The AppleR Pip

Life Science & Pharmaceutical News

In this issue...

...we look at a variety of cases and decisions, upcoming events and information on what needs to be considered when obtaining patent protection in the pharmaceutical field. **Find out more inside.**

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The ApplePip

Issue five April 2015

WELCOME TO THE APRIL EDITION OF APPLEPIP

In this issue, we look at a variety of cases and decisions, upcoming events and information on what needs to be considered when obtaining patent protection in the pharmaceutical field.

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Appeal for Herceptin Dosage Regime Patent Dismissed

Hospira UK Ltd v Genentech Inc.

We reported in the last issue of ApplePip about two UK High Court cases involving dosage regime and purified composition patents for the Herceptin® drug (the antibody trastuzumab used for the treatment of breast cancer). Both patents were found to be invalid.

Genentech appealed the decision on the dosage regime patent (EP(UK)1210115) on the basis of an incorrect analysis of inventive step. In particular, Genentech argued that the High Court judge should not have accepted the evidence from Hospira's expert which concluded that the dosage regime was obvious.

The appeal was dismissed, as evidence from Hospira's expert was deemed to be both admissible and relevant for the assessment of inventive step.

Interestingly, Genentech has not appealed the decision on the purified composition.

Simon Bradbury

Spotlight on Pharmaceutical Patents

The Theory behind the Practice

For this edition of the ApplePip we asked Kate Hickinson, one of our pharmaceutical patent experts, to discuss what points need to be considered when obtaining patent protection in the pharmaceutical field.

Kate is an attorney who has experience of working both in private practice and in-house. She works in all areas of chemistry but has particular expertise in the pharmaceutical field after spending several years working as an in-house attorney at AstraZeneca. At AstraZeneca, Kate regularly worked alongside scientists and as an active member of multifunctional project teams, primarily in the areas of oncology, infection, respiratory and inflammation. Kate's role at AstraZeneca included drafting and prosecuting a wide range of patent applications. She advised project teams on what applications to file and when to file them.

Here is what Kate said:
"Patents are, of course, invaluable to the pharmaceutical industry. Without them, new medicinal products would not be invented, developed and marketed. It is therefore crucial that the correct filing strategy is implemented in order to maximise protection.

First Patent Filing
Typically, the first patent filing around a new medicinal product is directed to a chemical compound, often termed a new chemical entity (NCE). After selecting a target, a number of compounds may be identified as being active against that target and possibly worthy of patent protection. The question often arises as to whether to file a broad patent application at this early stage, or whether to delay the filing until a lead compound has been identified as a possible candidate drug following further optimisation work. Numerous factors need to be considered and ideally the whole team should be involved in making this decision.

Important factors to consider include the scope of relevant prior art (often identified by the inventor(s) themselves who are most familiar with the field of research and/or by prior art searches conducted with input from a patent attorney) and whether competitors are known to be working in the same technical area. In a crowded area, a narrow focussed filing is often the best option.
Another factor to consider is the project's plans for future work (including the timing of that work). If it is clear that the project has plans to make and test further compounds in the short term, then it may be advisable to delay the filing until there is a clear picture of which compounds have the best efficacy and what protection is most desirable.

Delayed First Filing
Delays in filing are however always a risk because competitors may file before you and new prior art can emerge. I once worked on a project where a (very important) patent application covering a candidate drug had been filed late one afternoon, closely followed the next day by a competitor's filing in the same area. Had we delayed filing that particular application, even by a few days, the likelihood of obtaining grant of a patent directed to the candidate drug would have been much reduced. However, filing too broadly and too early can cause problems too. It can be difficult to obtain grant of claims with a broad scope, especially across the wide range of countries in which pharmaceutical companies typically pursue patent protection. For example, some countries have strict requirements for all chemical groups within a genus to be represented in the examples. Others have strict requirements for biological data to be included in the application as filed for all exemplified compounds across the scope of the claim. If these requirements are not met, then grant of a broad claim scope in these countries will be impossible.

Broad vs. Narrow Scope
If a broad application is filed, but only a narrow claim scope is eventually granted, then much of the scope is effectively "lost". The broad disclosure is of course published and could be helpful in preventing competitors from obtaining patent protection in the area. However, the publication of the broad disclosure is also prior art against any further applications filed by the patentee and can cause problems for any future filings on related (perhaps more desirable) compounds.
Of course, each individual case needs careful consideration and input from team members, but generally, unless the field of chemistry is entirely new, my advice would be to file narrow, focussed application(s) once one or more lead compounds have been identified. Such a claim scope is likely to result in easier prosecution of the application, leading to reduced prosecution costs and can provide advantages in relation to the doctrine of "file wrapper estoppel" in the US (the US clearly being a likely candidate for patent litigation should a lead compound eventually make it to the market as a new medicinal product).

The story does not end with patent protection for chemical compounds per se and the team should be actively involved with effective patent lifecycle management following the filing of patent application(s) directed to the lead compound(s)."

Kate Hickinson

Hep C Nucleoside Prodrug Patent Knocked-Out

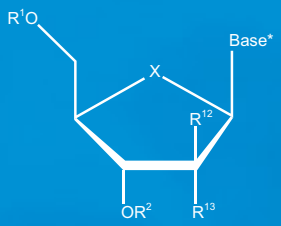
Idenix Pharmaceuticals Inc v Gilead Sciences Inc

Idenix claimed Gilead had infringed their Patent by the sale of Gilead's product sofosbuvir (Sovaldi). Gilead counterclaimed for revocation of the Idenix Patent. The Patent concerned nucleoside prodrugs for treating Flaviviridae viral infections (including chronic Hepatitis C) by the inhibition of RNA polymerase.

In a High Court decision on 1 December 2014 Idenix's Patent EP (UK) 1523489 was found to be invalid on the grounds of lack of novelty, lack of inventive step and insufficiency. If the claims had been valid, it was judged they would have been infringed by Gilead.

Claim 1

Claim 1 was directed to a compound of Formula (IX):



(IX)

or a pharmaceutically acceptable salt thereof, wherein:

R1 and R2 are independently H; phosphate; straight chained, branched or cyclic alkyl; acyl; CO-alkyl; CO-aryl; CO-alkoxyalkyl; CO-aryloxyalkyl; CO-substituted aryl; sulfonate ester; benzyl, wherein the phenyl group is optionally substituted with one or more substituents; alkylsulfonyl; arylsulfonyl; aralkylsulfonyl; a lipid; an amino acid; a carbohydrate; a peptide; or a cholesterol;

X is O;
Base* is a purine or pyrimidine base;
R12 is C(Y3)3;
Y3 is H; and
R13 is fluoro.

Novelty

All independent claims were found to lack novelty over an earlier PCT application filed by Gilead. But it was the findings in relation to inventive step and sufficiency which provided more cause for concern for pharmaceutical and biotechnology companies.

Inventive Step

Gilead argued that claim 1 of the Patent potentially covered trillions of compounds and that it was not plausible that all of these compounds would be effective against Flaviviridae. Technical experts called by Gilead and Idenix agreed on this point. Indeed even Idenix's own expert stated that some of the claimed compounds would not have been thought likely to have antiviral activity where the substituents R1 and R2 were either "straight chained, branched or cyclic alkyl" or "benzyl, wherein the phenyl group is optionally substituted with one or more substituents". Therefore the Judge concluded claim 1 lacked an inventive step because it covered compounds which made no technical contribution to the art.

For this reason Idenix applied to amend the claims of the Patent. Gilead contended that it was still not plausible that substantially all the compounds covered by proposed amended claim 1 would be effective against Flaviviridae. The Judge accepted this argument as there was no experimental data or rationale that the claimed compounds may be effective. It was also judged that nothing would be added to the common general knowledge of the skilled team and there would be no technical contribution to the art.

Even though Idenix successfully proved the claimed compounds were structurally similar to known active compounds and that the claimed compounds were worth testing this did not necessarily mean the compounds themselves were active nor were they any more worth testing than other nucleoside analogues in the relevant art.

There was also evidence that there would not necessarily be a positive result using the assays described in the Patent if the skilled team made and tested the claimed compounds and even if there was a positive result the skilled team would know this was not predictive of activity against other Flaviviridae.

Insufficiency

Gilead also alleged that it was not plausible for the skilled team to perform the invention without undue burden because it did not enable them to synthesise the nucleoside analogues claimed. In support of this Gilead provided a suitably qualified medicinal chemist who failed to make the claimed compounds despite prolonged effort and the assistance of eminent chemists. Idenix countered this by presenting experiments with a relatively accessible

route to achieve compounds of the claimed structure and argued this was within the common general knowledge of the skilled team. However, the Judge concluded that the specification did not enable the invention to be performed without undue burden because it did not disclose how to make the compounds nor gave them any real assistance in doing so.

Gilead also contended that the Patent did not allow the skilled team to perform the invention across the breadth of claim 1 without undue burden. Even if a nucleoside analogue was found to be active against one species of the Flaviviridae family the skilled team would still need to test its activity against other Flaviviridae. As claim 1 covers so many compounds this would mean a huge amount of work to select, synthesise and test the claimed compounds.

Infringement

Sofosbuvir was found to fall within Formula (IX) of the Idenix Patent as defined in claim 1. Sofosbuvir has a masked phosphate group which Idenix argued meant that it directly infringed claim 1. Gilead disputed that this masked phosphate group fell within the definition of "phosphate" as defined in claim 1. However the Judge disagreed and therefore concluded that, if the claims had been valid, sofosbuvir would have directly infringed the claims in question.

Conclusions

It seems that, in the UK at least, greater exemplification is now required to support broad claims which were once seen as valid and acceptable. Furthermore, if these broad claims are granted then they are much more vulnerable to attack for lacking inventive step or sufficiency. This will be a hard pill to swallow for the pharmaceutical and biotechnology industries as they are now being forced by new rules of the European Medicines Agency to disclose more clinical trial data earlier during the marketing authorisation application phase. This is pushing the filing of patent applications earlier so that the marketing authorisation applications don't prejudice patent protection.

Simon Bradbury & Alice Smart

Skinny Labelling

Divergent decisions in the National Courts of the UK and the Netherlands

Warner-Lambert Company, LLC v Actavis Group Ptc EHF & Others

The English Patent Court has refused an application made by Warner-Lambert for an interim injunction against Actavis in respect of their generic pregabalin drug, Lecaent.

Pregabalin is a drug sold by Warner-Lambert under the trade name Lyrica® and is authorised for the treatment of several conditions such as epilepsy, generalised anxiety disorder (GAD) and neuropathic pain. Patent protection for the product itself expired in 2013. However, Warner-Lambert have a second medical use patent, EP0934061, with Swiss-type claims directed towards the use of pregabalin for the preparation of a pharmaceutical composition for treating pain.

Therefore, although EP0934061 would be infringed by a generic company selling pregabalin for the treatment of pain, the generic company can in principle, launch a drug with a so-called 'skinny label'. This is an accompanying product leaflet that mentions only the permitted uses, i.e. excluding its use for the treatment of pain.

In view of this, Warner-Lambert were seeking a mandatory injunction forcing Actavis to take a series of steps to ensure that their generic drug, Lecaent®, is not dispensed for the treatment of pain; thus preserving their exculsive patented Lyrica pain market. Warner-Lambert requested that Actavis must ensure that any pharmacy entering into an oral or written agreement for the supply of Lecaent shall use "reasonable endeavours" not to dispense it for the treatment of pain and also, a requirement that each pack of Lecaent which is supplied must be accompanied by a notice stating that "this product is not authorised for the treatment of pain and must not be dispensed for such purposes".

In his decision, Mr Justice Arnold applied the principles as set out in American Cyanamid (i.e. is there a serious issue to be tried; where does the balance of convenience lie; and are there any special factors to consider?) He found that there was not a serious issue to be tried on the basis that Warner-Lambert did not have an arguable infringement case against Actavis. Furthermore, he concluded that even if there were an arguable case of infringement, an interim injunction should not be granted because the balance of convenience was in the favour of Actavis. On the latter issue, the Judge stated that granting relief "would create a greater risk of injustice than refusing it", considering that if an injunction was granted, pharmacists would be deterred from dispensing Lecaent for any treatment to the effect that Actavis may be excluded from the non-patent market.

This case raises several interesting issues, not least with regard to the interpretation of Swiss-type claims. On this subject, Mr Justice Arnold stated that "the word 'for' in Swiss type claims imports a requirement of subjective intention on the part of the manufacturer that the medicament or pharmaceutical composition will be used for treating the specified condition". The Judge therefore concluded that there was no serious issue to be tried because the sales which were planned by Actavis would not infringe EP0934061.

Warner-Lambert have appealed the decision and a full trial will take place in June 2015.

Novartis AG v Sun Pharmaceutical Industries BV

In a similar case, the Dutch Court of Appeal have issued a decision granting an injunction to Novartis against Sun Pharmaceuticals. The case concerns Novartis' patent, EP1296689, which includes the following Swiss-type claims:

5. Use of [zoledronic] acid, or a pharmaceutically acceptable salt thereof, or any hydrate thereof for the preparation of a medicament for the treatment of osteoporosis wherein said medicament is adapted for intravenous administration in a unit dosage form which comprises from about 1 up to about 10 mg of [zoledronic] acid, or a pharmaceutically acceptable salt thereof, or any hydrate thereof, wherein the period between administrations of bisphosphonate is at least about 6 months.

7. Use according to claim 5, wherein the unit dosage form comprises from about 2 up to about 10 mg and the period between administrations is about once a year.

Sun Pharmaceuticals were marketing zoledronic acid in an identical dosage form but it was approved only for use in Paget's disease (a chronic disorder that can result in enlarged and misshapen bones). Paget's disease is not covered by EP 1,296,689. However, Novartis claimed that the marketing of zoledronic acid by Sun Pharmaceuticals nevertheless amounted to indirect infringement of their patent.

In the decision, the Court of Appeal granted Novartis an injunction on the basis of "the justified interest of Novartis to act against indirect infringement of its patent rights". Sun Pharmaceuticals were therefore forbidden "with immediate effect…to commit indirect infringement of (the Dutch part of) EP1296689 on pain of penalty of an immediately eligible penalty".

This case is interesting in that it goes against not only one, but two decisions from the UK Courts.

Firstly, EP1296689 was previously held to be invalid by the UK Courts on the basis of lack of novelty as a result of an invalid priority right. In this regard, the Dutch Court of Appeal stated that "departing from the said criterion the Court of Appeal, other than the judge in summary proceedings and the English High Court and Court of Appeal, partly because of different insights (more in particular after reading of the priority document) and partly because of other arguments of parties…is for the time being of the opinion that Novartis is entitled to priority.

Secondly, the decision appears to be in contrast to Mr Justice Arnold's ruling in the Warner-Lambert Company versus Actavis case (discussed above), where Actavis were allowed to launch pregabalin with a 'skinny label'. However, it should be borne in mind that there are several factual differences between the cases. In particular, Sun Pharmaceuticals had won a tender to be the exclusive supplier of unlimited amounts of zoledronic acid for the healthcare insurer VGZ irrespective of the treatment that it would be used for, i.e. the intended uses were not necessarily limited to exclude osteoporosis. In contrast, the Judge in the UK ruled that the sales which were planned by Actavis were not intended to infringe Warner-Lambert's patent. Therefore, on closer inspection of the facts of the individual cases, the decisions may not be as divergent as they initially appear.

Sarah Dobson

SPC Update

Arne Forsgren v Austrian Patent Office

This was a referral to the Court of Justice of the European Union (CJEU) from the Austrian Patent Office on the question of whether a Supplementary Protection Certificate (SPC) could be obtained for a product in free form when the marketing authorisation was for a medicine in which the product is covalently bonded to other ingredients, and whether the SPC could rely on a marketing authorisation which only described the product as an inert 'carrier protein' and did not provide any information about a further therapeutic effect.

Background

SPCs have long been a topic of case law due to the brief nature of the regulation that governs them. There have been decisions on combination products, specific formulations, ownership of marketing authorisations and component pharmaceutical ingredients themselves. There are even diversions between decisions relating to the plant and agrochemical SPC regulation and the pharmaceutical SPC regulation, especially in relation to whether other component ingredients of a formulation may be protected under an SPC in their own right.

What does the Synflorix Market Authorisation Cover?

In the present case, European patent EP0594610 held by Forsgren covers the biologic 'Protein D' and describes its use in a vaccine against Haemophilus influenzae. Forsgren applied for an SPC in Austria for Protein D based on a separate marketing authorisation held by GlaxoSmithKline. The GSK marketing authorisation relates to Synflorix® which is a vaccine against conditions caused by Streptococcus pneumonia and contains polysaccharides covalently bonded to Protein D. Protein D in such a formulation is only acting as an inert component.

Forsgren argued that even though the GSK marketing authorisation did not mention the effects of Protein D alone, it would necessarily provide a vaccine against Haemophilus influenza, as well as performing its other role as an inert component in the Synflorix product. Furthermore, Forsgren argued that the SPC regulations do not require the marketing authorization to refer to the therapeutic activity of the product. It is indeed the case that the SPC regulation does not require the marketing authorisation to disclose the various activities of a substance considered to be an active ingredient in the product.

Covalently Bonded Carrier v Carrier *per se*

The Austrian court submitted that the covalently bound Protein D in Synflorix is not the same as the free Protein D in the Forsgren product and as such could not be regarded as the same product as that of the GSK marketing authorisation. They argued that a new marketing authorization for the free protein D should be required, and that it cannot be right to assume that the protein D is having a therapeutic effect in the Synflorix product when it is only described as an inert component.

The CJEU decided, under pressure from the European Commission to simplify the SPC procedure, that the matter of whether the active ingredient is covalently bonded or free is not an obstruction to obtaining an SPC. However, it also decided that an active ingredient of an SPC must produce 'a pharmacological, immunological or metabolic action of its own which is covered by the therapeutic indications of the marketing authorisation'. On this basis, it seems that the GSK marketing authorisation does not provide a basis for the Forsgren SPC because the pharmacological action Forsgren claim to be present is not indicated in the marketing authorisation.

Conclusions

The CJEU has left it for the Austrian Court to determine this matter. It seems likely that Forsgren will argue that the GSK marketing authorisation is in fact indicating that protein D is an adjuvant in the Synflorix product and that therefore it has a pharmacological action of its own, as well as the further effect as a vaccine now discovered by Forsgren.

Ellie Purnell

International Stem Cell Corporation v Comptroller General of Patents

Following the referral from the UK Patents Court on the question of whether unfertilised human ova whose division and further development have been stimulated by parthenogenesis are patentable, or excluded from patentability (as they could be considered to be a "human embryo" under Article 6(2)(c) of the EU Directive on Biotechnological Inventions), the CJEU has now issued a preliminary ruling on the matter.

As reported in the previous edition of ApplePip, the Advocate General's preliminary opinion was that an unfertilised human ovum which had been stimulated by parthenogenesis was patentable provided that the parthenote cannot, or is not manipulated to, develop further embryonically.

CJEU Statement

In a press statement on 17th December 2015, the CJEU confirmed that, 'an organism which is incapable of developing into a human being does not constitute a human embryo within the meaning of the Directive'. The court has elaborated that the mere fact that a parthenogenetically formed human ovum commences a process of development does not mean that it must always be considered to be a human embryo.

Background

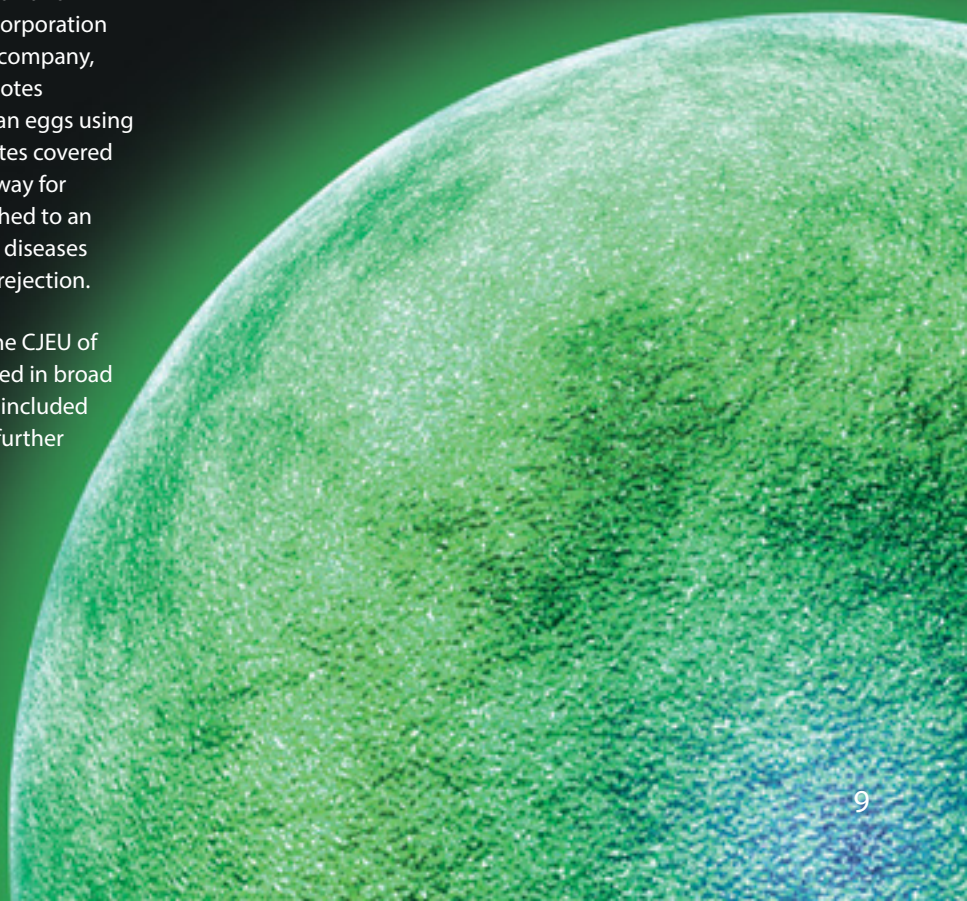
By way of background, parthenogenesis is an artificial process of stimulating an unfertilized human ovum into beginning development by mimicking the action of normal fertilisation using electrical stimulation and calcium treatment. International Stem Cell Corporation (ISCC), a California-based stem cell research company, were the first to intentionally create parthenotes containing stem cells from unfertilized human eggs using parthenogenesis. The process and parthenotes covered by the ISCC patent applications may offer a way for creating stem cells that are genetically matched to an individual for the treatment of degenerative diseases without the significant problem of immune rejection.

This case follows the landmark decision of the CJEU of Brustle vs. Greenpeace in which it was decided in broad terms that the concept of a 'human embryo' included unfertilised human ova whose division and further development have been stimulated by parthenogenesis, since such ova are, just like embryos created by fertilisation of an ovum, capable of commencing the process of development of a human being.

In the present case, the High Court had already determined that the parthenotes of the ISCC applications actually do not have the capacity to develop into human beings because they consist, in contrast to fertilised ova, only of pluripotent stem cells and are incapable of developing into human beings. It is therefore expected that the ISCC applications will now be allowed to proceed, and that the UKIPO will continue their examination.

Accordingly this preliminary ruling of the CJEU gives some encouragement to stem cell research for overcoming the problematic judgement of Brűstle.

Ellie Purnell



Indian Patent Office continues to reject pharmaceutical variants

Last year saw a number of decisions in India which continued to make it harder to obtain and enforce pharmaceutical patents in India. In the most recent decision of the Indian Patent Office on pharmaceutical variants or analogues, a patent application for protection of Gilead's Sovaldi® vaccine for hepatitis C became one of several now refused under the rather obscure section 3(d) of the Indian Patents Act.

Improved Efficacy

The relevant section 3(d) reads as follows:
"The following are not inventions…
…the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant…"

In effect, this means that chemical structures that have been only slightly altered by, for example, the formation of the ester, ether, salt, isomer, or a complex of a known chemical structure are not patentable unless they show significant improvements in efficacy. This can even apply to combinations or mixtures of known chemicals or isomers thereof. Such variants and combinations are typically the subject of secondary patents filed by pharmaceutical companies around an originator drug, and are prevalent in most other patent filing territories in the world. It is clear that the aim of this section, which was introduced into Indian law in 2005, is to prevent such evergreening of patent protection on drugs with no real contribution to the art over the originator.

In the present decision, the invention in question was already decided to be novel and to have an inventive step. However the Indian Patent Office still rejected Gilead's application stating that the hepatitis C vaccine was only a stereoisomer of a previously known drug and that therefore Gilead would have to show significant improvements in efficacy. Gilead had provided data showing that the new isomer had reduced cytotoxicity. However, the Patent Office decided that this was not showing improved therapeutic efficacy and therefore refused the patent application.

Conclusions

This seemingly unfair rejection follows similar cases involving patent applications to developments of originator drugs where data has been provided to show various qualities such as improved cytotoxicity, bioavailability, solubility, and stability but still have not been accepted by the Indian Patent Office as showing improved 'efficacy' as such. It is unclear exactly what is required to satisfy this requirement, and what is regarded as falling under improved efficacy. Some have speculated that clinical trials data may be required, or a direct comparison of the drug with the prior art drugs. In any case, pharmaceutical companies may have to rethink what data they need to include in their Indian patent applications, and consider providing further detailed examples and an explanation of how 'improved efficacy' is demonstrated.

Ellie Purnell

Patent Protection in Morocco via the EPO

Morocco has become the first country outside of the European continent to allow validation (effectively "extension") of a European patent in its territory.

Since 1st March 2015, anyone filing a European patent application can request validation for Morocco against the payment of a fee. European applications and patents validated for Morocco will have the same legal effects there as national Moroccan patents and will be subject to Moroccan patent law.

Simon Bradbury

Future Events

2015 BIO International Convention

June 15-18
Philadelphia, USA

This year, the BIO International Convention is heading to the heart of the U.S. biopharma industry in Philadelphia and so are our attorneys. Our BIO 'regulars', Simon Bradbury and Ellie Purnell, will be there and if you are planning to attend and would like to meet up please drop them a line!

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