Patent Prosecution Update

December 2010

Obviousness After *KSR*: The 2010 *KSR* Guidelines

*by Thomas L. Irving and Elizabeth A. Laughton**

In addressing the law of obviousness in its 2007 decision in *KSR International Co. v. Teleflex Inc*., 550 U.S. 398 (2007), the Supreme Court placed a different emphasis on the framework set forth in *Graham v. Deere*, 383 U.S. 1 (1966), and abrogated the exclusive application of the teaching-suggestion-motivation (TSM) test developed by the Federal Circuit. The Supreme Court held that the TSM test was merely one possible line of reasoning that could be used to support an obviousness determination. More

EPO Practice Tip

As reported in the July 2010 edition of "Full Disclosure," the European Patent Office (EPO) recently instituted a number of changes to the European Patent Convention (EPC). One of these changes relates to Rule 161 EPC Communications, which pertain to the deficiencies noted in a PCT Written Opinion or International Preliminary Report on Patentability (IPER). More

**Elizabeth A. Laughton is a Law Clerk with Finnegan.*

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Obviousness After *KSR*: The 2010 *KSR* Guidelines

*by Thomas L. Irving and Elizabeth A. Laughton**

(cont'd)

In response to the Supreme Court's decision, the U.S. Patent and Trademark Office (USPTO) developed guidelines to assist its examiners in making obviousness determinations. *See* Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc*., 72 Fed. Reg. 57,526 (Oct. 10, 2007). In addition to the TSM test, the 2007 Guidelines provided six examples of appropriate reasoning that could be used to support an obviousness determination.

In the three years since the *KSR* decision and the 2007 Guidelines, the law of obviousness has continued to develop through Federal Circuit case law. To account for those developments, the USPTO updated its *KSR* guidance on September 1, 2010. *See* Examination Guidelines Update: Developments in the Obviousness Inquiry After *KSR v. Teleflex*, 75 Fed. Reg. 53,643 (Sept. 1, 2010). The 2010 Guidelines provide a detailed analysis of twenty-four post-*KSR* Federal Circuit cases, synthesizing the lessons examiners and practitioners should learn from each and expanding upon the additional lines of reasoning set forth by the USPTO in the 2007 Guidelines. The 2010 Guidelines provide guidance to USPTO personnel as to the contours of the obviousness inquiry after *KSR* and assist practitioners in drafting applications and overcoming an obviousness rejection during examination. Notwithstanding an examiner's rationale for formulating an obviousness rejection, the 2010 Guidelines make it clear that the *Graham* factual inquiries remain the foundation of any determination of obviousness. 75 Fed. Reg. at 53,644. These inquiries include determining scope and content of the prior art and differences between the claimed invention and the prior art. This article highlights some of the other advice contained in the 2010 Guidelines.

COMBINING PRIOR ART ELEMENTS

The Supreme Court announced that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR*, 550 U.S. at 401. The 2010 Guidelines observe that recent cases highlight that it is especially important that an examiner, in determining obviousness, consider whether "the combination requires a greater expenditure of time, effort, or resources than the prior art teachings." 75 Fed. Reg. at 53,646. Consequently, "[w]hen a combination invention involves additional complexity as compared with the prior art, the invention may be nonobvious unless an examiner can articulate a reason for including the added features or steps. This is so even where the claimed invention could have been readily implemented." *Id*. In particular, the 2010 Guidelines reinforce that "[a]n inference that a claimed combination would not have been obvious is especially strong where the prior art's teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements." *Id*. at 53,649. In situations involving inventions which can be viewed as a combination of prior art elements, applicants may benefit from highlighting any additional effort and skill needed to practice the claimed invention. In addition, applicants could point out any reasons why one of ordinary skill would not have been motivated, based on the prior art, to undertake the extra work and greater expense in order to create the claimed combination.

SUBSTITUTING ONE KNOWN ELEMENT FOR ANOTHER

The 2010 Guidelines explain that "the substitution rationale applies when the claimed invention can be viewed as resulting from substituting a known element for an element of a prior art invention." *Id*. This rationale "applies when one of ordinary skill would have been technologically capable of making the substitution, and the result obtained would have been predictable." *Id*.

In the biological and chemical arts, for example, recent Federal Circuit cases have made it clear that for a compound to serve as a lead compound, there must be a reason for starting with that compound and then modifying it to obtain the claimed compound. In particular, the 2010 Guidelines declare that "[o]bviousness of a chemical compound in view of its structural similarity to a prior art compound may be shown by identifying some line of reasoning that would have led one of ordinary skill in the art to select and modify the prior art compound in a particular way to produce the claimed compound." *Id*. at 53,653. Therefore, the 2010 Guidelines make clear that it is insufficient for an examiner to simply cite a structurally similar compound and to observe the alleged ease of transforming that compound into the claimed compound. Instead, the examiner must articulate sufficient reasoning for selecting the structurally similar compound and modifying it in a way so as to achieve the desired compound.

THE "OBVIOUS TO TRY" RATIONALE

The question of when it is appropriate to invoke the rationale that a claimed invention is obvious because it was "obvious to try" has also been explored by post-*KSR* case law. The 2010 Guidelines note that "this rationale is only appropriate when there is a recognized problem or need in the art; there are a finite number of identified, predictable solutions to the recognized need or problem; and one of ordinary skill in the art could have pursued these known potential solutions with a reasonable expectation of success." *Id*. The 2010 Guidelines observe that the Federal Circuit has clarified the meaning of "finite" in this context, defining it as "'small or easily traversed' in the context of the art in question." *Id*. at 53,655. Moreover, the 2010 Guidelines caution that "Office personnel should recognize that even when only a small number of possible choices exist, the obvious to try line of reasoning is not appropriate when, upon consideration of all of the evidence, the outcome would not have been reasonably predictable and the inventor would not have had a reasonable expectation of success." *Id*. at 53,656. Thus, a mere reference by an examiner to a relatively small number of possible choices is inadequate to make a determination of obviousness, especially in situations where the art is unpredictable.

CONSIDERATION OF EVIDENCE

The 2010 Guidelines also observe that post-*KSR* case law makes clear that *all evidence*, including evidence rebutting a prima facie case of obviousness, must be considered in an obviousness analysis. Particularly useful to applicants is the 2010 Guidelines' discussion of *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007), in which the Federal Circuit held that the Board of Patent Appeals and Interferences erred in failing to consider evidence of unexpected results. *See* 75 Fed. Reg. at 53,657. Applicants should insist upon a consideration of *all evidence*, including evidence rebutting a prima facie case of obviousness, evidence establishing that no prima facie case of obviousness has been established, or evidence probative with respect to so-called “secondary considerations” of obviousness, such as commercial success or long-felt need.

**Elizabeth A. Laughton is a Law Clerk with Finnegan.*

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EPO Practice Tip

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As explained in our previous edition, in cases where the EPO acted as the International Searching Authority during the PCT stage, the amendments to Rule 161 EPC required a mandatory response to the Written Opinion or the IPER within one month, unless certain amendments were previously filed. In particular, a mandatory response is not required if amendments and/or comments were filed upon entry into the European national phase; amendments filed pursuant to Article 19 and/or 34 PCT were maintained on entry into the European national phase, provided these amendments were not considered in the issuance of an IPER; the Written Opinion or IPER was positive with respect to the claims; or a communication pursuant to Rule 161 had already issued before the rule changes became effective. If a mandatory response is not required, the EPO typically invites applicants to comment on the Written Opinion or IPER. We also observed that applicants may eliminate the need to file a response to a Written Opinion or IPER by filing amended documents, e.g., amendments reducing the number of claims pending upon national-phase entry or making the claims consistent with those in another jurisdiction where prosecution has matured.

With the benefit of another few months of practice, it has been further observed that Rule 161 practice shifted to now limit the entry of further amendments in applications where prior amendments or remarks do not address the deficiencies in the Written Opinion or IPER, and the applicant fails to respond to the Rule 161 Communication. In particular, in those situations, the EPO is allowing the entry of future amendments only with the consent of the Examination Division. Although it may be too early to determine whether this EPO practice will be permanent or strictly enforced, applicants should respond to all Rule 161 Communications and address the deficiencies noted in the Written Opinion and/or IPER, whether or not a response is required. Such practice may preserve the opportunity to submit future amendments should the need arise.

In addition, the EPO recently announced a further amendment to Rules 161 and 162 EPC. The further amendment will extend the time period for responding to a Rule 161 Communication from one month to six months. This amendment will become effective on May 1, 2011, and will apply to all Rule 161 Communications issuing after that date. The rule change will provide applicants with additional time to respond to the objections of the searching authority. For cases where the EPO was not the searching authority, the additional time will provide an extended period for considering potential preliminary amendments to the European application.

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Rule Review

As a result of the Drug Price Competition and Patent Term Restoration Act of 1984, the patent regulations provide owners of patents on certain drugs, food or color additives, medical devices, and biological products an opportunity to restore to the terms of those patents some of the time lost while awaiting premarket regulatory approval. Patents available for such extensions, however, are limited to those that cover an approved product. The formal requirements for applying for patent term extension are generally set forth in Rule 1.740, and Rules 1.775 to 1.779 set forth methods of calculating the extension periods. This brief article reviews Rule 1.777, which sets forth the method of calculating the extension period for a medical device patent. Though the method is somewhat complicated, extending the term of a patent on a medical device can protect market share for many years in very lucrative markets.

Paragraph (c) of Rule 1.777 establishes that the Secretary of Health and Human Services ("Secretary") first calculates the length of the review period for a medical device as the sum of (1) the days from the start of a clinical investigation on humans to submission of an application for the device under the Federal Food, Drug, and Cosmetic Act ("Act"); and (2) the days from the submission of the application to its approval, or the period from submission of a notice of completion of a product development protocol under the Act to the date the protocol was completed.

Paragraph (d)(1) of the Rule then requires certain subtractions from the calculated length of the review period. The amounts subtracted are: (i) the days in the review period on and before issuance of the patent; (ii) the days in the review period during which the Secretary determines that the applicant did not act with diligence; and (iii) one-half of the days remaining in the period defined by paragraph (c)(1) [i.e., the start of clinicals to submission of the application] after that period is reduced according to (i) and (ii).

Next, paragraph (d)(2) instructs to add the number of days determined by paragraph (d)(1) to the original patent term. Paragraph (d)(3) further instructs to add fourteen years to the date of approval of the application or the date a product development protocol was completed. Paragraph (d)(4) then requires comparing the end dates obtained by paragraphs (d)(2) and (d)(3), and selecting the earlier date.

If the patent issued after September 24, 1984, paragraph (d)(5) instructs to (i) add five years to the original expiration date of the patent and (ii) select the earlier of the dates obtained according to paragraphs (d)(4) and (d)(5)(i). This paragraph therefore restricts a patent term extension to at most five years for patents issued after September 24, 1984.

If, however, the patent issued before September 24, 1984, the extension is restricted to at most five or two years. For such patents, if no human clinicals were started or no product development protocol was submitted before September 24, 1984, paragraph (d)(6)(i) instructs to (A) add five years to the original patent expiration date and (B) select the earlier of the dates obtained according to paragraphs (d)(4) and (d)(6)(i)(A). However, if human clinicals were started or a product development protocol was submitted before September 24, 1984, and the commercial marketing or use of the product was not approved by that date, paragraph (d)(6)(ii) instructs to add (A) two years to the original expiration date of the patent and (B) select the earlier of the dates obtained according to paragraphs (d)(4) and (d)(6)(ii)(A).

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The Federal Circuit Says

"[A]n applicant is not entitled to a patent if another's patent discloses the same invention, which was carried forward from an earlier U.S. provisional application or U.S. non-provisional application." *In re Giacomini*, No. 09-1400, slip op. at 5 (Fed. Cir. July 7, 2010). In *In re Giacomini*, the Federal Circuit affirmed the USPTO's rejections of an application over a patent based on the filing date of that patent's priority provisional application. Additionally, the Court reminded the patent bar of the principles and applications of 35 U.S.C. § 102(e).

The Giacomini application was filed on November 29, 2000. The USPTO, however, rejected certain claims of the application as anticipated under 35 U.S.C. § 102 by U.S. Patent No. 7,039,683 ("the '683 patent"), which was filed on December 29, 2000. Although Giacomini did not dispute the USPTO's finding that the '683 patent taught all of the claimed features in the application, Giacomini argued that the '683 patent failed to qualify as prior art because the filing date of his application antedated the filing date of the '683 patent. The Court disagreed.

The Federal Circuit concluded that the '683 patent had a patent-defeating effect as of the filing date of its provisional application, which was filed on September 25, 2000, or over two months prior to Giacomini's application, because the provisional application qualified as an "application for patent" for the purposes of § 102. The Court then reasoned that since 35 U.S.C. § 119(e) provides for treating a nonprovisional application as though it was filed on the date of its corresponding provisional application, and Giacomini failed to argue a lack of written description support in the '683 patent's provisional application, the '683 patent would prevent Giacomini from receiving a patent covering the same subject matter disclosed in the '683 patent.

The Court reasoned that its conclusions are consistent with the spirit of the patent system's goals to award patent rights to the first inventor. Slip op. at 6. If Giacomini's application were allowed, it would create the irregular result of awarding a patent to someone who was not the first to invent in the United States. *Id.* at 7.

The *Giacomini* decision reminds us of the importance of filing patent applications as early as possible, even if those applications are provisional applications. Early filings may not only help to avoid potentially intervening prior art, but may also prevent "late" filers from securing patent rights.

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Did You Know?

The USPTO recently clarified its treatment of letters submitted by applicants and patentees concerning the USPTO's determination of a patent term adjustment (PTA) greater than what the applicant or patentee believes to be correct. Upon receipt of such letters, the USPTO now places these letters in the file of the application or patent without further review or issuance of a correction to the PTA. Although applicants and patentees may (1) request the USPTO to reconsider its calculation of PTA in accordance with 37 C.F.R. § 1.705 or (2) file a terminal disclaimer disclaiming any period considered in excess of the appropriate PTA, they are not required to do either.

Additional information regarding the USPTO's current practice may be found at the following link: http://www.uspto.gov/patents/law/notices/75fr42079.pdf.

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