

Obviousness. Problem-Solution Approach (Europe)

Understanding the invention using the problem-solution approach. The problem-solution approach toggles between the technical features and technical effects. The non-obviousness of the claimed subject matter is based only on technical effects derivable from the specification.

(1) Describe the technical field in the art.

(2) Describe the contribution that the inventor, subjectively, thinks that the invention has made to that field. The patent drafter should announce in the specification what technical effects this feature combination is delivering. This announcement can be represented as delivering a technical effect. The only subject matter that is patentable is subject matter in the specification that solves an objective technical problem. A discovery can be presented as the solution to a technical problem when the discovery yields a technical effect that can be reworked as the solution to a problem.

(3) Search the state of the art, including everything provided to the public, by written or oral description, by use or in any other way, by the filing date of the claim. Compare to the first Graham factor for determining obviousness in the United States under 35 U.S.C. § 103. Determining the scope and contents of the prior art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); M.P.E.P. § 2141.01.

(4) Find a realistic starting point from which another person skilled in the relevant art might reasonably have begun a solution to a technical problem. That starting point is reference D1. The D1 reference is the first fixed point in the problem-solution approach.

(5) What would the person skilled in the relevant art reviewing the universe of materials provided already to the public, for ways of achieving the technical effect that the inventor asserts that the claimed subject matter achieves. Compare to the third Graham factor for determining obviousness in the United States under 35 U.S.C. § 103. Resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); M.P.E.P. § 2142-2143.

(6) Examine the claim in the claims section below. First, satisfy yourself that its subject matter solves the problem, rather than merely recite a problem to be solved. The patent drafter must claim the invention by the recitation of a list of technical features. Compare to the first Graham factor for determining obviousness in the United States under 35 U.S.C. § 103. Ascertaining the differences between the prior art and the claims at issue. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); M.P.E.P. § 2141.02.

(7) Break the claim down into the technical features. How many technical features can one find disclosed in whole or in part in the D1 reference? Making a purely arbitrary selection from the prior art is not inventive. The rationale is that such choices are not a real technical advance, unless it is demonstrated that such selections have some different or improved property compared to the earlier ones described (and this is made plausible in the document). This test is higher than plausibility, because it requires the selection to be a technical advance.

(8) Identify the technical features (TF) in the claim that are not in the D1 reference.

(9) Beginning with the D1 reference, modify the disclosure by the notional injection into the D1 reference of the characterizing technical feature TF. What technical effect does that deliver? Technical feature TF might be nothing more than an alternative to the D1 embodiment. Technical feature TF might provide performance no different from that delivered by D1. Technical feature TF might cause a performance different from the D1 embodiment.

(10) Describe the performance difference or technical effect as the objective technical problem. The objective technical problem must be formulated so it owes nothing to the solution announced by the inventor in the patent application.

(11) Identify any motivation, hint, or suggestion to add the TF to the D1 reference that is disclosed in the prior art.

(12) If what has been provided to the public provides no motivation to put TF into D1, then the claimed subject matter is not obvious.

(13) The specification should distinguish the invention over the prior art by describing what the prior art does not teach.

(A) Whenever anything inventive is done for the first time it is the result of the addition of a new idea to the existing stock of knowledge. Sometimes it is the idea of using established techniques to do something which no one had previously thought of doing. In that case the inventive idea will be doing the new thing. *Biogen Inc v. Medeva Plc* [1997] RPC 1 (House of Lords) (Lord Hoffman).

(B) Whenever anything inventive is done for the first time it is the result of the addition of a new idea to the existing stock of knowledge. Sometimes it is finding a way of doing something which people had wanted to do but could not think how. The inventive idea would be the way of achieving the goal. *Biogen Inc v. Medeva Plc* [1997] RPC 1 (House of Lords) (Lord Hoffman).

(C) Whenever anything inventive is done for the first time it is the result of the addition of a new idea to the existing stock of knowledge. Sometimes many people may have a general idea of how they might achieve a goal but not know how to solve a particular problem which stands in their way. If someone devises a way of solving the problem, his inventive step will be that solution, but not the goal itself or the general method of achieving it. *Biogen Inc v. Medeva Plc* [1997] RPC 1 (House of Lords) (Lord Hoffman).

Obviousness. Reasonable expectation of success (United States).

Whether a person having ordinary skill in the art would have had a reasonable expectation of success for the purposes of determining obviousness depends on the specific nature of what was known from the prior art about closely related subject matter. Specific instructions that are relevant to the claimed subject matter or success in similar methods or products have directed findings of a reasonable expectation of success. Although the definition of “reasonable expectation” is somewhat vague, the case law makes clear that a certainty of success is not required. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165–66 (Fed. Cir. 2006), citing *In re O’Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988). Obviousness does not require absolute predictability of success. All that is required is a reasonable expectation of success.”

A reasonable expectation of success of nucleic acids encoding a specific protein was found because the prior art taught the same protein and also a five-step protocol for cloning nucleic acid molecules encoding the protein. In re Kubin, 561 F.3d 1351, 1360 (Fed. Cir. 2009).

A reasonable expectation of success of a method mediating sequence specific recombination of DNA in eukaryotic cells with a modified enzyme was found because the normal enzyme had previously been used to mediate similar recombination. In re Droge, 695 F.3d 1334, 1337-38 (Fed. Cir. 2012).

A reasonable expectation of success in the use of nanoparticle technology in formulation chemistry was found because that technology had become fairly reliable and had produced consistent results. Par Pharm., Inc. v. TWI Pharm., Inc., 773 F.3d 1186, 1196 (Fed.Cir.2014). To determine if there would have been an expectation of success, compare the specific evidence before us to the facts of the precedential case law. PAR Pharm., 773 F.3d at 1198.

A reasonable expectation of success was found because there was only one parameter to vary to obtain the specific salt of the drug claimed. Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1366 (Fed. Cir. 2007). One skilled in the art had several references available to use for direction and was capable of narrowing the possible salts previously approved to a small group from which to choose and verify by routine trial-and-error procedures. Id. at 1367-68.

A reasonable expectation of success for challenged claims directed to producing a particular protein in the milk of an animal was found because all of the elements were known in the prior art. Velandier v. Garner, 348 F.3d 1359, 1379 (Fed. Cir. 2003). It was known that several other proteins had been produced in a similar way.

A reasonable expectation of success in claims to a specific protein was not found because none of the prior art references suggested that screening a human genomic library would be likely to succeed in pulling out the gene of interest. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1207-08 (Fed. Cir. 1991). No one else had previously used the technique successfully for that purpose. The patentee provided a witness who testified that it would have been “difficult” to find the gene in 1983, and that there would have been no more than a fifty percent chance of success. Id. at 1208.

A reasonable expectation of success was not found for the method of growing and isolating a particular virus with monkey cells because the prior art reported failure with other viruses isolated with monkey kidney cells. Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1354 (Fed. Cir. 2003).

A reasonable expectation of success was not found because the problem encountered by the claimed method of commercial scale production of polyesters was not the same problem addressed in the prior art. In re Rinehart, 531 F.2d 1048, 1054 (CCPA 1976). There was evidence that a combination of the prior art steps could not be commercially scaled up successfully.

A reasonable expectation of success for claims to methods of site directed double-stranded break in chromosomal DNA with a “Group I intron” nuclease was not found because the prior art did not teach using the nuclease on chromosomal DNA within a yeast cell . Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino, 738 F.3d 1337, 1346 (Fed. Cir. 2013), citing Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1352 (Fed.Cir.2008). “The desire for that payoff could motivate pursuit of the method, but ‘knowledge of the goal does not render its achievement obvious.’” The Board of Patent Appeals & Interferences failed to give proper weight to prior art teaching toxic effects of the nuclease in cells. Institut Pasteur, 738 F.3d at 1346.

A reasonable expectation of success in optimizing a reaction was found because there were not too many parameters to vary and the principle parameter, concentration of tertiary amine, was known. Furthermore, the prior art gave more than merely general guidance, indicating that low concentrations were best. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1166–67 (Fed. Cir. 2006).

A reasonable expectation of success was not found for a method of isolating human CD40CR antibodies using mouse CD40CR antibodies because expert witnesses testified to the unpredictability in the state of the art at the relevant time. *Noelle v. Lederman*, 355 F.3d 1343, 1352–53 (Fed. Cir. 2004).

Obviousness. Objective indicia of nonobviousness (United States).

Evidence of commercial success of the invention. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). To be considered in the obviousness analysis, the considerations must be linked to the claimed invention, demonstrating a "nexus" between them.

(1) Evidence of commercial success. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459 (1966). See also *In re Fielder*, 471 F.2d 640, 644 (C.C.P.A. 1973) (evidence of commercial success may be directly relevant to issue of obviousness and therefore should always be evaluated before final decision is reached).

(A) The evidence of commercial success must prove that the solution to the problem was in fact commercially successful. *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1151 (Fed. Cir. 1983). See Boyer, *Commercial Success as Evidence of Patentability*, 37 *Fordham L. Rev.*, 573, 594-95. The evidence can be by showing market share, growth in market share, or displacement of existing prior art devices. *Kansas Jack*, 719 F.2d at 1150-51. Absolute sales figures alone are not sufficient to establish commercial success because there is no standard against which to compare the figures to determine if they are significant. See *Kansas Jack*, 719 F.2d at 1151.

(B) The evidence of commercial success must show that it is due to the merits of their inventions and not to extrinsic factors such as advertising or concentrated sales efforts. See *Cable Electric*, 770 F.2d at 1026; *Kansas Jack*, 719 F.2d at 1151.

Evidence of commercial success compelled a conclusion of nonobviousness, even though the invention would have been held obvious based on the prior art considerations alone. *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573, 1575-76 (Fed. Cir. 1984), cert. denied, 105 S. Ct. 2138 (1985). See Boyer, *Commercial Success as Evidence of Patentability*, 37 *Fordham L. Rev.* 573 (1969). The patent at issue in *Simmons* involved self-adhering screw anchor fasteners for refrigerators. *Id.* at 1573. At trial, the parties stipulated to commercial success because both the patentee and the accused infringer had sold millions of fasteners embodying the claimed invention. *Id.* at 1574. The Federal Circuit agreed with the trial court that the claimed invention would have been held obvious based on the prior art considerations alone but reversed because in this case commercial success was entitled to substantial weight. *Id.* at 1575-76.

A vehicle frame straightening device was invalid for obviousness based on the prior art. The evidence of commercial success was not probative of nonobviousness because the evidence consisted solely of the number of devices sold. *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1151 (Fed. Cir. 1983).

An integrally molded hinge for securing a marker pen to a pen arm was invalid for obviousness. *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 317 (Fed. Cir. 1985). The Federal Circuit discounted evidence of commercial success because the evidence showed that while devices combining the hinge

with disposable pens were commercially successful, the same was not true when the hinge was combined with non-disposable pens, indicating that commercial success was attributable to the public's desire for disposable pens, not the merits of the hinge. *Id.* at 315.

(2) Fulfillment of a long-felt but unsolved need. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966).

(A) The evidence of long-felt but unsolved need must show that the defect existed. See *Lyon*, 224 F.2d at 535. See *Chisum, Patents*, at 240.1.

(B) The evidence of long-felt but unsolved need must show that there was a need for a solution to the defect. See *Chisum, Patents*, at 240.1. Factors such as the length of time the need existed and the amount of research which the industry expended to find a solution will influence the weight which evidence of long-felt, but unsolved need is given. See *Lyon*, 224 F.2d at 535; *Safety Car*, 155 F.2d at 939. They can do this by showing that other skilled researchers in the field, working under the same state of the art, attempted to find a solution but failed. See *Chisum, Patents*, at 240.

(C) The evidence of long-felt but unsolved need must show that their solutions satisfied the need. See *Chisum, Patents*, at 242. They can do this by showing that their solutions achieved commercial success.

Evidence of long-felt but unsolved need and professional approval rebutted a prima facie case of obviousness based on the prior art considerations. *In re Piasecki*, 745 F.2d 1468, 1473-75 (Fed. Cir. 1984).

An increase in annual dollar sales from zero to seven million in the first five years that fabric laminates embodying the claimed invention were available indicated fulfillment of a long-felt need. See *Gore*, 721 F.2d at 1555.

Evidence showing that the patentee's process for removing sulfur from effluent gas fulfilled a long-felt need to remove a maximum amount of sulfur from the atmosphere and made stricter sulfur dioxide standards possible indicated that the claimed process would not have been obvious. *Environmental Designs, Ltd. v. Union Oil Co. of California*, 713 F.2d 693, 697-98 (Fed. Cir. 1983), cert. denied, 464 U.S. 1043 (1984). See also *Chisum, Patents*, at 242.

(3) The failure of others to find a solution to the problem plaguing the art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). To be considered in the obviousness analysis, secondary considerations must be linked to the claimed invention, demonstrating a "nexus" between them.

(4) Evidence of unexpected results or unexpected properties. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). To be considered in the obviousness analysis, secondary considerations must be linked to the claimed invention, demonstrating a "nexus" between them. Unexpected results or properties can be shown by demonstrating synergistic effects. *Ortho-McNeil Pharmaceutical Inc. v. Teva Pharmaceuticals Ind. Ltd.* (Federal Circuit, 2009). Unexpected results or properties in a combination can be shown by demonstrating the criticality of the combination.

U.S. Pat. No. 5,336,691 described that a composition of tramadol and acetaminophen has a synergistic effect. *Ortho-McNeil Pharmaceutical Inc. v. Teva Pharmaceuticals Ind. Ltd.* (Federal Circuit, 2009).

(5) Evidence of the industry's acquiescence in the invention's merit through licensing it. See *M.P.E.P. § 716.03(b)*, *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 55-56 (1923), *Philip v. Mayer. Rothkopf Indus.. Inc.*, 204 U.S.P.Q. 753, 763 (E.D.N.Y. 1979), aff'd, 635 F.2d 1056 (2d Cir. 1980).

(A) For evidence of licensing to be relevant, one must show that one in fact licensed the patent rights to a certain percentage of the total available license market. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983).

A method for producing wire mesh-reinforced concrete pipes having flared ends for mating with the straight ends of adjacent pipes was invalid for obviousness. *EWP Corp. v. Reliance Universal, Inc.*, 755 F.2d 898, 899-900 (Fed. Cir. 1985). The patentee offered evidence of a successful licensing program. *Id.* at 907-08. Successful licensing programs are not infallible guides to patentability because it is too difficult to establish that their success is related to the nonobviousness of the claimed invention and not factors such as the beliefs of licensees that licensing is less expensive than defending an infringement suit. *Id.*

(6) Evidence of copying by others. See *Diamond Rubber Co. v. Consol. Rubber Tire Co.*, 220 U.S. 428, 440-41 (1911); *Vandenberg v. Dairy Equip. Co.*, 740 F.2d 1560, 1567 (Fed. Cir. 1984). Copying by others can be used as evidence of non-obviousness in patent law, such as evidence that “competitors in the marketplace are copying the invention instead of using the prior art.” M.P.E.P. § 716.06 See *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 73 USPQ2d 1225 (Federal Circuit, 2004).

(A) For copying to be relevant to nonobviousness, one must show that the infringer's copying was related to the merits of their inventions, not because it was unlikely that the patentees would be willing or financially able to enforce their rights by instituting an infringement suit. See, e.g., *Jones v. Hardy*, 727 F.2d 1524, 1531-2 (Fed. Cir. 1984).

Evidence that the infringer copied the one piece cable ties of the invention, after trying unsuccessfully for many years to develop similar cable ties, was used to show that the cable ties of the invention filled a long-felt need, and that therefore the invention would not have been obvious at the time it was made. *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1099 (Fed. Cir. 1985).

A mold and method for casting decorated concrete panels. *Jones v. Hardy*, 727 F.2d 1524 (Federal Circuit, 1984). The copier, who had extensive experience in the field, copied the patented invention after abandoning prior art casting methods and failing to become a distributor or the patented products. *Id.* at 1532.

(7) Evidence of disbelief or acclaim by experts in the field. of the invention's success. Skepticism of experts can be used as evidence of non-obviousness in patent law, demonstrating that an invention was not readily apparent to those skilled in the art. If experts doubted an invention's feasibility or effectiveness, it suggests the invention was not obvious. M.P.E.P. § 716.05. “Expressions of disbelief by experts constitute strong evidence of nonobviousness.” *Environmental Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 698, 218 USPQ 865, 869 (Fed. Cir. 1983), citing *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 483-484 (1966).

(8) Evidence of admissions of nonobviousness by an adversary. See *Environmental Designs, Ltd. v. Union Oil Co. of California*, 713 F.2d 693, 697-98 (Fed. Cir. 1983), cert. denied, 464 U.S. 1043 (1984), In re *Piasecki*, 745 F.2d at 1475.

The evidence of long-felt, but unsolved need and professional approval rebutted a prima facie case of obviousness based on the prior art considerations. *Gore*, 721 F.2d at 1545. A method of rapidly stretching highly crystalline, unsintered Teflon to produce a soft, porous material which the patentee marketed as Goretex® would not have been obvious at the time it was made. *Gore*, 721 F.2d at 1556. The court considered evidence that suppliers of Teflon, such as ICI and du Pont, labeled the new product

magical and bewitching, and that du Pont scientists greeted the product with skepticism and disbelief. Id. at 1545, 1555-56.

(9) Evidence of near simultaneous invention by others in the field. See *Graham v. Jeoffroy Mfg. Co.*, 206 F.2d 769, 771 (5th Cir. 1953). The Federal Circuit has indicated that near-simultaneous invention is relevant as evidence of obviousness because it illustrates the state of the art prevailing at the time the patentee made his or her discovery. In *re Farrenkopf*, 713 F.2d 714 (Fed. Cir. 1983). Evidence of near-simultaneous invention should not, by itself, preclude patentability' because patent interference practice recognizes that an invention may be patentable, and hence by statutory definition nonobvious, despite contemporaneous development by two or more inventors. See *Environmental Designs, Ltd. v. Union Oil of California*, 713 F.2d 693,698 n.7 (Fed. Cir. 1983), cert. denied, 464 U.S. 1043 (1984); *E.I. du Pont de Nemours & Co. v. Berkley & Co., Inc.*, 620 F.2d 1247, 1265 (8th Cir. 1980).

(A) For evidence of near-simultaneous invention to be probative of obviousness, the other researchers must have been working under the same state of the art as the patentee. Chisum, Patents, at 258.

(B) Factors such as the level of skill of the simultaneous solvers and the amount of effort it took them to find the solution will influence the amount of weight given to near-simultaneous invention in the obviousness analysis.

(10) Evidence of progress of the patent application through the Patent and Trademark Office. See *United States v. Adams*, 383 U.S. 39, 52 (1966) (the fact that in a crowded field Examiner could find no references to cite against application weighs in favor of nonobviousness).

A patent covering a method of making glass-to-metal seals used in electrical devices was invalid for obviousness. *Philips Elec. & Pharmaceutical Indus. Corp. v. Thermal & Elec. Indus. Inc.*, 450 F.2d 1164, 1166 (3d Cir. 1971). The court drew a negative inference of patentability from the fact that it took twelve years for the patent to issue after a long and tortuous path in the Patent Office. Id. at 1175. However, the Federal Circuit has not considered progress through the Patent and Trademark Office. Litigants rarely present such evidence.

Obviousness of diagnostic inventions (Europe)

Under the EPC, claims related to a method of diagnosis are not patent eligible. Art 53 (c) EPC. In decision G1/04, the Enlarged Board of Appeal of the EPO defined the criteria that make such methods of diagnosis exempt from patent protection. In particular, the patent claim must include the steps of:

- (1) examination involving the collection of data,
- (2) comparison of the data with standard values,
- (3) the finding of any significant deviation (i.e. a symptom), and
- (4) the attribution of the deviation to a particular clinical picture.

Other options to obtain protection for respective methods provide the claiming of a method of prediction of a therapy success, or prognosis of disease progression, both of which are not diagnosis in strictu sensu.

In the United States, diagnostic method claims in general, and biomarker claims in particular, are subject to extreme scrutiny by the United States Patent and Trademark Office (USPTO) after the new guidance which came into effect with the Supreme Court landmark decisions *Association for Molecular Pathology*

case vs. Myriad Genetics Inc., case No. Twelve-398 (2013) and Mayo Collaborative Services v. Prometheus Laboratories, case No 10-1150 2012. This new policy led to a de-facto moratorium of allowances of patent applications related to diagnostic methods and biomarkers.