D YOUNG & CO PATENT NEWSLETTER no.63

February 2018
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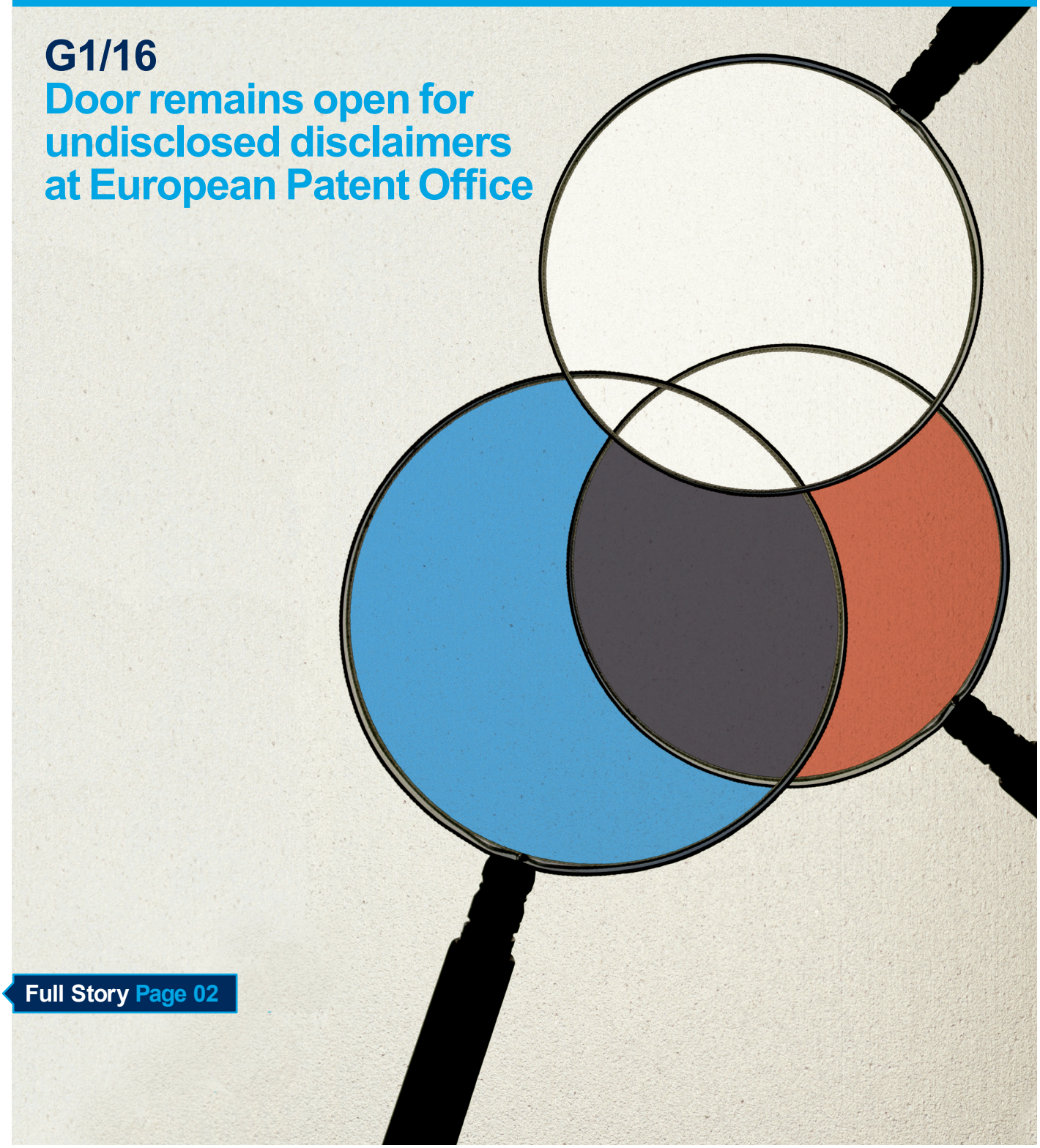

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Editorial

In this month's newsletter we report on some interesting developments in the US process of *inter partes* review, which could have significant impact in the US. In Europe, the European Patent Office is looking to increase its share of PCT work with reductions in fees for applicants who use the EPO in the international phase and then proceed in Europe. We also continue to keep a close eye on the unitary patent and will be following up in coming issues and on our website (www.dyoung.com/knowledgebank/up-upc) with information about the expected 'Sunrise' period.

We hope you find this month's articles from our attorneys and solicitors interesting and relevant.

Editor:
Anthony Albutt

Events

10 May 2018
Universities & Regional Innovation Conference, London, UK
Partner Catherine Mallalieu will be attending this conference entitled "Next steps for regional innovation policy - developing clusters, strengthening university-business collaboration and priorities for the Knowledge Exchange Framework" taking place in London.

04-07 June 2018
BIO, Boston, US
Biotechnology team partners Aylsa Williams, Simon O'Brien and Garreth Duncan will be attending the BIO International Convention which takes place in Boston this year. If colleagues and clients would like to arrange a meeting during the convention, please do get in touch.

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G1/16
Door remains open for undisclosed disclaimers at European Patent Office

The Enlarged Board of Appeal has now released its written decision in respect of G 1/16 (T 0437/14). This decision resolves the question regarding which standard is to be applied to determine whether an "undisclosed disclaimer" in a patent claim introduces added subject-matter (that is, it contravenes Article 123(2) EPC).

Previously G 1/03 and G 2/10 have both addressed issues regarding added subject-matter of disclaimers; this is therefore the third Enlarged Board of Appeal decision to be issued in just over a decade on this subject, which perhaps gives an indication of how contentious an issue the allowability of introducing disclaimers into patent claims is seen to be at the EPO.

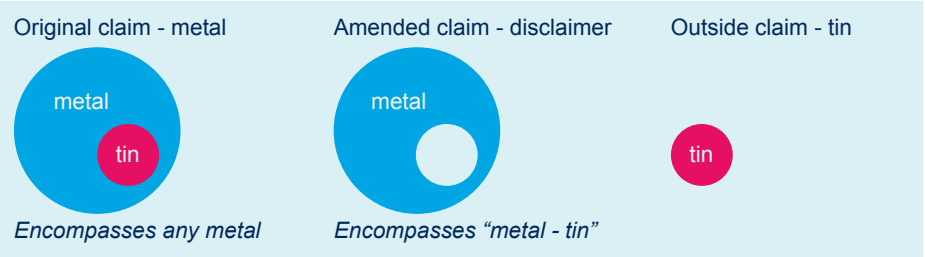
Background – undisclosed v disclosed disclaimers

In general, patent claims typically define the subject-matter for which protection is sought in terms of "positive" technical features of the claimed invention; meaning those technical features that define the elements and characteristics of the claimed subject-matter.

In contrast, a "disclaimer" was defined in G 1/03 as meaning an amendment to a claim resulting in the incorporation of a "negative" technical feature, typically excluding from a generally defined subject-matter specific embodiments or areas.

For example, a claim may define its subject-matter by the following positive features: "A composition comprising a metal".

However, it is also possible to define the claimed subject-matter in terms of "negative features"; for example, by introducing the feature that "the metal is not tin". This sort of amendment can be illustrated as shown below:



This is known as a disclaimer since what is left in the claim is less than that before the introduction of the negative feature.

> G 1/16 is concerned with the distinction between two types of disclaimer: a "disclosed disclaimer" and an "undisclosed disclaimer".

An undisclosed disclaimer refers to a disclaimer which is not disclosed in the application as filed, and nor is there any disclosure of the subject-matter excluded by it in the as-filed application; it is a disclaimer that excludes subject-matter that is not specifically mentioned in the application as filed. Using the above example of "metal – tin", this would be an undisclosed disclaimer in the case where there is simply no mention of tin anywhere in the application as filed.

In contrast, a disclosed disclaimer refers to a disclaimer which may not itself have been disclosed in the application as filed, but the subject-matter excluded by it is disclosed in the application as filed; it is a disclaimer that excludes subject-matter that is specifically mentioned (disclosed) in the application as filed, such as in an embodiment or example. Again, using the above example of "metal – tin", a situation in which there is an example in the application as filed of the metal being tin would constitute this disclaimer being a disclosed disclaimer.

G 1/03 – Allowability of undisclosed disclaimers under Article 123(2) EPC

G 1/03 first dealt with the question of allowability under Article 123(2) EPC of undisclosed disclaimers. In G 1/03, the Enlarged Board of Appeal held that an

Case details at a glance
Jurisdiction: European Union
Decision level: Enlarged Board of Appeal
Date: 18 December 2017
European Case Law Identifier: ECLI:EP:BA:2017:G000116.20171218
Case number: G 0001/16
Referral: T 0437/14
Full decision: http://dycip.com/g016disclaimer

Related article
Undisclosed disclaimers - Enlarged Board of Appeal, Catherine Keetch, 16 December 2016 (discussing G 1/03 and G 2/10): https://www.dyoung.com/knowledgebank/articles/undisclosed-disclaimers

amendment to a claim by the introduction of a disclaimer may not be refused under Article 123(2) EPC for the sole reason that neither the disclaimer, nor the subject-matter excluded by it from the scope of the claim, have a basis in the application as filed. However, such an undisclosed disclaimer is only allowable in certain, limited circumstances; namely, in order to:

1. Restore novelty against art under Article 54(3) EPC;

2. Restore novelty over an accidental anticipation; or

3. Disclaim subject-matter that is excluded from patentability for non-technical reasons under Articles 52 to 57 EPC.

It was thus clear that undisclosed disclaimers could only be introduced if the limitation does not contribute to the invention – it must not become relevant for assessment of inventive step or sufficiency. Furthermore, it was held that a disclaimer may only serve the purpose for which it is intended and nothing more; meaning it cannot disclaim more than is necessary to restore novelty or disclaim the non-technical subject-matter.

G 2/10 – Allowability of disclosed disclaimers under Article 123(2) EPC

Several years later, G 2/10 addressed a different question of whether a disclaimer infringes Article 123(2) EPC if its subject-matter was disclosed as an embodiment of the invention in the application as filed. In other words, G 2/10 was concerned with the question of allowability of disclosed disclaimers.

In G 2/10, the Enlarged Board of Appeal held that an amendment to a claim by the introduction of a disclosed disclaimer infringes Article 123(2) EPC if the subject-matter remaining in the claim after the introduction of the disclaimer is not, be it explicitly or implicitly, directly and unambiguously derivable from the application as filed. This therefore confirmed that the application of the "gold standard" for assessing added matter (what the skilled person would directly and unambiguously derive from the application as filed) of disclosed disclaimers.
A number of commentators have considered that this was seemingly in conflict with the decision in G 1/03. There followed a divergence in applicability of G 2/10 to undisclosed disclaimers: in a number of decisions, Boards applied the gold standard test of G 2/10 to undisclosed disclaimers in addition to the criteria set out in G 1/03, whilst in some cases the allowability was primarily assessed on the basis of the gold standard alone.

The question of which standard should be applied for undisclosed disclaimers was therefore referred to the Enlarged Board for consideration in G 1/16.

G 1/16 decision

In G 1/16, the Enlarged Board has confirmed that the criteria set out in G 1/03 are to be applied when considering whether a claim amended by the introduction of an undisclosed disclaimer is allowable under Article 123(2) EPC. The gold standard test of G 2/10 is not the relevant test for examining whether an undisclosed disclaimer complies with Article 123(2) EPC.

> The Enlarged Board of Appeal did, however, note that the gold standard defined in G 2/10 still remains the relevant test for assessing allowability of the introduction of a disclosed disclaimer.

Reasoning

Fundamental to the Enlarged Board of Appeal's decision was the inherent conceptual differences which exist between disclosed and undisclosed disclaimers. Indeed, the Enlarged Board of Appeal noted that, by virtue of what an undisclosed disclaimer is, when neither the disclaimer itself nor the subject-matter excluded by it is disclosed in the application as filed, it automatically follows that the subject-matter remaining in the claim after the introduction of such an undisclosed disclaimer can hardly have been considered to be derivable from the application as filed.
The Enlarged Board of Appeal held that: "It follows from the above that the choice of the proper test … is determined by the fundamental distinction between disclosed and undisclosed disclaimers. That distinction necessitates providing for each of the two classes of disclaimer a single specific test for assessing whether the introduction of a given disclaimer is in compliance with Article 123(2) EPC. For undisclosed disclaimers, the proper test is whether the criteria of G 1/03 are fulfilled, and for disclosed disclaimers the proper test is the gold standard disclosure test of G 2/10"

In arriving at this decision, the Enlarged Board of Appeal also noted that the idea underlying Article 123(2) EPC is that the applicant should not be given an unwarranted advantage, and precludes a new technical contribution being added by an amendment. G 1/03 was considered not to be in contradiction with this premise.

Conclusion

This decision has clarified that the door is not being shut entirely on the use of undisclosed disclaimers. This provides some relief as it will therefore still be possible for applicants to introduce undisclosed disclaimers where necessary in order to exclude prior art that is either an accidental anticipation or post-published, or in order to exclude non-technical features.

Of course, it still needs to be borne in mind that the criteria for allowability of undisclosed disclaimers under Article 123(2) EPC is very restricted. Applicants should therefore continue to draft applications with sufficient fall-back positions, preferably in terms of positive features, that allow for limitations to be made during prosecution without needing to rely on the introduction of such undisclosed disclaimers. The introduction of such disclaimers should be relied on sparingly.

Author:
Sophie Blake

New UK patent fees
Effective April 2018

The proposed revised UK patent fee and fee structure changes will take effect on 06 April 2018

The UK government launched a consultation on increases and changes to patent fees in April 2017, and has now proposed changes to patent fees and the fee structure that will take effect on 06 April 2018.

Proposed changes to statutory patents fees
Readers can view the original consultation and detail of outcome at the GOV.UK website: http://dycip.com/ukpatentfeeconsultation.

There are five main changes, relating to increases in existing fees, and the creation of new excess fees that echo those found in EP and PCT prosecution:

1. An increase in the application fee, and a surcharge if paid after filing
The fee for paper applications will increase from £30 to £90, whilst the fee for e-filed patent applications will increase from £20 to £60. Currently the application fee can be paid up to 12 months after filing, but this option will now incur a 25% surcharge.

2. An increase in the search and examination fees
The search fee for a UK application will increase from £130 to £150 (or to £180 if the request is filed on paper).

The search fee for an international application (UK) will increase from £100 to £120 (or to £150 if the request is filed on paper). Meanwhile the examination fee for a UK application will increase from £80 to £100 (or to £130 if the request is filed on paper).

3. The introduction of an excess claims fee scheme
There will be an excess claims fee of £20 per claim for the 26th and subsequent claims. There is no higher rate for more than 50 claims, unlike the EPO scheme.

The excess claim fee will be required as part of the search fee, making the search fee effectively variable as of 6th April 2018. Meanwhile, if the number of claims crosses the 25 claim threshold or increases above it during later prosecution, a corresponding fee would be payable at grant.

The government listened to feedback suggesting that the EPO limit of 15 claims was too low, particularly as UK applications are often used as priority documents for applications in many other jurisdictions, and so they have taken a more lenient approach than was originally suggested in the consultation.

The UK government estimate that 25% of UK applications contain more than 25 claims, while only 5% contain more than 50 claims.

4. The introduction of an excess page fee
There will be a fee of £10 for each additional page of the description over the initial 35 pages. Notably 'the description' does not include the claims, abstract or figures, or any of the application forms.

The excess page fee will be required as part of the examination fee, making the examination fee effectively variable as of 6th April 2018. Meanwhile, if the number of pages in the description crosses the 35 page threshold or increases above it during later prosecution, a corresponding fee would be payable at grant.

The government chose to implement the fee in this way so that applications which do not proceed as far as examination will not be charged. However as it is common practice to request a combined search and examination, in reality this fee is likely to apply.

The government meanwhile notes that only 11% of UK applications have a description that exceeds 35 pages, and so the overall impact is likely to be small.

5. An increase in life-end renewal fees
There will be a small increase of £10 to the patent renewal fee for years 12 onwards. The government suggests that this increase offsets a reduction in the fees

for excess claims and pages from those originally proposed in the consultation.

Impact

The impact of the changes is primarily a function of the number of claims and pages in an application. Hence, crudely, this may affect Chemical / Pharmaceutical clients more than Electronics / Mechanical clients, and affect US originating applications more than European or Japanese originating applications.

Three worked examples

Example 1

For the government's 'average' UK patent application, which is e-filed, has 22 claims and fewer than 35 pages of description, the changes represent an overall fee increase of about £80 pre-grant. As such, the change is modest and unlikely to change filing strategies.

Example 2

For a larger application with 75 pages of description and 40 claims, the changes amount to an additional £780 (+£400 page fees, +£300 claim fees, +£80 search and exam). This nearly quadruples the official fees payable for the UK case.

Example 3

For a large application with 120 pages of description and 60 claims, the changes amount to an additional £1,630 (+£850 page fees, +£700 claim fees, +£80 search and exam). Clearly this is significantly higher than previous official fee levels and some action may be needed to mitigate such costs.

Response

In the short term, you may wish to consider early entry of a PCT application into the UK national phase to avoid these fees, and similarly those planning a convention filing into the UK may also wish to bring their dates forward, and request search and examination on filing.

For the avoidance of doubt, a PCT application entering the EP national phase and designating the UK is not subject to these fees (other than the eventual renewal fee after grant and validation in the UK).

In addition, it is worth noting that an application can be amended upon entry into the UK national phase, and applicants may wish to take the opportunity to reduce the number of claims to 25 or fewer at this stage. We would be happy to help with this process.

Meanwhile for those applicants only planning to use a UK application as a priority document, it may be worth reviewing whether a joint search and examination is worth incurring both claim and page fees; a search alone would avoid the page fees, whilst no search would avoid both fees. Of course this has to be balanced against the need for an informed decision on subsequent overseas filings and so a policy weighing these factors may need to be devised, for example based on page or claim number thresholds.

Despite these changes, for a typical application the UK still represents one of the cheapest jurisdictions for official fees in the world, and continues to provide excellent value as a function of GDP covered within a portfolio.

Author:
Doug Ealey

Summary of new fees

A summary of the new fees can be found on the GOV.UK website:

http://dycip.com/2018patentfees

UPC constitutional complaint German Bar Association opinion

Those following the Unified Patent Court (UPC) will be aware that, following a constitutional complaint, the German Federal Constitutional Court asked the German President, Frank-Walter Steinmeier, not to sign into law the parliamentary act declaring Germany's accession to the Unified Patent Court Agreement pending the outcome of said complaint.

The Unified Patent Court Agreement cannot come into effect until it is ratified by the three member states in which the highest number of European patents had effect, namely France, the UK and Germany.

The constitutional complaint remains pending.

In the meantime, the German Bar Association has published its opinion on it, concluding that the complaint is unfounded.

German Bar Association Opinion

Opinion of the Deutcher Anwaltverein

To download the opinion of the German Bar Association (PDF) please visit:
http://dycip.com/germanbar-upc

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.

Author:
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EPO fee changes April 2018

In December 2017 we reported that the European Patent Office (EPO) was proposing some changes in certain fees. The EPO has now confirmed the fee changes that are to be implemented from 01 April 2018.

The changes relate to the fees charged in the international phase where the EPO is the International Search Authority (ISA) or International Preliminary Examination Authority (IPEA). The corresponding reduction in fees then applies on entry to the European phase when filing an appeal and also where documents are filed online in character-coded format.

Fee changes for PCT applications and fees applicable on entry to the European phase where the EPO was ISA or IPEA

- There will no longer be a reduction in the fee for supplementary search on entry to the European phase where the international search is carried out by any of the USPTO, JPO, SIPO, KIPO, IP Australia or Rospatent. Thus the supplementary search fee will be the same for all cases where the EPO is not the ISA.
- The international search fee and the international preliminary examination fee will both be reduced by EUR 100. The new international search fee will be EUR 1,875 and the new international preliminary examination fee will be EUR 1,775.
- The reduction in the examination fee payable on entry to the European phase when the EPO carries out the international preliminary examination will increase from its current level of 50% reduction to 75% reduction, thereby providing applicants who select the EPO as IPEA with a greater cost saving when entering the European phase.

These fee changes provide some significant discounts for applicants who follow the Chapter II path in the international phase with the EPO as IPEA and then enter the European phase.

Applicants may wish to reconsider their filing strategy in view of these changes but will need to consider whether the cost savings are sufficient reason to alter their strategy bearing in mind the business reasons behind their current strategy and the wider implications of any changes to that strategy.

EPO patent fee changes will come info force on 01 April 2018

Changes in appeal fee

The appeal fee payable when filing an appeal will increase by approximately 20% to EUR 2,255. This will apply to all appeal fees paid after 01 April 2018.

> Appellants intending to file an appeal may wish to consider filing their notice of appeal and paying the appeal fee in advance of 01 April 2018 (where the appeal deadline has already been set) in order to benefit from the current lower rate.

Changes in fees where documents are filed online in character-coded format

In an effort to encourage applicants to file documents in the newly proposed character-coded format, the EPO are offering a reduction in the filing fee and grant fee for European applications and a reduction in the transmittal fee for international applications (filed with the EPO as receiving office) where all filing documents (description, claims, drawings and abstract) are filed in character-coded format.

Whilst the reduction in fees is due to be applied from 01 April 2018, it is not currently possible to file documents at the EPO in this format due to delays in the implementation of the pilot project designed to test the new document submission format. So, whilst the relevant rule changes will be effective from 01 April 2018, it may not actually be possible to benefit from these changes until some time after that date. We are following the developments in this area closely and will report again in due course when it is possible to benefit from the proposed discounts.

To discuss the implications of these revisions to the fees on your patent portfolio or any strategic actions to take as a result of these changes, please contact your usual D Young & Co attorney.

Author:
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Supplementary Protection Certificates

CJEU considers end of procedure notice in Merck Sharpe and Dohme

There always seem to be multiple referrals to the Court of Justice of the European Union (CJEU) in the supplementary protection certificate (SPC) arena and 2017 was no exception. Towards the end of 2017 the CJEU issued C-567/16 Merck Sharpe and Dohme regarding the suitability of an end of procedure notice in lieu of a valid marketing authorisation.

SPC application for Atozet

The supplementary protection certificate application related to the product Atozet, a drug containing two actives: ezetimibe and atorvastatin, and was applied for in the UK. When the application was made, however, the UK Marketing Authorisation had not been granted and the patent covering the product was about to expire.

> The marketing authorisation for the UK was unfortunately not granted until after the patent had expired.

End of procedure notice

In view of this difficult situation, Merck Sharpe and Dohme filed an "end of procedure notice" with their SPC application and argued that the application complied with Article 3(b) of the SPC Regulation, that is, that a valid authorisation to place the product on the market as a medicinal product had been granted in accordance with Directive 2001/ 83/ EC, because the effect of the end of procedure notice was that all member states concerned, including the UK, had agreed to grant a marketing authorisation for Atozet.

In the alternative, Merck contended that to the extent the application did not comply with Article 3(b) at the application date, this was an irregularity that was capable of being rectified.

Unfortunately, the UK Intellectual Property Office (UKIPO) did not agree with either argument and refused the application.

C-567/16 Merck Sharpe and Dohme concerned the suitability of an end of procedure notice

Application for appeal

An appeal was then filed and two questions were referred to the CJEU, as follows:

1. Is an end of procedure notice issued by the reference member state under Article 28(4) of the Medicinal Products Directive equivalent to a granted marketing authorisation for the purposes of Article 3(b) of the SPC Regulation?

2. If the answer to question (1) is no, is the absence of a granted authorisation at the date of the application for a certificate an irregularity which can be cured under Article 10(3) of the SPC Regulation once the marketing authorisation has been granted?

These questions were referred to the CJEU because SPC applications were rejected on the same ground in Portugal and Sweden, but granted in Denmark, Greece, Italy and Luxemburg. There was therefore a lack of harmonisation on this issue.

The CJEU decided that the end of procedure notice represented an intermediate stage in the procedure and that it did not have the same legal effects as a 'valid' marketing authorisation. Their reasoning for this decision essentially was that unlike a valid marketing authorisation, an end of procedure notice does not authorise the applicant to place the medicinal product on a particular market.

The answer of the CJEU to the first question was therefore "no", with the result that an SPC may not be obtained on the basis of the end of procedure notice.

With regard to the second question, the CJEU decided that the absence of a marketing authorisation was not an irregularity which the applicant could rectify after the application date. This decision was based on the fact that a missing marketing authorisation constitutes an irregularity in connection with the product, as a medicinal product, not an irregularity in connection with the SPC application.

Author:
Rachel Bateman

In short

Although this decision from the CJEU makes legal sense, it seems unfair that an applicant be penalised because of timing. Nevertheless, when a patent is about to expire, an SPC application can only be made on the basis of a valid marketing authorisation, an end of procedure notice is not sufficient.

Oil States Energy Services v Greene's Energy Group
Are IPRs unconstitutional?

The year is 1789. In New York, the First United States Congress meets, and declares the new United States Constitution to be in force. Article I of the Constitution grants the legislative branch its powers, including the power to grant patents. Article III sets up the judicial branch and gives it its powers. A few years later, the Seventh Amendment codifies the right to a jury trial in cases involving private property. This First Congress does not specify whether patents are private property, and does not explicitly empower the legislative branch to revoke patents.

Nevertheless, the US Patent and Trademark Office (USPTO) gets along quite well, granting patents and – since 2012 – occasionally revoking them under a mechanism called "inter partes review" (IPR).

This is until 2015, when the USPTO's Patent Trial and Appeal Board (PTAB) carries out an IPR on a fracking-related patent, finds it invalid and revokes it. The patent belongs to Oil States Energy Services. The institutor of the IPR is its rival, Greene's Energy Group. Rather than appeal the decision only on the grounds that its patent is valid, Oil States Energy goes one step further and argues that the very process by which it was revoked – IPR – is unconstitutional.

The appeal finds its way, in late November 2017, to oral argument before the US Supreme Court in Oil States Energy Services, LLC v Greene's Energy Group, et al. In this case, Oil States questions whether Congress violated Article III and the Seventh Amendment when it authorised the USPTO (an agency of the executive branch) to invalidate patents through IPR, without giving patent holders the opportunity for a jury trial in a federal (Article III) court.

Criticism and support of IPRs

This question is of wider interest. The unusually high number of *amicus curiae* briefs (57 in total) reflects this.

Arguing that IPR is not constitutional are organisations that suffer disproportionately from the consequences of IPR.

The USPTO revoked Oil States Energy Services' fracking-related patent

Pharmaceutical and biotech organisations experience infringers successfully invalidating their patents under IPR. They criticise the expense and uncertainty this introduces. These organisations are joined by groups of patent owners and law professors concerned with property rights.

On the other side, supporting the IPR system, are a diverse range of industry coalitions and individual companies that benefit from being able to use IPR against competitors. Apple, Intel and Google are among those who have put their name to amicus briefs in support of Greene's. These high-tech companies are often targets of patent infringement suits and use IPR to attempt to invalidate the patents asserted against them.

Themes

The arguments made in the briefs of the parties and their amici and in the oral arguments heard before the court in November 2017 can be divided into those focusing purely on the question of whether Congress had the power to enact the IPR regime, and those taking into account policy considerations relating to IPR.

In Stern v Marshall (2011), the Supreme Court expressed "skepticism about [– firstly –] Congressional efforts to withdraw from Article III courts 'any matter which, from its nature, is the subject of a suit at the common law, or in equity, or admiralty' or [– secondly –] 'is made of the stuff of the traditional actions at common law tried by the courts at Westminster in 1789.'" Thus, the court in Oil States will need to consider: firstly, whether patents are private rights (that is, "the subject of a suit at the common law"); and, secondly, the details of practice in British courts of the mid-18th century. Regarding policy relating to the value of IPR, both sides recognise that the introduction of

the IPR regime was motivated by a perception that the existing patent litigation process had ended up working against, rather than for, innovation. The sides do not agree, however, on whether IPR resolves this problem.

Arguments: Do IPRs favour infringers?

In the arguments of those who consider IPR to be unconstitutional, these private rights, historical and policy considerations play out as follows:

Patent rights, they argue, are analogous to rights in land. They are private rights. This argument has precedent in McCormick Harvesting Machine Co. v. Aultman & Co. (1898). In this case, the Court found that once a patent is granted it "is not subject to be revoked or canceled by the president, or any other officer of the Government" because "[i]t has become the property of the patentee, and as such is entitled to the same legal protection as other property."

Further, they say, British courts traditionally used judges and juries to determine the rights of patent owners. Thus, patents are "the stuff of the traditional actions at common law tried by the courts at Westminster in 1789".

On a policy level, Oil States and its amici level a number of criticisms at the IPR regime. Its flaws, they say, lead to dramatically different outcomes than those before the federal district courts. The likelihood of a patent being invalidated through IPR is put at two to three times the likelihood of its being invalidated in the federal courts. This, they say, skews the system in favour of infringers.

Arguments: IPRs are constitutional

Those who argue that IPR is constitutional have a different twist on these private rights, historical and policy themes.

On the question of whether or not patents are private rights, and whether their validity must only be considered before a jury in a federal court, Greene's and its amici note that Congress created the regime for granting patents; it should also be able to create a regime for revoking them. Further, individual patents are granted by the executive branch and have never been a matter of common-law. The other side's analogy between patent rights and property rights is "inapt"; patents are more analogous to leases in public lands (subject to revocation by the executive branch) than simple grants in land. Thus, the scepticism expressed in Stern v. Marshall concerning the withdrawal from federal courts of matter which is the subject of common law need not arise here. Finally, the existence of IPR does not take considerations of validity away from federal courts because there is a right to an appeal to the Federal Circuit.

On the question of whether patent revocation was "the stuff of the traditional actions at common law tried by the courts at Westminster in 1789," the pro-IPR voices point out although the courts of that time may have tried patent cases, executive bodies such as the Privy Council also had this power. Further, although the courts of that time considered infringement, it is not clear that they considered validity or had the power to invalidate patents.

As for the policy question of whether IPR resolves the problems that it was intended to, those on Greene's side argue that is an efficient tool for invalidating patents that should never have been granted by the USPTO.

The answer?

Having heard oral arguments on the case, the Supreme Court is now considering its ruling. Commentators consider that the justices' questioning in oral argument suggests that they will be split. What makes the outcome particularly hard to predict is the fact that the questions concerned are unusually politically-charged for a patents case. Consideration of the extent and limits of the power of the administrative state over property rights, and the strengths and weaknesses of a system in which alleged infringers often triumph may divide the justices along partisan lines. Indeed, some have seen this trend in the justices' questioning during oral argument.

Possible consequences – the return of patent trolls?

Pro-IPR commentators have suggested that a ruling that abolishes the IPR regime may lead to such dramatic consequences as the "return of the patent trolls". IPR has proved an effective tool for invalidating asserted patents more cheaply and quickly than through bringing a revocation case in a federal court. This reduces the pressure on a company against which a patent is asserted to settle to avoid court proceedings.

Advocates of IPR argue that getting rid of the IPR regime will remove this check on patent-assertion entities' activity, leading to a resurgence in threats of infringement proceedings.

The threat of the patent zombie apocalypse?

Even more dramatic-sounding is the "patent zombie apocalypse" foreshadowed by some commentators.

If it is ruled that the IPR regime is unconstitutional and has always been so, IPR decisions from its inception in 2012 could be overturned, reviving patents that had been revoked under the IPR system.

A less spectacular (and perhaps more likely) result would be the imposition of limits on the IPR regime. It has been suggested that the court might introduce a time limit to challenges via IPR (which can currently be made until the patent lapses). This would provide increased certainty for patent-holders after the time-limited IPR period had elapsed. Alternatively, application of the IPR regime could be restricted to patents granted after enactment of the America Invents Act (AIA), which introduced the IPR regime. The reasoning for such a limit would be that owners of post-AIA patents would understand that IPR would be applicable to their patents.

Although the eventual ruling cannot be predicted, it is clear that if the Supreme Court justices decide on anything other than to uphold the status quo, the results will be far-reaching. The court is due to rule by the end of June 2018. We will update readers on the decision in future updates.

Author:
Holly Cowie

Challenging patent validity
Indian sovereign immunity

In US patent law, an *inter partes* review (IPR) may be filed against a granted patent by a third party in order to attempt to invalidate the patent (or cause narrowing amendments to be made).

An IPR may be filed on the grounds of a lack of novelty, or for being obvious in view of the prior art. In an IPR, the prior art is limited to patents and printed publications. The party filing the petition for review must be able to demonstrate a reasonable likelihood of success in challenging the validity of the patent in order to proceed.

> A number of entities are immune from IPR proceedings, by virtue of having sovereign status. Such entities include state governments, the federal government, and Native American tribes.

While the validity of patents belonging to these entities may still be challenged in federal court, this is a much longer and more expensive alternative – these considerations may be sufficient to prevent a party from challenging the validity of a patent altogether.

Allergan's Restasis patents

In the past there have been numerous attempts by patent holders to exploit this exception by assigning their patents to these sovereign entities, resulting in many successful dismissals of IPRs. In a recent example Allergan, the manufacturer of a treatment for dry eyes (called "Restasis"), transferred six US patents covering this product to the Saint Regis Mohawk tribe. In exchange for this transfer and the exclusive licensing of the patents back to Allergan, the tribe received $13.75 million up-front in addition to $15 million per year in royalties from Allergan. Upon completion of the transfer, the tribe filed a motion to dismiss all outstanding IPRs against these patents in view of the tribe's sovereign immunity.

This represents good value for money to Allergan; IPRs that run their full course have a success rate of 81% in either invalidating (65%) or restricting the scope of protection (16%) of a patent. Given that Restasis is Allergan's second largest product (accounting for around $1.5 billion of income annually), this financial outlay is a small price to pay for the dismissal of the IPRs.

Allergan's patents related to Restasis, a treatment for dry eyes

Is sovereign immunity an IPR loophole?

There have been many concerns raised about the impact of the exploitation of such "loopholes" in the law; by dismissing the IPRs, companies may be artificially extending the life of patents that should not be in force. This could therefore be seen to be artificially restricting competition in the market, which may be damaging to competitors and consumers alike. As one competitor stated in this case, this process of avoiding IPRs is

> "…a new and unusual way for a company to try to delay access to high-quality and affordable generic alternatives."

In October 2017 several of Allergan's US patents relating to Restasis were invalidated by a federal judge in Texas, so Allergan's efforts to protect their patents were in vain. Nevertheless, this case (as well as other recent cases in which similar transactions have occurred) has highlighted the existence of this loophole and may well lead to changes in legislation to prevent its exploitation in future.

Adapting the IPR process

Alternatively, it may be the case that the IPR process is adapted so as to remove the incentive to exploit such a loophole. One such modification could be that of modifying the claim construction – the rules for the IPR process state that the "broadest reasonable construction" shall be used. This means that the claims are often given a broader scope than they would be in court, which may lead to patents being invalidated much more frequently in IPR than in court. This may be seen as unfair by patentees, as they would likely not be afforded this same claim scope were they to seek to enforce the patents.

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In short

The take-away message from this would appear to be that an IPR is a very effective tool for challenging validity of granted US patents - and it is likely that as loopholes such as the exploitation of sovereign state are closed this tool will become even more valuable.

In addition to this, it appears that it would not be worth the expenditure to try and shield patents from IPR in this manner in the case that it is expected that a patent would be invalidated in a federal court anyway.

T 0699/12
EPO guidance on the therapeutic methods exclusion

Case details at a glance
Jurisdiction: European Union
Decision Level: European Patent Office
Citation: T 0699/12 (ECLI:EP:BA :2017:T069912.20171113)
Date: 30 November 2017
Link to full decision: http://dycip.com/t069912

The therapeutic methods exclusion is often problematic to navigate. In T 0699/12, the Technical Board of Appeal (TBA) of the European Patent Office (EPO) has provided some useful guidance on its application.

In an opposition before the Opposition Division, the division held that the patent in suit (which was for a method for performing in vivo dosimetry) was invalid pursuant to Art 53(c) of the European Patent Convention (EPC).

> Art. 53(c) of the EPC states: "European patents shall not be granted in respect of: ... methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body..."

On appeal the Technical Board of Appeal, considering the effect of this provision, referred to decision G 01/04 and explained that it "... clarified that a method claim falls under the prohibition of patenting methods for treatment by therapy or surgery under Art. 53(c) EPC if it comprises or encompasses at least one feature defining a physical activity of action that constitutes a method step for treatment of a human or animal body by surgery or therapy..."

It concluded that Art 53(c), therefore, did not exclude methods from patent protection that are used during a therapeutic or surgical treatment of a human or animal body, but methods that are therapeutic or surgical treatments of a human or animal body.

Applying this to claim 1 of the patentee's main request, this read as follows:

"1. Method for enabling quantification of dose delivery in radiotherapy treatment, characterized in that it comprises the steps of:

- irradiation of a phantom following a treatment plan of a patient,

- measurement of the irradiation in said phantom,

- collecting information regarding the irradiation by information means arranged between the phantom and the radiation source, wherein said measurements are divided in time-intervals, and

- analysing the measurements for obtaining information regarding the relationship between the measurements in the phantom and measurements in the information means between the phantom and the treatment source at each time-interval,

- using said relationship information during verification of the treatment of the patient."

The patent specification further explained that the "invention is thereby a method to calibrate the detectors to be used in vivo (during treatment) in a time-efficient and accurate way to achieve high quality, reliable dose measurements during treatment".

> The Technical Board of Appeal concluded that the wording of claim 1 did not include any step that could be considered as being of surgical or therapeutic nature, since no actual irradiating step was claimed. It reasoned that the "verification" (namely, 'quantification of the dose delivery' of the treatment) had no therapeutic or surgical effects as such. Rather, it only determined (verified) the radiation dose during a treatment.

Expressed another way, the claimed method only concerned the technical operation of a device (the radiation/ treatment source and the information means/ detectors) without any functional link to the effects of the device on the body.

The EPO prohibits patenting methods for treatment by therapy or surgery

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And finally...

Pozzoli test

Actavis v Eli Lilly
Ripples of UK Supreme Court decision

The ripples of the UK Supreme Court's decision in Actavis v Eli Lilly (as reported in August 2017: www.dyoung.com/knowledgebank/articles/pemetrexed-supremecourt) continue to be seen in UK jurisprudence. In BL 0/664/17 Ajit Lalvani, Kartar Singh Lalvani and Robert Peter Taylor, the UKIPO considered whether EPO jurisprudence was now binding in preference to UK jurisprudence except in specific circumstances. This may have had a bearing on whether the EPO's problem/solution approach or the English Pozzoli test should have been applied to the question of obviousness.

In Actavis v Eli Lilly, Lord Neuberger held as follows: "Further, while national courts should normally follow the established jurisprudence of the EPO, that does not mean that we should regard the reasoning in each decision of the Board as effectively binding on us. There will no doubt sometimes be a Board decision which a national court considers may take the law in an inappropriate direction, misapplies previous EPO jurisprudence, or fails to take a relevant argument into account. In such cases, the national court may well think it right not to apply the reasoning in the particular decision. While consistency of approach is important, there has to be room for dialogue between a national court and the EPO (as well as between national courts themselves). Nonetheless, where the Board has adopted a consistent approach to an issue in a number of decisions, it would require very unusual facts to justify a national court not following that approach."

The Hearing Officer, Dr Jim Houlihan, concluded that, in his view: "... it is clear from Lord Neuberger's comment that this is not the intention of the Supreme Court. Rather, my view is that EPO decisions may be persuasive where there is similarity on the nature of the facts between a case in question and an EPO decision. He, therefore, declined to depart from the Pozzoli test, concluding that the patent was invalid for lack of inventive step.

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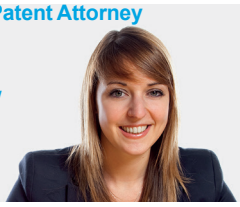

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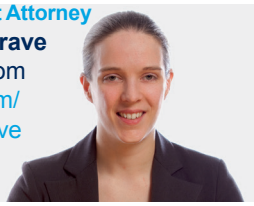

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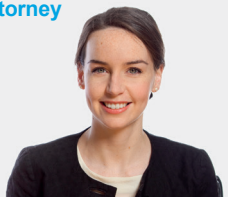

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