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In this issue:

Scope of second medical use claims
T 1673/11 treatment of Pompe's disease

Full Story Page 02

Editorial

I am pleased to announce the recent launch of our new unitary patent and Unified Patent Court website pages. Recent information published includes our 'UP & UPC Myths' and 'Preparatory Guide for the UP & UPC'. You can read and download both guides at www.dyoung.com/upandupc.

Readers will also find our online bank of ad hoc articles written by members of the D Young &Co patent team, which may not fall into our patent newsletter editorial schedule. One such article I would recommend catching up on concerns an overview of tips for speeding up prosecution proceedings at the European Patent Office. The full article can be located online here: www.dyoung.com/article-t082311.

Editor:
Aylsa Williams

Events

15-16 June 2016
Chemistry means business, London UK
Garreth Duncan will be attending this two-day networking conference.

26 July 2016
European biotech case law webinar
Simon O'Brien and Matthew Caines will be presenting our July European biotechnology case law webinar. Registration now open.

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Second medical use claims

Scope of second medical use claims T 1673/11 treatment of Pompe's disease

In this case a European Patent Office (EPO) Board of Appeal considered whether there is any extension of the protection conferred by a patent, under the provisions of Article 123(3) EPC, where an amendment only concerns a change in format of a claim from a Swiss-type use claim to an EPC 2000 medical use claim pursuant to Article 54(5) EPC.

Granted claim 1 of European patent No. EP1137762B to Genzyme Corporation was a Swiss-type second medical use claim and read: "The use of human acid glucosidase in the manufacture of a medicament for the treatment of infantile Pompe's disease, wherein the human acid alpha glucosidase is in the 100 to 110 kD form, wherein the medicament is to be administered intravenously, and wherein the treatment is to be continued for at least 4 weeks."

Two oppositions were filed against the patent, and in its interlocutory decision, the Opposition Division decided that the following claim in EPC 2000 format met the requirements of the EPC: "Human acid alpha glucosidase in the 100 to 110 kD form, for use in the treatment of infantile Pompe's disease, wherein the human acid alpha glucosidase is to be administered intravenously, and wherein the treatment is to be continued for at least 4 weeks."

Following an appeal against the decision of the opposition division by an opponent, the Board of Appeal considered whether the amendment to change the format of the claim from a Swiss-type claim to an EPC 2000 second medical use claim was allowable under Article 123(3) EPC.

The patentee argued that a purpose-limited process claim in the format of a Swiss-type claim was directed to a process of manufacture. According to Article 64(2) EPC the protection conferred by such a process extended to the products directly obtained. Because the manufacturing process in a Swiss-type claim was not limited by any technical feature, the patentee argued that manufacture could not be limiting on the product obtained by it. The Board of Appeal disagreed.

The Board of Appeal considered that the protection conferred by a purpose-limited process Swiss-type claim and an EPC 2000 purpose-limited product claim is not the same even if, for the sake of argument, it is accepted that Article 64(2) EPC is to be taken into account when assessing the extent of protection conferred by a Swiss-type claim.

The Board of Appeal judged that the product directly obtained in the Swiss-type claim is the manufactured medicament which contains as an active substance human acid alpha glucosidase in the alpha 100 to 110 kD form and which is packaged and/or provided with instructions for use in the treatment of infantile Pompe's disease. The Board of Appeal went on to say that in a Swiss-type claim, the medicament is characterised by the functional feature of the specified therapeutic application and that this implies limitations to the product directly obtained.

In contrast, the purpose-limited product EPC 2000 claim was viewed as conferring protection on the human acid alpha glucosidase in the 100 to 110 kD form, whenever it is being used for the treatment of infantile Pompe's disease. The board said that since the claim does not refer to a step of manufacture of a medicament, the product claimed is not limited to a manufactured medicament, packaged and/or with instructions for use in the treatment of infantile Pompe's disease.

The Board of Appeal also took the position that, for example, a medicament containing human acid alpha glucosidase in the 100 to 110 kD form packaged and provided with instructions for the use in a treatment other than that of infantile Pompe's disease is encompassed by the scope of the EPC 2000 claim, whereas the protection conferred by the granted Swiss-type claim does not encompass such use.

In view of the above, the Board of Appeal decided that the EPC 2000 claim was not allowable under Article 123(3) EPC. The patent was revoked as all requests on file contained EPC 2000 claims. A request for the referral of the issue to the Enlarged Board of Appeal was refused.

Author:
Catherine Mallalieu

Cheaper designs on the horizon

UK designers say "yes" to proposed fee reductions

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

In our February 2016 patent newsletter we reported on the UK Intellectual Property Office's (UKIPO) "Proposal for changes to Registered Design Fees", which suggested a decrease in the official fees payable to obtain and maintain registered design protection in the UK. The related consultation expired on 29 January 2016, and the UK Government has now published its response.

Our previous article predicted support for the proposed fee reductions from interested parties, and this has proved true. In response, the government has pledged to implement the proposed changes.

The UKIPO's proposal suggests a decrease in official fees for UK registered designs

The proposal

While several motivations for a reduction in official fees for registered designs were cited in the proposal, a significant driving factor was the introduction in September 2015 of an online application service for registered designs. This is cheaper for the UKIPO to administer than the traditional paper-based application process (which is still operational), and it was deemed appropriate that the financial savings should be passed to the users, with charges set to cover costs in line with the government's "Managing Public Money" agenda.

Accordingly, it was suggested that application fees via the online system be set lower than the corresponding fees for paper applications, with particular benefit being offered for applications comprising multiple designs. Among other changes, a decrease in design renewal fees was proposed, with the total cost of maintaining a design for the maximum term of 25 years being significantly reduced.

The consultation

Several questions were asked in the consultation, including a general request for comments on the proposal, and specific questions about the expected impact of the changes on respondents' design registration strategy and practice.

Sixteen responses were received, which may seem a small number, but several were from significant professional, industrial and business bodies, including the Design Council, thereby representing a much larger number of individual respondents. All respondents were in favour of the proposals, with particularly strong support from SMEs and individual designers, as might be expected.

In addition to approval of lower fees, it was noted that online applications and improved arrangements for multiple design applications would compare more favourably with the application process for registered Community designs (RCDs) run by the European Union Intellectual Property Office (EUIPO, formerly OHIM).

The consultation also comprised an anonymous online survey seeking agreement or not with particular aspects of the suggested fees, namely: the reduced cost for a single online application, the reduced cost for an online application for up to ten designs, and the lower total renewal fee charge. Averaged across these three questions, the overall response from 35 parties was a 73% approval rating. There was some feeling that the suggested lower fees were still too high, however. This was particularly true for renewal fees, but contradictorily, it was felt that lower renewal fees would undesirably encourage renewal of redundant designs.

The outcome

The high level of approval expressed has enabled the government to proceed with putting the proposal into effect. Amendment of the relevant UK designs legislation is required to change the current fees, which have been in force since 2006. This is to be done at the "next suitable opportunity", although there is no indication as to when this might be. The government will provide a regulatory impact assessment and guidance to business to support the changes.

The new fees

No alteration of the suggested fees as set out in the proposal is intended. A table of all relevant fees which will come into force can be found in both the proposal and response documents. Highlights include:

- A £50 fee for a single on-line application.
- A £70 fee for a multiple on-line application covering up to ten designs plus £20 for every additional 10 designs.
- A total renewal cost of £410 for 25 years (payable over five year intervals).

The new fees will represent a dramatic reduction in the cost of protecting designs in the UK, and will no doubt be hugely welcome to businesses. In particular, the much cheaper rates for multiple designs will ease the financial burden of protecting whole collections of designs and enable more parts and features of a design to be registered.

Author:
Cathrine McGowan

SPCs for NPEs? UK thinks yes but does the CJEU agree?

Non-practising entities (NPEs), patent assertion entities, patent trolls – whatever you choose to call them, their activities are hotly debated in the IP world. Although they first came to attention in the US, some have recently made the move into supplementary protection certificates (SPCs) in Europe.

> In the European Union (EU), SPCs are granted to patented medicinal and plant protection products which have required marketing authorisation (regulatory approval) prior to being placed on the market.

SPCs extend the lifetime of the patent (for the approved product) for up to five years (plus another six months if paediatric studies are carried out) – their value to industry is significant, as the term of the SPC is typically when the product achieves its peak sales.

An SPC can only be granted to the holder of the basic patent. However, there is nothing in the wording of the SPC Regulation which requires the SPC applicant to be the same as, or even have any connection with, the marketing authorisation holder. Companies regularly collaborate on the development of pharmaceutical products – in this situation it is common for the basic patent and SPC holder to be the licensor and the marketing authorisation holder its licensee. However, it has long been uncertain whether the SPC Regulation permits a party completely unconnected with the development of the product, but who simply owns a basic patent covering some aspect of the product, to obtain an SPC based on another party's marketing authorisation.

The majority of patent offices in European countries generally check only that both the SPC applicant and patent holder are the same: in most cases, they do not take into consideration who is the marketing authorisation holder.

A number of pharmaceutical companies have relied on this uncertainty to obtain SPCs based on a basic patent they own which covers a competitor's product, relying on the competitor's marketing authorisation. We have recently become aware that some NPEs have done the same, and a number of such SPCs have been granted by the UKIPO. This practice may cause some concern to the research-based pharmaceutical industry: faced with a third party SPC on their own marketed product, they must decide whether to take a licence from the third party or challenge the grant of the SPC.

> However, even if the wording of the SPC regulation is silent, there may be grounds for challenging such an SPC, on the basis its grant is contrary to the purpose of the SPC regulation, which is to encourage pharmaceutical research.

Eli Lilly and Human Genome Sciences

Some preliminary guidance on this issue may be found in the decisions of the UK High Court and the CJEU in the litigation between Eli Lilly and Human Genome Sciences. In its decision (C-493/12) the CJEU opined that, if a patent holder was not the holder of the medicinal product marketing authorisation, the grant of an SPC to such a patent holder may not be allowed. This is because, in their view, if a party had not made any investment in research, the grant of such an SPC to such a party could undermine the objective of the SPC regulation.

The UK High Court took a different view from the CJEU on this point, considering this issue not relevant to the question of whether or not an SPC should be granted. However, both the UK High Court's comments on the "third party issue" and those of the CJEU are asides – no decision was reached on this issue as it was not ultimately pursued before the courts.

We will continue to monitor developments in this area and report further in future editions of this newsletter. For further advice please contact your usual D Young & Co patent advisor.

SPCs extend the lifetime of a granted medicinal or plant protection patent for up to 5 years

Author:
Garreth Duncan

Notorious knowlege
Tips for applicants

Notorious knowledge, otherwise known as indisputable general knowledge or notorious prior art, refers to the mechanism by which an examiner relies on a purported 'notorious' technical teaching without explicitly referencing a document in which the technical teaching can be found. Notorious knowledge is usually cited when a claimed invention contains a mixture of technical and non-technical elements. An archetypal example of this would be a generic personal computer system as would have been known at the effective filing date of an application.

The legal basis for such notorious knowledge comes from the Technical Board of Appeal's decision in T 1242/04 which sets out the principle that, where a technical feature is extremely well known, the Examining Division is not obliged "to carry out an additional search for documented prior art on purely formal grounds".

T 690/06 and T 1411/08 specify that the term 'notorious' has to be interpreted narrowly, and require that the technical feature in question should be "so well known that its existence at the date of priority cannot be reasonably disputed" and that the "technical detail is not significant".

However, faced with the option of asserting that technical features of a claim are known without the need to explicitly reference a document, it could be said that certain examiners have overused notorious knowledge. Two particular problems have arisen: the failure to specify exactly which features an alleged notorious teaching is purported to embody; and the related temptation to automatically dismiss all non-physical features, or features involving non-technical concerns, as entirely non-technical.

Two recent decisions of the Technical Boards of Appeal should be of great help to applicants, serving to clarify how examiners should use notorious knowledge.

T 359/11 arose from the refusal of an application by the Examining Division on the grounds of inventive step in which no documentary evidence of the prior art was provided, due to the alleged notoriety of the technical features.

If technical features are notorious knowledge, specific documents need not be cited

During prosecution, the applicant attempted to add a number of new technical features to the claim, but the Examining Division maintained that no documentary evidence was needed.

Beyond reiterating that notorious knowledge must be interpreted narrowly, the Board of Appeal emphasised that "it is always incumbent upon the Examining Division to consider whether an additional search is necessary" and that an examiner should not refuse an application on the grounds of inventive step where there is at least one non-notorious technical feature. In other words, even in applications where it is legitimate for an examiner to initially provide no documentary evidence, if at any point in the prosecution a single non-notorious feature is added, the examiner should conduct an additional search.

The Board of Appeal also disputed the Examining Division's interpretation of which features were technical. In particular, the Board of Appeal noted that the claimed "tracking module" was technical, irrespective of whether this was a hardware or software feature. It stated that this feature was doubly not notorious as it was both reasonably debatable that it would have been known at the priority date, and also could not "legitimately be dismissed as merely generic". The Board of Appeal concluded that the examiner should have conducted an additional search before refusing the application for a lack of inventive step.

The theme of non-hardware features being dismissed as automatically non-technical was further explored in T 1145/10. The application was directed to a method for protecting regions within an electronic document in a word-processing application, again involving a mix of technical and non-technical features. Again the Examining Division refused the application for lack of inventive step based on a piece of "notorious closest prior art", namely "a standard computerized system". While the Board of Appeal agreed that in principle a rejection for lack of inventive step could be made based on such "notorious closest prior art", they found that the Examining Division had made a number of serious errors in their approach in this instance.

The Board of Appeal found that, where an examiner relies on notorious knowledge, the examiner should specify what technical features the purported notorious art embodies. This specification by the examiner should include the 'functionality' of the art and not just the hardware features. Just because a particular technical functionality was "originally motivated by a non-technical requirement", this does not mean that it was non-technical, and accordingly it might involve an inventive step.

From the above cases it is clear that the Boards of Appeal have been moving to improve the application of notorious knowledge. Such judgments should prove invaluable to applicants in guiding examiners towards an appropriate application of notorious knowledge.

Author:
Anton Baker

T 2451/13
Sensoric imprinting decision serves up a healthy update for non-therapeutic disclaimers and prior use

Two interesting points emerged from this recent decision of the European Patent Office (EPO) Board of Appeal. The first concerns the circumstances under which a new ground of opposition may be raised after expiry of the opposition period, and the second concerns the standard of proof for establishing a public prior use.

The patent in question concerned a non-therapeutic method for "sensoric imprinting" of different tastes in an infant by administering food products containing different vegetables. The patent explained that sensoric imprinting prevents an infant from acquiring a dislike for the taste of different vegetables, and stimulates vegetable consumption later in life.

Sensoric imprinting stimulates vegetable consumption later in life

Non-therapeutic disclaimers

The opponent had initially attacked the patent on the grounds of lack of novelty and inventive step, insufficiency and added matter. However, after expiry of the opposition period, a new ground was raised by the opponent, namely that the method concerned a therapeutic method and so was excluded from patentability under Article 53(c) EPC. The opponent was prompted to add this new attack by the publication of another decision (T1635/09), which held that if the therapeutic and non-therapeutic aspects of a use cannot be separated, the exclusion from patentability cannot be overcome simply by specifying "non-therapeutic" in the claim. In the present case, the patent taught that as result of healthier eating habits, junk food-related health problems such as obesity and diabetes were prevented. Hence the opponent argued that the method of sensoric imprinting of claim 1 was "inextricably linked" with the prevention of diseases later in life.

The Opposition Division exercised its discretion and decided to admit this new ground into the proceedings, on the basis that it was reasonable to accept the late filing as a reaction to publication of the other decision, and because the ground was prima facie prejudicial to the maintenance of the patent. The Board of Appeal agreed with the decision of the Opposition Division to introduce the new ground, as they had applied the correct principles in a reasonable way as required by G7/93. The Board of Appeal also agreed with the Opposition Division's finding that the claimed method was inextricably linked to the therapeutic effects and so claim 1 was held to be invalid under Article 53(c) EPC, despite the "non-therapeutic" disclaimer.

Prior use before the priority date

The second point concerns the alleged public prior use of the invention before the priority date. The opponent filed a new document (D16) with the grounds of appeal, in order to prove that the teaching of a document filed during the opposition proceedings (D2) was publicly available before the priority date. The copyright date indicated in D16 was 2002, which is about four years before the priority date of the patent. The patentee argued that a copyright date was of little value as evidence of public availability on that date (referring to T 1257/04). A copyright date was in particular not sufficient to show that this document was actually printed, let alone distributed, before the relevant date.

Furthermore, D16 originated from a company which was now a subsidiary of the opponent (Gerber). In cases of public prior use having taken place in the opponent's company or exclusive sphere of influence, the standard of proof applied by the boards is very strict. As stated in T 472/92, in these cases "… an opponent must prove his case up to the hilt, for little if any evidence will be available to the patentee to establish the contradictory proposition that no prior public use had taken place". The patentee argued that "up to the hilt" meant "absolute certainty", rather than merely the balance of probabilities.

The Board of Appeal noted that T 472/92 did not specify precisely the conditions to be fulfilled for a party to prove its case "up to the hilt", but that the conclusions were based on "an extremely high degree of certainty" and not "absolute certainty". The Board of Appeal also referred to a number of subsequent decisions where this standard of proof was interpreted to mean "beyond reasonable doubt" and agreed that this was the correct standard to apply.

The question was therefore whether the opponent had proven beyond reasonable doubt that D16 was available to the public before the priority date of the patent. D16 addresses parents and gives them instructions on how to feed their infants. In view of this, it would be "contrary to life experience to assume that D16 was not published but rather kept by Gerber in the drawer for about four years, ie, until at least (after) the priority date of the patent". This was corroborated by D17, which is an advertisement published in 2002 that gave the same recommendations and used the same pictures as in D16. The Board of Appeal was therefore convinced that it was quite clearly beyond reasonable doubt that D16 was published before the priority date of the patent.

Author:
Elizabeth Elmhirst

Global Dossier
One-stop online access to patent file histories (file wrappers)

Notes

1. The IP5 offices are the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of China (SIPO) and the US Patent and Trademark Office (USPTO).

The Global Dossier service is a joint undertaking by the five largest patent offices in the world, collectively known as the IP5 offices[1], to advance global patent protection by offering free access to aggregated patent information and documents related to the search and examination activities of related patent applications during the global patenting process. These file histories (or file wrappers) provide the most up-to-date information about a patent application's journey through the patenting process.

Being able to access global information pertaining to a family of patent applications is great news for users, and enhances transparency of the patent process in the IP5, particularly since the system provides automatic machine translation into English of original Chinese, Japanese and Korean file wrapper documents.

The Global Dossier service can be accessed via the European Patent Register, Espacenet (the European Patent Office's free online service for searching patents and patent applications worldwide) or direct via the USPTO's Global Dossier Public Access.

User experience: EPO Global Dossier v USPTO Global Dossier Public Access

The European Patent Register's implementation of the Global Dossier provides a clearly set-out list of file wrapper documents, however, it is only possible to sort the list by date and click through documents one at a time (each one opening in a new window), although the user is able to select several documents to download simultaneously. Page numbers for the documents are available if sent from the source patent office.

By contrast the USPTO Global Dossier Public Access interface offers sorting of file wrapper documents by date and by title, making it easier to locate documents alphabetically. There is also a very good preview window when viewing each document, enabling users to scroll rapidly through documents without the need to click through to each page individually, or open several new windows on your desktop. There is also a 'collections' tab, where documents of interest can be placed ready to be downloaded and/or printed, making it easier for users to accumulate documents from different files as they go along. Unfortunately, the documents placed in the collections area only remain available during the active session in which they are 'collected'. The 'history' option functions in a similar way in that users can easily return to previously searched numbers within a session, as long as users do not close the browser window or navigate to another web page.

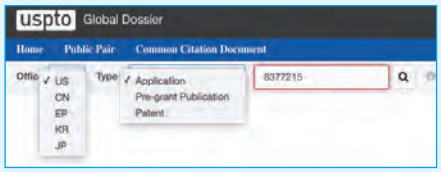
Espacenet takes you straight through to the file wrapper information for the IP5 patent member document via a Global Dossier icon in the bibliographic data view of the record, so by-passing the need to first search the European equivalent record (if one exists) and viewing the patent family.

Author:
Grayce Shomade

Step-by-step guide
Accessing the Global Dossier

1. Via the USPTO

Go to http://globaldossier.uspto.gov

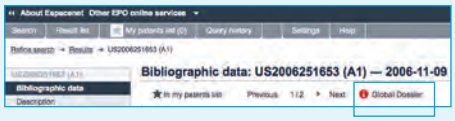


Select the office you wish to search in from the drop-down menu (US, CN, EP, KR or JP) and the type of document (application or publication, or for US documents, application, pre-grant publication or patent), followed by entering the number. Click the search button.

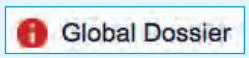
Your search results will display the file histories (file wrappers) for all the related applications and patents in the family from the different IP5 offices.

2. Via Espacenet

Go to http://worldwide.espacenet.com



In search results, in the bibliographic view, select the Global Dossier icon:

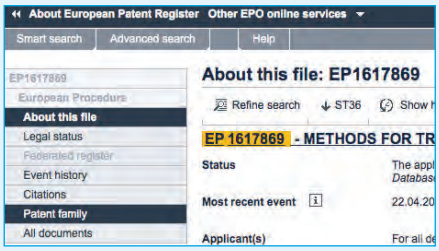


Or for European patents, simply click through to the **EP Register** from the bibliographic view.

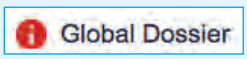
Your search results will be shown on a page entitled 'EPO Global Dossier'.

3. Via the European Patent Register

Go to https://register.epo.org



From the search results screen, select the 'Patent family' menu item in the left navigation. From the next screen, select the Global Dossier icon for each family member.



Your search results will be shown on a page entitled 'EPO Global Dossier'.

And finally…

Unified Patent Court
Judicial recruitment process begins

The success of the UPC is likely to be determined by the quality and consistency of its decisions. With that in mind, the recruitment of the Unified Patent Court (UPC) judges, both legal and technical, is a vitally important aspect of the setting up of the new system. The UPC's early decisions will set the tone and are likely to determine how successful the UPC is, in the short to medium term at least.

The process of recruitment has now begun in earnest, with the recent (09 May 2016) start of the formal application process. According to the information published on the UPC website, the UPC is looking for candidates to fill several full and part-time legal judge posts, as well as several part-time technical judge posts, in each case for terms of up to six years.

Candidates for the post of legal judge, whether for the Court of First Instance or Court of Appeal, must be nationals of member states that have signed the UPC Agreement, and in order to be appointed, their member state must also have ratified. They must be proficient in at least one European Patent Office (EPO) language (multiple languages preferred) and possess the relevant qualifications for appointment as a judge in their member state. They also should have extensive patent litigation experience as well as the capacity to work in a multilingual and multinational environment.

It is expected that most of the current patent court judges in the major EU jurisdictions will apply, even if for a part time post initially.

Candidates for the post of technical judge must meet the same nationality requirements as for legal judges, and possess the same language skills. They must also have a university degree and proven expertise in a field of technology, as well as proven knowledge of law and procedure in patent litigation. Actual patent litigation experience will be an advantage. Technical judges will serve in both the Court of First Instance and the Court of Appeal.

The application period will end on 04 July 2016, and there is an interview stage planned for the end of 2016. Successful candidates will be appointed some time in early 2017.

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