

## REPORT

## POST-KSR DEVELOPMENTS REGARDING OBVIOUSNESS

August 17, 2007

As reported in our May 7, 2007 Special Report, and as now well-known in the intellectual property community, the U.S. Supreme Court provided its most recent views of proper obviousness analysis in *KSR International Co. v. Teleflex Inc.*<sup>1</sup> As of the date of this subsequent Special Report, numerous articles have been published by academics, in-house practitioners and private practitioners, offering a wide variety of views regarding *KSR* and its potential impacts on obviousness analyses by the courts and the U.S. Patent and Trademark Office ("PTO").

As always, reality replaces speculation as the courts and the PTO begin to interpret and implement Supreme Court guidance. While it has been only a few months since the *KSR* decision, there is already a developing body of case law from the Federal Circuit and the PTO Board of Patent Appeals and Interferences ("BPAI" or "Board"), as well as recent draft PTO examination guidelines,<sup>2</sup> which provide some early indications of the ways in which *KSR* will be applied.

This Special Report: (1) provides in Part I an overview of eight exemplary post-*KSR* Federal Circuit and Board decisions, (2) provides in Part II an overview of the PTO's draft examination guidelines for determining obviousness in view of *KSR*, (3) provides in Part III conclusions and recommendations, (4) discusses in detail in Appendix A the eight exemplary post-*KSR* decisions, and (5) discusses in detail in Appendix B the PTO's draft examination guidelines.

<sup>1</sup> 550 U.S. \_\_\_, 82 USPQ2d 1385, 2007 WL 1237837 (April 30, 2007).

<sup>2</sup> We understand that the PTO is awaiting approval from the Office of Management and Budget ("OMB") before finalizing and officially releasing the guidelines, but that meanwhile the draft guidelines are being used to train Examiners. We will forward copies of the finalized guidelines when they are officially released.

## I. Overview Of Post-*KSR* Decisions

We discuss in detail in Appendix A the following eight exemplary post-*KSR* decisions, five by the Federal Circuit and three by the Board (grouped by technology type and then in the order in which they were decided):

- Mechanical/Electrical Technologies:

1. *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.* (Fed. Cir. 5/9/07) (Mayer, Lourie<sup>3</sup> and Dyk);
2. *Ex parte Smith* (BPAI 6/25/07) (Fleming (Chief Judge), Pate, Bahr, Horner and Walker - *Per Curiam*);
3. *Ex parte Catan* (BPAI 7/3/07) (Fleming (Chief Judge), Lorin, MacDonald, Horner and Fetting - *Per Curiam*);
4. *In re Icon Health and Fitness, Inc.* (Fed. Cir. 8/1/07) (Mayer, Schall and Prost);

- Chemical/Pharmaceutical Technologies:

5. *Pfizer, Inc. v. Apotex, Inc.* (Fed. Cir. 5/21/07) (*En banc* denial, Newman, Lourie and Rader dissenting);
6. *Ex parte Kubin* (BPAI 5/31/07) (Fleming (Chief Judge), Gron, Scheiner, Grimes and Linck);
7. *Takeda Chemical Indus., Ltd. v. Alphapharm Pty., Ltd.* (Fed. Cir. 6/28/07) (Lourie, Bryson and Dyk); and

<sup>3</sup> Underlining indicates the author of the opinion accompanying the decision.

August 17, 2007

8. *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.* (Fed. Cir. 7/9/07) (Bryson and Prost, Newman dissenting).

These early post-*KSR* Federal Circuit and Board decisions suggest a possible inclination by those tribunals towards an increasing number of obviousness determinations in the wake of *KSR*, given that all three Board decisions and four of the five Federal Circuit decisions (those other than *Takeda*) determined (or left intact determinations) that claimed inventions would have been obvious. However, only time will tell if the seeming trend in these early decisions continues, as these decisions provide only a small snapshot from which to project (and *Takeda* provides hope that nonobviousness will still be regularly found where appropriate). Regardless, the early post-*KSR* Federal Circuit and Board decisions certainly reflect greater flexibility in the approaches to determining whether or not claimed inventions would have been obvious.

In the decisions involving mechanical/electrical technologies, both the Federal Circuit and the Board take a "functional approach" to obviousness determinations, *i.e.*, they consider whether a claimed combination is nothing more than the predictable use of prior art elements according to their established functions (to obtain their known benefits) without necessarily further explicitly addressing motivation to combine. In the decisions involving chemical/pharmaceutical technologies, both the Federal Circuit and the Board nominally use the "obvious to try" standard that was endorsed by *KSR*, although there is apparently strong disagreement within the Federal Circuit, and between the Board and the Federal Circuit, as to the requirements and proper application of the standard.

The Federal Circuit's teaching-suggestion-motivation test ("TSM test") is optionally used by the Board only to buttress an obviousness determination, and is proclaimed as necessary by the Federal Circuit only in cases involving new chemical compounds. The general dispensing with the necessity of the TSM test is consistent with prior Supreme Court decisions cited in *KSR* (see Part II.A of our May 7 Special Report), which decisions did not consider (at least not explicitly) whether there was a motivation to combine prior art elements according to their established functions when doing so yields no more than predictable results.

The early post-*KSR* decisions also suggest that secondary considerations will continue to be considered in an obviousness determination, but that (1) it will now be even more important to clearly establish a nexus between such evidence and the claimed invention and (2) even in the presence of the requisite nexus, such evidence may now be less persuasive in the face of *prima facie* obviousness. Here again, the Supreme Court decisions cited in *KSR*, and discussed in our May 7 Special Report (Part II.A), likewise indicate that such evidence cannot establish nonobviousness of a combination lacking inventiveness. *See, e.g., Great Atlantic & Pacific Tea Co. v. Supermarket Equip. Corp.*,<sup>4</sup> cited in subsequent Supreme Court decisions ("commercial success without invention will not make patentability"). Nonetheless, as reflected in *Takeda*, secondary considerations evidence (in that case unexpected results) should continue to help tip the scales in favor of nonobviousness.

## II. Overview Of The PTO's Draft Examination Guidelines In View Of *KSR*

The PTO's draft "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.*" (discussed in detail in Appendix B) are commensurate with the above-referenced post-*KSR* exemplary decisions. Indeed, the draft guidelines cite several of those decisions (*e.g., Leapfrog, Smith, Catan, Pfizer* and *Kubin*), along with other pertinent Supreme Court, Federal Circuit and other decisions.

Like the cited decisions, the draft guidelines indicate that there are numerous possible "rationales" for obviousness determinations in addition to the TSM test. However, the draft guidelines advise that, in an obviousness rejection, an Examiner must (1) accurately resolve the factual inquiries required by *Graham v. John Deere Co.*<sup>5</sup> and reaffirmed by *KSR*, (2) clearly articulate the Examiner's fact findings within the *Graham* framework, and (3) clearly articulate a rationale, based upon the facts, leading to a conclusion of obviousness. The draft guidelines further indicate that an Examiner should fully consider a patent applicant's traversal/rebuttal of an obviousness rejection, and must clearly explain the Examiner's reasons for nonetheless maintaining an obviousness rejection.

<sup>4</sup> 340 U.S. 147 (1950).

<sup>5</sup> 383 U.S. 1, 17-18 (1966).

August 17, 2007

### III. Conclusions and Recommendations

It is evident from the post-KSR decisions and the PTO's draft examination guidelines that the courses of action recommended in our May 7 Special Report (Part IV) remain viable. However, pending receipt of any additional specific questions, we now more particularly suggest consideration of the following:

#### A. Patent Applicants And Patentees

- Patent applicants should be careful not to make undue or inaccurate statements anywhere in a patent application that could possibly be used as admissions as to the state of the art, what was known in the art, and what known problems and needs confronted practitioners in the prior art. At the same time, applicants must act with candor, provide material factual information to the PTO in the specification or an Information Disclosure Statement, and draft the application in view of such information to distinguish over it.
- Wherever possible, patent applicants should include in their mechanical/electrical patent applications at least some claims that (1) include an element either not found in the prior art or that does not merely perform a prior art function and/or (2) recite a combination of elements that together perform a new or different function, or provide a synergistic result, as compared to the individual elements found in the prior art.
- Wherever possible, patent applicants should include in their chemical/pharmaceutical applications at least some claims that recite unexpected properties or results for claimed compounds or methods, thus reflecting that it would not have been obvious to try such compounds or methods (either for lack of any motivation to attempt to make the compounds or practice the methods or for lack of a reasonable expectation of success). However, intended use limitations should be avoided in favor of property limitations or method limitations in method claims.
- Patent applicants and patentees should present corresponding arguments commensurate with and in support of the above types of claims. With respect to broader claims, the best possible submissions by applicants and patentees may include arguments and evidence (*e.g.*, declarations or publications) establishing that:
  1. the level of skill in the art was low;
  2. there was no known, viable reason or means prior to the invention to combine or modify the prior art references;
  3. the prior art taught away from the invention;
  4. ordinarily skilled persons did not have the requisite knowledge or skill to combine or modify the prior art references;
  5. a claimed feature or function is missing even after references are combined, and such feature or function would not otherwise have been known or obvious;
  6. the Examiner's or an opponent's assertions of general principles and common knowledge are erroneous;
  7. the Examiner's or an opponent's analysis or utilization of the prior art is erroneous;
  8. the Examiner's or an opponent's characterization of the claimed invention is erroneous;
  9. the results of a claimed combination were unexpected, unpredictable or surprising; and/or
  10. a claimed combination would not have been obvious to try in view of the large number of possibilities suggested in the prior art and lack of a reasonable likelihood of success.
- Patent applicants and patentees should continue to insist upon an explicit obviousness analysis with articulated reasoning and rational underpinning tied to the specific facts at issue (not just boilerplate form paragraphs), as required by both the Supreme Court and the Federal Circuit (and the PTO's draft examination guidelines).
- Patent applicants and patentees should continue to rely upon secondary considerations evidence, but

August 17, 2007

must be careful to establish a nexus to the claimed invention and, even then, to be objective and realistic concerning the weight that such evidence is likely to be given in an obviousness determination. Secondary consideration evidence should be used in conjunction with other reasonable nonobviousness arguments/evidence to tip the scales in an applicant's or patentee's favor.

- Patent applicants should avoid stating in the specification how the inventor(s) made the invention. Patent applicants and patentees should regardless, when appropriate, stress the last sentence of 35 U.S.C. §103(a), that "[p]atentability shall not be negated by the manner in which the invention was made."
- Patent applicants and patentees should consider that, in view of recent case law, nonanalogous art arguments (*i.e.*, different field of endeavor and addressing different problem) may now be better received, but that there are added risks resulting from the focus, in an analogous art analysis, on the problem confronting the inventor(s). *See In re Icon Health and Fitness, Inc.*, discussed in Appendix A hereto.

## B. Patent Challengers

- Patent challengers should make use of the various approaches to obviousness analysis reflected in the Federal Circuit and Board decisions and the PTO's draft examination guidelines, while at the same time continuing, when appropriate, to address the TSM test (as more flexibly viewed and applied in more recent Federal Circuit decisions).
- Patent challengers should, as suggested by *KSR*, continue to use *Graham's* factors as a framework for obviousness arguments, and to also rely upon other Supreme Court and Federal Circuit case law discussed herein and in our May 7 Special Report.
- Patent challengers should make liberal use of summary judgment motions to take advantage early in litigation of the seemingly increased inclination in post-*KSR* decisions toward a conclusion of obviousness.

- If confronted with nonanalogous art arguments, patent challengers should take advantage of the focus on the problems confronting the inventor(s), which may be helpful in demonstrating obviousness. *See In re Icon Health and Fitness, Inc.*, discussed in Appendix A hereto.

## C. All Parties

- Patent applicants, patentees and patent challengers should make effective use of inventor and expert declarations. As reflected in *Takeda*, and in the PTO's draft examination guidelines, expert testimony can be very useful in an obviousness determination. However, as reflected in *PharmaStem*, expert testimony needs to be consistent with the patent specification and the prior art in order to be credible.

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August 17, 2007

**APPENDIX A: POST-KSR DECISIONS****I. Mechanical/Electrical Decisions****A. Leapfrog**

*Leapfrog*, the Federal Circuit's first significant post-*KSR* obviousness decision, involved an electronic interactive learning device to help children read phonetically. The Federal Circuit affirmed the district court holding that the claimed invention was invalid for obviousness based on the combination of a prior art patent to Bevan (disclosing an electro-mechanical learning toy), a Texas Instruments Super Speak & Read (SSR) device (a commercial electronic learning toy), and the knowledge of one of ordinary skill in the art. Both the district court and the Federal Circuit concluded that the disclosed Bevan device has the same method of operation as the claimed invention, and that the SSR device, although having a slightly different mode of operation, was constructed with electronic components. Both the district court and the Federal Circuit also concluded that one of ordinary skill in the art would have found it obvious to update the disclosed Bevan device in view of the SSR device to use modern electronic components in order to gain the commonly understood benefits of such adaptation, such as decreased size, increased reliability, simplified operation and reduced cost.

The Federal Circuit stated that "the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not," quoting *KSR* in support ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."). The Federal Circuit further stated that "[a]ccommodating a prior art mechanical device that accomplishes [a claimed] goal to modern electronics would have been reasonably obvious to one of ordinary skill in designing children's learning devices" given that "[a]pplying modern electronics to older mechanical devices has been commonplace in recent years." According to the Court, "[t]he combination is thus the adaptation of an old idea or invention (Bevan) using newer technology that is commonly available and understood in the art (the SSR)."

The combination of Bevan and the SSR device lacked a recited "reader" for communicating with a claimed processor. However, the Federal Circuit found no clear

error in the district court's finding that readers were well-known in the art at the time of the invention. The Federal Circuit also noted that the reasons for adding a reader to the Bevan/SSR combination are the same as those for using readers in other children's toys (an added benefit and simplified use to increase marketability), and that Leapfrog had presented no evidence that the inclusion of a reader in this type of device was uniquely challenging or difficult for one of ordinary skill in the art.

The Federal Circuit disagreed with Leapfrog's argument "that the district court failed to give proper consideration to secondary considerations." More particularly, the Federal Circuit found "no basis to disagree" with the district court's determination that the "substantial evidence of commercial success, praise, and long-felt need" was inadequate, given the strength of the *prima facie* obviousness showing, to overcome a final conclusion of obviousness.

**B. Ex parte Smith**

*Smith* involved a pocket insert for a bound book for receiving and retaining supplemental material, such as a diskette or CD-ROM. The claims required a one-ply base sheet bound to the binding of the book, and a one-ply pocket sheet chemically bonded, fused or glued to the base sheet to form continuous two-ply seams defining one or more pockets. The Examiner rejected the claims for obviousness based upon two or three prior art patents (Wyant and Dick, some claims further in view of Ruebens), and the Board affirmed.

Regarding a first set of claims, the Board stated the issue to be "whether it would have been obvious to glue two separate sheets to form a continuous two-ply seam, as taught by Dick, rather than folding one sheet to create a seam along the folded edge, as taught by Wyant." With respect to a second set of claims, the Board stated the issue to be "whether it would have been obvious to improve a pocket insert by creating two pockets from a single pocket using an additional line of adhesive," as taught by Ruebens. In affirming, the Board noted *KSR's* endorsement of the "functional approach" of earlier Supreme Court cases,<sup>1</sup>

<sup>1</sup> *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *Hotchkiss v. Greenwood*, 11 How. 248 (1851).

August 17, 2007

under which one determines "whether the improvement is more than the predictable use of prior art elements according to their established functions." The Board also cited the Federal Circuit's *Leapfrog* decision, in addition to other Federal Circuit precedent.

Using the functional approach, the Board found that "the combination of Wyant and Dick [as applied to the first set of claims] would have taught one of ordinary skill in the art to use the Wyant teaching of bonding method to secure the Dick pocket," noting that "neither Appellant's Specification nor Appellant's arguments present any evidence that [combining Wyant and Dick] was uniquely challenging or difficult for one of ordinary skill in the art." Citing *KSR*, the Board further stated that "[t]he substitution of the continuous, two-ply seam of Dick for the folded seam of Wyant thus is no more than 'the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.'" Under a similar analysis, the Board held that the combination of Wyant, Dick and Ruebens (as applied to the second set of claims) "performs the same function when combined as it does in the prior art" and that "such a combination would have yielded predictable results." The Board also held that the prior art's silence as to the capabilities or function of a particular item does not constitute "teaching away" from its use.

### C. *Ex parte Catan*

*Catan* involved claims to a consumer electronics device comprising, *inter alia*, a bioauthentication device, such as a fingerprint sensor or a voice sensor, for authorizing users of a credit account to place orders over a communication network up to pre-set credit limits. The PTO Examiner rejected the claims for obviousness over a combination of three U.S. patents (Nakano, Dethloff and Harada), and the Board affirmed. The Board stated the issue to be whether Appellant had shown that the Examiner erred in holding that the combination of Nakano's consumer electronics device and Dethloff's and Harada's bioauthentication means would have rendered the claimed subject matter obvious to one of ordinary skill in the art at the time of the invention.

The Board indicated that Nakano disclosed all of the claimed subject matter, but used password authentication rather than bioauthentication. The Board further noted that Harada showed that it was known in the art at the time of the invention to use a bioauthentication device (fingerprint sensor) on a remote control, and that Dethloff taught that it

was known in the art to substitute bioauthentication in place of PIN authentication for enabling a user to access credit via a consumer electronics device.

Using a *Smith*-style analysis, with citations to *KSR*, *Graham* and *Leapfrog*, the Board held that the claimed subject matter would have been obvious from the combination of Nakano and Harada alone, because (1) the claims were directed to a structure already known in the prior art that was altered by the mere substitution of one element for another known in the field to yield a predictable result, and (2) Appellant did not present any evidence that including a bioauthentication device in a consumer electronic device was uniquely challenging or difficult for one of ordinary skill in the art. Stated differently, the Board held that the claimed device "is an adaptation of an old invention (Nakano) using newer technology that is commonly available and understood in the art (Harada)."

The Board stated that *KSR* "discussed circumstances in which a patent might be determined to be obvious without an explicit application of the teaching, suggestion, motivation [TSM] test." However, reflecting the continued utility of the Federal Circuit's TSM test, the Board also stated that "our holding is further buttressed by the teaching in Dethloff of the substitutability of a voice print authentication for a PIN authentication" to enable a user to more securely access credit.

### D. *In re Icon Health and Fitness, Inc.*

*Icon* involved claims to a treadmill with a folding base allowing the base to swivel into an upright storage position, the claims requiring, *inter alia*, a gas spring connected between the base and upright structure to assist in stably retaining the base in the upright position. On reexamination, the PTO rejected the claims for obviousness based upon the combination of an advertisement for a folding treadmill (Damark) and a U.S. patent disclosing gas springs for use in beds that fold up into a cabinet or recess (Teague). The Federal Circuit affirmed.

After finding Teague to be analogous art, the Federal Circuit addressed obviousness stating that "we consider a variety of sources that may have led one skilled in the art to combine the teachings of Damark and Teague," quoting *KSR* for the proposition that "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." Pointing to similar

August 17, 2007

problems addressed by both the claimed invention and Teague, the Federal Circuit stated:

One skilled in the art would naturally look to prior art addressing the same problem as the invention at hand, and in this case would find an appropriate solution. Indeed, while perhaps not dispositive of the issue, the finding that Teague, by addressing a similar problem, provides analogous art to Icon's application goes a long way towards demonstrating a reason to combine the two references.

The Federal Circuit found no teaching away, given that Teague "does not indicate the undesirability or unsuitability of either [disclosed gas spring] mechanism for Icon's purpose."

## II. Chemical/Pharmaceutical Decisions

### A. Pfizer

As discussed in our May 7 *KSR* Special Report, the Federal Circuit re-endorsed an "obvious to try" analysis in its pre-*KSR* decision in *Pfizer, Inc. v. Apotex, Ltd.*<sup>2</sup> In that case, involving claims to the besylate salt of amlodipine, the Federal Circuit reversed the district court in holding that a skilled artisan would have (1) been motivated to combine prior art references to achieve the claimed invention, and (2) had a reasonable expectation of success. In a post-*KSR* decision in that same case on May 21, 2007, the Federal Circuit denied Pfizer's petition for rehearing *en banc* of the earlier three-judge panel decision.<sup>3</sup> Three dissenting opinions in conjunction with the rehearing denial reflect the divergent views of the Federal Circuit judges with respect to the "obvious to try" test.

Judge Newman criticized "the panel's acceptance of the long-discredited 'obvious to try' standard, on which the panel superimposes the theory that the skill of these inventors guided them to trial of the besylate salt ...," noting that "[t]he panel's application of the obvious-to-try standard is in direct conflict with precedent" as "it has long been the law that 'patentability shall not be negated by the manner in which the invention is made.'" Judge Newman also opined that the panel erred in declining to give weight to

acknowledged secondary considerations evidence of unexpected results.

Judges Lourie and Rader articulated similar reasons for dissenting, stating more specifically that the panel had improperly placed greater importance on the therapeutic value of a claimed compound than on the value of its physical properties. More directly on the subject of "obvious-to-try," Judge Lourie stated that "holding an inventor's expectations of success against the objective unexpectedness of the properties of the compound unfairly suggests that an inventor should try only that which he doubts will work." Judge Rader added that "'obvious to try' jurisprudence has a very limited application in cases of this nature" where unpredictability rebuts any reasonable expectation of success.

### B. *Ex parte Kubin*

*Kubin* involved claims to an isolated nucleic acid molecule comprising a polynucleotide encoding a specified polypeptide.<sup>4</sup> The Examiner rejected the claimed invention over the combined teachings of a U.S. patent (Valiante) and two references relating to molecular cloning (Sambrook and Mathew). The Board affirmed, stating the issue to be whether the claimed nucleotide sequence would have been obvious to one of ordinary skill in the art, based on Valiante's disclosure of p38 protein and his express teachings of how to isolate its cDNA by conventional techniques.

Appellants cited the Federal Circuit's *In re Deuel* decision<sup>5</sup> in arguing that it is not proper for the PTO to use the p38 protein identified in Valiante together with the methods described in Sambrook and Mathew to reject claims drawn to specific sequences. Despite noting some factual similarities between *Deuel* and the *Kubin* case, however, the Board indicated that "*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." The Board further stated that "[t]o the extent *Deuel* is considered relevant to this case, we note the Supreme Court [in *KSR*] recently cast doubt on the viability of *Deuel* to the extent the Federal Circuit [in *Deuel*] rejected an 'obvious to try' test." The Board further stated that "[u]nder *KSR*, it's now apparent 'obvious to try' may be

<sup>2</sup> 480 F.3d 1348 (Fed. Cir. 2007) (Michel (Chief Judge), Mayer and Linn).

<sup>3</sup> 488 F.3d 1377 (Fed. Cir. 2007).

<sup>4</sup> The field of invention was polynucleotides encoding NK (natural killer) Cell Activation Inducing Ligand ("NAIL") polypeptides.

<sup>5</sup> 51 F.3d 1552 (Fed. Cir. 1995).

August 17, 2007

an appropriate test in more situations than we previously contemplated."

The crux of the Board's analysis is reflected by the following statement:

The "problem" facing those in the art was to isolate NAIL cDNA, and there were a limited number of methodologies available to do so. The skilled artisan would have had reason to try these methodologies with the reasonable expectation that at least one would be successful. Thus, isolating NAIL cDNA was "the product not of innovation but of ordinary skill and common sense," leading us to conclude NAIL cDNA is not patentable as it would have been obvious to isolate it.

The Board dispensed with Appellants' lack of motivation argument by noting that motivation to combine references may be found in implicit factors such as the knowledge of one of ordinary skill in the art and the nature of the problem to be solved as a whole (citing *KSR* along with the Federal Circuit's *Alza Corp.* and *In re Kahn* decisions discussed in our May 7 Special Report). The Board further held that Mathew did not teach away from the claimed invention by merely indicating that conflicting data existed regarding a homolog in humans.

### C. *Takeda Chemical Industries*

*Takeda* involved claims to compounds, and pharmaceutical compositions containing the compounds, for use in treating diabetes. Appellant Alphapharm contended that the claimed compounds and compositions would have been obvious from the prior art's disclosure of a structurally similar compound b, modified so as to achieve the claimed invention. The district court concluded that the claimed subject matter would not have been obvious from the prior art, and the Federal Circuit affirmed.

As the Board did in *Kubin*, the Federal Circuit in *Takeda* cited and discussed its prior *In re Deuel* decision, but with a different outcome. The Court noted that it had clarified in *Deuel* that, where *prima facie* obviousness is based upon structural similarity between a prior art compound and a claimed compound, "a showing that the 'prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention' was also required." The Court further opined that the *Deuel* test for *prima facie* obviousness for chemical

compounds is consistent with the legal principles enunciated in *KSR*, given the Supreme Court's acknowledgement of the importance in an obviousness determination of identifying a reason that would have prompted a person of ordinary skill to combine elements in the claimed manner. The Court then stated that "[t]hus, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound."

The Court concluded that Alphapharm had not shown that proffered lead compound b would have been selected as a lead compound, particularly given that the prior art disclosed "a broad selection of compounds any one of which could have been selected as a lead compound for further investigation" and taught away from compound b (noting its adverse side effects of increased body weight and brown fat that would contribute to insulin resistance and Type 2 diabetes). The Court also concluded that Alphapharm had not shown any reason to modify compound b to arrive at the claimed invention, particularly in view of the evidence of unexpected results of nontoxicity. The Court further concluded that the "obvious to try" test relied upon in *Pfizer* and endorsed by *KSR* was not applicable in this case (and thus did not mandate reversal), where there was not a finite number of identified, predictable solutions for antidiabetic treatment.

### D. *PharmaStem Therapeutics*

*PharmaStem* involved claims to a cryopreserved therapeutic composition comprising viable human neonatal or fetal hematopoietic stem cells derived from umbilical cord blood or placental blood, and a method for hematopoietic or immune reconstitution of a human using such a cryopreserved therapeutic composition. The district court determined that the claimed inventions would not have been obvious, but the Federal Circuit reversed (Judge Newman dissenting).

Once again using an "obvious to try" obviousness analysis based on a combination of several prior art references along with statements in PharmaStem's patent specification, the Federal Circuit majority concluded that a person of ordinary skill in the art would have had reason to attempt to make the composition, and carry out the claimed process, and would have had a reasonable expectation of success in doing so. Both the jury and district court below, based upon the testimony of the patentee's expert,



August 17, 2007

Dr. Bernstein, concluded that persons of ordinary skill in the art would not have known that umbilical cord blood contained stem cells. However, the Federal Circuit majority found Dr. Bernstein's testimony to be inconsistent with an admission in the patent specification, and disclosures in the prior art, that umbilical cord blood contained stem cells. Hence, the Federal Circuit majority concluded that "the inventors merely used routine research methods to prove what was already believed to be the case" and that "[s]cientific confirmation of what was already believed to be true ... does not give rise to a patentable invention."

The Federal Circuit so concluded despite the fact that one of the asserted patents had survived reexamination in the face of some of the same references that were cited at trial and despite substantial secondary considerations evidence of praise from and surprise by the industry. With respect to the secondary considerations evidence, the Federal Circuit majority found that such evidence had

not been shown to have been "based on any inventive contribution" or based on "the results reported in the patents."

Judge Newman dissented, as she had in *Pfizer* with respect to Pfizer's petition for rehearing *en banc*. Judge Newman accused the majority of relying upon impermissible hindsight analysis. More particularly, in Judge Newman's view: (1) the majority had improperly dismissed Dr. Bernstein's testimony explaining away the statements in the asserted patent specifications and the prior art relied upon by the Federal Circuit majority (as nomenclature mistakes), (2) the majority did not give due weight to the substantial evidence of secondary considerations, (3) by statute, an invention is not negated by the manner in which it came about, (4) the majority should have deferred to the PTO, and (5) there was substantial evidence to support the jury's verdict and the district court's upholding of it.

August 17, 2007

## APPENDIX B: THE PTO'S DRAFT EXAMINATION GUIDELINES FOR DETERMINING OBVIOUSNESS IN VIEW OF *KSR*

### I. Guiding Principles

The PTO's draft examination guidelines express a number of guiding principles based upon *KSR*, as follows:

1. In *KSR*, the Supreme Court reaffirmed *Graham v. John Deere Co.*, 383 U.S. 1 (1966), as providing the controlling framework for obviousness determinations. Under that framework, Examiners must (1) determine the scope and content of the prior art, (2) ascertain the differences between the claimed invention and the prior art, (3) resolve the level of ordinary skill in the pertinent art, and (4) evaluate any objective evidence of nonobviousness ("secondary considerations" evidence), such as commercial success, long-felt but unsolved needs, failure of others, and unexpected results. Examiners act as fact finders when resolving the *Graham* inquiries.

2. The Federal Circuit's teaching-suggestion-motivation test ("TSM test") is one of a number of valid rationales — not the only rationale — that may be used in obviousness determinations. However, a preferred search will nonetheless be directed to finding references that provide such a teaching or suggestion, if they exist.

3. Depending upon the factual circumstances, it may or may not be necessary to expressly explain level of skill in the art in an obviousness rejection. However, any obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill.

4. Examiners must clearly articulate findings of fact as to the scope and content of the prior art, and the differences between the claimed invention and the prior art, as necessary to support an obviousness rejection.

5. Examiners must also clearly articulate a rationale, based upon the facts, to support an obviousness rejection.

6. When determining obviousness, Examiners should focus on what a person of ordinary skill would have known at the time of the invention, and what such a person would have reasonably expected to have been able to do in view of that knowledge. The operative question is thus whether a claimed invention is more than the predictable use of prior art elements according to their established functions.

7. Thus, in general, Examiners must (1) resolve the *Graham* inquiries, (2) clearly articulate the appropriate findings of fact within the *Graham* framework, and (3) clearly articulate a rationale leading to a conclusion of obviousness.

8. Examiners may rely not only on published prior art, but also on general knowledge in the art and common sense. In addition, Examiners — who are persons of scientific competence in the fields in which they work — may rely upon their own technical expertise to describe the knowledge and skills of a person of ordinary skill in the art and to determine the meaning of prior art references to persons of ordinary skill in the art.

### II. Exemplary Obviousness Rationales

The PTO's draft examination guidelines set forth exemplary rationales for supporting obviousness determinations, while indicating that they are not intended to be exclusive or exhaustive. For each rationale, the draft guidelines provide specific examples and cite applicable case law. The PTO's exemplary rationales are as follows:

1. Rationale A ("Combining prior art elements according to known methods to yield predictable results"):

"The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention. '[I]t 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.'" (Draft guidelines in part quoting *KSR*).

Under this rationale, Examiners must articulate findings that (1) the prior art included each element claimed, although not necessarily in a single reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference, (2) one of ordinary skill in the art could have combined the elements as claimed by known methods and, in combination, each element

August 17, 2007

merely would have performed the same function as it did separately, and (3) one of ordinary skill in the art would have recognized that the results of the combination were predictable.

2. Rationale B ("Simple substitution of one known element for another to obtain predictable results"):

"The rationale ... is that the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention."

Under this rationale, Examiners must articulate findings that (1) the prior art contained a device (method, product, etc.) which differed from the claimed device by the substitution of some components (step, element, etc.) with other components, (2) the substituted components and their functions were known in the art, and (3) one of ordinary skill in the art could have substituted one known element for another, and the results of the substitution would have been predictable.

3. Rationale C ("Use of known technique to improve similar devices (methods, or products) in the same way"):

"The rationale ... is that a method of enhancing a particular class of devices (methods, or products) was made part of the ordinary capabilities of one skilled in the art based upon the teaching of such improvement in other situations. One of ordinary skill in the art would have been capable of applying this known method of enhancement to a 'base' device (method, or product) in the prior art and the results would have been predictable to one of ordinary skill in the art."

Under this rationale, Examiners must articulate findings that (1) the prior art contained a "base" device (method, or product) upon which the claimed invention can be seen as an improvement, (2) the prior art contained a comparable device (method, or product) that was improved in the same way as the claimed invention, and (3) one of ordinary skill in the art could have applied the known "improvement" technique in the same way to the "base" device (method, or product) and the results would have been predictable to one of ordinary skill in the art.

4. Rationale D ("Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results"):

"The rationale ... is that a particular known technique was recognized as part of the ordinary capabilities of one

skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to a known device (method, or product) that was ready for improvement and the results would have been predictable to one of ordinary skill in the art."

Under this rationale, Examiners must articulate findings that (1) the prior art contained a "base" device (method, or product) upon which the claimed invention can be seen as an "improvement," (2) the prior art contained a known technique that is applicable to the base device (method, or product), and (3) one of ordinary skill in the art would have recognized that applying the known technique would have yielded predictable results and resulted in an improved system.

5. Rationale E ("Obvious to try" — choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success"):

"The rationale ... is that 'a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.'" (Draft guidelines quoting *KSR*).

Under this rationale, Examiners must articulate findings that (1) there had been a recognized problem or need in the art, including a design need or market pressure to solve a problem, (2) there had been a finite number of identified, predictable potential solutions to the recognized need or problem, and (3) one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success.

6. Rationale F ("Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art"):

"The rationale ... is that design incentives or other market forces could have prompted one of ordinary skill in the art to vary the prior art in a predictable manner to result in the claimed invention."

Under this rationale, Examiners must articulate findings that (1) the scope and content of the prior art, whether in the same or a different field of endeavor as that of the applicant's invention, included a similar or analogous device (method, or product), (2) there were design

August 17, 2007

incentives or market forces which would have prompted adaptation of the known device (method, or product), (3) the differences between the claimed invention and the prior art were encompassed in known variations or in a principle known in the prior art, and (4) one of ordinary skill in the art, in view of the design incentives or market forces, could have implemented the claimed variation of the prior art, and the claimed variation would have been predictable to one of ordinary skill in the art.

7. Rationale G ("Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention"):

"The rationale ... is that 'a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.'" (Draft guidelines quoting *Dystar*<sup>1</sup>).

Under this rationale, Examiners must articulate findings that (1) there was some teaching, suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, and (2) there was reasonable expectation of success.

8. In the case of each of the above rationales, if any of the indicated required findings cannot be made, then the rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. Moreover, for each of the above rationales, Examiners must also articulate whatever additional findings based on the *Graham* factors may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

### III. Cautions And Treatment Of Replies

The PTO's draft examination guidelines also include some cautions to Examiners, and some guidance regarding applicant replies and rebuttal evidence, that provide useful "food for thought" for patent applicants. These include:

1. Rationale A caution: Combining known prior art elements is not sufficient to render the claimed invention obvious if the results would not have been predictable to one of ordinary skill in the art.

2. Rationale C caution: If the actual application of the technique (for improving a particular class of devices) would have been beyond the skill of one of ordinary skill in the art, then using the technique would not have been obvious.

3. Applicant's reply: If an applicant traverses an obviousness rejection under §103, a reasoned statement must be included explaining why the applicant believes the Examiner has erred substantively as to the factual findings or the conclusion of obviousness. 37 CFR §1.111(b). A mere statement or argument by a patent applicant that the Examiner has not established a *prima facie* case of obviousness, or that the Examiner's reliance on common knowledge is unsupported by documentary evidence, will not be considered substantively adequate to rebut or effectively traverse a rejection under 37 CFR §1.111(b).

4. Rebuttal evidence: In response to an obviousness rejection, applicants may submit evidence or argument to demonstrate that: (1) one of ordinary skill in the art could not have combined the claimed elements by known methods (*e.g.*, due to technological difficulties), (2) the elements in combination do not merely perform the function that each element performs separately, or (3) the results of the claimed combination were unexpected. Rebuttal evidence, which may be submitted by affidavit under 37 CFR §1.132, may include evidence of secondary considerations such as commercial success, long felt but unsolved needs, failure of others, and unexpected results.

5. Reconsideration: Examiners should consider all rebuttal evidence that is timely presented by the applicant and reconsider any initial obviousness determination in view of the entire record. This should include review of all rejections of record, proposed rejections, and their bases to confirm their continued viability. If an Examiner maintains a rejection after reconsidering all of the evidence, he or she must clearly explain the reason for doing so, *i.e.*, clearly communicate the Examiner's findings and conclusions, articulating how the conclusions are supported by the findings.

<sup>1</sup> *Dystar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006).