Haseltine Lake Kempner

Chemistry and life sciences newsletter

Summer 2019

Of Molecules & Medicine: A collection of articles

In this newsletter we take a look at the treatment of rare diseases, second medical use patents and how EPO co-operation is positive news for biotech innovators. We also review the recent court decisions in Helsinn v Teva, Actavis v ICOS Corporation and Actavis v Eli Lilly.

A message from the editor...

Welcome to Haseltine Lake Kempner's latest Chemistry and Life Sciences newsletter. The newsletter includes a collection of updates from the last six months, from case summaries to important points of law. This edition provides commentary on: the UK Supreme Court decision on the obviousness of a dosage regime in light of routine clinical trial protocols; infringement in the UK of numerical ranges in light of the doctrine of equivalents arising from Eli Lilly v Actavis; the EPO's approach to plausibility and second medical use claims; the on-sale bar in the US post-AIA in Helsin v Teva; a spotlight on rare diseases; an update on the Eli Lilly Pemetrexed litigation in Germany; and the cooperation between the UK IPO and the EPO on biotech patent applications. Finally, we have some news from the team.

The team have been working hard to produce articles frequently throughout the year and if you'd like to access them before our newsletter is sent out, then please follow our LinkedIn page to be the first to hear when we publish a new article.

We hope that you enjoy this edition and look out for the next edition coming later in the year.

Joseph Lenthall
Partner
UK and European Patent Attorney

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A spotlight on the treatment of rare diseases

Rare (or orphan) diseases are those diseases that affect only a tiny fraction of the population. In Europe, the disease or disorder is generally classified as rare if the disease affects fewer than 1 in 2,000 people. However, there are more than 6,000 rare diseases known. As a result, a significant proportion of the population are affected by a rare disease (thought to be around 30 million people in Europe and around 25-30 million in the USA). In addition, it is estimated that around 80% of rare diseases are genetic diseases and so many affect new-born and young children, with some symptoms being severely debilitating.

Written by Joseph Lenthall

The population available to recruit for clinical trials and the market size for the treatment of each rare disease are very small. As such, the development of treatments for rare diseases more difficult and less attractive than other indications for pharmaceutical companies. However, the Orphan Drugs Act of 1983 in the US sought to provide additional incentives for the development of treatments of rare or orphan diseases. Incidentally, one of the reported influences in bringing the US Orphan Drugs Act into effect was the popular US television series, "Quincy, M. E.," which aired an episode in 1981 addressing the challenges facing a Tourette's patient, and another episode the following year, about myoclonus.

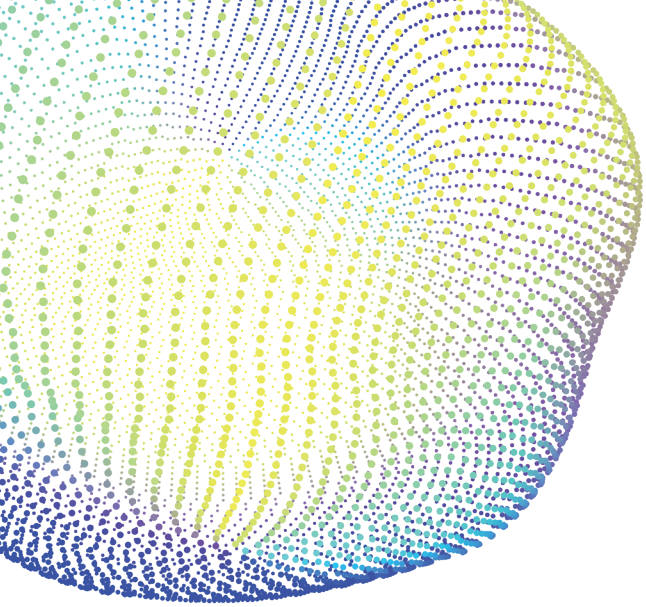
Similar legislation to the Orphan Drugs Act in the US was enacted in Europe in 1999 with EU Regulation (EC) No 141/2000. One of the most powerful incentives granted for orphan drugs by the European Medicines Agency (EMA) is ten year market exclusivity in the orphan indication for any drug with orphan drug status.

In more recent years, rare diseases have come into the focus of the public through campaigns, such as the "Ice Bucket Challenge" which raised the awareness of ALS (as well as in the order of $115 million to help fund ALS research). The UK government published its Strategy for Rare Diseases in 2013. The main focus of the strategy was to commit to taking action in five areas:

- empowering those affected by rare diseases
- identifying and preventing rare diseases
- diagnosis and early intervention
- coordination of care; and
- the role of research.

The UK Government published their progress report here in 2018. The progress report acknowledges the large role that developments in genomics have had in the area of rare diseases, including the 100,000 Genomes Project.

The legislative changes and focus on rare disease have had a significant impact on



the orphan drug market. As an indicator, the number of patent application families filed relating to the treatment of motor neurone disease (ALS), acute myeloid leukaemia (AML), cystic fibrosis, multiple myeloma or muscular dystrophy has risen from around 200 in 1997 to over 1200 in 2017.

This trend appears to translate into a marked increase in the number of medicinal products entering the market. A 2017 study suggests that 104 orphan medicines were approved by the EMA between 2000 and 2013 compared to 374 non-orphan medicines. Of the 55 medicinal products under evaluation at the EMA at the end of 2018 (excluding generics and biosimilars), 20 of these products are orphan medicinal products.

The success of Celgene's Revlimid (lenalodomide) may have contributed to their recent acquisition by Bristol Myer-Squibb. Big name pharmaceutical companies have had success with rare disease drug approval, but several small niche drug developers have made a name in the rare disease field. For example, Alexion Pharmaceuticals' Soliris (eculizumab) is one of the top rare disease therapies and the US FDA recently approving Alexion's follow-up PNH treatment, Ultomiris, which promises to reduce dosing frequency in PNH patients. Vertex Pharmaceuticals is a market leader in the treatment of cystic fibrosis with three FDA approved drugs on the market, and more in the pipeline (along with a significant proportion of patent applications filed in the area of cystic fibrosis). Roche announced this week that it would buy Spark Therapeutics for $4.8bn. Spark currently have approval for Luxturna for the treatment of the rare inherited retinal disease caused by mutations in both copies of the RPE65 gene. Treatment with Luxturna is reported to cost an eye-watering $850,000 in the US, making it the most expensive drug on the market.

It is not surprising then that the forecast for the worldwide orphan drug sale market will be $262 billion by 2024. The same report forecasts sales for pipeline orphan drugs will account for over a third of total R&D pipeline sales through to 2024. Inevitably, the number of patent application filings in the area of orphan drugs is likely to increase in the next few years.

An area of concern with respect to orphan drugs (and more generally in the pharmaceutical industry) is the pricing of the drugs. With such a small population affected by a particular rare disease, the cost for the treatment for rare diseases can be significantly higher than more common disease treatments. The price of treatment for some approved orphan drugs run in excess of $400,000.

This cost factor may be a reason why the number of approved drugs based on **known substances** at the EMA between 2000 and 2013 was proportionally higher for orphan drugs than non-orphan drugs. It is possible in Europe to get patent protection for a known drug if it can be plausibly shown that it will

> "The price of treatment for some approved orphan drugs run in excess of $400,000. "

treat another indication. The protection afforded by such "second medical use" claims is limited to the new indication and evidence (e.g. assay data) must be provided at the time of filing the new patent application.

As with any product, those looking to develop and bring to market rare disease treatments need to bear in mind their freedom to operate. It is possible in patent law for a product to be new and inventive (and therefore patented) but also to fall within someone else's patent rights. It is important to search for earlier patent rights before entering the market to avoid a risk of litigation.

Traditional treatment areas, such as cancer, cardiovascular disease and infectious diseases, will continue to dominate the drug development market. However, it is encouraging for patient outcomes that there is recognition and drug development in the rare disease area. As with conventional drug development, patent protection for treatments of rare diseases will provide crucial incentive for companies to develop such treatments and bring them to market.

UK IPO – EPO co-operation brings positive news for biotech innovators

On 1 February 2019 the UK IPO issued a notice that brings welcome news for biotech innovators wanting to use the services of the UK IPO. Searches on all UK initial patent filings in the biotech sector should be sped up, and for some applicants significant cost savings should be available in connection with subsequent European or PCT applications claiming priority from that UK patent filing.

Written by Isobel Finnie and Joanna Rowley

The United Kingdom Intellectual Property Office (UK IPO) is renowned for producing low-cost but high-quality searches, which are usually issued within 6 months of filing a UK patent application that does not claim priority. This makes the UK a highly attractive jurisdiction for first filings because applicants are able to get a valuable insight into the patentability of their invention well within the priority year, giving time to consider the subsequent global filing and prosecution strategy before priority claiming applications (e.g. a PCT application) need to be filed.

Unfortunately, due to backlogs at the UK IPO, applicants in the field of biotechnology have had to wait longer than 6 months to receive the UK IPO's search results. To tackle this backlog and to ensure that the UK IPO can continue to issue search reports quickly, the UK IPO announced on 1 February 2019 that they have signed a co operative searching agreement with the European Patent Office (EPO). Under this agreement, the EPO will perform 200-300 searches per year for UK applications relating to biotech inventions. The agreement will last for at least two years and is based on similar co-operation agreements which already exist between the EPO and other EPC

contracting states including Cyprus, Greece, Italy, Latvia, Lithuania, Malta, Monaco and San Marino.

This is positive news for biotech innovators because all applicants using the UK IPO can expect to receive the valuable information they are seeking in a useful time frame.

Although UK applicants cannot chose whether their UK application is searched by the EPO, the search report will indicate which authority has performed the search and applicants whose searches are performed by the EPO may be entitled to the following additional benefits.

Firstly, where the EPO has completed the search for a UK application, a later filed European application claiming priority from the UK application could be eligible for a refund of up to 100% of the European search fee. Similarly, a later filed PCT application claiming priority from the UK application could be eligible for a refund of up to 84% of the international search fee where the EPO is the International Search Authoring (ISA). In view of the fact that the search fee for a UK application is currently only £150 - compared to €1,300 for a European application and €1,775 for an international search by the EPO - this could result in significant cost savings for applicants.

Secondly, a PCT application claiming priority from a UK application that was searched by the EPO may be eligible for PCT Direct. Using this service applicants can file, together with their PCT application, comments in response to any objections raised in the search opinion drawn up by the EPO in respect of their UK priority application. The EPO as ISA will take these comments into account when drawing up the written opinion of the ISA (WO-ISA), which can help applicants to obtain a positive WO-ISA.

Continued issuance of high-quality search reports in a short time frame alongside these new, additional benefits make the UK an even more attractive jurisdiction for first filings.

The recent UK Supreme Court decision in Actavis v ICOS Corporation

ICOS Corporation and Eli Lilly & Company appealed against a judgement from the Court of Appeal, which held that the patent was invalid. The recent UK Supreme Court judgement Actavis v ICOS Corporation dismissed the appeal and upheld that the patent was invalid for lacking an inventive step.

Written by Catherine Williamson

Background

The patent related to the use of a new dosage regime of tadalafil (sold under the brand name CIALIS®) to treat sexual dysfunction. The claimed invention specifically related to the use of a unit dose containing 1 to 5 mg of tadalafil for administration up to a maximum total dose of 5 mg of tadalafil per day.

The closest prior art was taken to be a patent application ("Daugan") generally disclosing the use of tadalafil to treat sexual dysfunction. Daugan discloses tadalafil's potency against PDE5 (which was previously implicated in sexual dysfunction), and suggests that doses of tadalafil will generally be in the range of 0.5 mg to 800 mg daily, giving an example of a tablet containing 50 mg of the tadalafil.

The assessment of inventive step in the present case focused on what the hypothetical skilled team would have done in phase IIb clinical trials. Phase IIb clinical trials involve testing a range of doses with the aim of finding the optimum dose at which the drug shows biological activity with minimal side-effects.

The respondents argued that it would have been obvious for a skilled team to take tadalafil forward into a routine pre-clinical and clinical trial programme in view of the disclosure of Daugan. In particular, standard dose-ranging studies, involving routine work and not involving inventive effort, would have led to the new dosage regime claimed in the patent.

It was not disputed that it would have been obvious to take tadalafil forward into a routine pre-clinical and clinical trial programme as an oral treatment for sexual dysfunction in view of the teachings in Daugan. It was also not disputed that the skilled team would have first tested higher doses of tadalafil during the phase IIb trials and would have found the discovery of a therapeutic plateau between 25 mg and 100 mg doses to be surprising.

The respondents argued that it would have been obvious to go on to test doses as low as 5 mg per day after the discovery of the therapeutic plateau between 25 mg and 100 mg.

The appellants argued that it would not have been obvious at the start of the programme to try a dosage as low as 5 mg per day as there was no reason to think that it would be effective at that dosage. Further, it was not obvious at the start of the programme that a dosage as low as 5 mg per day would be safe and effective and also have minimal side effects.

The Decision

Lord Hodge was not persuaded that the law adopts the extreme position of either

> "Lord Hodge clearly stated that he does not consider that the product of well-established or routine enquiries cannot be inventive."

submission. The judgement provides a useful discussion of the assessment of inventive step and many factors that should be taken into account in the analysis. In the present case, Lord Hodge considered that the following factors were relevant considerations:

- whether it was "obvious to try" at the priority date;
- the routine nature of the research;
- the burden and cost of the research programme;
- the necessity for and the nature of the value judgements;
- the existence of alternative or multiple paths of research;
- the motive of the skilled person;
- the unexpected or surprising nature of the results;
- that hindsight must not be used in the assessment of inventive step;
- whether a feature of a claimed invention is an added benefit in a context in which the claimed innovation is obvious for another purpose.

In relation to the balance between whether something was "obvious to try" and the unexpected or surprising nature of the results, Lord Hodge stated that "…there is no requirement that it is manifest that a test ought to work; that would impose a straightjacket which would preclude a finding of obviousness in a case where the results of an entirely routine test are unpredictable. As Birss J observed in this case (para 276), some experiments which are undertaken without any particular expectation as to result are obvious. The relevance of the "obvious to try" consideration and its weight when balanced against other relevant considerations depend on the particular facts of the case" (paragraph 65 of the judgement). Further, it was stated that "the fact that the results of research which the inventor actually carried out are unexpected or surprising is a relevant consideration as it may point to an inventive step, at least in so far as it suggests that a test was not obvious to try or otherwise the absence of a known target of the research which would make it less likely that the skilled person would conduct a test" (paragraph 71 of the judgement).

Ultimately, it was decided in the present case that the skilled team would have obviously pursued the phase IIb tests in a routine way until the claimed dosage regime was ascertained, as this would have been the target of the phase IIb tests. The lack of an expectation of efficacy therefore provided little weight. This was supported by the experts of both parties who agreed that the skilled team would not stop the dose ranging studies when they had revealed the therapeutic plateau between 25 mg and 100 mg. The fact that the claimed dosage also provided minimal side effects was simply an added benefit that did not prevent the identification of the new dose.

Impact on Other Dosage Regime Patents

Although the decision may be disheartening for patent applicants and proprietors, it is important to note that Lord Hodge clearly stated that he does not consider that the product of well-established or routine enquiries **cannot** be inventive. It therefore seems that additional factors, such as a teaching away from a particular treatment or dose, or an improvement or unexpected effect going beyond a bonus effect, will be important when assessing the inventive step of a new dosage regime.

Getting your timing right - Demonstrating plausibility and when to file a second medical use patent

Deciding when to file a patent application can be a difficult decision. If you file a patent application too early there may not be enough information in the application as filed to convincingly show that the invention will work as proposed. However, waiting too long can mean that more prior art is citable against the patent application and it can be harder to show novelty and inventiveness. This balancing act is particularly difficult for second medical use type patents.

Written by Isobel Finnie

Second medical use claims are used before the European Patent Office (EPO) for inventions involving additional or improved treatments using already known drugs. For example, using a known drug to treat a different disease or changing the dosage regimen of a known drug to provide a better effect or to treat a different patient group. In the context of second medical use claims the EPO has made it clear that the therapeutic effect must be made plausible (in the sense of being very credible to a skilled reader) from the information in the patent document. This can play a part in assessing whether the new treatment claimed as the invention is sufficiently disclosed, and for assessing whether the problem of providing the treatment as claimed has been solved. The patent specification needs to contain enough information, and this usually means data from experiments from some stage during the drug development process, to make the therapeutic effect plausible.

Pharmaceutical developers are well aware that a new treatment is only definitively proved to be effective when the results of clinical trials are known. Many drugs fail during clinical trials. The EPO have also recognised that patentees must file their patent applications well before the clinical trials are completed and so will generally consider the therapeutic effect to be demonstrated as plausible without clinical trial results. However, the patent specification must have information in it, usually data from in vitro or animal models, to demonstrate the therapeutic effect claimed.

Therefore, if an announcement is made public that a clinical trial will be carried out (in future) before a patent application is filed, is that announcement to be viewed as a prior disclosure of something that can be expected to work and therefore deprive the claimed therapeutic treatment of novelty and inventiveness? These were issues considered in decision T239/16 (published in 2018).

"Deciding when to file a patent application can be a difficult decision."

The scrutinised document was information about a planned Phase II clinical trial aimed at prospective participants. The planned Phase II clinical trial involved a number of different dosage amounts and frequencies of the drug zoledronate for treating post-menopausal osteoporosis, as well as a placebo.

The EPO's Board of Appeal (BoA) was

able to conclude that information about the clinical trial in combination with general knowledge about the zolendronate meant there was no direct and unambiguous disclosure of an effective treatment being achieved and hence the claims were considered to be novel.

The BoA had to consider whether that information about the planned Phase II clinical trial made it obvious to try each of those dosage amounts and frequencies with a reasonable expectation of success and so rendering the claimed subject matter not inventive.

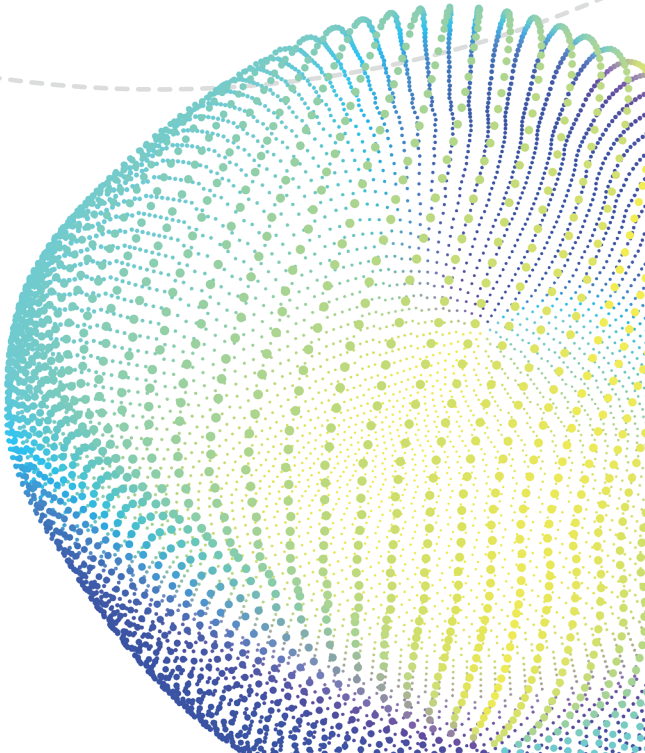
The BoA considered the fact that an active agent is being tested in a clinical study for the treatment of osteoporosis leads to an expectation of success, due to the fact that clinical studies are based on data obtained by pre-clinical testing, both in vitro and in animals, and require authority approval which takes ethical considerations into account. Therefore the skilled person would expect all study arms to treat osteoporosis effectively, unless he was dissuaded from this by the prior art. The BoA reviewed prior art documents and concluded that in the present case, the clinical trials were performed with more than a mere "hope to succeed" there was a reasonable expectation of success.

This conclusion sits uncomfortably with the current transparency rules for clinical trials requiring registration of a clinical trial and subsequent publication of the protocol long before any results of the trial are available.

It should be noted that Phase II clinical trials are scientific tests. The sponsor always hopes to get positive results, but the outcome cannot be known until after the clinical trials are performed and the data analysed. As noted above, drugs can fail at various stages during clinical trials. Furthermore, it is unlikely that every one of the study arms in a multi-arm clinical trial would be an effective treatment.

The patentees have subsequently asked the EPO's Enlarged Board of Appeal (EBoA) to review T239/16 on grounds including that the BoA was incorrect to assume that due to the ethical considerations associated with clinical trials there is an expectation of success for all arms of an announced clinical trial. The EBoA have accepted the review and the outcome is expected in early 2019. We will analyse the outcome in due course.

The outcome could have an impact on deciding when, during the drug development process, to file patents relating to second medical use inventions. If the EBoA uphold the findings of the BoA in T239/16 there may be the need for careful coordination between patenting and clinical trial programmes within pharmaceutical companies. There may also be a need for additional early testing (leading to additional time and expense) for the sake of fulfilling the plausibility requirements for patenting.



The Recent US Supreme Court Decision - Helsinn v Teva, and (not so) secret sales

The recent US Supreme Court decision Helsinn Healthcare S.A v. Teva Pharmaceuticals USA Inc. gives an insight into the definition of prior art under the Leahy-Smith America Invents Act (AIA), in particular, whether a 'secret sale' can deprive a claimed invention of novelty in a US patent application.

Written by Robyn Hardisty

Background

In 2000, Helsinn entered clinical trials relating to the dosage of a drug named palonosetron for treating chemotherapy induced nausea. Shortly thereafter, under a series of confidential agreements, Helsinn agreed a licensing agreement with MGI Partners Inc. who acquired the rights to distribute and market the product. While the cooperation between parties was publicly known, the technical details of the invention were not disclosed.

On January 30th 2003, Helsinn filed a provisional patent detailing the specific dosage of palonosetron. A series of patents were filed claiming priority from this application, the fourth of which, US 8,598,219 (US '219), was granted by the USPTO in May 2013.

In 2011, Teva Pharmaceuticals sought approval from the FDA to create a generic version of Helsinn's product. When Helsinn sued for infringement of their patent, Teva counterclaimed that the patent was invalid.

The amended AIA 35 U.S.C § 102 conditions for patentability stipulate that "a person shall be entitled to a patent unless (1) the claimed invention was patented, described in a printed publication, or in public use, **on sale, or otherwise available to the public** before the effective filing date of the claimed invention" [emphasis added] (see here). An exception to this rule includes anything disclosed by the

inventor 12 months before filing a relevant patent application (known as the "grace period").

Pre-AIA, Pfaff v. Well Electronics (1998) had previously established that a 'secret sale' in the US could invalidate a US patent. However, changes to the conditions for patentability raised questions about whether this interpretation was still valid. In particular, did the inclusion of the term **'or otherwise available to the public,'** not present in the previous statute, change the on-sale bar?

Decision

The Supreme Court held that the AIA rewording of this provision did not change the established case law with respect to "secret sales" as explained in Pfaff. Two conditions had to be met for there to be a sale: first, the product must be the subject of a commercial offer for sale and second the invention must be ready for patenting. The Supreme Court affirmed the Federal Circuit's ruling that "if the existence of the sale is public, the details of the invention need not be publicly disclosed in terms of sale in order to fall under the AIA 'on sale'

bar."

The Courts found that there was overwhelming evidence that Helsinn's dosing invention was ready for patenting and reduced to practice before the critical date (i.e. January 30th 2002, one year before filing the provisional patent application). Since Helsinn had sold this invention before the critical date, the sale to MGI Partners Inc. was deemed to deprive the US '219 patent claims of novelty.

It is important to note that the AIA definition of novelty now has no geographic restriction. It is therefore important to be aware that a confidential sale of a product anywhere in the world, more than one year before filing the relevant patent application, is likely to deprive a US patent application directed to that product of novelty.

A comparison with Europe

At the European Patent Office (EPO), under Article 54(2) EPC, the state of the art comprises everything made available to the public by means of a written or oral description, by use, or in any other way, before the filing or priority date of the European patent application. Unlike the US, there is no grace period for inventor disclosures 12 months before filing a European patent application.

The situation regarding 'secret sales' is also quite different at the EPO. According to the EPO's Case Law of the Boards of Appeal a single sale of a prototype was sufficient to render the article available to the public, but only because the buyer was not bound by an obligation to maintain secrecy (see here). While a secret sale does not deprive a claimed invention of novelty, the patentee is required to provide suitable evidence to prove that the sale was bound by confidentiality.

Furthermore, a product sold to the public is only deemed to be part of the art if it can be analysed and reproduced by the skilled person (see G 1/92). For example, the EPO Board of Appeal in T 1833/14 held that the opponent could not sufficiently prove that the skilled person had enough information to prepare a claimed polymer without knowing, among other things, which catalyst system was used to prepare said polymer product, despite the product being sold before the priority date.

A numbers game? – Infringement of numerical claims following Actavis v Eli Lilly

A recently reported case in the High Court of England and Wales has shed further light on how patent claims are being interpreted in the UK following the 2017 landmark decision of the Supreme Court in Actavis v Eli Lilly.

Written by Michael Ford

In Regen Lab SA v Estar Medical Ltd & Ors, claimant Regen was the proprietor of European patent EP2073862 with claims covering a method for the preparation of blood plasma enriched in platelets and other factors (known as platelet rich plasma or PRP). Regen accused various respondents of infringement of the patent by supplying kits in the UK which were subsequently used to prepare PRP according to the claimed method. The defendants counterclaimed for revocation of the patent.

Although the patent was ultimately found to be invalid for lack of novelty and inventive step, Judge Hacon expressed an opinion that, if the patent had been found valid, it would have been infringed. In his decision, Judge Hacon discussed the application of the doctrine of equivalents, introduced by

Actavis v Eli Lilly, to the interpretation of numerical values in claims.

By way of background, prior to Actavis v Eli Lilly, the practice of the UK courts was to determine patent infringement on the basis of a purposive construction of the claims as they would have been read by a person skilled in the art. Infringement was found if the product or process fell within the scope of the claims on the basis of this construction.

Following the Actavis decision, however, the test for infringement is now divided into two steps. The first step involves determining whether the alleged infringement falls within the scope of the claims on the basis of normal interpretation. If the alleged infringement does fall within the scope of the claims on that basis, infringement is proven and the assessment stops. However, if the alleged infringement does not fall within the scope of the claims on the basis of normal interpretation, it is now necessary to assess whether the so-called variant nevertheless infringes because it differs from the claimed invention in only an immaterial way. This is referred to as applying the doctrine of equivalents. Actavis v Eli Lilly set out a series of questions to be considered when applying this doctrine. In the Actavis case, application of the doctrine led to the finding that pemetrexed dipotassium was equivalent to pemetrexed disodium as claimed.

Returning to Regen Lab v Estar Medical, the claim in question required centrifuging blood in a separator tube containing a polyester-based thixotropic gel and a buffered sodium citrate solution at 0.10 M. The defendants' process made use of a thixotropic gel which contained Tris (2-ethylhexyl) trimellitate and a buffered sodium citrate solution at 0.136 M. It was found that there would be no infringement on the basis of a normal interpretation of the claims, as Tris (2-ethylhexyl) trimellitate is not a polyester and 0.136 M is considered to be sufficiently different from 0.10 M, as would be expected when considering the number of decimal places or significant figures usually taken into account in the interpretation of numerical claim limitations.

However, following Actavis, the Court went on to assess whether infringement could nevertheless be proved on the basis of the doctrine of equivalents. In this assessment, Judge Hacon had to consider two key points: first, how the doctrine should be applied when there are multiple differences between the alleged infringement and the claim; and second, whether the doctrine applies to numerical values. The defendants, in particular, had argued that the doctrine should not apply in relation to a numerical claim.

In respect of the first issue, Judge Hacon concluded that the key question is whether the accused product or process is a variant falling within the scope of the claim taking all equivalents into account. Although it may be convenient to consider each equivalent one by one, there must be a single overall answer in relation to each accused product or process.

In respect of the second issue, the Court concluded that the approach to claims containing one or more numerical limits should be no different to that applicable to any other type of claim, and that principle was not changed by the decision in Actavis v Eli Lilly. Furthermore, Judge

Hacon stated that to require strict compliance with a numerical limitation in a claim would put numerical claims into a special class, as strict compliance is not necessarily required of any other type of claim limitation.

Judge Hacon then went on to conclude that the inventive concept of the patent claim is exploited in substantially the same way as to achieve substantially the same result if the process uses a non-polymeric thixotropic gel and the sodium citrate buffer solution has a molarity of 0.136 M instead of 0.10 M. This fact would have been obvious to the skilled person at the priority date. Further, Judge Hacon thought that the molarity of the solution in particular was not essential to the inventive concept, such that strict compliance with the literal meaning of the claim would not have been intended. Accordingly, it was found that the respondents would have infringed the patent based on the doctrine of equivalents, had the patent been valid.

This case highlights the potentially far-reaching effects of the Actavis decision. Last year in Icescape v Ice-World, the Court of Appeal also found, by applying the Actavis doctrine, that a series arrangement of manifolds in a mobile ice rink would infringe a claim explicitly reciting a parallel arrangement. These decisions suggest that the UK's lower courts will continue to apply the doctrine of equivalents to all claim features, including chemical species, the arrangement of mechanical components, and numerical limitations, at least until further guidance from a higher court is received.

Pemetrexed: The continuing story in Germany

The German Federal Patent Court found the German part of the Eli Lilly patent, EP 1 313 508 B in the first instance to be void. An appeal against this decision has now been filed at the German Federal Court of Justice.

Written by Sandeep Basra

Few patents have led to such a large number of landmark decisions as have resulted from the Eli Lilly patent for pemetrexed. This run is continuing due to the aforementioned appeal which is being lodged at Germany's highest civil court.

After surviving opposition proceedings at the EPO, the validity of the patent in Germany has been challenged, and the first instance decision went in favour of the generic companies. The EPO found that the skilled person would have no motivation to use pemetrexed in combination with vitamin B12 to reduce the toxic effects of pemetrexed. The judges at the German Federal Patent Court saw things differently and concluded that there are ample pointers in the prior art to arrive at the claimed combination. In particular, the skilled person would have known that homocysteine elevation is a sign of folic acid deficiency that can inter alia be caused by a vitamin B12 deficiency. As such, the claims were found to be obvious to the skilled person.

The judges emphasised that the conclusion reached is not in direct contradiction to the EPO decision due to the extensive prior art filed by the parties during the proceedings in Germany. Based on these documents, the first instance decision was reached without the use of expert witnesses.

News from the team

The Haseltine Lake Kempner Chemistry and Life Sciences team continues to grow with the recruitment of Joe Lenthall as a Partner in Bristol and Iain Robertson as a trainee patent attorney in Glasgow. We are continuing to recruit for our expanding team and look forward to welcoming those starting in the next six months.

The team has also been celebrating exam success. Rachel McGlue passed her European Qualifying Exams to become a European patent attorney and was promoted to Associate within the team. Joanna Rowley and Michael Ford recently passed their UK Finals exams to become Chartered patent attorneys. We also congratulate trainee Robyn Hardisty for passing all her foundation exams, so she is now a part-qualified UK patent attorney.

The CLS team have also been busy with EPO hearings, attending over 25 hearings in the last six months with more than 25 hearings scheduled so far for the next six months. The CLS team are also looking forward to working closely with our IP litigators in the future following our recent merger.

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