boult
BOULT WADE TENNANT

Boult.bites Biotech

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

What is "plausible" in patent law?

The concept of "plausibility" is at the heart of several of the statutory requirements to patentability including inventive step, sufficiency and industrial applicability. It is an issue frequently discussed at length in decisions of both the European Patent Office (EPO) and UK courts, and many patents stand or fall based on what has been made "plausible" in the application as filed.

For example, inventive step relies on the existence of a technical effect exhibited by the claimed subject matter. However, a technical effect that is not rendered plausible by the patent specification may not be taken into consideration. In addition, it is clear from both EPO and UK decisions that post-filed data may only be cited to support a technical effect which is made plausible in the application as filed (see **T1329/04** and ***Generics v Yeda*** **[2013] EWCA Civ 925**).

Discussion of plausibility also crops up regularly in the consideration of sufficiency of disclosure for second medical use claims. A leading EPO Board of Appeal decision in this area is **T609/02**, in which it was held that to meet the requirements of sufficiency the application must disclose the suitability of the product for the claimed therapeutic application. Put another way, the use needs to be made plausible by the application as filed. This principle was approved by the English Court of Appeal in ***Regeneron v Genentech*** **[2013] EWCA Civ 93**.

In two recent Biotech cases, the English High Court has been required to take an in-depth look at the issue of plausibility as it relates to second medical use claims, and importantly has considered the standard or threshold to be applied in determining whether something is indeed plausibly shown or not. It would appear from these decisions that the bar may be set differently depending upon the particular context.

Actavis v Eli Lilly **[2015] EWHC 3294 (Pat)** – In this action for revocation, the patent at issue (EP(UK)0721777) included a Swiss-form second medical use claim directed to tomoxetine for treating attention-deficit/hyperactivity disorder (ADHD). The patent was held to meet the requirements of inventive step on the basis that it was not obvious from the prior art to try tomoxetine for the treatment of ADHD and the skilled team would not have had a fair expectation that this compound would be effective for this disease. Turning to sufficiency, the claimant Actavis argued that the test for plausibility in the context of sufficiency should be the same as the "reasonable expectation of success" for obviousness and as such, the patent was insufficient. In this regard, it should be noted that the patent (only being 4 pages long!) did not include any examples or data beyond those described in the cited literature. Lilly argued in relation to sufficiency that the hurdle for plausibility must be lower than obviousness and suggested that the test for plausibility is merely a filter to stop purely speculative patents. In finding in Lilly's favour, the judge noted that the policy considerations underlying plausibility for sufficiency are different from those underlying fair expectation of success for obviousness and concluded that the standard is not the same for each. In relation to sufficiency, it was further stated that the plausibility test is a threshold test which is satisfied by a disclosure which is "credible" as opposed to "speculative".

cont'd...

SPRING ISSUE

News from the Biotech team

> Boult Wade Tennant has recently launched a new website. To find out more about our top tier Biotechnology and Life Sciences Group, including the experience and work highlights of members of the team, see **here**.

> **Claire Baldock** and **Joanna Peak** will be attending the **BIO International Convention in San Francisco** from 6-9 June 2016. BIO is one of the world's largest biotech conferences with delegates attending from across the globe. If you would like to arrange to meet Claire and Joanna at BIO, please do not hesitate to contact us.

> **Matthew Spencer** has recently authored a publication titled: **"Considering the implications of a Brexit for UK and European patent attorneys"**. Although the UK will hold a referendum on 23 June 2016 to determine whether the UK will remain a member of the European Union, there are two important things to note. First, the UK will remain a member of the European Patent Convention irrespective of the outcome of the referendum and as such, the attorneys at Boult Wade Tennant will remain eligible to represent clients in all proceedings before the EPO. Secondly, the outcome of the referendum should not affect the UPC Agreement; when the Unified Patent Court comes into affect (currently expected in early 2017) the attorneys at Boult Wade Tennant will be able to represent clients in the various branches of the UPC.

cont'd...

***Merck v Ono* [2015] EWHC 2973 (Pat)** - In this case, the patent at issue (EP(UK)1537878) included second medical use claims directed to an anti-PD1 antibody for use in cancer treatment. In considering the issue of plausibility, the judge referenced the discussion set out by the Supreme Court in ***HGS v Eli Lilly* [2011] UKSC 51**, distinguishing "plausible", "reasonably credible" or an "educated guess" on one side from what was "speculation" on the other. Rather, plausibility conveyed that "there must be some real reason for supposing the statement is true". The judge then provided guidance on how to apply the concept of "plausibility" when considering second medical use claims; specifically, that (i) the experimental data in a patent application should make it plausible that the agent being claimed will have a similar effect to that observed in the data if the agent is not being tested directly, and (ii) that it is plausible that the effect observed is applicable across the breadth of the claimed therapeutic applications. What is necessary to pass this assessment will strongly depend on the facts of the case. This was demonstrated in the decision, in which the data in the patent were held to make the claim plausible whereas the prior art was found non-enabling, despite neither the patent nor the prior art exemplifying the claimed antibody in cancer treatment. For a more detailed discussion of this decision, see **here**.

There will undoubtedly be decisions that follow these two recent judgments that continue to debate the issue of plausibility. However for now, it would appear that context is all important. As evidenced by the *Actavis v Eli Lilly* case, it may be possible to avoid a "squeeze" between obviousness and insufficiency without experimental data, taking into account the teaching of the specification and common general knowledge. That said, we would strongly recommend including data to support a therapeutic use in any new patent filing and as evidenced by *Merck v Ono*, data can be crucial in tipping over the plausibility threshold, even if that bar is set low.

> We continue to report on progress concerning the launch of the Unified Patent Court. **Naomi Stevens** has authored a publication titled "**Unified Patent Court fees and recoverable costs**", which provides important information about the recently-published rules on UPC court fees. For more information about the Unitary Patent and the UPC, see **here**.

> Members of the Biotech team will be giving a number of presentations during April. In particular, **Naomi Stevens** will be presenting at the Careers Seminar at the Cancer Research UK Gurdon Institute in Cambridge. **James Legg** will also be giving a lecture as part of the postgraduate course in pharmaceutical medicine organised by the British Association of Pharmaceutical Physicians (BrAPP) and Cardiff University. James' lecture will focus on the issues surrounding the protection of inventions in the biotech and pharmaceutical sectors.

> Finally, the Biotech team would like to congratulate **Ed Ronan** who recently passed the UK Finals papers FD2 and FD3 (P3 and P4), and **David Wortley** who passed the European pre-examination with flying colours.

HEADLINE ARTICLES

Gene patenting update for Australia

New **guidance** for Examiners has been issued by the Australian Patent Office in view of the High Court of Australia's decision in D'Arcy v Myriad Genetics Inc. In this case the High Court was asked to decide whether claims from Myriad's patent directed to the nucleic acid sequences encoding the BRCA1 mutant polypeptide represented patent eligible subject matter (i.e. a manner of manufacture). The High Court decided that these claims did not define a manner of manufacture. Instead they considered that the substance of the invention was the information contained within the sequence of nucleotides of the molecule. The Court concluded that the information was not "made" (i.e. created or modified) by human action but was rather an inherent part of the molecule. Claiming the alleged invention as an isolated product was not sufficient to confer eligibility. For more information about the guidance issued following this decision, see **here** for our full bulletin.

Experimental models in patents – what is "plausible"?

In ***Merck v Ono* [2015] EWHC 2973 (Pat)**, the High Court has provided guidance on the nature of the experimental data required to support the disclosure of an invention, emphasising that what matters is what is made "plausible" by the data, as distinguished from what was mere "speculation". In this case, neither the patent nor the prior art contained experimental data relating precisely to the invention claimed; however, the experimental work in the patent was held to make the claimed therapeutic effect plausible to the skilled person, whereas the experimental data in the prior art did not meet this plausibility requirement. The patent was thus found to be valid and infringed. The decision builds on the notion of "plausibility" when considering what is enabled by a document, and details the application of this notion to the sufficiency and novelty of medical use claims. See **here** for our full bulletin.

Regeneron transgenic mouse patents infringed but invalid as insufficient

In a technically complex dispute, Kymab Limited and Novo Nordisk A/S have succeeded in the UK with their claim for revocation of two important patents owned by Regeneron Pharmaceuticals Inc (see **here**). These patents (EP(UK)1360287 and its divisional EP(UK)2264163) relate to Regeneron's Velocimmune® transgenic mice suitable for therapeutic antibody discovery. Regeneron initially brought a claim for infringement of their patents, and it was decided by the High Court that Kymab's transgenic mice were within the scope of the claims of both patents. The defendants were however, successful in challenging the validity of the patents for lack of sufficiency. This case is of significant interest for its consideration of fundamental platform technology in the therapeutic antibody field, in addition to the legal issues discussed concerning construction of product-by-process claims and insufficiency. See **here** for our 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**

WHAT WE DO > | MEET THE TEAM > | PUBLICATIONS >

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

EDITOR
Joanna Peak, Attorney

CONTRIBUTORS
Matthew Spencer, Partner
Ed Ronan, Attorney
Naomi Stevens, Attorney