IPO COMMITTEE NEWSLETTER
May 2013

Produced by Members of the IPO
International Patent Law and Practice Committee

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INDIAN SUPREME COURT DECISION IN NOVARTIS (GLIVEC) CASE

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Introduction

The Indian Supreme Court has upheld oppositions to Novartis's patent application for the beta crystalline form of the mesylate salt of imatinib and held that claims to this product are unpatentable.

The beta crystalline form claimed in the application is sold as Glivec (aka Gleevec), a widely acclaimed anti-cancer drug that acts by selectively destroying cancer cells. It was accepted during the Indian proceedings that imatinib itself was not suitable for oral administration because it has very little solubility, so that "if given in solid dosage form Imatinib free base would sit in the stomach like a brick and would pass out with no therapeutic effect." The beta crystalline salt of the mesylate salt, on the other hand, has a high bioavailability.

The application was opposed before grant on the basis of lack of inventive step over the disclosure of imatinib itself and failure to comply with the requirements of Section 3(d) of the Indian Patent Act, which *inter alia* provides that patents shall not be granted for something that is "a mere discovery of a new form of a known substance which does not result in enhancement of the known efficacy of the substance." The attack succeeded in opposition proceedings. On appeal to the Intellectual Property Appeal Board, the claim was found to possess inventive step but not to comply with Section 3(d). The Supreme Court held the claims to be unpatentable on both grounds.

Extraordinary Direct Appeal From Intellectual Property Appeal Board to Supreme Court

Novartis appealed the decision of the Intellectual Property Appeal Board directly to the Supreme Court rather than taking the normal route of an appeal to the High Court. The Supreme Court accepted the case because of the importance of the issues involved, assuming a later appeal to the Supreme Court was inevitable, and the fact that had an intermediate appeal been undertaken, any patent that might be granted would have expired before any Supreme Court decision.

Is Section 3(d) an Amplification of the Requirement for Inventive Step or Does it Impose Separate Requirements?

The first part of the Supreme Court's decision dealt with the question of whether Section 3(d) was simply an attempt to define inventive step more precisely or constituted a distinct ground for rejection.

The Court discussed the circumstances under which Section 3(d) had been amended by Parliament in 2005 into its present form. The present version of Section 3(d) had been adopted as part of a revision of Indian patent law to bring it into conformity with India's obligations under TRIPs, which had also included repeal of India's prior bar on the grant of patents for "substances intended for use, or capable of being used, as food or as medicine or drug." The Court noted that this bar had been incorporated into the law for the first time in 1970, and had been credited with promoting major developments in the Indian pharmaceutical industry.

It was also noted that passage of the 2005 amendment by Parliament was dependent on opposition support. In the debate leading up to its enactment, reference had been made to communications from *inter alia* the HIV/AIDS Director of the World Health Organization, pointing out that the 2001 Doha declaration showed that "the TRIPS Agreement can and should be implemented in a manner supportive of WTO Member's right to protect public health and in particular promote access to medicines for all."

As a result of the points made during the Parliamentary debate, and to address concerns raised about possible "evergreening" of pharmaceutical patents, in order to secure passage of the bill, the government had added amended Section 3(d) to provide that a patent could not be granted for

> the mere discovery of a new form of a known substance which does not result in enhancement of the known efficacy of that substance.

The amendment also added an "explanation" of Section 3(d) to the bill, which reads as follows:

> For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

The Court then considered arguments on whether these amendments were made simply to reinforce the requirement that an inventive step was required for patentability, and concluded:

> The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions, but at the same time to check any attempt at repetitive patenting or extension of the patent term on spurious grounds.

Application of Section 3(d) to the Present Case

The application of Section 3(d) presented two issues to be decided: (1) what was meant by a "known substance", and (2) what was meant by "efficacy."

Meaning of "Known"

Novartis argued that the known compound was the free base form of imatinib which, as noted above, is not suitable for oral administration. The Supreme Court disagreed, holding that the appropriate reference point was the mesylate salt. Novartis's first patent application (referred to as "the Zimmermann patent") covering imatinib itself had contained conventional language about converting free bases into corresponding salts, and specifically mentioned salts with "inorganic acids such as hydrochloric acid, sulfuric acid or a phosphoric acid or with suitable organic carboxylic acids or sulfonic acids ...". There was no specific mention of mesylate salt, although this is the salt of a sulfonic acid. No equivalent application had been filed in India because the invention had been made at a time when there was no product patent protection available for pharmaceutical products in India.

The Indian Supreme Court noted that prior to the priority date of the application in suit, Novartis filed an Investigational New Drug Application with the U.S. Food and Drug Administration (FDA) requesting permission to conduct clinical trials of the mesylate salt of imatinib in the United States and stating that this was "covered" by the Zimmerman patent in the United States. Subsequently, Novartis requested a patent term extension in the United States for that patent based on the FDA's approval of the mesylate salt. It was also noted that several publications before the priority date of the present application had referred to tests using the mesylate salt of "CGP 57148", although from the reports it not appear that CGP 57148 was identified publicly as imatinib before the priority date of the present application.

Against this background, the Indian Supreme Court stated "we are completely unable to see how Imatinib Mesylate can be said to be a new product ... Imatinib Mesylate is all there in the Zimmerman patent." The Court rejected arguments that just because something fell within the scope of the claims of a patent, this did not mean that there had

been disclosure of that specific thing, saying:

> The dichotomy that is sought to be drawn between *coverage* or claim on the one hand and *disclosure* or *enablement* or *teaching* in a patent on the other hand, seems to strike at the very root of the rationale of the law of patent. Under the scheme of patent, a monopoly is granted to a private individual in exchange of the invention being made public so that, at the end of the patent term, the invention may belong to the people at large who may be benefited by it. To say that the *coverage* in a patent might go much beyond the *disclosure* thus seem to negate the fundamental rule underlying the grant of patents.

The Court returned to this theme later saying:

> [B]efore ... proceeding further, we would like to say that in this country the law of patent, after the introduction of product patent for all kinds of substances in the patent regime, is in its infancy. We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the *coverage* and the *disclosure* under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its *claims* by skillful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent.
> In light of the discussions made above, we firmly reject the appellant's case that Imatinib Mesylate is a new product and the outcome of an invention beyond the Zimmermann patent. We hold and find that Imatinib Mesylate is a known substance from the Zimmermann patent itself.

Efficacy

Once the Court had established to its own satisfaction that the mesylate salt was known, it was clear that the beta crystalline form was a "form" of that substance to which Section 3(d) applied. Therefore, the question was whether the beta crystalline form had enhanced efficacy over non-crystalline forms of the mesylate salt. Comparisons with the properties of the free base became irrelevant.

As to what was meant by efficacy, the Court said the following:

> Efficacy means "the ability to produce a desired or intended result". ... [T]he test of efficacy would depend upon the function, utility or the purpose of the product under consideration.
> Therefore, in the case of a medicine that claims to cure a disease, the test of efficacy can only be "therapeutic efficacy." The question then arises, what would be the parameter of therapeutic efficacy and what are the advantages and benefits that may be taken into account for determining the enhancement of therapeutic efficacy? With regard to the genesis of section 3(d), and more particularly the circumstances in which section 3(d) was amended to make it even more constrictive than before, we have no doubt that the "therapeutic efficacy" of a medicine must be judged strictly and narrowly. ... [S]trict interpretation is based not only on external factors but there are sufficient internal evidence that leads to the same view. ... [T]he explanation requires the derivative to "differ significantly in properties **with regard to efficacy."** What is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy.

Consequently, "mere change of form with properties inherent in that form would not qualify as 'enhancement of efficacy.'". This being the case,

> the physico-chemical properties of beta crystalline form of Imatinib Mesylate: namely (i) more beneficial flow properties, (ii) better thermodynamic stability, and (iii) lower hygroscopicity, may be otherwise beneficial but these properties cannot even be taken into account for the purpose of the test of section 3(d) of the Act, since these properties have nothing to do with therapeutic efficacy.

This left the Court with the question of improved bioavailability. Despite argument to the contrary, the Court accepted that in appropriate cases, improved bioavailability could be regarded as demonstrating enhanced therapeutic efficacy, but this would need to be "specifically claimed and established by research data," There was no such data in the present case.

Conclusion

The Court concluded its discussion of whether the claimed invention was barred under Section 3(d) as follows:

> We have held that the subject product, the beta crystalline form of Imatinib Mesylate, does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be a grave mistake to read this judgment to mean that section 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of [the prohibition on the grant of patents on pharmaceutical products] from the Patent Act.

As noted above, the Court also found the claims lacked inventive step. However, there is no full discussion of the reasons for this finding. The Court apparently viewed this ruling as an inevitable concomitant of its decision on Section 3(d).

Comments

It is probably not surprising, although disappointing, that the Court held that only therapeutic efficacy and not properties relating, for example, to storage stability, cannot be considered in determining whether Section 3(d) has been complied with. Of perhaps more concern is the holding that a broad teaching renders "known" everything that falls within its scope. This may have implications for "genus/species" or "selection" inventions beyond the pharmaceutical industry.

Within the pharmaceutical field, the decision further complicates the "patent early or patent late" debate created by the different approaches in Europe where decisions, such as those of the U.K. Supreme Court in *Human Genome Sciences v. Eli Lilly* [2011] UKSC 51 and the European Patent Office in *Factor9/Johns Hopkins* T1329/04, which encourage early patent filing once a plausible utility has been identified, and in East Asia where data is required, thereby delaying filing. The present decision in India seems to indicate that protection for the effective drug could only have been obtained had there been no prior disclosure of imatinib salt. That is, the applicant should not disclose anything until it has a commercially viable product. This hardly seems a way to promote science and the useful arts, but there is no such requirement in the Indian Constitution.

IS IT AN INFRINGEMENT WHEN YOU REPLACE ONE COMPONENT OF A PATENTED COMBINATION? THE UK SUPREME COURT DECISION IN *SCHÜTZ V. WERIT*

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Introduction

In the case of *Schütz (UK) Limited v. Werit (UK) Limited* [2013] UKSC 16, the United Kingdom Supreme Court was faced with the question of whether there was infringement of a patent claim directed to:

> Pallet container for the transporting and storing of liquids, having
> (i) a flat pallet,
> (ii) an exchangeable inner container made of plastic material ...and also,
> (iii) surrounding the inner container, one outer sleeve which consists of vertical and horizontal lattice bars made of metal which support the plastic inner container filled with liquid, ...
> [the lattice bars being welded together to form a cage],
> **characterised in that** ... [the lattice bars have contact weld points which] form restrictedly elastic bending points with a reduced bending resistance moment relative to [a raised part of the lattice bars] for relieving the weld joints at the intersection points upon application of static and/or dynamic pressure on the lattice sleeve.

The defendant sells containers for reconditioning used pallets originally sold by the patent owner, and it was accepted that if reconditioning in this way results in an infringing product, the defendant also infringes.

The UK Supreme Court found that there was no infringement.

Background and Lower Court Decisions

Pallets of the type claimed are known as intermediate bulk containers, and the inner container noted as (ii) above normally contains about 250 gallons of liquid. Typically, the original containers cannot be reused because of concerns about toxic residues that may remain in them.

At one point in the proceedings, it had been claimed that an implied license existed for the reconditioning, but this claim was dropped when the patent owner pointed out that it had always strenuously opposed replacement of the containers by others for fear that it could face liability if contaminated or defective containers were used in its pallets.

The case reached the Supreme Court after prior decisions by Floyd J. in the Patents Court and Jacob LJ in the Court of Appeal.

At all three levels, there was a discussion of Lord Hoffman's speech *in United Wire Services v. Screen Repair Services (Scotland) Ltd* [2001] RPC 24 (House of Lords) in which he had rejected a "repair vs. reconstruction approach" to issues of the type raised in the present case and had held that the key question was whether the alleged infringer "made" the patented product. In that case, infringement was found where there had been replacement of mesh in a screen comprising a mesh and frame, but it seems that the House had viewed the inventive concept as lying in the combination and not in one part of it. The *United Wire* decision, of course, led to the need to decide what is meant by "made" and what was needed to be made for there to be infringement. This was the point on which the judges at first instance, the Court of Appeal, and the Supreme Court, differed in the present case.

At first instance, Floyd J. had taken the view that "the correct approach is to ask whether, when the part in question is removed, what is left embodies the whole of the inventive concept of the claim." Consequently he held that there was no infringement because "the

inventive concept ... is wholly embodied in the ... cage" and removal and replacement of the container made nothing relating to that inventive concept.

The Court of Appeal in a judgment by Jacob LJ reversed, taking the view that in *United Wire*, whatever the inventive concept may have been, the House of Lords had not relied on this in its decision, stating:
Accordingly I think that *United Wire* not only endorses the "making" test but excludes any additional "whole inventive concept" test.
Based on this view, he concluded that the fact that the reconditioners using the defendant's containers stated on their own website that they were "re-manufacturing" said it all.

The Supreme Court Decision

The Supreme Court, in an opinion by its president, Lord Neuberger, with which all four of his colleagues agreed, restored the first instance judgment of non-infringement, but stated that neither of the lower courts had adopted the right approach. Floyd J.'s view quoted above conflicted with the House of Lords decision in *United Wire*. The Court of Appeal, on the other hand, had erred by failing to note that "it is a matter of degree, to be assessed in each case, whether replacing a worn or damaged part of a patented article amounts to 'making' the patented article."

The lower courts had considered a number of German decisions based on the equivalent requirements of the German law, which like the current British definition of infringement, had their origin in Article 25 of the proposed Community Patent Convention. Lord Neuberger noted that such decisions should be sympathetically considered and given considerable respect, but the English courts were not obliged to follow them. Unlike the lower courts, however, the UK Supreme Court also had before it a decision of the German Supreme Court on the same issues *(Pallet Container II* Case X ZR97/11). The German Supreme Court had approached the case based on the relevant question of whether one normally expects parts of the patented combination to be replaced during the useful life of the product and the extent to which the technical effects of the invention are reflected in the replaced parts. It also noted as relevant the opinion of the market on whether replacement of the part would be seen as a repair or re-manufacture. Since it had no evidence before it on the latter question, the German Supreme Court had remitted the case to the lower courts for a determination of this issue.

Against this background, Lord Neuberger made the following points:

- The mere fact that an activity involves replacing a constituent part of an article does not mean that the activity involves "making" a new article rather than constituting a repair of the original article.

- Whether replacing a part of a patented article constitutes "making" is a matter of fact and degree.

- Where the article includes a component which is physically easily replaceable and in practice relatively perishable, those features must constitute a factor (which may, of course, be outweighed by other factors) in favor of concluding that the replacement of that component [is not an infringement].

- The extent to which a component of an article is a subsidiary part, so that its replacement is more likely to involve repairing than "making" the article, must be a matter of degree.

- In the context of addressing the question of whether a person "makes" the patented article by replacing a worn out part, it is legitimate to consider whether that part includes the inventive concept, or has a function which is closely connected with that concept. While there is nothing in the judgments in *United Wire* to support the notion that the inventive concept is relevant to the question raised in an appeal such as this,

there is nothing inconsistent with such a notion either.

After holding that there was nothing to be gained by remitting the case to the trial judge (like the case in Germany), Lord Neuberger concluded:

> Deciding whether a particular activity involves "making" the patented article ... an exercise in judgment, or, in Lord Hoffmann's words, it is a matter of fact and degree. In some such cases, one can say that the answer is clear; in other cases, one can identify a single clinching factor. However, in this case, it appears to me that it is a classic example of identifying the various factors which apply on the particular facts, and, after weighing them all up, concluding, as a matter of judgment, whether the alleged infringer does or does not "make" the patented article. In the present case, given that (a) the bottle (i) is a freestanding, replaceable component of the patented article, (ii) has no connection with the claimed inventive concept, (iii) has a much shorter life expectancy than the other, inventive, component, (iv) cannot be described as the main component of the article, and (b) apart from replacing it, [the reconditioner] does no additional work to the article beyond routine repairs, I am of the view that, in carrying out this work, [the reconditioner] does not "make" the patented article.

However, Lord Neuberger also said that it would be useful to "cross check" this conclusion with a "repair" approach, in view of the German case, and concluded that the result would be the same.

Comments

The idea of looking to see which parts of a combination involve an "inventive concept" to make a determination of whether there is infringement could be troubling. The plaintiff argued that such a requirement would impose an additional burden on the judge. Lord Neuberger disagreed, and noted this was either always apparent or an issue in patent cases. One wonders, however, whether the use of the characterizing language in the claim may have contributed to Lord Neuberger's opinion. With patents arising from European patent applications (as was the case here), however, one may have no option but to use such language.

The approach adopted by the Supreme Court avoids the problems that can otherwise arise where one claims an entire article based on the presence of one inventive component. However, it may affect the way in which multi-component products are to be priced for initial sale if the user is, in fact, going to have to purchase fewer of them over a period of time than would be the case if the entire product had to be replaced each time a component wore out.

The cross reference to the German Supreme Court's repair approach may indicate that contrary to *United Wire*, this approach may have a new lease of life in Britain.

DAMN THE TORPEDOES - ECJ ALLOWS NEGATIVE DECLARATORY JUDGEMENTS

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In a recent case (C-133/11, *Folien Fischer AG et al. v. Ritrama SpA*), the ECJ has allowed the so-called "Torpedo" system in European intellectual property law.

1. Background

In order to understand the high relevance of this case, some background information is needed. According to the European Patent Convention (EPC), infringement of a patent is handled by national laws. Since patent law belongs to civil law, for EU member states the so-called EuGVVO (= Directive No. 44/2001) comes into play. This directive is intended to avoid double-judgement within the EU and *inter alia* states that if two identical parties start court actions in two member states about the same subject, the court addressed first has to decide whether it is competent.[1] If it declares itself competent, then the second court has to refuse the case for formal reasons.

This was often used when an Italian (and sometimes Belgian) part of a European patent was involved. The (alleged) infringer hurried to file for a negative declaratory judgment before the Italian Courts, thus preventing and saving itself from being sued, e.g., in Germany or the Netherlands. Since Italian Courts were notorious for their lengthy proceedings, this sometimes was a safeguard against an injunction. Sometimes, after 10 or 12 years, the Italian Court (usually) came to the conclusion that there was a patent infringement, and therefore, the plaintiff's request would be refused. However, by that time, the patent term had also expired and the only remedy that was left for the patent owner was to sue for damages. This procedure has been called "The Italian Torpedo" or - in cases where Belgian courts were involved - "The Belgian Truffle." However, so far, there has been no ruling by the ECJ (the highest competent court since the EuGVVO is EU law) if such a procedural behavior is allowed after all.

Due to court reforms and other initiatives in Italy and Belgium, the "torpedoes" are not as prevalent, and are somewhat a thing of the past. Nevertheless it would be highly interesting if "Torpedoes" are still possible or not.

2. The Case on Trial

In the case on trial,[2] there were two parties involved, i.e., Folien Fisher (and related companies), a Swiss company which held several patents in the field of laminates and foils; and Ritrama, an Italian company, which was a competitor. For several years, Ritrama had tried to obtain licenses from Folien Fisher without success. In a 2007 letter to Folien Fisher, Ritrama stated that Folien Fisher's denial would be against competition law. Folien Fisher then started a negative declaratory judgement before the court in Hamburg, Germany, asking the court (mainly) to rule that Folien Fisher's refusal to grant licenses to Ritrama would not violate anti-competition law. Ritrama then started a (positive) court action in Milano, asking the court to force Folien Fisher to grant licenses to Ritrama.

Both the court of first and second instance in Hamburg ruled against Folien Fisher, stating that the EuGVVO would not come into play since negative declaratory judgements were not mentioned there. These courts also noted that - unlike a positive action for patent infringement, where the applicant in proceedings may file an action in the court at the place of infringement - it would not be possible to file an action in the court at the place of infringement in a negative declaratory

[1] Remark: As usual, the law is a little more sophisticated; however, for the sake of brevity and readability, I have shortened things a little.

[2] Remark: Here, too, the case is more complicated, so I have abbreviated.

judgment action, as the applicant in proceedings would be explicitly asking the court to rule that no infringement had happened, therefore, there would be no place of infringement whatsoever.

Only the German High Court (BGH) decided to stay the proceedings and asked the ECJ to rule whether negative declaratory judgements would be included in the EuGVVO, too.

3. The Judgement of the ECJ

The ruling of the ECJ is quite simple and short: Since in the EuGVVO negative declaratory judgements are not ruled out, they are included. This means that the "Torpedo" system is now legalized.

This ruling is quite remarkable because the Attorney General[3] had argued an opposite position. Usually the ECJ follows the Attorney General's statement; only in about 20% of all cases is this statement overruled.

4. Practical Implications

Although this ruling is really quite remarkable on a judicial basis, the practical implications will be rather small since things really do not change. The high tide of Torpedoes (which more or less was around the millennium) may or may not come back again. The Torpedoes are influenced by the behavior of Italian or Belgian courts (or courts by another member state of the EU) more than than anything else.

[3] Statement of General Attorney Jääskinnen of 19 April 2012