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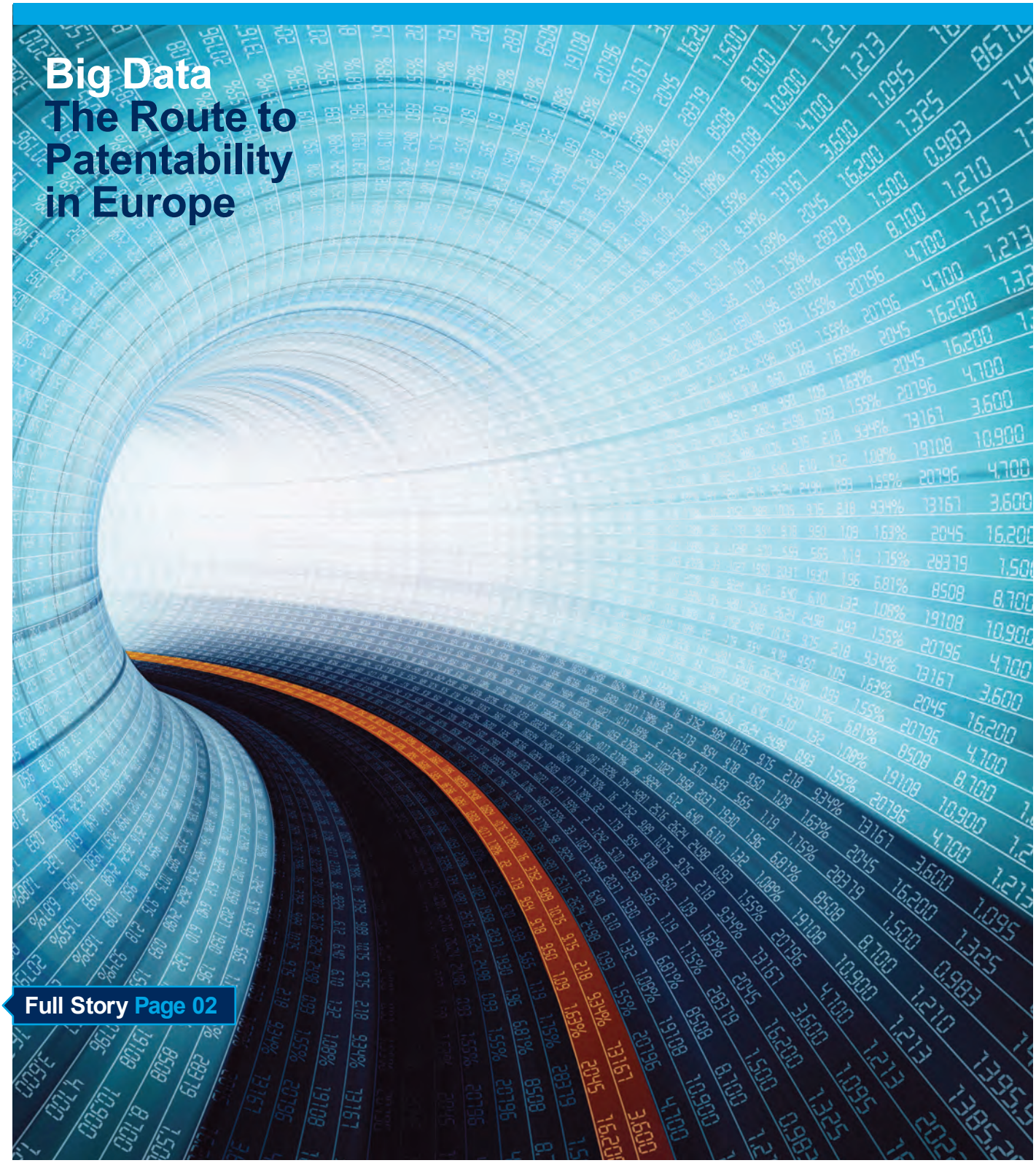
April 2014
In this issue:

Also, our guide to recent EPO changes of procedure and appeal, EPO divisional fee changes and C-661/13 Astellas Pharma referral to the CJ (Bolar exemption).



Editorial

As we finally experience a few genuine days of Spring in the UK, we bring you a stimulating mix of IP news. In addition to reports on specific cases this newsletter includes two articles setting out IP opportunities arising from 'big data' and wearable technology. April is also the month when various changes at the European Patent Office (EPO) take effect, particularly the relaxation of the rules regarding the filing of divisionals. Of the changes in fees, the new arrangement for the appeal fee is noteworthy.

We also continue to follow several recurring themes – the interaction of the UK court and the EPO, the fate of inventions requiring the use of human stem cells and, by now a regular feature, our update on developments regarding the unitary patent and Unified Patent Court. We trust you will find these articles of interest.

Finally, for those readers who have received this newsletter in the post you may be interested to know that this newsletter is also available as an email subscription. If you'd like to support our environmental policy and switch to our pdf edition, please contact us at subscriptions@dyoung.com with your details.

Editor:
Neil Nachshen

Events

23 April 2014 - Webinar
European Biotech Patent Case Law
European patent attorneys and D Young & Co partners Simon O'Brien and Robert Dempster present their ever popular biotech patent case law webinar. Register now via our website to secure your place.

15-16 May 2014 - Show
Business Show, London UK
Nicholas Malden and Richard Burton present 'Your Product, Your Business: Essential IP for Start Ups and SMEs' at this popular UK business show. See us at stand 2118.

25 June 2014 - Workshop & Convention
BIO 2014, San Diego US
Aylsa Williams will be participating in a mock EPO opposition workshop during the Biotechnology Industry Organization (BIO) International Convention, which takes place 23-26 June in San Diego.

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Article 01

Big Data
The Route to Patentability in Europe

Our world is becoming increasingly connected. We can order products from online retailers and track the package from the moment it is loaded into the delivery van right to point it reaches our front door. Our health and fitness levels are monitored by wearable sensors and the data is fed into an app allowing us to track our wellbeing. Google can even predict outbreaks of 'flu more quickly than public health authorities by analysing the geographical concentration of certain search terms.

> The rate at which data is created is astonishing. In 2010, it was stated that every two days we create as much information as we did from the dawn of civilization up until 2003. This rate will only continue to increase. The number of devices collecting information is set to explode from ten billion units now to over fifty billion units within the next five years.

These connected devices themselves will of course be subject to many patents. But, what about the technology that converts the data generated by these devices into meaningful and useful data? This article investigates the patentability in Europe of this conversion process, which is sometimes called 'data analytics' or 'big data'.

In Europe, an invention as a whole must have technical character. Unfortunately, a new method or algorithm for analysing data, no matter how innovative or sophisticated, is therefore unlikely to be patentable on its own in Europe in light of decisions such as T 208/84 (see useful links above right, page 03).The application of that method or algorithm to specifically defined data which results in a technical effect may be patentable.

This effectively gives two conditions which must be met in order for the method to be patentable:

1. The data to which the method is being applied to must be defined.
2. The application of the method to the defined data must result in a technical effect.

Generally, the first step of defining the data to which the method is to be applied will be relatively straightforward. For example, if you are in the business of collecting and analysing mobile phone location data, then the data to which the method is applied can be defined as mobile phone location data.

On the other hand, the second step of determining whether or not the effect of applying the method to the data is sufficiently technical can be difficult. It is difficult because, despite significant amounts of case law on the subject, determining whether or not a particular effect is technical must be determined on a case by case basis and remains very subjective. In this situation, it can help to consider whether or not the application of the method to the data is solving a technical problem.

This is probably best illustrated with the following examples:

Example 1: balancing network load
Let's take our previous example of the data being mobile phone location data. Let's say that a particularly innovative method for analysing the data is able to take the mobile phone location data as an input and use it to track the mobile phone to predict the movement of the mobile phone and then balance cellular network load. In this case, the problem solved by applying the innovative method to the collected data is the problem of balancing network load.

Example 2: relevant advertising
Let's now consider that a different but equally innovative method is applied to the mobile phone location data. This method is able to take the mobile phone location data as an input and

Useful links

Boards of appeal decision T 0208/84 (Computer-related invention) of 15.7.1986: http://dycip.com/t840208ep1

Boards of appeal decision T 0641/00 (Two identities/COMVIK) of 26.9.2002: http://dycip.com/t000641ep1

If a technical problem has been solved using technical means there is a chance that this could form the basis for a patentable idea

use it to select more relevant advertisements to push to individual users depending on their location. In this case, the problem solved by applying the innovative method to the collected data is the problem of producing advertisements which are more relevant to individual users.

Thus, for both examples, the methods employed are innovative and potentially very valuable. However, the respective problems which are solved by the methods are likely to be interpreted by the European Patent Office (EPO) differently as to whether or not they are technical problems and thus whether or not the effect resulting from the application of the method to the specifically defined data results in an effect which is technical. Specifically, for the first example, the EPO will accept that the problem of balancing network load is technical. On the other hand, for the second example, the EPO will not accept that the problem of producing adverts which are more relevant to individual users is technical.

The EPO justifies this approach by saying that the problem of producing more relevant adverts, even if performed on a technical means, is actually a business related problem. However, under Art. 52 EPC business methods as such are specifically excluded from patentability. Therefore, the business related problem cannot be a technical problem and the application of the method in the second example, no matter how innovative or on what device the method is performed, cannot have a technical effect. Case law at the EPO means that because of the lack of a technical effect the invention will lack an inventive step – see the leading case T 641/00 (see useful links above right) .

So, can anything be done to try and patent the application of an innovative data analysis method which, on the face of it, appears not to solve a technical problem? Well, it depends.

> There are instances when, although the overall method may not be deemed to solve a technical problem by the EPO, there may be aspects of the idea which solve a 'sub' technical problem when the idea is implemented using technical means. Such aspects could, in principle, form the basis of a patentable idea.

For example, consider again the method of processing mobile location data so as to send out targeted adverts to individual mobile users.

From the discussion above, the EPO will interpret the general problem solved by the method as not being technical. However, the method will almost certainly be implemented using technical means such as a specifically adapted data processing network. This network may, itself, have been adapted so as to improve the security, speed and/or reliability of the network in an innovative way. For example, the mobile location data may be collected using an innovative arrangement which prevents overloading of data channel capacity when many users are gathered in the same geographic location, whilst ensuring that sufficient mobile location data continues to be collected. This arguably improves the reliability of the system.

The problem of improving the security, speed or reliability of the technical implementation of an innovative data analysis method, when solved using technical means, is, in principle, a technical problem. If the EPO can be convinced of this, then there is a chance that the technical means in question could form the basis of a patentable idea (subject to the usual requirements of novelty, inventive step and industrial applicability).

It must be said, however, that the EPO is unlikely to accept arguments related to a technical problem solved by a feature of the technical implementation of a data analysis method (which, overall, appears to relate to a business method type problem) if no mention or teachings in the patent application allude to that problem being solved by that feature. In such a case, the EPO is likely to argue, perhaps rightly, that the problem is not derivable from the patent application as filed, and that it is therefore not a valid technical problem to consider.

When initially creating a patent application for a data analysis method which could be construed by the EPO as relating to a business method type problem, it is therefore important to ensure that any features related to the technical implementation of the method which (at least arguably) solve a technical problem

Continued on page 04

Big Data

Continued from page 03
Article 01: Big Data - The Route to Patentability in Europe

are discussed in detail in the application, along with any technical advantages that they might have. This approach will ensure that during prosecution, arguments presented to the EPO regarding a technical problem solved by the invention can be supported by what has been disclosed in the application. This ensures that the arguments have weight and ensures that the EPO will consider such arguments more seriously than if those same arguments were presented without such support.

Summary

Novel and innovative methods or algorithms for analysing data in a 'big data' context are potentially patentable as long as the data which is being processed is well defined and the method is applied to the data in a way which results in a technical effect. For a method which results in an effect which might be judged non-technical by the EPO (for example, if it is related to solving more of a business type problem), the applied method itself may not be patentable. However, there is still the possibility that a feature related to the technical implementation of that method solves a technical problem. For example, that feature may ensure that the technical implementation of that method operates with greater security, speed or reliability. Patent protection directed to such features could therefore still be valuable. In order to get the best possible chance of obtaining such patent protection at the EPO, you must ensure that such features are adequately described in the patent application and that any technical advantages associated with them are made clear.

Authors:
Jonathan Jackson and Arun Roy

Unitary Patent and Unified Patent Court Latest Updates

Peparatory Committee sets the UPC start date set back to 2015 - still too ambitious?

During March we published a number of unitary patent (UP) and Unitary Patent Court (UPC) updates on our website. Here we summarise the latest news. For information and commentary as it is published, please visit our dedicated website page: *www.dyoung.com/unitarypatent*.

UPC start date revised

On 18 March, at its 5th meeting, the Preparatory Committee reviewed its road map and concluded that in particular, the ambitious UPC starting date of early 2015 is clearly no longer achievable and late 2015 is the very earliest the court might be operational. Realistically we believe this date is also ambitious.

Judges' training centre opens

The Preparatory Committee has recently announced the opening of the training centre for UPC judges which, under the UPC Court Agreement will be in Budapest. We are still awaiting further news on how the Advisory Committee is doing in sifting through the huge number of expressions of interest from candidate judges.

16th draft Rules of Procedure

The Preparatory Committee made the 16th draft Rules of Procedure of the UPC available to the public on 06 March 2014. This is not for consultation but for information. A public meeting will be held at some point this year, details of which we will publish as soon as we have them. In addition, the expert group which has been preparing the various drafts has published a digest of comments presented and a note of their suggested approach.

Nordic/Baltic Regional Division

Finally, on 04 March, Estonia, Latvia, Lithuania and Sweden reached agreement on establishing a Nordic/Baltic regional division of the UPC. It remains to be seen whether the other participating Nordic states (Denmark and Finland) will join in.

Author:
Richard Willoughby

UP & UPC questions?

Visit our website to read our dedicated page of UP & UPC advice and information, including UP & UPC FAQ: www.dyoung.com/unitarypatent

Shanks v Unilever
Employee Compensation Under UK Patents Act

An inventor has lost his claim for compensation from his employer before the UK Intellectual Property Office (UKIPO).

Section 40(1) of the UK Patents Act 1977:

40(1) Where it appears to the court or the comptroller on an application made by an employee within the prescribed period that the employee has made an invention belonging to the employer for which a patent has been granted, that the patent is (having regard among other things to the size and nature of the employer's undertaking) of outstanding benefit to the employer and that by reason of those facts it is just that the employee should be awarded compensation to be paid by the employer, the court or the comptroller may award him such compensation of an amount determined under section 41 below.

Professor Shanks, a former employee of Unilever, was named as an inventor on patents directed to an electrochemical test device. The device was developed for use in monitoring the blood glucose levels of diabetic patients.

Unilever were not particular interested in moving into this testing field; however, the patents were eventually licensed. Indeed the UKIPO decided that the total income for Unilever from the Shanks patents, spread over several years, amounted to £24.5 million. The majority of this (£19.5 million) arose from licensing income and the remainder from the portion of the price paid when Unilever sold a subsidiary company.

UK law on employee compensation is intended to provide a means by which employees can obtain a share of an 'outstanding benefit' made by one of their inventions. Unilever accepted that if the UKIPO were to find that the Shanks patents were indeed of outstanding benefit to the employer, then it would be just for compensation to be awarded. The UKIPO therefore then went on to consider whether *"the patent is (having regard among other things to the size and nature of the employer's undertaking) of outstanding benefit to the employer."*

The level of benefit is provided by section 41 of the UK Patents Act 1977:

41(1) An award of compensation to an employee under section 40(1) and (2) above in relation to a patent for an invention shall be such as will secure for the employee a fair share (having regard to all the circumstances) of the benefit which the employer has derived, or may reasonably be expected to derive, from the patent or from the assignment, assignation or grant to a person connected with the employer of the property or any right in the invention or the property in, or any right in or under, an application for that patent.

41(2) For the purposes of subsection (1) above the amount of any benefit derived or expected to be derived by an employer from the assignment, assignation or grant of -

(a) the property in, or any right in or under, a patent for the invention or an application for such a patent; or

(b) the property or any right in the invention;

to a person connected with him shall be taken to be the amount which could reasonably be expected to be so derived by the employer if that person had not been connected with him.

Note that section 41(2) is an 'anti-avoidance section' intended to deal with the situation where inventions and patents are assigned between related companies for nominal sums for accounting reasons. The section operates so that the 'benefit' of the patent is considered to be what it would have been if the assignment had been made without the existence of a relationship between the companies concerned.

The UKIPO acknowledged that the benefit provided by the Shanks patents was a substantial and significant one in money terms. However, this was not a case as in Kelly (see useful links below) where without the patents the employer would have faced a crisis, nor was there any suggestion that the Shanks patents were crucial to Unilever's success. The UKIPO therefore decided that, taking into account the size and nature of Unilever's business, the benefit provided by the Shanks patents falls short of being 'outstanding'.

> The UKIPO, with one mind on a possible appeal, went on to form the view that, if the benefit had been deemed outstanding, then a fair share of the benefit would have been 5%.

Curiously this is higher than the 3% awarded in Kelly even though the UKIPO thought that the sort of skill and effort on Professor Shanks' part was nowhere near that involved in Kelly. Nevertheless the case shows that the award of £1.5 million to the inventors in Kelly may be seen as reflecting the exception circumstances of the Kelly case in which the employer's business was transformed.

Author:
Catherine Mallalieu

Useful links

Does 'Myoview' Show Vision of Future for Employee Inventor Compensation Claims? Commentary of Kelly and Chiu v GE Healthcare Ltd [2009] RPC 12:

www.dyoung.com/patentnewsletter-apr09

UKIPO ruling (PDF) on Shanks v Unilever:

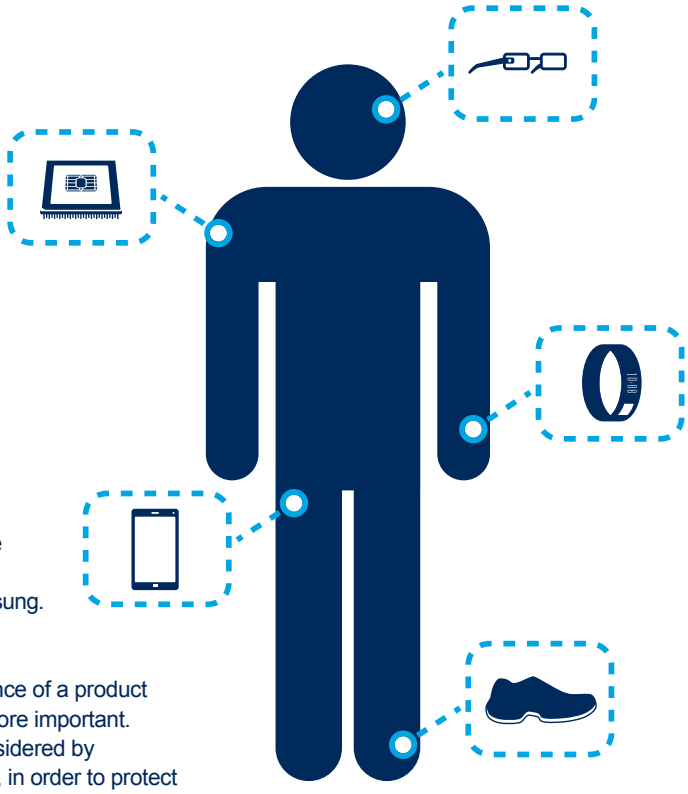
http://dycip.com/shanksvunilever

UKIPO website (PDF) *The Patents Act 1977*

http://dycip.com/ukpatentsact

Article 04

Fashion and Function
Your IP Wardrobe for Wearable Technology



The link between fashion and technology has been long established. This trend was evident over thirty years ago when the Walkman was the latest 'must have' high tech product. A few years ago, white ear buds associated with the iPod became a fashion statement. More recently, Beats headphones are the latest gadget wear.

Many technology companies have identified this trend and have started developing so-called wearable technology. Much of this technology is designed for style as much as function. Indeed Google have recently announced a tie up with Luxottica who are behind the Ray-Ban and Oakley brands.

> It is predicted that by 2016 we will buy nearly 93 million wearable devices a year. Many of these wearable technology products interact with other technology products such as smartphones.

As wearable technology is designed to look cool and be desired by tech-savvy consumers, these products will be sold at a premium price. Manufacturers therefore need to consider the intellectual property available to protect their products.

Registered designs

Registered designs protect the appearance of a particular product or graphical user interface (GUI). In electronics, the distinctive appearance of a particular product or of a GUI is sometimes crucial to the success of that product. Indeed, such is the importance of design in electronics, Steve Jobs at Apple considered Jonathan Ive (who designed the iPod, iPhone, iPad and iOS 7 amongst others) as his "*spiritual partner at Apple*".

Apple filed registered designs for the shape of an iPad, iPhone and associated GUIs. Apple then sued Samsung alleging that their Galaxy Tablet range infringed these designs. These designs took centre stage in the recent global battle between Apple and Samsung.

In the area of wearable technology, the appearance of a product will be, arguably, even more important. This will be carefully considered by manufacturers. However, in order to protect this distinctive appearance, manufacturers need to equally consider protecting the appearance using registered designs.

Patents

Patents protect the way in which a product operates. Specifically, a patent protects the way in which the product solves a technical problem. In the field of wearable technology, there are a number of issues to consider.

Firstly, although it is not possible to use patents to protect the appearance of a product (that is the purpose of registered designs), the wearable technology will usually include sensors measuring certain parameters such as a pedometer in a Sony SmartBand or location of the user in a Nike SmartWatch. These sensors may be capable of patent protection if the sensors are improvements over known sensors. For example, if the sensors consume less battery power or are smaller than known sensors.

Secondly, many wearable technology devices, in use, communicate information with other connected devices, such as a smartphone. The smartphone runs a dedicated app, usually produced by the manufacturer, in order to communicate with the wearable device. Therefore, the manufacturer will wish to protect both the wearable technology and separately the app. This will stop other manufacturers copying aspects of the app. However, in certain instances, it may not be possible to protect the app separately. Although beyond the scope of this article, in order for an app to be protected in its own right, the app must solve a technical problem. Examples of such technical problem include communicating with the wearable technology in a more efficient manner. See article 01 of this newsletter (*Big Data - The Route to Patentability in Europe* where this subject is examined in more detail.

Trade marks

A particular brand name or logo used to market the wearable technology product can be protected as a trade mark. Registered trade marks ensure that the goodwill and business reputation built up under that brand name or logo is protected in relation to specified goods or services. As wearable technology contains features that relate to both fashion and function, it will be important to ensure that trade mark protection is obtained for both aspects. For example, Smart Glasses would require protection both for the glasses themselves and the display device technology.

Conclusion

Wearable technology will provide many opportunities for technology companies over the next few years.

> In order to secure their market share, it is important for technology companies to protect every aspect of their wearable technology; from the appearance of the product, the way in which their product operates, to any branding associated with their product.

This synergistic approach will protect the market should their competitors get too close or should any copy-cat products appear.

Author:
Jonathan Jackson

This article was first published in Eureka Magazine: www.eurekamagazine.co.uk/design-engineering-magazine

T 2221/10
EPO Confirms the Extent of G 02/06

Useful links

Brüstle v Greenpeace (C-34/10): www.dyoung.com/article-brustlestemcells

C-34/10 - A Kiss of Death for the European Stem Cell Industry?' www.dyoung.com/article-c3410brustle

EPO Follows Brüstle CJ Decision: www.dyoung.com/article-hesc0712

EPO Revokes 'Brüstle' Patent and New CJ Referral on the Patentability of Parthenotes: www.dyoung.com/ipcases-stemcell0613

T 2221/10 : http://dycip.com/t102221eu1

T197/10: http://dycip.com/t100197du1

G0002/06: http://dycip.com/g0206dec

Over the past 18 months we have reported on the Court of Justice of the European Union (CJ) decision in Brüstle v Greenpeace (C-34/10) which relates to the patentability of technology based on the use of human embryonic stem cells (hESC). To date we have reported the CJ's decision, discussed its possible influence on the European stem cells industry and the implementation of such guidance into the European Patent Office (EPO) guidelines. At the time, the question remained as to how far the boards of appeal would implement G02/06 and whether it would follow the CJ decision. The recent boards of appeal decision T 2221/10 (Culturing stem cells/ TECHNION) has provided the response.

Inventions using hESC are likely to be refused under Art 3(a) EPC and Rule 28(c) EPC

T 2221/10

In refusing European application 03751238.1, the boards of appeal have confirmed what has been considered the lengthy arm of the prohibition of using of hESC wherein their preparation has involved the destruction of a human embryo. Thus, despite the claim not requiring the destruction of a human embryo, the fact that the stems cells originated from such a source was sufficient for the claims to be refused.

The invention related to the maintenance of hESC in an undifferentiated state by the addition of certain human foreskin cells and to such a culture *per se*. The boards of appeal considered the public availability of hESC and if available, whether they were derived from human embryos that had been destroyed. The conclusion was reached that if such hESC were derived from human embryos that had been destroyed, it was irrelevant as to how early in the performance of the invention such destruction occurred.

The boards of appeal examined the public availability of hESC cultures before the priority date and whether they were prepared by methods involving the destruction of human embryos. The evidence submitted by the appellant was not considered convincing of the fact that even if the hESC cell lines were publicly available, that such cell lines had been prepared without destroying a human embryo. All the evidence pointed to their origin in embryos that were destroyed.

The boards of appeal interpreted the guidance provided in G02/06 regarding Art 53(a) EPC and Rule 28(c) EPC that "*all steps preceding the claimed use of HES cells which are a necessary precondition for carrying out the claimed invention, have to be considered.*" The boards of appeal continued that there was no distinction between steps performed by the inventor or any third party, nor *"between steps which took place in direct preparation of the experiments leading to the invention and steps having taken place at a point in time further remote from these experiments."*

Germ cells

As an interesting aside, the boards of appeal made reference to an embodiment that referred to using human embryonic germ cells ie, prepared from primordial germ cells of 8-10 day old foetuses. Without commenting as to whether such a source would comply with the requirement of Art 53(a) EPC, the boards of appeal excluded the relevance of this embodiment as the claims were limited to hESC which, by the application of accepted laws on construction, would exclude a cell line derived from germ cells (with reference made to boards of appeal decision T197/10).

With deference to the CJ, the boards of appeal acknowledged that although the EPO is not bound by such decisions (Art 23(3) EPC), such decisions *"should be considered as being persuasive"* as there were good reasons of policy for there to be harmony within Europe on such matter. Thus, they confirmed that the decision was in line with the 2008 boards of appeal decision G 0002/06 (Use of embryos/WARF).

> The situation therefore remains that until a source of hESC can be demonstrated to have arisen from a source not involving the destruction of human embryos, inventions utilising hESC are likely to be refused under Art 53(a) EPC and Rule 28(c) EPC.

It should be remembered that the possibility of such an alternative source existing in a form that does not fall within the WARF decision is subject of a further referral to the CJ, as reported in our article 'Stem Cell News - EPO Revokes 'Brüstle' Patent and New CJ Referral on the Patentability of Parthenotes', published in the June 2013 edition of this newsletter (see useful links above).

Author:
Neil Nachshen

Apple v Samsung
The Impact of the Central Limitation of European Patents on Existing Litigation

From 13 December 2007, it became possible for a patentee to seek a 'central limitation' (or even revocation) of a granted European patent. If accepted, the effect of this would have retrospective effect back to the date of initial grant and would extend to all designated patents.

The intention was for this to be (relatively) quick – a few months – and only to involve an examination of issues, namely whether:

a. the new claims were a limitation of the current claims;

b. the new claims were clear and concise; and

c. they did not involve 'added matter' either extending the scope of protection or going beyond the subject matter of the application as filed.

If the new claims passed this examination, then the EPO had to accept the new claims.

In practice, this procedure has not been used a great deal so far and average times are nearer twelve months, but it is now becoming part of a patent litigator's armoury – particularly where there are proceedings in a number of European jurisdictions. It does, however, raise quite complex issues of res judicata/issue estoppel/abuse of process, as well as the relationship between existing local proceedings and this centralised procedure.

Apple v Samsung

This issue was raised in yet another round of the Apple and Samsung litigation, where the English Court of Appeal was asked by Samsung to delay their pending appeal (whose patents had been found invalid at first instance) whilst the European Patent Office (EPO) reviewed an application for central limitation of the two patents in issue.

The application to the EPO had been made after the appeal had been filed in England and the amended claims were different to conditional amendments filed by Samsung in the High Court proceedings, which the first instance judge had been asked to consider (and rejected as not overcoming his findings of invalidity). There were also parallel proceedings in Germany (where one of the patents was also held invalid), Italy and France (neither of which had yet come to trial).

The problem for the English Court of Appeal was that, in English litigation, there is a strong emphasis on parties putting all their arguments before the first instance court (and this should include any proposed claim limitations).

> The expectation is that litigation should be final and that parties should not have 'two bites of the cherry' by raising new issues either on appeal or in new proceedings.

For this reason, appeals theoretically only involve a review of the first instance decision, not a rehearing (as is the case in several other European countries).

If Samsung's amendments were accepted by the EPO, there was a risk that the appeal would be effectively rendered redundant, as the amended claims would now be different to those at issue and considered at trial (and in respect of which amended claims, no evidence would have been given at trial and no findings of fact or decisions made). This might mean that the case would have to be remitted back to a first instance court.

There have been a number of English cases over recent years, where a European patent (UK) was initially held invalid in England but subsequently the European Patent was held valid (ie, maintained) in opposition proceedings on the basis of new (amended) claims. In such cases, the Court of Appeal did consider the appeal on the basis of the new claims. There was no case dealing with a central limitation, although the Dutch Supreme Court had considered the issue in the Scimed case and had remitted the case back to the Dutch Court of Appeal to review the claims as limited on central limitation.

Central limitation in Apple v Samsung

Thus, on the face of these precedents, Apple was in difficulty in resisting the request for a delay. However, there was a line of cases in the English Courts that had held that applications to amend a patent after a first instance trial should be refused if they would require a second trial as to the validity of the amended claims (see Nikken v Pioneer, see useful links, above right). This was on the basis of an exercise of the court's overarching discretion as to how litigation should be conducted (ie, not having two bites at the cherry).

On these grounds, Apple argued that the first instance judge would never have granted Samsung leave to appeal if the central limitation procedure had been made known to him as, to do so, would be contrary to these cases. Further, they argued that Samsung now had to seek leave to amend its Notice of Appeal (to refer to the claims proposed to be amended at the EPO) and that application should be refused (based on the above case law). The problem for Apple was that the 'central limitation' procedure was a right which the European Patent Convention (EPC) has given Samsung and there is seemingly no discretion given to a national court to deny that right.

Whilst the Court of Appeal did not say there

Useful links

Virgin Atlantic Airway v Zodiac Seats UK - Absolute Defence to a Liability for Damages: www.dyoung.com/article-virginairway0713

Stays of UK Patent Proceedings: Court of Appeal Issues Revised Guidance: www.dyoung.com/article-ukpatentproceedings1213

Nikken v Pioneer: http://dycip.com/bailii_nikkon

could never be a situation where the court would not consider a late-filed application for central limitation as an abuse of process, this was held not to be the case in these proceedings. Given that the central limitation examinations were expected to be complete in a few months, the appeal was adjourned until after a final decision was reached (and Apple was allowed to reserve its position about any costs wasted as a consequence).

> This case highlights again the somewhat unsatisfactory interaction between the desire for finality and certainty in national court proceedings and the procedures at the EPO.

This relationship was discussed in last year's Supreme Court discussion in Virgin Atlantic v Zodiac (see useful links, above) where the subsequent amendment during an EPO opposition of a patent fully litigated in the UK resulted in no damages claim being allowed, despite the fact that the English litigation had found the patent valid and infringed and had become res judicata. This was on the basis that the effect of the amendment to the patent's claims was retrospective and, as these new claims were not infringed, there had never been infringement.

The relationship was further discussed in IPCom v Nokia (see useful links, above) where the court set out guidelines for considering whether to stay English proceedings where there are concurrent EPO opposition proceedings.

Whilst central limitation proceedings may remain relatively rare, they are worth considering in suitable cases. The advent of the unitary patent and the Unified Patent Court may reduce their use (although even that is not clear), but for the time being at least it is a strategy that should not be ignored.

Authors:
Ian Starr and Alan Boyd

Article 07

Shaking Things Up
Guide to Recent EPO Changes of Procedure

There has been a fair amount of procedural change at the European Patent Office (EPO) recently. As a guide for applicants, here we summarise ten of these changes:

1. **Druckexemplar (text intended for grant) produced electronically**
   From 01 April 2014.

2. **Handwritten amendments and corrections abolished**
   From 01 January 2014, replacement documents of the application must be typed or printed. Any handwritten amendments/corrections filed will be treated as a formal deficiency and the applicant will be invited to file a typed or printed version.

3. **Prior art sequence listings**
   From 01 January 2014, prior art sequence listing can be referenced by the accession number and the version or release number in a publicly available database. The actual sequence is not required.

4. **No correction of the patent**
   By the decision of G 1/10 of 23 July 2012, it is not permissible to correct the text of a patent (claims, description and drawings) under Rule 140 EPC. It is still usually possible to correct the bibliographic details of the patent.

5. **Divisional application time limit removed**
   From 01 April 2014, there is no time limit for filing voluntary divisional applications. There is also an additional fee for second and subsequent generation divisionals.

6. **Start of search or examination**
   From 28 June 2013, the start of search or examination is indicated on the European patents register.

7. **Translation of priority application**
   From 01 April 2013, failure to file a translation of a claimed priority application on invitation from EPO results in loss of the priority right.

8. **Non-unity prosecution**
   From 01 November 2014, both Euro-direct and Euro-PCT applicants, irrespective of the International Search Authority, can request a European search report on any invention claimed. Applicants can also then choose any searched invention as the basis for further prosecution.

9. **Laptops in oral proceedings**
   Laptops and other electronic devices are now allowed to be used during oral proceedings as long as they are not used to record sound or cause any disturbance.

10. **Summons to oral proceedings**
    A summons to oral proceedings will in general be issued between four to five months before the date of the oral proceedings, unless a shorter time is agreed with the applicant beforehand.

Your EPO procedural checklist

If you have any questions about these changes, please contact your usual D Young & Co attorney.

Author:
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Bolar Exemption
C-661/13 - Astellas Pharma Referral to the CJ

The Düsseldorf Court of Appeal has referred questions to the Court of Justice of the European Union (CJ) concerning the applicability of the so-called European 'Bolar' exemption to a third party manufacturer of a patented active substance.

> The European Bolar provision is provided by Article 10(6) of European Directive 2001/83/EC and principally provides that conducting the necessary studies and trials with a view to obtaining a marketing authorisation for a generic medicinal product and the consequent practical requirements, shall not be regarded as contrary to patent rights or to supplementary protection certificates (SPCs) for medical products.

The CJ's guidance is likely to have a major impact on API manufacture in Europe

Polpharma SA Pharmaceutical Works v Astellas Pharma Inc

Polpharma SA Pharmaceutical Works is a Polish company which produces and sells its medical products as well as generic active pharmaceutical ingredients (API) worldwide.

Polpharma advertised the active substance solifenacin succinate in the professional journals *SCRIP* and *Generics Bulletin,* as well as on its website. Polpharma supplied 30.5kg of solifenacin succinate at a sales price of EUR 127,000 to Hexal AG, a German manufacturer of generics.

Astellas Pharma Inc, a Japanese company, sued Polpharma in Poland and Germany for infringement of its European patent 0 801 067 directed to solifenacin succinate.

Polpharma denied infringement. Its defence was that when concluding the business transactions, it was in agreement with Hexal that the product would only be used in studies and trials whose aim is to produce a solifenacin-based generic drug and to obtain a corresponding marketing authorisation.

> Whether or not Polpharma's defence is correct therefore depends on the interpretation of the European Bolar provision.

Polish Supreme Court

In Poland, the Supreme Court rejected Polpharma's defence stating that the Bolar exemption does not cover its sales of the patented API, even if made for the benefit of a party developing a generic product.

Düsseldorf Court of Appeal

In Germany the matter has been referred to the CJ to determine whether the Bolar exemption does indeed extend to third party supply to a generic manufacturer of a patent-protected active substance which that generic manufacturer plans to use for obtaining a marketing authorisation.

The questions referred to the CJ are translated here:

Knowledge Bank
Scan the QR code below using your internet enabled smart phone to access our ip knowledge site

Missed anything?
We regularly publish IP case updates and articles between newsletters. For up to the minute IP related articles and news visit www.dyoung.com/ipknowledge

C-661/13 ASTELLAS PHARMA
Questions referred for a preliminary ruling

1. Must Art. 10 para. 6 of Directive 2001/83/EC be interpreted as meaning that those acts of delivery are also excluded from patent protection by which a third party offers or delivers a patented active substance to a manufacturer of generic products for purely commercial reasons, which the manufacturer of generics intends to use for studies or trials in order to obtain a marketing authorisation or approval within the meaning of Art. 10 para. 6 of Directive 2001/83/EC?

2. If this first question is to be answered in the affirmative:

a. Does the privileged status of the third party depend on whether the manufacturer of generics supplied indeed uses the provided active substance in privileged studies or trials within the meaning of Art. 10 para. 6 of Directive 2001/83/EC? In such a case, does the exclusion from patent protection also apply if the third party is unaware of its customer's intended privileged use and has not ascertained whether this is the case?

Or does the privileged status of the third party merely depend on whether, at the time of the act of delivery, the third party can rightly assume that, judging all of the circumstances (i.e. profile of the supplied company, small amount of the provided active substance, imminent expiration of the patent protection of the relevant active substance, experience gained concerning the customer's reliability), the supplied manufacturer of generics will use the provided active substance for privileged trials and studies in the context of a marketing approval only?

b. In the context of its act of delivery, is the third party obliged to take separate precautions to ensure that its customer will indeed use the active substance for privileged trials and studies only or do the precautionary measures of the third party differ, depending on whether the patented active substance is merely offered or actually delivered?

The CJ's guidance, when issued, is likely to have a major impact on API manufacture in Europe. We will ensure that our clients remain abreast of these issues.

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

Author:
Catherine Mallalieu

Useful links

Polpharma SA Pharmaceutical Works:

http://www.polpharma.pl/en/

Astellas Pharma Inc:

http://www.astellas.com/en

Directive 2001/83/EC of the European Parliament and of the Council of 06 November 2001 on the Community code relating to medicinal products for human use:

http://dycip.com/directive200183ec

Article 09

EPO Fees Appeal and Divisional Fees Now in Effect

Inflation adjusted EPO fees will increase by an average of about 4.3%, although the European Search Fee will rise by about 10.3% (to EUR 1285) in order to bring it more into line with the cost of an International Search carried out by the EPO as International Search Authority (EUR 1875). At the same time the EPO will implement more substantial changes to the appeal fee and introduce a new fee for filing second and higher generation divisional applications.

Appeal Fee
The appeal fee will rise 50% to EUR 1860. As of 01 April 2014, Rule 103 EPC (reimbursement of appeal fee) has been amended to extend the possibility of obtaining a 50% refund of the appeal fee to situations after the deadline for filing the Grounds of Appeal has expired. The EPO consider that allowing a partial reimbursement after the deadline for filing the Grounds of Appeal will provide parties with an incentive to reflect on whether or not to proceed with appeal proceedings and thus may have a positive effect on the Appeal Boards' workload and thus appeal pendency times.

New Fee for Divisional Applications
Rule 36 EPC is being amended to once more allow the filing of divisional applications at any time, provided that the parent application is still pending. However, in an attempt to discourage applicants from filing long sequences of divisional applications (a practice that the EPO consider detrimental to the legal certainty of third parties as well as increasing office workload), the EPO propose to levy an additional fee for second and higher generation divisional applications. The additional fee will not be incurred by a first generation divisional application, but the fee for higher generation divisionals will progressively increase. The fee for divisional application of second generation will be EUR 210, of third generation EUR 420, of fourth generation EUR 630 and of fifth or higher generation EUR 840.

For further details please see our February alert: *www.dyoung.com/article-epofees*.

Author:
Matthew Johnson

And finally…

IP Essentials for Start Ups and SMEs
Join us at the Business Show, London, 15 & 16 May 2014

We are delighted to be exhibiting at this two-day exhibition in May. The Business Show declares itself "*a hotbed of entrepreneurial activity*", and is expected to draw more than 25,000 aspiring entrepreneurs and small-medium business owners looking for inspiration, advice and networking. The event's overriding goal is to help drive businesses onwards and upwards, across all industries.

Your product, your business: IP essentials for start-ups and SMEs
In a seminar session crucial to any start-up or growing established business, Nicholas Malden (European patent attorney) and Richard Burton (European trade mark attorney) will provide a succinct and commercially relevant IP checklist to support SMEs. Their talk will take place at 11.45am on Thursday 15 May.

IP advice at the show
Members of our patent and trade mark teams will be on hand throughout the duration of the show to answer questions and share information. The UKIPO will also be exhibiting at the show to run their their popular 'branding workshop'.

If you are attending and would like to join us, you'll find us at stand 2118.

Hot topics we'll be on hand to discuss with delegates will be the UK Patent Box and other schemes provided by the government to provide financial support for innovation.

For further information about the show, and to book tickets to attend, visit the Business Show website: *www.thebusinessshow.co.uk* or call 0117 930 4927.

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