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In this issue:

Also in this edition: Novartis v Hospira and Virgin Atlantic Airway v Zodiac Seats UK

Gene Sequence Patents in the US
Actions to Take Because of Myriad

Full Story Page 02

Editorial

In this edition we focus on the practical implications of several important decisions from the EPO, UK and US courts. From the EPO there has been a further referral to the Enlarged Board of Appeal in the 'essentially biological' cases. In the US the Supreme Court has declared genomic DNA as unpatentable, and not to be left out, the UK Supreme Court passed judgment in the long-running dispute between Virgin Airways and Zodiac. We also pick up on two decisions on procedural matters. First regarding TFK's failure to utilise the procedural flexibility of actions before the PCC and second a decision of great importance to the pharmaceutical industry regarding the granting of interim relief when a first instance ruling revoking a patent is on appeal.

With patent law moving apace and a further set of draft procedural rules for the Unitary Patent Court in circulation, news that a senior patent specialist will soon be joining our Dispute Resolution & Legal Group looks to be a well-timed move (see page 12). We look forward to introducing Richard Willoughby to our clients.

Editor:
Neil Nachshen

Important email update

Our email addresses are now .com
Please update your records to guarantee receipt of our email communications.

Events

23 September - Seminar
Patent Protection for Software-Related Inventions in Europe and the US, London UK
Ian Harris will be presenting this Management Forum Seminar at the Rembrandt Hotel.

02-03 October 2013 - Conference
Engineering Design Show, Coventry UK
Workshops and face to face, practical and commercially focussed IP advice for innovators.
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Article 01

Gene Sequence Patents in the US Actions to Take Because of Myriad

Isolated DNA: unpatentable. Synthetic cDNA: patentable.

In the much awaited Myriad decision (Association for Molecular Pathology v Myriad Genetics Inc) on the patentability of gene sequences, the US Supreme Court unanimously held that a **naturally occurring DNA segment** is a 'product of nature' and is **not patentable** subject matter merely because it has been isolated. However, it was held that **cDNA is patentable** subject matter because it is not naturally occurring - it is distinguishhable from the natural DNA.

This decision is a significant change in US patent law and reverses the US Patent and Trade Mark Office's (USPTO's) practice of granting patents on naturally occurring substances as long as they are 'isolated' from nature.

As discussed below, we are still faced with uncertainties over the patentability of proteins and other naturally occurring substances and what constitutes sufficient modification for a sequence to be considered patentable subject-matter. It seems that we need to wait and see how US practice develops. In the meantime, below we suggest some courses of actions which you may wish to consider at this stage.

Background

Myriad Genetics Inc (Myriad) obtained several patents after determining the precise location and sequence of the BRCA1 and BRCA2 genes – mutations of which can significantly increase the risk of breast and ovarian cancer. Myriad did not create or alter the genetic information encoded by these genes.

Some of the claims of some of Myriad's patents were challenged by the Association for Molecular Pathology (AMP).

The District Court held that the challenged claims were invalid because they covered products of nature. On appeal, this decision was reversed with the Federal Court finding that both isolated DNA and cDNA was patentable subject matter. Whilst the Federal Court judges were unanimous concerning the patentability of cDNA, the judges were not unanimous with regard to the patentability of isolated DNA.

The decision was then appealed to the US Supreme Court which, as mentioned above, has reversed the Federal Court's decision in part. In this case, the US Supreme Court considered nine composition claims from three of Myriad's patents.

Under US patent practice (35 USC paragraph 101) laws of nature, natural phenomena and abstract ideas are not patentable. The US Supreme Court considers that they are basic tools of scientific and technological research that lie beyond patent protection and a balance needs to be created between *"incentives that lead to creation, invention and discovery"* and *"impeding the flow of information which might permit, indeed spur, invention"*.

> The question posed was whether Myriad's patents claim a *"new and useful composition of matter"* or *"a naturally occurring phenomenon"*.

Influencing decisions

Two previous judicial decisions (Diamond v Chakrabarty and Funk Brothers Seed Co v Kalo Inoculant Co) have influenced the Supreme Court in this case.

Chakrabarty claimed a bacterium which had been modified so that it contained four plasmids which enabled it to breakdown components of crude oil. In this case, the Supreme Court held that non naturally occurring genetically modified microorganisms are patentable.

Funk Brothers Seed Co claimed a mixture of naturally occurring strains of nitrogen fixing bacteria to help leguminous plants take nitrogen from the air and fix it in the soil.

The Supreme Court held that in this case the composition was not patentable subject-matter because the bacteria had not been altered in any way.

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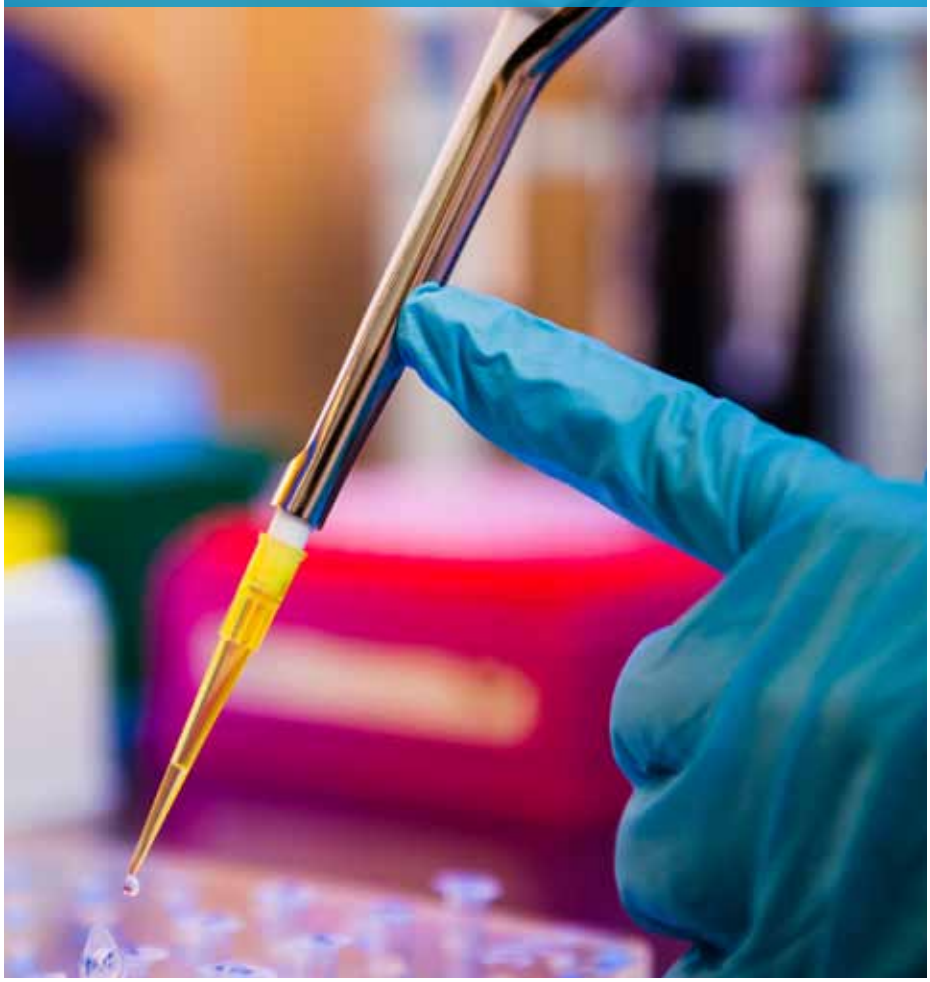
The US Supreme Court decision is a significant change in US law



Isolated DNA claims

Myriad's patents describe the extensive efforts which they had taken to identify the BRCA1 and BRCA2 genes.

The Supreme Court held that extensive effort alone is not sufficient. Moreover, isolating the DNA from the genome, thereby creating a non-naturally occurring molecule, does not save the claims. Further, the past practice by the USPTO of awarding gene patents is not sufficient reason to hold that isolated DNA is patentable subject matter.

In summary, the Supreme Court held that a **naturally occurring DNA segment** is a "*product of nature*" and is **not patentable** subject matter merely because it has been isolated.

cDNA claims

The Supreme Court noted that the creation of cDNA results in an exon only molecule which is not naturally occurring. Therefore **cDNA is patentable** subject matter because it is not naturally occurring.

An **exception** to this is the situation where the DNA does not have an intervening intron which is removed when creating the cDNA. Here the **cDNA is indistinguishable from the natural DNA** and therefore is **not patentable** subject matter. This point could impact on claims to short cDNA fragments.

Unanswered points

In this decision, the Supreme Court did not consider any method claims or new applications of the BRCA1 and BRCA2 genes (eg, diagnostics). Further, the Supreme Court did not consider the patentability of nucleotide sequences in which the order of naturally occurring nucleotides has been altered.

It is unclear from this decision alone as to the minimal number of modifications and the nature of the modifications which need to be made to a sequence for it to be considered not naturally occurring and therefore patentable subject matter.

Further, the impact of this decision on other naturally found biological molecules (such as antisense DNA, microDNA, siRNA, viruses, proteins, antibodies and stem cells) has yet to be established.

Changes to USPTO practice

The USPTO has issued **preliminary** guidance to its examiners.

Unsurprisingly, in view of the Supreme Court's decision, examiners have been instructed to reject *"product claims directed solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not"*. However, claims clearly directed to *"non-naturally-occurring nucleic acids, such as a cDNA or a nucleic acid in which the order of the naturally-occurring nucleotides has been altered (eg, man made variant sequence)"* remain patentable subject matter.

The USPTO will issue more comprehensive guidance to examiners at a later date.

Until the USPTO issues this further guidance, it seems that we will be faced with uncertainty on how method claims and claims to proteins and other naturally occurring biomolecules will be treated. We may find that different examiners will take different stances on the same facts. Further, we may find that we need to wait for further developments in US case law.

On the day that the Supreme Court issued

Continued on page 04

Actions to take because of Myriad

Continued from page 03
Gene Sequence Patents in the US
Actions to Take Because of Myriad

its decision, a number of companies announced that they would provide genetic diagnostic testing for the BRCA1 and BRCA2 genes. Interestingly, Myriad has now started infringement proceedings against two of these companies, Ambry Genetics and Gene by Gene.

In brief, amongst the claims which Myriad alleges are infringed, are isolated DNA claims, claims directed to single-stranded DNA primers and claims directed to methods for screening/detecting a germline alteration of a BRCA1/BRCA2 gene.

These will most certainly be cases to watch.

No change to EPO practice

This development in the US should have no effect on the current situation in Europe where gene sequences isolated from their natural environment can be patented (Directive 98/44/EC) if the sequences fulfil the requirements of patentability (novelty, inventive step, industrial applicability, etc). Under European patent practice, the function of the gene must be known and disclosed in the specification in order to meet with industrial applicability requirements. It is interesting to note that, in Europe, a claim directed to a DNA sequence may only cover that sequence when it is "*performing*" its stated function (CJEU Monsanto Technology LLC v Cefetra BV and others).

Actions to take

There has been much speculation and debate about the impact of this decision on the biotechnology industry.

Some commentators suggest that the impact on future biotechnology business interests in the US will not be as restrictive as initially thought by many with the claims of pending applications being drafted with this decision in mind. Nevertheless, this decision will undoubtedly undermine the validity of patents with isolated DNA claims affecting both the business plans of patentees and potential infringers.

Patentees may find that some of their patents are invalid at least in part. Potential infringers may find that they now have more freedom in which to operate.

It will take some time before we can truly evaluate the impact of this decision on US practice. In the meantime, we suggest you review your US cases to determine if you have any applications or patents with 'isolated DNA' claims. If you are concerned about any of your US cases then you may wish to contact your attorney for advice.

Pending US applications with 'isolated DNA' claims

Obviously, if you have pending applications with claims to 'isolated DNA' then we would suggest amending these claims in light of the Myriad decision.

US patents with 'isolated DNA' claims

If there is a pending sister divisional or continuation application to a US patent which has 'isolated DNA' claims then you could consider pursuing 'synthetic DNA' claims (if such claims have not already granted) in a divisional or continuation application.

If there are no further pending US applications then you could consider using the US reissue procedure in order to strengthen key US patents with 'isolated DNA' claims. Under the US reissue procedure, a narrowing amendment can be filed at any time during the life of the patent and a broadening amendment may be filed within two years after the patent is granted. Nevertheless, there is no requirement for you to take such action because of the Myriad decision.

US freedom to operate opinions / licences /infringement actions

Since 'isolated DNA' claims are no longer valid, you might wish to review any US freedom to operate opinions you may have obtained to determine if any of your business plans require alteration.

Similarly, you may need to review any licensing arrangements you have made or are considering making.

Further, you should review any infringement actions which you have made, that you were considering taking or which have been made against you.

Author:
Stephanie Wroe

Useful link

Supreme Court decision of 13 June 2013:

http://dycip.com/opinionmyriad0613

D Young & Co article, 2 June 2010, author Anthony Albutt, 'ECJ Considers Monsanto Technology LLC v Cefetra BV Case Following Advocate General Mengozzi Opinion of March 2010':

http://dycip.com/monsantocefetra

More Broccoli Please
Second Referral Concerns Product-by-Process Claims

Product-by-process claims extend to products which are structurally identical but produced by a different process

Previously, questions were referred to the European Patent Office's Enlarged Board of Appeal (EBA) concerning **methods** of producing brassicas with elevated levels of anticarinogenic glucosinolates (the so-called 'broccoli case'; EP1069819 - T 83/05). The questions were joined with similar questions from the so-called 'tomato case' (EP1211926 – T1242/06).

It was held by the EBA in this first referral that a non-microbiological **process** for the production of plants which contains the step of sexually crossing the whole genome of plants and subsequently selecting plants is in principle **excluded from patentability** because it is **'essentially biological'** (see G02/07 and G1/08).

Product claims, in particular product-by-process claims, were not at issue in this first referral.

Following the outcome of the referral, new claim sets were filed by the Proprietor of the 'tomato case'. These claim sets did not have any method claims but did have **product claims** directed to the tomato fruit. This resulted in a second referral to the EPO – which is pending as G2/12.

In addition, new claim sets were also filed by the proprietor of the 'broccoli case'. These claim sets did not have any method claims but did have product-by-process claims directed to the plant as such, an edible portion and to the seed of the plant wherein the process to produce the product uses an 'essentially biological' process. Under established European case law, product-by-process claims are not limited to the product produced by the relevant process but also extend to products which are structurally identical but which are produced by a different process. These new claim sets have lead to the following questions being referred to the EBA:

1. Can the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC have a negative effect on the allowability of a product claim directed to plants or plant material such as plant parts?
2. In particular: (a) Is a product-by-process claim directed to plants or plant material other than a plant variety allowable if its process features define an essentially biological process for the production of plants? (b) Is a claim directed to plants or plant material other than a plant variety allowable even if the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application?
3. Is it of relevance in the context of questions 1. and 2. that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53(b) EPC?
4. If a claim directed to plants or plant material other than a plant variety is considered not allowable because the plant product claim encompasses the generation of the claimed product by means of a process excluded from patentability under Article 53(b) EPC, it is possible to waive the protection for such generation by 'disclaiming' the excluded process?

Questions 1, 2(b) and 3 are the same as those of the second referral in the 'tomato case'. Question 1 has been modified to additionally refer to 'plant parts' and question 2(b) has been added to encompass 'product-by-process claims'. To determine if disclaimers are allowable for product-by-process claims, question 4 has been added.

Author:
Stephanie Wroe

Useful links

The 'broccoli case' EP1069819:

http://dycip.com/ep1069819

G2/07 (pdf):

http://dycip.com/epog207

G1/08 (pdf):

http://dycip.com/g108dec

T1242/06 - second interlocutory decision (pdf):

http://dycip.com/epot124206

Article 03

3D Printing
Your IP Strategy Against Unauthorised Copying

From time to time, we see the emergence of completely new and un-envisaged technology being suddenly made available to consumers. Whilst, from one perspective, such blue-sky innovation is obviously to be applauded, this type of innovation is often referred to as 'disruptive technology'. This is because such innovations usually challenge and disrupt the current state of the law (which was inevitably drafted without the new technology having been envisaged). 3D printing is the latest such disruptive technology.

In the next few years, 3D printers are expected to be found in many homes across Europe and otherwise to be widely publicly available.

> 3D printers allow consumers to 'build' complex products using layers of sometimes different materials.

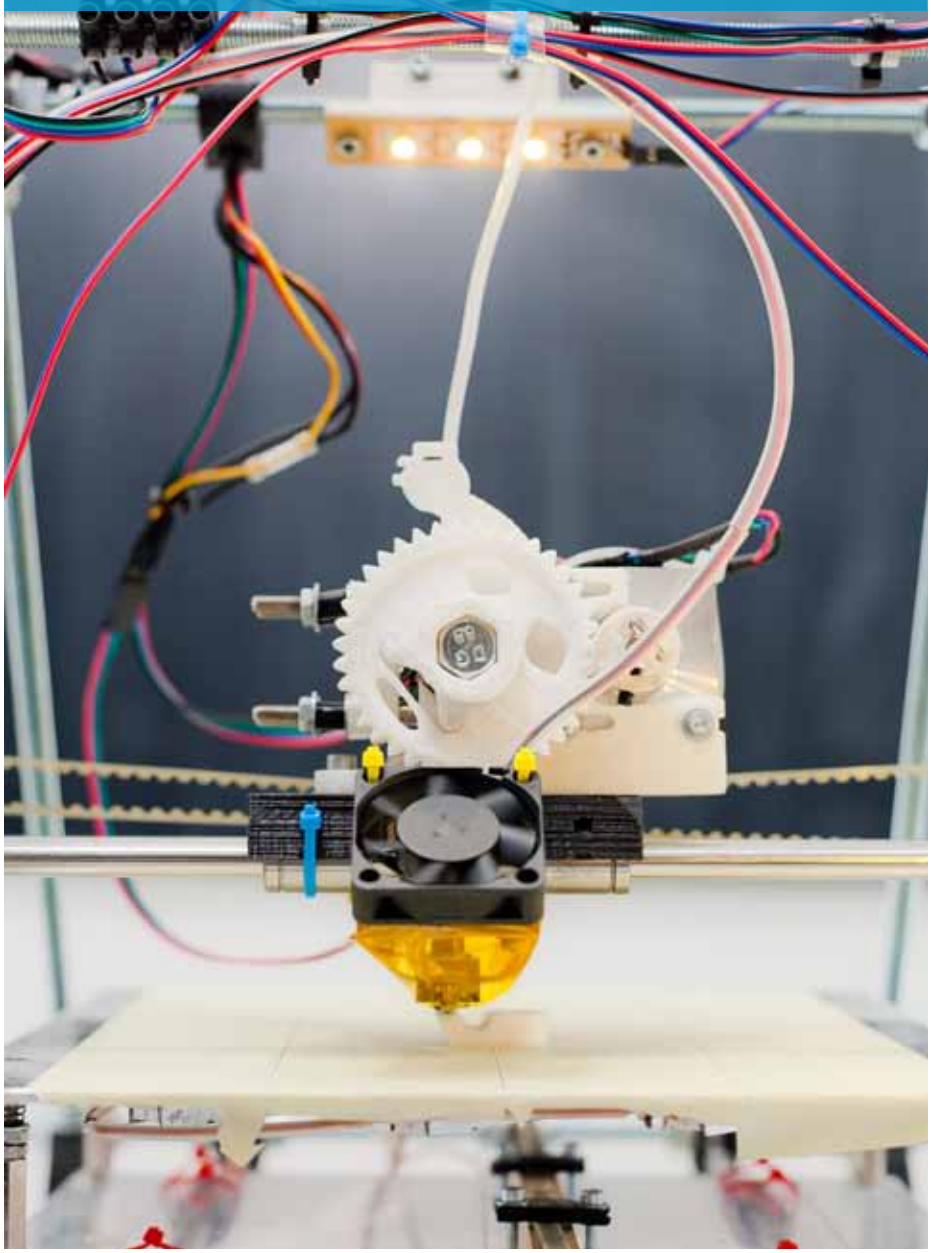
Recently, a working gun was produced using this technique. A national newspaper in the UK also tested the technology to successfully produce a copy of a designer pair of shoes.

The blueprints for the complex products are provided in an electronic form and can be downloaded over the Internet.

> With such a combination of a 3D printer in a consumer's home and a blueprint that can be simply downloaded over the Internet, manufacturers need to consider how to protect their products from unauthorised copying.

In particular, manufacturers need to consider how their range of intellectual property rights can be used to stop such unauthorised reproductions.

Manufacturers need to review their IP strategies to protect unwanted reproductions



Copyright

In the UK, copyright (an unregistered right in the UK) may exist in the artistic elements of the produced 3D object. However, the scope of this protection is limited as physical objects can only be protected as sculptures, works of artistic craftsmanship or works of architecture. Clearly, this restricted coverage is not sufficient protection given the wide range of products that may be produced by a 3D printer.

However, copyright will exist in the electronic blueprint which is originally used to create the 3D artistic object. This protection is similar to the protection given to other artistic works such as music downloaded over the Internet.

Therefore, in theory, manufacturers may sue customers for downloading the blueprints for designs and also sue those third parties

Related article

'IP - A Commercial Perspective" (video of presentation by Ian Harris, October 2012), discussing the IP issues that businesses should be aware of when developing a product for market: http://www.dyoung.com/article-ipvideo1112

storing the blueprints on their server.

In reality, however, this approach is unlikely to be particularly successful. Indeed, over the years, many music companies have found that taking group actions against individual consumers has simply led to bad publicity and the companies providing the music on their servers often move their servers off-shore and out of jurisdiction.

Designs

There are two types of design; registered designs and unregistered designs. Both these types of designs protect the appearance, shape, colour and other aesthetic qualities of a particular physical object.

In contrast to copyright, the physical object does not need to have an artistic quality in order to be encompassed by design protection. This type of protection is likely to be the most effective tool currently available against 3D reproductions of many types of consumer products – such a designer shoes or handbags, for example.

However, once again, there are obvious limitations in pursuing the real 'home copier' who makes the item for personal use and efforts would be better concentrated on more prolific copiers who reproduce items for sale.

Patents

A patent protects technical innovation. In other words, the appearance of a product is irrelevant as far as a patent is concerned; if a product contains the innovation, it infringes the patent. Given the rapid rise in complexity of products produced by 3D printers, the patent may become a very useful tool. For example, in the produced working gun, there may be several patents that were infringed to ultimately produce that functioning product. These infringements would be easily detected from the blueprints making policing the relevant patents quite straightforward.

Trade marks

Registered trade marks can be obtained in Europe for any distinctive sign, such as brand names, logos or shapes. Trade mark protection is obtained in relation to specified goods or services.

In broad terms, trade mark infringement occurs where a third party uses the registered sign (or a sign so similar to the registered sign so as to cause customer confusion) in the course of trade in relation to the same or similar goods or services.

In the example of the designer shoes, the brand owner may well have protected not only the name of shoes, but also aspects of their appearance (which may exist alongside design right) which would be infringed by the copy produced even if the brand name did not actually appear on the copy.

Once again, however, the home copier may escape liability if they are not reproducing goods 'in the course of trade' and the brand owner should instead target more prolific copiers.

Practical advice

Although intellectual property in its current form offers little protection against the home copier, there are many important steps that can be taken against the more prolific copier who tries to sell the produced items for commercial gain.

In reality, prolific copiers are a bigger threat to manufacturers than the home copier as economies of scale mean that prolific copiers sometimes sell copied goods cheaper than a home copier may be able to produce the goods. In this case, it is vital for manufacturers to know what intellectual property is available to leverage against the prolific copier and to make use of all available options.

Also, manufacturers may wish to consider embracing this new technology to engender customer loyalty and to generate new revenue streams. For example, phone manufacturers could sell a blueprint for a customisable phone cover which consumers can produce on a home printer.

Design protection is likely to be the most effective IP protection against reproductions

As we await further developments in 3D printing and discernible trends in the law develop, infringements will clearly be dealt with on a case by case basis. If you have any concerns about particular infringements of your intellectual property or would like to devise an appropriate defence strategy, please do not hesitate to contact your usual D Young & Co advisor. We will also be speaking about IP protection (from concept to production) at the 'Engineering Design Show' in Coventry, UK this October (see page 02 of this newsletter for further information).

Author:
Jonathan Jackson

Article 04

A Patent in 90 Days? UK Proposes 'Superfast' New Patent Service

The United Kingdom Intellectual Property Office (UKIPO) has published a proposal for a 'superfast' patent service, and has collected feedback on its idea from interested parties.

Under current UK patent law and rules, the typical time in which the UKIPO grants a patent application is between two and five years. There are already several mechanisms in place for reducing this time, however. The simple and free procedure of requesting combined search and examination when filing your application can give you a granted patent in about 21 months. This timescale is determined by the need for a 'top up' search to be carried out after publication of the application at 18 months to find any relevant prior art with a filing date close to that of the application. To reduce the time further, you can request early publication of your application.

Other more formal procedures for accelerated grant are available. Both search and examination can be accelerated upon request if you are able to provide an adequate reason, such as potential infringement or the need for results to secure investment. There are also three specific acceleration schemes available, all of which are free.

1. **The Green Channel** permits accelerated search and/or examination for environmentally friendly inventions. To access this, you need to file a written request explaining the environmental benefits of your invention.

2. The UKIPO participates in the **Patent Prosecution Highway (PPH)**. Under the PPH agreements, you may request accelerated examination of an application if its claims have already been acknowledged as patentable by another PPH patent office.

3. The **PCT(UK) Fast Track** allows you to request accelerated examination of the UK national phase of a PCT (international) application if your application has claims which have been considered patentable during the international search and examination.

These schemes, in conjunction with combined search and examination and early publication, can enable you to obtain a granted patent in less than a year, considerably faster than standard patent prosecution before most of the world's patent offices.

However, the UK Government has decided that the UKIPO could usefully offer an even quicker service, and has proposed the introduction of a new 'superfast' service capable of granting patents in as little as 90 days.

There is, of course, a catch – it is intended that the new service will only be available on payment of a substantial fee, suggested to be in the range of £3,500 to £4,000 and payable in addition to the usual official fees for filing, search and examination. At the UKIPO these are currently just a few hundreds of pounds, so use of the superfast service would increase the total official fees about ten-fold. In comparison, though, the 'Track One' prioritised patent examination service offered by the United States Patent and Trademark Office (USPTO) carries a charge of $4,000 plus usual official fees, and only promises the chance of a granted patent in under a year.

> Various conditions are proposed for using the superfast service, including electronic filing and electronic delivery of all correspondence, and requesting the service on or shortly after filing.

The UKIPO also proposes to reserve the right to refuse a request in the event that current office capacity is insufficient to adhere to the promised timescale.

Grant within 90 days is indicated as being potentially achievable for an application claiming a priority date at least one month before its filing date. However, for first filed applications claiming no priority, a time scale of around 120 days is indicated, to allow sufficient time for a complete prior art search to be conducted. Also,

UKIPO proposes 'superfast' service

a top up search will be necessary after grant to ensure that all novelty only prior art has been found; this may lead to post grant amendment by the patentee or revocation by the UKIPO. However, this is already true for any patent granted less than 21 months after its priority date using the existing acceleration procedures.

The high proposed official fee will no doubt be prohibitive or at least off-putting to many applicants, but for others the prospect of such a speedy grant procedure might be very appealing.

> The 'superfast' procedure ties in neatly with the UK's new 'Patent Box' scheme which enables companies to pay a reduced rate of corporation tax on profits arising from products protected by granted UK and European patents.

If the potential tax savings for a new product exceed the official fee, the 'superfast' scheme may look very attractive.

The UKIPO ran a consultation period to obtain users' views on both the 'superfast' patent service proposal and on its existing acceleration procedures; this ended on 12 June 2013. We await further developments with interest.

Author:
Cathrine McGowan

Bringing Evidence
Failure to Follow Judge's Directions (Phil & Ted's v TFK)

This case, being heard at the Patents County Court (PCC), was as the judge described it, a "*conventional patent action*". The action concerned products known as baby buggies.

Background

TFK threatened to bring proceedings against Phil & Ted's Most Excellent Buggy Company Limited (Phil & Ted's) for patent infringement. Phil & Ted's launched proceedings for unjustified threats and revocation of the patent on the grounds of invalidity. TFK denied invalidity and counterclaimed for infringement of the patent. The patent was found to be invalid in that it was obvious over prior art.

> What is interesting about this case is that it provides further understanding of the PCC rules in relation to witnesses and evidence.

The PCC deals with less complex intellectual property claims, often of a smaller monetary value than the Patents Court, and imposes a cap on damages at £500,000 (although the cap can be waived by written agreement of the parties) and a cap on legal costs of £50,000.

It is intended to be a more streamlined approach and provide an avenue for smaller companies to have access to justice, without the somewhat hefty costs that can at times be associated with High Court actions.

In order to facilitate this, the court determines at the case management conference (CMC) whether expert or fact evidence needs to be adduced at trial.

Evidence of common general knowledge

In a patent action, the parties are required to provide evidence of what was the 'common general knowledge' in the relevant field, at the time of the invention.

In this case, Phil & Ted's relied on Mr David Cocks, an industrial designer with experience of designing buggies, as their witness to give expert evidence in the case,

Baby buggy patent infringement

including giving evidence about the common general knowledge in the relevant field. TFK called Mr Whyte, who was an experienced mechanical engineering designer. However, Mr Whyte has never designed a buggy and could not provide evidence of common general knowledge. Consequently, Mr Whyte was unable to assist the court on this issue, and TFK did not produce any further evidence to support their position. As TFK were in the market, they were in a position to produce a witness to contradict the evidence of Mr Cocks, or by producing documents which undermined his views.

> TFK argued that they could not produce such evidence contradicting Mr Cocks even if they wanted to because there was no permission from the court to bring factual evidence in this case.

The judge disagreed. He held that TFK had chosen to call an expert who was unable to comment on the common general knowledge.

> The directions at the CMC specifically provided that one of the issues about which experts would give evidence was common general knowledge.

It is true that the rules make it difficult for a party to rely at trial on material for which no permission was given at the CMC, however in this case the judge held that TFK did have permission to call evidence about common general knowledge.

> If, after deciding to rely on Mr Whyte they then wanted to call evidence on common general knowledge through a different channel, they could, and should have raised this matter with the court.

The judge commented that in this instance, it was hard for him to see how such an application could have been refused, and he did not accept that TFK could rely on the rules as an excuse for not calling evidence about common general knowledge in this case.

Comment

In order to streamline cases in the PCC, the court has strict guidelines and rules which the parties must abide by. What this case highlights however, is the degree of flexibility that the court will exercise in order to allow parties to properly argue their cases, in order to ensure the administration of justice. This flexibility comes with the caveat that it must be used. Failure to do so can be fatal as TFK discovered to their cost.

Author:
Claudia Rabbitts

Novartis v Hospira
Interim Injunction Granted Pending Appeal When Patent Found Invalid

Interim injunctions are a discretionary remedy granted prior to full trial to restrain an alleged infringer from committing the alleged infringing act. The well known, leading case which set out three principles for the English courts to follow when granting an interim injunction is American Cyanamid [1975] AC 396. These three principles are:

1. Is there a serious case to be tried?
2. Adequacy of damages to either party: would the claimant be adequately compensated by an award of damages at trial?
3. Is there a doubt as to the adequacy of damages? If so, the extent of any uncompensatable disadvantage will determine the 'balance of convenience'.

In general, these three principles are applied by the English courts when deciding whether to grant an interim injunction. However, recently the High Court heard a case between Novartis AG and Hospira UK Limited (a generic pharmaceutical supplier) in which slightly different considerations were applied, on the basis that a trial had already taken place. The Court of Appeal has subsequently reversed the decision.

This case and its subsequent appeal to are of interest to innovators and generic companies alike. There is now precedent for the English courts to grant an interim injunction pending appeal even if the patent at issue has been found invalid at first instance.

Novartis had two European patents (EP (UK) 1296689 and EP(UK) 1591122) covering the use of zoledronic acid for the treatment of osteoporosis. They also had a compound patent and a Supplementary Protection Certificate (SPC) covering zoledronic acid. The SPC was due to expire on 15 May 2013, whilst the two medical use patents expired much later on 17 June 2021.

In order to 'clear the way' for the launch of their generic, Hospira began revocation proceedings against Novartis' two medical use patents in December 2011. In late November 2012, Hospira then obtained a marketing authorisation for zoledronic acid, with the intention to launch their generic zoledronic acid as soon as possible after the SPC expiry date.

The revocation proceedings were started in sufficient time to ensure that the trial was heard before the compound SPC expired, and came before Arnold J in February 2013. In March 2013, Arnold J declared both of Novartis' two medical use patents as invalid on the grounds that they were not entitled to priority and an intervening publication rendered them invalid. Some of the claims were also found invalid for insufficiency.

Following Novartis' appeal of the invalidity decision, Hospira informed Novartis that it intended to launch in the UK upon expiry of the SPC. Two days later, Novartis commenced infringement proceedings and sought an interim injunction to restrain Hospira's launch of their generic pending the appeal of the invalidity decision.

Prior to this decision, there was no precedent for the grant of an interim injunction pending appeal when the patent had been found invalid. Birss J therefore held that in exercising the court's discretion to grant or refuse an interim injunction, he must consider the risks of harm which cannot be compensated in damages along with the nature of the proceedings.

In this case, the parties' rival cases had been heard at a full trial and a detailed judgment had been given. This could not be ignored when considering whether or not to grant an interim injunction.

With regard to the nature of the proceedings, Birss J firstly agreed with Novartis that the appeal was plainly arguable since the issue of priority relied on construction, but he also noted

Novartis AG v Hospira UK Limited

that he could not conclude who would win.

Then in considering the harm to both parties, he gave weight to:

1. the possibility that Hospira would lose their 'first mover advantage' since they appeared to be the first generic ready to launch immediately on the expiry of the SPC;
2. the real risk that an injunction now, would cause direct loss to Hospira which is difficult to quantify;
3. the real risk that if an injunction was not granted and the appeal succeeded, that Novartis would be unable to restore their prices fully without significant harm to their reputation; and
4. the higher uncertainty associated with Hospira's losses assessed on a cross-undertaking than the uncertainty associated with Novartis' losses assessed as damages if no injunction was granted but they won the appeal.

Further information
Full decision of the High Court:
http://dycip.com/novartisdecision

Overall, Birss J held that granting or refusing the injunction would lead to a risk of significant unquantifiable loss for both parties. He also held that if this was the case before trial, then he would probably grant an interim injunction. However, as a trial had already taken place, he concluded that the overall balance of convenience was different. If Novartis won the appeal, their monopoly would be restored and any financial loss during the lapse of the patent would be recoverable from damages paid by the Hospira and any other generics that launch in that period. He therefore refused to grant the interim injunction.

Novartis appealed this decision to the Court of Appeal where Floyd LJ held that Birss J should not have found that the first instance decision affected the balance of convenience. He held that once Birss J had decided that the appeal was arguable with real prospects of success, he should have moved to the balance of convenience, where on the facts of the case, Novartis succeeded. The 'unquantifiable damage' to Novartis outweighed that to Hospira as there would be an immediate downward price spiral if generic zoledronic acid were to be launched. The Court of Appeal was also unconvinced that Hospira would lose its 'first mover advantage' pending the invalidity appeal.

Accordingly the Court of Appeal granted the interim injunction pending appeal of the first instance decision.

Comment

There is therefore now precedent for the English courts to grant interim injunctions pending appeal even if the patent(s) at issue have been found invalid by the courts at first instance. Patentees must also prove the same factors in applying for an interim injunction pending appeal as they would for an interim injunction pending trial. In other words, follow the principles set out in American Cyanamid.

For further information, please contact your usual D Young & Co advisor.

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Article 08

Virgin Atlantic Airway v Zodiac Seats UK
Absolute Defence to a Liability for Damages

The Supreme Court has handed down a long awaited decision in Virgin Atlantic Airway Ltd v Zodiac Seats UK Ltd, which overturns a controversial line of previous UK case law including Poulton v Adjustable Cover and Boiler Block Co, Coflexip SA v Stolt Offshore MS Ltd, Unilin Beheer BV v Berry Floor NV and the 2009 Court of Appeal judgment of this case.

Commentators have welcomed the decision, which has held that the subsequent amendment or revocation of a patent is an absolute defence to liability for damages in relation to an earlier finding of infringement of that same patent. Such amendment or revocation may be made by the European Patent Office (EPO) or a UK court.

In the Court of Appeal, Virgin's European patent was held to be valid and infringed by Zodiac, and Virgin subsequently obtained judgment against Zodiac for damages in relation to infringement. After this decision, the EPO's Technical Board of Appeal (TBA) ruled that that the claims held to be infringed by Zodiac were in fact invalid. The TBA allowed an amendment of the patent so as to remove all the relevant claims but, of course, this amendment was retrospective in effect.

Virgin submitted that it was still entitled to recover damages for infringement following a string of earlier case law (such as Coflexip v Stolt) on the basis that the Court of Appeal's decision that Zodiac had infringed valid claims of Virgin's European patent was res judicata and therefore Zodiac could not now rely on the subsequent amendment. Zodiac, on the other hand, logically argued that Virgin's European patent was retrospectively amended and therefore the claims it had been held to infringe should be dealt with as never existing.

The law of *res judicata* was revisited by the Supreme Court, providing reasons why this principle could no longer be used by Virgin in relation to the finding of infringement in its favour.

The court listed the three forms of *res judicata*:

1. The principle that once a cause of action has been held to exist or not to exist, that outcome may not be challenged by either party in subsequent proceedings.
2. Where the claimant succeeded in the first action and does not challenge the outcome, they may not bring a second action on the same cause of action.
3. The doctrine of merger which treats a cause of action as extinguished once judgment has been given upon it.

The Supreme Court stated that as the infringed claims of Virgin's patent, as they had existed, had been held invalid by the authority which granted them, they must then be treated as never having existed. Further, Zodiac had not raised this issue before, as the EPO decision came after the Court of Appeal judgment. Therefore, it was held that Zodiac could use the subsequent revocation/amendment of the patent as an absolute defence to a liability for damages.

The judgment also calls for a review of the guidelines established in Glaxo Group Ltd v Genetech Inc that currently state that an English court should generally refuse a stay of its proceedings if such proceedings could resolve validity issues earlier than the EPO. The call for consideration of these guidelines appears to be on the basis that providing a stay of the UK proceedings may save duplication of costs and prevent the risk of conflicting judgments at national and EPO level. This will put pressure on the next court to face this issue. If this assumption is revisited, this may ultimately be what this decision is remembered for. The proposed rules of the pending Unified Patent Court (UPC), expected in 2015, currently provide for a stay pending EPO proceedings, however it is not yet clear whether the rules will be implemented in this form nor how they will be applied in practice.

Author:
Verity Ellis

Judgment of the Supreme Court

http://dycip.com/virginzodiac

And finally…

D Young & Co Welcomes Top Class Patent Ligitator
Richard Willoughby Joins Litigation and Patent Practice

The arrival of Richard Willoughby in September 2013 will enable us to consolidate our success on being the first UK Legal Disciplinary Practice and to continue with our growth strategy for the Dispute Resolution & Legal Group. The firm's bold move to integrate the specialist IP services of patent and trade mark attorneys and solicitors in a single entity was due to client demand and has received an overwhelmingly enthusiastic response. Moreover, it has led to the new team winning significant client mandates from existing clients.

Richard is a senior patent litigator with 20 years' experience and has extensive knowledge of multi-jurisdictional litigation in the US, Europe and Asia. He has worked with clients in a wide range of technological fields including life sciences, chemicals and mechanical engineering as well as fast moving consumer goods; fitting perfectly with D Young & Co's existing sector specialisms. Richard is regarded as a leader in his field by all the major legal and professional directories, with IAM Patent 1000 2013, saying:

"A nice guy whose practice has developed well – he works in all technical fields, but his life sciences contribution is legendary."

Richard is also well known for his lobbying efforts in respect of the EU unitary patent and Unified Patent Court and is the current Chair of the Laws Committee of LES (Britain & Ireland). LES Britain & Ireland is one of 32 member societies of the global umbrella organisation LES International (LESI) and is also one of the most active.

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Our email addresses have updated to .com

Our main incoming email address is now **mail@dyoung.com**. Please update your records to guarantee receipt of our email communications.

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