

## Obviousness and Inventive Step -New Differences?

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### 1. Introduction

In a paper presented at the Fordham Conference two years ago, I asked the question when considering the requirement of non-obviousness or inventive step in patent law is “what is the requirement for?”<sup>1</sup> Implicit in the question was the idea that these requirements had the same purpose. Internationally, it has been agreed that the term “non-obvious” used in the United States statute and possession of an “inventive step” as required by the laws of many other countries are “synonymous” (see the footnote to Article 25 of TRIPs). Rule 65.2 of the PCT Regulations draws a similar parallel.

The last two years have, however, seen developments on both sides of the Atlantic.

In the United States, the Supreme Court has spoken on the question for the first time in three decades. In Europe, the amended version of the European Patent Convention<sup>2</sup> has come into effect providing the EPO with more arguments to support its view that inventive step requires a technical solution to a technical problem.<sup>3</sup> This has been accompanied by thinking that has gone beyond

<sup>1</sup>See [http://www.fordhamipinstitute.com/ip\\_conference/archive.html](http://www.fordhamipinstitute.com/ip_conference/archive.html) for papers from the 2007 Conference. Based on a comparison of the history of the law on these topics in the United States, the European Patent Office, England and Germany, the, Australia, Canada and Japan, I reached a tentative conclusion that although at different times, systems have drifted off into attempts at trying to judge patentability on the “merit” of the invention (which is inevitably subjective) application of the concepts have normally reverted to the less subjective test of whether the grant of a patent for that which is being claimed would have the effect of depriving the public of the right to do that which it was already poised to do.

<sup>2</sup>EPC 2000, which came into effect on December 13, 2007, unlike the original text of the Convention states that patents shall be granted in “all fields of technology”, a phrase which EPO Appeal Boards have read as being restrictive in its effect. See for example **Odour selection/Quest International** T 619/02 [2007] OJ EPC 63

<sup>3</sup>The requirement for inventive step is in European Patent Convention Article 52. It is worth noting that in the German text the words “*erfinderische Tätigkeit*” and in the French text the words “*activité inventive*” are used where the English text refers to “inventive step”. According to Pagenberg “The Concept of ‘Inventive Step’ in the European patent Convention” 5 IIC 157 (1974), the choice of words in German deliberately avoided using the more traditional German term “*Erfindungshöhe*”, partly to avoid implicit incorporation of specific national traditions into the interpretation of the EPC and partly to avoid the possibility that a literal translation of the term into other languages as “inventive height” would set the bar for inventivity at too high a level.

asking whether the solution provided was obvious into questions such as whether there was enough evidence in the application to make it at least plausible that a solution was found to the problem which was purportedly solved.<sup>4</sup> Such thinking surfaced again in *Eli Lilly v. Human Genome Sciences Inc*<sup>5</sup> where claims were found invalid as lacking an inventive step because “the specification contains no more than speculation about how the claimed material might be useful. The court noted that the specification did not “teach the person skilled in the art how to solve any technical problem and its teaching as to the range of applications is implausible.”<sup>6</sup>

## 2, The European Patent Office's Approach

The countries of Europe have in large measure agreed to share the task of examining patent applications and have set up the European Patent Office to carry out examination of patent applications which can then become effective in all member states of the European Patent Convention by taking only formal steps after examination is complete. Once granted, however, such patents are governed by national law as to their validity. In general such national laws have been “harmonized” with the standards applied by the European Patent Office, but national variations remain.

Under the European Patent Convention, to be patentable, an invention must be susceptible of industrial application, new and involve an inventive step.<sup>7</sup>

<sup>4</sup>**Factor9/Johns Hopkins** T1329/04.

<sup>5</sup> [2008] EWHC 1903(Pat)

<sup>6</sup>The approach was considered by the House of Lords in *Conor Medsystems v Angiotech Pharmaceuticals* [2008] UKHL 49 where Lord Hoffmann felt that it should be confined to cases of real speculation, which the House found not to be the case in the matter before it. Lord Walker, however, seems to have thought that the case almost failed to meet the required standard, observing:

The European Patent Office focuses on the need for an invention to solve a particular technical problem: see for instance *AGREVO*, Case-T0939/92, paras 2.4 to 2.4.2.[In the present case, the prior art showed} there was a particular technical problem ... The specification, fairly construed, did put forward [an]answer to this problem. But that teaching had to be disentangled from so much extraneous matter that it nearly got lost.

<sup>7</sup>European Patent Convention Article 52. It is worth noting that in the German text the words “*erfinderische Tätigkeit*” and in the French text the words “*activité inventive*” are used where the English text refers to “inventive step”. According to Pagenberg “The Concept of ‘Inventive Step’ in the European patent Convention” 5 IIC 157 (1974). The choice of words in German deliberately avoided using the more traditional German term “*Erfindungshöhe*”, partly to avoid implicit incorporation of specific national traditions into the interpretation of the EPC and partly to avoid the possibility that a literal translation of the term into other languages as “inventive height” would set the bar for inventivity at too high a level.

Inventive step is defined in the following terms:

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.<sup>8</sup>

In an Inventor's handbook on its web-site, the EPO has the following to say about the need for an inventive step<sup>9</sup>:

To be regarded as an invention, an idea needs to include an inventive step. An inventive step must be **non-obvious** - that is, it would not readily occur to an expert in the relevant technology.

The word 'obvious' comes from the Latin term for 'upon the road' (*ob via*), and in the sense of inventions it means something that would be the next logical step along your path from the problem to the solution.

Judging what might be obvious can be very difficult. Many inventions involve combining equipment (for example, fitting a miniature torch to a key-ring). The result of such combinations might be a new product, but its properties or functionality might be entirely predictable as soon as one knew its components. As such, it could be considered obvious.

A product in which one component has been replaced for a different one with equivalent properties could be considered to be obvious (for example, a small metal spring is replaced with a rubber cone).

In another situation there might be a new problem which can be solved with a well known piece of equipment: the 'novel' process for solving this problem might be considered obvious if there was only one solution to the problem, and it would be known to the typical technician facing the problem (the so-called 'person skilled in the art').

On the other hand, when components are combined to make a product or process with properties which are greater than the sum of its parts, or better than expected, then that could be a non-obvious invention. Or an invention could come from where there are many possible solutions to a problem, but the inventor has had to research and select the best one. Or an inventor might defy some technical prejudice and solve a problem by doing something every other expert had previously believed would not work.

<sup>8</sup>European Patent Convention Article 56. It should be noted that the words equivalent to "obvious" in the English text are "*naheliegend*" (which has a similar connotation to "obvious") in the German text, but "*manière évidente*" (which may not) in the French text.

<sup>9</sup> <http://www.epo.org/topics/innovation-and-economy/handbook/novelty/idea.html>

The European Patent Office has adopted what has come to be known as the “problem and solution” approach to the question of obviousness. This is, however, something of a misnomer since the words “problem” and “solution” have connotations not fully consistent with the decisions that are actually made and the terms “task” and “means for implementation” might be more accurate. In any case, the approach put considerable emphasis on the formulation of what it was that needed to be done ( the task to be accomplished or the problem to be solved) rather than taking, for example, the approach of the British courts prior to the advent of the European system, which had asked, "was it obvious that something useful could be obtained?"

As noted above, the understanding of the problem to be solved (which might more appropriately be referred to as the task to be accomplished) may vary as additional facts come to light. For example if it becomes clear that not all of the options covered by a claim may achieve a particular advantage referred to by the applicant, the task to be solved may have to be reformulated as one having a more modest objective, which may lead to a conclusion that there were obvious ways to achieve that objective.<sup>10</sup> Similarly, if the originally stated objective was to provide something having particular properties but it becomes clear that the prior art already taught something having such properties, it may be necessary to reformulate the problem. In suitable cases, however, this reformulation may be to define the problem as being to find an alternative to that which is shown in the prior art.<sup>11</sup>

A succinct statement of the developed “problem and solution” approach is found in **Fibre reactive compounds/Bayer**<sup>12</sup> where the Board expressed the position as follows:

In accordance with the “problem and solution approach” consistently applied by the Boards of Appeal, to assess inventive step on an objective basis, it is necessary to identify the closest state of the art as the starting point, to determine in the light thereof the technical problem which the invention addresses, to verify that the technical problem is solved by all embodiments encompassed within the claimed solution and to examine whether the claimed solution is obvious or not in view of the state of the art.

<sup>10</sup>**Transitioning between catalysts/Exxon Mobil** T357/02 [2005] EPOR 27

<sup>11</sup>**Glide shoe arrangement/Valmet** T92/92

<sup>12</sup>T0159/95

The problem must be a technical one. It has been explained in **Two identities/Comvik**<sup>13</sup>

For the purpose of the problem and solution approach, the problem must be a technical problem, it must actually be solved by the solution claimed, all features of the claim should contribute to the solution, and the problem must be one that the skilled person in the particular technical field might be asked to solve at the priority date. ... If no technical problem can be derived from the application, than an invention within the meaning of Article 52 EPC does not exist.<sup>14</sup>

The EPO's approach involves a number of inquiries:

### **What is the Closest Prior Art?**

As the case law has evolved, criteria have been adopted for determining what is the closest prior art, although in some cases the difficulty in doing this has led to the use of alternative analyses based on differing starting points.<sup>15</sup> When selecting the closest prior art for the purpose of identifying an inventive step, one should choose the piece of prior art that is most closely related to the problem to be solved,<sup>16</sup> often something that the skilled worker might use as a springboard for further development. In Case T1203/97, the board summarized the position as follows:

According to the established case law of the Boards of Appeal the closest prior art for the purpose of objectively assessing inventive step is generally that which

<sup>13</sup>T641/00 [2003] OJ EPO 352.

<sup>14</sup>This case was one where the EPO had granted a patent for a method for distributing costs in a digital mobile telephone system by using incorporating SIM cards (subscriber identifying modules) which are allocated at least two identities so that the user could opt to charge calls to separate accounts. The only novel features in the claim seem to have been that the SIM cards had multiple identities, the user could choose which identity to use and costs were allocated according to the identity used. The patent was opposed by Deutsche Telekom MobilNet GmbH. The Appeal Board agreed with the revocation of the patent on the ground that allocation of costs, stated in the application as being the primary object of the invention, is not a technical problem. The only technical problem was how to do it. Since this clearly required some form of identifier and since mobile phones used SIM cards as identifiers, it was obvious to provide for multiple identities on the SIM card. See also the decision in **Auction method/Hitachi** T 258/03 [2004] OJ EPO 575.

<sup>15</sup>**Bayer/Thermoplastic moulding** [1984] OJ EPO 357

<sup>16</sup>In T 0334/92 it was held that a twenty year old document that had been disregarded, never used and silent about the proposed activity was not a suitable document to be taken as the closest prior art.

corresponds to a similar use or purpose and relates to the same or a similar technical problem as the claimed invention.<sup>17</sup>

The Guidelines state:

The closest prior art is that combinations of features, disclosed in one single reference, which constitutes the most promising starting point for an obvious development leading to the invention. In selecting the closest prior art, the first consideration is that it should be directed to a similar purpose or effect as the invention or at least belong to the same or a closely related technical field as the claimed invention. In practice, the closest prior art is generally that which corresponds to a similar use and requires minimum of structural and functional modifications to arrive at the claimed invention ...<sup>18</sup>

This may mean that the closest piece of prior art for determining inventive step is not the same as the closest for determining novelty.

### **Who is the Person Skilled in the Art?**

The question of exactly who is the person skilled in the art has not been considered all that often. The Guidelines<sup>19</sup> make it clear that he/she should be presumed to be an ordinary practitioner aware of what was common general knowledge in the art at the relevant date and that in high technology cases there might be no one person who filled this role but rather a research or production team.

In **Polymer powders/Allied Colloids Limited**<sup>20</sup> the Board referred to the description of those skilled in the art in certain texts and went on to say,

Whilst such generally accepted definitions of the notional "person skilled in the art " do not always use identical language to define the qualities of such a person, they do have one thing in common, namely that none of them suggests that he is possessed of any inventive capability. On the contrary, it is the presence of such a capability in the inventor which sets him apart from the notional skilled person.

### **Formulating the Technical Problem to be Solved**

According to the EPO Guidelines, formulation of the technical problem solved by the invention requires an objective determination of the technical and structural features that

<sup>17</sup>However, in **Microspheres/Biomaterials Universe Inc.** T 0151/95 in dealing with a chemical case, the Board decided that it had to look at all of composition, structure and properties to decide which of two references was the closest prior art.

<sup>18</sup>Guidelines C-IV, 11.7.1[formerly C-IV, 9.8.1}

<sup>19</sup>Guidelines C-IV, paragraph 11.3 [formerly 9.6].

<sup>20</sup>T 39/93 [1993] OJ EPO 134.

distinguish the invention from the closest prior art. However, features which cannot be seen to make any contribution, either independently or in combination with other features, to the solution of a technical problem are not relevant for assessing inventive step.

It is noted that this approach may mean that

The objective technical problem ... may not be what the applicant presented as "the problem" in his application. The latter may require reformulation, since the objective technical problem is based on objectively established facts, in particular appearing in the prior art revealed in the course of the proceedings, which may be different from the prior art of which the applicant was actually aware at the time the application was filed.<sup>21</sup>

In any such reformulation one may take account not only of any effects described in the application but also any effects that are submitted subsequently as long as "the skilled person would recognize these effects as implied by or related to the technical problem initially suggested".<sup>22</sup>

Finally, the guidelines point out:

The expression "technical problem" should be interpreted broadly; it does not necessarily imply that the solution is a technical improvement over the prior art. Thus the problem could be simply to seek an alternative to a known device or process providing the same or similar effects or which is more cost-effective.

### **Making the Determination of Whether the Claimed Invention is Obvious.**

The Guidelines were reorganized and edited when EPC 2000 came into effect.<sup>23</sup>

The definition of inventive step set out in the European Patent Convention requires that the hypothetical skilled person or team makes a determination of whether the claimed invention was obvious. The EPO Examination Guidelines put it this way:

The term "obvious" means that which does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art, i.e. something which does not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art.<sup>24</sup>

<sup>21</sup>EPO Examination Guidelines C-IV, 11.7.2

<sup>22</sup>EPO Examination Guidelines C-IV, 11.7.2 [formerly 9.8.2].

<sup>23</sup>EPO Guidelines C-IV, 11. In this context it should be borne in mind that the Guidelines are treated as the authoritative statement of law by the examiners. Board of Appeal decisions, other than decisions of the Enlarged Board of Appeal are not regarded as being binding precedent for the examiners. They follow the Guidelines/

<sup>24</sup>EPO Examination Guidelines C-IV, 11.4 [formerly 9.4].

In making a determination as to whether this standard is met, the Guidelines state:

the question to be answered is whether there is any teaching in the prior art as a whole that would (not simply could, but would) have prompted the skilled person, faced with the objective technical problem, to modify or adapt the closest prior art while taking account of that teaching, thereby arriving at something falling within the terms of the claims, and thus achieving what the invention achieves<sup>25</sup>

The current Guidelines make a number of other points:

While combinations of features may be patentable, mere aggregations are not: the distinction is whether there is a functional interaction between the features that achieves a synergistic technical effect.<sup>26</sup>

Noting the origin of an invention can be useful because it is recognized that invention can lie in formulation of a new idea or of an as yet unrecognized problem, in devising a solution to a known problem or in having an insight into the cause of an observed phenomenon. However the invention is made, however, it remains necessary to define it in terms of technical features.<sup>27</sup>

The test of obviousness is not whether the teaching in the prior art could have prompted one skilled in the art to modify it to achieve the claimed invention but rather whether it would have done so.<sup>28</sup>

On the question of combining teachings, it is noted that “the mere fact that more than one disclosure must be combined with the closest prior art in order to arrive

<sup>25</sup>Guidelines C-IV, 11.7.3.

<sup>26</sup>Guidelines C-IV, 11.5.

<sup>27</sup>Guidelines C-IV, 11.6.

<sup>28</sup>Guidelines C-IV, 11.7.3. In a book published by the EPO, *Case Law of the Boards of Appeal (5<sup>th</sup> ed) it is put this way at 131-132*

It is the boards' established case law that the question is not whether the skilled person **could** have carried out the invention, but whether he **would have done** so in the hope of solving the underlying technical problem or the expectation of some improvement or advantage – the so-called "could-would" approach (**T 2/83**, OJ 1984, 265; **90/84, T 7/86** OJ 1988, 381; **2000/94, T 885/97**). So the point is not whether the skilled person could have arrived at the invention by modifying the prior art, but rather whether, in expectation of the advantages actually achieved (ie in the light of the technical problem addressed), he would have done so because of promptings in the prior art (**T 219/87, T 455/94, T 414/98**).

at a combination of features may be a sign of the presence of an inventive step. On the other hand, the Guidelines caution that there are cases where an invention is a solution to a plurality of “partial problems”, in which case it is necessary to assess each partial problem separately. If anyone of the solutions is inventive, this suffices. Combination of prior art is normally permissible in such cases unless there are reasons why one skilled in the art would have been unlikely to combine them (for example because they contain incompatible teachings) or they relate to remote technical fields. In any case, common general knowledge may be used as a basis for making a combination.<sup>29</sup>

The Guidelines give a number of what are referred to as “indicators” for determining the existence of an inventive step:

Indicators of lack of inventive step include:

Avoidance of a predictable disadvantage in the prior art, a non-functional modification of the prior art, a modification making an arbitrary choice.

Indicators of an inventive step include:

Surprising technical advantage, unexpected technical effects (unless these are simply a “bonus” in situations where a development was in a “one way street”, for example when there was a lack of alternatives), long felt need coupled with commercial success when the need is met, as long as that success derives from the technical features of the invention and not some extraneous factor.

The question of whether by being drafted too broadly may expose a claim to an obviousness attack that would not otherwise succeed has, however, also been recognized in the European Patent Office in, for example, **Triazoles/Agrevo**<sup>30</sup>. In this case, the examining division had held that a claim was so broad that it covered compounds for which it was not credible that they had the stated technical effect and that the specification was therefore insufficient in failing to describe how to obtain this effect. The Appeal Board found that this was not a valid ground for rejection as such but went on to hold that in a case where the question of inventivity was dependent on showing that compounds had a particular effect (in this case they were similar to prior art compounds so that the problem to be solved was selection of those compounds that had meritorious properties) then a claim that extended beyond those compounds for which it was credible that they had the technical properties in

<sup>29</sup>Guidelines C-IV, 11.8.

<sup>30</sup>Case T 939/92 [1996] OJ EPO 309.

question would cover obvious compounds and so be unpatentable because it lacked an inventive step.

Although issues of “utility” in the sense in which that term is used in the United States do not arise under the European Patent Convention, it is to be noted that in order to meet the standards for inventive step under the problem and solution approach, it is necessary that the specification make it at least plausible that the problem in question has been solved. Thus in **Factor9/Johns Hopkins**<sup>31</sup> the question was whether a claimed polynucleotide provided the solution to the problem of providing an additional member of the TGF- $\beta$  superfamily. The polynucleotide lacked regions of homology common to other members of the TGF- $\beta$  superfamily and there was no evidence in the specification (although some later evidence existed) to show that it had properties common to those of the that it possessed properties common to the TGF- $\beta$  superfamily. The board held that there was lack of an inventive step because

there is not enough evidence in the application to make it at least plausible that a solution was found to the problem which was purportedly solved.

As noted above, the applicants filed evidence later showing that the invention worked. The board rejected this saying:

The said post-published documents are indeed the first disclosures going beyond speculation. For this reason, the post-published evidence may not be considered at all. Indeed, to do otherwise would imply that the recognition of a claimed subject-matter as a solution to a particular problem could vary as time went by. Here, for example, had the issue been examined before the publication date of the earliest relevant post-published document, GDF-9 would not have been seen as a plausible solution to the problem...and inventive step would have had to be denied whereas, when examined thereafter, GDF-9 would have to be acknowledged as one such member. This approach would be in contradiction with the principle that inventive step, as all other criteria for patentability, must be ascertained as from the effective date of the patent. The definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve. Therefore, even if supplementary post-published evidence may in the proper circumstances also be taken into consideration, it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve.”

<sup>31</sup>T1329/04

## Prejudice

One good way to overcome an objection of obviousness in the EPO is to show a prejudice against the solution claimed. This concept was of course an important one in meeting obviousness objections before the Dutch and German Patent Offices prior to the adoption of the European Patent Convention. The Appeal Boards have addressed the question of prejudice in a number of cases. For example, in **Gelation/Exxon**<sup>32</sup> it was emphasized that the applicant bears the burden of proving that a prejudice existed against the step he took to make the claimed invention. On the other hand, in seeking to establish prejudice one can combine documents (including contradictory documents) in a way that would be impermissible in seeking to establish obviousness.<sup>33</sup>

### 3. England

In England, the courts have continued to apply a test of obviousness that was adopted in a case decided on the law as it existed prior to the adoption of the European Patent Convention.<sup>34</sup> Under the old law<sup>35</sup> the test was whether the invention as claimed was “obvious and did not involve any inventive step”. When British law was harmonized with the European Patent Convention, this changed to a simple requirement that the invention “involved an inventive step”<sup>36</sup>, which in turn was defined as “was not obvious to a person skilled in the art having regard to [the relevant prior art]”.<sup>37</sup>

<sup>32</sup>T 119/82, [1984] OJ EPO 217

<sup>33</sup>**Methylene bis(phenyl isocyanate)/Mobay** T 02/81 [1982] OJ EPO 394.

<sup>34</sup>It should, however, be noted that in **Actavis UK Ltd v Merck & Co Inc** [2008] EWCA Civ 444; [2008] WLR (D) 168 the Court of Appeal held that it was not bound by its own precedents in cases where these were in conflict with established law of the Boards of Appeal of the EPO. The Court of Appeal continues to be bound by decisions of the House of Lords.

<sup>35</sup>Patents Act 1949 S.32(1)(f).

<sup>36</sup>Patents Act 1977 S.1(1)(b)

<sup>37</sup>Patents Act 1977 S3.

The test used in the English courts for most of the last two decades was set out in **Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.**<sup>38</sup> is as follows:

There are, we think, four steps which require to be taken ...

The first is to identify the inventive concept embodied in the patent in suit.

Thereafter, the court has to assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and to impute to him what was, at that date, common general knowledge in the art in question.

The third step is to identify what, if any, differences exist between the matter cited as being “known or used” and the alleged invention.

Finally, the court has to ask itself whether, viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they require any degree of invention.

However, in 2007 in **Pozzoli SPA v. BDMO SA**<sup>39</sup> Jacob LJ noted that one could not logically identify the inventive concept without first adopting the mantle of skilled person and identifying the common general knowledge of such a person. As reformulated, and set out in the U.K. Manual of Patent Practice, the test is now:

- 1(a) Identify the notional “person skilled in the art”;
- 1(b) Identify the relevant common general knowledge of that person;
  - 2 Identify the inventive concept of the claim in question or if that cannot be done, construe it;
- 3 Identify what, if any, differences exist between the matter cited as forming part of the “state of the art” and the inventive concept of the claim or the claim as construed;
  - 4 Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been

<sup>38</sup>[1985] RPC 59. This was a decision on a patent granted under the old (1949) law and to which the old law tests of validity applied. Attempts to provide a “proper” test for determining obviousness in England go back to the “Cripps question” first set out in **Sharpe & Dohme v. Boots** (1928) 45 RPC 153 which originally read

Was it for all practical purposes obvious to [the skilled worker in the field concerned], in the state of knowledge existing at the date of the patent, which includes the literature then available to him and his general knowledge, that he could [make the invention claimed].

Subsequent formulations, substituted “should” for “could” (**Technograph Printed Circuits Ltd. v. Mills and Rockley (Electronics) Ltd.** ([1969] RPC 395 [CA]) and tried to define “obvious” by asking whether a notional research group would “be directly led as a matter of course. to try [the invention claimed] in the expectation that it might well produce [something useful for any purpose]” (**Olin Mathieson Corporation v. Biorex Ltd.** [1970] RPC 157 [ChD]).

<sup>39</sup>[2007] EWCA Civ 588

obvious to the person skilled in the art or do they require any degree of invention?

It will be noted that these tests require two different assessments of what has occurred prior to the filing of the patent application: a determination of what is common general knowledge forming part of the background against which obviousness is to be judged and the prior art that is to be considered in making the definitive determination of obviousness.

It should, however, be noted that Lord Hoffmann has twice<sup>40</sup> recently approved the following comment by Kitchen J in **Generics (UK) Ltd v H Lundbeck A/S**<sup>41</sup>

The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success.

The **Windsurfing** test places a high premium on assessing the common general knowledge in the art in question.

Common general knowledge has been distinguished from specific art being relied upon as prior art in a determination of obviousness as being "what would in fact be known to an appropriately skilled addressee".<sup>42</sup>

As explained by Kitchin J said in **Generics (UK) v Daiichi Pharmaceutical**<sup>43</sup>  
</ew/cases/EWHC/Patents/2008/2413.html>

I can readily accept that, faced with a disclosure which forms part of the state of the art, it may be obvious for the skilled person to seek to acquire further information before he embarks on the problem to which the patent provides a solution. But that does not make all such information part of the common general knowledge. The distinction is a fine one but it may be important. If information is part of the common general knowledge then it forms part of the stock of

<sup>40</sup>**In H. Lundbeck A/S v Generics (UK) Ltd** [2008] EWCA Civ 311, [2008] RPC 19 and **Conor Medsystems Inc v Angiotech Pharmaceuticals Inc** [2008] UKHL 49, [2008] RPC 28

<sup>41</sup>[2007] RPC 32, para 72:

<sup>42</sup>**General Tire & Rubber Company v. Firestone Tyre and Rubber Co. Ltd** [1972] RPC 457

<sup>43</sup>[2008] EWHC 2413 (Pat).

knowledge which will inform and guide the skilled person's approach to the problem from the outset. It may, for example, affect the steps it will be obvious for him to take, including the nature and extent of any literature search.

As noted by As Floyd J said in **Ratiopharm v Napp** [2008] EWHC 3070 at [159]:

the common general knowledge does not include knowledge which does not inform the skilled person's approach from the outset.

He went on to say

That is not to say that it is illegitimate, in assessing an obviousness attack, to take account of material which would inevitably be found and treated as reliable in consequence of a step or steps which it is obvious to take. If the material so found is such as would be accepted, then it may assist in showing obviousness of a further step. But what it cannot be used for is in support of an argument that the series of steps being undertaken were obvious from the start."

Hence, to quote Pumfrey J in **Angiotech Pharmaceuticals Inc's Patent**<sup>44</sup>

In most cases of obviousness, the primary evidence of obviousness comes from the expert witnesses. The question of whether the difference between the inventive concept of the patent in suit and the state of the art represents an obvious step is one upon which their evidence is crucial.

In **Angiotech Pharmaceuticals Inc v Connor Medsystems Inc**<sup>45</sup> Jacob LJ described it as follows:

Common general knowledge is not formulaic – it is a term used in patent law to describe what the notional skilled person would know and take for granted. If the evidence shows that he knows people are looking at drug eluting stents as a way forward, then even if that has not been proved to work, it is nonetheless part of his mental equipment, not on the basis that he knows it will work but on the basis that it may.

The case related to taxol-coated stents for use in angioplasty. It went on to the House of Lords where the key issue had little to do with what did or not constitute common general knowledge. Taxol was known to be toxic and when administered systemically had caused cardiac disturbances. In Pumfrey J's, view at first instance:

in this case obviousness will be established if on balance the evidence shows that the skilled man would consider taxol to be worth testing to see what its properties were. If

<sup>44</sup>[2006] RPC 28

<sup>45</sup>[2007] RPC 20

the skilled man would reject taxol a priori even from a test then the position is otherwise.

On the basis of the testimony, he found the claimed invention obvious.

The House of Lords did not agree. in **Conor Medsystems v Angiotech Pharmaceuticals**<sup>46</sup> Lord Hoffmann, with whom the rest of the panel agreed, noted that the key to the defendant's argument that the claimed invention was obvious lay in their skeleton argument which had set out the case as follows:

The inventive step purportedly resides in the idea of seeking to treat or prevent restenosis by coating a stent with a taxol/polymer composition. The disclosure is of no more than this. The idea is not shown to work (either in humans or in animals), nor to work to any particular extent, nor to work with any particular polymer nor with any particular amount of drug. The invention thus lies in the idea of trying some, one or more, taxol/polymer combinations to determine whether restenosis can thereby be treated. It is at this level of generality that inventiveness must be assessed.

47

The argument was therefore similar to, but not identical with a conventional "obvious to try" argument.

After commenting that the argument was "an illegitimate amalgam of the requirements of inventiveness (article 56 of the EPC) and either sufficiency (article 83) or support (article 84) or both", Lord Hoffmann disposed of it as follows:

[T]he patentee sufficiently clearly indicates in the patent that it is advantageous to use taxol (inter alia but also specifically for restenosis) and states as reason for this that taxol...scores well in the CAM assay to demonstrate its anti-angiogenic effect, bearing in mind that the patentee saw the solution for restenosis in the use of an anti-angiogenic factor.<sup>48</sup>

Lord Hoffmann went on:

<sup>46</sup>[2008] UKHL 49

<sup>47</sup>The argument is therefore similar to the old one that if the claim simply covers all ways of achieving an obvious desideratum, then the claim itself must be invalid as being obvious.

<sup>48</sup>Lord Hoffman did, however, note the EPO's decision in Johns Hopkins/Factor 9 noted above that "[t]he definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve." However, in the case before him the invention claimed was indeed plausible.

The question was whether that was obvious and not whether it was obvious that taxol (among many other products) might have this effect. It is hard to see how the notion that something is worth trying or might have some effect can be described as an invention.

This being the case, he concluded that neither the trial judge nor the Court of Appeal answered what he consider to have been the correct question, namely,

whether it was obvious to use a taxol-coated stent to prevent restenosis, not whether it was obvious to test it

He concluded that it was not obvious to use taxol in this way and so this line of attack on validity failed.

Lord Hoffmann then had to deal with a more conventional "obvious to try" argument. The law on this in England goes back 40 years to the John's Manville case. In that case it had been held that something was obvious to try and therefore unpatentable if the person versed in the art would assess the likelihood of success as sufficient to warrant actual trial. On this Lord Hoffmann noted that the degree of expectation of success had to be based on the facts of the case and quoted

The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success.<sup>49</sup>

Without any detailed reasoning Lord Hoffmann then held the invention claimed not to be obvious.

Lord Walker, while agreeing with everything Lord Hoffmann had said expanded on the question of "obvious to try".. He noted:

Johns-Manville was decided over forty years ago, and was concerned with a fairly low-tech process. During the last forty years the volume of high-tech research has increased enormously, especially in the fields of pharmaceuticals and biotechnology. The resources committed to research are enormous, because the potential rewards in world-wide markets are so great. Competition is fierce. In this climate "obvious to try" has tended to take on a life of its own as an important weapon in the armoury of those challenging the validity of a patent.

<sup>49</sup>Kitchen J in **H. Lundbeck v Generics (UK) Limited** [2007] EWHC 1040.

Unfortunately, however, after pointing out a number of problems with the obvious to try approach and noting, apparently with approval, that the EPC's approach was to look to see whether the prior art pointed to a solution to the particular technical problem solved by the invention, rather than enunciating a new test or clearly rejecting the old one, he simply concluded that in the present case, the prior art had set out that there was a problem still to be solved at the time of the patent application and the present invention solved that technical problem.

As noted above, the English approach places a heavy premium on the general knowledge of one skilled in the art. However, this is not to say that documents cannot be combined to formulate an obviousness attack on a patent. However, as noted in **Ivax Pharmaceuticals UK Ltd. v. Akzo Nobel BV (No 2)**,<sup>50</sup>

In dealing with obviousness, unlike novelty, it is permissible to make a 'mosaic' out of the relevant documents, but it must be a mosaic which can be put together by an unimaginative man with no inventive capacity.

One should not conclude that it is never possible to read two documents together in the light of the common general knowledge to conclude that an invention was obvious. It is just that it is rare. In **Glaxo Group's Patent**<sup>51</sup>, Pumfrey J.'s view were:

[The statutory] provisions do not permit what is sometimes called mosaicing of individual documents or prior uses said to form part of the state of the art unless it can be shown that a skilled person, confronted with a particular citation, would turn to some other citation to supplement the information provided by the first. Such cases are not common ...

In **Sabaf v. MFI**,<sup>52</sup> Lord Hoffmann asserted that the old English law on collocations was fully compliant with the European patent Convention After noting that "you have to decide with one invention or two or more inventions. and that "two inventions do not become one invention because they are included in the same hardware", he referred to the EPC Guidelines in the following terms

"What the Guidelines do is to state the principle upon which you decide whether you are dealing with a single invention or not. If the two integers interact upon each other, if there is synergy between them, they constitute a single invention having a combined effect and one applies the (test of whether the claimed invention is obvious to a person skilled in the art) to the idea of combining them. If each integer "performs its own proper function independently of any others then each is for the purposes of (the test), a

<sup>50</sup>[2006] EWCH 1089 (Ch)

<sup>51</sup>[2004] RPC 43

<sup>52</sup>[2005] RPC 209 (House of Lords).

separate invention and (the test) has to be applied to each one separately." It was concluded that what was claimed was in fact two separate obvious features without any interaction and so the invention as claimed was obvious.

Furthermore, if something is obvious as a result of its being obvious to try, the fact that surprising or useful results are obtained from the trial does not make the invention any less obvious.<sup>53</sup>

Secondary evidence may, however, be of use in determining whether or not there is an inventive step. However, as noted in **Molnlycke v. Procter & Gamble Ltd.** (No. 5),<sup>54</sup> such evidence should not "obscure the fact that it is no more than an aid in assessing the primary evidence".

Factors that have been held to be relevant are the existence of a long-felt need and commercial success, as long as this was attributable to the invention and not to external factors.<sup>55</sup> Overcoming technical, and perhaps commercial prejudice may also be relevant.<sup>56</sup> Unexpected advantages, if explained in the specification, may also support a finding of non-obviousness if one is selecting from a variety of alternatives.<sup>57</sup> However,

if in fact the step taken was an obvious step, it remains an obvious step however astonishing the result of taking it may be.<sup>58</sup>

In **H. Lundbeck A/S v. Generics (UK) Ltd.**,<sup>59</sup> the issue on inventive step was whether the patent owner was entitled to a claim to the (+) enantiomer of citalopram when in the light of what was known about similar compounds, there was no particular reason to separate this isomer from a known racemate. Jacob L.J. noted on the question of inventive step:

In essence [the patent challenger]'s argument was that the skilled man could have come by the invention by doing a short and simple experiment. But one could say that, with hindsight, of many an invention. It is not enough that an experiment revealing an invention would have been short and simple. There has to be a reason why the skilled

<sup>53</sup>**Hallen v. Brabantia** [1991] RPC 195 (Court of Appeal)

<sup>54</sup>[1994] RPC 49

<sup>55</sup>**Haberman v. Jackal** [1999] FSR 685. (Patent Court)

<sup>56</sup>**Dyson Appliances Ltd. V. Hoover Ltd.** [2001] RPC 26 (Patent Court), upheld [2002] RPC 22 (Court of Appeal).

<sup>57</sup>**I. G. Farbenindustrie AG's Patent** 47 RPC 289

<sup>58</sup>Whitford J. In **Union Carbide Corporation (Hostettler's) Application** [1972] RPC 601.

<sup>59</sup>[2008] EWCA Civ 311 (Court of Appeal 2008),

man would have carried it out. Normally that would require at least an expectation that something might come out of it. Otherwise, short and simple though it would have been, doing the experiment would have been pointless.<sup>60</sup>

Finally, it should be noted that in **Eli Lilly v. Human Genome Sciences Inc.**<sup>61</sup> Kitchen J. Showed the effects of the EPO's **John's Hopkins** decision on English law. HGS had found Netrokine-a, a new cytokine. The field was an active one and Kitchen J noted

Not surprisingly, other teams found Neutrokin-a soon after the priority date. Perhaps anticipating this, HGS filed its application very promptly. But in doing so it failed to disclose how the protein might be used and it required a research program to make good this deficiency. HGS secured broad protection over an unexplored technical field without providing adequate compensating benefit to the public.

The Judge found there to be a lack of inventive step because

the specification contains no more than speculation about how Neutrokin-a might be useful. It does not teach the person skilled in the art how to solve any technical problem and its teaching as to the range of applications is implausible.<sup>62</sup>

In reaching this conclusion, the judge noted the House of Lords decision in **Conor Medsystems v Angiotech Pharmaceuticals**<sup>63</sup>, but concluded that Lord Hoffmann had confirmed that a patent will not be granted for an idea which is mere speculation and had summarized the line of EPO cases to the effect that product claims which have no evident utility provide no technical contribution, solve no technical problem and hence are obvious.

Whether the emphasis on technical contribution will survive the Lundbeck decision remains to be seen. As noted by Lord Walker in *Generics v. Lundbeck*:

<sup>60</sup>The case later went to the House of Lords, [2009] UKHL 12, but the issue there was confined to that of sufficiency, no appeal being taken on the lower courts' findings that the isomer claimed was novel and inventive.

<sup>61</sup>[2008] EWHC 1903(Pat), decided on

<sup>62</sup>The specification read as if the invention provided the universal panacea.

<sup>63</sup> [2008] UKHL 49, decided on July 8, 2008.

During the oral argument before your Lordships there was some discussion of whether “inventive concept” means the same as “technical contribution to the art.” Neither expression is a statutory term of art. Lord Hoffmann used both expressions several times in his opinion in *Biogen*, the former mostly in section 10 (headed “Inventive Step”) and the latter mostly in section 12 (“Support for the Claims”). Mr Thorley QC submitted in his reply that the two expressions (as used in Lord Hoffmann’s opinion) are synonymous.

I do not think that this is quite right. The expressions are certainly connected, but I do not think it is helpful (either in considering Lord Hoffmann’s opinion, or generally) to treat them as having precisely the same meaning. “Inventive concept” is concerned with the *identification* of the core (or kernel, or essence) of the invention—the idea or principle, of more or less general application (see *Kirin-Amgen* [2005] RPC 169 paras 112-113) which entitles the inventor’s achievement to be called inventive. The invention’s technical contribution to the art is concerned with the *evaluation* of its inventive concept—how far forward has it carried the state of the art? The inventive concept and the technical contribution may command equal respect but that will not always be the case.

The UK IPO Manual of Patent Examination suggests that the holding in **Eli Lilly v. Human Genome Sciences Inc.** may be confined to biotechnology.<sup>64</sup>

## The United States

In its decision in **KSR v. Teleflex**, the United States Supreme Court rejected the use of a strict “teaching, suggestion, motivation” test which it felt had been applied by the panel of the Federal Circuit that had heard the case, but noted:

[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

The Federal Circuit Court of Appeals had made three errors<sup>65</sup> in reaching its decision in the present case:

1. Failure to recognize that the problem motivating the patentee may be only one of many addressed by the patent’s subject matter. ... any need or problem known in a field of

<sup>64</sup>Section 3.51.1

<sup>65</sup>Note the PTO in MPEP 2141 lists what it sees as a fourth error of the Federal Circuit identified by the Supreme Court : “by overemphasizing “the risk of courts and patent examiners falling prey to hindsight bias” and as a result applying “[r]igid preventative rules that deny factfinders recourse to common sense”

endeavor at the time of the invention and addressed by the patent can provide reason for combining elements in the manner claimed.

2. Assuming that a person of ordinary skill attempting to solve a problem will be led ONLY to those elements of those elements of prior art designed to solve the same problem; The court noted that “[i]t is common sense . . . that familiar items may have obvious uses beyond their primary purposes and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.” (Emphasis added.)
3. Improperly dismissing the possibility that if something was obvious to try this could lead to a conclusion of obviousness under 35 USC 103. The Supreme Court noted, “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified predictable solutions, a person of ordinary skill in the art has good reason to pursue known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product [is] 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 S 103.”

Applying the teaching of KSR, the Federal Circuit in chemical cases has noted two elements to finding such a rational underpinning: first in selection of the appropriate starting material for the move to the transition to what is claimed and secondly in making the necessary changes from the selected prior art starting point to reach what is claimed. Furthermore it has been cautious about concluding that the number of options has been sufficiently finite to make any particular option obvious because it was obvious to try. The first post-KSR chemical case was **Takeda Chemical Industries v. Alphapharm Pty. Ltd.**<sup>66</sup> The claim in question covered pioglitazone, a drug widely used for treatment of Type 2 diabetes. The defendants alleged that the compound was obvious over a structurally similar prior art compound which was mentioned in a prior patent covering a very large class of compounds that were said to be useful inter alia for treating diabetes. In affirming the district court’s finding that the compound was not obvious, the Court of Appeals for the Federal Circuit reviewed its case law on the question of what constitutes prima facie obviousness for chemical compounds and found this case law ‘consistent with the legal principles enunciated in KSR. The Federal Circuit noted that the Supreme Court had “indicated that there is ‘no necessary inconsistency between the idea underlying the TSM test and the Graham analysis” and that as long as it was not applied as a rigid and mandatory formula, the TSM could be a helpful insight to an obviousness inquiry. Thus, said the Federal Circuit:

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 chemical compound.

<sup>66</sup>83 USPQ2d 1169 (Fed. Cir. 2007).

In **Eisai Co. Ltd. v. Dr Reddy's Laboratories Ltd.**<sup>67</sup> it was found that although there may have been reasons to select the particular starting compound that had been modified to produce the claimed compound, (the point was left undecided) there was no reason to modify it in the manner that had been done to produce the claimed compound. It was noted that “post-KSR a *prima facie* case of obviousness for chemical compounds still in general begins with the reasoned identification of a lead compound” that is modified in a particular way to achieve the claimed compound. In the present case, the compound that had been modified itself had particularly useful properties (lipophilicity) that would be destroyed by making the necessary modification. Hence there was no reason to make the modification required to produce the claimed compound.

Of course under its earlier case law structural similarity between a claimed compound and the prior art may in itself provide a motivation or reason to make a claimed compound and so establish a *prima facie* case of obviousness.<sup>68</sup> This is because a known compound may suggest its homolog, analog or isomer because such compounds often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties. There is, however, a need for the prior art to have suggested making the specific molecular modification necessary to achieve the claimed invention.<sup>69</sup> In the case before it, the Court of Appeals found that there was no clear and convincing evidence that one skilled in the art would have chosen the particular compound noted by the defendants as the starting point for making modifications to its structure. Indeed that compound was noted as having defects in causing gains in body weight and brown fat.

Returning to the impact of KSR, the Federal Circuit Court of Appeals noted that the Supreme Court had indicated that when there are a finite number of identified predictable solutions to a problem, this gives a person of ordinary skill a good reason to pursue the known options within his or her technical grasp and so in such cases the fact that a combination was obvious to try might show that it was obvious under 35 USC 103. The Federal Circuit held that this was not the situation before it because “rather than identify predictable solutions for antidiabetic treatment, the prior art disclosed a broad selection of compounds any one of which could have been selected as the lead compound for further investigation. Therefore

the case fails to present the type of situation contemplated by the [Supreme] Court when it stated that an invention may be deemed obvious if it was “obvious to try”.

In **Aventis Pharma Deutschland GmbH v Lupin Ltd.**<sup>70</sup> the claim was to one of 32 possible stereoisomers of a chemical compound. Prior art included a mixture of the compound with other stereoisomers. The evidence showed the claimed isomer 18 times more potent than

<sup>67</sup>87 USPQ2d 1452 (Fed. Cir. 2008).

<sup>68</sup>**In re Dillon** 919 F.2d 688 (Fed. Cir. 1990)

<sup>69</sup>**In re Deuel** 51 F.3d 1552 (Fed. Cir. 1995).

<sup>70</sup>84 USPQ2d 1197 (Fed. Cir. 2007)

the next most active isomer. The Federal Circuit treated the case as being one of purification. "a purified compound is not always prima facie obvious over the mixture, for example it may not be known that the purified compound is present in or an active ingredient of the mixture, or the state of the art may be such that discovering how to perform the purification is an invention of patentable weight in itself. However, if it is known that some desirable property of a mixture derives in whole or in part from a particular one of its components, or if the prior art would provide a person of ordinary skill with a reason to believe that this is so, the purified compound is prima facie obvious over the mixture even without an explicit teaching that the ingredient should be concentrated or purified". (The district court had relied on a lack of TSM to purify to hold that the invention was non-obvious) Attempts to rebut the *prima facie* case failed because the comparison had been carried out with the next most potent isomer, not with the prior art mixture of isomers. Efficacy was proportional to the amount of the claimed isomer in the mixture.

However, in **Forest Laboratories Inc. v. Ivax Pharmaceuticals Inc.**<sup>71</sup>, another post-KSR case - albeit one in which KSR is not mentioned, claims to a "substantially pure" (+)-isomer of citalopram were upheld on the basis that there were significant problems in producing this isomer and that it was not obvious that this particular isomer would have very good properties. Similarly in **Sanofi-Synthelabo v. Apotex Inc**<sup>72</sup> claims to a specific salt of a specific isomer of a known active compound survived an obviousness attack where separation of isomers from racemic mixtures of similar compounds had revealed no significant difference in the properties of the separated isomers, but there was a dramatic difference in such properties for the claimed product from its "opposite" isomer. Outside the chemical field, patent owners have fared less well.

In the first few months after the Supreme Court's decision, the Federal Circuit Court of Appeals issued only one decision on obviousness, **Leapfrog Enterprises v. Fisher Price**<sup>73</sup>, a case which is factually quite similar to the KSR case. This time, the appeal court upheld a district court determination that the claimed invention (an interactive learning device in which the key feature was that selection of a letter in a depiction of a sequence of letters activated a switch to cause a processor to cause a sound device to produce a sound associated with that letter, the device including a reader configured to communicate the identity of the depiction to the processor) was obvious.

After noting that the KSR decision required that a flexible test be used to assess obviousness<sup>74</sup>, the court stated

<sup>71</sup>84 USPQ2d 1099 (Fed. Cir. 2007)

<sup>72</sup>89 USPQ2d 1370 (Fed. Cir. 2008).

<sup>73</sup>82 USPQ2d 1687 (Fed. Cir. 2007)

<sup>74</sup>Noting that an obviousness determination "is not the result of a rigid formula disassociated from the considerations of the facts of a case. Indeed the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not."

..Accommodating a prior art mechanical device that accomplishes [the] goal [of allowing a child to press a switch associated with a single letter and hear the sound of the letter] to modern electronics would have been reasonably obvious to any one of ordinary skill in designing children's learning devices. Applying modern electronics to older mechanical devices has been commonplace in recent years.

But the court did not rely on this broad brush approach. It looked at two specific pieces of prior art. One was a 1973 patent relating to a puzzle having a board with a plurality of varied shaped openings each of which had a word, sound or phrase associated with it. When a puzzle piece of the correct shape was placed in the opening, a pressure-activated link caused a pre-recorded voice to 'say' a word associated with the shape. The other was Texas Instrument's "Super Speak and Read" device which contains switches that can detect when a child presses on different areas of a book page and uses a processor to produce sounds associated with whatever the child has pressed. The combination of the prior art did not include a reader that as noted above was an essential element of what was claimed. However, the appeal court agreed with the district court that

readers were well known in the art at the time of the invention. ... furthermore the reasons for adding a reader to the ... combination are the same as those for using readers in other children's toys, namely providing an added benefit and simplified use of the toy ... to increase its marketability. [The patent owner] presents no evidence that the inclusion of a reader of this type was uniquely challenging or difficult for one of ordinary skill in the art.

Hence the invention claimed was obvious.

In **PharmaStem Therapeutics Inc v. ViaCell Inc.**<sup>75</sup> the Federal Circuit by a 2-1 majority over-turned a jury verdict on nonobviousness, holding that the trial court should have granted a motion for judgment as a matter of law that the claims in question were invalid on the ground that there was a lack of substantial evidence to support the jury's verdict. The invention provided broadly defined compositions and methods for isolating human neonatal or fetal blood (typically umbilical cord blood) components containing hematopoietic stem cells, cryopreserving them and later thawing them and introducing them into a suitable human host. The inventors were the first to achieve this and had attained commercial success. Nevertheless, the Federal Circuit found the claims obvious over prior art references that showed that had shown that cord blood could be cryopreserved without loss of cells and suggested the idea of cryopreserving cord blood for later use to effect hematopoietic reconstitution. Noting that in **KSR**, the Supreme Court had emphasized that a combination of elements "must do more than yield a predictable result" for their combination to be nonobvious and that there was patentable invention in combining elements to work together "in an unexpected and fruitful way", the Federal Circuit framed the question to be answered in the present case as:

whether the prior art would have given rise to a reasonable expectation of success.

<sup>75</sup>83 USPQ2d 1289 (Fed. Cir. 2007)

The plaintiff's main argument was that it was not known that cord blood contained stem cells until their experiments showed this. Based on its own interpretation of the experts testimony at trial the Court concluded that at the time of the invention although there had been no definite proof that cord blood (the normal form of neonatal blood) contained stem cells, the evidence that was available at that time made it appropriate to infer their presence. This being the case, the court concluded that no reasonable jury could have found it unreasonable to expect that one could cryopreserve cord blood components to cryopreserve stem cells. Judge Newman dissented arguing that there was sufficient evidence for a reasonable jury to have come to the conclusion that it did, in doing this she noted skepticism in the art as to whether cord blood could be used for the claimed purpose and the fact that the claims had twice survived re-examination in the PTO. She also feared that the majority's view would confine patent protection to the serendipitous and the unexpected and was a misconception of the scientific process and the patent purpose.

In **In re Icon Health and Fitness Inc**<sup>76</sup> the Federal Circuit Court of Appeals was faced with an appeal from a finding of obviousness by the Board of Patent Appeals and Interferences in a patent that had undergone re-examination. The invention was a folding treadmill in which a gas spring was used to assist in maintaining stability when the treadmill was folded. The prior art showed a treadmill having all of the claimed features except the gas spring. Other prior art showed gas springs in folding beds to assist in opening and closing them. Noting that in KSR, the Supreme Court had noted that "familiar items may have obvious uses beyond their primary purposes" and that "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 affirmed the Board's decision. In doing so, it rejected the appellants arguments that beds were not analogous art to treadmills and an argument that the specific type of spring used in the bed was inapplicable to the problem it had solved. On the first point, the Court of Appeal held that teaching in any area describing hinges, springs, latches counterweights or similar mechanisms was relevant. There was nothing peculiar to treadmills about the folding mechanism required. On the appellants second issue, the claim defined the spring in very broad terms and so, although there might have been some force in the appellants arguments had the spring been defined more narrowly, for example as a single action spring, one skilled in the art could view the folding bed spring (a double action spring) as assisting in providing stability in the same way that it did for the bed. Therefore it was obvious to employ it on the treadmill.

In another appeal from a Board of Appeals decision on obviousness, **In re Trans Texas Holdings Corp.**<sup>77</sup> The Court of Appeals for the Federal Circuit again upheld a determination of obviousness made by the board. Noting the Supreme Courts holding that "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 held that a claim to a system adjusting mortgage interest payments based on inflation was obvious over a combination of description of

<sup>76</sup>83 USPQ2d 1746 (Fed. Cir. 2007).

<sup>77</sup>83 USPQ2d 1835 (Fed. Cir, 2007).

a banking practice used in Finland in the 1950's and “the well-known practice of offering loans secured by mortgaged real estate”.

In **In re John B. Sullivan**<sup>78</sup> The Federal Circuit Court of Appeals vacated the Appeal Board’s finding of obviousness and remanded the case for further consideration of whether the evidence submitted by the applicant to overcome a finding of *prima facie* obviousness was sufficient to achieve this. The invention related to an antivenom composition containing fragments of a known rattle snake antivenom antibody. The issue was whether there was invention in use of the fragments rather than the whole antibody, it being known that fragments of an antibody had been used in enzyme immunoassays to detect the toxin of the Australian brown snake. The Federal Circuit accepted that a *prima facie* case of obviousness had been made out

because [one reference] teaches whole antibodies for use against rattlesnake venom and [another reference] teaches using ... fragments to detect venom of a different snake. It was not unreasonable for one skilled in the art of snake venom to consider that a ... fragment of a whole antibody that neutralizes one type of venom might be used to neutralize the venom of another species.

In support of this conclusion the court quoted from KSR as follows  
if a technique has been used to improved one device and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

When considering rebuttal evidence, however, the Board had erred in declining to look at evidence of the use of the composition. In the Court’s view such evidence went to the properties of the composition which, since **In re Papaesh**<sup>79</sup> had to be regarded as being inseparable from the composition itself. Thus the evidence needed to be considered to see whether the composition possessed an unexpected property that might rebut a finding of *prima facie* obviousness.

In **Daiichi v Apotex**<sup>80</sup> the Federal Circuit decided that the definition of one skilled in the art used by the district court was not skilled enough and that once one identified a person of proper skill, the claims were clearly obvious. The invention was a method of treating ear infections by administering ofloxacin to the ear. The district court had found the skilled person to be a pediatrician or general practitioner; the Federal Circuit that it was an otologist an otolaryngologist or otorhinolaryngologist. The Federal Circuit reached this conclusion after noting that while the general practitioner or pediatrician would be the person who used the invention, he/she would not be the person "to develop the claimed compound absent some speciality training such as that possessed by the patent's inventors".

<sup>78</sup>84 USPQ2d 1034 (Fed Cir, 2007).

<sup>79</sup>315 F.2d. 381 (CCPA 1963)

<sup>80</sup>84 USPQ2d 1285 decided on July 11, 2007 and reissued as a precedential opinion on September 12, 2007

In **Muniauction Inc. v. Thomson Corp**<sup>81</sup> where it was held that a prior art system met all of the limitations of the claim except for the use of a Web browser. The court held that such browsers were known and that what was claimed was simply modification of the prior art system to incorporate browser functionality and thus represents combination of two well-known prior art elements.

In **In re Translogic Technology Inc**<sup>82</sup> Judge Rader made the following points on the Supreme Court's decision in **KSR**:

- 1) KSR featured rather simple technology – an adjustable throttle pedal for an automobile. Adjustable pedal technology accommodates an automobile throttle to drivers of different heights. This patented technology combined an adjustable pedal with an electronic sensor to measure the pedal depression. Both of these features were in the prior art.
- 2) On one level, KSR corrected a rather straightforward error of the panel decision ... where it had held a piece of prior art irrelevant as being related to a different problem. As now noted by Judge Rader, this approach overlooked the fundamental proposition that obvious variants of prior art references are themselves part of the public domain.
- 3) The Supreme Court also criticized the Federal Circuit's "rigid and mandatory" application of the motivation to combine test: "... Instead, the Supreme Court advised that "common sense" would extend the use of customary knowledge in the obviousness equation: In particular the Supreme Court had noted that "a person of ordinary skill is also a person of ordinary creativity, not an automaton."
- 4) The Supreme Court observed that the Federal Circuit had also "elaborated a broader conception of the TSM test" ... wherein the Federal Circuit noted: "Our suggestion test is in actuality quite flexible and not only permits, but requires, consideration of common knowledge and common sense." The Supreme Court suggested that this formulation would be more consistent with the Supreme Court's restatement of the TSM test.
- 5) In any event, as the Supreme Court suggests, a flexible approach to the TSM test prevents hindsight and focuses on evidence before the time of invention, without unduly constraining the breadth of knowledge available to one of ordinary skill in the art during the obviousness analysis.

The reasoning in **Translogic** was followed in **Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc.**<sup>83</sup> to uphold a finding of non-obviousness where the court found that the challenges faced by one skilled in the art coupled with powerful unexpected results justified

<sup>81</sup>87 USPQ2d 1350 (Fed. Cir. 2008)

<sup>82</sup>84 USPQ2d 1929 (Fed. Cir. 2007)

<sup>83</sup>86 USPQ2d 1196 (Fed. Cir. 2008).

a conclusion of non-obviousness. The claimed compound was an anti-epilepsy drug. The compound was made by a series of steps starting from a known compound. Similar to its reasoning in the **Takeda** case, the court noted that the prior art presented one skilled in the art with a number of possible starting points and that even if the correct starting material had been chosen, one skilled in the art had a number of options to consider. Contrary to KSR, there were therefore not just a finite number of options to pursue.

In **CSIRO v. Buffalo Technology (USA) Inc.**<sup>84</sup> the Federal Circuit vacated a pre-KSR district court summary judgment of non-obviousness and remanded for further investigation of the facts in a case where similar techniques had been used in other fields and it might be obvious to apply them to the problem in hand, namely indoor wireless networks where problems were caused by echoes. The pre-KSR argument that the problems to be solved were different no longer applied.

In **Asyst Technologies Inc. v. Emtrak Inc.**<sup>85</sup> the Federal Circuit, applied KSR's statement "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." to find it obvious to use of a multiplexer to replace a bus in a tracking system used to track parts in a fabrication system.

The USPTO has issued Guidelines as to how to handle obviousness issues since KSR. the Guidelines point out that it may be appropriate for the examiner to make specific factual determinations and also that a requirement that "any obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill", noting as set out in **KSR** that "a person of ordinary skill is also a person of ordinary creativity, not an automaton." A number of factors for determining the level are set out and it is specifically stated that "office personnel may rely on their own technical expertise to describe the knowledge and skills of the person of ordinary skill in the art. The factors include: (1) the type of problems encountered in the art; (2) prior art solutions to these problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology; and (5) the educational level of active workers in the field."<sup>86</sup>

<sup>84</sup>Case 2007-1449 decided September 19, 2008.

<sup>85</sup>Case 2007-1554 decided October 10, 2008.

<sup>86</sup>See also **Ex parte Jud** 85 USPQ2d 1280 (BdPatApp&Int 2007) - although this case was decided before **KSR**.

The MPEP notes the following possible bases for finding an invention obvious: a reference or combination of references, reasoning from common knowledge in the art, scientific principles, art-recognized equivalents, or legal precedent.<sup>87</sup>

After noting the Supreme Court's requirement for a rational underpinning to any rejection based on obviousness, the Guidelines go on to set out a number of rationales that may be used for such a purpose. These include:

- A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- C) Use of known technique to improve similar devices (methods or products) in the same way;
- (D) applying a known technique to a known device (method or product) ready for improvement to yield predictable results;
- (E) "obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (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 variations would have been predictable to one of ordinary skill in the art; and
- (G) some teaching, suggestion or motivation in the prior art 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.<sup>88</sup>

The MPEP in Section 2144.04 sets out a number of situations in which there is legal precedent as a basis for a finding of *prima facie* obviousness. Such a finding can of course be rebutted by submission of evidence overcoming the *prima facie* case in the particular circumstances encountered. Situations in which the MPEP indicates that the examiner may rely on legal precedent to support a *prima facie* case are as follows:

- I. Aesthetic design changes;
- II. Elimination of a step or an element and its function if the function of the element is not desired (although omission of an element with retention of the element's function is an indicium of unobviousness);
- III. Automating a manual activity;
- IV. Changes in size, shape, or sequence of adding ingredients;
- V. Making portable, integral, separable, adjustable, or continuous;
- VI. Reversal, duplication, or rearrangement of parts;
- VII. Purifying an old product.

<sup>87</sup>MPEP 2144.

<sup>88</sup>Now discussed in MPEP 2141 (III).

Similarly, the MPEP takes the view that case law establishes that there is prima facie obviousness when claimed ranges "overlap or lie inside ranges disclosed by the prior art".<sup>89</sup>

Of course finding of prima facie obviousness may be able to be overcome if rebutted by showing of one or more of the objective criteria of patentability, or superior or unexpected results.<sup>90</sup>

## Conclusions

While the approach of the Federal Circuit in chemical cases focusing whether it was obvious to choose a particular starting material for making a new compound and then whether the modification was obvious has some superficial similarity with the EPO approach of choosing the closest prior art and then seeing whether the changes required were obvious, in most other cases the law is moving in opposite directions.

The U.S. Supreme Court has warned that if something within the scope of the claim is obvious for any reason, irrespective of the problem the inventor sought to solve, the claim is bad. This scarcely fits with the EPO's approach that the starting point for an inventive step analysis is the closest prior art seeking to solve the same problem as the inventor or the English approach of determining the inventive concept. Nor does the European approach that something may lack inventive step if it is not a plausible solution to the problem sought to be solved find any echo in any case law on obviousness in the United States.

Indeed it almost seems that whereas the United States is moving towards a more strictly logical approach to obviousness, Europe may be moving back to a pre-codification environment when courts would hold patents invalid for lack of invention, but obviousness might not be the only reason why invention was absent.

<sup>89</sup>MPEP 2144.05

<sup>90</sup>Although if the claimed invention is really really obvious, even these may not help. **Richardson-Vicks Inc. v. Upjohn Co.** 44 USPQ2d 1181 (Fed Cir. 1997). Where reasoning somewhat similar to the EPO's approach to a "bonus" was applied.