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The ten minute read that highlights topical issues for bio and life science sector participants

Spotlight on second medical use claims

Claims directed to new therapeutic uses of known compounds, so-called second medical use claims, have been accepted by the European Patent Office for over 30 years. It has been widely recognised that the granting of second medical use patents incentivises important medical research. However, a great deal of uncertainty surrounds the enforcement of such patents, which creates problems for pharmaceutical companies and generics manufacturers alike.

As reported in our **November newsletter**, this topic was debated internationally at the AIPPI World Congress in Toronto last autumn. This led to the adoption of an **AIPPI Resolution**, the purpose of which is to seek harmonisation of the laws governing second medical use patenting and enforcement around the world. As part of this debate **Claire Baldock**, Head of the Biotechnology team at Boult Wade Tennant, led the AIPPI UK Working Committee in preparing a report summarising the current status of second medical use patenting in the UK (see **here**).

The start of 2015 has seen second medical use claims back in the spotlight as a result of a dispute in the UK courts between Warner-Lambert (part of the Pfizer Group) and Actavis over the drug pregabalin. The Hague Court of Appeal has also recently ruled on a dispute between Novartis and Sun Pharmaceuticals relating to generic supply of zoledronic acid. These cases are two of the first to provide important insights into how courts in Europe will tackle the difficulties in this area.

There are two key problems associated with enforcement of second medical use claims. First, such claims cannot be treated simply as claims to products or processes *per se*. Swiss-form second medical use claims (*Use of substance X for the manufacture of a medicament for the treatment of disease Y*) may be regarded as purpose-limited process claims whilst EPC2000 claims (*Substance X for use in the treatment of disease Y*) are purpose-limited product claims. In the UK, direct infringement is typically absolute such that the knowledge or intention of any alleged infringer is irrelevant. This same approach clearly cannot be applied to claims limited by purpose. The second problem stems from current prescribing and dispensing practices for prescription drugs. In the UK, the vast majority of prescriptions are written generically (with reference to the international non-proprietary name or INN) and do not state the indication for which the drug has been prescribed. This means that pharmacists typically do not know whether they are dispensing a drug for a patented or non-patented indication and therefore may simply dispense the generic version of a drug for all indications even where second medical use patents exist.

Continued

SPRING ISSUE

News from the Biotech team

> The Boults' Biotech team will be attending two key events in this year's conference calendar: **BioTrinity 2015**, the leading European Biopartnering and Investment Conference, to be held in London from 11-13 May; and the **PraxisUnico Conference** to be held in Dublin from 10-12 June. If you would like to arrange to meet one of our team at either of these events, please do not hesitate to contact us.

> Senior Partner **Claire Baldock** has been elected to UK Counsel of AIPPI and is looking forward to contributing to the group's activities in addition to her role chairing the International AIPPI Biotechnology Committee.

> **Dr James Legg**, based in our Cambridge office, will be speaking at the Antibody Drug Conjugate conference taking place on 18-19 May in London. The conference will focus on recent technical developments in relation to Antibody Drug Conjugate (ADC) therapeutics, and will be attended by leading individuals from academia, biotech and pharma. For more information, see **here**.

> And finally, Boults' Biotech team has been celebrating yet more exam success with **Naomi Stevens** and **Edward Ronan** passing UK Finals examinations this Spring. We would also like to congratulate **David Wortley** who has successfully passed the Queen Mary Certificate in Intellectual Property Law.

The UK judgments – Warner-Lambert v Actavis: The patent at issue in the proceedings between Warner-Lambert and Actavis includes a Swiss-form claim directed to pregabalin for treating neuropathic pain. Pregabalin (marketed by Warner-Lambert as Lyrica) is also indicated for the treatment of epilepsy and generalised anxiety disorder (GAD) and Actavis has obtained a marketing authorisation for the use of generic pregabalin (Lecaent) for these non-patented indications. Warner-Lambert has alleged that Actavis' supply of generic pregabalin will infringe their patent, notwithstanding the 'skinny labelling' to be applied to Actavis' product restricting its use to epilepsy and GAD. Since the start of 2015, Arnold J has handed down three judgments which have addressed both of the difficulties noted above. The first judgment considered in particular the interpretation of Swiss-form claims and concluded that: *"the word "for" in Swiss-form 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"*. In the third judgment, Arnold J ordered NHS England to issue guidance stating that pregabalin should only be prescribed for the treatment of neuropathic pain under the brand name Lyrica. This Order by the High Court follows a significant effort on the part of Warner-Lambert to urge the relevant authorities in the UK to prescribe pregabalin for pain by reference to Lyrica specifically.

The Dutch judgment – Novartis v Sun Pharmaceuticals: In the decision handed down by the Hague Court of Appeal, Sun Pharmaceuticals were held to indirectly infringe Novartis' Swiss-form claim covering the use of zoledronic acid for treating osteoporosis. Sun Pharmaceuticals' generic zoledronic acid was held to infringe despite there being a legitimate market for using the generic product to treat Paget's disease. In Arnold J's second UK judgment, he commented on the somewhat divergent conclusions of the Dutch court and noted in particular that the Swiss-form claim in Novartis' Patent had been interpreted as a product claim and that there had been a failure to discuss the meaning of the words "for treating" or the mental element which these words import.

Are things any clearer? It is still early days but the recent judgments represent an important step forward in this difficult field. The differing interpretation of Swiss-form claims by the UK and Dutch courts highlights the difficulties associated with this claim format. Indeed, where Novartis succeeded with their claim of indirect infringement in The Netherlands, Arnold J did not consider Warner-Lambert's claim for indirect infringement to be appropriate on the basis that no one further down the supply chain would prepare a medicament using the Lecaent supplied by Actavis. Arnold J's strict interpretation of Swiss-form claims also appears to run contrary to the approach taken in other High Court judgments, in which we have seen a willingness for Swiss-form claims to be treated as equivalent to EPC2000 claims (see our previous comments on this topic **here**). Whether the focus on the manufacturer's intention will be equally applicable to EPC2000 claims remains to be seen. As to the changes in prescribing practice for pregabalin ordered by the UK High Court, this clearly represents an interesting practical solution to the problem of generic pregabalin being dispensed for the patented indication. However, as detailed in the AIPPI UK report on this topic (see **here**), it would seem that more fundamental changes to prescribing and dispensing practices may be advantageous in achieving the transparency needed to determine infringement of second medical use claims. There is clearly a great deal still to be achieved to bring certainty to this field.

NEWS FROM THE EPO AND BEYOND

The Enlarged Board of Appeal at the EPO has recently issued the following decisions:

1. In conjoined decisions **G2/12** and **G2/13** (colloquially referred to as Tomatoes II and Broccoli II, respectively), the EPO has confirmed that product claims directed to plants or plant material produced by an essentially biological process are not excluded from patentability, even though Article 53(b) EPC excludes *"essentially biological processes for the production of plants"*. In decisions unanimously welcomed by all parties, the Enlarged Board confirmed that such product claims would be permitted provided the product *per se* is both novel and inventive.

2. In decision **G3/14**, the EPO has addressed the issue of to what extent the clarity of amended claims can be challenged during post-grant proceedings before the EPO. Clarity is not a ground of opposition; however, once claims are amended during opposition proceedings, the amended claims must be assessed to determine whether they meet all requirements of the EPC. With regard to clarity, the Enlarged Board has confirmed that this assessment should be limited such that clarity is considered only when, and then only to the extent that the amendment introduces non-compliance with Article 84 EPC.

The UK Intellectual Property Office has recently published a **Practice Notice** relating to inventions involving human embryonic stem cells. This Notice has been updated to include the CJEU's decision, **C-364/13**, which ruled that an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis does not fall within the definition of a 'human embryo' according to Article 6(2)(c) of the Biotech Directive. The implications of this CJEU Referral are discussed in more detail in our bulletin **here**.

HEADLINE ARTICLES

English Patents Court Judgment provides guidance on the scope of second medical use claims

In an important judgment for the interpretation of second medical use claims in the UK, Mr Justice Arnold refused a request by Warner-Lambert for an interim injunction against Actavis in relation to its plans to launch a generic version of the drug pregabalin (**Warner-Lambert v Actavis [2015] EWHC 72 (Pat)**). The request was based on Warner-Lambert's claim that Actavis would infringe its second medical use patent directed to pregabalin for treating pain. In refusing the request for interim relief, Arnold J held that the case did not raise a "serious issue to be tried". This judgment provides some much needed clarity in relation to the scope of protection conferred by second medical use claims.

Please click **here** for full bulletin

CJEU confirms that mere carrier proteins are not active ingredients in the context of SPCs

The Court of Justice of the European Union (CJEU) has recently handed down yet another judgment (**C-631/13**), which seeks to clarify what can, and cannot, be protected under EC Regulation No 469/2009 (the SPC Regulation). Here the CJEU has decided that an SPC may be granted for an active ingredient covalently bound to another substance only if the active ingredient for which supplementary protection is sought has a therapeutic effect covered by the wording of the marketing authorisation.

Please click **here** for full bulletin

Hospira successfully challenge further Herceptin® follow-on patents

In April 2014 we reported on the outcome of a dispute between Hospira UK Limited and Genentech Inc. The court battles have continued between these two parties with Hospira seeking revocation of two further Genentech follow-on patents in order to clear their way to market biosimilar lyophilised Trastuzumab. In November 2014 the UK High Court handed down its judgment deciding in favour of Hospira, revoking one of the patents in dispute and ordering amendment of the second patent to delete the challenged subject matter (see **here** for the full judgment).

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**

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

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