D YOUNG & CO

PATENT NEWSLETTER

February 2010

COURT OF APPEAL CLARIFIES UK LAW ON SELECTION INVENTIONS[1]

ELI LILLY'S OLANZAPINE PATENT, EP0454436B, UPHELD AT COURT OF APPEAL

In upholding the High Court decision[2] to reject Dr Reddy's Laboratories' challenge to the validity of Eli Lilly's patent on olanzapine, the Court of Appeal have clarified the UK position in respect of "selection inventions". In effect, the Court has said that, under the new law (Patents Act 1977), the question of selection does not arise. Selection criteria arose and existed as a result of the old law - IG Farbenindustrie's Patents (1930) 47 RPC 289 and Du Pont (Witsiepe's) Patents (1982) FSR 303, cases decided under the 1949 Patents Act.

The IG Rules required:

1. "A selection patent to be valid must be based on some substantial advantage to be secured by the use of the selected members... "

2. "The whole of the selected members must possess the advantage in question."

3. "The selection must be in respect of a quality of a special character which can fairly be said to be peculiar to the selected group."

The Court, having concluded that it was not bound by IG, decided to follow the EPO method of dealing with inventions using the criteria set out in T939/92 Agrevo. Summarised briefly, the EPO examine the claimed subject for the technical contribution to the art (under Art 56 EPC), thereby excluding from patentability, subject matter which amounts to no more than an arbitrary choice (selection) from what was previously known. Such analysis obviously depends on the extent of teaching in the patent and/or the extent to which the EPO may permit the late introduction of data into the proceedings. In these respects, the EPO and UK courts have differed and may continue to differ.

CONTINUED ON PAGE 2

[1] Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Company Ltd [2009] EWCA CIV 1362 (18 December 2009)
[2] Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Company Ltd [2009] EWCH 2345 (Pat) (13 October 2008)

CONTENTS

Turning to the facts of the case, the patent, EP0454436B, related to a single compound, olanzapine, marketed by Lilly as the anti-psychotic Zyprexa®. The compound fell within the general disclosure of a prior art document GB1533235, published in November 1978. That patent was calculated to cover over 10^{19} compounds, with a preferred embodiment that covered an estimated 86,000 compounds including olanzapine. GB1533235 contained no pharmacological data but alleged that the compounds had "useful central nervous system activity".

The argument that olanzapine was an inadmissible selection failed. The patent in suit included extensive data including that from early human trials - the leading decision of LJ Jacob's believing the data to be "much greater than that generally provided in a patent for a new pharmaceutical compound". The data clearly demonstrated the compound to be active and avoid the side effects associated with prior art antipsychotics. Thus, with the understanding that close to the priority date a general review of antipsychotics expressed little hope of a major development in the treatment of schizophrenia and the lack of motivation or direction in the prior art, the claims to olanzapine were considered valid.

A further challenge had been raised on the basis of a paper authored by some of the inventors (Chakrabarty 1980) describing a structure activity relationship (SAR) of 57 of the compounds in GB1533235 including the ethyl derivative of olanzapine. At first instance there had been a difference of opinion between the two chemical experts as to the nature of the "further development" the paper then urged to be taken when the authors stated: "this profile of activity needs further development of this class of compounds". On the one hand it could refer to the development of the compound identified from the tests to be most promising or the alternative, preferred by Dr Reddy, was that the SAR should be completed - a step they considered would inevitably have resulted in the identification of olanzapine (the most promising compounds include 18 variants, 7 of which were disclosed in the SAR study, leaving 11 further to be investigated). The Court of Appeal could find no fault in the High Court conclusion that the former approach was the intended meaning as the alternative amounted to no more than an "exploration of further compounds without any real prospect that any of them would have solved the problem with which the art was concerned". This was supported by the extent of data in the prior art paper.

Although this decision brings UK law into line with the approach used by the EPO, it does not as such consign their earlier concept of selection inventions to the wilderness. Many EPO Appeal decisions still discuss selection inventions and use the three step test of T279/89 which are not too dissimilar from the IG rules - though it is most usual for a claim to stand or fall on the basis of the third arm of the test - arbitrary selection, i.e. is there a technical contribution to be derived from the specific class claimed (i.e. the test is applied in T939/92). This decision does not appear in the Court of Appeal decision or that of the High Court. The question posed by T279/89 in respect of a selection is whether the following points are satisfied:

1. The selected sub-range should be narrow.

2. The selected sub-range should be sufficiently far removed from the known range illustrated by means of examples.

3. The selected area should not provide an arbitrary specimen from the prior art, i.e. not a mere embodiment of the prior description, but another invention (purposive selection).

T279/89 is an often cited decision by the Boards of Appeal. Arguably, even applying it to the olanzapine patent, the benefits observed in the comparison with ethyl olanzapine disclosed in Chakrabarty would probably support the presence of a selection.

Thus, the major point that can be taken from this decision is that EPO case law on the question of selection now overrides the IG rules, rules Lord Justice Jacob concluded should be regarded "as part of legal history, not as part of the living law".

NEIL NACHSHEN

CASE LAW UPDATE
REVOCATION OF EP(UK)0509752B AT THE UK HIGH COURT

In another round of the legal battle between the generic and branded pharmaceutical sectors, Teva has successfully sought revocation of Merck's EP(UK) patent no. 0509752 at the UK High Court[1]. EP0509752 covers Cosopt®, a topical formulation containing dorzolamide hydrochloride and timolol maleate.

The patent had formulation and (Swiss-style) second medical use claims directed to dorzolamide and timolol in the treatment of ocular hypertension and glaucoma as well as claims relating to a process for making the formulation which included the step of "adjusting the pH of the composition obtained [that containing dorzolamide and timolol] to 5.0-6.0 by addition of a suitable reagent."

ADDED MATTER

In response to an objection of added matter, Merck sought to amend the patent and limit the claimed range of the pH adjustment step to 5.5 to 6.0. The only disclosure of the pH of the co-formulation is in examples 1 and 2 of the patent as granted (examples 1 and 10 of the application as filed). Example 1 discloses a pH of 6.0 and example 2 discloses a pH range of 5.5 to 6.0. Merck therefore identified example 2 as providing basis for the amended range.

Example 2 however contains a number of additional features not present in the amended claim. For instance, in the formulations of example 2 dorzolamide and timolol are present at a certain ratio (4:1 and 1:2.5) and the formulations contain gellan gum as a viscosifier. The amended claim was silent as to the presence of a viscosifier and recites a much broader range for the two actives (500: to 1:20).

Thus, Teva argued, and the Judge accepted, that to claim a pH range of 5.5 to 6.0, irrespective of the presence of the additional features in example 2, amounted to an impermissible intermediate generalisation. As the amendment was not allowed, the Judge found the unamended claim invalid.

The Judge's analysis in this case appears to be in line with the way EPO Boards of Appeal approach the issue of added subject matter. Further, it serves to illustrate the point that when drafting patent applications, particularly for Europe, it is necessary to ensure that all potentially important features are adequately described in the main body of the description and not unnecessarily linked to particular embodiments or examples. Otherwise, later claim amendments which seek to incorporate such features, either during prosecution or after grant, may be refused.

NOVELTY AND OBVIOUSNESS

In raising lack of novelty, Teva relied on a single piece of prior art, Nardin, an abstract co-authored by Merck scientists delivered to the British Library only 6 days before the priority date. Nardin disclosed the sequential administration, twice daily, of timolol and a drug disclosed as MK-507.

Merck argued that Nardin did not anticipate the second medical use claims because (a) Nardin did not disclose the identity of MK-507 (Merck's internal name for dorzolamide) and (b) Nardin disclosed sequential administration of the two drugs but the use claims were limited to co-formulation in a single product.

With regard to the construction of the second medical use claims, the Judge noted that "A legitimate canon of construction is that, normally, one would expect the claims to extend to all the ways of performing the invention described in the specification, not merely those which are said to be preferred." In this case, the specification discussed both sequential administration and co-formulation and example 3 specifically exemplified sequential administration of first timolol and then 10 minutes later dorzolamide. Thus, the Judge decided that claim 1 was not limited to a co-formulation and was not distinguishable from Nardin on that basis.

The Judge further held that the skilled person would have easily identified MK-507 as dorzolamide, not least by telephoning Merck and asking their scientists. He went on to note that one could have a fruitless debate about whether the claim lacked novelty or was merely obvious but in either event claim 1 could not survive the publication of Nardin.

Merck proposed to save the patent by amendment. The second medical use claims were to be limited to make clear that only use of a co-formulated product was claimed.

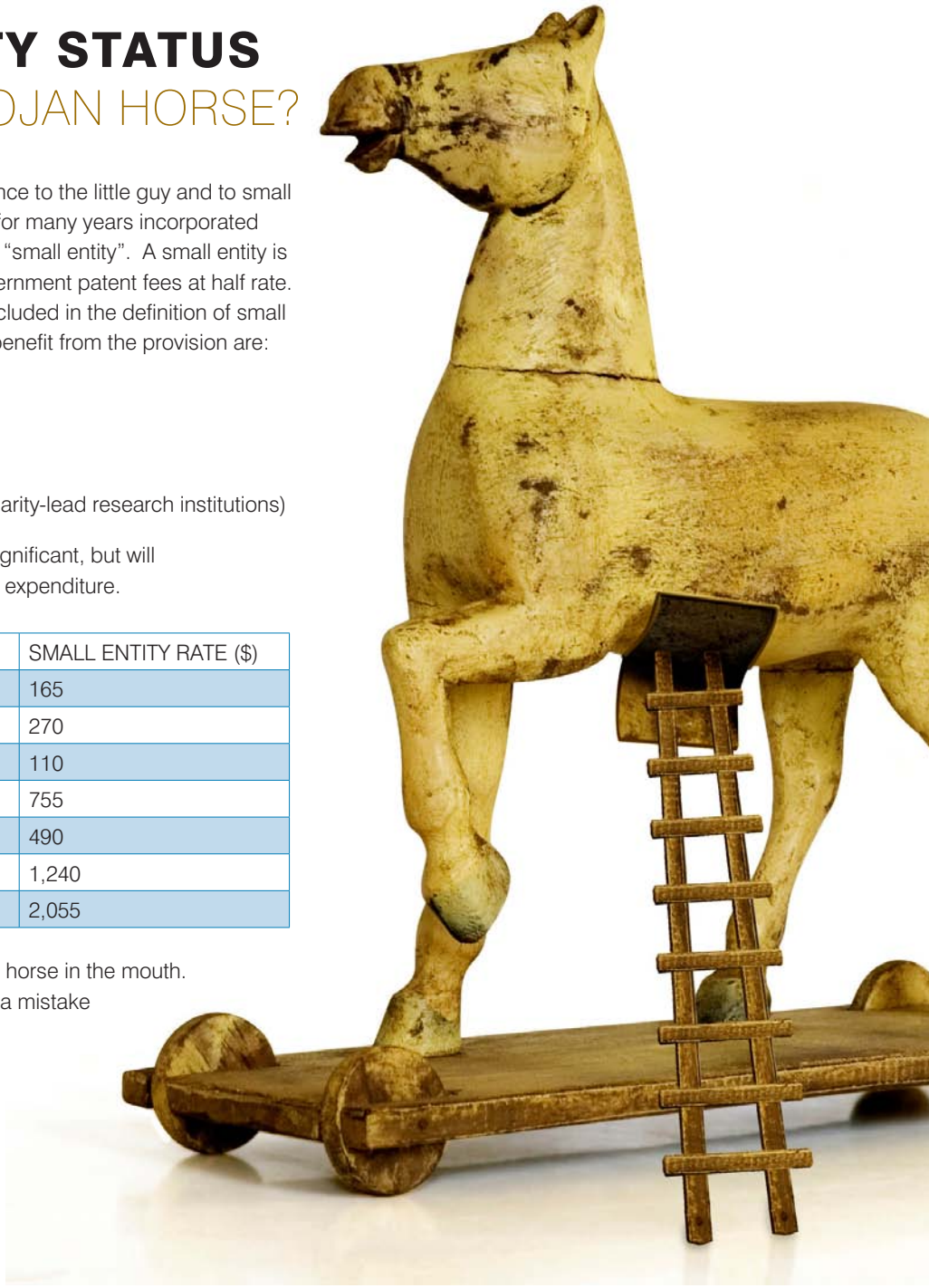
The Judge quoted from recent authorities which indicate that for a finding of non-obviousness it is not normally sufficient to show that the later claimed subject matter was "obvious to try", it being necessary to also show that the skilled person would have had a fair expectation of success. Thus, the Judge agreed with Merck that one must proceed with caution when faced with an obviousness attack based on a suggestion that the skilled person would embark on a research program in the course of which he would discover that a product or compound was effective, particularly where the technical effect is one which is newly discovered, or impossible or very hard to predict. That is because the expectation of success may be zero, or inadequate to drive the research forward. In the end it will all depend on weighing the various factors as they appear from the evidence in the case.

On the evidence presented, the Judge found that the skilled team starting from Nardin would have been highly motivated to achieve the claimed result and would have entertained throughout a fair expectation of success arriving at their goal without any invention.

KIRK GALLAGHER

[1] [2009] EWHC 2952 (Pat)

US SMALL ENTITY STATUS
GIFT HORSE OR TROJAN HORSE?



Most governments like to give financial assistance to the little guy and to small businesses. The patent system of the US has for many years incorporated financial assistance through the concept of the "small entity". A small entity is allowed to pay many of the most common government patent fees at half rate. Universities and non-profit organisations are included in the definition of small entity, so the most important groups that may benefit from the provision are:

- Individual owner/inventors
- Small businesses
- Universities (and other governmental or charity-lead research institutions)

As tabulated below, the fee savings are not insignificant, but will still be relatively small compared to total patent expenditure.

USPTO FEE	FULL RATE ($)	SMALL ENTITY RATE ($)
Basic Filing	330	165
Search	540	270
Examination	220	110
Issue	1,510	755
1st Renewal	980	490
2nd Renewal	2,480	1,240
3rd Renewal	4,110	2,055

The old proverb says one should not look a gift horse in the mouth. But are the savings only tempting you to make a mistake in the sense of a Trojan horse?

The relevant rule is 35 U.S.C. 1.27 (a)(2) which defines a small business concern as any business concern that:

1. Has not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person, concern, or organisation which would not qualify for small entity status as a person, small business concern, or non-profit organisation; and

2. Meets the size standards set forth in 13 CFR 121.801 through 121.805 to be eligible for reduced patent fees. Questions related to standards for a small business concern may be directed to: Small Business Administration, Size Standards Staff, 409 Third Street, SW., Washington, DC 20416.

For small businesses, the definition is to be found in 13 CFR. 121.802:

A concern eligible for reduced patent fees is one:

a) Whose number of employees, including affiliates, does not exceed 500 persons; and

b) Which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organisation or a small business concern under this section.

Part (a) is the familiar 500 employee limit, but this limit is unfortunately not a rule in itself in view of the logical "and" with part (b) which essentially paraphrases the above-quoted 35 U.S.C. 1.27 (a)(2)(i).

An important distinction is that an entity that qualifies as a small entity, such as a small business concern or a University, is not given a blanket permission to pay reduced fees on all its cases. Rather, each individual patent application and patent must be assessed to check if it has been disqualified by the granting of any rights in the invention to a disqualified entity. Moreover, this is an ongoing obligation that needs to be re-assessed every time the next government fee falls due on every case[1].

There are many practical situations that result in the granting of rights in the invention to a large entity:

1. Granting a patent licence to a large entity;

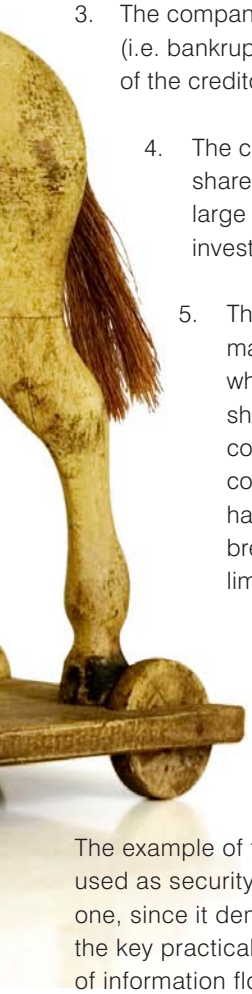
2. The company uses its intellectual property as security on a bank loan (so-called lien) and the bank is a large entity;

3. The company is in administration (i.e. bankruptcy) and at least one of the creditors is a large entity;

4. The company has a major shareholder who is a large entity, such as an investment bank;

5. The company has a major shareholder who has a major share holding in other companies, and all these companies together have a size which breaches the small entity limit; and

6. A licensee who is a small entity granting a sub-licence to a large entity.



The example of the patent being used as security on a loan is a good one, since it demonstrates one of the key practical problems - lack of information flow. This example is explored in the case of a small company with a person responsible for IP matters who is not a qualified patent attorney - for example an engineer. In this example, an existing patent application has been allowed and the issue fee is payable. Moreover, since the patent application was filed the company took a bank loan secured on the IP. The company's outside patent attorney writes to the IP contact at the company reporting allowance and asking for confirmation that the case is still eligible for small entity status. The IP contact may be unaware of the terms under which a bank loan has been secured. Indeed he may be unaware that the bank loan exists at all. Moreover, it is almost certain that the CEO/CFO who secured the bank loan on the company's intellectual property would not make the relevant connection.

Universities are not immune from these kind of problems, since they often grant licenses to spin-outs and the information flow from spin-out to University may be imperfect. For example, would a spin-out inform the University when a bank loan was taken or if it granted a sub-licence to a large entity?

The seemingly transparent and unproblematic category of granting a licence (point 1 above) is also not as it might seem. For at least a hundred years, the chemical industry has used "bag" licences or "label" licences to distribute products. In its oldest form, a bag of say fertilizer would not be sold to the customer, but rather licensed to the customer, with the licence being printed on the label of the bag. In more recent times, this approach has been almost universally adopted by the software industry in the so-called "shrink-wrap" license. Indeed it is quite unusual for any software application to be sold - it is almost always licensed. Therefore, if a software application is distributed using a licence to customers and one of the customers is a large entity, and if the invention is embodied in the software application, then arguably the small entity status has been lost[2]. This is a very difficult situation to keep track of at an administrative level, since the mapping between what is contained in released software and what is covered by a company's patents and patent applications is usually complex and evolving.

So if one accepts that mistakes will be made by organisations taking advantage of the reduced fees, what are the consequences? The consequence is stipulated at 35 USC 1.27(h)(2) where it is specified that improperly paying fees as a small entity, where there is intent to deceive, shall be considered as a fraud on the Office. Fraud is an invalidity ground. The possible consequence of mistakenly paying the reduced fees is therefore catastrophic - invalidity of the patent. One could perhaps be comforted that there was no intent to deceive, so the patent would not be lost. However, in litigation, such behaviour could be portrayed by the other side as relying on ignorance of the law and poor internal management procedures! A more practical consideration is that if a patent with such a problem were ever litigated, large amounts of money and time are likely to be expended on determining the point.

Another possibility would be to obtain clarity in advance by requesting a ruling from the Small Business Administration (SBA). Such a ruling is binding and so should eliminate any risk of fraud provided that all relevant facts are put forward for consideration. However, the legal costs of requesting such a ruling are likely to outweigh any savings, so this is not practical.

It should also be remembered that many small businesses for whom patents are relevant have the ultimate aim of selling out with a trade sale or IPO. If the company has claimed small entity status on its patents, this is likely to be identified in due diligence by the purchaser and, depending on the facts, may be deemed to be a weakness that depresses the company's valuation.

In summary, for all but the most transparent scenarios, claiming small entity status is associated with risk. As a result, for the majority, the short term advantage of fee saving is probably outweighed by the possibility of negative consequences in the future.

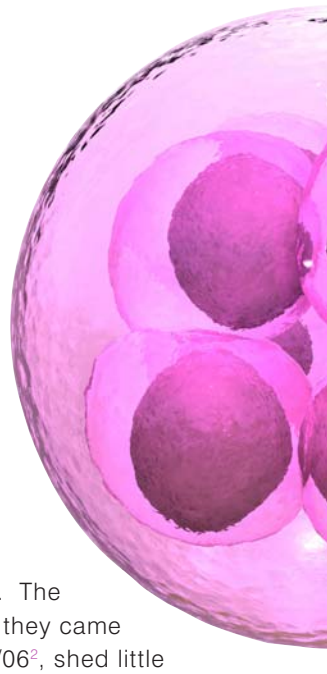
MILES HAINES

[1] There is an exception that if a patent application qualifies for small entity status on filing it retains that status until the issue fee becomes due regardless of the facts.

[2] There is some interesting material on this point in the consultation that took place in 2004 when the current version of 35 U.S.C. 1.27 was drafted - see www.uspto.gov/go/og/2004/week41/patchng.htm

EMBRYONIC STEM CELLS PATENT IS REFERRED TO THE ECJ

GERMAN FEDERAL COURT OF JUSTICE STAYS PROCEEDINGS TO SUBMIT QUESTIONS TO THE EUROPEAN COURT OF JUSTICE



Since the first isolation and culturing of human embryonic stem cells (hESC) in 1995, hESC technology has become one of the most exciting, and controversial, areas of biomedical research. Embryonic stem cells are undifferentiated and 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 replacement cells or tissues to treat a range of serious and debilitating medical conditions, including spinal cord injury, heart disease, diabetes, Parkinson's disease and Alzheimer's disease.

However, hESC research is highly ethically contentious as, in the most widely used procedure, isolation of embryonic stem cells involves the destruction of a blastocyst (a very early pre-implantation stage embryo consisting of approximately 150 cells) which may otherwise give rise to a viable human embryo.

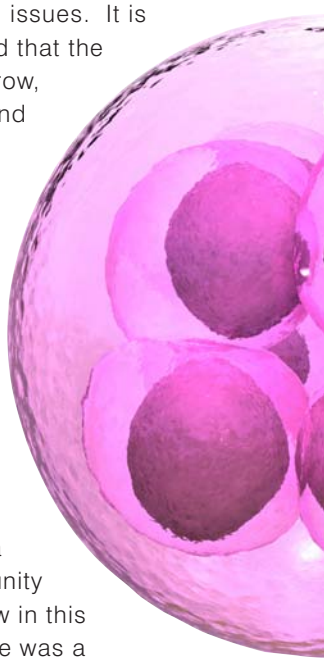
There is considerable divergence across Europe on the ethical acceptability of hESC research. Some member states, notably the UK and Sweden, adopt a fairly liberal position, allowing the use of embryos for hESC using "spare" embryos from IVF procedures and also allowing the extraction of hESC from embryos specifically created for research purposes. Intermediate countries such as France, the Netherlands and Portugal permit the derivation of hESC from IVF embryos but not the creation of new embryos solely for research purposes. Other countries, such as Germany, Italy and the Republic of Ireland, allow the importation of hESC lines created outside the country for research purposes, but prohibit the derivation of hESC from embryos within their territory. Finally some countries, such as Austria, take an extremely restrictive approach and forbid all forms of embryo research.

There is also considerable divergence between member states on the patentability of inventions relating to hESC and their uses. In general the level of restrictiveness shown towards hESC research in each country is reflected in the patentability of products or processes arising from such research, with more liberal countries being more likely to allow patents in this area.

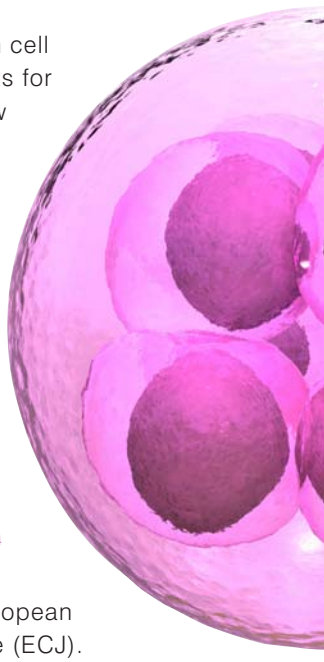
The diverse ethical and patent landscape across Europe makes it complicated to predict what type of protection (if any) will be available in each country. This acts as a disincentive for commercialisation of stem-cell technology in Europe and as a result stifles innovation in the field.

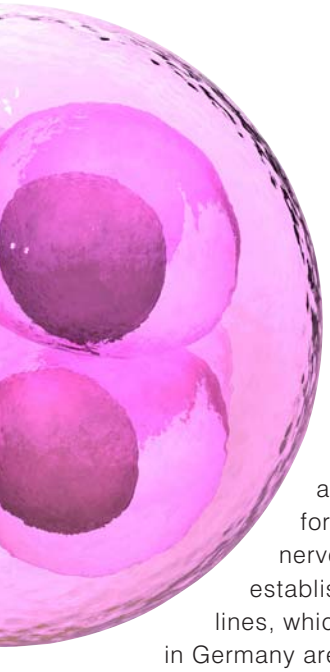
The Directive 98/44/EC on the Legal Protection of Biotechnological Inventions (the "Biotech Directive") has done little to clarify or harmonise European patent law in this area. This is perhaps unsurprising as the Directive was drafted before stem cell technology has developed as a science. The most relevant part of the Directive is the confirmation that patents shall not be granted for inventions which concern "uses of human embryos for industrial or commercial purposes". The meaning of this phrase and the question of how it should be applied to 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 with various questions relating to the patentability of hESC cultures[1]. The answers, when they came in Decision G2/06[2], shed little light on the real issues. It is widely accepted that the Decision is narrow, case-specific and inward-looking and that it fails to engage the wider fundamental points and arguments that are of critical importance in this area. The Decision is perceived as "a missed opportunity to clarify the law in this area whilst there was a vital need for such clarification"[3].



So, as the stem cell community waits for further case-law to develop to provide some degree of predictability to stem cell patenting in Europe, a ray of light has emerged in the shape of the referral concerning a German patent[4] from a German court to the European Court of Justice (ECJ).





The patent in question relates to a technique for generating nerve cells from established hESC lines, which researchers in Germany are allowed to use (see above). The method is a first step in generating neurons that could be used clinically to repair damage to the brain and spinal cord. The patent was granted in 1999. Greenpeace then filed a nullity action with the Federal Patent Court arguing that claims to neural precursor cells derived from hESC contravened the morality provisional of German patent law. In 2006, the Federal Patent Court decided to maintain the patent in an amended form which excluded neural precursor cells derived from hESC produced on their part from human embryos. The patentee filed an appeal with the German Federal Court of Justice (BGH). Oral proceedings relating to the appeal were held on 12 November 2009. The outcome of these is that the BGH have stayed the proceedings and will submit questions on the interpretation of the Biotech Directive to the European Court of Justice. The questions are expected to be along the following lines:

1. Is a stem cell obtained from a blastocyst to be considered as an embryo, even though the stem cell no longer has the capacity to develop into a human individual?

2. Is the blastocyst to be considered as an embryo within the meaning of the law?

3. If the answer to question 2 is in the affirmative, is the use of embryos within the meaning of the law already the case, if obtaining the stem cells to be used according to the invention necessarily implies "use" of blastocysts?

4. Is commercial (i.e. non-private) use within the meaning of the Patent Act a "use for industrial or commercial purposes"? In particular, is any use for research purposes or for therapeutic purposes a "commercial" use within the meaning of Article 6[5] of the Directive?

A preliminary Decision of the ECJ is expected in approximately 1 to 2 years and will be eagerly awaited by practitioners in this area across Europe.

LOUISE HOLLIDAY

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[1] T1374/04 Wisconsin Alumni Research Foundation (WARF) appeal

[2] See D Young & Co February 2009 patent newsletter: 'Stem Cell Patents' Louise Holliday

[3] P. Torremans "The Test Case: WARF before the Enlarged Board of Appeal", Chapter 6 in Embryonic Stem Cells Patents OUP 2009

[4] German patent No. DE 197 56 864 in the name of Professor Oliver Brüstle

[5] Article 6 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions:

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to order public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
   a) processes for cloning human beings;
   b) processes for modifying the germ line genetic identity of human beings;
   c) uses of human embryos for industrial or commercial purposes;
   d) processes for modifying the genetic identity of animals which are likely to cause them suffereing without any substantial medical benefit to man or animal, and also animals resulting from such processes.

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OUT AND ABOUT

STEM CELLS 2010
15-16 February 2010

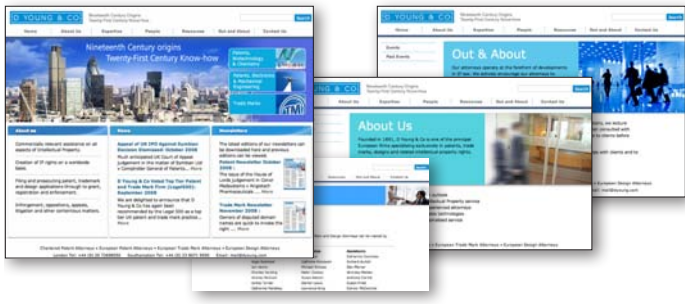
Charles Harding and Louise Holliday will be speaking at the Stem Cells 2010 conference, organised by SMi and taking place in London. Charles and Louise will be discussing practical steps and strategies on obtaining patent protection for stem cells.

IPREG.ORG.UK

The Intellectual Property Regulation Board (IPReg) has been set up to regulate UK-qualified patent and trade mark professionals. In January 2010 IPReg launched its new code of conduct. For more information visit the IPReg website: www.ipreg.org.uk.

Managing Intellectual Property Global Awards 2009

D Young & Co has been awarded MIP UK Patent Prosecution Firm for 2009 and named MIP Top Tier Trade Mark Firm 2009. We have also been ranked as a top tier Patent and Trade Mark Firm by Legal 500 2009 and feature in the Expert Guides Leading UK IP Practitioners publication.



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