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Warner-Lambert v Actavis – further guidance on infringement of second medical use claims

In the full trial of **Warner-Lambert v Actavis**, the High Court of England and Wales has ruled that Warner-Lambert's patent directed to pregabalin for treating pain is invalid, but in any event, is not infringed by the manufacture and supply by Actavis of its generic product, Lecaent. Importantly, the judgment provides guidance as to how infringement of Swiss-type second medical use claims should be assessed.

To recap, Warner-Lambert markets pregabalin under the trade name Lyrica for the treatment of epilepsy, generalised anxiety disorder (GAD) and neuropathic pain. Basic patent protection for pregabalin has expired leaving Warner-Lambert's patent, EP0934061 (the Patent), as the only barrier to generic companies. Generics UK Ltd. (trading as Mylan) and Actavis challenged the validity of the Patent in 2014. Then, after learning of Actavis' intended launch of Lecaent, Warner-Lambert counterclaimed for infringement. Actavis subsequently launched Lecaent in February with a "skinny label" limited to the non-patented indications of epilepsy and GAD.

The recent judgment is the decision in the combined revocation and infringement actions. Although the Patent was held to be invalid for lack of sufficiency, both the direct and indirect infringement claims were considered at trial. With regard to direct infringement, the Swiss-type claims of the Patent were construed in accordance with the **Court of Appeal's judgment** of June this year, in which it was stated that:

> *"In my judgment, therefore, the skilled person would understand that the patentee was using the word 'for' in the claim to require that the manufacturer knows (in the above sense) or can reasonably foresee the ultimate intentional use for pain, not that he have that specific intention or desire himself."*

In light of the above, the question considered by the High Court was whether it was foreseeable to Actavis that, in cases where the prescription indicated that generic pregabalin had been prescribed for pain (only 5%), the pharmacist would dispense Lecaent despite the fact that it was not licensed for pain. It was concluded that the answer to this question was "*no*" save for a small number of exceptional cases. One of the main justifications for this conclusion was Actavis' decision to notify superintendent pharmacists before launch of Lecaent that it was not licensed for the treatment of pain. Therefore, Actavis' activities did not amount to direct infringement of the Patent.

With regard to the indirect infringement claim, this claim was swiftly dismissed on the basis that there was no act of manufacture by any party downstream of Actavis. It was concluded that, for the Swiss-type claim of the Patent, the invention had already been put into effect or was not put

AUTUMN ISSUE

News from the Biotech team

> The Biotech team welcomes **Nadia Tyler-Rubinstein** to the team as a trainee in the London Office. Nadia recently received a PhD from the Clinical Sciences Centre of Imperial College London.

> Later this month, **Claire Baldock**, Head of the Biotech team, will be attending the annual **AIPPI World Congress in Rio de Janeiro**. Claire is Chair of the Biotechnology sub-committee, and will be actively involved in debating this year's AIPPI working questions as a Standing delegate representing AIPPI UK.

> **Matthew Spencer** and **James Legg** will be hosting a workshop entitled ***"A Case Study Based Guide to Freedom to Operate – Navigating the CRISPR-Cas Patent Landscape"*** at the Festival of Genomics in California on 3 November 2015. Please do not hesitate to contact Matthew or James if you would like to meet them at this event.

> **Nina White** will be travelling to Israel in November to visit a number of patent attorney firms in the country. Please contact Nina if you would be interested in speaking to her about her trip.

> The Biotech team would like to congratulate **Ed Ronan** who passed the European Qualifying Examination this summer, and is now qualified as a UK and European Patent Attorney. Earlier this year, Ed was also awarded the Strode Prize for achieving the highest mark in the P2 UK Finals paper.

into effect at all after it left Actavis' hands. As such, there was no indirect infringement. Given the manufacturing step included in Swiss-type claims, it seems likely that this same reasoning would not apply to EPC2000 second medical use claims.

For more information on this case, see our full bulletin **here**.

Nagoya Protocol provisions come into force on 12 October 2015

The Nagoya Protocol is an international treaty that implements the third objective of the **Convention on Biological Diversity**, namely the fair and equitable sharing of benefits arising from the utilisation of genetic resources. The Protocol establishes a legally binding framework determining how researchers and companies who use genetic resources or traditional knowledge associated with genetic resources obtain access to those resources. The Protocol further details how any benefits from using the genetic resources will be shared.

EU Regulation No. 511/2014 was passed to implement mandatory elements of the Nagoya Protocol for the European Union and came into effect on 12 October 2014. However, some of the key provisions of the EU Regulation, in particular Articles 4, 7 and 9, only take effect after one year and hence shall apply from 12 October 2015.

From this date, all users of genetic resources (e.g. institutes/universities/companies conducting R&D on the genetic and/or biochemical composition of genetic resources) are required to perform due diligence to confirm that the genetic resources have been accessed in an appropriate manner and in line with benefit-sharing legislation (Article 4). Primarily this is expected to be achieved by obtaining an International Certificate of Compliance via a dedicated clearing house system, although other possibilities exist such as obtaining the genetic resource from the European Commission's register of collections (not yet established). Due diligence documentation must also be retained for a period of 20 years after the period of utilisation has ended.

User compliance with the new due diligence process shall also be monitored going forward. A user, for example, that receives research funding or advances a product to the final stage of development will have to declare that they have exercised due diligence (Article 7). Also, competent authorities have new powers to carry out checks to verify that users have met their obligations (Article 9). The competent authority in the UK for enforcing the legislation will be the National Measurement and Regulation Office.

Penalties will apply to users that contravene these new provisions, with implementation and enforcement falling under the remit of the EU Member States. **The Nagoya Protocol (Compliance) Regulations 2015 (2015/821)** were passed to fulfil the UK's obligations and these outline primarily civil but also criminal sanctions for non-compliance with certain provisions. Civil sanctions include the imposition of a compliance notice requiring a user to take any necessary steps to comply, and the issuance of a stop notice prohibiting a user from carrying on their activities, such as placing a product on the market. Criminal sanctions mainly relate to a failure to comply with the above-mentioned notices and include fines and imprisonment. A criminal sanction is also specified in relation to the retention of due diligence documentation with failure to keep documents for the full 20 year period resulting in a fine up to £5,000. These penalty provisions in the UK Regulation also come into effect on 12 October 2015.

For further information about the Nagoya Protocol or the provisions coming into effect this month, please do not hesitate to contact a member of the Boults **Biotechnology and Life Sciences team**.

NEWS RELATING TO THE UNIFIED PATENT COURT

The Unified Patent Court (UPC), once in existence, will represent a significant change to patent litigation in Europe. The UPC will be a new court, which will have jurisdiction over 25 EU member states regarding litigation of "Unitary Patents" and all existing European Patents that have not opted-out of the system.

Although there is still some uncertainty as to when the UPC will enter into force, there have been some interesting developments in recent months.

- In August, the Intellectual Property Office announced that the London section of the Central Division and the UK Local Division of the UPC will be based at Aldgate Tower.
- In September, the Preparatory Committee of the UPC agreed the court's Rules of Procedure relating to representation rights before the UPC (see **here**). Importantly, the transitional provisions ensure that for a period of one year after the entry into force of the UPC Agreement, it will be possible for UK patent attorneys having certain national qualifications to apply to the Registrar for entry on the list of entitled representatives.
- On 1 October, a **Protocol to the UPC Agreement** was finalised, which will allow certain aspects of the UPC Agreement to be applied early. This includes the registration of opt-outs, which will now be possible during the provisional application phase. The Protocol is intended to facilitate opening of the UPC at the start of 2017.

In light of these developments, the patent attorneys at Boults will be well placed to assist those seeking to obtain and enforce European patents under the new system. We look forward to the challenges ahead!

If you have any queries or require any further information relating to the Unitary Patent or the UPC, please do not hesitate to contact a member of the Biotech team or your usual Boults adviser.

Essentially Biological Products – EPO decides on Broccoli and Tomato II

The Enlarged Board of Appeal (EBA) at the EPO has decided that plant products produced by "essentially biological processes" (for example, sexual crossing) are eligible to be patented.

The EBA had previously decided in **G2/07** and **G1/08** (the so-called Broccoli I and Tomato I decisions) that a claim to a *method* which included as a step an "essentially biological process" could be excluded from patent eligibility by A. 53(b) EPC, even if it included other technical steps.

In referrals **G2/13** and **G2/12** – the so-called Broccoli II and Tomato II referrals – the EBA was asked whether the same provision also excluded from patent eligibility those plant *products* produced by essentially biological processes. The EBA has now concluded that the exclusion of essentially biological processes from patentability should not be understood to exclude plant *products* from patent eligibility. This is the case even if the product claimed can only be produced by such an essentially biological process, or if the product is defined by the essentially biological process used to produce it.

Please click **here** for full bulletin

Indirect infringement confirmed in Actavis v Lilly appeal, but no weight given to prosecution history

Last year we reported that the High Court of England and Wales had ruled that Actavis UK Ltd would not infringe Eli Lilly & Company's European patent EP1313508 by launching a generic pemetrexed product. In that Decision, Mr Justice Arnold construed the claims using the prosecution history and concluded that claims directed to pemetrexed disodium in combination with vitamin B12 excluded any one of the active ingredients pemetrexed diacid, dipotassium or ditromethamine, which Actavis were seeking to launch (see **here**). The Court of Appeal has now confirmed that pemetrexed disodium would not constitute a direct infringement of Lilly's claims, but has dismissed the weight given to the prosecution history by Mr Justice Arnold at First Instance. Further, in a Decision contrary to the First Instance Decision, the Court of Appeal has concluded that there would be indirect infringement and declined to issue a declaration of non-infringement relating to direct infringement alone (see **Actavis UK Limited & Ors v Eli Lilly & Company [2015] EWCA 555 (Civ)**).

Please click **here** for full bulletin

We've listened to what our clients told us. Now we're acting on it

We know that it makes business sense to get to know our customers and to build our services around their needs. For us, our service is about people, not just IP. That means responding to our clients with commercial understanding as well as technical and legal expertise if we are to guide them to the best solution for their needs. We want people to choose Boult Wade Tennant and stay with us because they know we will work with them, not just for them.

To strengthen our understanding of what excellent service means to our clients and to ensure we are well placed to respond to changing client needs, we have invested in a programme of client research, conducted by an independent agency. This research has measured our service against those indicators that really matter to our clients and has, for the first time, allowed us to accurately benchmark ourselves against competitors in our sector. You're invited to read our **Client Feedback Report**.

> Missed the last edition of boult.bites Biotech? Catch up by clicking **here**

We aim to work with our clients, not just for them

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