# D YOUNG<sup>&</sup>CO PATENT NEWSLETTER<sup>no. 22</sup>

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### **Events**

#### 5-6 April 2011

#### International Patent Forum, London

Simon Davies (as Chairman of the CIPA Computer Technology Committee) will be speaking at Managing Intellectual Property's International Patent Forum.

#### 13-14 April 2011, Florida USA 12-13 May 2011, London, UK Claim & Specification Draffing

# Claim & Specification Drafting for a Single EPO/USPTO Patent

David Meldrum will be presenting at these intensive, practical courses on how to draft and prosecute one patent application which will comply with the differing requirements for both the EPO and the USPTO.

For more information: www.dyoung.com/events

### Editorial

We have been deeply shocked to witness the devastating earthquake and tsunami in Japan. We wish to express our sympathy to all those who have been affected by this catastrophic event.

Applicants experiencing problems meeting deadlines owing to the disruption in Japan can make use of the special extension arrangements which many IPOs have put into place, including the EPO, UK IPO and USPTO. For more information about the EPO's statement visit our website: www.dyoung.com/epojapan or contact your usual D Young & Co adviser.

We hope that some degree of normality can be restored soon for the people in the north of Japan.

Editor:	5
Anthony Albutt	l l

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# Peer to Patent Social Networking Applied to Patent Searching... Is this the Future of Patent Prosecution?

he United States Patent and Trademark Office (USPTO) is currently running a pilot program for the public submission of peer reviewed prior art for use in the examination of patent applications. This is commonly called 'peer to patent', and is a concept growing in popularity.

An earlier pilot scheme run in the US in 2007–09 was judged a success, and Australia and Japan have recently run pilot schemes themselves. In November 2010, the United Kingdom Intellectual Property Office (UK IPO) announced its intention to trial a peer to patent project.

#### What is peer to patent?

Peer to patent takes the architecture of internet-based social networking and applies it to patent searching, with the aim of improving the quality of granted patents. Using a dedicated website, the public can submit prior art references for later use by the patent office examiner. It is acknowledged that today's patent examiners have difficulty in accessing all available prior art. The volume of material is huge, and an increasing amount, particularly so-called non-patent literature, is not organised in a readily searchable manner. Hence a search may be inadvertently incomplete, and a patent can be granted despite the existence of highly relevant prior art. This is especially true in areas such as software and business methods, where repositories of conventional prior art documents are sparse. However, there are many experts with detailed prior art knowledge in their fields, and peer to patent seeks to access this.

#### The process

A patent application made available for peer to patent review is posted on the website. There, it can be reviewed by a community of reviewers. The reviewers post prior art references which they think are relevant, plus comments explaining the relevancy. Other reviewers can rate the references and the comments. At the end of a fixed review period, the references rated as most relevant are selected. These references, with the comments, are sent to the patent examiner. This information supplements the patent office's own search, to give a more complete search result. Hopefully, the subsequent examination of the application is thereby made more robust. The comments can be a detailed analysis with annotations linking parts of a reference to features in the patent claims. This enables the examiner to quickly assess the peer to patent references, so that efficiency does not suffer.

#### The USPTO's pilot<sup>1</sup>

The current pilot is an enlarged version of the earlier study. It aims to better assess whether the peer to patent process can effectively contribute prior art of value to the examiner.

A maximum of 1,000 unexamined patent applications will be accepted into the pilot, at the request of the applicants. The applications must be in specified technical fields, including life sciences, business methods, telecommunications and software. A balance of applications will be achieved by limiting the total number of submissions per applicant, and by reserving a proportion of places for 'small entity' applicants.

Applications which receive at least one reference from the peer to patent reviewers will be moved to the top of the examination waiting list. This ensures that the results of the study will be available quickly.

The peer to patent website is operated by the New York Law School, which is running the pilot in cooperation with the USPTO (see the links at the end of this article).

#### The UK IPO's pilot

The UK IPO is seemingly to use the existing New York Law School system. However, initial plans suggest some differences from the USPTO's scheme. It will be on a smaller scale, with about 200 applications expected to be included.

More importantly, the UK IPO intends to select the applications for the pilot. This is in contrast with applicants submitting their own applications for the USPTO pilot. The UK IPO plans to search the applications before the peer to patent procedure, and choose applications placed in the 'electrical digital data processing' International Patent Classification class. The applicants of the

#### > Notes

 Official Gazette of the USPTO, 1361(4), p230, 28 Dec 2010.
Daniel R Bestor and Eric Hamp "Peer to Patent: A Cure for Our Ailing Patent Examination System", Northwestem Journal of Technology and Intellectual Property, 9(2), pp16-28, Nov 2010.



selected applications will be notified before the applications are placed on the peer to patent website.

As in the USPTO pilot, the New York Law School will compile the information posted by reviewers, and pass it to the UK IPO. The examiners will use this information together with the UK IPO search results when examining the applications.

Is peer to patent a good idea? The establishment of the pilots suggests that the USPTO and the UK IPO think peer to patent may have a future. Many individuals involved in the US project are reported as viewing it as a success so far<sup>2</sup>. Many wellknown companies (eg, IBM, Bayer and Visa) are taking part in the USPTO's current pilot, so are presumably interested in peer to patent. And anything that can genuinely strengthen granted patents would surely be widely deemed as a good thing. The process might be viewed differently by applicants compared to their competitors and others seeking to invalidate patents, however. Will peer to patent be seen as an integral part of the examination procedure, or will it be treated as an alternative to existing third-party interventions such as opposition and third-party observations? It seems capable of performing these two functions concurrently. In fact, the New York Law School already maintains a sister website dedicated to granted US patents (see link below), where interested parties can post a patent and ask the review community to help find relevant prior art. Potential weaknesses in patents can thereby be exposed. Unlike peer to patent, the cited references are not passed to the USPTO. Many features will require clarification before peer to patent can become an established part of the patenting process. The different approaches of the USPTO and the UK IPO highlight this.

# Will the procedure be optional or compulsory?

Compulsory participation might be limited to subject areas most likely to benefit from a broadened search arena, such as software and business methods. Limited use of peer to patent review could lead to a perception that some patents are stronger than others, however. But if all applications are posted for peer to patent review, there may be insufficient reviewers to make the system worthwhile.

#### The future

A reported desire of the peer to patent pioneers is to extend the system to an international platform<sup>2</sup>. It would be available to every patent office and applicant, and attract reviewers from around the world. This would make excellent and efficient use of the peer to patent concept. The future of this idea depends on the outcome of the pilot schemes. We await the results with interest.



# Article 02

# The Patent Box Beginning to Take Shape

Useful links Further information about the Patent Box can be found on the HM Treasury website: http://bit.ly/hszxx4



ollowing the confirmation by the UK Government in November 2010 that it intends to implement a 'Patent Box', some proposed details about the system have been published. The system is aimed at encouraging the ownership of patents in the UK. By providing a lower rate of corporation tax on profits derived from granted patents held in the UK, the Government is aiming to provide a more competitive taxation policy. Whilst the system is unlikely to transform the UK into a haven for companies investing in patents, it is likely to present a more favourable setting overall, especially when it is implemented alongside the already available tax credits for research and development costs.

The Patent Box will be optional and so it will provide a degree of flexibility where companies do not wish to implement unnecessary additional compliance procedures. As had been announced previously, the Government intends to introduce a 10% rate for profits arising from patents. This rate would apply from 1 April 2013.

However, there are many uncertainties surrounding the Patent Box. As a result, the Government is consulting on the detailed design of the Patent Box and welcomes input from businesses as to how they think it should be implemented. Some of the issues which are being considered by HMRC are set out below.

#### Eligibility

The Government is looking at two main options for identifying patents which are eligible for inclusion in the Patent Box. The first is to assess the eligibility based on the date of grant of the patent. The other is to consider the date where the patent was first commercialised.

Clearly, the second option would require a clear definition of what commercialisation means. For example, in many cases licence agreements are concluded on the basis of patents which have not (and which may never) grant. From a business perspective, the invention has certainly been the subject of commercialisation, but has the patent? It would not seem sensible to allow the tax incentive to apply to products solely on the basis that a patent application has simply been applied for; surely the grant of the patent should be required?

Further, it is not clear whether there must even be a UK patent in the portfolio. If a UK patent is not required, it is noted that some countries do not perform a substantive examination of a patent application. Therefore, it is conceivable that patents which have not been substantively examined could form the basis of the Patent Box and profits derived from the commercialisation of the product could be included.

At present, the Government intends that all patents first commercialised after 29 November 2010 will qualify for inclusion in the Patent Box. It may be that transitional rules which account for specific situations are also implemented. This is one of the main areas which the Government is seeking views on.

#### Income

The Government intends to make the Patent Box available to income from royalties as well as income 'embedded' in the patent product. Of course, the calculation of royalty income is relatively straightforward. However, determining the income which is 'embedded' in a patented product is far more complex. With this in mind, the Government is considering two possible options. One is to use the 'arm's length principle' as set out in the Organisation of Economic Co-Operation and Development Transfer Pricing Guidelines. The other is to take a more formulaic approach.

According to the Government, both options have their pros and cons. The former may provide a more accurate picture of the income derived from a patent, whilst the latter may provide a system with greater certainty and ease of administration.

At present, the Government feels that the 'arm's length principle' may be too onerous for businesses as it would require them to conduct a valuation of individual patents. As a result, the Government appears to favour a more formulaic approach. However, it seems that such an approach would have to be extremely flexible, as the ways in which a patent can protect a product are vast.

One point to consider is that in the UK, the sale of means essential for putting the invention into effect can also be prevented by the patent owner. Therefore, is it possible to incorporate into the Patent Box profits which are derived from selling a component of the patented product? Again, the Government is actively seeking views on how the income should be calculated.

#### Consultation

The initial round of consultation ended in February 2011, with the results to be published shortly. However, the timetable for introducing the Patent Box envisages a further round of consultation before draft legislation is published in Autumn 2011.

We have recently met with a representative of HMRC to discuss the above proposals. Accordingly, if you would like an opportunity to present your views to HMRC in person, or would like further, specific advice on the Patent Box, please contact your usual D Young & Co adviser.

Author: Connor McConchie

### Article 03

# UK IPO Goes Online Expansion in Availability of Prosecution Documents

he UK Intellectual Property Office (UK IPO) will shortly make significant changes to the availability of prosecution documents. From April 2011, as well as the information already available online, the UK IPO's information service will additionally include forms filed, citation information and copies of selected documents from the open part of the file.

There will be two stages to the implementation of the new service. From April of this year the following documents will be available:

- A and B specifications
- A and b specification
- Abstracts
- Claims
- Descriptions
- Drawings
- Examination reports
- External search reports
- PCT forms and documents
- Correspondence sent by the UK IPO after 1 November 2010

The second stage, commencing from October 2011, will add agents' letters, applicants' letters and also priority documents.

Exempt from inclusion in the service will be documents which are not part of the open file, documents which cannot be conveniently put online, non patent literature and letters relating to purely administrative matters. It would also seem to be the case that assignment documentation containing personal and/or confidential information will not be made available.

Some files may also contain third party observations, documents relating to litigation over the patent or application (eg, statements of case, submissions, witness statements,



evidence) and other documents which have been filed as part of the patent process. The UK IPO is currently consulting on exactly what additional documents it can and should make available (because of copyright concerns, amongst other reasons). However it is expected that most documents will be made available and this would include copies of the above documents from court proceedings (where, at least, validity was in issue).

This is a useful service for attorneys and other interested parties and brings the UK IPO into line with many other patent offices which routinely make this information available.

Authors: Charlotte Musgrave & Anthony Albutt

#### As published at www.dyoung.com/ article-eupatentcourt 23 March 2011

### Article 04

# CJEU Decision Pan-European Patents Court Falls Foul of EU Law

his Court of Justice of the European Union (CJEU) decision is unfortunately not surprising. The court was to be established not solely within the judicial structure of the EU but as a court to be used by all interested members of the European Patent Convention. The CJEU was averse to the idea of a non-EU regulated court deciding cases which affect EU citizens. It is hard to see how the proposed court can meet the CJEU's concerns without making it very different, and one which may not be so acceptable to its users.

The ideal of a Community patent and a centralised patent litigation system has been mooted for over four decades and, whilst it is seemingly closer to fruition than previously, it is still some way off. Recently, the EU Commission has spearheaded an 'enhanced procedure' mechanism aimed at creating a partial Community patent for those countries which want it. The Commission hopes that 25 of the 27 Member States will adopt it (Spain and Italy are currently against, due to the refusal to provide for translations into their languages).

The 'enhanced procedure' does not yet deal with the proposed court system of this partial Community patent. No doubt the Commission is hoping to utilise many of the features of the (failed) pan-European court, although it will have to take into account the judgment of the CJEU. Whatever happens, progress is likely to be slow and problematic and it is unlikely to happen any time soon.

Litigating European patents in one or more Member States and the options for a degree of forum-shopping will continue. Whilst this may be seen as detrimental to the concept of a single market, this is not necessarily a bad thing for system users as it can often be useful to counteract some of the procedural and evidential differences amongst national courts which in themselves might be said to undermine legal certainty.

Author:

lan Starr

# Article 05

# Antibody Patents and US Written Description Requirements Recent US Court of Appeal Ruling Does Away With 'Antibody Exception'



n 23 February, 2011, the Court of Appeal for the Federal Circuit in *Centocor v Abbott Laboratories*' set aside a \$1.7 billion jury verdict in favour of the patentee (Centocor) and held that the claims were invalid for lack of written description. The patent related to antibodies to human tumor necrosis factor  $\alpha$  ('TNF- $\alpha$ ').

#### **Humanisation of antibodies**

An antibody, or immunoglobulin, molecule has the basic structure shown right. It is made up of two different polypeptide chains, the heavy chain (blue) and the light chain (pink). The overall shape of an antibody molecule is basically that of a Y, and the sub-regions at the tips of the arms are known as the variable regions as they show most sequence variability.



The antigen-binding site of the antibody molecule is found within these variable regions, and that is the portion which determines the antigen-binding specificity of the antibody. Traditional methods for making antibodies of a desired specificity produce non-human (usually mouse) antibodies. Non-human antibodies are often unsuitable for use for therapeutic purposes in humans, because the antibody is recognised as foreign, leading it to be rapidly removed by the immune system. In order to overcome this hurdle, various recombinant approaches have been adopted in order to make a given antibody 'more human'.

Chimaeric antibodies have been developed which comprise the variable region, and thus the antigen-binding specificity, from a murine antibody, but which have human constant regions (see below).





However, the holy grail for therapeutic antibody technology is to produce a 'fully humanised' immunoglobulin molecule, which contains effectively no murine sequence.

# The technology behind the patent at issue

Centocor identified a mouse antibody to human TNF- $\alpha$  that had high affinity and neutralizing activity (the A2 antibody). They then created a chimaeric antibody by exchanging the mouse constant region with a human constant region, in order to reduce the antibody's immunogenicity.

Centocor filed a patent application in 1991

claiming the mouse antibody and chimeric antibody. In 1993 and 1994, Centocor filed a series of continuation-in-part applications, and in 2002, Centocor added claims reciting human variable regions in the 13th member of the application family, which issued in 2006. Claim one of the issued patent covered the murine and chimaeric antibodies, whereas claim two specifically recited an antibody comprising "a human constant region and *a human variable region*" (ie, a fully human antibody).

Abbott, meanwhile, used an entirely different technology to produce human anti-TNF-a antibodies. By a process known as 'phage display' they directly screened a library of human variable regions to find ones that bind human TNF-a, and then used various techniques to improve the binding affinity of selected variable regions. The resulting variable regions were then combined with human constant regions to create fully-human antibodies, from which the therapeutic antibody Humira® was identified.

On 29 June 2009, a jury in Marshall, Texas, awarded the largest patent verdict in history: Abbott Laboratories were to pay \$1.67 billion to Centocor, because its Humira® arthritis treatment was determined to infringe Centocor's US patent.

When the case was brought to the Federal Circuit, the pivotal issue was whether the patent provided adequate written description for the claimed human variable regions. According to the Federal Circuit, the specification indicated that the inventors had actually made a mouse antibody and a chimeric antibody. Therefore, there was an actual reduction to practice of claim one. However, there was no disclosure in the specification that the inventors actually made the narrower invention of claim two which was directed to a fully human antibody having the claimed characteristics.

The 'antibody exception' to the written description requirement Up until now, it has been routine practice for many patent offices, the USPTO included, to grant broad generic antibody claims for new antigenic targets. If a researcher discovered a new polypeptide that might be useful as a disease marker, broad claims were routinely allowed, for example to 'A purified antibody which specifically reacts with protein X'. If the structure of the antigen was known, it was possible to get a claim to any antibody that bound to that antigen, even in the absence of any working examples.

The USPTO explicitly recognised an 'antibody exception' to the heightened requirements for the written description of biomolecules, which was apparently endorsed by the Federal circuit<sup>2</sup>.

Analysis of written description in Centocor v Abbott Laboratories In its opinion, the Federal Circuit honed in on the lack of disclosure of any human variable regions in the patent. The court concluded that

"[T]here is nothing in the specification that conveys to one of skill in the art that Centocor possessed fullyhuman antibodies or human variable regions that fall within the boundaries of the asserted claims."

"While the patent broadly claims a class of antibodies that contain human variable regions, the specification does not describe a single antibody that satisfies the claim limitations. .. It does not disclose any relevant identifying characteristics for such fully-human antibodies or even a single human variable region... Nor does it disclose any relationship between the human TNF-a protein, the known mouse variable region that satisfies the critical claim limitations.

# and potential human variable regions that will satisfy the claim limitations."

Essentially, the claims were considered to constitute a wish list of properties for a fullyhuman, therapeutic TNF- $\alpha$  antibody would possess - but a mere wish or plan for obtaining the invention was not considered sufficient to satisfy the written description requirement.

### Conclusion

The Centocor v Abbott Laboratories decision apparently does away with the established 'antibody exception' to the written description requirement, as it makes it clear that disclosure of a protein does not necessarily suffice to support claims to all associated antibodies.

There seems to be a trend at the Federal Circuit that a patent should not be able to encompass significant developments which are made years after the patent application was filed. This trend is reflected in the following statement made in the Centocor v Abbott Laboratories case:

The actual inventive work of producing a human variable region was left for subsequent inventors to complete. The scope of Centocor's rights to exclude cannot "overreach the scope of [its] contribution to the field of art as described in the patent specification".

Non-compliance with the written description requirement is effectively being used as an 'easy button' to curb the scope of patents which, with the benefit of technological hindsight, are now considered to be overly broad.

Author: Louise Holliday

Decision: http://bit.ly/centvabb

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