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Events

1 March 2012
Young & Emerging Healthcare Business, Stevenage, UK
Connor McConchie is attending this conference, organised by Praxis Unico.

20 March 2012
Patenting Antibodies Seminar, London, UK
See the back page for more information about this D Young & Co event.

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Editorial

Welcome to our first newsletter of 2012. 2011 was an exciting year for us: we launched our Dispute Resolution & Litigation Group and were named IP Law Firm of the Year. We also maintained our excellent track record at oral proceedings at the EPO; see the report from our Biotechnology, Chemistry & Pharmaceuticals Group on our website: www.dyoung.com/news-eposuccesses. Our aim is to build upon this and continue to provide the service our clients have come to expect.

Looking ahead, our newsletter covers interesting developments in patent law and procedures, and we lead with part one of a two-part article on some interesting strategic issues derived from the well-publicised dispute in the tablet market between Samsung and Apple. We also discuss some significant developments in UK tax law which could prove to be of considerable benefit to technology companies based or operating in the UK.

2011 brought with it tragic stories from Japan where we have been working with clients and associates for decades. Our thoughts continue to be with our friends and clients in Japan as businesses continue to recover.

We hope you enjoy this issue and look forward to working with you in 2012.

Editor
Anthony Albutt

Article 01

Validation of European Patents Selection Strategies

The year 2011 saw a number of disputes between companies in the electronics sector. Of these, the highest profile dispute was between Samsung Electronics Co Ltd and Apple Inc. In this first part of a two part article, we will discuss how different courts within Europe were effectively utilised by the parties in the patent aspect of this dispute, and we will discuss whether patentees should re-evaluate the traditional selection of validation states. In the second part of the article, to be published in the next newsletter, we will discuss how different forms of IP were utilised in this ongoing dispute.

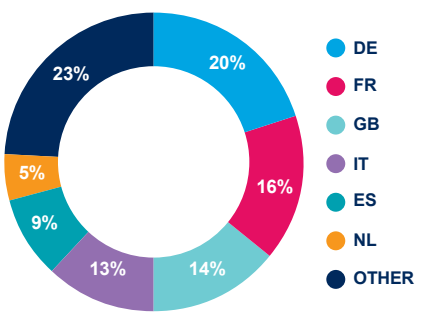
Since the introduction of the European Patent Convention, patentees of European patents have agonised over the important question of where to validate their European patents. Factors which have been taken into account include size of market and cost of validation and the ongoing cost of renewals in each country.

As a result of this balance between size of market and cost, many patentees traditionally only validate in the three largest European markets; namely Germany, France and the United Kingdom.

Market

The graph in Figure 1 (below) shows the size of the largest markets in the EU. By having a patent in each of Germany, France and the United Kingdom (UK), a patentee can gain protection over approximately 50% of the Gross Domestic Product (GDP) of the whole European Union (EU). Traditionally, patentees next look to Italy and Spain as the next largest markets in the EU.

Figure 1 – EU market size (GDP)



Cost

As noted, when deciding validation states, one must consider the cost of the patent in each state. The cost of each patent can be split into two; validation fees and maintenance fees. The validation fee is typically dominated by the cost of any translation into a language of that state. In countries which have adopted the London Agreement the cost of validating in these countries has been significantly reduced. This is because in London Agreement countries the requirement for translation of the granted patent into the language of the state has been removed altogether or reduced significantly as only the claims of the granted patent require translation.

However, the most significant cost over the lifetime of a European patent is maintenance fees. A graph showing a comparison between the cost of validating a typical patent in each of the above countries against the annual maintenance fee is shown in Figure 2 (above right). Maintenance fees for the 10th year onwards tend to be high and sometimes exceed the cost of validating the patent in that country.

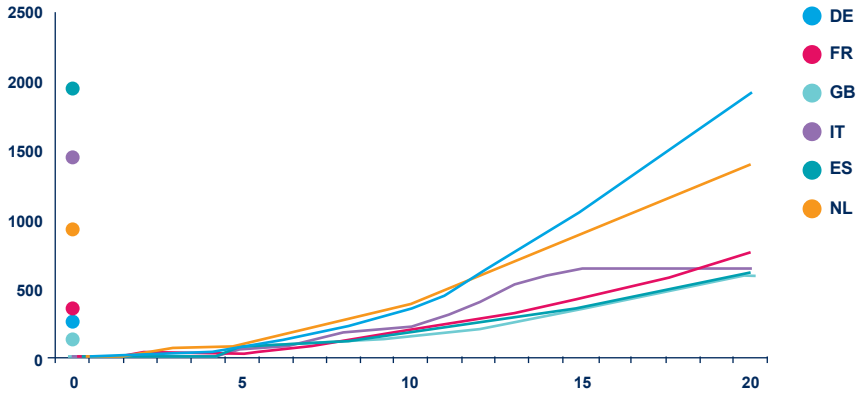
A New Selection?

An often overlooked feature of the European patent system is that although a patent is granted centrally by the European Patent Office (EPO), litigation takes place before national courts. In other words, if a patentee wishes to bring an infringement action against a third party, this has to be brought before a national court in which the European patent was validated. As each national court has different characteristics, patentees can use the characteristics of each court strategically. It is generally recognised that the courts in some countries are more 'pro-patentee' and more willing to grant injunctions than in other countries. The strategic use of the courts is sometimes called 'forum shopping' and was

Missed anything? *In between issues of this newsletter we posted news about the increase in the EPO's fees from 1 April 2012: http://dycip.com/epofees0412. Visit our website for up to the minute IP related articles and news.*

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

Figure 2 – Cost of validation of a typical patent v annual maintenance fee



used in the dispute between Samsung Electronics Co Ltd and Apple Inc. During this pan-European dispute, Apple sued Samsung in the Netherlands. As is seen in Figure 1, the Netherlands has a relatively modest GDP. So why was an action brought in the Netherlands? The answer to this came in August 2011 when the Rechtbank's-Gravenhage granted a pan-European preliminary injunction on the basis of patent infringement. This pan-European preliminary injunction currently prevents the sale of Samsung's range of smartphones by their Dutch subsidiaries in several European countries, including (amongst others) the UK, France and Germany. These are countries in which Apple benefitted from holding a validated European Patent.

The decision in the Netherlands' case is reflective of the Dutch court's willingness to grant swift interim action. Indeed, prior to the Apple/Samsung dispute, in *LG Electronics Inc v Sony Supply Chain Solutions (Europe) B.V*, the seizure of Sony's PS3 and Bravia TV products in Rotterdam was authorised in early 2011 (Order dated 28/02/2011). In this case, had Sony not succeeded in promptly overturning the injunction, the impact may well have been significant to Sony's supply of some of its core products into the European market. With that said and in recognition of the logistical significance of the Netherlands as a 'gateway to Europe' (Rotterdam and Schipol being two major points of entry into the EU), it is suggested that patentees should perhaps reconsider their traditional approach to validation, which until now often overlooks this key jurisdiction. This is particularly the case given the strategic impact a border seizure and preliminary injunction can have at a major point of entry into the EU.

This use of the preliminary injunction can be particularly effective in disrupting supply chains within the EU, especially where goods enter the EU through a single port, such as Rotterdam. However, would the effectiveness of a Dutch patent be reduced if courts stopped granting preliminary injunctions? Possibly. The size of the Dutch market is small and other countries within the EU could be used as an entry point into the EU market. This would mean that without the Dutch courts granting preliminary injunctions, the value of the Dutch patent by itself may be quite low.

Conclusion

In light of the recent decisions from the Dutch courts, patentees may wish to select the Netherlands as an additional strategic country to their portfolio. Indeed, the cost of validating the European patent in the Netherlands is relatively low as the Netherlands is a signatory of the London Agreement and so only the claims need to be translated into Dutch. Therefore, in the event that Dutch courts do become more reluctant to grant preliminary injunctions in the future, such that the strategic value of the Dutch patent diminishes, the Dutch patent can be abandoned without having incurred significant costs. However, if the European patent is never validated in the Netherlands, then it can never be enforced through the Dutch courts. For key patents, the potential benefits of a strategic selection of the Netherlands jurisdiction clearly outweigh these additional costs.

As a final point, the practice of 'forum shopping' has been shown to often produce disparate results between jurisdictions. It is anticipated that the proposed introduction of a central patent court (the Unified Patent Court) will, to an extent, bring greater harmony to the European Patent system, potentially minimising the number of 'forum shopping' exercises which are currently undertaken. However, the scope and powers of such a court have not yet been fully determined although a recent draft agreement does suggest that it would have the power to grant both interim and permanent injunctions[1]. As a consequence, it is hoped that the proposed centralised judicial system would have the benefits of greater legal certainty, equality and economy, although at present it is very much a case of 'watch this space'.

To conclude, when developing national validation strategies for European patents, in addition to considering a wide variety of economic factors, patentees must have particular regard to contemporary disputes which go far in highlighting the divergent approaches of national courts and the protection which should be sought.

Authors:
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Notes

1. **Council of the European Union. "Draft agreement on a Unified Patent Court and draft Statute", Document No. 16741/11.**

SPCs on Combination Products
Only if the Claim Wording Says So

Five related decisions of the Court of Justice of the European Union (CJEU)[1] have finally provided some degree of clarity to the law on Supplementary Protection Certificates (SPCs) for medicinal products comprising a combination of active ingredients. Although these decisions still leave a number of questions open, they may require a change in drafting practice for patent applications directed to pharmaceutical and plant protection products, as well as a review of existing patent applications and even granted patents, so that they claim specific combination products if SPC protection is desired for such combinations in the future.

It is almost 20 years since SPCs were introduced across the European Union, firstly for medicinal products, and later for plant protection products, that require authorisation by a regulatory body prior to marketing. The aim of SPCs is to compensate the patent holder for the patent term lost due to the need to obtain regulatory approval. In the EU, SPCs can extend the term of protection for such a patented product by up to five years[2]. As the term of the SPC is often the time when the product achieves its peak sales, obtaining SPCs is of critical importance to the pharmaceutical and agrochemical industries.

Thousands of SPCs have been granted for medicines and plant protection products containing a single active ingredient which has obtained regulatory approval. However, the award of SPCs for products containing a combination of active ingredients has been a controversial matter in EU countries. This issue is particularly important for vaccines, which frequently contain a combination of active ingredients: health authorities often insist that multiple vaccines be administered in a single dose to minimise the cost and inconvenience to patients.

Over recent years, a number of conflicting decisions have issued from national courts regarding SPCs for combination products. Three particular questions have arisen:

1. Can an SPC be granted for an authorised medicinal product which contains a combination of active ingredients (A + B) when the basic patent protects only active ingredient A (or a combination of A and an unspecified further active) and does not specifically claim the combination A + B?

2. Can an SPC be granted for an authorised medicinal product containing only active ingredient A even when the marketing authorisation additionally refers to other active ingredients in addition to those claimed in the patent (A + B; A + C; A + B + C; and so on)?

3. Can an SPC be granted for an authorised medicinal product which contains a single active ingredient (A) when the basic patent protects only a combination A + B and does not specifically claim A alone?

Decisions could mean changes in drafting pharmaceutical and plant protection applications

These questions resulted in the above cases being referred to the CJEU. The Medeva case, which considered both questions (1) and (2), related to a vaccine for diphtheria, tetanus, whooping cough, polio and meningitis which contained between eight and 11 active ingredients, only two of which were specifically claimed in the basic patent. The Georgetown University case, which considered only question (2), related to the human papilloma virus (HPV) vaccines Gardasil® and Cervarix® used to prevent cervical cancer, and which contain a number of active proteins. The University of Queensland case related to the same cervical cancer vaccines, but considered both questions (1) and (2) and also the applicability of these questions to process patents. The Yeda case considered questions (1) and (3) and related to the anticancer drug Erbitux® (cetuximab).

The Daiichi Sankyo case related to the combination anti-hypertensive product Olmetec Plus® (olmesartan medoximil and hydrochlorothiazide), but considered only question (1).

Useful links:
C-322/10 Medeva:
http://dycip.com/c32210dec
C-422/10 Georgetown University:
http://dycip.com/c42210dec

Useful links:
C-630/10 University of Queensland:
http://dycip.com/c63010dec
C-518/10 Yeda:
http://dycip.com/c51810dec
C-6/11 Daiichi Sankyo:
http://dycip.com/c611dec

Two opposing arguments were put to the CJEU regarding question (1). These reflected the conflicting positions adopted by the referring national IP offices and courts. Some parties argued only the literal wording of the claims was relevant for deciding the question of whether the product was 'protected' by the basic patent, and therefore any combination products containing active ingredients not specifically recited in the claim wording should be excluded from SPC protection. Other parties argued that an 'infringement test' should be adopted, and that any product containing the authorised active and which would have infringed the basic patent should be considered 'protected' by the basic patent and therefore the SPC: if such an 'infringement test' were to be adopted, an authorised medicinal or plant protection product containing A + B would infringe a basic patent reciting only A in the claims.

There is currently no European Union law which determines the scope of protection of a patent: harmonisation of the national patent laws of European countries is based on the European Patent Convention (which is an inter-governmental agreement independent of the EU) rather than EU legislation. However, the CJEU pointed out that the EU SPC regulations provide that any SPC confers the same rights as conferred by the basic patent and is subject to the same limitations and the same obligations. Based on this, the CJEU considered in Medeva (and followed in Daiichi Sankyo) that Article 3(a) of the medicinal products SPC regulation (469/2009) precludes the grant of an SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent.

Furthermore, the CJEU ruled that if a patent claims that a product is composed of two active ingredients but does not make any claim in relation to one of those active ingredients individually, an SPC cannot be granted on the basis of such a patent for the one active ingredient considered in isolation. The combined effect of the above rulings means question (1) can be answered as follows:

- An SPC must not be granted for an authorised medicinal product which is a combination of two active ingredients (A + B) if the literal wording of the basic patent claims A in isolation. This applies even if the claims use "comprising" or similar language which does not exclude the presence of another active.
- An SPC must not be granted for an authorised medicinal product which is a combination of A + B if the literal wording of the basic patent claims a combination of A with another unspecified active ingredient.
- An SPC may be granted for an authorised medicinal product which is a combination of A + B if the literal wording of the basic patent claims A in combination with the specified active ingredient B.

Regarding question (2), in both the Medeva and Georgetown cases the CJEU referred in detail to the objectives behind SPCs and the particular issues regarding combination products, especially vaccines. The CJEU considered that, if the holder of a basic patent relating to an innovative active ingredient (or an innovative combination of active ingredients) were to be refused an SPC on the ground that the marketed product also contained other active ingredients or combinations which may have other therapeutic purposes and may or may not be protected by another basic patent in force, the objectives of the SPC Regulation could be undermined. The CJEU was also of the opinion that such an approach would tend to favour the development of monovalent medicinal products, in particular vaccines, which may not be in the interests of patients or health authorities. For these reason, in the Georgetown University case, question (2) was answered as follows:

- An SPC may be granted for an active ingredient (A) if the wording of the claims of the basic patent relied on specifies A, even if the authorised medicinal product contains not only that active ingredient but also other active ingredients (A + B, A + C and so on).

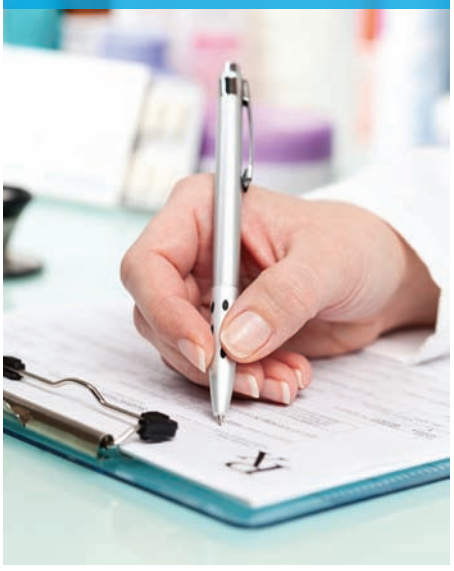
In the Medeva case, for the same reasons, the CJEU similarly ruled that question (2) can be answered in a similar manner for SPCs based on basic patents specifying a combination of actives (A + B) even if the authorisation covers A + B + C, A + B + D and so on.

In the Yeda case, the CJEU also followed the reasoning given in Medeva and extended it to answer question (3) as follows:

- An SPC must not be granted for an authorised medicinal product which contains a single active ingredient (A) when the wording of the claims of the basic patent specifies only a combination A + B and does not relate to A alone.

In the University of Queensland case, the CJEU also followed the reasoning given in Medeva and extended it to the situation where, when the basic patent relied upon relates to a process for producing a product, Article 3(a) also precludes the grant of an SPC relating to a product other than that identified in the wording of the claims of the basic patent as the product deriving from that process. The CJEU ruled it irrelevant whether it is possible to obtain the product directly as a result of that process.

SPCs for combination products have been controversial in some EU countries



SPCs were introduced in the EU for medicinal and plant protection products 20 years ago

It is difficult to understand how the clear reasoning applied by the CJEU regarding the underlying purpose of SPCs to answer question (2) was not also applied to questions (1) and (3). Moreover, it is unclear from the rulings how specific the claim language has to be for the product to be 'specified' in the claim wording. For example, do claims to products defined by therapeutic class (for example, antibiotics) or by general Markush formulae 'specify' the individual active ingredients they cover? In addition, do biologic patents that claim, for example, antibodies to a particular antigen without disclosing the antibody 'specify' the antibody that is eventually authorised?

The decisions also leave open the question whether if an SPC is granted for a single active A, the SPC owner could enforce it against a competitor marketing a combination of actives A + B. The CJEU judges have seemingly sidestepped this question in view of the lack of EU law governing the scope of protection conferred by a patent. The decisions reached in these cases, as well as denying SPC protection for the products in question, may also leave the validity of granted SPCs for some combination products, both medicinal and plant protection, in some doubt. In addition, in the Medeva decision the CJEU also opined that when a patent protects a product, Article 3(c) permits only one SPC to be granted for that basic patent. This comment (which itself refers back to a similar comment in the earlier Biogen decision regarding multiple SPCs for the same product) was not referred to in any of the questions referred to the CJEU, and could be considered an aside. However, if followed in a later decision it may make it difficult to obtain two or more separate SPCs for different authorised products covered by the same basic patent, even though basic patents which support more than one SPC already exist.

In view of these decisions, we would recommend the following changes be considered for future pharmaceutical and plant protection patent applications covering a single active ingredient A, either as a species or as part of a broader genus of compounds:

- New applications: if a likely commercial product A has already been identified, these should include claims explicitly directed to any specific combination products (A + B, A + C, and so on) considered likely to be of commercial interest at the time the application is filed. For example, for pharmaceutical patent applications, the specific actives B, C and so on may be marketed products (or those currently undergoing clinical trials) for the same therapeutic indication as A. Before deciding to include such combinations explicitly in the text, the possible prior art effect on a later patent application specifically directed to such combinations should be considered.

- Pending European patent applications: if active ingredient A has received or is likely to be submitted for regulatory approval, these applications should be reviewed to ensure that any specific combinations of actual or potential commercial importance, but which are currently disclosed in the description only, are included in the literal wording of the claims when granted.

- Granted European patents: if active ingredient A has received or is likely to be submitted for regulatory approval, these should be reviewed to consider whether any specific combinations of actual or potential commercial importance which are disclosed in the application as filed, but not specified in the literal wording of the claims as granted, could be claimed using the EPO's post-grant limitation procedure. Such a limitation may not extend the protection conferred by the patent. However, if the granted patent contains a claim to a combination of A with another unspecified active ingredient, such a claim could be validly limited by specifying the active as B, C and so on.

Author:
Garreth Duncan

Notes:

1. ***Medeva C-322/10; Georgetown University C-422/10; Yeda C-518/10; University of Queensland C-630/10; Daiichi Sankyo C-6/11***
2. ***For pharmaceutical products, a further 6-month extension to the SPC term can be obtained if agreed paediatric studies are carried out, whatever their outcome.***

Negative Term SPCs
A Positive Outcome

> *Useful links:*
> *Full text of decision C-125/10:* ***http://dycip.com/c12510dec***

The CJEU has recently issued a decision allowing SPCs to be granted with negative terms. Whilst this might initially seem surprising it is actually an encouraging outcome for innovator pharmaceutical companies.

This is because, although the duration of the SPC is negative, it may provide an overall extension of a patent term by allowing a paediatric extension (that is a reward for carrying out a paediatric investigation) to be added to the SPC. This extension to the SPC, which is available as a result of carrying out the paediatric investigation, can provide an extremely valuable period of patent protection: the end of the SPC term is frequently the time when the product reaches peak sales.

As a result, obtaining an SPC, even one which has a negative or zero term, could be very valuable.

Background

Merck Sharp & Dohme Corp. (Merck) is the owner of a European patent covering dipeptidylpeptidase inhibitors for the treatment or prevention of diabetes. The patent had a filing date of 5 July 2002. Merck applied for an SPC covering the specific product that had obtained a marketing authorization, sitagliptin phosphate monohydrate (Januvia®). The marketing authorization was issued on 21 March 2007.

As a result of the marketing authorization being granted relatively quickly, less than five years had elapsed from the date of filing of the patent to the date of the first marketing authorization (compared with 12 to 14 years for most pharmaceuticals).

In effect, this early grant of the marketing authorization meant that if an SPC were to be granted, it would have a negative term. The calculation below shows how this is worked out:

According to Article 13 of Regulation 469/2009 (the codified SPC regulation), the duration of an SPC is:

> *"a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years."*
>
> ***Therefore:***
> - *Difference between 5 July 2002 (date of 'lodging') & 21 March 2007 (first MA) = 4 years, 8 months,16 days.*
> - *4 years, 8 months & 16 days (4 years & 259 days) – 5 years = (-)106 days*
>
> ***Result:***
> - *A negative SPC duration of (-)106 days (3 months, 14 days).*

Merck submitted that they should be granted an SPC, even if the term would be negative, because without one they could not proceed to obtain a six month extension of the SPC term for carrying out a paediatric investigation. If such a six month extension could be obtained, it would in this case extend overall protection beyond the normal basic patent term.

In view of the differing decisions taken by various national authorities throughout Europe on this issue (some allowed the negative SPC, some refused it, some allowed it but rounded it up to zero), the German Patent and Trademark Office (DPMA) made a referral to the CJEU. The DPMA questioned whether, in light of the possibility to obtain a six month extension to the SPC following a paediatric investigation, negative term SPCs should be allowed. Accordingly, the following question was referred to the CJEU:

> *"Can an [SPC] for medicinal products be granted if the period of time between the filing of the application for the basic patent and the date of the first [marketing authorisation] in the Community is shorter than five years?*

Decision

The CJEU considered that an SPC can be granted even if the resulting term of the SPC is negative (or zero). Their reasoning was based on the fact that without the availability of such negative SPCs, the objective of compensating for the effort made to evaluate the paediatric effects of the medicinal product at issue would be compromised.

It was also clarified that the six month extension that is available following a paediatric investigation should be applied to the end of the negative SPC term, not to the expiry of the patent term. Thus, the negative term SPC is not rounded up to zero. In the Merck case, the application of the paediatric extension results in an overall extension of 77 days (2 months and 16 days).

To summarise:

- Negative term or zero term SPCs may be granted;
- Negative or zero term SPCs may be beneficial where the period between the filing date and the date of the first marketing authorisation is between four and a half and five years;
- A six-month paediatric extension may be added to the end of the negative SPC term, not to the expiry date of the patent.

Author:
Connor McConchie

Article 04

The Patent Box
What it Means and How it Works

The Patent Box is an opt-in scheme for obtaining a reduced rate of corporation tax on certain IP-derived profits in the UK. The scheme is scheduled to start in April 2013 and is an area of tax law that any IP-active company will want to watch.

The reduced rate of 10% applies to a proportion of profits obtained from using patent rights, or from the sale of products incorporating a patented invention or made by a patented process. The UK Government's aim is to 'create a competitive tax environment for companies to develop and exploit patents in the UK and maintain the UK's position as a world leader in patented technologies'.

On 6 December 2011, it released draft legislation refining its original proposals to include some beneficial updates discussed below, as we review how the Patent Box system works.

Who can benefit?

In line with the aim of stimulating UK investment in innovation, a company can qualify for the Patent Box if it owns or takes a licence for a UK or EP patent, providing:

- The company made a significant contribution to the creation or development of a product covered by the patent; or
- **Updated** – Subject to a group agreement, if a first group company undertook the qualifying development, then a second group company can qualify if it actively owns and manages the IP rights and receives their economic benefits; or
- If the company licences-in the rights, that the licence is exclusive.

Some other IP rights also qualify, including plant variety and data exclusivity rights. In the legislation these are treated like the patent rights for the purposes of calculating the tax reduction.

- **Updated** – The Government reports that it may now extend this provision to patents issued by other EU member states with comparable patentability criteria. This is excellent news as it will broaden the eligible patent portfolio. We await the Government's list of states with interest.
- **Updated** – The development criterion in option 1 above has been made easier for those acquiring existing patents, by including a roll-over of development activity from the previous owner for the past twelve months.
- **Updated** – The active management of rights is now applied at a company level rather than a per-patent level, requiring a 'significant amount' of management activity across a portfolio.

What profits are eligible?

There are five types of qualifying IP income from which profits are eligible:

- Income from the sale anywhere of a patented item (or items from patented processes) or an product incorporating such an item;
- Fees and royalties from UK or EP granted rights over the patented item that are licenced to others (including the use of a patented process);
- Income from sale or other disposal of the UK or EP patent;
- Damages awarded for infringement of UK or EP granted rights; and
- A notional arms-length royalty for use of the patent to generate otherwise non-qualifying parts of the company's total gross income where this is derived from exploiting the patented item.

The corollary is that some common income streams are ineligible and remain taxed at the standard corporation rate, including:

- Income from financial arrangements, such as financial return components of leases for patented products;
- Income from services sold with a patented product;
- Income from bundled parts or peripheral products sold with the patented product but which do not form a single patented product; and
- Income prior to the patent application or after expiry of the patent (though revocation does not result in the need to repay tax).

In addition to the above, many hoped that the Government would make income from design rights and (perhaps less practically) trade secrets eligible; however this has not happened.

These exclusions mean that for commonly bundled products, a dependent system claim to combine these with the main patented item may be useful in extending the eligible profits.

Similarly, end user licence agreements (EULA) may now critically determine whether or not a company's activities qualify for the Patent Box benefits. For example, if a company with a patented cloud computing platform has an EULA stating only that they provide a service, they may be excluded from the scheme. By contrast, a corresponding EULA stating that the end user is licenced to access the platform may make their company's profits eligible for the reduced tax rate. Similar considerations can be foreseen for telecoms, e-payment services and the like.

Clearly it is also important to manage your patent portfolio in order to maintain eligibility, and to factor the benefit of the Patent Box in to any annuity review process.

Consequently, if you wish to review the scope of a portfolio with regards to what eligible income streams it might cover, or wish to review service agreements with a view to compliance with Patent Box eligibility, please contact your normal D Young & Co attorney.

How are the qualifying profits calculated?

The government propose a three-step process that reduces IP-based profit down to a proportion of specifically patent-based profit as follows.

Step 1 – Pro-rata profit

Updated – A company can either apportion total profits according to a ratio of relevant IP income (RIPI) to total gross income; or it can allocate its expenses on a just and reasonable basis to two streams of income (RIPI and non-qualifying income) to arrive at a profit from the RIPI stream.

Hence pro-rata profit equals qualifying income minus qualifying expenditure (company expenditure for tax purposes), either for total income or divided per stream.

Step 2 – Residual profit

The residual profit is the pro-rata profit minus a 'routine profit' assumed to arise from owning IP and is calculated as a routine return based on certain qualifying expenditures, multiplied by a mark-up. **Updated** –The original mark-up was 15%, but the Government has now reduced it to 10% after agreeing it was too high.

Step 3 – Residual patent profit (RIPP)

The final profit is based upon a ratio of costs split between patents and other IP in the RIPI. **Updated** – For companies where marketing intangibles (i.e, branding etc.) contribute to 10% or more of residual profit, this is removed by deducting a notional marketing royalty.

Meanwhile for SMEs, an optional 'small claims' process on profits up to £1m assumes a 75/25 split in favour of patents. Whilst simpler to administer, this assumes a very high proportion of profit from non-patent IP.

According to the Government, many companies will not need this third step as they have no commercial brand, or they licence the IP to

third parties without rights to such marketing intangibles. However, this may be wishful thinking on the part of the Treasury, and RIPP might constitute a significant reduction in eligible profits for many firms.

Phase-In and transitional features

The Patent Box relief is to be phased in over a five-year period, with the proportion of the full benefit incrementing in 10% steps from 60% on profits in 2013/14 to 100% in 2017/18. This avoids the alternative of setting a start date for eligibility, with the associated complex determinations of initial product commercialisation and/or patent subject-matter priority dates. The Government also recognises the frequent lag between cost and profit from R&D, and has attempted to reduce the disparities this may cause upon joining the Patent Box Scheme.

Firstly, in the first four years of a company using the Patent Box, their current R&D expenses will be compared to their average R&D expenses in the four years prior to opting into the Patent Box. If their actual expenditure drops below 75% of the pre-Patent Box level, then this threshold will be substituted for the actual R&D expenditure in the Patent Box calculations. This allows any higher costs incurred early product development to be used to artificially reduce the taxable profit in subsequent years. This is good news, particularly for start-ups.

Secondly, the Government recognises that products are commercialised while their patent applications are still pending. Consequently the Patent Box provides that for each tax year, a company can calculate what the RIPP would have been if the patent had granted that year, and then the aggregate RIPP for up to six previous years can be added to the RIPP in the actual year of grant. This provision is of course also good news as it allows pre-grant profits to be reappraised at the lower tax rate.

Will the Patent Box achieve its goals?

The Patent Box appears to combine some good tax incentives with provisions to avoid abuse by passive holding companies, and hence it appears well placed to encourage take-up by genuinely innovative firms in the UK who will benefit from increased net profits.

Increased profitability from the exploitation of R&D can only be a good thing for promoting the development of innovation in the UK, and we expect many UK businesses will exploit the new Patent Box scheme.

Author
Doug Ealey

Useful links:
UK Government Consultation:

http://dycip.com/pbx1211

Article 05

UK IPO Green Channel
Fast-Track Filing for Green Technology Patents

At the UK Intellectual Property Office (UK IPO) it can typically take two to three years after filing for the average mechanical patent application to be granted. In the biotechnology field the corresponding time to grant can often be much longer. Having a granted patent can often be crucial in the early stages of funding for many businesses.

The UK IPO helpfully provides an alternative route to expedite some applications. Specifically, applications covering technology which is considered to be 'environmentally-friendly' can be fast-tracked using what is called the 'Green Channel'. The UK IPO aims to handle cases in the Green Channel such that they can be granted within a year or less from filing the fast-track request. This route offers significant benefits to companies seeking to attract new investment, customers, and licensees.

How does the Green Channel work?

The Green Channel fast-track scheme encompasses any technology that provides an environmental benefit. For example, applications may relate to wind power, solar power, energy saving devices, transportation or biofuels in any field.

In order to enter the Green Channel all that needs to be done is:

i file a written request for the Green Channel;
ii provide an explanation as to why the application relates to a green technology; and
iii state which actions are to be accelerated eg, search, combined search and examination, publication and/or examination.

There is no fee for making such a request.

Further, there is a dedicated database for applications which are undergoing the Green Channel fast-track process which is free to users and updated weekly.

The criteria for examination and the standard of examination under the Green Channel are the same as for applications which undergo normal examination channels. The only difference is that each step is handled promptly by the UK IPO.

The Green Channel fast-track procedure was introduced on 12 May 2009 and, at the time of writing, nearly 400 applications have used the Green Channel fast-track procedure.

Example Case Study

A Danish green-technology company exploited the UK IPO's Green Channel to secure early patent protection in the biofuels field. The prosecution of the case through to grant was expedited thereby supporting investor negotiations for the business.

By requesting the Green Channel D Young & Co's Biotechnology, Chemistry & Pharmaceuticals Group were able to obtain the grant of the patent within 11 months of the filing date.

The time line for this case was as follows:

- the first Examination report issued within six weeks of making the Green Channel request;
- the second Examination Report issued within eight weeks of responding to the first Examination Report;
- the third Examination Report issued within six weeks of responding to the second Examination Report;
- the letter advising that the application was in order for grant issued within four weeks of responding to the third Examination Report; and
- the patent granted four weeks later.

"Stephanie Wroe at D Young & Co suggested and recommended to us that we use the UK Green Channel fast-track procedure for our UK national filing. Following the recommendation has resulted in a granted UK patent within only 11 months from the filing date.

We have thereby at an early stage been provided with the ultimate and best possible way to convince potential investors and customers that patent protection of our technology based on our filed PCT application is feasible worldwide and likely to be obtained in the sought countries and regions.

A serious concern by prospective stakeholders can thus be remedied immediately by showing this patent, and an otherwise time-consuming analysis may be avoided."

Applicants who believe their technology offers some form of environmental benefit are finding the Green Channel very effective. As in the case study above, having a granted patent, even in one jurisdiction, can be very useful for the applicant in terms of securing investment as well as for investors conducting due diligence.

Author
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Useful links
Database of Green Channel applications:

http://dycip.com/ukipogcdb

Inventive Step
Is It Still Plausible?

Notes
1. T0578/06 – see point 21 of the Reasons for the Decision
2. T1642/07 – see point 18 of the Reasons for the Decision
3. T0578/06 – see point 15 of the Reasons for the Decision

Readers will be aware that the 'problem-and-solution approach' is used by the EPO to determine the question of inventive step.

The closest prior art is first established and then differences between this prior art and the claimed subject matter are identified. The next step is to determine the technical effect arising from such differences. This is a key step in the problem-and-solution approach and often determines how difficult the prosecution of the case will be.

Where there is no technical effect, the problem may be formulated as merely providing 'an alternative' to the prior art. Accordingly, the chances of successfully demonstrating an inventive step can be reduced. In contrast, where the technical effect is significant or unexpected, the problem to be solved and the solution are more likely to be found to be inventive.

This raises the question of the amount of evidence required in a patent application if one wants to rely on a particular technical effect. Some of the Examining Divisions at the EPO are starting to routinely question whether or not the claimed technical effect relied on by the applicant is plausible based on the patent application as filed. This has followed from a decision (T1329/04) where the plausibility of an alleged technical effect was raised. In this case, there was a substantiated reason to doubt the plausibility of the alleged technical effect and the patent was found to lack an inventive step.

An important question has been: should the initial burden of proof lie with the patentee to provide evidence that the technical effect is plausible in the patent application as filed? Thankfully, following two recent cases from the Boards of Appeal of the EPO (namely T0578/06 and T1642/07) the answer is perhaps not.

According to these decisions, the initial burden of proof to substantiate doubts about the plausibility of the alleged technical effect lies with the EPO[1]. In general, there is no requirement for the patent application to have experimental evidence of the claimed technical effects[2]. Thus, only when such doubts are substantiated can plausibility be raised[3]. Therefore, in some situations, it may be enough that the claimed technical effect is simply disclosed in the description of the patent application[3]. However, when doubts about the plausibility of the technical effect need to be substantiated, evidence of the technical effect in the patent application may be required.

Ideally experimental evidence showing a technical effect is already included in the patent application as filed. However, where this is not the case there may now be some hope from these two recent decisions that the earlier case (T1329/04) should be cited with care by EPO Examiners. If these two later decisions are followed, in many instances experimental data may be filed during prosecution of a European patent application to confirm the alleged technical effect. However, such data may only be admissible if there is no substantiated reason to doubt the plausibility of the alleged technical effect.

Author
Catherine Coombes

Useful links

Full text of decision T-0578/06:

http://dycip.com/t057806dec

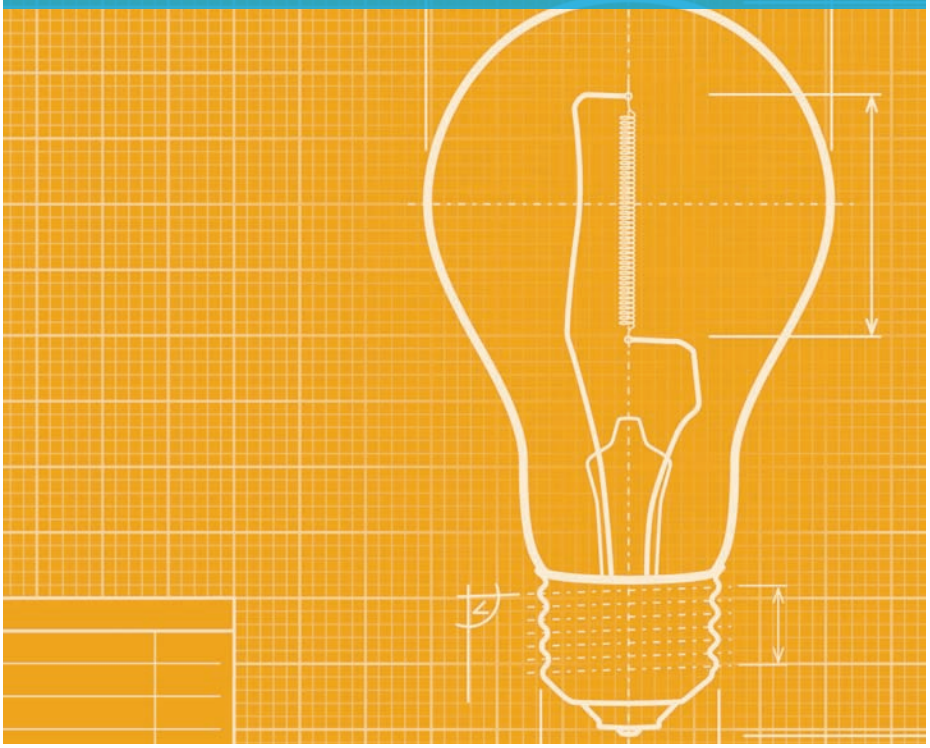
Full text of decision T-1642/07:

http://dycip.com/t164207dec

Full text of decision T-1329/04:

http://dycip.com/t132904dec

Recent decisions could mean the burden of proof lies with the EPO to substantiate doubts about plausibility of technical effect



Track One Has Arrived
Prioritised Examination at the USPTO

Useful links
- *Federal Register 23/09/2011:* ***http://dycip.com/fedreg0911***
- *Federal Register 19/12/2011:* ***http://dycip.com/fedreg1211***
- *FAQs:* ***http://dycip.com/trackfaq***
- *D Young & Co patent newsletter August 2010:* ***http://dycip.com/pnlaug10***

In our August 2010 newsletter, we described the United States Patent and Trademark Office's (USPTO) plans to introduce a three-track procedure for patent examination. The plans aimed to give applicants greater control over the speed and timing of the examination of their patent applications. The Track 1 procedure, named Prioritised Examination, is now in operation.

Prioritised examination became available on 26 September 2011, following the enactment of the Leahy-Smith America Invents Act. An applicant who makes a request for prioritised examination can expect a final result for their patent application within twelve months. The final result includes the issue of a notice of allowance, or the issue of a final office action giving the Examiner's final reasons for rejection.

There are a number of conditions for obtaining and maintaining prioritised examination:
- You must pay the official fee, currently USD 4,800 (USD 2,400 for small entity applicants).
- You must submit the request for prioritised examination at the time of filing the application.
- Your application must be fully complete on filing, including payment of all official fees, and must be filed electronically.
- Your application can be any original non-provisional application, including divisional, continuation and continuation-in-part applications, and applications claiming priority from earlier US or foreign applications. International (PCT) applications entering the US national phase are currently excluded.
- You must limit your application to a total of thirty claims, including no more than four independent claims and no multiple dependent claims. Any amendment during examination that exceeds these limits will terminate the prioritised examination.
- If you file a request for an extension of time for responding to an office action, the prioritised examination will be terminated.
- If you file a notice of appeal or a request for continued examination the prioritised examination will cease.

The three-track system aims to promote greater efficiency in the patent examination process

An annual limit of 10,000 requests for prioritised examination has been set, although there is scope for revising this upwards in the future. The USPTO maintains statistics on its website so that applicants can check if the limit has been exceeded before submitting a request. At an initial rate of around 300 requests per month, it seems unlikely that this will happen.

More recently, on 19 December 2011, the USPTO extended the prioritised examination procedure to the continued examination of patent applications. If an applicant receives a final office action on his application, he can generally only make amendments to address the rejections in the office action by filing a request for continued examination (RCE) and paying the associated official fee. As mentioned above, filing an RCE terminates the prioritised examination. It is now possible to submit a new request for prioritised examination to accompany the RCE, together with a further prioritised examination official fee. Additionally, you can submit a request for prioritised examination if you file an RCE on an application not previously processed under Track 1. This makes the speedier examination process available to applicants who declined to use the procedure when originally filing their applications. Interestingly, you can request prioritised examination for an RCE filed on an application that is the national phase of a PCT application, despite the exclusion of national phase applications from prioritised examination requests made at the time of filing.

Requesting prioritised examination for an RCE is largely the same as making a request when filing an original application. However, unlike with an original application, there is no requirement to submit the request at the same time as the RCE. Rather, you can file the request at any time up until the first office action of the continued examination is issued. You are only permitted to file one request for prioritised examination with an RCE per application.

Further information can be found in the 23 September 2011 and 19 December 2011 editions of the Federal Register, and in a useful set of FAQs provided by the USPTO.

Author:
Cathrine McGowan

D YOUNG & CO INTELLECTUAL PROPERTY

And finally…

D Young & Co Seminar
Patenting Antibodies

A half day seminar and hosted by D Young & Co LLP in conjunction with Marshall Gerstein and Borun LLP.

Topics for discussion will include:

- Patenting antibodies: drafting antibody patent applications to maximise granted claim scope and flexibility between jurisdictions
- Prosecuting antibody patent applications in Europe: how to counter-argue objections of lack of inventive step or support
- Protecting commercial antibody products: ideas for follow-on patent applications to extend the time of patent protection for antibody products
- US antibody patent issues: the standard for non-obviousness and the written description requirement

Date and location
20 March 2012, London

Who should attend?
IP managers and in-house attorneys from biotech companies working in the antibody field.

Registration
There is no charge to attend this seminar however places are limited. Please send your details to registrations@dyoung.co.uk

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