

IN SUMMARY

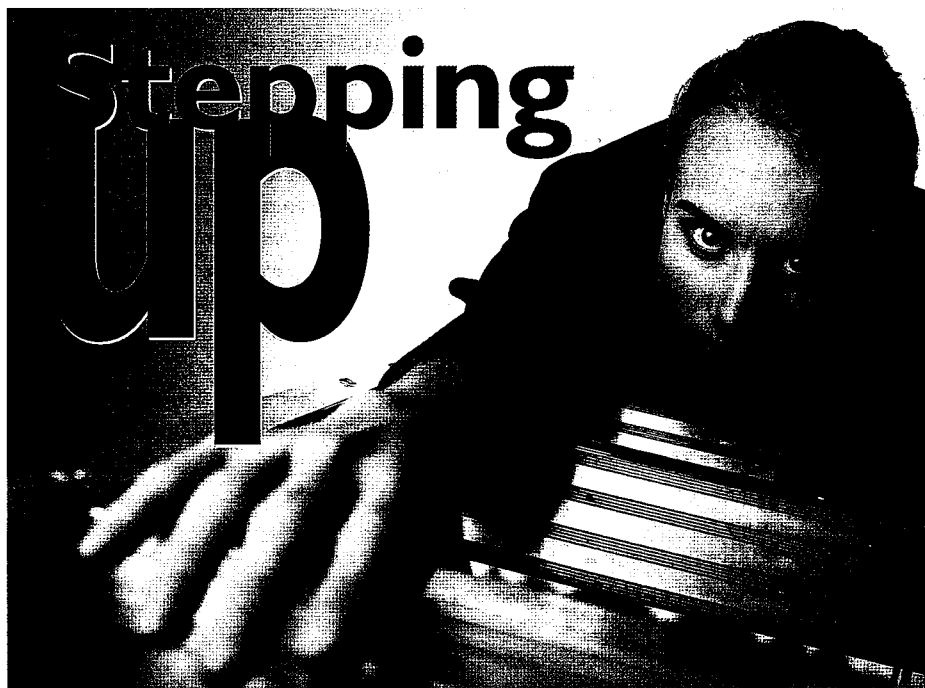
- The decision of Kitchin J in *Ivax Pharmaceuticals v Chugai* provides a useful indication of the English courts' current approach to the issue of inventive step, giving an insight into the level of "hurdle" which must be overcome in order to justify a valid patent
- This article argues that pending the outcome of the UK Patent Office's review of the inventive step requirement, the *Ivax* decision applies the test for inventive step in a fair manner, insofar as a distinction is drawn between, on the one hand, use of a substance for its conventional purpose (obvious), and on the other hand, a useful and cost-saving improvement in a process (not necessarily obvious)

AUTHORS

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Ivax v Chugai analysed

The UK Patents Court recently handed down a decision that gave an insight into its approach to the issue of "inventive step". Addleshaw Goddard's Dr Brian Whitehead, Stuart Jackson and Richard Kempner discuss

The recent decision of Kitchin J. in *Ivax Pharmaceuticals (UK) Ltd v Chugai Seiyaku Kabushiki Kaisha* provides a useful indication of the English courts' current approach to the issue of inventive step. *Ivax* sought revocation of Chugai's patent EP(UK) 0,230,932 ("the Patent"), and Chugai in turn counterclaimed for infringement, as well as also applying to amend the Patent. In holding the Patent obvious over one, but not the other, of the pieces of prior art cited by *Ivax*, the decision gives an insight into the level of the inventive step "hurdle" which must be overcome in order to justify a valid patent.

Background

The Patent relates to a process of preparation of a stable formulation containing the ingredient nicorandil, for use in the treatment of angina. Nicorandil, a method of making it and its use in treating circulatory disease were disclosed in a prior patent, US 4,200,640 ("the '640 Patent"), which includes magnesium stearate in a list of excipients with which nicorandil may be formulated.

The evidence presented to the court established that nicorandil presents two problems which must be overcome in order

to prepare stable tablets containing the substance. First, nicorandil preparations are unstable in humid conditions, and must be prepared and stored accordingly. Secondly, the compressive forces used in the preparation of tablets lead to deformation and distortion of the nicorandil crystals, which results in the nicorandil becoming unstable and prone to degradation.

In an earlier Japanese patent application, 57 146 659 ("the '659 Application"), which was cited in the Patent and relied upon by *Ivax*, the problem of instability was overcome by the application of a coating of "one or more fatty or waxy substances which are solid at ordinary temperatures" to the nicorandil crystals prior to compression into tablet form. Stearic acid and stearyl alcohol are given as examples of suitable substances to coat the nicorandil crystals, which is effected with a solution of the substance in an organic solvent. The drawback of this method is that it introduces additional steps, requiring additional equipment, into the tableting process, which increases the time and cost of tablet preparation.

The Patent teaches preparation of a stable nicorandil formulation by simply mixing nicorandil with at least 0.5% of a saturated

aliphatic acid or saturated higher alcohol, both of which are solid at ordinary temperatures, and optionally with at least 0.1% of fumaric acid, oxalic acid, salicylic acid, tartaric acid and/or glutaric acid. In other words, the need to apply a coating to the crystals is obviated, with concomitant savings in equipment, time and costs. Preferred examples of the saturated aliphatic acid and saturated higher alcohol include stearic acid and stearyl alcohol respectively.

The common general knowledge in the relevant field is set out in detail in the judgment. In particular, the judge held that magnesium stearate (i.e. the magnesium salt of stearic acid) is the preferred choice for a lubricant additive (to facilitate removal of the tablets from the metal dies and to reduce the level of wear of the dies) in formulation technology. He held further that stearic acid was also known to be used for the same purpose (indeed, it would be

in the '640 Patent (which includes magnesium stearate).

Ivax contended that this difference was obvious, on two alternative grounds. First, Ivax contended that given that stearic acid is second only to magnesium stearate as the lubricant of choice in formulation tests, it would be obvious to the skilled person to test both substances as part of a routine screen. The skilled person would therefore produce a stable formulation falling within the scope of the Patent, without the need for an inventive step. Alternatively, and as a second ground of attack, if magnesium stearate proved to be unsuitable, stearic acid would be the obvious alternative lubricant to try.

Chugai, in response to the first ground set out above, contended that the skilled person, in considering the teaching of the '640 Patent, would use magnesium stearate unless there was a positive reason not to

The judge rejected the second ground of the obviousness attack based on the '640 Patent, primarily on the basis that if magnesium stearate failed to produce a stable formulation, the skilled person would not attribute that failure to the use of magnesium stearate, nor would he appreciate that a different lubricant might assist in solving the problem.

Obviousness over '659 application

Again following the *Windsurfing* approach, the judge held that the difference between the Patent and the '659 Application is that the latter requires the nicorandil crystals to be pre-coated with the stearic acid, which requires use of stearic acid dissolved in an organic solvent, whereas the former simply requires the nicorandil to be mixed with solid stearic acid prior to tableting.

Ivax submitted that the skilled man would want to try to remove the requirement for an organic solvent, and would therefore try simply mixing the two components together as part of his normal investigations. Chugai countered with the argument that the skilled man would consider that the formation of the coat around the crystals was necessary for stabilisation, and that the coating process, involving use of solvent, was essential.

The judge rejected Ivax's argument, holding that the Patent is inventive over and above the '659 Application. In fact, given that the '659 Application specifically states that simply mixing magnesium stearate and nicorandil does not yield a stable formulation, and that the skilled man would know that stearic acid is not as good a coating agent as magnesium stearate, the judge held that the '659 Application actually teaches away from the invention claimed in the Patent.

The judge also held that if the Patent were valid, it would have been infringed. In addition he ruled that if the proposed amendments to the Patent were allowed, the obviousness attack would have failed and the amended Patent would also have been infringed. The judge however declined to allow the proposed amendments, on the grounds that they resulted in the disclosure of additional subject matter, contrary to s. 76(3)(a) of the Patents Act 1977.

Discussion

In this case, there were in effect three separate obviousness attacks (based on two pieces of prior art), only one of which succeeded. Furthermore, as each of the attacks was concerned with a different level

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the most preferred lubricant after magnesium stearate) and that the skilled person would know to use stearic acid as a lubricant if magnesium stearate proved to be unsuitable. Importantly, however, the judge held that it was not common general knowledge to use a lubricant in order to increase stability of the formulation against degradation resulting from compaction or humidity.

Ivax did not argue that the Patent lacked novelty, but contended that it was obvious over either of the two pieces of prior art, namely the '640 Patent and the '659 Application.

Obviousness over '640 Patent

Applying the familiar structured approach to obviousness as set forth in the *Windsurfing* case³, the judge identified the inventive concept of the Patent claims as the production of a stable nicorandil preparation by mixing nicorandil with a saturated aliphatic acid or saturated higher alcohol, both of which are solid at ordinary temperatures. The difference between this and the '640 Patent was held to be use of stearic acid in place of the excipients listed

do so. Neither the '640 Patent nor formulation studies would lead the skilled person to consider magnesium stearate as unsuitable, and it would therefore not be obvious to change to stearic acid. In response to the second ground, Chugai contended that if formulation studies revealed stability problems with a magnesium stearate-containing formulation, the skilled person would have no reason to attribute the instability to the use of magnesium stearate, and would not therefore think to solve the problem by switching to an alternative lubricant.

The judge held that the skilled person would be most likely to select both magnesium stearate and stearic acid (as the first and second most widely used lubricants) as possible lubricants in a formulation study, and would, on the basis of the Patent, therefore prepare a stable formulation falling within the scope of the Patent. In determining whether this rendered the Patent itself obvious, the judge said this was a “very difficult question to answer”, but ultimately held that the first ground of the obviousness attack succeeded.

of alleged inventiveness, the judgment may give an insight into the current thinking of the courts on the question of inventive step. The alleged inventive steps, at their highest level of generality, can be summarised as follows (in order of increasing level of inventive step):

1. Trying a known compound for a known purpose, in circumstances where it would be common practice to try the known compound (i.e. the first ground of the '640 Patent attack);
2. Trying the commonest compound in its class for a known purpose, and on discovering that the resulting formulation is unstable, for reasons unrelated to the known purpose of the compound, deducing that the instability is nonetheless attributable to the choice of compound and hence selecting the second most common compound in the class (i.e. the second ground of the '640 Patent attack); and
3. Eliminating what was previously thought to be an essential step in a procedure (i.e. the '659 Application attack).

It is submitted that step 1 is the most straightforward to decide. In particular, in coming to his decision that step 1 is not inventive, the judge relied in part on the principle set forth in *Hallen v Brabantia*³, namely that if a claimed invention is obvious for one purpose, an added and unexpected benefit, however great, will not found a valid patent. Applying this to the facts of the case, the judge held that whilst using stearic acid yields an unexpected benefit (i.e. stabilisation of the nicorandil crystals, which the judge had already held was not common general knowledge), it would be obvious to use stearic acid for its lubricating properties, and the Patent is therefore invalid for obviousness.

Step 3 is also fairly clear-cut. A large number of patents, both in the chemical/pharmaceutical sectors and in other areas of technology, are concerned with the elimination of costly and time-consuming steps in production processes. Whilst such improvements may sometimes be obvious, in the authors' view the courts should be slow to revoke a patent on the grounds that a clear improvement in a process is obvious, in the absence of clear and cogent evidence that the skilled man would arrive at the improved process as part of his normal investigations and considerations as to implementing the (original) process. The '659 Application

teaches that pre-coating nicorandil crystals with stearic acid (or a similar substance) is necessary to achieve a stable formulation. It cannot therefore be obvious to omit the step of coating, even though this would have the desirable consequence of avoiding a process involving the use of an organic solvent, followed by drying to remove that solvent.

Step 2 is perhaps the most difficult to decide, and is heavily dependent upon the particular facts of the case. As the judge held that it was not common general knowledge that different lubricants may affect stability, the decision in this particular case was straightforward – the selection of an

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alternative lubricant would not in the circumstances be obvious. However, it is worth asking whether the same decision would have been reached had the evidence suggested that the skilled man would have realised that the choice of lubricant could affect stability, and would therefore have tried a range of lubricants. This raises the “obvious to try” issue, discussed recently in *St Gobain v Fusion Provida*⁴ and in other cases since⁵. Prior to the *St Gobain* case, it was generally thought that to show that an alleged invention is obvious, it is sufficient under English law to show that it would have been obvious to try the idea to see whether it would work, in circumstances where the skilled man would assess the likelihood of success as being sufficient to warrant trial⁶. Applying such a test, presumably the selection of any commonly used lubricant would have been held to be obvious, as the skilled man would be likely to try the range of common lubricants, with a reasonable prospect of finding one that leads to a stable formulation.

In *St Gobain*, however, Jacob LJ held that the “obvious to try” test “really only works where it is more or less self-evident that what is being tested ought to work”. This is a more stringent test, and it is not clear whether selection of another common lubricant would fall within the scope of the test. In particular, even in circumstances where the skilled man knew that the choice of lubricant may affect stability, it is by no means clear that he would find it “more or

less self-evident” that another lubricant may yield a stable formulation – a mere reasonable prospect of success would not, according to *St Gobain*, render the invention obvious. Accordingly, it is submitted that the judge may well have come to the same decision that he did even if he had held that it was common general knowledge that different lubricants may affect stability. It is possible that the distinction may in practice have a less profound effect than might first appear. If the skilled man knew that different lubricants may affect stability, then it is likely that he would automatically have tested two or three without even waiting to

see if one was suitable. If so, then the position would be as in step 1 above, and the patent would be obvious.

Review

In the *Ivax* case, the judge was faced with three separate obviousness attacks, each concerning a different alleged level of inventive step. The UK Patent Office is in the process of reviewing the inventive step requirement in UK patent law and practice (<http://www.patent.gov.uk/about/consultations/inventive/index.htm>). One of the questions in that review asks “*In your opinion is the level of inventive step appropriate in patents granted by the UKPO, in the sense that the interests of patentees and of third parties are fairly balanced?*”. Pending the outcome of that review, it is submitted that the decision in *Ivax* applies the test for inventive step in a fair manner, insofar as a distinction is drawn between, on the one hand, use of a substance for its conventional purpose (obvious), and on the other hand, a useful and cost-saving improvement in a process (not necessarily obvious). 

Notes

- 1 [2006] EWHC 756 (Pat)
- 2 *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd* [1985] R.P.C. 59
- 3 [1991] R.P.C. 195
- 4 [2005] EWCA Civ 177
- 5 See for example *Schering Plough Ltd v Norbrook Laboratories Ltd* [2006] F.S.R. 18
- 6 *Johns-Manville Corp'n's Patent* [1967] R.P.C. 479