Actavis v Eli Lilly
Decision of the decade?
Mairi Rudkin

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Occasionally, patent infringement sees a truly landmark ruling that forces everyone to sit up and take notice – and one such ruling arrived in July. Indeed, it has been hailed as the most important decision on patent infringement for more than a decade. It also represents a very patentee-friendly decision.

Until now the UK courts did not apply what is known as a ‘doctrine of equivalents’ when considering patents. This is a legal principle which allows parties to be held liable for infringing a patent even if the infringement does not fall within the literal scope of a patent claim. But following a ruling in the case of Actavis UK Limited v Eli Lilly & Company – concerning the use of a chemical compound called Pemetrexed, used for the treatment of cancerous tumours – a new precedent has been set.

Essentially, claims may now be interpreted by UK courts more broadly than previously – which in turn means that patent owners could enjoy a broader scope of protection. For example, a product or process which is not covered by a literal interpretation of the claim language may now be held to infringe if the variant feature is considered to be immaterial (eg if the variant feature achieves substantially the same result in substantially the same way).

The ground-breaking ruling also brings the UK more closely into line with German and Dutch courts and it is expected that the new Unified Patents Court will adopt a similar approach. It further means that third parties may find it harder and more complex to design around patents, in the hope of avoiding infringement. The ruling of this recent case may mean that companies will be some instances where a third party previously considered to avoid infringement may now be held liable. As a consequence, some patent owners could now take action against third parties who previously avoided infringement only by making immaterial changes to a product or process. Equally, on the other side, a third party may have cause to revisit any previous FTO search results to ensure that their position has not changed as a result of this decision.

This way, if any conflicting rights are identified, it may still be possible to design around them and so avoid infringement. It can also be a comfort for investors to see that preliminary investigations have revealed that there are no barriers to market. Don’t forget that IP rights are specific to different jurisdictions, so an FTO search should be carried out in each particular country or region in which you want to operate.

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Working with the new EU Trade Mark Regulation

It will now be possible for non-traditional marks such as sound or motion marks to be submitted by audio and video files.

On 1 October new amendments to the EU Trade Mark Regulation (EUTM Regulation), Implementing Regulation (EUTMIR) and Delegated Regulation (EUTMDR) come into effect across all member states.

Graphical representation of a mark will no longer be a requirement for EUTM applications. Representation can be in ‘any appropriate form’ provided it is ‘clear, precise, self-contained, easily accessible, intelligible, durable and objective.’ It will now be possible for non-traditional marks such as sound or motion marks to be submitted by audio and video files. A description is no longer mandatory, although it is optional for certain types of mark. Colour marks are to be represented by submitting a reproduction of the colour and reference to a colour code is now obligatory. Furthermore, whereas currently priority claims can be made within three months of filing an application, from October priority may only be claimed at the time of filing.

EU certification marks will be introduced. These will differ from ordinary EU marks by indicating the quality of the goods and services covered, not their origin. Applicants will need to submit regulations certifying the characteristics of the goods and services including their material, mode of manufacture (in respect of goods) or mode of performance (in respect of services), their quality and accuracy. Certification of geographical origin of the goods or services cannot be a requirement of the regulations. The regulations will, however, need to certify how the characteristics are to be tested and monitored and which parties are authorised to use the mark.

Applications will have the option to claim acquired distinctiveness either at the point of filing or (as now) when replying to an absolute grounds objection. If the claim is made on filing it may be as either a principal or subsidiary claim. If the claim is made as a subsidiary claim, inherent distinctiveness may be argued (and, if necessary, appealed) before filing evidence of acquired distinctiveness. This should provide applicants with greater flexibility as it postpones the need to collate evidence (often from multiple EU jurisdictions) until exhaustion of any appeal on inherent distinctiveness.

Arguments and evidence in support of invalidity and revocation proceedings can now be filed at a later date rather than with the application. This brings procedural rules on cancellation into line with opposition proceedings.

Further changes have been made to the format and structure of evidence filed in the course of proceedings. It must now be contained within consecutively numbered annexes. This should allow for greater clarity. When submitting a copy of a trademark registration this can now simply be referenced to the online registers, instead of being submitted as a copy or register extract.

The Intellectual Property Corporation of Malaysia (MyIPO) and the European Patent Office (EPO) have initiated a Patent Prosecution Highway (PPH) pilot program lasting three years from 1 July 2017. This adds to the PPH agreement Malaysia already has in place with Japan.

PPH allows examination of an application in one of a pair of countries to be accelerated based on a positive examination report (where at least one claim has been deemed allowable) of a corresponding application in the other country. While the agreement is bidirectional, examination reports tend to be issued more quickly by the EPO compared to MyIPO, so the majority of PPH requests are likely to assist in accelerating the prosecution of Malaysian applications. The agreement covers PCT national phase Malaysian applications where the International Search Authority was the EPO, such that the international search report and written opinion may be also used for a PPH request in Malaysia. Normally the first examination report in Malaysia takes several years to be issued. However, based on our experience with the Japan-Malaysia PPH agreement, we would expect requests under the EPO-Malaysia PPH agreement to reduce this time to around six to nine months.

New PPH program between Malaysia and EPO

Brexit, a first look at the UK’s EU Withdrawal Bill’s implications for IP

The UK government has published its draft EU Withdrawal Bill. Although frequently dubbed the “Great Repeal Bill” it does not in fact seek to repeal all the European law that currently has force in the UK. On the contrary, the aim of the Bill is to incorporate the vast majority of EU law into UK law, so that so far as possible the law in force in the UK the day after Brexit is the same as that the day before.

So far as IP is concerned, whilst this might work for some aspects of European law, such as the IP Enforcement Directive, other laws, such as those that provide for European IP rights, including EU trade marks and Registered Community Designs, cannot simply be adopted into UK law and transitional provisions will need to be enacted. The EU Withdrawal Bill gives the UK government wide powers to introduce such provisions but the scope and use of these powers is likely to be the subject of much opposition in Parliament as the Bill is debated.

The EU has published its own position paper on intellectual property rights (described in detail by Will Jensen on pages 6–7 of this edition of ReMarks). It would like existing European IP rights, including the important protections for agricultural products such as champagne and parmesan cheese, to be automatically recognised in the UK following Brexit. The UK may well be happy to agree to much of what the EU has proposed in this regard, as the UK also has an interest in continuing the existing protection for UK products, for example, scotch whisky – a very important export for the economy.

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European Commission publishes position paper on IPRs

On 7 September, the European Commission published a position paper on intellectual property rights (including geographical indications), setting out how the transition of the UK leaving the EU should take place with respect to certain IPRs to ensure minimum disruption to the UK and the remaining EU27.

The paper contains the main principles of the EU position on IPRs, to be discussed by the EU27 for agreement and then presented to the UK in the context of negotiations under Article 50. It sets out the EU’s position on what the Withdrawal Agreement between the UK and the EU should ensure in relation to:

- the scope of protection in the UK of certain rights;
- the treatment of applications for certain rights; and
- the exhaustion of rights conferred by IPRs.

All rights with unitary character within the EU are considered:

- Community Trade Marks
- Registered Community Designs
- Unregistered Community Designs
- Community plant variety rights
- EU database rights
- Protected geographical indications or protected designations of origin.

Essentially, the EU’s position is that holders of unitary IPRs should not be affected by the UK’s withdrawal from the EU.

Scope of protection

Following the UK’s withdrawal, the holder of a unitary IPR should have a comparable right in the UK.

The implementation of this principle should include the automatic recognition of an IPR in the UK on the basis of an existing unitary IPR in the EU and should not result in financial costs or unnecessary administrative burden for the holders of unitary IPRs.

The paper specifically states that the implementation of these principles in the UK should include appropriate adaptation of “genuine use” requirements and “reputation” rules to the specific situation under consideration. The paper gives two respective examples: a TM in the UK should not be refused on the ground that the equivalent EU TM had not been put into genuine use in the UK before that date, and a EU TM owner should be able to temporarily exercise rights in the UK equivalent to those in the EU even if the TM does not yet have a reputation in the UK.

Applications

Where an application has been submitted before the date of withdrawal, the applicant should be entitled to keep the benefit of any priority date when applying for an equivalent right in the UK after the withdrawal date.

As for SPCs or paediatric extensions, where an application has been submitted before the withdrawal date, an applicant should be able to obtain a right in the UK providing protection equivalent to that under EU law.

Legal protection of databases

Makers or right holders of databases should continue to enjoy protection: Articles 11(1) and (2) of Directive 96/9/EC should be waived in the EU27 in respect of UK nationals, and conversely the UK should waive any equivalent provisions in future legislation and not exclude EU27 nationals and EU27 companies from database rights in the UK on nationality and establishment grounds.

Exhaustion of rights

Rights exhausted in the EU before the withdrawal date should remain exhausted in the EU27 and the UK. The conditions for exhaustion should be those defined by EU law.

Conclusions

The EU’s position is fairly straightforward: right holders should not be affected or placed under any extra financial or administrative burden by the UK’s withdrawal from the EU.

The practical implications of the EU’s proposals are that the cost and effort will have to be borne by the UK government. They would have to ensure that the UKIPO systems and infrastructure can cope with the extra registrations that will eventually be needed and that the right legislation is put in place to ensure the EU’s desired principles (to be included in the Withdrawal Agreement) are implemented properly.

There will no doubt be an interesting period when some very interesting questions will arise in relation to UK and EU rights. The EU is wise to mention specifically the difficulties of genuine use and reputation in the UK in regard to TMs, but there will undoubtedly be many more.

The UK has now published its draft EU Withdrawal Bill and the implications for IP are discussed by Graham Burnett-Hall on page 5 of this edition of ReMarks.
Canadian Federal Court of Appeal Indicates that a “Promise” is not the Solution

The meaning of the “inventive concept” of a claim and of the “claim as construed”, and how to determine their subject matter, has been an issue of much contention and many opinions in Canada. This issue especially gained relevance when the Supreme Court of Canada stated in 2008 that in a case of a chemical formula where the inventive concept of the claims is not readily discernible from the claims themselves it must be acceptable to read the specification in the patent to determine the inventive concept of the claims. For example, the validity of Sanofi-Aventis’ Plavix patent CA1396777 had been repeatedly considered by Canadian courts in the past with, in part, different results. In 2013 the Federal Court of Appeal affirmed the validity of the Plavix Patent in line with the above mentioned 2008 Supreme Court of Canada decision after the patent was found invalid by a 2011 Federal Court decision for failure to meet a promise identified by the court in the patent’s description. However, the 2013 FCA decision also affirmed – inconsistent with the 2008 Supreme Court of Canada decision – the presence of the “Promise of a Patent” doctrine in Canada.

Now, in 2017 the FCA referred to the 2008 Supreme Court decision as Plavix 1 and the 2013 Federal Court of Appeal decision as Plavix 2 and held that “inventive concept” is typically synonymous with “the solution taught by the patent” which is often synonymous with “what is claimed in the patent” or “the invention”. Further, the Court held that one should be wary of seeing things in Plavix 2 that have no foundation in Plavix 1 and that the governing authority remains Plavix 1, the 2008 Supreme Court of Canada decision. In other words, the FCA now indicates without making any use of the word “promise” that the “Promise of a Patent” doctrine is not the solution and has no place in Canada.

The approach expressed by the FCA is entirely consistent with the Supreme Court of Canada decision of June 30 2017 which concludes that the Promise Doctrine is not the correct method of determining whether the utility requirement under section 2 of the Patent Act is met.

The “plausibility” requirement at the EPO

A recent Federal Court of Appeal (FCA) decision, Bristol-Myers Squibb Canada Co. v Teva Canada Limited, has provided welcome clarification of the FCA’s understanding of the “inventive concept” of the claims and the “claims as construed”. The decision related to the validity of a patent claim directed to a specific crystalline form of a pharmaceutically acceptable salt having increased bioavailability over the free base and increased solid-state stability.

Decision T 488/16 of the Boards of Appeal of the EPO has been published setting out the reasoning for the revocation of European patent number EP1169038B1 protecting the anti-cancer drug Dasatinib (Sprycel®). The Decision represents an interesting development of the doctrine of “plausibility”, particularly in relation to small molecule pharmaceuticals.

The patent owner had sought to defend the patent on the basis of just one claim directed to the single compound Dasatinib. The novelty of this compound was not in dispute, and the case hinged on the extent to which the patent owner was entitled to rely on the activity of the compound (as a PTK inhibitor) as a technical effect when seeking to establish an inventive step.

According to established EPO jurisprudence (see, eg, T 939/92 and T 1329/04), a technical effect can only be relied upon for inventive step to the extent that it was “at least made plausible” in the application as filed. Post-published evidence cannot be used to demonstrate a technical effect that was not made at least plausible by the application as filed (although it can be used to corroborate a technical effect which was at least made plausible by the application as filed). Here, the application as filed disclosed a broad group of compounds generally and 580 specific compounds including Dasatinib. It also discussed PTK inhibition and associated disease targets, and described assays by which PTK inhibitory activity can be tested. It also stated that compounds of the examples had been tested in one or more of the assays and had shown activity. However, no actual activity data were presented.

The mere statement that compounds had been found to be active was not considered sufficient to make it at least plausible that Dasatinib would be active. The Board noted that a skilled person’s acceptance of an assertion of activity “must be based on verifiable facts”, and concluded that none were available.

Since activity had not been “at least made plausible” for Dasatinib in the application as filed, the patent owner could not rely on post-published activity data. As such, it could not rely on the PTK inhibitory activity of Dasatinib for inventive step. The problem to be solved was therefore the mere provision of a further chemical compound, which is not considered to be inventive (see, eg, T 939/92). The patent was therefore revoked.

A number of important facts influenced the Board’s conclusion, particularly the breadth of the application as filed, lack of structural commonality between the compounds disclosed, missing details in the PTK inhibition assays, and lack of relevant common general knowledge at the filing date. Nevertheless, the complete absence of any verifiable data was decisive to the outcome.

This Decision appears to raise the plausibility threshold somewhat (at least for small molecule pharmaceuticals) and underlines the importance of including verifiable facts (eg actual data) at the time of filing. It also seems that attacking plausibility will become a more popular approach in opposition proceedings.

The meaning of the “inventive concept” of a claim and of the “claim as construed”, and how to determine their subject matter, has been an issue of much contention and many opinions in Canada. This issue especially gained relevance when the Supreme Court of Canada stated in 2008 that in a case of a chemical formula where the inventive concept of the claims is not readily discernible from the claims themselves it must be acceptable to read the specification in the patent to determine the inventive concept of the claims. For example, the validity of Sanofi-Aventis’ Plavix patent CA1396777 had been repeatedly considered by Canadian courts in the past with, in part, different results. In 2013 the Federal Court of Appeal affirmed the validity of the Plavix Patent in line with the above mentioned 2008 Supreme Court of Canada decision after the patent was found invalid by a 2011 Federal Court decision for failure to meet a promise identified by the court in the patent’s description. However, the 2013 FCA decision also affirmed – inconsistent with the 2008 Supreme Court of Canada decision – the presence of the “Promise of a Patent” doctrine in Canada.

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The Singapore Court of Appeal (COA) recently dismissed Warner-Lambert’s appeal, upholding the decision of the High Court, in Warner-Lambert Company LLC v Novartis (Singapore) Pte Ltd. The High Court judge had denied Warner-Lambert leave to amend its patent relating to a method of treating pain by administering Pregabalin. The COA agreed with the High Court that there had been an undue delay by Warner-Lambert in seeking the amendments, and that the amendments, if made, would extend the scope of the protection of the patent (previously reported in ReMarks 4th Quarter 2018).

Although the COA was not required to comment on the validity of Swiss-style second medical use claims, the COA made some interesting observations, which, though not binding, are the first to be made in the Singapore courts in relation to Swiss-style claims. The Singapore Patents Act does not explicitly provide whether a second/further medical use of a known substance/composition is considered to be patentable. To date, s.14(7) of the Act has been interpreted as protecting only the first medical use of known substances. However, following the Act, it has been the practice of the Intellectual Property Office of Singapore (IPOS) to accept claims for second/further medical use of a known substance/composition in the form of Swiss-style claims.

IPOS’s Examination Guidelines for Patent Applications provide that “...if the substance or composition has already been known to be useful for a medical purpose, then in order to protect a further medical use of the substance or composition, a second medical use format (Swiss type format) must be used”.

The COA made some interesting observations, which, though not binding, are the first to be made in the Singapore courts in relation to Swiss-style claims.

Whilst the validity of second medical use claims in the UK has been clarified by recent legislation, whereby a purpose-limited product claim (i.e. “Substance X for use to treat disease Y”) is now considered the acceptable form of such claims, corresponding legislative changes have not been made in Singapore. Consequently, the Swiss type format remains the only acceptable form of second medical use claims in Singapore. In fact, the Examination Guidelines provide that “second or subsequent medical uses of a known substance or composition may only be claimed in the form of “Swiss-type” claims”, with an example of a suitable form being: “Use of substance X for the manufacture of a medicament to treat disease Y”.

The COA commented that s.14(7) of the Singapore Patent Act appeared to support the patentability of second and subsequent medical uses of known substances because by “its ordinary meaning, [it] does protect any use, first or subsequent, which is not part of the state of the art”. By virtue of this interpretation, the COA endorsed the position that the patenting of second and subsequent uses of a known substance was enabled, and a purpose-limited product claim in the form of “compound X for use in the treatment of disease Y” may suffice to obtain protection, thereby removing the necessity of Swiss-style claims. The COA further added that while it did not disagree with the validity of Swiss-style claims as currently allowed by IPOS, it believed that if the COAs interpretation of s.14(7) was given, Swiss-style claims would not be needed. Although Swiss-style claims remain the current form of protection of second/further medical uses, the comments of Singapore’s highest court may lead to legislative changes. In fact, soon after the COAs decision was published, IPOS issued a note stating that it was reviewing the COA’s observations in relation to Swiss-style claims. The COA’s comments may suffice to support a similar purpose-limited product claim as in the UK. In the meantime, applicants should seek the advice of a qualified Singapore patent attorney with experience in second medical use claims to ensure that suitable forms of second medical use claims are included in their patent application.

Obtaining a UP

UPs can be obtained based on granted European patents by making a request to the effect up to one month following grant. If this due date is missed then reinstatement of the date can be requested within two months. It is to be noted, however, that traditional validation of a European patent has to be completed within three months from grant so that a request for reinstatement of the due date is likely to not leave any time to validate the European patent in the usual manner instead of obtaining a Unitary Patent.

Changes to the EPO register

The EPO has been given the task to provide a register of Unitary Patent protection. This register will be a continuation of the already existing European patent register, albeit with some extra panel views. As will be known, although 25 EU member states have signed up to the UP agreement, not all have ratified the agreement yet. After the UP system goes live a granted Unitary Patent, including dealing with requests for UPs are filed as early as possible post grant.

The time limit for filing such an application is, however, a short three weeks from receipt of the decision. The said, the sum of the one month period for requesting a UP and the two three week periods are more than the three months period post grant for validating a European patent in the traditional manner. It is therefore recommended that requests for UPs are filed as early as possible post grant.