" as a high standard to meet,[234] the Federal Circuit was of the opinion that "'obvious to try'' is

225. *See id*.

226. *Id.* (citing Cross Med. Prods., Inc., v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1321–24 (C.A. Fed. 2005)).

227. *Id.*

228. *Id*. at 1294.

229. *Id.* at 1293.

230. *Id.* at 1290.

231. *Id*.

232. *Id.* at 1291.

233. *Id*.

234. *See* Sanofi-Synthelabo Canada, Inc. v. Apotex, Inc., [2008] 69 C.P.R. (4th) 251, ¶ 66 (Can.).

not a standard under § 103.[235]

As the Federal Circuit explained in *In re O'Farrell*, "obvious to try" often leads to mainly two kinds of errors.[236] First, 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, though it is obvious to try, the inventor has to vary all parameters or try each of numerous possible choices before reaching a successful result.[237] Second, where the prior art gave only general guidance, though it is obvious to try, what the inventor is doing is to explore a new technology or general approach that seemed to be a promising field of experimentation.[238]

Commentators have also cautioned about the use of "obvious to try." For instance, George S.A. Szabo has cautioned about using "obvious to try" in determining obviousness by explaining the connection among reasonable expectation of success, obvious to try, and the size of the reward.[239] In view of a high probability of success, a degree of uncertainty or some residual risk may remain, even if obvious to try.[240] When the expected size of the reward is low, there should be no obvious good reason for a skilled person to try, and therefore it may be oddly found non-obvious.[241] On the other hand, when the expected size of the reward is enormous, there is obvious good reason to try, even if the degree of uncertainty or residual risk remains high.[242] As a result, it may be oddly found obvious.[243] The odd results should be avoided in estimating the mental likelihood for a skilled person to proceed with the available information toward the invention in certain disciplines, such as chemistry, pharmacy, and biotechnology.

Moreover, it appeared that "obvious to try" was merely a factor under the "reasonable expectation of success" standard, rather than a separate test, under the obviousness jurisprudence established by the Federal Circuit before *KSR*.[244] As Professor Merges has observed, "[i]f

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235. *See, e.g., In re* O'Farrell, 853 F.2d 894, 903 (C.A. Fed. 1988); *In re* Deuel, 51 F.3d 1552, 1559 (C.A. Fed. 1995).

236. *In re* O'Farrell, 853 F.2d at 903.

237. *Id.*

238. *Id*.

239. Szabo, *supra* note 64, at 475.

240. *Id*.

241. *Id*.

242. *Id*.

243. *Id*.

244. Merges, *supra* note 49, at 42.

an inventor is faced with a large number of variables, and the prior art does not provide enough guidance to narrow those down to a manageable level, then an inventive step is needed to proceed."[245] Consequently, the skilled person in the art could not be reasonably certain of success, and it rendered the invention non-obvious.[246] On the other hand, based on the Federal Circuit's "obvious to try" cases, such as *Merck & Co. v. Biocraft Laboratories, Inc.,*[247] "if the number of possible permutations has been limited by the prior art, then a mechanic could plod through them one at a time and be reasonably certain of success."[248] Therefore, the finding of "obvious to try" alone, without more, does not render an invention obvious.

Long before *KSR*, the Federal Circuit had demonstrated a judge-made industry-specific obviousness standard in the biotechnology context that has taken the nature of the specific technology into consideration. For instance, it was suggested in *In re Bell*[249] and was reaffirmed in *In re Deuel* that "the existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs."[250] This principle has recognized the building-block nature of biotechnology research.[251]

The Federal Circuit has also concluded that chemistry, pharmaceutical research, and biotechnology are inherently uncertain disciplines.[252] Though the Federal Circuit is in the view that the results of biotechnology research are unforeseeable or unpredictable and thus may avoid the problem of obviousness, the court has imposed an

245. *Id*.

246. *Id*.

247. Merck & Co. v. Biocraft Labs., Inc., 874 F.2d 804 (C.A. Fed. 1989).

248. Merges, *supra* note 49, at 42.

249. *In re* Bell, 991 F.2d 781 (C.A. Fed. 1993).

250. *In re* Deuel, 51 F.3d 1552, 1559 (C.A. Fed. 1995).

251. For example, the laboratory handbook entitled *Molecular Cloning: a Laboratory Manual*, which was published by the Cold Spring Harbor Laboratory Press, is widely used in almost every biotechnology laboratory as a basic research tool. Nonetheless, the handbook providing standard research procedures in the industry was cited in various cases as one of the prior art providing "motivation to combine." *See, e.g., In re* Kubin, 561 F.3d 1351, 1360 (C.A. Fed. 2009). "Valiante cites to the very same cloning manual, Sambrook, cited by Kubin and Goodwin for their proposition that the gene sequence is identified and recovered 'by standard biochemical methods.'" *Id*.

252. *See, e.g.,* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1208–09 (Fed. Cir. 1991) (finding that biotechnology is an uncertain discipline); Burk & Lemley, *supra* note 7, at 1655.

extremely stringent standard for disclosure and description.[253] As a result, biotechnology patents may be relatively easier to pass the Federal Circuit's obviousness standard, but the accompanying high enablement and written description standards dramatically narrow the scope of the patents eventually issued.[254] The Federal Circuit's practice before *KSR*, to some extent, had avoided the broad blocking-patent problems in the biotechnology industry while offering patent protections as the industry needed.

As Professors Burk and Lemley have observed, the Federal Circuit's jurisprudence has increasingly treated patents from various industries differently.[255] For instance, "the Federal Circuit has gone to inordinate lengths to find biotechnological inventions non-obvious, even if the prior art demonstrates a clear plan for producing the invention."[256] Though Professors Burk and Lemley have a different view concerning obviousness standards for biotechnology inventions, the Federal Circuit's practice has essentially echoed Professors Burk and Lemley's proposal for a judge-made industry-specific patentability standard.

In the mean time, Professors Burk and Lemley criticized the Federal Circuit that "while the patent statute leaves ample room for courts to consider the needs of particular industries, the Federal Circuit has proven somewhat reluctant to embrace its role in setting patent policy."[257] "Not only has it proven unwilling to pay much attention to the empirical evidence about innovation, but it has also taken a number of steps toward eliminating the flexible standards of the patent common law in favor of bright-line rules."[258] It was the general dissatisfaction of the Federal Circuit's attempt in setting bright-line rules, if any, which led to the Supreme Court's *KSR* decision in 2007.

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253. Burk & Lemley, *supra* note 7, at 1681. Alternatively, Professors Burk & Lemley suggested that "a fairly high obviousness threshold coupled with a fairly low disclosure requirement will produce a few very powerful patents in uncertain industries." *Id*. at 1682. "It will therefore solve the anti-commons problem often identified with biotechnology while at the same time boosting incentives to innovate." *Id*. However, biotechnology research requires high level of precision. Without high level of disclosure in prior art, researchers referring to the prior art would fall into undue experimentation and it would in turn increase inefficiency in research and impede innovation.

254. *Id*. at 1678.

255. *Id*. at 1593.

256. *Id*.

257. *Id*. at 1579.

258. *Id*.

B. KSR International Co. v. Teleflex, Inc.

The Supreme Court in *KSR* disagreed with the Federal Circuit's rigid application of the TSM test and favored an expansive and flexible approach instead.[259] Nevertheless, it may be beyond the *KSR* court's expectation that its *KSR* decision has created the same problem that its predecessor sought to resolve in *Graham*[260] more than four decades ago.

The framework for applying the statutory language of § 103 was set out by the Supreme Court in *Graham*.[261] Though the Supreme Court in *KSR* embraced the obviousness principles laid out in *Graham*, the *KSR* decision has unexpectedly created the same problem confronting the *Graham* court more than forty years ago. That is, "a notorious difference between the standards applied by the Patent Office and by the courts."[262]

KSR is a case involving a mechanical invention, namely an "adjustable pedal assembly with electronic throttle control."[263] The *KSR* court identified the principles set forth in *Graham* as an objective analysis.[264] The *Graham* test is the following:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.[265]

It is worth noting that the Supreme Court in *KSR* did not oppose the TSM test but that the Federal Circuit has applied it too rigidly in the case at issue. The *KSR* court also recognized that the principles laid out in *KSR* may not be applicable outside the factual context of that case.[266]

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259. KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 411 (2007).
260. Graham v. John Deere Co., 383 U.S. 1 (1966).
261. *KSR Int'l Co.*, 550 U.S. at 407.
262. *Graham*, 383 U.S. at 18.
263. *KSR Int'l Co.*, 550 U.S. at 405.
264. *Id.*
265. *Graham*, 383 U.S. at 17–18; *KSR Int'l Co.*, 550 U.S. at 405.
266. *KSR Int'l Co.*, 550 U.S. at 417.
Following these principles may be more difficult in other cases than it is here

As the *KSR* court has stated, "[t]here is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis."[267] However, "when a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs."[268] "What we hold is that the fundamental misunderstandings identified above led the Court of Appeals in this case to apply a test inconsistent with our patent law decisions."[269]

In rejecting the rigid application of the TSM test, it appears that a rigid step-by-step obviousness analysis, such as the EPO's problem-and-solution approach, may not be acceptable in the Supreme Court's view.[270] Instead, the Supreme Court seemed to suggest that the analysis of obviousness should be industry-specific.[271]

In addition to the rejection of a rigid application of the TSM test, the *KSR* court also faulted the Federal Circuit's long-standing caution about "obvious to try."[272] However, the *KSR* court's statement about "obvious to try" may be subject to various interpretations, as its declaration regarding the "expansive and flexible" approach. For instance, on the one hand, the *KSR* court appeared to be of the opinion that merely "obvious to try" is sufficient to find obviousness.[273] On the other hand, the Court seemed to suggest that several conditions, such as a finite number of identified solutions and anticipated success, need be met before "obvious to try" amounts to obviousness.[274]

> because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement.

Id.

267. *Id.* at 419.

268. *Id*.

269. *Id*. at 422.

270. *See id.*, at 419. "The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents." *Id*.

271. *See id*. "The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way." *Id*.

272. *Id.* at 421.

273. *Id*. "The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was 'obvious to try.'" *Id*.

274. *Id*.

> 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, 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

The Supreme Court in *KSR* acknowledged the importance of avoiding hindsight judgment,[275] yet it has rejected a rigid step-by-step approach of obviousness analysis. It leaves open for the later courts to develop a device serving such purposes. As examined in Part III, an industry-specific obviousness standard may be an appropriate solution. Moreover, as a common law system, the United States has more leeway to develop a judge-made industry-specific obviousness standard than civil law systems, such as China or Japan, which have no option but to promulgate agency rules in the Examination Guidelines.

Though the Supreme Court identified the *Graham* test as an objective one,[276] the irony is, if a test is expansive and flexible it may be subject to various interpretations and inferences. Consequently, the test is more likely than not, subjective. The inconsistency in its application follows suit. That is what occurred after *KSR* within the American patent system, specifically between the Federal Circuit and the PTO.

C. Federal Circuit's Interpretation and Application of KSR

Despite the Supreme Court's *KSR* decision, the Federal Circuit assures inventors that "a flexible TSM test remains the primary guarantor against a non-statutory hindsight analysis."[277] In the post-*KSR* era, the Federal Circuit continues to develop its industry-specific approach, at least in cases involving chemical arts.

KSR is a case involving a mechanical invention, namely an "adjustable pedal assembly with electronic throttle control."[278] It is not factually similar to a chemical invention, a pharmaceutical invention, or a biotechnological invention.

After *KSR*, the Federal Circuit continued to develop its industry-specific obviousness standard, at least in chemical related fields, with little disturbance by *KSR*. As Judge Newman has stated in *Abbott Laboratories v. Sandoz, Inc.*,[279] "[t]he 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,' without considering

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might show that it was obvious under § 103.

Id.

275. *Id*.

276. *Id.* at 405.

277. Takeda Chem. Indus., Ltd. v. Alphapharmpty, Ltd., 492 F.3d 1350, 1357 (C.A. Fed. 2007); Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1364 (C.A. Fed. 2008).

278. *KSR Int'l Co.*, 550 U.S. at 405.

279. Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341 (C.A. Fed. 2008).

the nature of the science or technology."[280] It remains that "[e]ach case must be decided in its particular context, including the characteristics of the science or technology."[281]

In several cases, the Federal Circuit has expressed the opinions that the obvious-to-combine scenario in *KSR* is difficult to apply to chemical arts,[282] such as selection of components[283] or structurally similar compounds,[284] without modification. In the Federal Circuit's view, such flexibility in establishing prima facie obviousness for chemical compounds is consistent with the legal principles enunciated in *KSR*.[285] As Judge Rader has stated in *Eisai Co, Ltd. v. Dr. Reddy's Laboratories, Ltd*.,[286] "[t]o the extent an art is unpredictable, as the chemical arts often are, *KSR*'s focus on these 'identified, predictable solutions' may present a difficult hurdle because potential solutions are less likely to be genuinely predictable."[287]

Though the Supreme Court in *KSR* expressly stated that a flexible approach of obviousness is desirable, the Court did not define flexibility in any material way. Thus, it can be inferred from the proposal made by Professors Burk and Lemley years before *KSR* that a flexible approach of obviousness may include a judge-made industry-specific standard of obviousness. Various industries have different characteristics, and a nominally uniform rule would affect them differently.[288] As Professors Burk and Lemley have suggested, "[i]f the court is to make intelligent policy, it must take the needs of those industries into account."[289]

Professors Burk and Lemley further suggested that courts are better situated to engage in tailoring the standard of patentability than the legislature.[290] "Courts have substantial ability to profile an industry and adapt innovation policy according to the profile, within a reasonable time frame and at reasonable cost."[291] On the other hand, contrary to the "flexible" application of the Supreme Court's *KSR* decision in

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280. *Id.* at 1352.

281. *Id*.

282. Eisai Co., Ltd. v. Dr. Reddy's Labs., Ltd., 533 F.3d 1353, 1359 (C.A. Fed. 2008).

283. *Abbott Labs.*, 544 F.3d at 1351.

284. *Eisai Co., Ltd.*, 533 F.3d at 1356–57.

285. Takeda Chem. Indus., Ltd. v. Alphapharmpty, Ltd., 492 F.3d 1350, 1356 (C.A. Fed. 2008).

286. *Eisai Co, Ltd.*, 533 F.3d at 1353.

287. *Id.* at 1359.

288. Burk & Lemley, *supra* note 7, at 1675.

289. *Id*.

290. *Id*. at 1668.

291. *Id*.

Federal Circuit cases, the PTO's literal application of the *KSR* decision word-by-word in its examination proceeding has essentially created another set of rigid and inflexible rules of obviousness.

D. U.S. PTO's Response to KSR

Around the time the Supreme Court's *KSR* decision was issued, statistics showed that the PTO had drastically adopted a higher patentability requirement. Decisions issued by the Board of Appeals and Interferences, after *KSR*, also indicate that the PTO has adopted a more generous view of obvious-to-try, which is a significant departure from the Federal Circuit's consistent caution.

It is said that the PTO's post-*KSR* obviousness rules do not constitute substantive rule making and hence do not have the force and effect of law.[292] If the PTO's practice is ignored, one may comfortably conclude that the obviousness standard did not change much, since the Federal Circuit has applied *KSR* flexibly. However, before a patent applicant can reach any federal court, the applicant has to tackle the PTO for years. Especially for a pharmaceutical or biotechnological invention, the patent prosecution on average is much longer than other types of patents, and therefore more expensive.[293] The aggregate expenses of time, money, and other societal resources devoted to the lengthy process are too enormous to count.

Coincident with the Supreme Court's issuance of its *KSR* decision in April 2007, the rate of patent rejection reversed by the Board of Patent Appeals and Interferences of the PTO dropped approximately 10% in fiscal year 2007 compared to the previous year.[294] The trend continued to fiscal year 2008 and the reverse rate was 23.9%.[295] In fiscal year 2009, by December 31, 2008, the average reverse rate was as low as 18.6%,[296] compared to approximately 37.7% before *KSR*, which was the average

292. D. Christopher Ohly et al., *It Is Not So Obvious: The Impact of* KSR *on Patent Prosecution, Licensing, and Litigation*, 36 AIPLA Q.J. 267, 281 (2008).

293. John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent Prosecution*, 53 VAND. L. REV. 2099, 2124–32 (2000).

294. The reporting period of a fiscal year is from October 1, of the previous year to September 30, of the present year. According to the statistics released by the Board of the Patent Appeals and Interferences of the PTO, the reverse rate in fiscal year 2007 was 25.1%, compared to 34.8% in fiscal year 2006. USPTO, Receipt and Dispositions by Technology Center, http://www.uspto.gov/web/offices/dcom/bpai/docs/receipts/index.htm (last visited Jan. 22, 2009).

295. *Id*.

296. *Id*.

reverse rate from fiscal year 2000 to 2006.[297] In addition, as Ohly has observed, the PTO's patent allowance rate has dropped approximately 10% since 2006.[298]

Collectively, the low patent allowance rate at the examination level and the low reverse rate at the appellate level suggest that the PTO has drastically raised the standard of patentability coincident with the issuance of the *KSR* decision. However, statistics alone do not necessarily reflect how the PTO's practice has changed or the extent of change because there are always other factors that may contribute to the figures.[299] Therefore, a closer examination into the decisions issued by the Board of Patent Appeals and Interferences of the PTO before and after *KSR* in similar invention contexts may be necessary.

Despite the Federal Circuit's continuous caution about "obvious to try" before and after *KSR*,[300] the PTO has interpreted the Supreme Court's *KSR* teachings as if merely "obvious to try" is sufficient to find obviousness.[301] For instance, as the Board of Patent Appeals and Interferences stated in *Ex Parte Kubin*,[302] "[u]nder *KSR*, it's now apparent 'obvious to try' may be an appropriate test in more situations than we previously contemplated."[303] In *Ex Parte Kubin*, the applicants claimed a DNA sequence encoding a polypeptide whose amino acid sequence is "at least 80% identical" to a known CD48 binding polypeptide.[304] In rejecting the applicant's reliance on *In re Deuel*, the Board stated that "[t]o the extent *Deuel* is considered relevant to this case, we note the Supreme Court recently cast doubt on the viability of *Deuel* to the extent the Federal Circuit rejected an 'obvious to try' test."[305]

On the other hand, before *KSR*, the Board of Patent Appeals and

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297. *See id*. The reverse rate was 38.9% in fiscal year 2000; 36.8% in fiscal year 2001; 37.4% in fiscal year 2002; 39.1% in fiscal year 2003; 37.4% in fiscal year 2004; and 39.6% in fiscal year 2005 respectively. *Id*.

298. Ohly et al., *supra* note 292, at 286. *See also* Eugene Quinn, PTO Hiring Freeze and Budget Problems, http://www.ipwatchdog.com/2009/03/02/pto-hiring-freeze-and-budget-problems/id=2099/ (last visited Mar. 17, 2009).

299. Ohly et al., *supra* note 292, at 286.

300. Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1352 (C.A. Fed. 2008).

301. *See, e.g.*, *Ex Parte* Kubin, 2007 WL 2070495 (Bd. Pat. App. & Interf. May 31, 2007); *Ex Parte* Haruo Watanabe, 2008 WL 838777, at *3 (Bd. Pat. App. & Interf. Mar. 26, 2008); *Ex Parte* Trono, 2008 WL 1993030 (Bd. Pat. App. & Interf. May 7, 2008).

302. *Ex Parte* Kubin, 2007 WL 2070495.

303. *Id.* at 5.

304. *Id.* at 1–2.

305. *Id.* at 5.

Interferences had consistently found that "obvious to try" alone does not constitute obviousness.[306] For instance, in *Wen-Hwa Lee v. Thaddeus P. Dryja*, the Board stated that "[a] general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out."[307] The statement aptly recognizes the nature of biotechnology research.

As explained in Part III, "obvious to try" is an anomaly in the biotechnological and pharmaceutical contexts. Because of the high costs of biotechnology and pharmaceutical research, a research proposal is unlikely to receive grants or any sort of financial support without the projection of a "reasonable expectation of success." Nevertheless, a documented "reasonable expectation of success" would render an invention "obvious to try" under a "one-size-for-all" obviousness jurisprudence. As a result, only very few, if any, biotechnology or pharmaceutical inventions can escape from the suspicion of "obvious to try" if the nature of the industry and the characteristic of the technology is not taken into consideration.

Regardless of the inconsistency of obviousness standard before and after *KSR*, there is uncertainty regarding the obviousness standard in the reexamination proceeding for patents issued under the "old" obviousness standard before *KSR*. It is unclear whether the PTO would apply the "new" and higher obviousness standard to reevaluate a patent issued under the "old" and lower standard. If the latter is the case, an invention which was found "obvious to try" but nonetheless non-obvious under the old standard, would be easily struck down under the new standard without the assistance of any newly discovered prior art.

The Patent Act provides that any person at any time may file a request for reexamination by the PTO of any claim of a patent on the basis of any prior art cited.[308] The Director of the PTO will then determine "whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications."[309] If a substantial new question of patentability is found, the Director will issue an order for reexamination and a reexamination proceeding will

306. *See, e.g., Ex Parte* Kamboj, 2002 WL 1801076 (Bd. Pat. App. & Interf.); Wen-Hwa Lee v. Thaddeus P. Dryja, 2005 WL 3121465 (Bd. Pat. App. & Interf.).

307. *Wen-Hwa Lee*, 2005 WL 3121465 at 30.

308. 35 U.S.C. § 302.

309. 35 U.S.C. § 303(a).

follow.[310]

It is worth noting that the "substantial new question of patentability" does not necessarily rely on a newly discovered issue or any newly discovered prior art which did not exist in the examination of the original application. 35 U.S.C. § 303(a) provides that "[t]he existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office."[311] Therefore, the threshold for initiating a reexamination proceeding is considerably low.

It is well established that patent is a property right[312] and it is generally understood that patent is a contract between the government and the inventor.[313] If an obviously higher obviousness standard is applied in a reexamination proceeding and the patent previously issued under a lower standard is revoked as a result, though the issue has not been adjudicated, it may not be excluded that the possibility of a finding of governmental takings would follow.

The extent to which a person had changed position in reliance upon the prior law is an element in Fifth Amendment analysis.[314] As the Supreme Court has stated in *Pfaff v. Wells Electronics, Inc.*,[315] "the patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time."[316] "It would be manifestly unfair if, after issuing a patent, the Government as a representative of the public sought to modify the bargain by shortening the term of the patent in order to accelerate public access to the invention."[317]

Governmental takings may arise at the administrative level as well as the legislative level. For instance, "Congress in performance of its legislative functions may leave it to administrative officials to establish

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310. 35 U.S.C. § 304.

311. 35 U.S.C. § 303(a).

312. Florida Prepaid Postsecondary Educ. Bd. v. College Savings Bank, 527 U.S. 627, 642 (1999). "Patents, however, have long been considered a species of property." *Id.* "As such, they are surely included within the 'property' of which no person may be deprived by a State without due process of law." *Id.*

313. Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998).

314. Patlex Co. v. Mossinghoff, 758 F.2d 594, 602 (C.A. Fed. 1985).

315. *Pfaff*, 525 U.S. at 55.

316. *Id.* at 63.

317. Eldred v. Ashcroft, 537 U.S. 186, 226 (2002) (Stevens, J., dissenting).

rules within the prescribed limits of the statute."[318] "A statute that is valid on its face may nevertheless be administered in such a way that constitutional or statutory guarantees are violated."[319] However, though the PTO's generous view concerning "obvious to try" after *KSR* may be unique among major patent systems worldwide, the PTO's generous application is traceable to the Supreme Court's self-contradictory statement regarding "obvious to try."

Nevertheless, there are signs showing that the Federal Circuit may have begun cautiously loosening its defensive stance regarding "obvious to try." After the Board rejected Kubin's patent application, the applicants appealed to the Federal Circuit.[320] The Federal Circuit affirmed the Board's rejection on the ground of obviousness.[321]

The Federal Circuit's recent decision in *In re Kubin* has resolved the inconsistency of obviousness standard between the court and the PTO to some extent, though the Federal Circuit has indicated that the Board of Patent Appeals and Interferences's reasoning regarding obviousness in *Ex Parte Kubin* was somehow misguided.[322]

E. In re Kubin

In re Kubin signifies the cautious revival of "obvious to try" in the biotechnological context under the Federal Circuit's obviousness jurisprudence.[323] The court officially rejected the formalistic approach as represented by *In re Deuel*.[324] Even so, the decision does not contradict the Federal Circuit's continuing judge-made industry-specific obviousness approach because the essence of such approach is flexibility.

The claim in *In re Kubin* was directed to the DNA encoding the CD-48 binding region of NAIL (Natural Killer Cell Activation Inducing Ligand) proteins,[325] rather than the DNA encoding the NAIL proteins or the NAIL protein itself. The appellants claimed a genus of DNA whose sequences are at least eighty percent identical to the CD-48 binding region, but the specification only disclosed two examples.[326]

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318. *Patlex Co.*, 758 F.2d at 605.
319. *Id.*
320. *In re* Kubin, 561 F.3d 1351 (C.A. Fed. 2009).
321. *Id.* at 1361.
322. *Id.* at 1356.
323. *Id.* at 1359.
324. *Id*.
325. *Id.* at 1353.
326. *Id*.

In that case, the Federal Circuit did not address the issue of enablement under 35 U.S.C. § 112, ¶ 1, because the court had found the invention obvious and affirmed the Board's decision under 35 U.S.C. § 103(a).[327] However, the court should have affirmed the Board's decision under § 112 rather than under § 103. The insufficient disclosure in this application is more obvious than the insufficiency of inventiveness. There are technical factual issues unclear in this case regarding the extent of inventiveness that may lead to a totally different outcome.

The appellants lost the battle probably because they did not draw the court's attention to the critical step in their application, namely the discovery that NAIL proteins bind CD-48 proteins and the identification of CD-48 binding site on NAIL proteins.[328] The claim at issue was directed to the CD-48 binding region of NAIL proteins.[329] However, throughout the opinion the court's discussion of obviousness was focusing on DNA encoding the entire NAIL proteins and the amino acid sequences of the NAIL proteins as a whole, which has become a routine technique in biotechnology research.

Though the appellants acknowledged in their application that CD-48 binding is "a property necessarily present in NAIL,"[330] it should be noted that the difficulty in identifying a critical binding region on a receptor is not comparable to the routine screening of DNA sequences encoding the receptor from a commercialized cDNA library. The issue is then how difficult it is to locate the range of the sequences, both in DNA and in protein, which determine the specific binding property, even if the property can be predicted in general. The shorter the sequence which retains the same property, the higher specificity and medical applicability is the peptide in human bodies. The appellants did not explain, and neither the court nor the PTO has considered inventiveness on this point.

In addition, the court did not address and the appellants did not explain how difficult it is to screen the CD-48 as the binding protein of NAIL extracellular domain, though the appellant did mention in the brief that the Board has completely ignored "the number of options related to the ultimate discovery that CD-48, a single protein among the

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327. *Id.* at 1361.

328. Brief of Marek Z. Kubin and Raymond G. Goodwin at 48, *In re* Kubin, 561 F.3d 1351 (2009 WL 877646 (C.A. Fed.)) (No. 2008-1184), 2008 WL 2505893 (C.A. Fed.).

329. *In re* Kubin, 561 F.3d at 1353.

330. *Id.* at 1357.

undeniably large number of human proteins, binds to NAIL."[331] As a result, the obviousness of the invention in *In re Kubin* is not quite obvious because certain technical factual issues were unclear when the court made the finding of obviousness. [332]

On the other hand, it is obvious that the written description of the application in *In re Kubin* was not enabling. As explained in Part III, the studies of single mutation or point mutation have shown that, even one single deletion, insertion, or substitution either at the DNA level or the protein level, may cause drastic change of the characteristics of a DNA or protein. The appellants in *In re Kubin* claimed all possibilities of combination of DNA sequences which are at least eighty percent identical to a certain polypeptide. Some DNA sequences fall within the scope may have unique properties due to one single deletion, insertion, or substitution of nucleotide. What the appellants claimed was something he or she could not characterize. In other words, the appellants did not have possession of the claimed genus of DNA molecules encoding at least eighty percent identical to the CD-48 binding region of NAIL proteins.[333] Therefore, the court should have affirmed the Board's rejection under § 112.

The Federal Circuit in *In re Kubin* also cautiously revived "obvious to try" as an indicator of obviousness with some clarification.[334] The Federal Circuit's recent rejection of a formalistic approach as represented in *In re Deuel* does not contradict with the Federal Circuit's continuing judge-made industry-specific obviousness standard, since flexibility is the essence of such an approach.[335]

The reason why the Federal Circuit had developed a rigid TSM test and restricted the application of "obvious to try" in the past may be a response to the bias that often resulted from analyzing the combination of multiple prior art.[336] In the EPO's practice, the comparison between

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331. Brief of Marek Z. Kubin and Raymond G. Goodwin at 33, *In re* Kubin, 561 F.3d 1351 (2009 WL 877646 (C.A. Fed.)) (No. 2008-1184), 2008 WL 2505893 (C.A. Fed.).

332. Though the Federal Circuit affirmed the Board's finding that Kubin's invention was obvious, the court pointed out that the Board's reasoning was misguided. As the court stated, the Board's "emphasis on similarities or differences in methods of deriving the NAIL DNA misses the main point of this obviousness question." *In re* Kubin, 561 F.3d at 1356. What the appellants claimed was DNA sequences, not cloning technique. Whether the cloning technique is obvious is irrelevant in the analysis. *Id*.

333. *Id.* at 1353.

334. *Id.* at 1359. In referring to *In re* O'Farrell, the court cautioned that the meaning of "obvious to try" is not as broad as what is often misunderstood. *Id*.

335. *In re* Deuel, 51 F.3d 1552, 1560 (C.A. Fed. 1995).

336. *See* Alza Corp. v. Mylan Lab., Inc., 464 F.3d 1286, 1290 (C.A. Fed. 2006).

the claimed invention and prior art is limited to one single reference.[337] The combination of multiple prior art indicates that inventive step may exist.[338]

It may be appropriate to apply "obvious to try" in *In re Kubin*. In that case, the Federal Circuit has essentially reduced the prior art under consideration to one single reference.[339] Therefore, it is proper to caution that whenever "obvious to try" is to apply, the cited references for comparison should be able to reduce to one or two as the court did in *In re Kubin*. In doing so, hindsight judgment and bias would be avoided.

VI. CONCLUSION

Avoiding hindsight judgment and being more objective are the universal and ultimate goals of obviousness analysis in almost every patent system. An expansive and flexible obviousness approach as stated in *KSR* should not be literally applied to all types of inventions without further consideration.

An expansive and flexible approach is inconsistent with the international norms of obviousness analysis if it is literally applied. For instance, the problem-and-solution approach in the EPO practice, which is followed by numerous countries, is a rigid step-by-step test. Even if an expansive and flexible obviousness approach is preferable and can be justified, the need for flexibility should be interpreted in a way that an industry-specific obviousness standard is favorable, as exemplified by the Canadian selection patent doctrine and its application in pharmaceutical cases, which is traceable to English case law.

Though the *KSR* court reversed *Graham* as the highest principle in making obviousness determinations, the *KSR* decision has unexpectedly created the same problem that the *Graham* court sought to resolve.[340] That is, the inconsistency among the courts and the Patent Office. The

337. Guidelines for Examination in the European Patent Office, *supra* note 65, pt. C, ch. IV, § 11.7.1.

338. *Id*. § 11.8.

339. The Board rejected appellants' claims over the combined teachings of Valiante, Sambrook, and Mathew. *In re* Kubin, 561 F.3d at 1353. Nevertheless, the Board found Mathew's teachings only cumulative. *Id*. at 1354. Furthermore, as the Federal Circuit stated that the Board's emphasis on the similarities or differences in methods misses the main point of the obviousness question, Sambrook's teachings in *Molecular Cloning: A Laboratory Manual* has essentially been disregarded, though mentioned, in the "obvious to try" analysis. *See id*. at 1356.

340. KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 407 (2007).

KSR decision has created legal uncertainty regarding obviousness from at least three aspects: first, the inconsistency between the Federal Circuit and the PTO; second, the inconsistency between the PTO's practice before and after the *KSR* decision; and third, the uncertainty of the obviousness standard in a re-examination proceeding for a patent issued before *KSR*.[341]

Because of the high costs of biotechnology and pharmaceutical research, a research proposal is unlikely to receive grants or any sort of financial support without the projection of a "reasonable expectation of success." Nevertheless, a documented "reasonable expectation of success" would render an invention "obvious to try" under a "one-size-for-all" obviousness jurisprudence. As a result, only very few, if any, biotechnology or pharmaceutical inventions can escape from the suspicion of "obvious to try." Consequently, "obvious to try" may not be an appropriate test under § 103 in the biotechnological and pharmaceutical contexts under most circumstances.

Even if the application of "obvious to try" is desirable for certain inventions, as shown in *In re Kubin*, a close examination and elimination of cited references should be conducted before "obvious to try" can be applied. If multiple references demonstrate equal weights to the invention at issue and none of them can be regarded as cumulative, then it may be an indication that the invention is non-obvious.

341. *Id*. at 398.