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This issue discusses the law of patent invalidity due to obviousness under 35 U.S.C. § 103. We will look at how the "obvious to try" test has evolved for pharmaceutical formulations since the Supreme Court's *KSR* decision in 2007. We also will discuss how the Federal Circuit has interpreted *KSR*'s motivation to combine requirement. Finally, we will examine cases dealing with an analogous topic, obviousness-based "double patenting." In particular, we will focus on product-process patents, one-way and two-way obviousness tests, and double patenting of continuation and divisional applications.

"OBVIOUS TO TRY" IN PHARMACEUTICAL FORMULATIONS

A patent claim may be found invalid under 35 U.S.C. § 103 if a person having ordinary skill would have found it obvious to try a course of conduct. In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Supreme Court defined a framework for the "obvious to try" determination based on market pressure and predictability of the claimed solution. *See, e.g.*, the discussion of *KSR* in the October 2008 issue of *Federal Circuit Review*. The Federal Circuit has recently applied this framework in several cases involving pharmaceutical compositions.

In re Kubin, 561 F.3d 1351 (Fed. Cir. 2009), involved a biotechnology invention concerning the isolation and sequencing of a human gene that encoded a particular domain of a protein. The applicants argued for patentability based on *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995), where the court stated that "'[o]bvious to try' has long been held *not* to constitute obviousness." (emphasis added). In *Deuel*, the Federal Circuit explained that in assessing the obviousness of a biomolecule, the prior art should render the biomolecule itself obvious, not just the general method of isolating it. *Id.* The Board of Patent Appeals and Interferences (the Board) nevertheless rejected Kubin's patent application because *KSR* may have "cast doubt on the viability of *Deuel* to the extent the Federal Circuit rejected an 'obvious to try' test." *Kubin*, 561 F.3d at 1358 (citing the Board decision).

The Federal Circuit affirmed the rejection based on obviousness. It added, "[t]he Supreme Court [in *KSR*] repudiated as 'error' the *Deuel* restriction on the ability of a skilled artisan to combine elements within

the scope of the prior art." *Id.* at 1359. The court agreed with the Board that the claimed methodology of isolating the gene sequences was essentially the same as in the prior art, and thus it was "obvious to try" based on the known properties of the proteins. *Id.* at 1360.

The Federal Circuit, however, acknowledged that there are two classes of cases in which an invention that is "obvious to try" might not be obvious under 35 U.S.C. § 103. *Id.* at 1359. The first is "where a defendant [challenging the patent] merely throws metaphorical darts at a board filled with combinatorial prior art possibilities." *Id.* The second is in a "technology or [a] promising area of experimentation that was only hinted at in the prior art." *Id.*

About a month later, the Federal Circuit demonstrated that application of the newly resurrected "obvious to try" test might still result in a finding of non-obviousness. *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 989 (Fed. Cir. 2009). Procter & Gamble (P&G) held a pharmaceutical compound patent for risedronate, the active ingredient in its osteoporosis drug, Actonel. *Id.* at 992. Teva argued that this patent was obvious over disclosures made in an earlier P&G patent concerning osteoporosis treatments. *Id.* at 993. The earlier patent disclosed 36 compounds, including 2-pyr EDHP, a positional isomer of risedronate that contained the same atoms arranged in different ways. *Id.* The issue was whether a person of ordinary skill in the art would have had a "reasonable expectation of success" in synthesizing and testing risedronate for the treatment of osteoporosis.

The Federal Circuit held that the risedronate patent was not obvious because (1) the structural modification necessary to synthesize risedronate was not routine and (2) the results of the new compound were unexpected. *Id.* at 996-97. The court acknowledged that the question of obviousness of pharmaceutical compounds "often turns on structural similarities and differences." *Id.* at 995. But a *prima facie* case for obviousness also requires "'adequate support in the prior art' for the change in structure." *Id.* (quoting *In re Grabiak*, 769 F.2d 729, 731-32 (Fed. Cir. 1985)). The court relied on a P&G technical expert who wrote that "'every compound [of this type] exhibits its own physical-chemical, biological, and therapeutic characteristics'" and it is "'dangerous'" and "'misleading'" to "'infer from one compound the effects in another.'" *Id.* at 996 (quoting expert). Here, the court noted that it "'should not succumb to hindsight claims of obviousness'" when the prior art "'gives no indication as to which of many possible choices are likely to be successful.'" *Id.* at 997 (quoting *Kubin*, 561 F.3d at 1359 and *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 2008)).

The Federal Circuit visited the "obvious to try" test for pharmaceutical compounds in a third case a few months later. *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341 (Fed. Cir. 2009). Bayer held a patent on the compound, drospirenone, one of the active ingredients of the daily oral contraceptive pill marketed as "Yasmin." *Id.* at 1343. Drospirenone had been known in the art for some time before the patent application was filed. *Id.* Bayer's patent claimed a normal, non-enteric-coated tablet, containing micronized drospirenone particles for oral contraceptive use. *Id.* at 1345-46. (An "enteric-coated" tablet contains a barrier that prevents the release of medication before it enters the small intestine.) The issue was whether Bayer's patent disclosing a specific delivery method, particle size, and use for drospirenone was obvious over prior art.

The Federal Circuit affirmed the district court's decision that Bayer's patent claims were "obvious to try." The court deconstructed *KSR's* obvious-to-try inquiry into two prongs. First, the field of search of prior art must be reduced to a "finite number of identified" solutions where the number of options searched must be "small or easily traversed." *Id.* at 1347. Second, the prior art cannot be vague and must guide an inventor toward a "predictable" and particular solution. *Id.* The court held that a person having ordinary skill in the art would have been directed to the patent claims by two prior art references. *Id.* at 1350. The first identified the use of micronized particles of a related compound, spirorenone, in a normal pill delivery. *Id.* The second called for the delivery of drospirenone by an enteric-coated pill. *Id.* The court affirmed that the patent claims were obvious because these references "funneled the formulator" toward a "finite number" of options. *Id.*

Cases Referenced:
Bayer Schering Pharma AG v. Barr Labs., Inc., 575 F.3d 1341 (Fed. Cir. 2009)
In re Deuel, 51 F.3d 1552 (Fed. Cir. 1995)
In re Kubin, 561 F.3d 1351 (Fed. Cir. 2009)
In re Grabiak, 769 F.2d 729 (Fed. Cir. 1985)
In re O'Farrell, 853 F.2d 894 (Fed. Cir. 2008)
KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007)
Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc., 566 F.3d 989 (Fed. Cir. 2009).

Motivation To Combine

The Federal Circuit recently defined the type of motivation that is necessary to combine prior art references in the wake of *KSR*. *KSR* demands a flexible inquiry that takes into account "the inferences and creative steps" that an inventor would employ. *KSR*, 550 U.S. at 418. Yet the Supreme Court's opinion refers to an "explicit" analysis of this motivation. *Id.* The Federal Circuit determined the proper context of this statement in *Ball Aerosol & Specialty Container, Inc. v. Limited Brands, Inc.*, 555 F.3d 984 (Fed. Cir. 2009).

The claimed invention was a candle tin with a removable cover that also acts as a base for the candle holder, to minimize scorching or damage to the surface below. *Id.* at 986. The closed end of the candle tins contained "protrusions" or feet. *Id.* One prior art reference disclosed "protuberances" or "bumps" on the bottom of a candle can while another reference disclosed a candle holder resting on top of its cover. *Id.* at 991-92. The district court declared, *sua sponte*, that the claimed invention was valid. *Id.* at 990. The issue before the Federal Circuit was whether *KSR* requires that the teaching in the prior art that is used to support obviousness must also demonstrate an "explicit" motivation to combine.

The Federal Circuit vacated the holding of validity and determined that the district court misconstrued the intention of the Supreme Court in *KSR*. *Id.* at 993. The portion of *KSR* under review is as follows: "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the

background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit." *KSR*, 550 U.S. at 418. The Federal Circuit concluded that "the analysis that 'should be made explicit' is not the teachings in the prior art of a motivation to combine but rather the court's analysis." *Ball Aerosol*, 555 F.3d at 993. In other words, the court must explain its motivation for combining references to invalidate a patent for obviousness. The Federal Circuit found that "the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute." *Id.* The court, therefore, held that "a person of ordinary skill can implement a predictable variation" of the disclosures in the prior art. *Id.* at 992. Finally, the Federal Circuit added that the secondary factor of commercial success has little weight when compared to the "clear indication of obviousness apparent from the prior art." *Id.* at 994.

Cases Referenced:
Ball Aerosol & Specialty Container, Inc. v. Limited Brands, Inc., 555 F.3d 984 (Fed. Cir. 2009)
KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

Obviousness-Type Double Patenting

The doctrine of double patenting prevents a patentee from receiving a second patent for a single invention, and thereby extending the term of exclusivity for that invention. This doctrine does not appear in the Patent Act, but instead has been developed by the courts. The proscription against double patenting takes two forms. The first, commonly referred to as "anticipatory" double patenting, occurs when two patents by a single patentee have claims of identical scope. The second, "obviousness-type" double patenting, is designed to foreclose claims that are not identical, but nonetheless are obvious variations. In an obviousness-type double patenting analysis, courts may employ prior art references in combination with the claims of the earlier patent to determine if the claims of the later patent are obvious to those skilled in the art. This analysis is similar to an obviousness inquiry under 35 U.S.C. § 103. The Federal Circuit addressed obviousness-type double patenting several times within the past year.

Product-Process Double Patenting

Takeda Pharmaceutical Co. v. Doll, 561 F.3d 1372 (Fed. Cir. 2009), concerned whether the date of invention of prior art governs the timing of double patenting analysis. Takeda Pharmaceutical (Takeda) held a *product* patent, with a priority date in 1974, disclosing certain cephem compounds, a type of antibacterial agent. *Id.* at 1373. Takeda later obtained a *process* patent, with a priority date in 1990, for making the same cephem compounds. *Id.* at 1374. The PTO determined in a reexamination that the process patent was invalid for obviousness-type double patenting over the earlier filed product patent. *Id.* Takeda appealed to the district court and presented new evidence in the form of a third-party patent application, filed in 2002, that disclosed an alternative, non-infringing, process for making the same cephem compounds. *Id.* The district court relied on this alternative process in determining that Takeda's product and process are "patentably distinct" and overturned the PTO's double patenting rejection. *Id.* The PTO appealed to the Federal Circuit. *Id.* at 1375.

The issue before the Federal Circuit was whether a later-developed alternative process is relevant in the product-process "patentably distinct" analysis. The PTO contended that the date of invention of the primary product patent governs the timing of the double patenting analysis because other issues related to patentability (e.g., novelty and obviousness) are judged from that date. *Id.* at 1375-76. Takeda, on the other hand, argued that processes developed after the date of invention should be considered to allow a patent applicant to come forward with any evidence that a product and process are "patentably distinct," even if the alternative process is developed after the filing date of both patents. *Id.* at 1377.

The Federal Circuit opted to take the middle ground and held that the cut-off time frame for considering alternative processes is the filing date of the secondary process application. *Id.* at 1377. This gives the applicant "the benefit of future developments in the art" while preventing the "inequitable situation that arises when an applicant attempts to rely on developments occurring decades [later]." *Id.* This approach also "encourage[s] the swift development of materially distinct, alternative processes." *Id.* The court thus held that Takeda could not rely on the alternative process disclosed in 2002 to show that its 1974 product and 1990 process were "patentably distinct" and remanded the case to the district court. *Id.* at 1378.

Case Referenced:
Takeda Pharmaceutical Co. v. Doll, 561 F.3d 1372 (Fed. Cir. 2009).

One-Way and Two-Way Obviousness Tests For Double Patenting

Obviousness determinations under 35 U.S.C. § 103 are typically made using a one-way test. Under this test, the examiner asks whether the patent application claims are obvious over the prior art. *In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998). This same approach is used by patent examiners in obviousness-type double patenting analysis except that the prior art is the applicant's own earlier patent. *See id.* Occasionally, when reviewing a PTO determination of double patenting, courts require a more stringent two-way test and ask the converse, "whether the [earlier] patent claims are [also] obvious over the application claims." *Id.* The two-way test arose out of a desire "to prevent rejections for obviousness-type double patenting . . . through no fault of the applicants." *Id.* It is applicable in situations where "the applicants filed first for a basic invention and later for an improvement, but, through no fault of the applicants, the PTO decided the applications in reverse order of filing." *Id.*

In *In re Fallaux*, 564 F.3d 1313 (Fed. Cir. 2009), Dr. Fallaux's patent application was rejected for obviousness-type double patenting over earlier issued patents sharing a common inventor. The PTO applied a one-way test in making this determination. *Id.* at 1315. Dr. Fallaux appealed to the Federal Circuit, arguing that the examiner should have applied the two-way test, which would not have resulted in a double patenting rejection. *Id.* Although Dr. Fallaux had waited six years after the original patents were filed to prosecute the later application, he claimed that the delay was "in the ordinary course of business" and that he did not "proactively manipulate prosecution for an improper purpose or to gain some advantage." *Id.* at 1317. Instead Dr. Fallaux argued that he filed the later application as soon as he learned of a potential product of a competitor. *Id.* He also noted that he was not seeking an unjustified patent term extension. *Id.* at 1318.

The Federal Circuit agreed with the PTO and upheld the double patenting rejection. The court found that the delay in prosecution of the patent application was "entirely attributable" to Dr. Fallaux. *Id.* at 1317. Dr. Fallaux "dictated" the "rates of prosecution" of his patents by filing the applications at commercially advantageous times. *Id.* The court held that to require a two-way test in this situation would distort the rule by allowing applicants to use the test "absent proof of nefarious intent to manipulate prosecution." *Id.* The two-way test is reserved for "when the PTO is at fault for the delay that causes the improvement patent to issue prior to the basic patent." *Id.* at 1316.

Cases Referenced:
In re Berg, 140 F.3d 1428 (Fed. Cir. 1998)
In re Fallaux, 564 F.3d 1313 (Fed. Cir. 2009).

Double Patenting Of Continuation And Divisional Applications

The patent examiner may require that the claims in an application be restricted to a single "independent and distinct" invention by issuing a restriction requirement. The applicant must then elect an invention for prosecution in the original application and has the option to pursue other inventions in divisional applications. The Patent Act provides a safe harbor to protect divisional applications from validity challenges based on the parent application. *See* 35 U.S.C. § 121. Courts have interpreted the safe harbor as insulating divisional applications from charges of obviousness-type double patenting as well. *See, e.g., Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc.*, 98 F.3d 1563, 1568 (Fed. Cir. 1996). The Federal Circuit recently addressed whether the § 121 safe harbor applies to continuation applications, which also derive from a parent application but may contain additional claims to an invention not previously disclosed in the parent application. *See Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 1353 (Fed. Cir. 2009).

Amgen held five patents ("patents in suit") related to the production of the protein erythropoietin ("EPO") using recombinant DNA technology. *Id.* at 1345. The five patents stemmed from continuation applications filed after the PTO subjected the parent application to a restriction requirement. Amgen brought a declaratory judgment action against F. Hoffmann-La Roche ("Roche") alleging that Roche's product, MIRCERA, would infringe Amgen's five patents if imported into the U.S. *Id.* at 1348-49. The district court granted declaratory relief and permanently enjoined Roche from marketing MIRCERA in the U.S. *Id.* at 1349. Roche appealed several rulings of the district court, including the ruling that none of the five patents were invalid for obviousness-type double patenting. *Id.* Roche argued that the continuation applications were not protected by the § 121 safe harbor, which applies only to divisional applications. *Id.* at 1350-51. Amgen countered that the continuation applications conform to the definition of the divisional applications in the MPEP and could have been filed as such. *Id.* at 1351. In essence, Amgen admitted that the applications were erroneously filed as continuations following the restriction requirement on the parent application.

The Federal Circuit vacated the district court's ruling of validity of the five patents and remanded the case. The court analogized to its prior opinion in *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008), where it held that a patent that issued from a continuation-in-part, rather than a divisional, was not entitled to receive the § 121 safe harbor. *Id.* at 1362. Although the *Pfizer* decision dealt with a continuation-in-part while Amgen's applications are continuations, the court held that this distinction "does not justify departing from a strict application of the plain language of § 121, which affords its benefits to 'divisional application[s]'" *Amgen*, 580 F.3d at 1353. The court emphasized that the statute must be read literally. Since Amgen chose to "check[] the continuation application box on the submitted form" for its applications, the court declined to treat them as divisional applications for the purposes of § 121. *Id.* at 1354.

Cases Referenced:

Amgen Inc. v. F. Hoffmann-La Roche Ltd., 580 F.3d 1340 (Fed. Cir. 2009)
Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc., 98 F.3d 1563 (Fed. Cir. 1996)
Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc., 518 F.3d 1353 (Fed. Cir. 2008).

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