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PATENT

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New European Patent Office (EPO) Guidelines for Examination come into force (<http://dycip.com/epoguidelinesnov17>) in November 2017. The EPO will be able to issue a summons to oral proceedings as the first communication from the Examining Division. To allow the applicant sufficient time to prepare submissions ahead of oral proceedings, it should be issued with at least six months' notice. This change forms part of the EPO's Early Certainty initiatives to speed up prosecution and opposition proceedings.

We would like to share the good news that Sophie Blake, Martin Bicker, Emma Hamilton and Ryan Lacey recently qualified as European Patent Attorneys. We wish them well as they embark on their careers.

Editor:
Aylsa Williams



Events



14 November 2017

European biotech patent webinar

Simon O'Brien and Matthew Caines present our popular European biotech patent case law webinar at 9am, noon and 5pm (GMT). Early registration is highly recommended to secure your place at this webinar.

16-17 November 2017

CIPA Life Science Conference, UK

Kirk Gallagher and Simon O'Brien, will attend this event for patent and IP professionals active in the pharmaceuticals, medical technology and biotechnology sectors.

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Novelty / disclosure

Hiding in plain sight Was Apple's use of complex URLs public disclosure?

Just before the release of their latest iPhone, Apple suffered a major information leak. Two news sites were given access to an unreleased version of the iOS operating system. This code included details of some new facial recognition technology developed by Apple.

Apple's leaked URLs

This type of leak has happened to many other manufacturers. However, in this case the person leaking the information provided a list of URLs to the news sites where the code was located. A URL is the internet address where the code was located. Therefore, by putting the URL into a web browser, the news sites were taken straight to the code.

Securing against brute force attacks

Although it appears the code was not encrypted, these URLs were very long and complex and so could not be guessed.

The very long and complex URL was the mechanism Apple used to conceal the code from the public.

This type of mechanism for hiding sensitive information is becoming increasingly common. A URL is randomly generated and blocked to search engines. The random nature and the complexity of the URL is such that a person would not be able to guess the URL and, as the URL is blocked to search engines, the URL should not appear in web search results.

This method is also very secure against a so-called "brute force" attack, where a computer program automatically tries every possible combination of letters and numbers. This is because to "guess" a simple URL such as www.dyoung.com would take a computer around 55 million years!

Whilst this mechanism seems quite secure, in theory anyone can access the information; it is on the Internet and is not secure so if found can be accessed by anyone. This raises an important question: Is data stored in this

Apple used complex URLs to conceal data



manner actually disclosed to the public and so not novel from a patent point of view?

Website and email prior art in T1553/06

The leading case in Europe for the public availability of documents on the Internet is T1553/06, which was issued in 2012.

This was a test case and information was intentionally put onto the Internet. The way in which the information was put onto the Internet was carefully controlled to test the various mechanisms by which information is normally placed onto the Internet and subsequently searched.

The Board of Appeal held in this case that "the mere theoretical possibility of having access to a disclosure does not make it become available to the public within the meaning of [the EPC]". The threshold required is that one or more members of the public must have "direct and unambiguous access" to the information.

The Board of Appeal examined several scenarios regarding the meaning of "direct and unambiguous access".

➤ **Related case T 1553/06**
Jurisdiction: European Patent Office
Decision level: Boards of Appeal
Parties: Koninklijke Philips Electronics N.V. (patentee), DSM IP Assets B.V. (opponent)
Date: 12 March 2012
Citation: T 1553/06
Decision: <http://dycip.com/t155306dec>

In the case of information being stored on the Internet which can be only accessed by guessing the URL, “direct and unambiguous access” is possible only in exceptional cases. The Board of Appeal held that an exceptional case may be that the URL is so straightforward or so predictable that it can be readily guessed.

Of course, users do not typically find information on the Internet by simply guessing URLs. Instead, most people use publicly available search engines such as Google, Bing or Microsoft Edge to provide search results identifying URLs containing information.

In the case where the information was found using an Internet search, the Board of Appeal held that even if the information could be found by entering keywords into a search engine, this was not enough to satisfy the “direct and unambiguous access” test.

Instead, what was needed was that the keywords all related to the essence of the information. In particular, if the information was found as a result of a search containing words completely unrelated to the content of the information, that would not provide the requisite “direct and unambiguous access”.

The Board of Appeal also reviewed the time period for which that information must be located at that URL as the Board of Appeal appreciated that it is possible to store information at a URL for a very short period of time. In this regard, however, the Board of Appeal did not define a specific period of time. Instead, the Board of Appeal held that the period of time must remain accessible at that URL for a period of time required to allow “direct and unambiguous access” to the information. This should be determined on a case-by-case basis.

As yet, a time period for which that information must remain at that URL has yet to be defined in other case-law.

Board of Appeal test for disclosure of a document on the Internet

As a conclusion, the Board of Appeal set out a test to determine whether information was made available to the public. In order to have been made available, all conditions of the test have to be met.

The wording of the test is defined as follows:

“If, before the filing or priority date of the patent or patent application, a document stored on the World Wide Web and accessible via a specific URL

(1) could be found with the help of a public web search engine by using one or more keywords all related to the essence of the content of that document and

(2) remained accessible at that URL for a period of time long enough for a member of the public, i.e. someone under no obligation to keep the content of the document secret, to have direct and unambiguous access to the document, then the document was made available to the public in the sense of [the EPC].”

So, in the case that the URL at which the information resides is random in nature and is long and complex, and that the URL is blocked to search engines, it is unlikely

that the first condition of the test is met and the information is not made available to the public in the sense of the EPC.

There has been no test of this case-law in respect of this particular method of hiding information in plain sight. However, as it is becoming an increasingly common method, it will be undoubtedly tested at some point in the future.

Author:
Jonathan Jackson



Want to read more?

In an earlier article, published on our website in 2012, we discussed the uncertainty of email and web pages becoming part of the state of art under Article 54(2) EPC in relation to appeal decisions T-0002/09 and T-1553/06. Under Article 54(2) EPC the state of the art comprises everything made available to the public by means of a written or oral description, by use, or in any other way, before the filing of a European patent application.

The patent applications in question were intentionally filed as test cases to provide clarity on these issues.

Read the full article on our website at: www.dyoung.com/knowledgebank/articles/priorartinternet



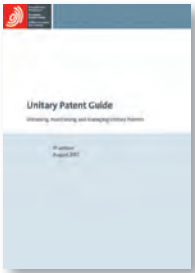
UP & UPC

Ratification and timings

Over the course of the summer there have been a number of developments in the unitary patent and Unified Patent Court (UPC) project which we summarise below. We also include a note on commencement timing, which remains uncertain at the time of writing.

European Patent Office Guide to the Unitary Patent

On 18 August 2017 the EPO published a Unitary Patent Guide.



Link to download the PDF guide at: <http://dycip.com/epo-upguide>.

The guide sets out how to obtain unitary patent protection and other useful information relating to the process and fees.

UPC Provisional Application Period

In July we reported that the UK had agreed to apply the Protocol on Provisional Application of the UPC. This brought to ten the number of countries that had consented to this Protocol, which will ultimately allow the UPC to come into existence before formal commencement of the court itself, and also enable the so-called sunrise period (for pre-commencement opt-outs) to begin. In order for the Provisional Application Period to start, however, at least three further countries must agree to apply Protocol, and these must include Germany (which we discuss below). From what we understand, Bulgaria, Portugal and Slovenia are close to completing the necessary steps.

Further ratifications of the UPC Agreement

On 24 August, Lithuania deposited its instrument of ratification of the UPC Agreement with the European Council. There are therefore now 14 countries that have ratified: Austria, Belgium, Bulgaria, Denmark, Estonia, France, Italy, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Sweden and Finland.

In order for the UPC Agreement to come into effect, however, ratification by the UK and Germany is still required.

UK ratification

Readers will of course be aware that the UK indicated its intention to ratify in November 2016, notwithstanding the vote to leave the EU, and that it has since then continued with the steps necessary to enable ratification to happen. However, delay has been caused to that process by the snap UK General Election that took place on 08 June 2017, the “Hung Parliament” outcome of that election and the summer Parliamentary recesses of both the UK and Scottish Parliaments.

Two minor pieces of legislation are necessary before the UK will ratify, one from each of the UK and Scottish Parliaments. Both have now been published and laid before their respective Parliaments.

UK legislation at least will have to wait until mid-October 2017 at the earliest to be considered (because of political party conferences) so it may not be until November 2017 before the UK is in a position to ratify.

We assume it will do so, although the question of whether (and how) the UK can remain in the UPC post Brexit remains somewhat open. We are aware that business is continuing to press for clarity on that issue, which is likely to be resolved as part of the overall Brexit negotiations. Our current expectation is, however, that the UK will complete the process of ratification, probably before the end of the year.

German ratification

Readers will also be aware that in March 2017, a private individual lodged a complaint with the German Constitutional Court (FCC),

challenging the constitutionality of the German legislation implementing the UPC Agreement. This led to a request from the FCC to the German Government not to sign that legislation into law, which request was heeded. Details have since been emerging as to both the grounds of the complaint and the identity of the complainant (who is an individual known for his opposition to the UP/UPC project).

We are not in a position to comment on the merits of the complaint, whether it will be admitted or indeed any possible outcome. What we do know is that a number of entities and organisations (including one in which we are involved) have been asked to comment on the complaint, before the FCC decides on admissibility. Those comments are due by 31 October 2017, after which the FCC will make that initial decision. If the complaint is not-admitted, delay to commencement of the system should (all things being equal) be relatively minor – perhaps a couple of months. If on the other hand it is accepted, then the delay is likely to be more considerable because the German Government is unlikely to be able to ratify the UPC Agreement, or indeed agree to apply the Provisional Application Protocol, while the case is pending.

We will post any news and other developments on our website as soon as we hear them.

Possible timing

As indicated, while the FCC is considering the admissibility of the complaint before it, it is hard to give a new estimate on timing for the commencement of the UPC.

We would nevertheless advise businesses and users, however, to continue with their preparatory steps. If the complaint before the FCC is rejected, it is possible that the sunrise period will begin more or less as most recently (and of course provisionally) suggested by the UPC Preparatory Committee, namely at some point early in 2018.

Author:
Richard Willoughby



T 488/16

Plausibility denied – how much data are required in a patent application?

In T 488/16, a European Patent Office (EPO) Board of Appeal upheld a decision of the Opposition Division revoking Bristol-Myers Squibb's patent EP 1169038 for lack of inventive step. Significantly, the Board of Appeal decided that there was insufficient evidence in the application at the filing date to render plausible the alleged technical effect of the single claimed compound. As a result, post-published data were not taken into consideration for the assessment of inventive step.

Background to T 488/16

EP 1169038 relates to the compound dasatinib, which is approved in the US and the EU for the treatment of chronic myeloid leukaemia (CML). Dasatinib is produced by BMS and sold as Sprycel® with sales of about USD 1.8 billion worldwide.

The significance of this case was well recognised, with third-party submissions made by the European Federation of Pharmaceutical Industries and Associations (EFPIA) due to the potential impact on patenting in the life sciences.

Patent EP 1169038

EP 1169038 was filed in April 2000 and disclosed a very broad genus of compounds defined by a Markush formula. In addition, the application disclosed 580 synthetic examples falling within the scope of the broad general formula, which included dasatinib. The sole claim of the only request under consideration by the Board of Appeal related to the compound dasatinib, defined by its chemical structure, or salts thereof.

The original application disclosed a number of protein tyrosine kinases (PTKs) as potential inhibitory targets of the disclosed compounds, and generically described assays that are suitable for ascertaining the activity of a compound as a PTK inhibitor.

Crucially, however, the application did not disclose any data as evidence of the PTK inhibitory activity of any of the compounds encompassed by the general formula, let alone dasatinib itself. Instead, the only support for such activity was the statement that: "Compounds described in the following Examples have been tested in one or more of

The Board of Appeal upheld the decision to revoke EP 1169038 for lack of inventive step



these assays and shown to have activity".

As was not uncommon practice at the filing date, BMS appeared to have been in possession of data, but chose not to include this in the application.

Plausibility and inventive step

The patentee argued that there is no requirement in the European Patent Convention (EPC) to include data in an application, and that the statement in the application confirming the inhibitory activity of compounds of the examples, along with the well-known assays that could be used to assess activity, made it plausible that the technical effect was solved and that this could be readily verified.

The patentee also filed post-published evidence, which it was argued demonstrated that dasatinib was an improved PTK inhibitor compared to the prior art. In the patentee's view, this proved inventive step.

The Board of Appeal disagreed. Although agreeing that experimental data are not always required, the Board of Appeal reasoned that if the invention relies on a technical effect that is "not self-evident nor predictable or based on a conclusive theoretical concept" some evidence must be provided at the filing date to show that a technical problem has been solved. A "mere verbal statement" was not sufficient. The Board of Appeal stated: "it is not acceptable to draw up a generic formula, which covers millions of compounds, vaguely indicate an "activity" against PTKs and leave it to the imagination of the skilled reader or to future investigations

to establish which compound inhibits which kinase and is therefore suitable to treat the respective diseases associated therewith".

Conclusion of the Board of Appeal

In the Board of Appeal's view, plausibility had not been demonstrated at the filing date, thus post-published evidence could not be considered. Applying established case law the Board of Appeal then concluded that the claim of the main request lacked inventive step, because it only provided a new structure that did not show any effect.

Referral to the Enlarged Board of Appeal

Requests by the patentee to refer questions to the Enlarged Board of Appeal were rejected. The Board of Appeal reasoned that the questions were primarily technical questions answered in view of the facts and evidence of the case, and that questions relating to plausibility cannot be answered in general, but are case-specific.

Lessons for patent applicants

This decision emphasises the importance of establishing plausibility at the filing date. Although data not included but shown to have been generated before filing might hold some persuasive value, applicants should aim to include as much experimental data as possible relating to the primary technical effect and not rely solely on general statements. Including data substantiating other technical effects, such as solubility and toxicity, might also prove beneficial.

Author:
Matthew Caines

UK patent benefits UKIPO analyses the UK patent system

An effective patent system is a critical aspect of the UK Government's drive for innovation, as the protection offered by patents may be considered to be a catalyst for innovation.

In August, the UK Intellectual Property Office (UKIPO) published a report analysing the performance of the UK patent system. This report uses data analysis, attorney and company interviews and existing academic literature to review how companies patent in the UK, who patents in the UK, and how the UK system compares to other countries and regions.

The report is available from the UKIPO website, or at <http://dycip.com/ipo-ukpatents> (PDF).

Patent filing numbers in the UK and beyond

Patent protection is a rapidly-growing field worldwide, with the number of new patent applications globally rising by an average of 5% annually between 1995 and 2006. Growth is particularly strong with European patent (EP) applications (7.7% per year). When including EP applications in UK patent counts, the UK was ranked sixth in the world in terms of numbers of filings in 2014. This is comparable to Germany (fourth with EPs) and France (seventh with EPs).

While the number of new patent applications being filed may be considered an important indicator of innovation, this data cannot be taken in isolation. These numbers do not consider factors such as the scope of the claims, the number of patents granted, the quality of the patent system, or the filing strategies of companies using that patent system (or not, as the case may be). For example, some companies may consider the use of trade secrets to be more appropriate to protect their inventions.

UK patents offer high returns on investment

The majority of companies base their filing strategies upon consideration of where the consumer markets exist for

their products. Attractive markets (and therefore targets for patent application filings) have high GDP and large populations with high levels of consumer spending.

The UK is therefore seen as an important consumer market by applicants; the UK market is where many companies and their competitors are active in manufacturing and selling products. It is therefore important to protect market share in the UK, which may be achieved with the use of relevant patents. This leads to a large number of filings covering the UK market; adjusting patent counts for GDP or population, the UK is fourth or second in the world (respectively) for number of filings. This is ahead of comparable European markets, illustrating the importance of the UK market.

The UK is also seen as a cost-effective jurisdiction to patent in as, when adjusted for GDP, it is the third cheapest major patent office and the cheapest in Europe.

UK patents therefore represent a good-value investment, as the potential consumer market is large relative to the costs of patenting.

Who patents in the UK?

93% of UK patents (including EP-originating applications) belong to foreign applicants; almost a quarter of these have US owners, with German and Japanese owners making up another 31% of the total. When considering patents filed only directly at the UKIPO, 50% of the granted patents are held by UK-based applicants. It is clear that non-UK companies rarely take the direct route for obtaining a GB patent; US companies are most likely to do so with only 8.5% of published applications in 2012 resulting from direct filings at the UKIPO.

Considering the high returns on investment that are provided by a UK patent, it is apparent that many applicants may be

underestimating the importance of filing directly at the UKIPO when drawing up their patent filing strategies.

Benefits of the UK patent system

In general, the UK patent system is seen as an attractive one; the application and renewal costs are low compared to most other major patent systems, and the standards for both examination and customer service are seen as excellent.

The options available for accelerating prosecution are seen as good, although awareness of them could be improved, and this may allow applicants to reduce costs and expedite prosecution elsewhere by utilising schemes such as the Patent Prosecution Highway (PPH).

While there has been an increase in processing times in recent years, this is common amongst most major patent offices. This may be driven by the worldwide increase in the number of new applications filed, in addition to a trend of an increase in the number of amendments per application before proceeding to grant. Nevertheless, in 2012 it was reported that 38% of applications at the UKIPO granted within two years (comparable with other major patent systems, with only France performing significantly better) and 92% within four years (the highest rate in the patent systems considered).

The courts of England & Wales have traditionally been well regarded for patent litigation. The report notes that, in 2015, the US Chamber of Commerce ranked the UK the best jurisdiction in the world in terms of the enforcement of IP rights, with a score of 5.48 out of 6.

The UKIPO review of the UK patent system: <http://dycip.com/ipo-ukpatents>



The competence, reputation and specialisation of the judges are seen as being advantageous, and the consistency of their decisions is beneficial for all parties. These decisions often have a large influence in other jurisdictions, further increasing their value.

The UK may also be seen as a desirable jurisdiction to litigate in in view of the opportunities for a quick resolution. One example of this is that of *Napp Pharmaceutical Holdings Limited v Dr Reddy's Laboratories (UK) Limited and Sandoz Limited* [2016] EWCA Civ 105 (we have discussed this case previously, see: www.dyoung.com/knowledgebank/articles/patent-litigation); here, the UK courts recognised the commercial importance of the case and ordered an expedited trial. The opportunity for a quick resolution meant that the defendant agreed not to launch their product (removing the need to consider an injunction, streamlining the process), and the court gave its decision less than six months after commencement.

In conjunction with the weight that UK judgements carry in other jurisdictions, an early judgement can be very significant for multinational litigation strategies.

The report notes that the cost of enforcement is sometimes more expensive than other jurisdictions, although the report notes that respondents listed overall costs behind 'competence, reputation and specialisation of judges' and 'ability of competent professional advisors'. In addition to this, it may be the case that views on the cost of UK litigation are outdated. In recent years there have been a number of changes in UK courts, reducing the costs and bringing litigation costs closer to those of continental Europe.

One area in which this is particularly true is that of the Intellectual Property Enterprise Court (IPEC). Procedure in the IPEC is streamlined with the trials usually limited to two days lowering costs significantly. While the IPEC does have

a damages limit of £500k, the limits on cost recovery (£50k) and the possibility of pursuing an injunction (which is often more important than the awarded damages) make this an attractive option for many.

In addition to this, since October 2015 the Patents Court has been running a pilot scheme, the Shorter Trial Scheme, that aims to make the litigation process more streamlined. This scheme is intended for use with cases that are expected to be resolved quickly, or that are particularly suitable for a flexible approach. These schemes place restrictions on disclosure and cross-examination, as well as the length of the trial, which should make sure that costs do not rise to unreasonable levels.

It is clear that the UK has become an increasingly attractive jurisdiction in which to litigate, in view of the lowering costs, quick resolution, and considerable expertise of both judges and advisors.

Conclusions

Not surprisingly, the primary motivation in where businesses choose to patent is based on where their markets are.

Differences between patent systems are of relatively minor importance for companies when developing an international filing strategy; although this may not be the correct approach. For example, the benefits of the UK patent system are clear and yet some of the advantages are not available to those seeking to gain protection in the UK via an EP application. It may therefore be beneficial to file directly at the UKIPO in addition to filing a European application in order to fully exploit the advantages of the UK patent system.

Author:
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And finally...

Webinar invitation

Biotech patent case law Significant EPO decisions

Registration is now open for our popular European biotech patent case law webinar



We are pleased to announce that our European biotech patent case law webinar returns this November with a round up of recent and significant EPO decisions from European Patent Attorneys Simon O'Brien and Matthew Caines.

Simon and Matthew will be presenting a summary of European biotech case law three times on Tuesday 14 November so that our clients, associates and contacts from around the world are able to listen in at a time that is convenient to you. You can sign up to attend the 9am, 12pm or 5pm webinar (GMT) via our website at <http://dycip.com/biopat-web>.

This is usually a popular webinar subject so early registration is recommended in order to secure your webinar seat.

If you are unable to attend this particular webinar but would be interested in signing up to receive notifications of future events of this nature, please email your contact details to: subscriptions@dyoung.com.

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