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The Obvious to Try Doctrine: Its Use, Misuse, and Abuse

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The Supreme Court jettisoned more than twenty years of Federal Circuit jurisprudence regarding the standard for determining obviousness in *KSR v. Teleflex*². At issue in *KSR* was whether the attachment of an electronic pedal position sensor to a support member of an adjustable pedal assembly in a vehicle was obvious in view of the prior art.

The authors were surprised to see a discussion of the obvious to try doctrine in the *KSR* decision. As the Supreme Court noted “... attaching the sensor to the support member allows the sensor to remain in a fixed position while the driver adjusts the pedal.”³ The authors wondered what the obvious to try doctrine had to do with appreciating the advantage of attaching a sensor to a fixed position on a pedal.

In order to determine why the obvious to try doctrine found its way into the *KSR* decision, the authors investigated the origin of the doctrine, and how it has been applied in cases leading up to, and following,

KSR. They concluded that, in a few cases where it was used appropriately, the obvious to try doctrine has been useful in an analysis of obviousness. In general, however, they observed that the doctrine has often been misunderstood.

Below, the authors will trace the history of the obvious to try doctrine, and will use the history to suggest guidelines for determining when the doctrine is useful in determining obviousness, and when it is not. The authors will then point out cases in which the obvious to try doctrine has been appropriately used, and other cases in which it has been misused, and even abused. They hope that by doing so, the doctrine will be placed in its proper perspective. and will be used appropriately more often.

History of the Obvious to Try Doctrine

The obvious to try doctrine can be traced to two decisions written by Judge Rich on behalf of the

¹ Hoffmann & Baron, LLP. The opinions expressed in this article are solely the current opinions of the authors, and not necessarily those of Hoffmann & Baron, LLP; any of its attorneys or agents; any of its clients; and not necessarily even the future opinions of the authors. The authors acknowledge and thank Ronald J. Baron for his helpful comments.

² *KSR International v. Teleflex*, 550 U.S. ___, 127 S.Ct. 1727 (2007).

³ *Id.*, 127 S.Ct. at 1737; *Id.*, 127 S.Ct. at 1737.

Court of Customs and Patent Appeals (C.C.P.A.). In these cases, the solicitor of the Patent Office⁴ raised “obvious to try” as a standard for obviousness.⁵ The two cases, *Application of Huellmantel*⁶ (*Huellmantel*) and *Application of Tomlinson*⁷ (*Tomlinson*) are discussed below. In both cases, Judge Rich rejected the solicitor’s attempts to establish “obvious to try” as an absolute standard of obviousness.

Application of Huellmantel

Judge Rich addressed the obvious to try doctrine for the first time in 1963 in *Huellmantel*. At issue was the obviousness of anti-inflammatory drug compositions that included salicylate and either prednisone or prednisolone⁸. According to the solicitor, cortisone was known to be used in a composition with salicylate for treatment of an inflammatory disease, and to have the same effect as prednisone or prednisolone.⁹ The solicitor asserted, therefore, that it would have been “obvious to at least try” to substitute prednisone or prednisolone for cortisone.¹⁰ The court affirmed the rejection, but used a rationale different from that of the solicitor.¹¹

In a footnote, Judge Rich felt “compelled” to criticize the Patent Office’s reliance on the obvious to try doctrine in determining patentability.¹² He noted that the Patent Office dismissed the improved results of the claimed composition because it was “obvious to at least try” to substitute one steroid for another.¹³

Judge Rich flatly rejected the reasoning of the Patent Office, and stated that it “flies in the face of the plain language of the statute as interpreted by this court.”¹⁴ He pointed out, for example, that in § 103: “Nothing is said about ‘obvious to try.’”¹⁵

Application of Tomlinson

Judge Rich revisited the obvious to try doctrine in 1966 when the Patent Office tried again to raise it as the standard for obviousness in *Application of Tomlinson*. For the purpose of this article, the claimed invention in *Tomlinson* will be considered to relate to an ultraviolet light-stable com position comprising polypropylene and certain cobalt dithiocarbamates.¹⁷

The prior art disclosed cobalt dithiocarbarnates as being useful for stabilizing polyethylene against ultraviolet light.¹⁸ Also disclosed in the prior art were other light stabilizers that were useful for stabilizing both polypropylene and polyethylene.¹⁹

The examiner and the Patent Office Board of Appeals²⁰ again mentioned the obvious to try doctrine in their argument for obviousness of the invention in *Tomlinson*. According to Judge Rich, the examiner stated the following, with which the board expressed “total agreement”:

... ‘it would be obvious for a skilled chemist *to try* to stabilize polypropylene with a known stabilizer for polyethylene,’ and ‘that it would

⁴ As it was then known, now the Patent and Trademark Office.

⁵ The Court of Customs and Patent Appeals was the predecessor of the Court of Appeals for the Federal Circuit.

⁶ Application of Alan B. Huellmantel, 324 F.2d 998 (C.C.P.A. 1963); *Huellmantel* was decided prior to the authoritative interpretation of 35 U.S.C. 103 by the United States Supreme Court in *Graham v. John Deere*, 383 U.S. 1 (1966).

⁷ Application of Arthur R. Tomlinson, Harry H. Hall and William F. Geigle, 363 F.2d 928 (C.C.P.A. 1966).

⁸ *Huellmantel*, 324 F.2d at 998

⁹ *Id.* at 1000.

¹⁰ *Id.*

¹¹ *Id.* at 1001.

¹² *Id.* at 1001 n.3.

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ See above.

¹⁷ 363 F.2d at 930. The claims also included the corresponding nickel dithiocarbamates, which were disclosed in the prior art as being useful in heat stabilization of polypropylene, although of inferior quality *Id.* at 929, 930. Judge Rich affirmed the rejection of any claim that covered compositions comprising nickel dithiocarbamates, although he considered “...the rejection to be a highly technical one for lack of novelty.” *Id.* at 934.

¹⁸ *Id.* at 929.

¹⁹ *Id.* at 929-930.

²⁰ As it was then known, now the Patent and Trademark Office Board of Patent Appeals and Interferences.

be routine experimentation for a skilled chemist *to attempt* to stabilize polypropylene against the deteriorative effect of light by first *trying* the known stabilizers for polyethylene such as the ... cobalt dialkyldithiocarbamates’(emphasis is added).²¹

Judge Rich demonstrated a characteristic understanding of the mechanics of patent law, as well as an ability to get to the heart After what he described as “extensive of an issue, by stating:

Our reply to this view is simply that it begs the question, which is obviousness under section 103 of *compositions* and *methods*, not of the direction to be taken in making *efforts* and *attempts* (original emphasis).²²

He also expressed an understanding of the nature of progress in science and technology by placing the examiner’s and board’s argument in its proper context:

Slight reflection suggests, we think, that there is usually an element of ‘obvious to try’ in any research endeavor, that it is not undertaken with complete blindness but rather with some semblance of a chance of success...²³

Judge Rich continued this sentence with an insight demonstrating his understanding of patent law policy:

... patentability determinations based on [obvious to try] as the test would not only be contrary to statute but result in a marked deterioration of the entire patent system as an incentive to invest in those efforts and attempts

which go by the name of ‘research.’²⁴

After what he described as “extensive deliberation,” Judge Rich reversed the rejection of the claimed composition by the examiner and board.²⁵ He explained that “[n]early every reference of record speaks of the *unexpectedness* of the behavior of ‘related’ materials” when applied to the problem Tomlinson attempted to solve.²⁶ He pointed out, for example, that one such reference reported “no known basis for *predictability* of results.”²⁷

It is clear that Judge Rich based his decision in *Tomlinson* on the *unexpectedness* and *unpredictability* of the behavior of polymer stabilizers. He did not, however, find it necessary to articulate a precise standard in *Tomlinson* for when there is sufficient unexpectedness and unpredictability to establish patentability in an obvious to try context. Apparently, the facts spoke for themselves, and the decision was sufficiently clear. A precise standard would have to wait for another day.

in re O’Farrell

As discussed above, the solicitors in *Huellmantel* and *Tomlinson* failed to convince Judge Rich that “obvious to try” is sufficient to establish obviousness. No doubt encouraged by the solicitors’ failure, the appellants in *In re O’Farrell*²⁸ attempted to raise the obvious to try doctrine in their favor, and to convince Judge Rich that obvious to try is sufficient to establish non-obviousness.

The claimed invention in *O’Farrell* related to the expression of a heterologous (*i.e.*, non-host)

²¹ *Tomlinson*, 363 F.2d at 931

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.* at 932.

²⁶ *Id.* at 933.

²⁷ *Id.*

²⁸ *In re O’Farrell*, 853 F.2d 894 (Fed. Cir. 1988).

protein fused to an indigenous (*i.e.*, host) protein in bacterial cells (*i.e.*, - the host).²⁹ The expression of a heterologous protein in a host cell was a historic development in genetic engineering.

Nevertheless, the examiner and the United States Patent and Trademark Office Board of Patent Appeals and Interferences (the Board) rejected the claims because “so much of the applicants’ method was revealed” in a prior art journal article of the inventors.³⁰ Therefore, the Board held that the claimed invention would have been obvious.³¹

According to the appellants, however, a heterologous protein had never been conclusively proven to be expressed in a bacterial cell.³² They argued that there was uncertainty regarding whether the claimed method would work even after the suggestion in their prior art article.³³ The appellants asserted that, in view of such uncertainty, the prior art reference constituted “merely invitations to those skilled in the art to try to make the claimed invention.”³⁴ The appellants in *O’Farrell* argued therefore, that the rejection “amounts to the application of a standard of ‘obvious to try.’”³⁵ According to the appellants, apparently, the Board should have held that the claimed invention was merely obvious to try, and was, therefore, *non*obvious.

Judge Rich conceded the following:

It is true that this court and its predecessors have repeatedly emphasized that ‘obvious to try’ is not the standard (for obviousness) under § 103.”

But he did not stop there. He continued by

emphasizing that ‘obvious to try’ is also not the standard for non-obviousness under § 103. According to Judge Rich:

Any invention that would in fact have been obvious under Sec. 103 would also have been, in a sense, obvious to try. The question is: when is an invention that was obvious to try nevertheless nonobvious?³⁷

O’Farrell presented a case in which the claimed invention was obvious to try, but, unlike the facts in *Huellmantel* and *Tomlinson*, it was not clear whether the invention was “nevertheless nonobvious.” Therefore, Judge Rich finally found it necessary in *O’Farrell* to articulate a standard for resolving the issue of obviousness under § 103 when the prior art renders an invention obvious to try.

In such a case, Judge Rich held that, for establishing obviousness: “... all that is required is a reasonable expectation of success.”³⁸ This standard is still relevant today.

The court in *O’Farrell* reasoned that the prior art reference contained not only “a suggestion to modify the prior art to practice the claimed invention,” but also “evidence suggesting that it would be successful.”³⁹ Therefore, the claims on appeal were held to be obvious in view of the cited prior art.⁴⁰

The Obvious to Try Doctrine

As was explained above, the obvious to try doctrine was developed by Judge Rich in *Huellmantel*, *Tomlinson*, and *O’Farrell*. It is apparent from these

²⁹ *Id.* at 895.

³⁰ *Id.* at 901.

³¹ *Id.*

³² *Id.* at 902.

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.* at 903.

³⁷ *Id.*

³⁸ *Id.* at 904.

³⁹ *Id.* at 902.

⁴⁰ *Id.*

decisions that Judge Rich considered the proper use of the obvious to try doctrine to require resolution of two issues: (i) when is the obvious to try doctrine relevant, and (ii) how does one determine obviousness when an invention is obvious to try.

With regard to the first issue, Judge Rich thought the relevance of the obvious to try doctrine depended on the nature of the prior art. When the prior art suggests the possibility of a claimed invention, but expresses or infers at least some uncertainty that the invention can be made or will function as expected, Judge Rich considered the obvious to try doctrine to be relevant.

According to Judge Rich in *O'Farrell*,⁴¹ for example, the reference cited against the claims contained "... a suggestion to modify the prior art to practice the claimed invention ..."⁴² As he further noted, however: "Appellants argue that after the publication of [the reference], successful synthesis of protein was still uncertain."⁴³ Therefore, the obvious to try doctrine was clearly relevant in *O'Farrell*.

When the obvious to try doctrine is relevant, Judge Rich identified the crucial issue to be: "... when is an invention that was obvious to try nevertheless nonobvious?"⁴⁴ According to Judge Rich in *O'Farrell*, resolution of this issue is based on the degree to which success is unexpected and unpredictable.

More precisely, the standard is whether there is a reasonable expectation of success.⁴⁵ If there is, the invention is obvious. If not, the invention is nonobvious.

If, however, the prior art leaves little or no doubt that the claimed invention can be made and will operate to achieve its stated purpose, the obvious to try doctrine is not relevant.⁴⁶ Under such circumstances, one analyzes the differences between the prior art and the claimed invention in the traditional sense under § 103, *i.e.*, "... differences between the prior art and the claims at issue are to be ascertained."⁴⁷

Appropriate Use of the Obvious to Try Doctrine

Where relevant, the obvious to try doctrine can assist the United States Patent and Trademark Office (PTO) or a court to precisely identify the issue as whether there is a reasonable expectation of success. A recent case in which the obvious to try doctrine did so is discussed immediately below.

PharmaStem Therapeutics, Inc. v. ViaCell, Inc.

At issue in *PharmaStem Therapeutics v. ViaCell* (PharmaStem)⁴⁸ were patents of PharmaStem based on the discovery that blood from the umbilical cord of a newborn infant ("cord blood") is a rich source of hematopoietic stem cells.⁴⁹

The claimed invention involved a method relating to the use of cryopreserved cord blood in hematopoietic reconstitution (*i.e.*, rebuilding an individual's blood and immune system after the system has been compromised by disease or medical treatment, such as chemotherapy).⁵⁰ The method included isolating and cryopreserving cord blood, thawing the blood when needed, and introducing the blood into a human.⁵¹

⁴¹ See above.

⁴² *In re O'Farrell*, 853 F.2d at 902.

⁴³ *Id.*

⁴⁴ *Id.* at 903.

⁴⁵ See, for example, *id.* at 904 ("...all that is required is a reasonable expectation of success.")

⁴⁶ In addition to *KSR*, further examples of such circumstances include the facts of *Deuel* and *Kubin*, which are discussed below.

⁴⁷ According to the Supreme Court: "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 of nonobviousness of the subject matter is determined (emphasis added)." *KSR*, see above, citing *Graham v. John Deere Co.*, 383 U.S. 1 (1966) and *Hotchkiss v. Greenwood*, 52 U.S. 248 (1851)

⁴⁸ 491 F.3d 1342 (Fed. Cir. 2007).

⁴⁹ *Id.* at 1347; Stem cells are fundamental (or "primitive") cells from which specialized (or "mature") cells derive. Hematopoietic stem cells are stem cells that are ultimately responsible for producing all of the specialized cells of the blood and immune ("*i.e.*, hematopoietic") system. Hematopoietic stem cells produce progenitor cells and more hematopoietic stem cells. For a more complete discussion of the technology behind the claimed inventions, see *id.* at 1347.

⁵⁰ *Id.* at 1347.

⁵¹ *Id.* at 1348.

The defendants in *PharmaStem* alleged, *inter alia*, that the patents in suit were invalid for obviousness based on a combination of several prior art references.⁵² At trial in the United States District Court for the District of Delaware, the jury disagreed, and found that PharmaStem's patents were not obvious.⁵³ The district court judge denied the defendant's motion for JMOL, and upheld the jury's finding that the patents are valid.⁵⁴

The defendants appealed the district court judge's denial of their motion for JMOL to the Federal Circuit.⁵⁵ The opinion of the three member panel was written by Judge Bryson, with whom Judge Prost agreed.⁵⁶ Judge Bryson conceded that the JMCIL motion "...presented the district court with an unusually difficult set of challenges."⁵⁷

In order to establish obviousness, Judge Bryson stated that the defendants had the burden to show by clear and convincing evidence the following two elements:

- (i) ... that a person of ordinary skill in the art would have had reason to *attempt to ...* carry out the claimed process, and (ii) would have had a reasonable expectation of success in doing so (emphasis and numbers added).⁵⁸

It is clear that the court considered the obvious to try doctrine to be relevant, although it did not explicitly say so.

The court found that the possibility of using cryopreserved cord blood to effect hematopoietic

reconstitution had been clearly suggested at the time the applications were filed.⁵⁹ Therefore, the court concluded that the first element, namely whether "a person of ordinary skill in the art would have had reason to attempt to ... carry out the claimed process," was "plainly satisfied here."⁶⁰

The patentee, PharmaStem, relied on extrinsic evidence in arguing that problems existed with transplant tissues, and that "those in the field of hematopoietic reconstitution 'would not have expected cord blood to be a successful transplant tissue.'"⁶¹ Given the court's opinion that there was a reason to attempt to carry out the claimed invention, and PharmaStem's evidence of uncertainty regarding success, the obvious to try doctrine was, in fact, relevant in *PharmaStem*, and was so treated by the court.

"The more difficult question" for the court was resolving the question "whether the prior art would have given rise to a reasonable expectation of success in creating [the claimed inventions]."⁶² Judge Bryson framed the issue as follows: "whether the inventors had a reasonable expectation that cord blood could be successfully used in transplants for hematopoietic reconstitution."⁶³

Judge Bryson considered it important that, PharmaStem's denial notwithstanding, the prior art disclosed stem cells in cord blood as well as in bone marrow.⁶⁴ He further noted prior art disclosures stating that "cord blood contains sufficient hematopoietic stem cells to effect a transplant,"⁶⁵

52 *Id.*

53 *Id.* at 1346,1359.

54 *Id.* at 1347,1359.

55 *Id.* at 1347.

56 *Id.* at 1346.

57 *Id.* at 1367.

58 *Id.* at 1360.

59 *Id.*

60 *Id.*

61 *Id.*

62 *Id.* at 1360.

63 *Id.*

64 *Id.* at 1362.

65 *Id.* at 1363.

and that “... bone marrow transplants can result in hematopoietic reconstitution.”⁶⁶

Judge Bryson concluded that:

While the inventors may have proved conclusively what was strongly suspected before - that umbilical cord blood is capable of hematopoietic reconstitution ...the inventors merely used routine research methods to prove what was already believed to be the case.⁶⁷

In other words, judge Bryson considered there to be a reasonable expectation of success.

Accordingly, Judge Bryson held that PharmaStem’s claims were obvious, and that it was unreasonable for the jury to have reached the opposite conclusion at trial in the district court. Therefore, he reversed the district court’s denial of JMOL, and remanded to the district court for entry of judgment in the defendant’s favor.⁶⁸

The third member of the Federal Circuit panel in *PharmaStem* was Judge Newman.⁶⁹ She filed a vigorous dissent to the majority’s holding that PharmaStem’s patents were invalid for obviousness.⁷⁰

Judge Newman appeared to agree that the obvious to try doctrine was relevant in *PharmaStem*.⁷¹ She vehemently disagreed, however, that there was a reasonable expectation of success.⁷²

Abbott Laboratories v. Sandoz, Inc

Judge Newman was on a more recent Federal Circuit

panel that also appropriately applied the obvious to try doctrine. This time, however, she drafted the majority opinion.

The case, *Abbott Laboratories v. Sandoz, Inc.*⁷³ (*Abbott*), arose out of an infringement action brought by Abbott against the generic drug company Sandoz after Sandoz filed an Abbreviated New Drug Application (ANDA) for an extended release formulation of the antibiotic drug, clarithromycin.⁷⁴ The Abbott patents-in-suit related to extended release formulations of clarithromycin having certain pharmacological properties.⁷⁵ In response to the infringement charge, Sandoz argued, *inter alia*, that the claims of the patents-in-suit were invalid on the ground of obviousness.⁷⁶

According to Sandoz, a person of ordinary skill in the art would have “desired to improve” the administration of clarithromycin by finding an extended release formulation having optimum properties, and “would have selected and tested” a prior art polymer to arrive at the claimed pharmacological properties.⁷⁷ Sandoz further argued that “no more than routine experimentation was needed.”⁷⁸

Abbott responded by pointing out that its extended release formulations were not shown or suggested by the prior art to produce the pharmacological properties of the claimed invention.⁷⁹ According to Abbott, the prior art disclosed no more than *in vitro* data for “scores” of possible formulations containing drugs other than clarithromycin. Abbott asserted that the *in vitro* data disclosed in the prior

66 *Id.*

67 *Id.*

68 *Id.* at 1367.

69 *Id.* at 1346.

70 *Id.* at 1367.

71 *Id.* at 1377 (“There has been much hopeful speculation about the potential of stem cells, although this remedy eluded those who came before.”).

72 *Id.* at 1378 (“My colleagues go too far in limiting the patent system to the serendipitous and the unexpected.”).

73 544 F.3d 1341 (Fed. Cir. 2008).

74 *Id.*

75 *Id.* at 1343-44.

76 *Id.* at 1344.

77 *Id.* at 1347.

78 *Id.*

79 *Id.* at 1348.

art were “not predictably transferable” to the *in vivo* activity of clarithromycin.⁸⁰

The district court issued its initial decision granting Abbott’s motion for a preliminary injunction shortly before the Supreme Court’s decision in *KSR*.⁸¹ After *KSR* was decided, however, the court requested supplemental briefing and argument.⁸²

In its supplemental argument, Sandoz stressed that, in light of *KSR*, it was “obvious to try” various prior art polymers such that “any successful [clarithromycin] composition would be unpatentable, whether or not the results were predictable.”⁸³ Sandoz further argued that it would have been “obvious to experiment to determine which formulations were effective” in view of the differences and similarities between clarithromycin and related prior art drug.

Abbott pointed out that the subject matter in its patents differed from that in *KSR*. According to Abbott, the claims in its patents related to:

... new biological compositions whose performance and effectiveness in combination **cannot be confidently predicted** but must be made and evaluated, while the claims involved in *KSR* related to:

new mechanical combinations of known elements each of which **predictably** performs its known function in the combination.⁸⁵

In its supplemental decision following *KSR*, the district court maintained that Abbott was likely to prevail on the merits regarding, *inter alia*,

obviousness and therefore granted a preliminary injunction.⁸⁶ The district court explained that Sandoz had not produced evidence indicating that the pharmacological property limitations were disclosed in the prior art or were inherent in the structural limitations of the prior art compositions.⁸⁷ The district court further observed that *KSR* “did not mention or affect the requirement that each and every claim limitation be found present in the combination of the prior art references before the analysis proceeds.”⁸⁸

The Federal Circuit agreed with the district court’s decision.⁸⁹ Writing for the majority, Judge Newman noted that

the [Supreme] Court [in *KSR*] provided guidance that “a court must ask whether the improvement is more than the **predictable** use of prior art elements according to their established functions.” 127 S.Ct. at 1740. (emphasis added).⁹⁰

Judge Newman reasoned that:

... the district court appropriately applied the *KSR* standard of whether the patents in suit represented an “identified, **predictable** solution” and “anticipated success,” the words of *KSR*, to the problem of producing extended release formulations having the pharmacokinetic properties in the claims (emphasis added).⁹¹

Based on the guidance of the Supreme Court in *KSR*, and the unpredictability of the prior art, the

⁸⁰ *Id.* at 1348-49.

⁸¹ *Id.* at 1346.

⁸² *Id.*

⁸³ *Id.* at 1350.

⁸⁴ *Id.*

⁸⁵ *Id.* at 1348. ⁸⁶ *Id.* at 1346.

⁸⁷ *Id.* at 1351.

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.* at 1352.

Federal Circuit affirmed the district court's ruling in favor of Abbott.⁹²

Judge Newman's opinion in *Abbott* demonstrates that she had a clear understanding of the principles of the obvious to try doctrine as developed by Judge Rich. Indeed, she cited Judge Rich's insightful discussion from *Tomlinson* regarding the role of the obvious to try doctrine in scientific and technological research and in patentability.⁹³

Misuse of the Obvious to Try Doctrine

Unfortunately, the obvious to try doctrine has not always been used correctly. As explained below, it has also been misused.

For the purpose of this article, the authors consider a misuse of the obvious to try doctrine to occur when: (i) it is used in a case in which it is irrelevant, or in which the wrong standard is used; but (ii) the improper use of the doctrine constitutes harmless error.

An example of a misuse of the obvious to try doctrine was the Supreme Court decision in *KSR v. Teleflex*.⁹⁴ The doctrine was irrelevant in *KSR* because there was no uncertainty regarding whether attachment of a sensor to a support member of a pedal would remain in a fixed position. Nevertheless, the Supreme Court mentioned the obvious to try doctrine in *KSR*,⁹⁵ although it is not clear why. See above.

Ultimately, the holding of obviousness in *KSR*

was based on a traditional § 103 analysis⁹⁶, *i.e.*, motivation to solve a problem in combination with the presence of "a finite number of identified, *predictable* solutions that are within the technical grasp of a person of ordinary skill" (emphasis added).⁹⁷ Therefore, mention of the obvious to try doctrine in *KSR* constituted nothing more than a harmless distraction.

In re Deuel

An earlier example of a case in which the obvious to try doctrine was misused in an analysis of obviousness under § 103 is *In re Deuel (Deuel)*.⁹⁸ *Deuel* was an appeal of a decision by the Board upholding a rejection of claims to DNA molecules that encode a heparin-binding protein (*i.e.*, heparin-binding protein gene).⁹⁹

The issue before the Federal Circuit in *Deuel* was whether the claimed DNA molecules were obvious.¹⁰⁰ A prior art reference taught a general method of gene cloning and a reference disclosing a partial amino acid sequence of an apparently identical heparin-binding protein.¹⁰¹

The examiner asserted that one skilled in the art could have obtained the claimed DNA by using the partial amino acid sequence of the heparin-binding protein disclosed in the prior art and known cloning methods.¹⁰² Based on the cited references, the examiner concluded that "it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to clone a gene for [the heparin-binding protein]."¹⁰³

92 *Id.* at 1352-53.

93 *Id.* at 1352, citing *Tomlinson*, 363 F.2d at 931. See above, footnote 23.

94 127 S.Ct. 1727.

95 *Id.* at 1742.

96 *Id.* at 1743 ("As did the District Court, we see little difference between the teachings of [the prior art] and the [claimed invention]. A person having ordinary skill in the art could have combined [the prior art] with a pedal position sensor in a fashion encompassed by [the claim at issue], and would have seen the benefits of doing so.")

97 *Id.* at 1742.

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

99 *Id.* at 1553-54.

100 *Id.* at 1557.

101 *Id.* The court noted that no explanation was given by the Board or the examiner for the assertion that the brain heparin-binding proteins disclosed in *Deuel's* application are the same as the placental proteins disclosed in the prior art, or that the genes encoding these proteins are identical. *Id.* at 1556.

102 *Id.*

103 *Id.*

The Board affirmed the examiner's rejection.¹⁰⁴ According to the Board, the references suggested a reason to make the gene and taught a method for cloning the gene with a reasonable expectation of success.¹⁰⁵

On appeal to the Federal Circuit, Deuel argued that:

... the PTU has not cited a reference teaching [the claimed DNA] molecules, but instead has improperly rejected the claims based on the alleged obviousness of a method of making the molecules.¹⁰⁶

The Federal Circuit agreed with Deuel,¹⁰⁷ and held that:

...the existence of a general method of isolating ...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 (emphasis added).¹⁰⁸

The Federal Circuit found the "specific molecules themselves" claimed in *Deuel* to be patentable because "the prior art does not disclose any relevant [DNA] molecules, let alone close relatives of the specific, structurally-defined [DNA] molecules of [the claims] that might render them obvious."¹⁰⁹ As in *KSR*, such reasoning constitutes a traditional § 103 obviousness analysis.

In its *Deuel* decision, the Federal Circuit addressed an argument made by the examiner as follows:

Thus, even if, as the examiner stated, the existence of general cloning techniques, coupled with knowledge of a protein's structure, might have provided motivation to prepare a [DNA] or made it obvious to prepare a [DNA], that does not necessarily make obvious a particular claimed [DNA].¹¹⁰

The court could have, and, in the authors' opinion, should have, ended its analysis there. The decision is based on traditional obviousness principles, and appears to be well reasoned.

Unfortunately, the court then added that:

"Obvious to try" has long been held not to constitute obviousness. *In re O'Farrell* ...¹¹¹

This statement is unfortunate because the obvious to try doctrine is not relevant under the facts of *Deuel*.

First, the prior art did not suggest the specific DNA sequence claimed by Deuel, as explained above.¹¹² Although the amino acid sequence of the human heparin-binding protein that existed in nature was known, the precise DNA sequence that encoded the protein was not known, and could not be predicted.¹¹³ Accordingly, *Deuel* did not present a case in which "virtually everything in the claims was present in the prior art [reference] article,"¹¹⁴ as in *O'Farrell*.

Furthermore, the prior art did not raise doubts that the invention could be made or would operate to achieve its purpose.

Clearly, there was no question that the claimed

¹⁰⁴ *Id.*

¹⁰⁵ *Id.* at 1557.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* at 1559.

¹⁰⁹ *Id.* at 1558.

¹¹⁰ *Id.* at 1559.

¹¹¹ *Id.*

¹¹² *Id.* at 1558, 1560.

¹¹³ *Id.* at 1558.

¹¹⁴ 853 F.2d at 901.

DNA sequence could be made. The court conceded that, at the time of the invention at issue in *Deuel*, “cloning procedures [were] routine in the art.”¹¹⁵

Nor did the prior art raise doubt that the claimed DNA would operate to achieve its purpose, which was to express its encoded protein. The claimed DNA existed in nature, and had been expressing its encoded protein for millions of years.

Accordingly, the obvious to try doctrine was irrelevant under the facts in *Deuel*. The lip service paid to the obvious to try doctrine was gratuitous and unfortunate, but, in the end, harmless. The court in *Deuel* used a traditional obviousness analysis based on the lack of a disclosure in the prior art of the structure of the claimed molecule.¹¹⁶ The traditional analysis rests on solid legal ground and did not need to be supplemented with a discussion of the obvious to try doctrine.

The holding in *Deuel* set the stage for many biotechnology patents that are based mainly on using known amino acid sequences to discover new DNA molecules. The decision constituted a milestone in the history of the biotechnology patent effort and the biotechnology industry.

It will be important to remember below that, according to the court in *Deuel*, it is “irrelevant” that there are methods for isolating claimed DNA molecules, and that methods for doing so are known.¹¹⁷ What is critical is that the structure of the molecules, *i.e.*, the sequences of the claimed DNA, is unknown and unpredictable.

The misuse of the obvious to try doctrine, although harmless in *KSR* and *Deuel*, constituted a precedent that caused more serious mischief in later cases. See below.

Abuse of the Obvious to Try Doctrine

When a misuse of the obvious to try doctrine is so egregious that it leads to an incorrect and/or unfair decision, the authors consider that the misuse is elevated to the level of an abuse. An example of such an abuse is the Board’s decision discussed immediately below.

Ex parte Kubin

*Ex parte Kubin*¹¹⁸ involved a patent application that claimed a DNA molecule encoding a receptor protein called “NAIL.”¹¹⁹ The Board affirmed the examiner’s obviousness rejection based on a prior art patent that disclosed: (i) the same receptor protein; (ii) a general method to isolate DNA that encodes the receptor protein; (iii) a journal article that disclosed a mouse version of the DNA sequence encoding the receptor protein; and (iv) a reference disclosing general cloning methods.¹²⁰

Accordingly, the facts and legal issue of *Kubin* and *Deuel* are similar. For example, both cases involved a claimed DNA molecule encoding a known protein. The claimed inventions in both *Kubin* and *Deuel* were rejected as being obvious under § 103 in view of prior art that disclosed the amino acid sequence of a related protein and a general method of isolating or cloning DNA molecules. Most significantly, none of the prior art references cited in *Kubin* or *Deuel* suggested the specifically claimed DNA sequences.

¹¹⁵ *Id.* at 1557 (“the Board noted that it is ‘constantly advised by the patent examiners, who are highly skilled in this art, that cloning procedures are routine in the art.’ ... [T]he examiners urge that when the sequence of a protein is placed into the public domain, the gene is also placed into the public domain.”).

¹¹⁶ *Id.* at 1558 (“[The prior art] teaches proteins, not the claimed or closely related [DNA] molecules. ...What cannot be contemplated or conceived cannot be obvious.”).

¹¹⁷ *Id.* at 1559.

¹¹⁸ 83 U.S.P.Q.2d (BNA) 1410 (B.P.A.I. 2007).

¹¹⁹ *Id.* at 1411. NAIL stands for NK (natural killer) cull activation inducing ligand.

¹²⁰ *Id.* at 1412.

As mentioned above, the Federal Circuit in *Deuel* found the claimed DNA molecules to be nonobvious because “the prior art does not disclose any relevant [DNA] molecules...”¹²¹ Accordingly, the court applied a traditional § 103 analysis based on structural differences. It is important to remember that, according to the court in *Deuel*, it is “irrelevant” that methods for the isolation of DNA molecules are known.¹²²

Given the similar facts and legal issue of the respective cases, the Federal Circuit’s *Deuel* decision was, or at least should have been, binding on the Board in *Kubin*. Indeed, the Board in *Kubin* noted that the “Appellants heavily rely on *Deuel*.”¹²³

However, the Board in *Kubin* disagreed with the appellants, and distinguished the case from *Deuel* based on the increased level of skill in the art and other “factual differences”:

Regardless of some factual similarities between *Deuel* and this case, *Deuel* is not controlling and thus does not stand in the way of our conclusion, given the increased level of skill in the art and the factual differences. See *In re Wallach*, 378 EM 1330, 1334, 71 USPQ2d 1939, 1942 (Fed. Cir. 2004) (“state of the art has developed [since] *In re Deuel*”).¹²⁴

The other factual differences mentioned by the Board in *Kubin* are unexplained. It is not apparent what these factual differences are, let alone why they render *Deuel*, a Federal Circuit decision, “not controlling” on the Board.¹²⁵

The Board’s other reason mentioned in the

quote above for distinguishing the facts in *Kubin* from those in *Deuel* was based on “the increased level of skill in the art.”¹²⁶ The Board attempted to support this assertion by citing *In re Wallach* for the proposition that the “state of the art has developed [since] *In re Deuel*.”¹²⁷, See the quote above.

However, as was acknowledged by the Federal Circuit in *Deuel*, methods for cloning and isolating DNA based on a known amino acid sequence were already “routine in the art.”¹²⁸ Therefore, the Board’s attempt to distinguish *Deuel* on the basis of an increased level of skill in the art is difficult to understand.

The Board may have appreciated that its attempt to distinguish the facts in *Kubin* from those in *Deuel* was, at best, tenuous. In any event, the Board grasped for one more straw. Citing *dicta* from *KSR* regarding the obvious to try doctrine, the Board in *Kubin* stated:

To 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. See *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, ___, 82 USPQ2d 1385, 1394, 1396 (2007) (citing *Deuel*, 51 F.3d at 1559). Under *KSR*, it’s now apparent “obvious to try” may be an appropriate test in more situations than we previously contemplated.¹²⁹

The above quote from the Board’s *Kubin* decision contains at least two legal errors.

First, the viability of *Deuel* did not rest on the obvious to try doctrine. As explained above, the

¹²¹ *In re Deuel*, 51 F.3d at 1558.

¹²² *Id.* at 1559.

¹²³ *Ex parte Kubin*, 83 U.S.P.Q.2d at 1414.

¹²⁴ *Id.* at 1413.

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ See above. See also *In re Deuel*, 51 F.3d at 1557.

¹²⁹ *Ex parte Kubin*, 83 U.S.P.Q.2d at 1414.

central holding of *Deuel* is that general methods of isolating DNA molecules are “essentially irrelevant” to the question whether a specific DNA molecule is structurally obvious.¹³⁰ What is relevant is whether the same or a similar DNA molecule was known in the prior art. Therefore, the Federal Circuit in *Deuel* relied on a traditional analysis of obviousness, and not on the obvious to try doctrine. See above.

Accordingly, the decision in *KSR* did nothing to “cast doubt” on the holding of *Deuel*, contrary to the statement by the Board in *Kubin* quoted above. It was, in fact, the Board in *Kubin* that questioned the viability of *Deuel*, not the Supreme Court in *KSR*.

The second error in the above quote from the *Kubin* decision was the Board’s reliance on *KSR* for the proposition that “...‘obvious to try’ may be an appropriate test in more situations than we previously contemplated.”¹³¹ Citing the relevant passage from *KSR* regarding the obvious to try doctrine, the Board states:

When there is motivation ‘...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 *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. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, ___, 82 USPQ2d 1385, 1397 (2007)’ (emphasis added).¹³²

According to the Supreme Court in *KSR*, then, if a combination was obvious to try *and* there are “predictable solutions” that lead to “anticipated success,” then, and only then, “might” obviousness under § 103 be established.

The terms “predictable solutions” and “anticipated success” in *KSR*¹³³ are comparable to the term, “reasonable expectation of success” in *O’Farrell*.¹³⁴ Accordingly, *KSR* did not change the obvious to try analysis set forth by Judge Rich in *O’Farrell*. The Board in *Kubin*, therefore, misinterpreted the statement in *KSR* regarding the obvious to try doctrine. Specifically, the Board erred when it stated: “Under *KSR*, it’s now apparent ‘obvious to try’ may be an appropriate test in more situations than we previously contemplated.”¹³⁵ See above.

Unlike the harmless error in *Deuel*, however, the misuse of the obvious to try doctrine in *Kubin* resulted in serious legal consequences. The Board’s erroneous decision in *Kubin* is based, in part, on its misinterpretation of *KSR* as expanding the obvious to try doctrine “in more situations than we previously contemplated.”¹³⁶

In its *Kubin* decision, the Board ignore the admonition by Judge Rich in *O’Farrell* that “‘obvious to try’ is not the standard under § 103,”¹³⁷ but confirmed Judge Rich’s concern that “the meaning of this maxim is sometimes lost.”¹³⁸

Kubin was appealed to the Federal Circuit on December 21, 2007.¹³⁹ As maybe surmised from the discussion above, the authors expect the Board to be reversed.

¹³⁰ *In re Deuel*, 51 F.3d at 1559.

¹³¹ *Ex parte Kubin*, 83 U.S.RQ.2d at 1414

¹³² *Id.*

¹³³ 127 S. Ct. at 1742.

¹³⁴ 853 F.2d at 904.

¹³⁵ *Ex parte Kubin*, 83 U.S.P.Q.2d at 1414.

¹³⁶ *Id.*

¹³⁷ *In re O’Farrell*, 853 F.2d at 903.

¹³⁸ *Id.*

¹³⁹ *In re Kubin*, No. 2008-1184 (Fed. Cir. filed December 21, 2007).

Board of Trustees of the Leland Stanford Junior University v Roche Molecular Systems, Inc et al.

A case in which the wrong standard for determining obviousness in an obvious to try context strongly influenced a court's decision, and thus led to an abuse of the doctrine, is a decision by the United States District Court for the Northern District of California. The decision is called *Stanford University v. Roche Molecular Systems (Stanford)*.¹⁴⁰

The case involved three patents of Stanford University relating to methods for determining whether a particular treatment of AIDS is effective.¹⁴¹ The method involved measuring the amount of HIV nucleic acids, and correlating the amount with effectiveness of a drug treatment.¹⁴² Of immediate concern to the court was a motion by Roche for summary judgment that the patents are invalid.¹⁴³

One of the issues involved in the *Stanford* case was whether the use of HIV RNA as a marker for evaluating drug efficacy was obvious.¹⁴⁴ According to the court, the prior art provided "an explicit suggestion to try" HIV RNA as a potential marker, as well as a "precise method to quantify HIV RNA."¹⁴⁵

The district court concluded, however, that "HIV RNA was not believed to be a proper marker."¹⁴⁶ The court explained its conclusion by pointing to the uncertainty surrounding selection of a successful marker:

The only thing that is clear from the library of references submitted by the parties is that

HIV research - particularly quantification...and identification of surrogate markers - was in a state of uncertainty.¹⁴⁷

In addition, the court acknowledged the skepticism in the prior art at the time of the invention:

It is clear that contemporaneous to the publication of the [prior art] article, there was *great confusion* as to which marker would eventually be found successful (emphasis added).¹⁴⁸

Accordingly, the prior art suggested the claimed method of using HIV RNA as a marker for evaluating drug efficacy, but expressed doubt that the method would be successful. Under the facts of *Stanford*, therefore, the obvious to try doctrine was relevant, and the case should have been resolved by analyzing whether there was a reasonable expectation of success.

However, Judge Marilyn Hall Patel of the United States District Court for the Northern District of California, who decided *Stanford*, modified Judge Rich's standard for determining obviousness when the prior art renders an invention obvious to try. According to Judge Patel's standard, a reasonable expectation of success is not necessary to establish obviousness of an invention that is obvious to try. Thus, she stated that:

... although the use of HIV RNA as a surrogate marker was arguably not obvious to try with any reasonable expectation of success, the claims-at-issue may still be obvious."¹⁴⁹

¹⁴⁰ Bd. of Trustees of Leland Stanford Jr. Univ. v. Roche Molecular Systems, Inc., et al, 563 F. Supp. 2d 1016 (N.D. Cal. 2008)

¹⁴¹ *Id.* at 1020-21.

¹⁴² *Id.* at 1021.

¹⁴³ *Id.* at 1020.

¹⁴⁴ *Id.* at 1039-40.

¹⁴⁵ *Id.* at 1043.

¹⁴⁶ *Id.* at 1040.

¹⁴⁷ *Id.* at 1027.

¹⁴⁸ *Id.* at 1040.

¹⁴⁹ *Id.* at 1044.

This statement is inconsistent with Judge Rich's obviousness analysis in *O'Farrell*, which, until overturned, is binding on the district courts. According to Judge Rich, it will be remembered, under the obvious to try doctrine: "The question is: when is an invention that was obvious to try nevertheless nonobvious?"¹⁵⁰ He answered the question by stating what is required to establish obviousness, *i.e.*: "all that is required is a reasonable expectation of success."¹⁵¹

Judge Patel further modified Judge Rich's standard for determining obviousness by stating:

The combination of great motivation to solve this problem with the limited number of available quantifiable options is *sufficient* to independently make HIV RNA an obvious choice for further research. Consequently, the *expectation of success* of HIV RNA as a marker *then becomes proportionally less important* (emphasis added).¹⁵²

Based on this standard, Judge Patel reviewed the individual claims and granted defendant Roche's motion for summary judgment of invalidity based on obviousness.¹⁵³

It is instructive that Judge Patel did not cite any authority for her sliding scale of motivation and the number of options on the one hand, and expectation of success on the other. The authors are unaware of any such authority for this proposition.

It is interesting to note that Judge Patel quoted the same passage from *KSR* that was quoted by the Board in *Kubin* regarding the obvious to try

doctrine as the basis of her new standard.¹⁵⁴ As did the Board in *Kubin*, Judge Patel misinterpreted the passage from *KSR*. Her misinterpretation caused her to place undue emphasis on the phrase "a finite number of identified solutions," and to ignore the requirement that the solutions be "predictable."¹⁵⁵

Under her new standard of obviousness, Judge Patel minimized the importance of evidence presented at trial showing that there was extreme skepticism concerning the possibility of successfully using HIV RNA as a marker for drug efficacy.¹⁵⁶ In doing so, she improperly analyzed the issue of obviousness when the claimed invention was obvious to try

As stated above, such an analysis requires asking only one question: whether there is a reasonable expectation of success. This question received short, if any, shrift from Judge Patel.

The question whether there is a reasonable expectation of success raised a genuine issue of material fact that should have resulted in a denial of Roche's summary judgment motion. Judge Patel's misinterpretation of *KSR*, and the unauthorized standard of obviousness she used to grant summary judgment of invalidity, causes the authors to classify this decision as an abuse.

In re Omeprazole Patent Litigation

It is encouraging to be able to conclude this article on a positive note. In a recent case, a correct understanding of the obvious to try doctrine assisted the Federal Circuit in avoiding another abuse.

In *In re Omeprazole Patent Litigation*,¹⁵⁷ a patent owned by Astrazeneca claimed a solid

¹⁵⁰ *In re O'Farrell*, 853 F.2d at 903.

¹⁵¹ *Id.* at 903.

¹⁵² 563 F. Supp. 2d at 1045.

¹⁵³ *Id.* at 1045 and 1048-49.

¹⁵⁴ *Id.* at 1041 (citing *KSR*, 127 S. Ct. at 1742).

¹⁵⁵ *KSR*, 127 S. Ct. at 1742.

¹⁵⁶ See 563 E Supp. 2d at 1027 and 1040-41.

¹⁵⁷ *In re Omeprazole Patent Litigation*, 536 FM 1361 (Fed. Cir. 2008).

pharmaceutical composition containing an inert sub-coating that is soluble in water.¹⁵⁸ Astrazeneca sued a group of generic drug companies for patent infringement.¹⁵⁹ During a trial in federal district court, Astrazeneca convinced the court that the patents were valid.¹⁶⁰

On appeal, the generic companies tried to convince the Federal Circuit that the patents were invalid, and that "...the district court failed to recognize that adding a subcoating would be 'obvious to try,' standard referred to in *KSR*."¹⁶¹

The Federal Circuit rejected this argument because the generic drug companies:

...mischaracterize(s) the district court's decision. The [district court] found that a person of skill in the art would not have seen a reason to insert a subcoating in the prior art formulation shown in [a prior art reference].¹⁶²

In other words, the Federal Circuit recognized that the district court had properly used a traditional obviousness

analysis (*i.e.*, lack of a suggestion in the prior art), and that the obvious to try doctrine was irrelevant.

Conclusions

The obvious to try doctrine was developed by Judge Rich in three decisions: *Huellmantel* (C.C.P.A. 1963), *Tomlinson* (C.C.P.A. 1966), and *O'Farrell* (Fed. Cir. 1988). The first step in its proper use is to determine if it is relevant to the facts at issue. The obvious to try doctrine is relevant if a prior art reference suggests the claimed invention, but expresses or infers doubt that the invention can be made or will be operative for its intended purpose.

When the obvious to try doctrine has been misused, *i.e.*, used in cases where it is not relevant, the misuse was sometimes harmless, *e.g.*, *Deuel*, *KSR*. Even where harmless, however, such misuse can serve as a precedent for more serious abuse of the doctrine, *e.g.*, *Kubin*, *Stanford*.

Accordingly, attorneys should not raise the doctrine in cases where it is not relevant, and, if they do, the PTO and the courts should simply dismiss it as irrelevant, as did the Federal Circuit in *In re Omeprazole Patent Litigation*.

In cases where the obvious to try doctrine is relevant, one should focus on the question asked by Judge Rich in *O'Farrell*, *i.e.*:

...when is an invention that was obvious to try nevertheless nonobvious?¹⁶³

One should then focus on Judge Rich's standard for finding obviousness under the obvious to try doctrine, which is easily stated, but not always easy to apply in practice. For a finding of obviousness: "...all that is required is a reasonable expectation of success."¹⁶⁴

When properly used, the obvious to try doctrine helps to focus attention on the critical issue in a case, *i.e.*, whether there is a reasonable expectation (*i.e.*, predictability) of success. The doctrine was helpful, for example, in focusing the attention of both the majority and the dissent in *PharmaStem* on the same question, albeit with different answers.

If the patent community understands the obvious to try doctrine, and properly applies it, the authors hope they will not be surprised by future decisions of the Board and the courts, as they were when they read *Kubin* and *KSR*.

¹⁵⁸ *Id.* at 1364-65.

¹⁵⁹ *Id.* at 1364.

¹⁶⁰ *Id.* at 1366.

¹⁶¹ *Id.* at 1381.

¹⁶² *Id.*

¹⁶³ 853 F.2d at 903.

¹⁶⁴ *Id.* at 904.