

CASE COMMENTS

OBVIOUSNESS IN CHEMICAL AND BIOTECHNOLOGY PATENTS: A POST KSR V. TELEFLEX ANALYSIS

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Patent jurisprudence with respect to chemical and biotechnological inventions is quite at its nascent stage. The jurisprudence of patentability is constantly in a flux with the thresholds of novelty, utility and obviousness changing to fit into the contours of new technological advances. This is a case comment on KSR v. Teleflex, a US Supreme Court decision, which is observed to be one of the landmark cases in patent law and has shaken the foundation of our understanding of the test of obviousness. The paper particularly deals with the implications of the judgment on chemical and biotechnological patents.

INTRODUCTION

Patent Jurisprudence has developed all around the world with the aim to give rights to the inventor so that her invention is protected from misuse by the public. In order to ensure that the patent rights are vested on the worthy, certain thresholds have been established accordingly.¹ In the beginning novelty² and utility³ were installed as gatekeepers of the patent regime. When these thresholds failed, a new requirement of nonobviousness⁴ was enacted. Scholars have pointed out that when novelty and utility remain as easier requirements to be met⁵, obviousness becomes the “ultimate condition of patentability”.⁶ Every patent system has to identify trivial improvements or obvious combination of prior art from a patentable invention. Thus, in a perfect system, only true inventions rather than insignificant improvements are patentable. This principle is theoretically meant to encourage the improvement of technology by providing economic incentives to create valuable new products while not rewarding minor improvements.⁷ Despite its significance, obviousness as a criterion has been seldom used to determine patentability.⁸

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1 Jeanne C. Fromer, *The Layers of Obviousness in Patent Law*, 22 Harv.J.L.&Tech. 75.

2 35 U.S.C. § 101 (1952).

3 35 U.S.C. § 102 (2002).

4 35 U.S.C. §103 (2004).

5 Daniel Becker, *KSR v. Teleflex: How “Obviousness” Has Changed*, 4 Duke J. Const.L.&Pub. Pol’y Sidebar 45.

6 P.J. Federico, NONOBVIOUSNESS - THE ULTIMATE CONDITION OF PATENTABILITY (Part I), p. 101-111.

7 Timo Minssen, *The US Examination of Non- Obviousness After KSR v. Teleflex with Special Emphasis on DNA- Related Inventions*, IIC 200, 39(8), 886-916.

8 Fromer, *Supra n.I.*

In *KSR v Teleflex*,⁹ the Supreme Court clarified the various contours of obviousness test earmarking it as the ‘most important patent case of the last twenty years and perhaps since the passage of Patent Act, 1952.’¹⁰

This paper develops along four axes. Part I discusses the test of obviousness as it existed pre KSR, Part II analyses obviousness as applied to biotechnology and chemical patents; in Part III, the decision of the Supreme Court in KSR is analysed; Part IV addresses possible implications of the decision on biotechnology and chemical patents by analysing the case decisions post KSR; and finally Part V summarises and concludes the findings.

PART I

I. BACKGROUND ON OBVIOUSNESS

§103 of the US Patent Act¹¹ embodies the principle of obviousness and functions as a significant gatekeeper that denies patent protection for trivial improvements.¹² As per the statute, an invention does not deserve patent protection if it represents only a trivial modification of a prior art.¹³ Thusly, the basic guidepost test as per this section stands as: at the time of invention, a claim shall be beyond the predictable variation of a prior art to a person having ordinary skill in the art.¹⁴

The nonobviousness hurdle to patentability was discussed in 1850 by US Supreme Court in the case of *Hotchkiss v. Greenwood*.¹⁵ Followed by this, there were many decisions by lower courts and Supreme Court which resulted in great confusion as to the degree of non obviousness of an invention.¹⁶ Confronted by this doctrinal confusion in 1952, Congress codified the nonobviousness factor in the 1952 in the Patent Act, which is observed to have

9 KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007) [hereinafter, “KSR”].

10 Peter Lattman, *KSR v. Teleflex; The Supreme Court's Big Patent Rule*, <http://blogs.wsj.com/law/2007/05/01/ksr-v-teleflex-the-supremecourts-big-patent-ruling/> (March 15, 2010, 09:15 IST) (quoting Michael Barclay).

11 35 U.S.C. §103 (a) : A patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains

12 Timothy R. Holbrook, *Obviousness in Patent Law and the Motivation to Combine : A Presumption Based Approach* available at <http://lawreview.wustl.edu/slip-opinions/obviousness-in-patent-law-and-the-motivation-to-combine-a-presumption-based-approach/> (March 12 ,2010, 16:00 IST).

13 Alison M. Taroli, *Obvious Fallacy : Improving the Standard of Obviousness for Chemical Compounds To More Accurately Reflect Common Practice in the Art*, 21 Syracuse Sci. & Tech. L. Rep. 87).

14 Great Atlantic & Pacific Tea Co. v. Supermarket Equipments, 340 U.S. 147, 153 (1950).

15 Hotchkiss v. Greenwood, 52 U.S. 248, 264-67 (1850).

16 Jeanne C. Fromer, *The Layers of Obviousness in Patent Law*, 22 Harv.J.L.&Tech.75

taken the *Hotchkiss's* initial position.¹⁷ In short, the statutory provision reiterates the following¹⁸

- It adopts the position of a person having ordinary skill in the art (PHOSITA)
- It states only a negative test, that is, it denies the patentability to that which would have been obvious, without making any effort to state, much less describe a positive standard of ingenuity or inventiveness
- It expressly forbids the use of hindsight
- It adds an extra guard against hindsight by restricting the body of prior art only to the art to which the invention pertains
- It underscores that the test is objective and not subjective by ruling out any consideration of the specific manner in which the invention was made

Approximately after about ten years, the Supreme Court in *Graham v. John Deere Co. of Kansas City*¹⁹ assessed the new statutory provision as a codification of the Hotchkiss standard of inventiveness and articulated for a three part test on obviousness and suggested for including secondary considerations to the test. The four limbs of the test are as follows The Examiner has to determine the

- scope and content of the prior art, which is essentially the state of art at the time when the invention was made
- the differences between the prior art and claimed invention
- the level of ordinary skill in the relevant technology field
- non technical, secondary considerations determining the “circumstances surrounding the origin” of the invention²⁰

These four Graham factors thus comprehensively deal with the level of skill of person, focuses on the economic value of an invention, and asserts a need for an enquiry of whether the prior art teaches away, or whether there was a guarantee of commercial success, or whether there have been past failed attempts by others to carry out the conception.

¹⁷ *Id.*

¹⁸ Peter K. Yu, (ed.), *INTELLECTUAL PROPERTY AND INFORMATION WEALTH: PATENTS AND TRADE SECRETS* (Vol.II), 1st ed. (2007), p.8.

¹⁹ 383 U.S. 1 (1966).

²⁰ *Id* at 17-18, *Merck & Co., Inc. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1369 (2005); Rebecca S. Eisenberg, *Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA*, 19 *Berkeley Tech.L.J.* 885, 893-94 (2004).

Test of Reasonable Expectation

In re O'Farrell, another limb was added to the above test of obviousness, which was with respect to the reasonable predictability of success of implementation of an idea, by relying on a prior art which mentions possible successful combinations that might help in making the conception practical. This reasonable predictability would mean that based on the recording of a prior art, a method could be rendered to be obvious or not, by looking into the reasonable expectation of success stemmed from the prior art.²¹ Thus the Court held that obviousness does not require absolute predictability; however at least some degree of predictability would do, motivating the practitioner for carrying out the invention.²² Alternatively, if evidence can be shown that there was no reasonable expectation of success, then it would support a claim for non-obviousness.²³ Thus the law encourages only efforts that solve problems, where the prior art only suggests success among impractically large number of possibilities or general success in a field, with many approaches and there is no absolute predictability of success for reducing it to practice.²⁴

Teaching, Suggestion, Motivation (TSM) Test

In re O'Farrell, the position as to how “obviousness does not require absolute predictability of success”,²⁵ but requires only a “reasonable expectation of success” was established.²⁶ This element of reasonableness is further addressed through the Teaching Suggestion Motivation (TSM) test²⁷ which was developed by the Federal Court and subsequently made flexible by the KSR decision.²⁸ The Federal Court developed the TSM test to determine whether a teaching, suggestion or motivation in the prior art was used to modify an existing prior art to arrive at the claimed invention.²⁹ The TSM test strengthened the *O'Farrell* test and also predicated on the combination of two or more prior art references. It was observed that the prior art can be implicit or explicit, as long as it motivated the inventor to make the invention; thus satisfying the TSM test for obviousness.³⁰

21 Jonathan M. Spenner, *Obvious to Try: Obviousness of Chemical Enantiomers in View of Pre and Post KSR Analysis*, 90 J. pat. & Trademark Off. Soc'y 475.

22 *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988)

23 *Id.*

24 *Supra n.* 21 at 894, 903 (Fed. Cir. 1988).

25 *Supra n.* 21 at 903.

26 *Id.*

27 *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d. 1340, 1348 (Fed. Cir. 2000).

28 *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 399 (2007) (holding that the “teaching, suggestion, or motivation” (TSM) test should be flexibly applied, not as “rigid and mandatory formulas”).

29 Spenner, *supra n.* 21.

30 John Knight, *Motivation for the Federal Circuit*, <http://digital-law-online.info/papers/jk/tsm.pdf>, (March 26, 2010, 06:00 IST).

The TSM test and the Graham factors hold a symbiotic relationship. Graham framework identifies the full range of obviousness under §103 whereas the TSM test is the methodology used to carry out the Graham analysis and to determine the motivation factor of the inventor.³¹ The TSM test is fundamentally a search for a reasonable rationale as to why an invention is obvious, based on the appropriate prior art.³² The inventive step for the same would be some sort of motivation to make the combination, and this motivation could come from the prior art, such as the nature of the problem, the knowledge of the person having ordinary skill in the art (PHOSITA) and the prior art teachings that might direct to such a combination.³³ While these remain as means to establish a case of obviousness, teaching away³⁴ and reasonable expectation of success³⁵ are well used defences to show non-obviousness.

This test took the limelight in the case of *KSR*, wherein the Supreme Court rejected the rigid application and held that account has to be taken of the interferences and creative steps that a person of ordinary skill would employ while making an invention.

OBVIOUS-TO-TRY TEST

Obvious-to-try test has been used as a subcategory of obviousness to establish a prima facie case. Prior to *KSR* the obvious to try test was rarely used by the court to establish obviousness under §103.³⁶ The obvious-to-try test has two subcategories: a permissible ‘finite’ obvious to try results and an impermissible ‘non finite’ argument.³⁷ The ‘finite’ argument can be understood as explained in the case of *In re Merck*, where in the prior art refers to a particular combination or a method that would result to finite number of ways of carrying out the invention in question; whereas in the ‘non-finite’ string, as could be understood in *In re Berge*³⁸ means that there exists a large group of combinations to start with, and through trial and error method the result one is looking for, could be reached. But it was held that in such cases of ‘non-finite’ obvious-to-try combinations, there would be no motivation and hence would not be considered to be obvious. Even if an invention comes under the former,

31 *Id.*

32 *Id.*

33 Holbrook, *Supra* n.17.

34 As per this test, if a prior art exists which teaches away sufficiently from arriving at the claimed invention, then it may eliminate any motivation or reasonable expectation of success, *United States v. Adams*, 383 U.S. 39, 51 (1966).

35 *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995); explained under *O’Farrel* decision.

36 Jonathan M. Spenner, *Obvious to Try: Obviousness of Chemical Enantiomers in View of Pre and Post KSR Analysis*, 90 J. Pat. & Trademark Off. Soc’y 475.

37 *Id.*

38 292 F.2d at 956.

the finding may be rebutted by a sufficient showing of unexpected results or secondary considerations.³⁹

Thus the caveat that is usually attached while applying the obvious to try test are as follows:

- In some cases, what would have been “obvious-to-try” would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices was likely to be successful
- In others, what was “obvious-to-try” was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.⁴⁰

As it could be understood from the nuances of this test, it is susceptible to hindsight bias because it uses an inventor’s own reasoned approach to solve a problem against him. Thus effecting the extensive use of the ‘obvious-to-try’ test to deny patent protection for logically guided research; while rewarding patent protection for inventions obtained through irrational behaviour or luck and discouraging thoroughly researched inventions on account that they are obvious.⁴¹ In *KSR*, obvious-to-try test was resurrected and used in consonance with the TSM test for determining obviousness.

It could be summarised that the *Hotchkiss* standard of obviousness received statutory recognition with the legislation of §103; whereas the decision of *Graham* tried to explain the comprehensive test for obviousness under the section. The motivation factor that was touched upon by *Graham* was explained by the ‘reasonable expectation of success’ test in *O’Farrel*, which lead to the discussion of ‘obvious-to-try’ claims. Later on the Federal Court developed the TSM test to determine the *Graham* factors on obviousness and adhered to a very rigid application of the same.

II. OBVIOUSNESS IN CHEMICAL AND BIOTECHNOLOGICAL PATENTS PRE-KSR

As explained in the above section, through various case decisions the Court developed an equation for determining obviousness of inventions; but

³⁹ *Id.*

⁴⁰ *In re O’Farrell*, 853 F.2d 894 (Fed. Cir. 1988) at 903.

⁴¹ Scott R.Conley, *Irrational Behaviour, Hindsight, And Patentability: Balancing The “Obvious To Try” Test With Unexpected Results*, available at <http://ssrn.com/abstract=1445553>, last assessed on April 18, 2011.

these tests were held to be insufficient for unpredictable arts.⁴² Chemical patents and biotechnological patents which include physiological process are considered to be unpredictable arts.⁴³ Firstly, this part would briefly touch upon test of obviousness in chemical arts, followed by biotechnological arts.

Due to the intrinsic unpredictable nature of chemical arts, the Courts have seemingly found it difficult to determine chemical obviousness through the existing tests.⁴⁴ This dilemma has been expressed *In re Hass*⁴⁵ and *Application of Henze*⁴⁶, the pioneer cases on chemical obviousness in which the Court aimed for a balance with the existing tests and came up with an evolved version of obviousness tests for chemical and biotechnological patents, called as the “structural obviousness” test. As mentioned earlier, it became problematic for the authorities to determine chemical obviousness since the precedents have focused only on combination patents. So it became necessary to cull out a test for determining the genuineness of an invention of a new chemical compound.⁴⁷ Before these two seminal cases, *In re Papesch*⁴⁸ laid out the modern chemical obviousness regime. According to *Papesch* regime, the obviousness analysis of a chemical compound proceeds on two stages. This two stage process could be explained with the following example: Consider the claimed compound is B; the first limb of the test is- to find whether there is a prior art compound A, which is sufficiently close in structure to the claimed compound B. If the answer is negative, then the inquiry is completed and there is no obviousness for such a compound. Usually, there is a high predictability of properties of a compound keyed to structure, such that the disclosure of a prior art compound suggests that the claimed compound can and shall be synthesised to achieve like results. Thus the claimed compound becomes obvious on the basis of “structural obviousness”. Therefore according to *Papesch*, when there is a prima facie obviousness case based on the closeness of structure, it is vested on the patent applicant to demonstrate that there are actual differences between the claimed compound and the prior art such that the invention as a whole is non obvious.⁴⁹

42 Janice M. Mueller, *Chemicals, Combinations and Common Sense: How the Supreme Court's KSR Decision is Changing Federal Circuit Obviousness Determinations in Pharmaceutical and Biotechnology Cases*, 35. N.Ky.L.Rev. 281.

43 Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. Rev. 127.

44 *Id.*

45 *In re Hass*, 141 F.2d 122 (C.C.P.A. 1944)

46 *Application of Henze*, 181 F.2d 196 (C.C.P.A. 1950).

47 Seymore, *Supra n.43*.

48 *In re Papech*, 315 F.2d 381 (CCPA 1963) (Rich, J.)

49 Harold C. Wegner, *Chemical and Biotechnological Obviousness in a State of Flux*, 26 Biotechnology L. Rep. 437.

Whereas the resulting principle of law derived from the above mentioned seminal cases known as the *Haas-Henze doctrine*⁵⁰ is that if an examiner finds a compound in the prior art that is close enough to the claimed compound such that it would motivate a PHOISTA to make the claimed compound (e.g. a homologue as *In re Haas* and *Henze*) it would be obvious, unless evidence is provided which shows that the claimed compound possess unexpected properties.⁵¹ Along with these requirements as mentioned earlier “structural similarity”⁵² with a prior compound which motivated the inventor to come up with the new compound was also considered as a ground for obviousness.⁵³ Thus an obvious rejection based on structural similarity and function in a chemical patent case would essentially mean that there was sufficient motivation for a PHOSITA to create a new compound that would exhibit properties similar to that of a prior art compound because of their structural similarity.⁵⁴ But as mentioned in *Papesch*, it can be rebutted by showing that the compounds exhibited unexpected properties.⁵⁵ The Haas-Henze doctrine thus uses “structural similarity” to determine motivation or suggestion to an inventor to modify existing compounds or to obtain new compounds, establishing obviousness.⁵⁶

Biotechnology patents mainly include DNA and gene patents.⁵⁷ Since things that occur in nature cannot be patented, the additional steps of isolating and purifying the gene, aid inventions in biotechnology to overcome the initial hurdle to patentability.⁵⁸ However, disclosure of only an isolated and components of the DNA (i.e. the purified nucleotide sequence) is not sufficient to obtain a patent.⁵⁹ The inventor must disclose a “specific, substantial, and credible utility for the claimed isolated and purified gene” in order to be awarded a patent.⁶⁰ While the patentability of genes was questioned originally, the United States Patent and Trademark Office (USPTO) issued guidelines stating affirmatively

50 Harold C. Wegner, *Prima Facie Obviousness of Chemical Compounds*, 6 AIPLA Q. J. 271 (1978).

51 Harold C. Wegner, POST-KSR CHEMICAL OBVIOUSNESS IN LIGHT OF PFIZER V. APOTEX8(2007), available at http://www.patenthawk.com/blog_docs/070613_PostKSR_ChemicalObviousness.pdf (March 26, 2010, 9:30 IST).

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

53 *Id.* at 692.

54 *Id.*

55 Application of *Papesch*, 315 F.2d 381 (C.C.P.A. 1963).

56 Wegner, *supra* n. 49.

57 Rebecca Hays, *Biotechnology Obviousness in the Post- Genomic Era: KSR v. Teleflex and In re Kubin*, MINN. J.L.SCI. & TECH.2009;10(2):801-835.

58 *Id.*

59 *Id.*

60 *Id.*

that once genes have been identified and isolated, they can be patented⁶¹, provided that the invention satisfied the requirements of the U.S. Patent Act.⁶² The USPTO further clarified its statement that “an inventor’s discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.”⁶³

Many commentators believe that while applying the requirements of obviousness to biotechnology patents, the Federal Court has taken a slightly different stand.⁶⁴ The Graham factors along with TSM are used to determine obviousness by the Court for biotechnological patents⁶⁵ but the application of the same can be understood better by analysing two cases that have been decided before KSR. In the case of *In re Bell*⁶⁶, the Federal Court was presented with the issue of whether a *prima facie* case of obviousness existed for a gene, wherein the prior art disclosed a biological relationship (both the amino acid sequence of the corresponding protein and a general method of cloning) between the molecules disclosed in the prior art and those claimed by the patent.⁶⁷ The prior art contained two scientific articles: one which disclosed the amino acid sequence corresponding to the claimed DNA and RNA sequences and a second one which had a patent that disclosed a method for isolating a gene when at least a sequence of amino acid is known.⁶⁸ The patent examiner rejected the claim and the Board of Patent Appeals and Interferences affirmed the rejection on the basis of structural similarity between the nucleic acid and amino acid sequence stating that the prior art references make the claims obvious.⁶⁹ The Federal Circuit Court reversed the Board’s decision on appeal, holding the claimed DNA and RNA sequences to be non-obvious.⁷⁰ The court probed into whether a PHOSITA could arrive at the claimed invention in the light of references in the prior art. The Court held that the standard of

61 Varu Chilakamarri, *Structural Nonobviousness: How Inventiveness is Lost in the Discovery*, Va. J.L. &Tech. Vol. 10, No. 7, P3 (Summer 2005), available at http://www.vjolt.net/vol10/issue3/v10i3_a7-Chilakamarri.pdf (March 28,2010, 07:00 IST).

62 Steven P. Smith & Kurt R. Van Thomme, *Bridge Over Troubled Water: The Supreme Court’s New Patent Obviousness Standard in KSR Should Be Readily Apparent and Benefit the Public*, 17 Alb. L.J. Sci. & Tech. 127, 148 (2007).

63 Utility Examination Guidelines, 66 Fed. Reg. at 1093.

64 Dan L. Burk & Mark A. Lemley, *Biotechnology’s Uncertainty Principle*, 54 Case W. Res. L. Rev. 691, 691 (2004).

65 Kate M. Lesciotto, *KSR: Have Gene Patents Been KO’D? The Non-Obviousness Determination of Patents Claiming Nucleotide Sequences When the Prior Art Has Already Disclosed the Amino Acid Sequence*, 86 Wash. U.L. Rev.209.

66 *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993).

67 *Id.* At 782- 83

68 *Id.*

69 *Id.*

70 *Id.* at 785.

structural similarity reasoning as put forward in chemical patent cases as *In re Dillon*, cannot be applied to biotechnology patents that deal with genetic relationship between nucleic acids and amino acids.⁷¹ The Federal Court further stated that the prior art divulging information of amino acid sequences would only allow one to “hypothesize possible structures” and motivate one on to assess “the potential for obtaining that gene”.⁷² It has to be kept in mind, that such an amino acid sequence disclosed in the prior art can have been encoded by 1036 different nucleotides⁷³, thus rendering it non obvious on the ground that none could have possibly fathomed as to which possible sequences would constitute for the claimed gene.⁷⁴ The court also rejected the notion that the use of a generally known method to isolate gene sequences renders the sequences themselves obvious.⁷⁵

The other important case is *In re Deul*⁷⁶; the question that was presented in this case was of whether a prior art reference for teaching a method of gene isolation could be combined with another reference disclosing a partial amino acid sequence to establish a case of prima facie obviousness.⁷⁷ Whereas the prior art *In re Bell* disclosed the full amino acid sequence of the protein, *In re Deul* it was only the first nineteen amino acids.⁷⁸ The Federal Circuit while reversing the judgment of the Board of Patent Appeals, affirmed its stand as it held *In re Bell* decision.⁷⁹ The Court held that knowledge of a general technique and partial knowledge of a protein’s amino acid sequence would not necessarily lead a person of ordinary skill in the art to prepare the specific sequence claimed⁸⁰, although it may have been obvious-to-try to prepare the claimed sequences even if the actual sequences themselves were not obvious.⁸¹

PART II

I. OBVIOUSNESS AS ADDRESSED IN **KSR v. TELEFLEX**

KSR v. Teleflex has become one of the important cases under Patent regime. It addresses one of the primary foundations of patentability. The case

71 *Id.* at 783 (quoting *In re Rinehart*, 531 F.2d 1048,1051 (C.C.P.A. 1976).

72 *Id.* At 784.

73 *In re Bell*. 991 F.2d at 784, Anita Varma & David Abraham, DNA Is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market, 9 Harv. J.L. & Tech. 53,68-69 (1996) (stating that at the time of *In re Bell* that technology has developed in a way to determine al the 1036 possibilities).

74 *In re Bell*, at 784

75 *Id.* at 785.

76 51 F.3d. 1552 (Fed. Cir. 1995).

77 *Id.* at 1557.

78 *Id.* at 1556.

79 *Id.* At 1560.

80 *In re Deul* ar 1559.

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

dealt with the “need for caution in granting patents based on combination of elements of prior arts.”⁸² The invention at issue in KSR was of a pedal assembly that could be adjusted to accommodate drivers of different statures. Teleflex sued KSR, for infringement on its patent. KSR refuted the allegation by countering that Teleflex’s patent was obvious. The District Court granted summary judgment to KSR, as each component of the invention existed in previous patents. Teleflex approached the Court of Appeals for the Federal Circuit which reversed the District Court’s Judgment. The reason advanced by the Court was that the District Court did not apply the TSM test fully. According to the test, the Court would have needed to identify the specific “teaching, suggestion or motivation” that

would have led a knowledgeable person to combine the two previously existing components. KSR appealed to the Supreme Court on the ground that the Circuit Court’s decision conflicted with the precedents by the Supreme Court. Justice Kennedy, who wrote the opinion for the Court ruling in favour of KSR, stated that a patent for an invention which is a combination of two previously existing components may not amount to be obvious. It would be helpful in such cases for a court to identify, a reason that would have motivated a knowledgeable person to combine the components.

The Court held that the TSM test makes the obviousness test too narrow and rigid as it looks only on the specific problem the patentee was attempting to solve. Teleflex’s invention was inspired by previous inventions aimed at different problems. The Court stated that even though no one had combined the technology in the way Teleflex had done, it held that the existence of the technology would have caused any person of ordinary skill to see the obvious benefit of combining the two, solving the specific problem before the patentee, thus making the patent obvious and invalid.⁸³

II. CHANGES IN OBVIOUSNESS JURISPRUDENCE DUE TO KSR

The following were the changes made in the jurisprudence of obviousness as a result of this decision:

Teaching Suggestion Motivation Test

The issue of contention in the KSR case was that the United States Patent No. 6,237,565 B1 entitled “Adjustable Pedal Assembly with Electronic Trottle Control” (Engelgau Patent)⁸⁴ was inspired by various prior arts. KSR

82 KSR at 1395

83 Stephen G.Kunin, Andrew K. Beverina, *KSR’s Effect on Patent Law*, 106 Mich.L.Rev. First Impressions 50.

84 KSR Int’l Co. v. Teleflex Inc., 550 U.S. 398, 421-22., at 405-06, 82 U.S.P.Q.2d (BNA) at 1387.

contended that there existed enough teachings and suggestions which motivated Teleflex to come up with the invention, making the patent obvious. In *KSR*, the Supreme Court of America identified the difference in interpretation of §103 by the Federal Court, stating that a combination of pre-existing elements will not constitute an ‘invention’ and will not satisfy the ‘conditions of patentability’, if each element in the claimed combination does nothing more than what it was previously known or designed to do.⁸⁵ Thus the apex Court indicated the rigid application of the obviousness test by the Federal Courts⁸⁶ and pointed out how the TSM test was wrongly applied by them.⁸⁷

The Supreme Court recommended “an expansive and flexible approach” to the application of the TSM test with its own precedents to be applied to determine obviousness.⁸⁸ The Court, instead of killing the TSM test, set out to rehabilitate it from the Federal Circuit Court’s allegedly misguided application. The Apex court restructured the test with the following limbs

- in instances of existing prior arts, the applicant must show that the claimed invention has unexpected or superior results
- or that the invention goes beyond a combination of known elements yielding predictable results
- the steps undertaken by the applicant are not apparent
- and that the invention is not a result of market pressure or an identifiable predictable solution that could have been reached by a person of ordinary skill with common sense by relying on the prior arts (PHOSITAACS – Person Having Ordinary Skill In The Art And Common Sense).

Since the inception of the Patent Act in 1952, the United States Supreme Court has not explicitly given the qualifications of a person with ordinary skill. But implicit from the decisions prior *KSR*, a PHOSITA constituted a hypothetical “reasonable man specialised in the pertinent art.”⁸⁹ In *KSR*, the Court relied on the problem-solving capabilities of a person of ordinary skill in the art while determining the patentability.⁹⁰ Previously, it had been held that if a person of ordinary skill applies domain-specific principles mechanistically, then the invention would be obvious.⁹¹ *KSR* changed the perspective of a PHOSITA from an

85 Petition for Certiorari, at 4.

86 Janice M. Mueller, *Chemicals, Combinations and Common Sense: How the Supreme Court’s KSR Decision is Changing Federal Circuit Obviousness Determinations in Pharmaceutical and Biotechnology Cases*, 35. N.Ky.L.Rev. 281.

87 Kunin et. al, supra n. 83.

88 *Id.* at 415, 82 U.S.P.Q.2d (BNA) at 1394.

89 *Anderson’s-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 60 (1969); *United States v. Adams*, 383 U.S. 39, 51-52 (1966)

90 550 U.S. 398, 415- 418 (2007)

91 *Id.* At 421.

unsophisticated, unimaginative, uncreative plodder to someone with creative skill who can identify solutions to existing problems from identifiable predictable solutions that exist in the prior arts.⁹²

- Obvious- to- try test

Before the KSR decision, the Federal Court had reiterated how the obvious-to-try test is improper to determine obviousness.⁹³ In KSR, the Supreme Court concluded that the Federal Circuit had committed a mistake while determining the obviousness of an invention by merely showing that the combination of elements was ‘obvious-to-try’.⁹⁴ In doing so the Supreme Court addressed the obvious to try standard as follows:

“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 might show that it was obvious under §103.”⁹⁵

However it is important to note that the Supreme Court limited this standard to “finite predictable solutions” and “anticipated success”⁹⁶ derived by a PHOSITA with “common sense”.

Part III

I. Analysis of Chemical and Biotechnological Patents Post KSR

Eventhough it is true that KSR has dismantled the overly rigid application of TSM test, it has breathed new life into the overall obviousness test. The prongs that remain contentious are as follows:

- Whether after KSR it is unquestionably easier to establish a prima facie case of obviousness
- Whether the combination of prior art teachings can inspire a person skilled in the art and having common sense to expect reasonable success by relying on the existing material.

92 Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. Rev.127

93 76 Fordham L.Rev. 2625

94 KSR Int’l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1742 (2007).

95 Id.

96 Id.

- Whether a prima facie case of obviousness if established can be rebutted.⁹⁷

As far as the unpredictable sciences are concerned, the post KSR decisions are testimonial to the fact that the implications of the decision on the pertinent arts are immense.⁹⁸ One such impact is the raising of the standard of the ordinary skill of a person in the art to one having common sense.⁹⁹ In the case of similar compounds, KSR gives enough scope to use unexpected results and varying results to rebut it.¹⁰⁰ The chemical and the biotechnological patent cases that followed KSR also show that now the “obvious-to-try” test can be applied to unpredictable arts.¹⁰¹

The USPTO has also issued the following guidelines for examiners post KSR to test obviousness¹⁰²:

- Combining prior art elements according to known methods to yield predictable results
- Simple substitution of one known element for another to obtain predictable results
- Use of known technique to improve similar devices (methods, or products) in the same way
- Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results.¹⁰³

In lieu of this, the Federal Circuit has decided the obviousness factor for various chemical and biotechnological cases, some of which are listed hereunder. The pertinent case laws post KSR show that the Courts still continue to use secondary considerations and the skill of the person to decide on obviousness thus misapplying *KSR*. This confusion among the lower Courts has been duly pointed out by scholars in the field.¹⁰⁴

97 35 N.Ky.L.Rev.281.

98 35 N.Ky.L.Rev.281.

99 Daiichi Sankyo Co., Ltd. v. Apotex, Inc., 501 F.3d 1254 (Fed. Cir. 2007).

100 Jonathan M. Spenner, 90 J. Pat. & Trademark Off. Soc’y 475.

101 Gabriel J. McCool, “*Obvious to Try*”: A New Standard for Biotechnology Inventions?, available at http://www.martindale.com/biotech-life-sciences/article_Edwards-Angell-Palmer-Dodge-LLP_821118.htm (April 15, 2010, 05:00 IST).

102 Mary Ann Liebert, *Examination Guidelines for Determining Obviousness under 35 U.S.C 103 in view of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*, 26 Biotechnology L.Rep.649.

103 Mueller, *Supra* n.81.

104 Spenner, *supra* n.21.

II. CASES

Takeda v. Alphapharm

Takeda v. Alphapharm is the first pharmaceutical case decided by the Federal Circuit Court post KSR.¹⁰⁵ The Court considered whether genus and species claims covering a compound called pioglitazone were invalid as obvious; as the claimed chemical compound showed structural similarity between the closest prior art. The Federal Court while handing the decision stated that KSR hasn't modified the manner of establishing the prima facie obviousness of a new claimed compound by showing some reason that would have led a chemist to modify a known compound in a particular manner.¹⁰⁶ The Federal Court focused on predictability as a touchstone while determining the obviousness in this case. The Court found that one of ordinary skill in the art would not have selected compound B as the lead compound based on the prior teachings that disclosed its toxicity and activity. Thus the obvious to try argument of the Alphapharm was dismissed on the position as laid down *In re Deuel*¹⁰⁷ and *In re Dillon*.¹⁰⁸ Also, the Court held that the prior art at the time of Takeda's invention did not disclose a "finite number" of "predictable solutions", but rather gave a "broad selection" of compounds for further investigation and directed the PHOSITA away from the claimed compound.¹⁰⁹

Sanofi-Synthelabo v. Apotex

In *Sanofi-Synthelabo v. Apotex*, the matter of contention was the patentability of enantiomers. Enantiomers are molecules that are mirror images,¹¹⁰ of one another and individually have nearly identical physical properties,¹¹¹ but different biological activities. Through the process of racimization, one enantiomer may be converted to the other.¹¹² In the case, the validity of the patent covering the active enantiomer ingredient in Plavix was challenged. Apotex contented that the pharmaceutical salt clopidogrel bisulfate used in the drug was obvious. The *Sanofi* Court held that eventhough there existed prior art which disclosed the similarities of enantiomers developed through

105 Michael R. Dzwonczyk, *Implementing a "Predictable" Obviousness Standard Post KSR*, <http://www.sughrue.com/files/Publication/c184ddaf-8489-4b7c-84a9061409df7037/Presentation/PublicationAttachment/35de691e-b34e-4e83-9ce6-092161dca7d8/Implementingapredictable.pdf> (April 18, 2010, 09:00 IST)

106 *Takeda Chem. Indus. V. Alphapharm Pty.,Ltd.*, 492 F.3d.1350 (Fed. Cir. 2007) at 1357.

107 *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995).

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

109 *Takeda*, 492 F.3d at 1359.

110 *Ortho-McNeil*, 348 F. Supp. 2d at 720.

111 Jonathan M. Spencer, *Obvious-To-Try Obviousness of Chemical Enantiomers in View of Pre and Post- KSR Analysis*, 90 J.Pat.& Trademark Off. Soc'y 475.

112 *Sanofi-Synthelabo v. Apotex, Inc.*, 492 F. Supp. 2d 353, 369 (S.D.N.Y. 2007).

racimization, the unexpected results of the salt invalidated the *prima facie* case of obviousness. Thus, the obvious to try test was rebutted by the Court's long standing employment of expectation of success test.¹¹³

Board of Trustees v. Roche

The obvious to try test was applied by the District Court to invalidate a claim involving a biotech patent. The invention claimed a method of evaluating the effectiveness of anti- HIV therapy through quantifying the amount of HIV RNA by PCR.¹¹⁴ Prior art existed in form of an article authored by Holdniy disclosing a method of quantifying the amount of HIV RNA molecules by PCR and using it as a marker for the amount of HIV virus¹¹⁵ ;whereas the correlation between therapeutic effectiveness of a drug and the amount of HIV virus though viral culture was disclosed by an article of Ho.¹¹⁶ The Court found the claim to be obvious even though it was arguably not obvious to try with any reasonable expectation of success. Any difference between the claims and Holdniy's article was obvious in light of Ho's article.¹¹⁷

In re Kubin

The impact of the KSR decision on unpredictable arts like biotechnology was established in this case. The Federal Circuit applied the obvious-to-try test and held that the isolation and sequencing of a human gene that encodes a particular domain of protein is obvious. While rendering the judgment the court classified two situations. First, an obvious-to-try combination may not be obvious when the inventor "merely throws metaphorical darts at a board filled with combinatorial prior art possibilities" ¹¹⁸ Secondly, an obvious-to-try combination may not be obvious "where the prior art give only general guidance as to the particular form of the claimed invention or how to achieve it rather than providing a detailed enabling methodology for practicing the claimed invention."¹¹⁹ The case to a certain extent overruled *In re Deul*.¹²⁰

113 Andrew V.Trask, *Obvious to Try: A Proper Patentability Standard in the Pharmaceutical Arts?*, 76 Fordham L.Rev. 2625.

114 Kamrin T. MacKnight, *Polymerase Chain Reaction (PCR): The Second Generation of DNA Analysis Methods Takes the Stand*, 20 Santa Clara Computer &High Tech. L.J. 95, 108-16 (2003).

115 Roche, 563 F. Supp. 2d at 1023 n.2.

116 *Id.*

117 *Id.* at 1044.

118 *Id.* at 1359.

119 *Id.*

120 Hays, *Supra n.* 39.

PART IV

CONCLUSION

In *KSR*, the Supreme Court by flexibly applying the TSM test directed the Court of Appeal to follow its own precedents as decided in *DyStar*¹²¹, *Alza*¹²² etc. Furthermore the Court stated that finite obvious-to-try results to be a permissible basis for determining obviousness. Such a rationale was propounded in some of the cases prior *KSR*.¹²³ In light of the cases decided after *KSR*, application of obvious-to-try test in the unpredictable arts has been dicey. There are various positions with regard to understanding the obviousness regime post *KSR*. Some say, that it has changed the position of law substantively; some say it has not been changed and that the Apex Court had directed the Federal Court to look into its rigid application. As mentioned in the paper, atleast with the unpredictable arts like chemistry and biotechnology, the position of law has been more or less the same; i.e. in these arts, it is easier to establish a prima facie case on obviousness on structural similarity and the like but it is vested on the applicant to prove that the claimed compound/gene has unexpected properties and superior properties, thus rebutting the presumption of obviousness.

The researcher feels that an interpretation of *KSR*'s obvious-to-try test with respect to unpredictable arts should be context-specific. When *KSR* calls for a finding of obviousness where there is a "finite number of identified, predictable solutions,"¹²⁴ the Federal Court has limited the standard to an "easily traversed, small and finite number of alternatives"¹²⁵ a standard specifically tailored to accommodate the biotechnology and pharmaceutical industries.¹²⁶ Thus, *KSR*'s flexible application of TSM might result in a situation where certain deserving inventions in biotechnological and pharmaceutical arts may fail to achieve the requirements of patentability. Even though one believes that *KSR* decision has risen the bar for patentability of chemical and biotechnological inventions, it is always a best option to develop industry specific obviousness requirements.

121 *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d1356, 1367 (2006).

122 *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (2006).

123 *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 348 F.Supp. 2d 713 (D.W.Va. 2004), aff'd, 161 Fed. Appx. 944 (2005); *In re Merck & Co.*, 800 F.2d 1091, 1098 (Fed. Cir. 1986).

124 *KSR Int'l*, 550 U.S. at 421.

125 *Ortho-McNeil*, 520 F.3d at 1364.

126 *Hays*, *Supra n.* 39..