

D YOUNG & CO

PATENT

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Following our top tier ranking
by both Legal 500 and Chambers,
we have been awarded IP Law Firm
of the Year 2011 by Lawyer Monthly.

See page 3 for details.



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Events



8-9 December 2011

Intellectual Property Protection for Plant Innovation 2011, Amsterdam

Catherine Mallalieu is attending this conference, organised by Forum Institut.

17-19 January 2012

5th Annual Recombinant Antibodies Conference

Louise Holliday will be speaking at this Visiongain conference in London, UK

24-25 January 2012

5th Annual Pharmaceutical Product Lifecycle Management Conference

Garreth Duncan is speaking at this Visiongain conference in London, UK

More information: www.dyoung.com/events

Editorial



As we near the end of 2011 we reflect on a busy year in the patent courts with a number of key decisions being made. Following the CJEU's recent decision in *Brüstle v Greenpeace*, which has had a negative impact on stem cells patenting in Europe, it was nice to see some manner of sensibility in the HGS v Lilly decision, meaning that it's not all bad for biotech patenting in Europe. And the recent decision relating to 'mental acts' by the UK Courts in the *Halliburton* case shows that this sensibility appears to be also stretching to software patenting. We are looking forward to see what the Courts will bring us in 2012!

Just as we go to press we are delighted to announce that we have been named IP Law Firm of the Year by Lawyer Monthly. This follows our recent top tier rankings from Chambers UK and the Legal 500.

Finally, as the festive season approaches, I would like to wish you all season's greetings and best wishes for a prosperous 2012.

Editor:

Aylsa Williams



Article 01

CJEU Decision C-34/10 A Kiss of Death for the European Stem Cell Industry?

C-34/10 has dramatically altered the outlook for stem cell patenting in Europe



Replacement neurons to treat spinal cord injury, insulin-producing cells to treat diabetes, dopamine-producing neurons to treat Parkinson's disease... the possibilities are endless. As embryonic stem cells are undifferentiated, they theoretically have the ability to develop into any one of the specialised cell or tissue types found in the human body. This offers enormous potential for generating cells or tissues for therapy and drug screening.

However, the patentability of human embryonic stem cells (hESC), their uses and derived products has been uncertain, which has the effect of stifling investment in the technology. The source of the uncertainty is Rule 28(c) of the European Patent Convention (EPC), which states that European patents shall not be granted in respect of biotechnological inventions which concern "uses of human embryos for industrial or commercial purposes". The most widely used procedure for the isolation of hESC involves the destruction of a blastocyst, a very early pre-implantation stage embryo consisting of approximately 150 cells.

The question of whether Rule 28(c) EPC should prohibit patent applications relating to hESC has given rise to considerable legal and ethical debate. In 2007, a referral was made to the Enlarged Board of Appeal of the European Patent Office (EPO) with various questions relating to the patentability of hESC cultures (G2/06).¹ It was held that a patent cannot be granted for an invention which necessarily involves the use and destruction of human embryos.

G2/06 effectively precluded patent protection for old patent applications for which the only technology available for the generation of hESC involved destruction of a blastocyst. However, human embryonic stem cell lines are now publicly available, which are suitable as a starting point for many stem-cell based inventions.

Following G2/06, an unofficial interim practice arose at the EPO. Patent applications which post-date the deposit of hESC cell lines by the Israel Institute of Technology (Technion) at the US National Institutes of Health in May 2003 were generally considered to escape the

> Footnotes

1. G2/06: Official Journal EPO 5/2009, 306.
2. C-34/10 Paragraph 49
3. <http://dycip.com/vnWSAZ>

> Missed anything?

In between issues of this newsletter we posted news about the recent UK High Court ruling in *MedImmune v Novartis*, and the UK Court of Appeal's decision in the registered designs case involving *Dyson and Vax*. Visit our website for up to the minute IP related articles and news.

> Knowledge Bank

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exemption on the grounds that, as deposited human embryonic stem cells lines were available, it was not necessary to destroy a human embryo as part of the practice of the claimed invention.

However, the Court of Justice of the European Union (CJEU) has now issued its decision in case C-34/10 *Brüstle v Greenpeace* which relates to the patentability of technology based on the use of human embryonic stem cells.

The decision of the CJEU appears to have gone one step further than G2/06: it holds that an invention is excluded from patentability where the technical teaching which is the subject matter of the patent application requires the prior destruction of human embryos or their use as a base material, whatever the stage at which that takes place.

It also specifically states that:

"The fact the destruction may occur at a stage long before the implementation of the invention, as in the case of the production of embryonic stem cells from a lineage of stem cells the mere production of which implied the destruction of a human embryo is...irrelevant".²

This appears to mean that a patentee cannot rely on the existence and availability of stem cell lines to argue that a stem cell-related invention is outside the scope of the exclusion. The current practice of the EPO in generally considering patent applications filed after May 2003 to be outside the exclusion may need to be rethought.

However, stem cell technology evolves at a very fast pace, and there are now other ways of obtaining stem cells which do not involve the destruction of an embryo. For example, Advanced Cell Technology, based in Santa Monica, California, uses hESC cells obtained from a blastocyst in such a way that the blastocyst is still viable (ie, it is not destroyed). Also, in 2007, induced pluripotent stem (iPS) cell technology was described in which adult cells may be reprogrammed to an embryonic-like state.

The most likely outcome in terms of EPO

practice is that there will be a flurry of argumentation and evidence to establish the date on which such alternative technologies were available. It will also be necessary to establish that such alternative technologies are suitable for use with the invention in question. It is likely that the date for such technologies, however, will be after the May 2003 date of availability for the Technicon stem cell lines.

What will happen to the European and national patents already granted which cover such inventions? In the immediate term, they will remain in force until challenged, but they will become essentially unenforceable.

A further extended period of uncertainty is very bad news for European stem cell companies in terms of investment. The fact that it is possible to obtain patents on such technologies in the US and elsewhere may mitigate the situation, or it may mean that both the funding and the expertise are eventually driven out of Europe.

The European patent situation may act as a general disincentive for stem cell investment and research – on 14 November 2011, Geron, the California-based flagship company for stem cell therapies, announced that it is dumping its stem cell research program and axing 38% of its workforce.³ The timing may be coincidence, or the question mark over patentability in Europe may have been a contributing factor. Time will tell whether this represents the first of a general move away from stem cell technology, with companies and investors taking the view that it is just too risky.

Author:
Louise Holliday



Useful links:
Brüstle v Greenpeace C-34/10:

<http://dycip.com/c3410dec>

G2/06:

<http://dycip.com/g0206dec>

Article 02

D Young & Co IP Law Firm of the Year

We are delighted to announce that D Young & Co has been named IP Law Firm of the Year 2011 by Lawyer Monthly. This award follows hot on the heels of our recent top tier ranking in all IP categories from Chambers UK 2012, and our top tier ranking from Legal 500 2011.

The Lawyer Monthly Legal Awards 2011 recognise firms that have dedicated their resources to innovation, built on their depth of expertise and performed outstandingly over the year. The award recognises our decision to bring together the specialist IP services of patent and trade mark attorneys

with those of solicitors in a single Legal Disciplinary Practice (LDP). We were the first UK IP firm to establish an LDP and in so doing raised the bar for the quality and depth of IP services offered in the UK.

Ian Starr, Partner in our Dispute Resolution & Litigation Group, comments:

"For us (and our clients) being able to rely on the breadth and depth of expert knowledge in IP is a real benefit. Being in a firm whose beating heart is IP is invaluable and exciting."

The benefits of the LDP structure have been immediately clear, bringing about a more efficient and effective service that reassures clients that they are obtaining the best value for their IP investment. Integrated D Young & Co teams including both solicitors and patent and/or trade mark attorneys can share knowledge, work more efficiently and offer a truly comprehensive IP service.

Useful links:

<http://www.dycip.com/ipfirm>

UK Courts Have a Rethink on Mental Acts

Scope of Mental Act Exclusion Clarified and Reduced

Useful links:

Halliburton Energy Services Inc [2011] EWHC 2508 (Pat) (05 October 2011) <http://dycip.com/hallib11dec>
 Aerotel Ltd v Telco Holdings Ltd & Ors Rev 1 [2006] EWCA Civ 1371 (27 October 2006) <http://dycip.com/aerotel06dec>
 Kapur v Comptroller General of Patents, Designs & Trade Marks [2008] EWHC 649 (Pat) (10 April 2008) <http://dycip.com/kapur08dec>
 Symbian Ltd v Comptroller General of Patents [2008] EWCA Civ 1066 (08 October 2008) <http://dycip.com/symbian08dec>
 T0453/91: <http://dycip.com/t045391dec>
 T1227/05: <http://dycip.com/t122705dec>

In a recent case, *Halliburton 2011*, the UK Courts have significantly clarified (and reduced) the scope of the mental act exclusion in UK patent law.

Mental acts are one of the items excluded from patentability under Article 52(2) EPC, along with computer programs, business methods, etc. These things ("as such") are considered not to be inventions, and hence represent non-statutory subject matter for the purposes of European patent law. The same list of exclusions is present in UK national law, although the UK Courts have tended to adopt a somewhat different approach to non-statutory subject matter from the European Patent Office (EPO). The UK Courts generally attribute more weight to the specific individual items listed in Article 52(2) EPC (and corresponding section 1(2) of UK national law); in contrast, the EPO tends to ignore the details of the individual exclusions in favour of an umbrella approach in which anything 'non-technical' falls outside the scope of patentability.

Historically, the UK Courts have had some difficulty determining the exact boundaries of the Article 52(2) exclusions, no more so than for the mental act exclusion. UK case law has developed two possible interpretations of 'a method for performing a mental act'. The first interpretation, generally referred to as the narrow view, is that the exclusion only covers an act that is actually performed in the mind. According to this narrow view, any computer-implemented method necessarily falls outside the scope of the exclusion, since the method is performed by the computer (not in the mind). Alternatively, there is the broad view, in which the exclusion covers an act that could, in theory, be performed in the mind, even if the claim is limited to exclude such a possibility, eg, even if the claimed method is explicitly restricted to a computer implementation.

The case law regarding excluded subject matter was reviewed extensively in the *Aerotel* decision in 2006 from the Court of Appeal. Although the mental act exclusion was not at issue in that case, the Court made the obiter comment that: "we are doubtful as to whether the exclusion extends to electronic means of

doing what could otherwise be done mentally". Following the decision in *Aerotel*, the UK Intellectual Property Office (UK IPO) issued a revised practice notice on how it would handle excluded subject matter. This advised that although the comments of the Court of Appeal regarding the mental act exclusion were obiter, "examiners will lean towards the view expressed in the current judgment, on the grounds that this is probably a better reflection of current judicial thinking".

Shortly after *Aerotel*, the UK High Court did specifically consider the scope of the mental act exclusion in the *Kapur* decision. In this case, the Judge came down clearly on the side of the narrow interpretation: "In my judgement the narrow view of the exclusion is the correct one". Unfortunately however, *Kapur* was soon followed by another decision from the Court of Appeal, *Symbian*, which again considered non-statutory subject matter. As with *Aerotel*, the *Symbian* case was not specifically concerned with the mental act exclusion, but nevertheless it contains some obiter comments that appear to support the broad interpretation. Certainly this was how the UK IPO understood *Symbian*, since it issued a further practice notice which reverted back to the broad interpretation.

Actually, there are a number of comments about the mental act exclusion in *Symbian*, and some of them appear to favour the narrow interpretation rather than the broad interpretation. Also, it is doubtful whether the UK IPO was at liberty to follow selected obiter comments in *Symbian*, rather than the apparently binding decision of *Kapur* (even though *Symbian* was from a higher court). Nevertheless, the UK IPO took the broad interpretation of the mental act exclusion, as set out in the practice notice, when rejecting four patent applications filed by Halliburton, which concerned, *inter alia*, improving the design of roller cone drill bits for drilling oil wells.

In fact, Halliburton are no strangers to the issue of non-statutory subject matter in the UK Courts. Back in 2005, the UK High Court had held another Halliburton case, also relating to the design of drill bits, to represent excluded subject

matter. In that case, the Court approved an EPO decision, T0453/91, concerning the design of a VLSI-chip. In T0453/91 the EPO Board of Appeal had rejected claims to the design method itself, but then allowed claims which had been amended to include "and materially producing the chip so designed", ie, to include the physical manufacturing step for the designed product.

However, since the *Halliburton* case in 2005, there has been a further decision from the EPO, T1227/05, which departs from the decision in T0453/91. This second case allowed claims to a computer-implemented method for the numerical simulation of a circuit. The Board felt that such simulation was now very much a 'technical' activity, and hence should be open to patentability.

These were the circumstances that confronted Judge Birss when he heard the appeal by Halliburton against the rejection of their four applications. The Judge was unusually well-acquainted with the case law in this area, having represented the UK IPO (as a barrister) in the *Aerotel* case. His decision was unequivocal: "the balance of authority in England is in favour of the narrow approach to the mental act exclusion". He further confirmed that he would also "favour the narrow interpretation on its own merits", and seemed generally comfortable with the EPO approach set out in T1227/05.

Accordingly, the Judge overturned the refusal by the UK IPO, and allowed the Halliburton applications, and further observed that he thought the practice notice issued after *Symbian* was wrong as regards the mental act exclusion.

Since the decision in *Halliburton*, the UK IPO has issued a brief practice notice indicating that they will now follow the narrow interpretation of the mental act exclusion. For practitioners, this represents a sensible and welcome (and overdue!) outcome.

Author:
Simon Davies



Obtaining a Quick Grant in the UK

Five Ways to Accelerated Prosecution

The UK Intellectual Property Office (UK IPO) provides patent applicants with plenty of options for accelerating prosecution of their UK applications with a view to achieving grant more quickly. While in some circumstances applicants may find an accelerated prosecution undesirable, achieving grant quickly has its benefits. Grant is required for the applicant to have any enforceable rights in the patent, and thus can be an important asset in commercial, mergers and acquisitions or licensing negotiations. Furthermore, in the event that the applicant has corresponding applications pending at other patent offices, a first grant in the patent family can also reinforce the family because grant of the corresponding patent applications is more likely.

When trying to achieve grant quickly, there are five different ways for a UK patent application to benefit from an accelerated prosecution (search and/or examination) at the UK IPO, as described below.

1. Infringement

An applicant can request accelerated prosecution if he believes that someone might be an infringer, with a view to being in a position to enforce his rights against the possible infringer more quickly.

2. Securing an investment

The UK IPO recognises that the grant of a patent may be helpful or even required to secure an investment and an applicant can justify an acceleration request on this ground.

3. Green channel

Since May 2009, acceleration can be obtained for green applications. This scheme is not limited to inventions relating to clearly green technologies, such as wind turbines or solar panels, but it is in fact intended to encompass any invention that provides an environmental benefit. For example, a suitable invention may enable a reduction in energy consumption when in use, or a reduction in the amount of raw material required to manufacture a product.

4. Patent Prosecution Highway (PPH)

PPH agreements are generally bi-lateral

The UK could become a popular choice for applicants requiring a quick grant



agreements between two patent offices whereby each patent office agrees to accelerate examination of an application if a corresponding application has received a favourable decision at the other patent office (provided that the applicant requests the acceleration). The UK IPO has currently entered into agreements with the Japanese, Korean and US patent offices. Despite the current efforts to harmonise the terms of the various PPH agreements, the requirements for using a PPH generally vary depending on the patent offices involved. In the UK, it is required that the two corresponding applications are related (for example both may claim priority from the same earlier application). Also, the claims pending at the UK IPO should be substantially the same as the claims allowed by the partner patent office and examination at the UK IPO should not have begun.

5. PCT(UK) Fast Track

Since May 2010, PCT applications that have received a positive International Preliminary Report on Patentability (IPRP) can benefit from an accelerated prosecution in the UK national phase, upon request by the applicant. Each and every claim of the PCT application

must have received a positive opinion with respect to novelty, inventive step and industrial applicability in the IPRP. The UK IPO's intention is to use this PCT(UK) Fast Track as an incentive for applicants to address patentability objections during the international phase, and to amend their applications then before national or regional phase starts. Thus, an application where all claims that received a negative opinion in the IPRP have been deleted on UK national phase entry (ie, not during the international phase) would not be eligible for the PCT(UK) Fast Track.

The UK may therefore become the place of choice for applicants who wish to obtain results quickly when they need to and want to, thereby reinforcing their rights and position not only in the UK but also possibly in any country where they have a corresponding patent application pending.

Author:

Bénédicte Moulin



UK Supreme Court Rules on 'Industrial Application' Human Genome Sciences v Eli Lilly

The new UK Supreme Court has made its first decision in a patent case. Human Genome Sciences (HGS) applied for patent EP0939894 ('the patent') in 1996. The patent in question identified a gene sequence coding for a human protein named neutrokin- α , along with the tissue distribution, expression information and antibodies to the protein.

Eli Lilly challenged the validity of the patent in the UK on the basis of insufficiency and, unusually, industrial application.

Background

The referral of this case to the UK Supreme Court came after a long history of opposition and appeal for the patent.

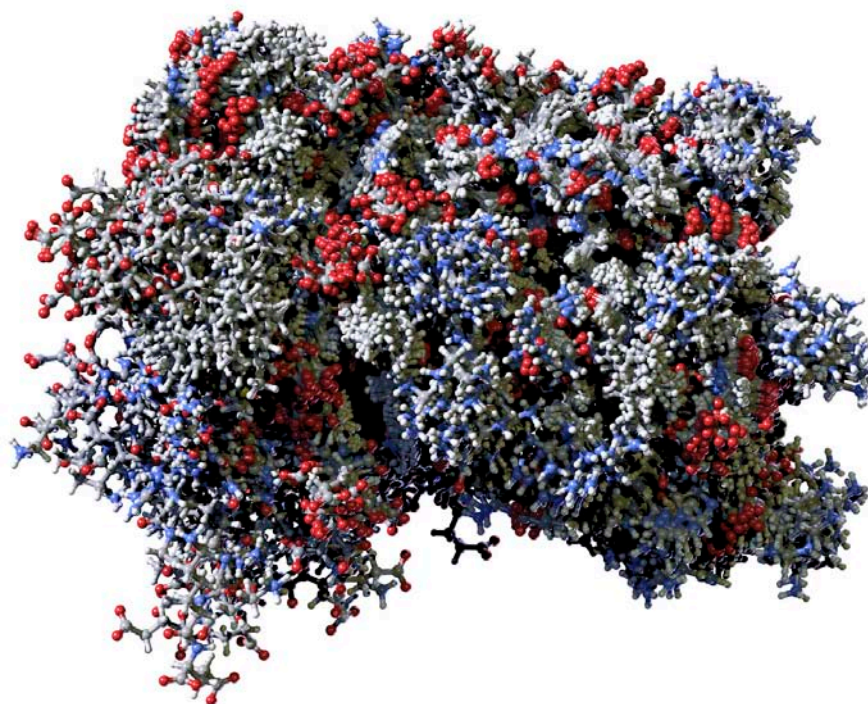
The European patent application was granted in August 2005, after nine years of prosecution. This was opposed centrally at the European Patent Office (EPO) by Eli Lilly, which action resulted in revocation of the patent. However, the EPO Technical Board of Appeal later reversed the decision and ordered that the patent be maintained.

The UK Patents Court revoked the patent in parallel proceedings on the basis that a person skilled in the art would have understood that the functions of neutrokin- α "were, at best, a matter of expectation and then at far too high a level of generality to constitute a sound or concrete basis for anything except a research project". This decision was based on a lack of industrial application (Article 57 of the European Patent Convention (EPC)) and insufficient disclosure (Article 53 EPC).

The Patents Court decision was then upheld by the UK Court of Appeal after consideration of Article 57 EPC only.

The patent

It is very common for gene sequences to be identified and classified using bioinformatics techniques. Essentially this means deducing the function of the gene based on existing data, in this case similarity to previously characterised gene sequences, rather than specifically conducting experimental tests on



the new sequence. Such techniques make use of widely available databases and computer programs.

At the time of filing their patent application, in this case HGS had identified, based on sequence similarity, that neutrokin- α was likely a member of a protein family known as TNF ligand superfamily. Other members of this protein superfamily were known at the time of filing to be involved in regulation of cell proliferation, activation and differentiation. Therefore it was proposed that neutrokin- α shared the properties of the other TNF ligand proteins.

In the UK Supreme Court decision, as summarised by Lord Neuberger, the patent in question:

"describes the claimed invention as potentially useful for the diagnosis, prevention, or treatment of an extraordinarily large and disparate number of, sometimes widely expressed, categories of disorders of the immune system, and other conditions and actions, either through neutrokin- α itself or through its antagonists. However, nowhere in the patent is there any data or any suggestion of in vitro or in vivo studies, so there is no experimental evidence to support any of those suggestions... In very summary terms, the disclosure of the patent thus includes the following features: (i) the existence and amino acid sequence of neutrokin- α , (ii)

the nucleotide sequence of the gene encoding for neutrokin- α , (iii) the tissue distribution of neutrokin- α , (iv) the expression of neutrokin- α by its mRNA (the encoding gene) in T-cell and B-cell lymphomas, and (v) the information that neutrokin- α is a member of the TNF ligand superfamily".

Eli Lilly were of the belief that the functions of neutrokin- α given in the application as filed were purely speculative and not based on experimental evidence.

The decision

Article 52(1) EPC states that, in order to obtain a European patent, an invention must be "susceptible of industrial application". Article 57 EPC furthermore states that an invention is susceptible of industrial application if it can be made or used in any kind of industry, including agriculture. Section 4 of the UK Patent Act is derived from this.

There is relatively little UK case law on the subject of industrial application, and the Supreme Court was loath to disagree with the lower courts. However, in this particular case a notable intervention was made.

The BioIndustry Association (BIA), a UK bioscience trade association with 36,000 members, submitted that clarity and certainty was required in this area of law because it is important for bioscience companies to be

able to decide at what stage to file for patent protection. Specifically the BIA submitted the following:

"If the application is filed early, . [t]he company will be left with no patent protection, but would have disclosed its invention in the published patent application to competitors. If the application is filed late, there is a risk in such a competitive environment where several companies may be working on the same type of research projects, that a third party will already have filed a patent application covering the same or a similar invention, in which case the company may not be able to gain any patent protection for its work and by continuing their programme they may risk infringing that third party's patents. In both cases, the company will have lost much of the benefit of its costly research and development."

The BIA further suggested that if the Supreme Court upheld the decision of the Court of Appeal there is at least a risk that it will "make it appreciably harder for patentees to satisfy the requirement of industrial applicability in future cases." And "would cause UK bioscience companies great difficulty in attracting investment at an early stage in the research and development process".

Lord Neuberger in particular was sympathetic to the BIA's case and did not agree that determining the precise uses of neutrokin-α would entail a substantial research project. In particular he considered, "Just as it would be undesirable to let someone have a monopoly over a particular biological molecule too early, because it risks closing down competition, so it would be wrong to set the hurdle for patentability too high, essentially for the reasons advanced by the BIA."

The result is, the earlier UK court decisions were overturned, and the patent maintained.

Conclusions

In the judgment, Lord Neuberger states that though this case raises an important question of principle, its resolution is fact-sensitive. Therefore, any answer may be of limited value in other cases. It remains to be seen whether this judgment will be applied to other cases, especially in the biotechnology field. However, it is clear that the Supreme Court aimed to bring the UK into line with fellow European countries with this decision, and also did not wish to negatively impact the UK biotech industry.

Author:
Zoë Birtle



Useful links:

Full text of decision: Human Genome Sciences Inc. v Eli Lilly and Company [2001] UKSC 51

<http://dycip.com/hgs11dec>

Article 06

America Invents Act A European Perspective

On 16 September 2011, President Obama signed into effect the America Invents Act (AIA). Over the course of the next 18 months, this act will introduce sweeping changes to how US patent applications are examined and to how disputes can be handled in the USA. As European patent attorneys, and hence outside observers, we now look at one of the most significant changes from a European perspective.

As of 16 March 2013, the US will move from a first-to-invent (FTI) system to a first-inventor-to-file (FITF) system. As we discuss below, however, this change-over will be complex, and the FITF system introduces new differences that set it apart from both the original FTI system and the first-to-file (FTF) system found in Europe and the rest of the world.

Two US systems in parallel

The AIA provides that the new FITF system applies to all applications having an effective filing date on or after 16 March 2013. Hence, US applications filed after this date but claiming an earlier priority will still use the FTI system, resulting in a year's overlap of first-filed US applications and those claiming priority in which each uses a different system. Moreover, new US continuation applications can be filed into the foreseeable future that could ultimately claim an effective filing date prior to 16 March 2013 (whereas continuation-in-part applications will use the new FITF system if they include any claim based on material added after 16 March 2013). As a consequence, we can expect prosecution under the FTI and FITF systems to run in parallel for many years to come.

A true first-to-file system?

Whilst the new FITF system is often referred to as an FTF system in US commentaries, as noted above it in fact contains a series of provisions that mean the outcome for a US patent application can be very different to that of a corresponding application in the rest of the world.

The AIA marks huge changes to the US patent system



The FITF system is in effect created by the definition of citeable prior art found in the new sections §102 and §103 of the US patent act as modified by the AIA. The new §102(a)(1) provides a European-style system of absolute novelty for any public dissemination of prior art. Meanwhile, the new §102(a)(2) provides for the citation of US applications filed earlier and published later than an examined application, in a similar manner to European Article 54(3) (excepting that the USPTO can cite these documents for both novelty and inventive step).

Hence at first glance the FITF system appears to take a harmonising step towards the FTF system used in Europe and the rest of the world.

However, 35 USC §102 then introduces a series of exceptions to the definition of prior art that mean it is possible for an applicant – despite being both the first to invent and the first to file an application – to lose out to a competitor's later patent application. These exceptions can mean that there is an incentive to publish an invention at the earliest opportunity before filing in the US, placing the new FITF system in direct conflict with the absolute novelty requirements of the European FTF system.

Author:
Doug Ealey



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<http://dycip.com/dycartaia>

D YOUNG & CO INTELLECTUAL PROPERTY

And finally...

D Young & Co Webinar European Biotech Patent Law Update

Join D Young & Co patent attorneys Robert Dempster and Simon O'Brien for a free 45 minute round up of significant recent EPO biotech case law, including presentations and live Q&A.

Wednesday 11 January 2012

12.00 GMT and 17.00 GMT

For more information and to register online please visit: www.dyoung.com/webinar-biotech0112



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