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Supporting Innovation in the Middle East and Gulf Region

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Patent Protection in the Middle East
An Introduction

Much of the tremendous growth and development of countries in the Middle East over the past 30 years or so has traditionally come from oil and gas revenues, particularly in those countries surrounding the Gulf region. However, there has been increasing focus on investment in technology as the Gulf states look to reduce reliance on technology licensed from outside the region.

Additionally, overseas companies are seeing the region as an increasingly important market especially in those countries which form the Gulf Cooperation Council (the GCC countries are Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates (UAE)). For example, the number of patent applications filed at the GCC Patent Office grew by around a factor of 50 from when the GCC Patent Office first opened in 1998 up to 2008. Applications dropped off slightly in 2009 to 2011 but have since picked up again with 3001 being filed in 2012. The vast majority of these applications are from countries outside the GCC, with over 16 times as many applications being filed by companies from overseas as those from the GCC.

The GCC Patent Office is based in Riyadh in Saudi Arabia and a GCC patent provides a centralised system for obtaining protection in all six states of the GCC. This brings cost reduction benefits as well as providing a longer patent term than if the patent was applied for via a national office (20 years duration as opposed to typically 15 years).

The specification must be filed in both Arabic and English. There are also requirements for many of the documents such as the power of attorney and assignment from inventor to applicant to be legalised up to a consulate of one of the GCC states. A legalised certificate of incorporation or similar document, such as a legalised extract from the commercial register, is also needed. So, when considering applying for a GCC patent, the extra time scales and costs associated with these formalities should also be taken into account.

Substantive examination of a GCC application is often outsourced to the Austrian, Chinese or Australian patent offices. Applicants who have already dealt with these offices may therefore have a slight advantage due to similarities in working practices when it comes to substantive exam.

It is important to note that the GCC is not a signatory of either the Paris Convention or the Patent Cooperation Treaty (PCT). While it is possible for a GCC patent application to claim priority from a prior convention application as if the GCC were a signatory to the Paris Convention, it is not possible to claim priority under the Paris Convention to an application that was first filed at the GCC Patent Office. Therefore, it is generally thought to be more flexible to file in a Paris Convention country as a first filing rather than a GCC application.

Also, as the GCC is not a signatory of the PCT, it is not possible to select a GCC application for PCT national phase entry. Having said that, four of the GCC countries are also members of the PCT (Bahrain, Oman, Qatar and UAE), although significantly Kuwait and Saudi Arabia are not members. So, if protection in the Gulf states may be desirable this should be considered during the priority year rather than waiting until PCT national phase entry is due, otherwise it may be difficult to obtain the desired protection. It is therefore common to file both a PCT application and a GCC application at the same time if protection in the Gulf states is sought, especially if Saudi Arabia or Kuwait are key markets.

It is also possible to seek patent protection via a national application. However, whilst the patent systems in some states such as UAE and Saudi Arabia are fairly well established (the Saudi Arabian Patent Office has recently started to accept online filing of applications), it is fair to say that others are very much in their infancy. For example, the Omani Patent Office has only very recently started formal examination of all pending applications, and the Qatari Patent Office has recently started accepting local applications and national phase PCT applications. Since both Oman and Qatar are already part of the GCC and the PCT, it may be more desirable to seek protection via a GCC or PCT application in
Although the ongoing battle between Apple v Samsung has taken centre stage in the smartphone wars, one other skirmish in the UK involved Apple and a different opponent - the Taiwanese company HTC. Peace broke out in this skirmish at the end of 2012. However, recently, the Court of Appeal heard a case which concerned the fall-out from that battle. The case is of interest to practitioners as it may affect the UK IPO’s interpretation of the exclusion of “computer programs as such” from patent protection.

The original trial was held before Mr Justice Floyd in the High Court in July 2012 and involved four patents owned by Apple. Mr Justice Floyd held that three of the patents were not valid and the remaining patent was not infringed. This decision was appealed in part. As HTC and Apple had settled their dispute, HTC did not take part in the appeal. However, Apple appealed the decision relating to the validity of two of their patents found invalid during the High Court trial, namely EP(UK) 2 098 948 and EP(UK) 1 964 022.

During the original trial, Mr Justice Floyd found EP(UK) 2 098 948 to be invalid for two reasons:

1. It was found to be nothing more than a “computer program as such”
2. It was found to be obvious. EP(UK) 1 964 022 was also found to be obvious.

Although the Appeal Court upheld the decision in respect of EP(UK) 1 964 022 and the obviousness finding in respect of EP(UK) 2 098 948, the Appeal Court overturned the decision that EP(UK) 2 098 948 was nothing more than a computer program as such. This may impact the UK IPO’s interpretation of the computer program exclusion.

EP(UK) 2 098 948 deals with the issue of multi-touch gestures. Specifically, certain multi-touch ‘flags’ are set if certain views on the screen can accept multi-touch gestures. If the multi-touch flag is not set, then a second, contemporaneous, touch on the view is ignored by the software. During the original trial, it was held that the claimed invention related to “a computer program as such” and so was excluded subject matter under UK law. However, the Court of Appeal found that Mr Justice Floyd incorrectly identified the contribution in a first aspect of the invention as simply laying in software processing multi-touch inputs and in a second aspect made it easier to write software for multi-touch devices.

Instead, Lord Justice Kitchin (for the Appeal Court) said that the problem which the invention addresses, namely how to deal with multiple simultaneous touches on a multi-touch device, is essentially technical. Further, dividing the screen into a number of views, and associating a multi-touch flag to each view, essentially concerns the internal operation of the device. The fact that the solution is embodied as software is irrelevant and importantly, in paragraph 57 of the judgment, Lord Justice Kitchin said that:

“an invention which is patentable in accordance with conventional patentable criteria does not become unpatentable because a computer program is used to implement it.”

Lord Justice Lewison (for the Appeal Court) also commented in respect of the second aspect identified by Mr Justice Floyd that even if the contribution lay in making it easier to write software for a multi-touch device, this was not a computer program as such and should not be excluded.

This decision provides further evidence that the UK courts are taking a rather pragmatic view to the computer program exclusion, and look to the substance of invention rather than how the invention is embodied. This should provide further weight to the UK IPO to change their current restrictive view on the computer program exclusion.

Author: Jonathan Jackson

In summary, there are several different routes by which patent protection may be obtained in the Gulf states depending which countries are of interest. A combination of a PCT application and GCC application is generally thought to provide the most flexibility and coverage, but for any specific query, please contact our Dubai office team (see www.dyoung.com/dubai or email dubai@dyoung.com) or contact your usual D Young & Co advisor.

Author: Anthony Carlick
Article 03

Stem Cell News
EPO Revokes ‘Brüstle’ Patent and New CJEU Referral on the Patentability of Parthenotes

Brüstle v Greenpeace (C-34/10) concerned the patentability of technology based on hESC

As previously reported in this newsletter, the question of the patentability of technology based on the use of human embryonic stem cells (hESC) was considered in the Court of Justice of the European Union (CJEU) referral Brüstle v Greenpeace (C-34/10) in October 2011. The CJEU referral related to a German national patent granted to neuroscientist Oliver Brüstle in 1999, for a method of turning mammalian embryonic stem (ES) cells into neurons.

Following the ruling of the CJEU, it was then left for the German courts to decide on the allowability of the original patent. In these proceedings, the German Federal Court of Justice ruled the patent could be maintained if it included a general disclaimer excluding the destruction of human embryos.

Parallel opposition proceedings have also been on going at the European Patent Office (EPO) with respect to the corresponding European patent. In contrast to the German case, the EPO opposition division has revoked the European patent.

An equivalent amendment to that made on the German national case was rejected on the grounds of ‘added matter’ ie, the claims were considered to contain subject matter not disclosed in the original patent application.

The EPO has therefore avoided consideration of moral issues surrounding the patentability of inventions relating to human ES cells.

The decision of the Opposition Division is open to appeal. If the case goes to appeal and the added matter issue is resolved, the morality issues may be reconsidered, either by the Technical Board of Appeal or by the Opposition Division (if the case is remitted). However, it is likely to be a matter of years before this takes place.

In the meantime, a separate referral has been made to the CJEU on a stem cell related matter.

The UK’s High Court has made a referral to the CJEU to clarify if human ‘parthenotes’ fall under the definition of a human embryo under the Biotechnology Directive. Parthenotes are activated unfertilised oocytes which may be used for the production of human stem cell lines.

To quote from an article in Scientific American: “Human embryonic stem cells typically come from fertilized eggs. In 2007, however, scientists at International Stem Cell, a California-based biotech firm, reported the first successful creation of human stem cell lines from unfertilized eggs. They used a process called parthenogenesis, in which researchers use chemicals to induce the egg to begin developing as if it had been fertilized. The egg - called a parthenote - behaves just like an embryo in the early stages of division. Because it contains no genetic material from a father, however, it cannot develop into a viable fetus.”

The US High Court referral concerns an appeal brought by International Stem Cell Corporation (ISCC) against a decision made by the UK Intellectual Patent Office (UK IPO) in 2012 to reject two patent applications over a method for inducing pluripotent stem cells from human eggs that have undergone parthenogenesis.

The UK IPO’s decision said: “A parthenogenetically-stimulated human oocyte is considered, on the basis of the Brüstle judgment to be capable of commencing the process of development even if it is not able to complete this development.”

The Brüstle judgment (CJEU referral C-34/10, mentioned above) defined a ‘human embryo’ under European law as “any [fertilised] human ovum [...] if that fertilisation is such as to commence the process of development of a human being”.

It further said that this definition includes “a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis”.

ISCC argued that the key question was what the CJEU meant by “capable of commencing the process of development of a human being”. It was unclear whether this referred to an entity that could in fact develop into a human being or something that could start the process of becoming a human being but was unable to complete that process.

A parthenote is capable of developing into a blastocyst-like structure but cannot develop into a human being because it lacks paternal DNA. On the evidence before the High Court, human parthenotes were shown to develop to the blastocyst stage, over about five days, but after that period the requirement for paternal genes became acute and the oocyte did not develop further, and never to term.

There was, however, no consensus on the scientific evidence as to the developmental potential of parthenotes put before the CJEU in the Brüstle judgment.

The High Court judge therefore found that the law was not acte clair on this point, and so there shall be another referral to the CJEU on patentability of stem cells, specifically on the patentability of unfertilised human ova.

Author: Louise Holliday

Related articles and notes
1. D Young & Co patent newsletter, October 2011, author Louise Holliday, article “CJEU Stem Cell Patents Decision - Brüstle v Greenpeace (C-34/10)”: http://dycip.com/cjeuc34101
The Supreme Court of India recently rejected Novartis AG’s attempt to win patent protection for an updated version of its cancer drug Gleevec. This landmark judgment has been roundly criticized by pharmaceutical companies but praised by public health activists, who said it would protect India’s ability to make inexpensive generics for the developing world. This article investigates the facts behind the case and considers the general impact of the Supreme Court decision on the patentability of pharmaceutical products in India.

The patent in question relates to the beta-crystalline form of Imatinib Mesylate. Imatinib is a specific protein kinase inhibitor which can be used in the preparation of pharmaceutical compositions for use as anti-tumour and atherosclerosis drugs. The US patent covering Imatinib was granted in 1996 (the ‘Zimmermann Patent’) and disclosed various derivatives of a compound, of which Imatinib was a single example, in addition to corresponding salts.

Novartis was granted US Food and Drug Administration (FDA) approval for Gleevec (marketed as Glivec in Europe) in 2001. The active component listed for Gleevec was Imatinib Mesylate, which Novartis claimed was covered by the Zimmermann Patent. Indian patent law is traditionally viewed as hostile to pharmaceuticals and Section 5 of the 1970 Patents Act, which was in force at the time of the Zimmermann Patent application, expressly excluded the patentability of substances intended for use as a medicine or drug. This exclusion prevented Novartis prosecuting the original Zimmermann Patent application in India. During the late 1990s, however, India was twice taken to the World Trade Organisation panel for contravening the ‘Trade Related Aspects of Intellectual Property Rights’ (TRIPS) agreement due to a lack of provision for the protection of pharmaceutical and agricultural chemical products. These actions compelled the Indian Government to amend the definition of an ‘invention’ in Indian patent law such that pharmaceutical products were no longer excluded. In order to placate domestic angst regarding how this amendment would impact India’s generics pharmaceuticals industry and its reputation as ‘the pharmacy of the world’, the government concurrently amended Section 3(d) of the Patent Act to introduce a second tier of qualifying standards for pharmaceutical products. The principle requirement of this amendment was that a new form of a known pharmaceutical substance must have enhanced efficacy over the known substance. It is within this framework of Indian patent law that the substantive issues of the present case were heard by the Supreme Court.

Novartis submitted that the teachings of the Zimmermann Patent did not extend beyond Imatinib itself and that arriving at the beta-crystalline form of Imatinib Mesylate required two inventions from the Zimmermann Patent. To produce Imatinib Mesylate one would be required to select Imatinib from the extensive list of possible compounds and subsequently choose methanesulfonic acid to produce the salt. An additional invention would then be necessary to arrive at the beta crystal form.

The Supreme Court accepted that the beta-crystalline form of Imatinib Mesylate was not known from the Zimmermann Patent and proceeded to test it for inventiveness under Section 3(d) of the Act. The central issue for assessing inventiveness under Section 3(d) was determined as the requirement for improved efficacy over the known substance. In the case of a medicine, the Court defined that efficacy related to ‘therapeutic efficacy’ and therefore, contrary to the approach followed in many other regions, non-therapeutic advantages such as improved safety or stability could not be considered to confer inventiveness.

Novartis submitted that the beta-crystalline form provided beneficial flow properties, improved thermodynamic stability, lower hygroscopicity and improved bioavailability compared to Imatinib Mesylate itself. However, due to the Supreme Court’s narrow interpretation of the term efficacy, flow properties, thermodynamic stability and hygroscopicity were considered to be physical properties which had no impact on therapeutic efficacy. Critically, when considering bioavailability the Court determined that “increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy”.

The Supreme Court therefore ruled that the beta-crystalline form of Imatinib Mesylate fails both the tests of invention and patentability as set out in Indian patent law and dismissed the appeal.

This decision has clearly caught the imagination of the wider public due to the emotive backdrop in which it has been set by numerous editorials and blogs. On further reflection, however, it appears that the decision is a matter of patentability in a jurisdiction which is notoriously hesitant to grant patents for pharmaceutical products. In its summary, the Supreme Court is careful to note that the decision does not bar protection for all incremental inventions of pharmaceutical substances. Nonetheless, it seems that the threshold for patentability of pharmaceutical products will remain a challenge in India and that data demonstrating an improved therapeutic effect will be essential for protecting incremental pharmaceutical inventions in this jurisdiction.

Authors:
Tom Pagdin and Louise Holliday
UK IP Bill Supports Innovation in the UK
Proposed Modernisation of the UK IP System

The UK government has announced an intellectual property Bill which aims to modernise the IP system in the UK so that it “operates more efficiently, is clearer and is more accessible”.

The Bill was included in the programme of legislation announced in the Queen’s Speech on 8 May, and the Bill has already started its progress through parliament with the formality of a first reading in the House of Lords on 9 May. Substantive debate started with the second reading on 22 May.

Primary legislation in the UK (such as this Bill) is a rare occurrence, and the Bill has therefore attracted keen attention from observers with an interest in IP. Its provisions mainly relate to patent and designs. The Bill is part of the government’s response to the Hargreaves Review of IP and Growth, which was published in May 2011.

In a press release, issued in response to the announcement, the UK IPO commented:

“...the Bill, published today, proposes changes that would help businesses to better understand what is protected under the law, reduce the need for costly litigation, and provide greater certainty for investors in new designs and technologies.

Furthermore, an impact assessment performed on the Bill estimates that the net benefit to the UK will be £19.61 million over a ten year period.

Some of the more notable provisions of the Bill are discussed below.

Patents

In relation to the marking of patent numbers (so as to avoid an innocent infringer being able to escape liability for paying damages), the patent proprietor will now be able to mark a product with an internet link to a website or webpage which specifies the patent number(s) associated with the product.

The existing Opinions service offered by the UK IPO will be made more flexible in that the UK IPO will now have freedom to expand the areas relating to a patent on which an Opinion can be requested.

The Bill also allows Opinions to be requested on the validity or infringement of a Supplementary Protection Certificate (SPC) that has been granted on a patent.

At present, the UK IPO has limited powers to revoke a patent on its own initiative. The Bill will extend those powers so that an Opinion adverse to validity may result in the UK IPO revoking the patent. Apparently, it is envisaged that this new power “will only be exercised in the clearest of cases, where it is indisputable that the patented invention lacks novelty or inventive step”. Where this new power is to be used, the patent proprietor will be able to apply for a review of the adverse Opinion, and to amend the patent to fend off the envisaged revocation.

In relation to the EU’s Agreement on a Unified Patent Court (UPC) which was signed by the UK government in February 2013, and which will enable the long-awaited ‘unitary EU patent’ (UP), the Bill includes provisions enabling the Agreement to be brought into effect in the UK and aspects of national UK patent law to be brought into alignment with the Agreement.

The UK IPO will be able to share search results with overseas patent offices, before a UK patent application is published at the 18-month stage as an ‘A’ publication. However, an agreement will need to be in place between the UK IPO and the overseas patent office governing issues such as confidentiality of the shared information.

Designs

In relation to unregistered designs under national UK law, the definition of a design will no longer include ‘any aspect’ of part of an article. This amendment is intended to prevent the protection of trivial features of an article and to reduce the speculative assertion of a broad scope of unregistered design right in infringement actions before the courts.

An unregistered design is not protectable if it is ‘commonplace’ in its design field. The Bill limits commonplace to being assessed in the same ‘qualifying countries’ as are capable of giving rise to unregistered design right (broadly, the EU countries).

Ownership of unregistered design right in designs which are commissioned will no longer reside with the commissioner. Instead, the designer will retain initial ownership. This brings national UK law into harmony with the provisions of EU law governing ownership of unregistered community designs.

Subsistence of unregistered design right is governed by the concept of ‘qualification’. The Bill simplifies and expands the concept so that, broadly speaking, those who are economically active in the EU will qualify for unregistered design right protection.

It will no longer be an infringement of an unregistered design to perform a private act, an experiment or teaching. This brings unregistered designs into harmony with the law governing registered designs at the national and EU level.

Registered designs at the national UK level already benefit from a provision that use with the permission of the owner will excuse any infringement of associated copyright. The Bill extends this benefit to registered community designs.

For a registered design, where the design has been commissioned, ownership will no longer pass to a commissioner, and will remain with the designer. Again, this harmonises UK law with the EU law governing registered community designs.

There will now be a defence of ‘prior use’ in relation to registered designs, and this brings UK law into harmony with EU law which already provides a prior use defence in relation to infringement allegations concerning community registered designs. The Bill includes enabling provisions for the UK to be able to accede to the Hague system of international design registration. This will enable an international design application
to designate the UK nationally, rather than, as at present, only via an EU designation giving rise to a registered community design. The government anticipates that this will make the Hague system more attractive to SMEs in the UK. Business Secretary, Vince Cable commented:

Figures show that UK business invests nearly £16 billion in design each year, which represents 1.1% of GDP. The changes in this Bill are to help SMEs and innovative businesses get on and grow.

When assigning a registered design, it will no longer be necessary also to assign any associated unregistered design right before the UK IPO will be prepared to record the assignment on the public Register. This brings national UK law into closer harmony with EU design law.

In relation to the defence of ‘innocent infringement’ of a registered design, the defence will be narrowed, and a successful proprietor of a registered design will now be able to claim some or all of the profits made by the infringer. This brings national UK law into closer harmony with EU design law.

The Bill allows for a non-binding Opinions service to be set up for registered designs, along the lines of the Opinions service already in place for patents.

The deliberate copying of a national UK registered design or EU registered community design will now also be a criminal offence (although this is already being scrutinised by practitioners).

There are limitations, such as that the registered design must have been registered prior to the copying taking place. The copying must be deliberate copying in the course of business. The accused person must have acted without the consent of the proprietor of the registered design, and must have known or had reason to believe that the registered design had been copied. A defence will be for the accused person to show that they reproduced the registered design unintentionally. They will also not be liable if they can show reasonable grounds for believing that the registered design was invalid or that their product did not reproduce the registered design. The penalties for proven deliberate copying include a fine and/or a prison sentence of up to ten years.

The Bill imposes a requirement for an annual report to be published by the Secretary of State for Business, Innovation and Skills as to whether the activities of the UK IPO (in relation to patents, designs and trade marks) have supported innovation and economic growth in the UK. This implements one of the recommendations of the Hargreaves Review.

When the Bill receives Royal Assent and becomes law in due course, it will be known as the Intellectual Property Act 2013. Our full analysis will follow as and when the bill gains Royal Assent.

Author: Paul Price

Useful links

The Bill and its explanatory notes:
http://dycip.com/ukipbill

The official report (Hansard) of the 22 May 2013 House of Lords debate:
http://dycip.com/ukipbill22maydebate

UK IPO press release 10 May 2013:
http://dycip.com/IPOipbill
USPTO ‘Patents for Humanity’ Winners Announced

In April 2012 we reported on the US Patent and Trademark Office’s (USPTO’s) competition ‘Patents for Humanity’. The project, an initiative of the Obama administration, sought to promote and reward humanitarian applications of technologies patented in the US. On its launch, the competition anticipated up to fifty winners, but in the end just ten entrants have been rewarded – two in each of the five categories – plus six honourable mentions across three of the categories. Perhaps the smaller number of winners (and a two month extended deadline for entries) indicate fewer entrants than expected. Nevertheless, the competition has been applauded by a number of senior US government officials and has itself received the ‘National IP and Technology Transfer Policy Award’ from the non-profit group Licensing Executives Society International (LESI). The winners in each category are:

Medical – Medicines and Vaccines
- University of California, Berkeley: low-cost production of anti-malarial compounds.

Medical – Diagnostics and Devices
- SIGN Fracture Care International: distribution of low-cost fracture implants in developing world hospitals.
- Becton Dickinson: placement of new tuberculosis diagnosis machines in the TB ‘high burden’ countries.

Food and Nutrition
- DuPont Pioneer: development of a fortified strain of sorghum for sub-Saharan Africa.
- Intermark Partners Strategic Management LLP: extraction of edible protein and vitamins from waste rice bran in Latin America.

Clean Technology
- Proctor & Gamble: worldwide distribution of a small chemical water purification packet.
- Nokero: provision of solar light bulbs and telephone chargers to villages without electricity.

Information Technology
- Sproxil, Inc: deployment in sub-Saharan Africa of a cell phone system for identifying counterfeit drugs.
- Microsoft Corporation: provision of machine learning tools for analysis of large health data sets.

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