

NEWS

PATENTABILITY OF BIOLOGICAL PROCESSES: The Broccoli Case

The Enlarged Board of Appeal of the EPO (the highest instance of the EPO's Boards of Appeal) is to consider a question of some importance to the patentability of methods of breeding and producing plants and animals. The question concerns the extent to which the exclusion to patentability of Article 53(b) EPC (see box overleaf) can be escaped.

The patent in question is for methods of producing new *Brassica* plants, in particular broccoli, with elevated levels of anticarcinogenic glucosinolates. The

claimed method involves the selective breeding of "double haploid" lines of broccoli with wild species. The process would be deemed "essentially biological" (and therefore unpatentable) if it consisted entirely of natural phenomena such as crossing or selection (Rule 26(5) EPC 2000), but this is put in question by the inclusion of certain steps in the method claim that require human intervention (*viz.* selecting, through use of molecular markers, hybrids and plants having certain levels of glucosinolates).

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WHAT'S GOING ON AT THE EPO?

The New President of the European Patent Office is Alison Brimelow, former Comptroller of the UK Patent Office (now renamed the UK Intellectual Property Office). Her headline vision for the EPO is "What we need is not more patents, but more good patents" – an ambiguous statement, and one that raises the question "is the EPO raising the bar on patentability?"

Statistics show a rising number of patent applications being filed year on year. Does the EPO have the political will and the ability to grant more patents in pace with the rising demand? The number of patents granted in 2007 actually fell by 8,100, a fall of 13%, but this may well be a temporary dip and output still may increase while maintaining a high standard of examination.

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The patentability of the product claims (to the broccoli plants themselves) are not a subject of the referral. Inventions concerning plants have been regarded as patentable from the inception of the European Patent Convention and remain so under Rule 27(b) of the EPO 2000 (implementing Article 4(2) of the Biotechnology Directive).

Plant Bioscience Ltd is the proprietor of the patent, No. EP 1 069 819, which has so far been maintained in an amended form as a result of opposition and appeal proceedings brought by Syngenta and Limagrain. The Opponents argue that the patent should be revoked on the basis that the claims refer to an essentially biological process i.e. conventional breeding.

Various *amicus* briefs have been filed by interested parties. The case is pending as Referral G02/07.

Comment

This Referral to the Enlarged Board of Appeal is of some importance, as the outcome will clarify the degree and nature of human technical intervention which is required to escape the process exclusion of Article 53(b) EPC.

It is seen as a test case for the patentability of conventional seeds and breeding methods and will set a precedent as to whether applications relating to crossing and selecting of plants and animals are likely to be allowable. On the one hand, many argue that the patent should be revoked on the basis that the patent does not refer to a genetically modified plant but rather covers conventional seeds and breeding methods. On the other hand, the opponents (who are involved in plant breeding themselves) are more interested in obtaining clarification from the EPO with regards to the exact interpretation of the exclusion. Examination of many other applications in this field may be suspended until the Enlarged Board issues its decision. ■

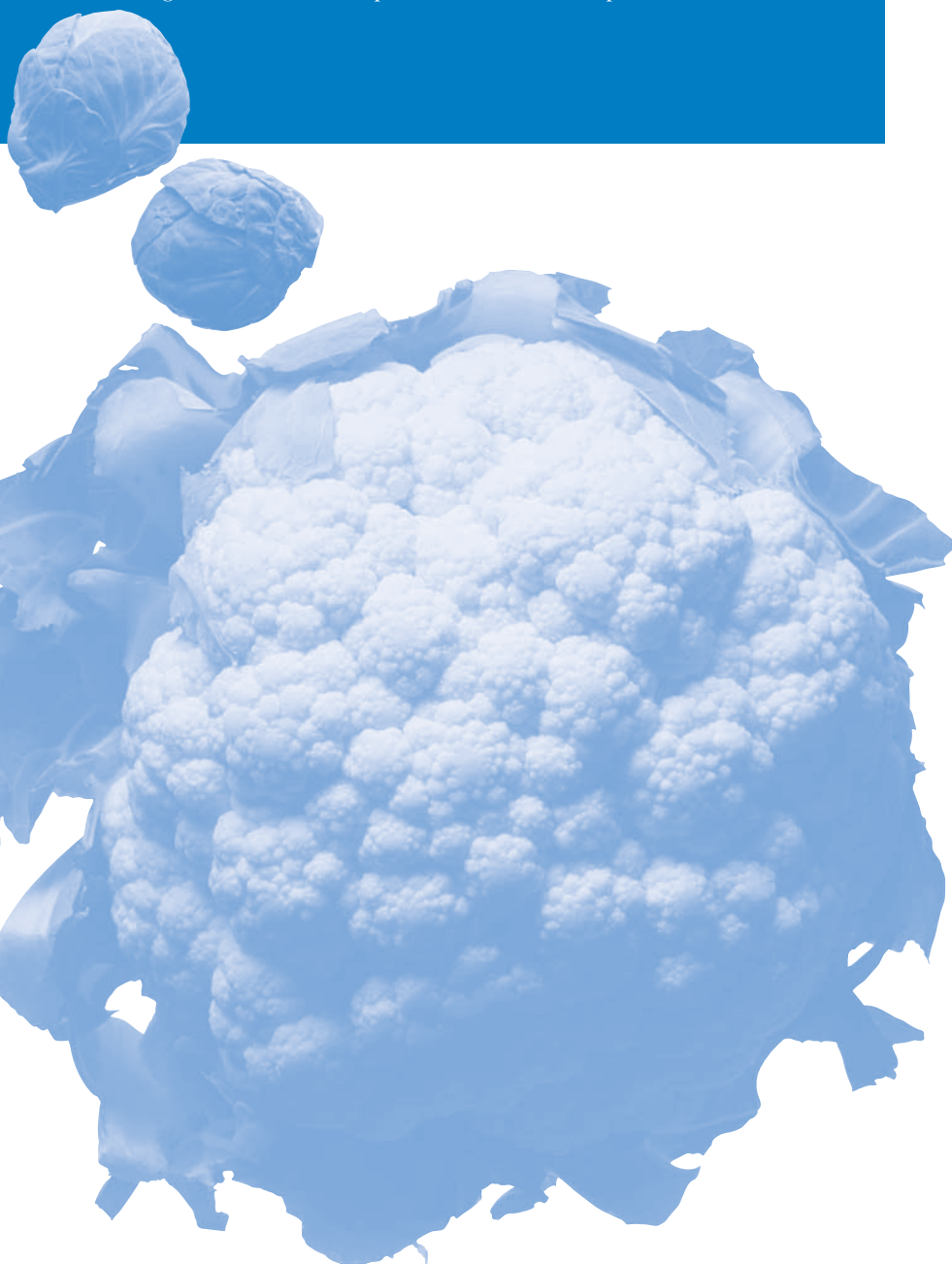
EPC 2000 CODIFIES THE BIOTECHNOLOGY DIRECTIVE

Rule 27 of the EPC 2000 provides that biotechnological inventions shall be patentable if they concern:

- (a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;
- (b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety; or
- (c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

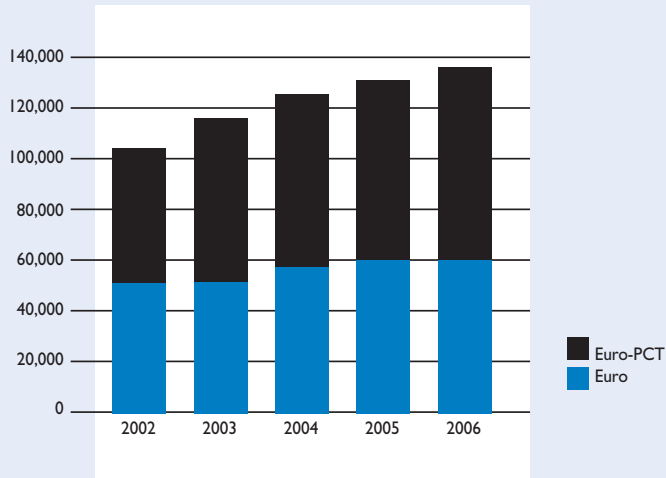
Article 53(b) of the EPC 2000 excludes from patentability plant or animal varieties or essentially biological processes for the production of plants or animals (but this exclusion does not apply to microbiological processes or the products thereof).

By these provisions, the EU Directive 98/44/EC on the legal protection of biotechnological inventions is implemented in the European Patent Convention.

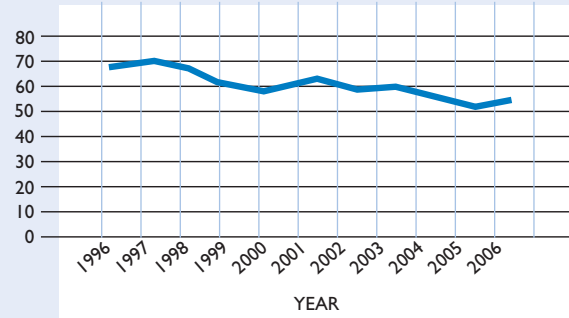


EPO ANNUAL FILING AND GRANT STATISTICS

TOTAL EP APPLICATIONS FILED



EPO GRANT RATE



The EPO allowance rate¹ has fallen over the last ten years, from nearly 70% in 1996 to about 55% in 2006.

Factors that may account for a falling allowance rate include:

- A. poorer quality of patent applications (e.g. more patent applications chasing the same number of inventions and/or briefer descriptions that leave room for fewer compromises);
- B. raising of the bar at the EPO (for inventive step, sufficiency of disclosure and prohibition on added matter).

In the meantime, a factor that may account for the 2007 drop in total patents granted may be:

- C. A growing backlog of applications awaiting oral proceedings.

A particular question to be explored is whether B and C are related.

¹Grant rate is defined as the number of applications that were granted during the reporting period, divided by the number of disposals in the reporting period (applications granted plus those abandoned or refused).

POORER QUALITY OF APPLICATIONS?

The huge increase in numbers of patent applications filed at the USPTO and other offices around the world, and the corresponding increase of PCT applications, begs a number of questions.

Is there a corresponding rise in inventing?

We can suppose that the rate of inventing somewhat outpaces the world economic or population growth rate, and reflects the higher rate of growth of the knowledge economy, but the increased rate of filing of patent applications also has a bandwagon factor, with many countries and sectors of the world economy having “woken up” to the power of patents. If research groups around the world are chasing the same goals, it may be that there are ever more cases of runners-up who think they have something new but find that someone else got there first.

Are applicants cutting corners in preparation and filing of applications?

We hear of more and more schemes for bringing down the cost of patent drafting. These include various outsourcing initiatives such as competitive online tendering for drafting, and outsourcing to countries like India. Outsourcing has the tendency to put another layer between the inventor and the draftsman. This can lead to second-hand analysis of what it is that the inventor believes he or she has invented. This in turn can lead to an “all-or-nothing” patent application or, worse, a misdirected patent application. By “all or nothing”, we mean an application that presupposes a certain state of the art, and is vulnerable to the search results, especially to “accidental” anticipation – i.e. anticipation by some prior document that is related only by virtue of the words chosen by the draftsman.

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The EPO perceives an opposite trend - to “voluminous” applications.

The Board of the Administrative Council of the EPO has published a study of anticipated workload, in which it considers the efficiency of the examination process. A complaint expressed is that the EPO has to “spend a lot of resources on the search and examination of voluminous applications or applications which include a great number of claims.” We see no reason to suppose that this is a new or significantly worsening phenomenon. It is true that the PCT system is increasingly popular and carries no penalty for large numbers of claims, and it is also true that a greater proportion of EP applications each year come from this route, but numbers of

direct EP applications have also risen. In percentage terms, the trend towards the PCT route is minor.

For those that choose the PCT route, there is an opportunity to amend the PCT application upon entry into the European phase, but on cost grounds or for fear of inadvertently adding subject matter under Article 123(2) EPC (see below), this opportunity is often passed over. Many applications enter the Examining Divisions without any review by a European Patent Attorney. The EPO has addressed this head-on with its more than four-fold increase in the claims fees. Each claim over 15 now costs an extra EU 200, creating an enormous incentive to cut the claims down upon European phase entry, a task preferably done by the European patent attorney familiar with the pitfalls

of Article 123(2). At the same time, the European patent attorney can add reference numerals as required, which assist the examiner.

RAISING THE BAR?

There seems little doubt that when the President of the EPO makes reference to “quality” she is not merely referring to thoroughness of searching and examination, but she is also referring to perceived inventiveness. This is clear from the Administrative Council’s study, which discusses quality under the heading “Raising the bar – Challenges and Strategic Direction”, saying:

The pressure on the patent system has given rise to concerns about its capability to maintain high quality



standards. These concerns have been addressed in the notes on the patenting situation in Europe by the DE, DK and NL delegations. The general support expressed by the Council and the Patent Law Committee for the reflections laid down in this document on the need for maintaining a high quality patent system indicate that there is a clear European view in this respect, a view which is shared by many users of the patent system.

The Board is of the view that there is a need to ascertain clearly what is expected from the patent system in terms of the quality of patents and to reflect on ways to meet the expectations. The general goal is to ensure that the European patent system will continue to fulfil its main objective, the promotion of innovation, by granting exclusive rights only for innovations with sufficient inventive merit.

The study mentions that the level of inventive step is “perceived in a certain number of quarters as being too low” and suggests further study into measures that may be taken within the existing legal framework to “raise quality standards” such as “reinforcing the importance of the problem and solution approach in the assessment of inventive step”. Other changes such as redefining the definition of “a person skilled in the art” would require changes in the legislation and should only be undertaken if there is a “compelling case.”

Has the EPO raised the bar for inventive step?

Even before the “Big Five” patent offices meeting in Hawaii in May 2007, we have suspected an internal policy of raising the bar on inventive step. The press announcement from the meeting said “the five heads agreed that the quality levels and standards should be raised, and that quality should be given priority over application filing figures”. The

EPO view is that *KSR v Teleflex* raised the bar in the United States, and we have heard comments direct from one EPO Examining Division chairman that the *KSR* decision is prompting a further raising of the bar at the EPO. This would be an irony. In our view, *KSR* brings the bar up to the level of the EPO but no further. It is difficult to point to specific cases that represent a change in the legal standard. Decision T301/90 is perhaps one such case, in which it was stated that an application may be rejected on the basis of the “mental furniture” of the skilled person, which may never be in writing.

In the particular field of business methods and computer systems that implement novel (and indeed inventive) business or administrative practices the bar has been unashamedly raised to the point where any amount of ex post facto analysis of the business problem is permitted, leaving only the “technical” aspects of the software implementation to be scrutinized for inventive step.

Has the EPO raised the bar for sufficiency of disclosure?

Aside from the specific area of genes, and the need to describe a credible function, we cannot point to any increase in refusals on the grounds that it does not sufficiently disclose at least one embodiment of the invention. On the other hand, we do observe more objections on the grounds of claims missing essential features – effectively insufficiency on the grounds of overbroad claiming. Often the objection can be overcome by argument, and if necessary it can be cured by amendment (adding the missing feature to the claims). Only occasionally is lack of an essential feature ultimately fatal to an application.

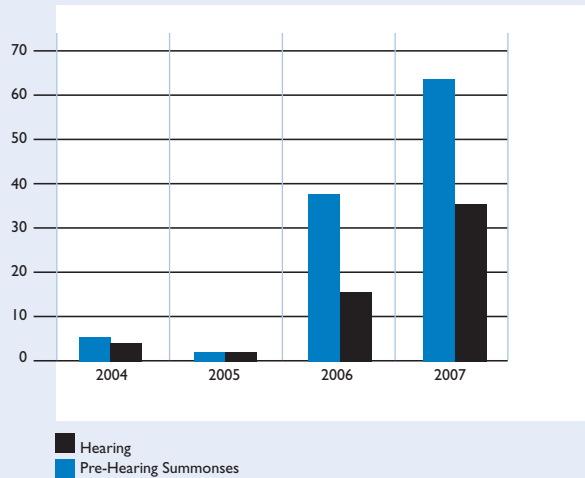
Has the EPO raised the bar for prohibition on added matter?

Undoubtedly. There was a time when examiners would give the benefit of the doubt over added subject matter. In the early years of the EPO, it was policy that

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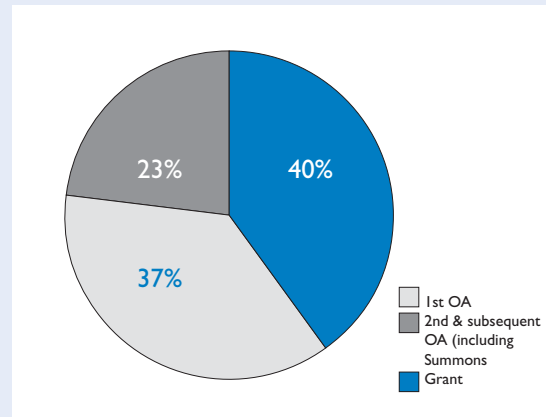


JENKINS HEARINGS AT EPO



Summonses to Oral Proceedings increased markedly in 2006 following an internal EPO directive. Almost half of Jenkins cases are concluded (amended or withdrawn) in the month before the hearing.

EPO PROSECUTION 2007



Jenkins is able to achieve grant with average 1.5 office actions per allowance. Sample size 578 applications

added subject matter was the concern of the applicant. That changed some years ago. Now it seems examiners could not be more strict. Any deviation from the exact words of the original patent application is scrutinized with suspicion. If an examiner believes there is the slightest doubt as to whether the new wording does not mean the same as the original description, objection is raised. The book *Case Law of the Boards of Appeal* published by the EPO supports this stance. E.g. Decisions T383/88 and T581/91 state that a rigorous standard of proof is required, equivalent to “beyond reasonable doubt”.

A GROWING BACKLOG?

It is enshrined in the European Patent Convention that an applicant has a right to a hearing before a patent application is refused. This is problematic for the EPO because applicants almost invariably maintain this right at the early stages of prosecution of applications. It means in practice that the EPO cannot refuse the application until oral proceedings have been appointed and either the hearing goes ahead or the applicant agrees to

proceed in writing. Convening a hearing is not a simple matter. All three members of the Examining Division must be available as well as a hearing room. We are constantly told that there is pressure on booking hearing rooms, and that this is one of the bottlenecks in the system. Generally a whole day needs to be set aside for a hearing, however we recently have received summonses to hearings set for the afternoon only. Therefore it now seems that hearing rooms are being booked for two hearings per day.

A growing backlog of applications waiting for oral proceedings might distort the grant figures. If easy cases are being granted and difficult cases are stacking up waiting for oral proceedings, the true situation may be worse than the headline grant rate.

In the last two years, examiners have been encouraged or directed to call a hearing at an earlier stage in proceedings, where objections have been raised but the examiner is still unable to envisage granting a patent from the applicant’s response. This is intended to bring

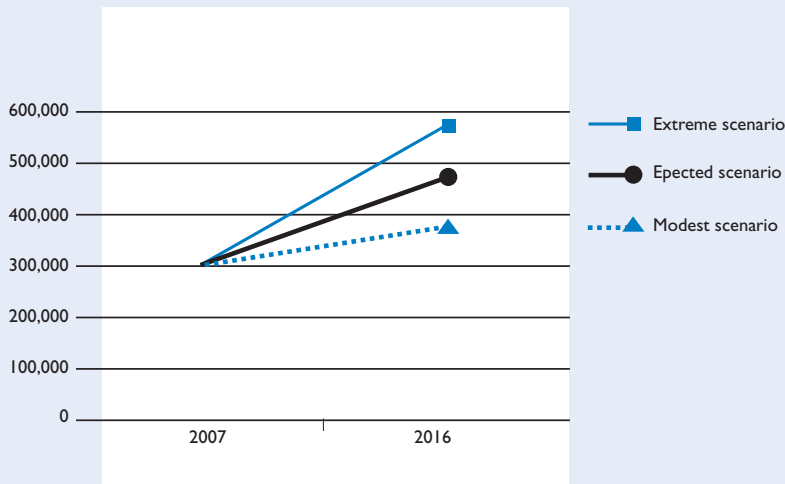
proceedings to an earlier conclusion, and avoid drawn-out written correspondence.

Summonses to Oral Proceedings increased markedly in 2006 following an internal EPO directive. Almost half of Jenkins cases are concluded (amended or withdrawn) in the month before the hearing.

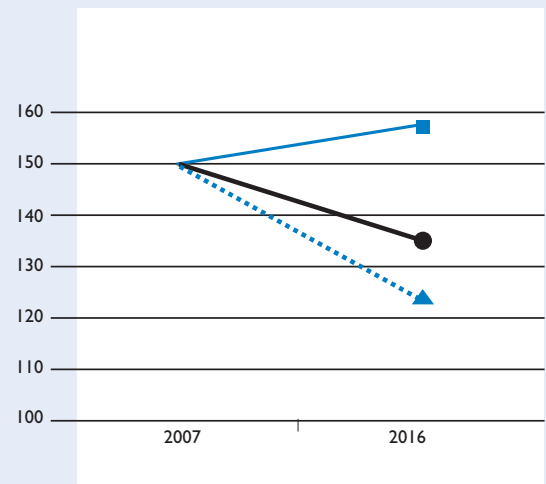
Our statistics indicate that in about half of cases where a summons issues, a hearing is unnecessary. After final written submissions, the procedure continues in writing because an allowable amendment is put forward, or the application is withdrawn (or the request for a hearing is withdrawn for an appealable decision to issue in writing). In these cases, the effect of the summons is merely to compress the final prosecution into the remaining time between the summons and the hearing – a burden more on the applicant than on the examiner. The other half proceed to oral proceedings, tying up the three-man division for most of one day.

2007 saw a slight rise in the grant rate but a fall in numbers granted – i.e. an even greater fall in numbers refused or

EPO GROWTH SCENARIOS



CASELOAD PER EXAMINER



withdrawn. Does this indicate that the tactic of calling more oral proceedings is clogging up the system?

We took a look at work for a large client from the electronics industry having a steady-state situation of annual filings, and we did not find a mismatch between numbers of first office actions and number of allowances, i.e. no evidence of a build-up of cases awaiting oral proceedings. For this particular sample, we noted an average of about 1.5 office actions per allowance. The sample size was 578 and only about 1-2% required Oral Proceedings.

In the software field, the picture is somewhat different.

Our evidence against a growing backlog is not conclusive, but comfort can be found in the Administrative Council Survey, which indicates that the EPO's production is growing faster than its incoming workload. The Survey considers three scenarios for the next decade and anticipates that except in a scenario of extreme growth, the program of recruitment, building and training at

the EPO will more than cope with the demand.

CONCLUSIONS

The EPO granted 13% fewer patents in 2007 than in 2006, in spite of a steady rise in applications. The EPO has not yet published the grant rate figure for 2007, so at present we cannot say whether there has been a corresponding rise in other dispositions (refusals and withdrawals), representing a continued trend of increased toughness on the part of examiners, or a corresponding fall in other dispositions indicative of a growing backlog.

Regardless of a rising or falling grant rate, it is clear that applications continue to enter the examining divisions at a faster rate (140,700 new requests for examination in 2007) than the rate at which the examining divisions can dispose of them (98,000 calculated on the basis of numbers granted and a 55.9% grant rate). We believe there is a growing backlog. We are aware of visible efforts to grow the office to meet the demand, but are concerned that these may not go far

enough and may take time to come on stream. EPO President Alison Brimelow is recently quoted as saying "I am coming to the conclusion that the backlog will not be mastered" and she muses over possible long-term strategic and possible legislative initiatives. The system has worked for 30 years, is popular and is self-funding. It is a victim of its own success and the Office needs to build on that success and plan for it rather than contemplate throwing the baby out with the bathwater.

HURRAH FOR PRODUCT CLAIMS

“Biogen” insufficiency has been an accursed ground of patent insufficiency ever since introduced in 1997 by Lord Hoffman’s ruling in *Biogen v Medeva*. Since then, it has been open for a defendant to allege that a patent claim is overbroad by pointing to something within the scope of the claim and alleging that it “owes nothing to the teaching of the specification”. The Court of Appeal revisited the doctrine in *Amgen* in 2002 but fell far short of reining it back. It has taken the unusual occasion of Lord Hoffman coming down to sit in the Court of Appeal to tell us all that he has been mis-interpreted over the years (and not for the first time if we recall his rescinding of the “Protocol Questions” for infringement). The English Patents Court has been seen in recent years to be quite “anti-patentee”. This decision is a welcome step in restoring balance.

The EPO has no doctrine directly equivalent to *Biogen* insufficiency. For an opponent before the EPO to argue insufficiency on the grounds that the patent monopoly is broader than is justified by the description, it is necessary to show that the claim is an obvious desideratum or to identify a missing essential feature. Nevertheless, insufficiency has been one of the main grounds that the EPO has been using to limit claim scope in the biotech field. With the EPO President openly saying that their aim is to grant better (narrower?) patents, and the English Court of Appeal saying there are claims the validity of which “will be particularly sensitive to the context of the teaching of the patent and the prior art”, patent attorneys and their clients will need to sharpen their pencils to ensure that claims are both broad and valid.

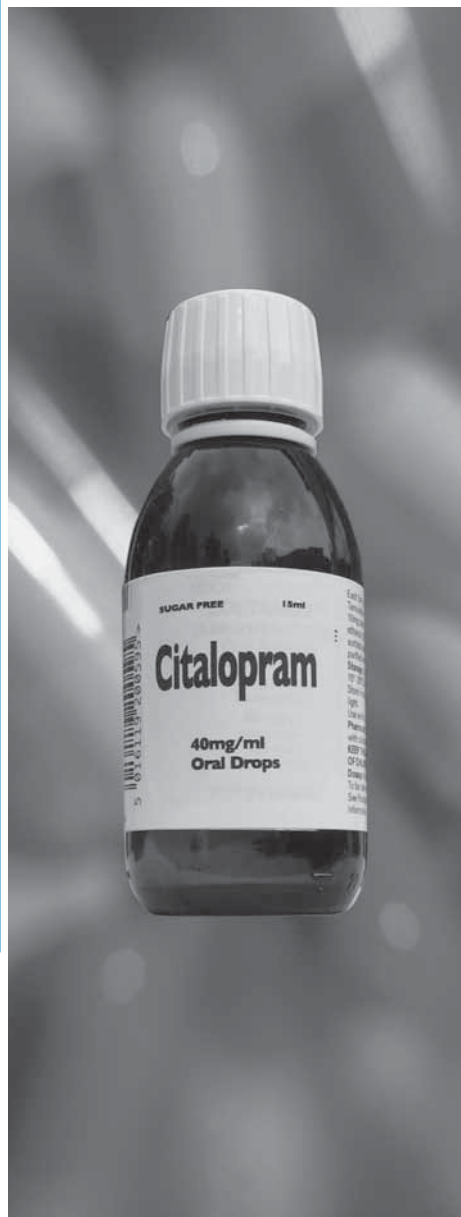
The patent in question in this case concerned an enantiomer of citalopram, which is an anti-depressant in the class known as selective serotonin re-uptake inhibitors (SSRIs), of which Prozac™ and Seroxat™ are the best known examples. Citalopram was originally patented by the Danish company H Lundbeck A/S, but the patent expired several years ago. Citalopram is a “racemate” in that it comprises equal quantities of two mirror-image isomers, otherwise known as stereoisomers or enantiomers. As has been routine for at least two decades, medicinal chemists seek to resolve racemates to determine which (if either)

enantiomer has more activity (or less toxicity – recall Thalidamide™). Patents for the enantiomers often follow some time after the patents for the underlying formulae and represent very valuable extensions of the term of protection for the drug companies. The UK High Court is now accustomed to battles over patents for enantiomers (see *Ranbaxy v. Warner-Lambert* discussed in the Spring 2006 edition of this newsletter, and the topic “Stereochemistry” in that edition).

It was known that (+) and (-) enantiomers of citalopram existed. (Of course, it was not known which might be preferred, although this would readily become apparent once they were separated or ‘resolved’.) The challenge was either to resolve them, or to resolve an intermediate product, from which the pure enantiomers of citalopram could be made. There were many ways available to a chemist to try the former, and several possible ways to try the latter.

There was a seven-year gap before a way of resolving the enantiomers was devised. When this was achieved, it was found that all the re-uptake inhibitor activity was due to the (+) enantiomer. Lundbeck named it Escitalopram. (More recently it has been shown that the (-) enantiomer actually slows down the inhibitory effect.) The patent for the first time described how to succeed. The question was “did this entitle the inventors to a patent for the product or just to the method of making it?”

At trial, the claims to the product were held to be invalid for insufficiency. The trial judge said “everyone knew that the two enantiomers existed and that one or other or both had a medicinal effect. What Lundbeck discovered was one way of making it. But that did not entitle them to a monopoly of every way of making it.”



BIOGEN REVISITED

In *Biogen* the DNA molecule that expresses the antigens of the hepatitis B virus was not new, so the inventor in that case (Professor Murray) could not claim it. Not only did it exist naturally in people suffering from hepatitis B, but it had also been isolated outside the human body by purification of samples of the infective agent. Prof. Murray had invented a process for making the DNA. But simply patenting the process would not give much of a monopoly, because the science was rapidly advancing, and scientists would find other methods of making the antigens, outside the scope of any process claim he could justify (as indeed happened).

What Prof. Murray's patent attorney tried to do therefore, was to make a product claim to a DNA molecule which defined the product partly by the way it had been made and partly by what it did, namely to express the antigens. It was a hybrid or "product-by-process" claim. Such claims are relatively rare since *Kirin-Amgen Inc v Hoechst Marion Roussel* discussed in the Autumn 2002 edition of this newsletter. It was not a simple product claim, because that would have failed for lack of novelty.

The claim was to a recombinant DNA molecule characterised by a DNA sequence coding for a polypeptide . . . displaying HBV

antigen specificity . . . when a suitable host cell transformed [therewith] is cultured etc. It was for a molecule identified partly by the way it has been made ('recombinant DNA') and partly by what it does.

The word 'recombinant' was necessary to distinguish the product from DNA isolated from humans. The word imported a process element to the claim, extending the claim to the DNA molecule made by any recombinant DNA technology process. As such the claim was construed as being to a class of products.

The specification in *Biogen* described only one method of making the molecule by recombinant technology and disclosed no general principle. It was easy to contemplate other methods about which the specification said nothing and which would owe nothing to the matter disclosed.

The law of sufficiency, both in the United Kingdom and in the EPO, is that a claim to a class of products is only 'sufficient' if every member of the class is enabled - either by empirical demonstration, or by disclosing a principle which can reasonably be expected to work across the class. In revisiting *Biogen*, Lord Hoffman in *Lundbeck*, said that, as a matter of

construction, the House of Lords in *Biogen* (and he wrote the opinion of the House) interpreted the claim as being to a class of products which satisfied the specified conditions, one of which was that the molecule had been made by recombinant technology. He said that expression obviously includes a wide variety of possible processes.¹ The *Biogen* patent only disclosed one process – therefore the *class* of products claimed in *Biogen* was insufficient and the claim was invalid.

¹What the House of Lords actually said was "*The claims of the patent in suit are invalid for lack of support and/or insufficiency of because [the patent] does not enable products across the claim. It is a claim defined in terms of process, a kind of product-by-process claim, yet [the patent] enabled only one process out of the entire class of possible processes.*"

The judge was applying the principals of the House of Lords 1997 decision in *Biogen v Medeva* discussed in the "Articles" section of our newly relaunched website (<http://www.jenkins.eu/articles/biogen-insufficiency-asp>).

In Lord Hoffman's opinion, therefore, the decision in *Biogen* is limited to the form of claim which the House of Lords was there considering, and cannot be extended

to an ordinary product claim in which the product is not defined by a class of processes of manufacture.

It is true that the House in *Biogen* endorsed the general principle stated by the Board of Appeal in EPO Board of Appeal Decisions T409/91 Fuel Oils/ EXXON [1994] OJ EPO, that —

the extent of the patent monopoly, as defined by the claims, should correspond to the

technical contribution to the art in order for it to be supported or justified.

The judge in *Lundbeck* said that in holding claim 1 insufficient, he was applying this principle. But then he treated the relevant "technical contribution to the art" as being the inventive step, namely a way of making the enantiomer. In Lord Hoffman's opinion, that was a mistake. "When a product claim satisfies the

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requirements of section 1 of the 1977 Act, the technical contribution to the art is the *product* and not the process by which it was made, even if that process was the only inventive step.”

Biogen should therefore not be read as casting any doubt upon the proposition that an inventor who finds a way to make a new product is entitled to make a product claim, even if its properties could have been fully specified in advance and the desirability of making it was obvious.

EPO cases such as *Kawasaki Steel Corporation* and *Du Pont* made it clear that if the product satisfies the requirements of novelty and inventive step, the “technical contribution” is the product. However, there is no statutory link between “sufficiency” and “inventive step”.

There are obviously arguments of public policy on both sides: The Kawasaki Steel line of cases shows that sometimes the “real invention” does not lie in the discovery of the new substance but in finding a process of manufacture. But Parliament has chosen to allow product claims, and the jurisprudence of the EPO, which we have always regarded as carrying great weight, shows that such claims can be made in the latter case as well. It is too late to have regrets about the breadth of the monopoly which the claims confer.

Lord Justice Jacob gave a concurring but separate opinion. He seems to prefer not to dismiss *Biogen* as applying only to the facts of its case (product-by-process claims). He gave the example where a man may find a particular way of making a new substance which is 10 times harder than diamond. According to Jacob LJ, he cannot just claim “a substance which is 10 times harder than diamond.” He can claim his particular method and he can claim the actual new substance produced by his method, either by specifying its composition and structure or, if that cannot be done, by reference to the method but no more. The reason he cannot claim more is that he has not enabled more – he has claimed the entire class of products which have the known desirable properties yet he has only

enabled one member of that class. Such a case is to be contrasted with the present where the desirable end is indeed fully enabled – that which makes it desirable forms no part of the claim limitation.

Comment

Any other decision would have eviscerated the pharmaceutical industry. Not only would a swathe of enantiomer patents be invalid, but also claims to other “desirable” but not yet isolated molecules – a wide sphere in the present day industry in which molecules are designed in theory and their effects are predicted before they are synthesized.

Is ‘*Biogen* Insufficiency’ dead? Lord Hoffman’s judgement seems to limit *Biogen* to almost nothing – just product-by-process claims (which are of very limited value following the Court of Appeal ruling in *Amgen*), but Jacob LJ’s opinion will carry more weight. He may not be quite so venerable, but it is before him that appeals will be heard on a day-to-day basis. Jacob LJ does not seem to want to let it go so completely. He concedes there may be cases between one extreme (a novel substance) and another extreme (“free beer”) where the invention may lie in appreciating that a particular combination of desirable properties is of special value, and he concedes “the validity of that sort of claim will be particularly sensitive to the context of the teaching of the patent and the prior art.”

The *Amgen* Court of Appeal has already said that *Biogen* insufficiency is not a separate ground of insufficiency, and there is only one kind of insufficiency - see the Spring 2002 edition of this newsletter. At that time we said it was not very helpful guidance. And *Biogen* insufficiency will not go away. Lord Hoffman says it applies only in rare cases. But it seems *Biogen* can still be argued if the claim is to a class or genus. Most claims try to claim a class. In this instance it seems

that Lord Hoffman has backtracked and said that *Biogen* claimed a class because of the word “recombinant” (all members of the class of artificially created DNA).

One might take the view that the Court of Appeal has simply carved out an exception to *Biogen*. The exception is for product claims defined by their structure (rather than defined as a class of products that perform a common function). The existence of the (+) enantiomer was known, but no-one had yet devised a way of making it in isolation. Lundbeck were the first, and Parliament intended that this should entitle Lundbeck to a monopoly in the product, howsoever it is made.

Perhaps ‘obviously desirable goal’ has no place in patent sufficiency, but does that mean you can claim the known *desideratum* just because you are the first to achieve it? It seems to hinge on a fine distinction between a goal that is known to exist (or is obvious) but has never been achieved, and a product that is known (or is obvious) but has never been reduced to practice.

So the critical words are perhaps “Lundbeck’s claim was to a single product”. You first have to decide if you have a claim to a single product or a class of products. If the former then, OK, there is only one kind of insufficiency. If the latter well, hey, you still have *Biogen* insufficiency to consider. ■

UKIPO ALLOWS CLAIMS TO computer programs

Following the decision in *Astron Clinica v. Comptroller General*, the UKIPO has issued a practice note making it clear that claims to a computer program itself or a program on a carrier will no longer be objected to by examiners where certain conditions are met:

- i) where claims to a method performed by running a suitably programmed computer or to a computer programmed to carry out the method are allowable; and
- ii) where the claim to the computer program reflects the features of the invention which would ensure the patentability of the method which the program is intended to carry out when it is run.

In another recent decision, *Symbian v. Comptroller General*, Symbian Ltd., the UK-based developer of an open operating system for smartphones (owned by Sony Ericsson, Nokia, Panasonic, Samsung and Siemens) successfully appealed a decision of the UKIPO concerning patentability of an improved operating system. In particular, the application describes how a computer system can index a library of functions (DLLs) to ensure that the computer will continue to operate reliably after changes are made to the library. The judge, Mr Justice Patten, held that the Hearing Office took too narrow a view of the technical effect of the invention and pointed to improved reliability of a machine as an indication of technical contribution.

In this case, the Hearing Officer had followed the four steps set out by the

Aerotel/Macrossan test (as discussed in the Spring 2007 edition of this newsletter) and found that the third step of the test was not met, because the alleged contribution of an interface which enables an executable program to link to updated functions in a DLL, fell solely within excluded subject matter. Having found that the contribution failed the third step, the fourth step of checking that the contribution is actually technical was not considered. Patten J., however, said the steps of the test should not be considered as self-contained steps. The question of whether the invention makes a relevant technical contribution has to be asked at some point, whether this question is as part of step 2, 3 or 4 of the test.

The UKIPO intends to appeal this judgment with a view to seeking clarification from the Court of Appeal as to precisely how the *Aerotel/Macrossan* test should be applied to inventions of this type. In the meantime, the office will continue to follow the recent practice founded on the established *Aerotel/Macrossan* test, taking account of the *Symbian* judgment in appropriate cases to consider the question of whether an invention makes any relevant technical contribution.

Careful What you Say at the EPO – CONTESTED PROCEEDINGS CAN CREATE ESTOPPEL

There is no recognised doctrine of ‘file wrapper estoppel’ in UK patent law. If a patent proprietor has convinced the UK Intellectual Property Office (UKIPO) or the European Patent Office (EPO) to grant a UK patent on the basis of a particular claim construction, the UK courts are free to construe the same claim differently. The lack of this doctrine benefits those patent proprietors involved in litigation who feel that they must now argue for a different claim construction in order for their patent to be held infringed and/or to be held valid.

However, the recent decision of the UK Patents Court in *Monsanto v Cargill*, (10 October 2007) indicates that an interpretation placed on a claim by an EPO Technical Board of Appeal (TBA) in opposition proceedings is very relevant, should the same construction point arise during UK litigation.

The patent was concerned with enzymes, referred to as EPSPs, which, if expressed in a plant, conferred resistance to the herbicide “Round Up” (trade mark), resulting in an improvement to crops. Cargill bought soya beans in Argentina grown from seed carrying the gene in question, manufactured meal using the soya beans and imported a cargo of 5,000 tonnes of the meal into the UK. The vast majority of soya bean meal exported from Argentina came from seeds carrying a gene for an enzyme called CP4R, generally referred to as “Round Up Ready” seed.

In opposition proceedings, the EPO accepted a narrow interpretation of the phrase ‘Class II EPSPS enzyme’ contended by the opponent Cargill (which imported into the meaning a certain contrast with Class I enzyme set out in the specification). It seems that this was also the interpretation preferred by the proprietor Monsanto. In its decision, the EPO Board of Appeals disposed of an allegation of anticipation on the basis of this interpretation.

In the UK litigation, Monsanto argued for a broader interpretation of the phrase for the patent to be found infringed. The Court accepted that Monsanto was entitled to ‘argue in this Court for a different interpretation’ and also accepted that the House of Lords had made it clear that ‘reference to the EPO file is discouraged’ for the purpose of claim construction. Nevertheless, the Court went on to say

Here we are considering an interpretation arrived at in contested proceedings by a Board of Appeal of the EPO which should be treated with respect. I think one needs a good reason to depart from an interpretation placed on a claim by a Board of Appeal in contested proceedings and which forms part of one of the grounds of the decision.

In its judgement, the Court agreed with the construction adopted by the Board of Appeal and hence held that the patent was not infringed.

In any event, mere importation of meal made from plants that were descended

through many generations from an original “Round Up Ready” soybean plant was not an infringement of a claim to “A method of producing genetically transformed plants” because the meal was not the *direct* product of the original transformation. The product was just soybean meal with no special intrinsic characteristics from one of the generations of plants.

Comment

In our Autumn 2002 edition of this newsletter, we said every practitioner must be wary of the doctrine of prosecution history estoppel, not merely because a foreign jurisdiction might consider evidence from a file history, but because we cannot predict the circumstances in which the file history may some day influence the Court. At that time we made reference to a Dutch case (*Ciba-Geigy v. Oté Optics*), and a UK case (*Rohm & Haas v. Collag*). In the latter case, the Court of Appeal referred to a letter filed by the patentee during prosecution to clarify the meaning of a claim.

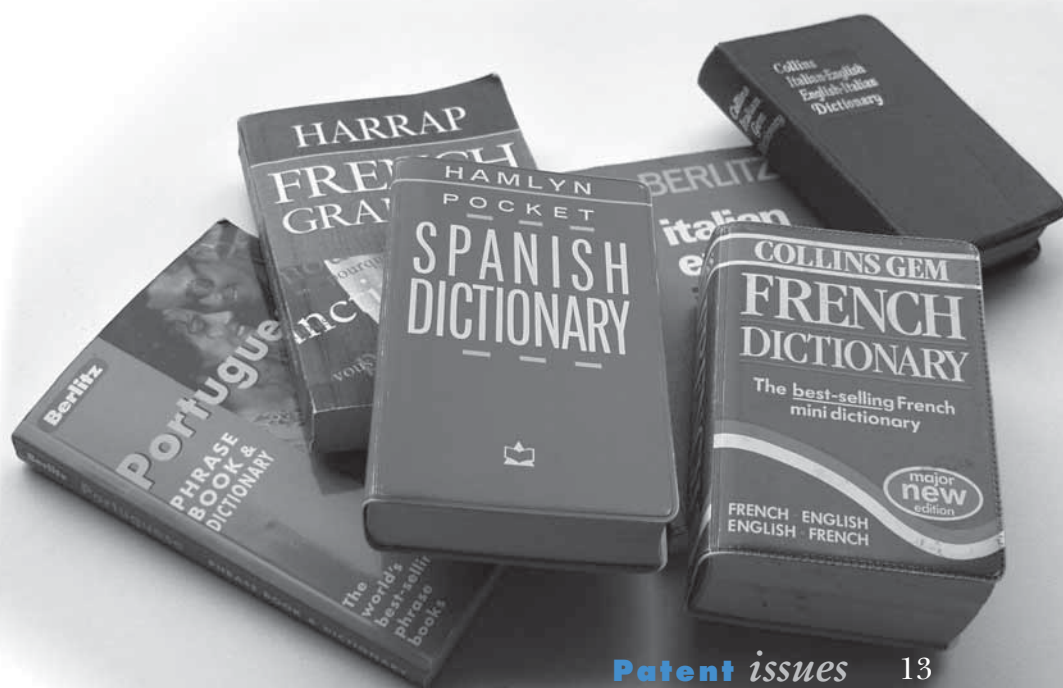
Here, now, we have a case in which the UK Patents Court is willing to attach great significance to an interpretation accepted in contested (Opposition) proceedings by an EPO Board of Appeal. ■

LONDON AGREEMENT IN FORCE

The London Agreement significantly reduces the cost of the grant stage of a European patent by reducing the requirements for translations in many EPC contracting states. It finally entered into force on 1st May, 2008, and our clients are already seeing the benefit. For contracting states party to the London Agreement, it is no longer necessary to furnish a translation of the entire patent specification.

The current states include Germany, France and the UK, i.e. the European countries in which patent protection is sought most frequently. The Netherlands and Sweden are also popular states for national validation where significant savings are now available. A table of the EP contracting states rank-ordered by GDP and population is available for download from our website.

Germany experienced a minor hiccup in the timely ratification of the London Agreement, due to an “editorial error” in the original implementing provisions. However, according to the German Ministry of Justice, this error has been corrected, and the retroactive ratification as of 1st May 2008 will be effected in June. Thus, no harm should have been done, and we expect the relevant laws to be in place by the time this newsletter goes to press. For more information, please contact our Munich office at Munich@Jenkins.eu.

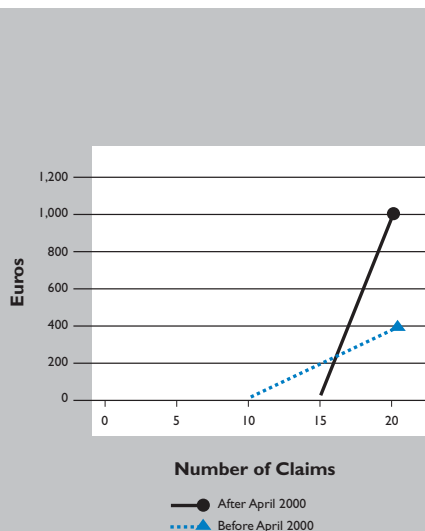


NEW INCENTIVE TOWARDS FEWER CLAIMS

In a move to cut down on “voluminous” European patent applications, the EPO has increased the excess claim fee from EU 45 per claim to EU 200. The number of “free” claims is increased from 10 to 15. The change came in on 1 April 2008, and we have experienced a rush of filings ahead of the increase. We now enter a new regime of a high incentive to keep down claim numbers, or trim them down on European regional phase processing of PCT applications.

As our chart shows, the change represents a lower cost for applications with 16 claims or less, but a much higher cost for applications with more.

For applicants using the PCT route, the claims fees do not have to be paid immediately. There is a period of at least *one month* for amending the claims following entry into the European phase and for paying excess claims fees on the claims as amended. We envisage that it will become routine to use that time to file a



preliminary amendment.

Deleted claims can be reintroduced later, except that:

- i) if there are more claims at the time of grant than were paid for at the time of filing, the difference in claims fees must be paid at that time;
- ii) unsearched claims must be deleted and can only proceed in a divisional application.

This latter point came in with the EPC 2000 (see the Autumn 2007 edition of this newsletter). Applicants used to be invited to pay a further search fee for unsearched claims. That is no longer an option.

MULTIPLE DEPENDENT CLAIMS

One way of saving on claim numbers without compromising claim scope is to use multiple dependencies. There is no penalty against a claim that is, for example, dependent from “any one of the preceding claims”, even where it depends from a similar claim. If care is taken to ensure that the multiple combinations created by multiple dependencies are unequivocally contemplated by the original disclosure, multiple dependencies can be introduced on European regional phase entry and no objection need arise under Article 123(2) EPC. If amendments are extensive, it is wise to give the examiner a marked-up set of claims or a list of where the new claims come from. But ask the question “are these claims really worth EU 200 each?” If you get article 123(2) wrong it can be a nuisance unwinding the work and, worse, can create ammunition for an opponent.

At the same time as reducing the claims, applicants can take the opportunity to forestall objections against multiple independent claims in the same category under Rule 43 EPC 2000 (old Rule

29 – see the Spring 2002 edition of this newsletter).

PREPARE PCT APPLICATIONS WITH THE EPC IN MIND

In the future we expect to see PCT applications prepared with a much closer eye on the EPC. Cases with more than 15 claims will be the exception, and more specifications will be drafted and filed with multiple dependent claims from the outset. It is much easier to amend the claims for US compliance by stripping out the multiple dependencies than to amend them for EPO fee saving by collapsing down lengthy claim sets using multiple dependencies while complying with Art 123(2).

Large numbers of claims are not the only way of creating fall-back positions in a patent application. It has been traditional in Europe to have “consistory clauses” in the specification (historically to provide unequivocal support for the claims) setting out, in claim-like language, “preferred” or “optional” features of the invention. We advise applicants should make more use of such clauses so that, if necessary, they can be introduced into the claims during prosecution or after grant (using the new post-grant amendment provisions of the EPC 2000) or (where permitted) before national courts.

European patent applications with large numbers of trivial claims that do no more than introduce features known in the prior art will become much less common. The late Mr. Justice Pumfrey (as he then was) criticized such claims in *Research in Motion v. Inpro Licensing* [2006] R.P.C. 20 para. 32, saying: “I cannot conceive how these claims could be supposed to survive a successful obviousness attack on claims 1 and 2”.

UNIVERSITIES

AND LICENSING OF EU FUNDED RESEARCH

The European Union annual budget for funded research was increased to EU 5.3 billion when the 7th Framework Program (FP7) was launched in 2006, which represents a 41% increase on the previous program (at 2004 prices). This represents 4.3% of the EU Commission's spending commitments¹. This budget is projected to increase to over EU 10 billion by 2012.

FP7 allocates EU 32.4 billion to the "Cooperation Programme", which supports all types of research activities carried out by different research bodies in trans-national cooperation and aims to gain or consolidate leadership in key scientific and technology areas. The budget is devoted to supporting cooperation between universities, industry, research centres and public authorities throughout the EU and beyond. The key

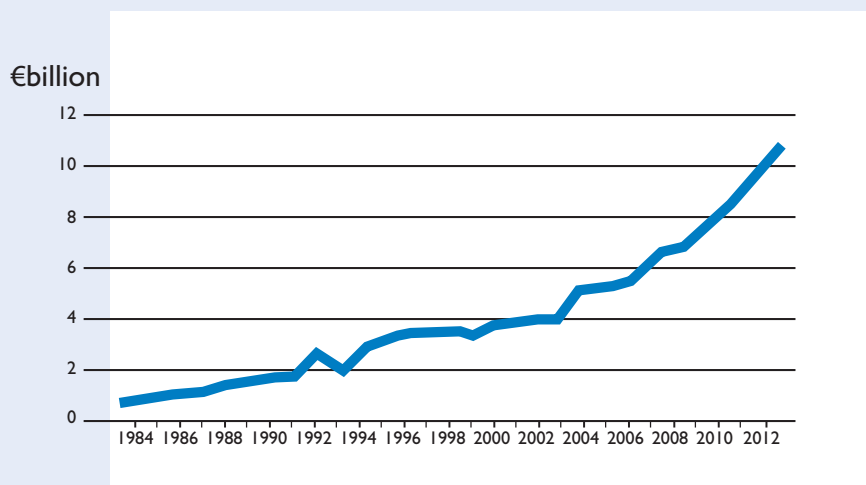
areas for research funding within the Cooperation Programme are:

- Health (EU 6050m);
- Food, Agriculture and Biotechnology (EU 1935m);
- Information and Communication Technologies (EU9110m);
- Nano-sciences, Nano-technologies, Materials and new Production technologies (EU 3500m);
- Energy (EU 2300m);
- Environment (including Climate Change) (EU 1800m);
- Transport (including Aeronautics) (EU 4180m);
- Socio-economic Sciences and Humanities (EU 610m);
- Space (EU 1430m); and
- Security (EU 1350m).

¹Agriculture EU 52.6bn, Structural actions EU 44.6bn, External actions EU 5.6bn, Preaccession aid EU 3.6bn, Administration EU 6.5bn and Other policies EU5.6 bn.

EU RESEARCH FRAMEWORK PROGRAMMES

Annual budgets between 1984 and 2013



Universities no longer have to SET LICENSING TERMS UP-FRONT.

Aside from a string of minor changes in the FP7 rules of participation, we take this opportunity to draw attention to one change that benefits universities in particular and is at risk of going unnoticed.

Under the previous (FP6) rules, access rights for use of the results of a project were royalty-free unless otherwise agreed before signature. Under FP7 the rule (Regulation (EC) No 1906/2006, Article 50) is that access rights for use of foreground, as well as essential background, can be granted under fair and reasonable conditions (or indeed royalty-free), but there is no time limit for agreement on terms. This change is brought in because some participants, especially universities, may not have the possibility to exploit their results commercially. So greater flexibility has been introduced for negotiating licensing terms.

Provided Universities do not sign away these access rights at the time of entering into an FP7 agreement, there is an opportunity for a revenue stream from foreground and background. It is all the more important that background is protected before entering into the project, and universities may seek to enter projects in which protected background can be developed.

OUT AND ABOUT

Some of our Patent Partners and Professionals will be attending and/or exhibiting at many conferences this 2008 summer and autumn (see box right). If you are planning on attending any of these events then please drop by our booth or contact us to set up a meeting.

DAVID MUSKER

David Musker, Head of our Community Designs Group, has spoken on various patent and design topics at many industry events. Since Autumn 2007 David has contributed to:

- the **Asian Patent Attorneys Association** meeting in Adelaide in November 2007, where he gave a talk to the Designs Committee on the Design/Trade Mark Crossover in Europe;
- the **2008 International Conference on Design & Management** at Kookmin University, Seoul, Korea in April 2008 where he spoke on Design Protection in Europe;
- the **2008 Inaugural QMIPRI Annual Conference**, at the Queen Mary, University of London, in February 2008, where he gave a talk on Hot Topics in Design;
- the **INTA** meeting in Berlin in May 2008, chairing a Table Topic Discussion on a Case Law Update for the European Union Community Design Protection;

| WHO | WHERE | WHEN |
|--|--|-------------------|
| Reuben Jacob Hugh Dunlop Sarah Taylor Kei Enomoto | BIO - 2008 San Diego, USA London Development Pavilion Exhibiting at London Booth #1743 | 17 June - 20 June |
| Hugh Dunlop Neil Condon | Venturefest Oxford, UK Exhibiting at the Venturefest Marquee | 30 June - 1 July |
| Reuben Jacob Hugh Dunlop | AIPPI Boston, USA | 6 Sept - 11 Sept |
| Reuben Jacob David Musker | APAA Singapore | 18 Oct - 21 Oct |
| Hugh Dunlop | AIPLA Washington, USA | 23 Oct - 25 Oct |

- the **WIPO** and **AIPPI's** International Conference on Privilege in Geneva in May 2008 where he spoke on Pitfalls and Practical Problems; and
- the **2008 UNION Congress** in Porto in May 2008 where he chaired a session on trade marks as prior rights against designs and vice versa.

RECENTLY QUALIFIED

Alvin Lam

We are proud to congratulate Alvin Lam who recently qualified as a UK Chartered Patent Attorney after successfully qualifying as a European Patent Attorney in 2007.



The main focus of Alvin's work is in

obtaining patents involving computer-related technologies, and he has a particular interest in novel computer-controlled systems and internet-based inventions. Alvin has experience in drafting patent applications in a variety of subject-matter areas, ranging from improved graphical user interfaces and media streaming technologies to fuel cell control systems and plug arrangements for electrical devices.

Dr. Kei Enomoto

We are also proud to congratulate Kei in successfully completing her UK Chartered Patent Attorney qualification.



Kei has experience in the prosecution of patent and design applications on a worldwide basis. Specialising in the field of life sciences; Kei has particular interest in chemistry, for example in pharmaceutical and agrochemical inventions and the legal issues surrounding these types of inventions. Kei also handles work on medical devices, packaging, biochips, industrial materials and polymers, materials for semiconductors, and food products.

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Please either return a copy of this page to Lauren Culley at Jenkins. Fax No. +44(0)20 7222 4660 or email: lculley@jenkins.eu

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Address: _____

The information contained within this Newsletter is not intended to provide an exhaustive or comprehensive statement of current law or practice. No reliance should be placed upon it as a basis for any legal action or commercial decision and for any individual case specialist professional advice should always be sought in order to determine the applicability of any relevant legislation.

If we can offer you advice on the topics discussed in this Newsletter or any other intellectual property matter, please contact us at:

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