D YOUNG & CO

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PATENT NEWSLETTER

IS THERE ABSOLUTE PROTECTION FOR DNA PATENTS IN EUROPE?

A decision in the Dutch Courts unfolds yet further development in the on-running infringement action between Monsanto and soy meal importers (supported by the Argentine government).

Monsanto is attempting to use its European patent to stop imports of soy meal from Argentina in pan-European litigation. In its 24 September 2008 decision, the District Court of The Hague (having heard the parties' observations in respect of the draft questions included in its 28 March Decision) referred several questions to the European Court of Justice (ECJ).

At stake is whether the Biotech Directive determines the scope of DNA patents, or whether there is room for a more absolute protection conferred by national patent laws.

Questions arise as to whether or not this ECJ decision will bring a consistent approach to the interpretation of the Biotech Directive by different member states.

THE MONSANTO PATENT – A BRIEF BACKGROUND OF THE CASE

Monsanto is the proprietor of European patent EP 0 546 090 relating to glyphosate-tolerant 5-enolpyruvylshikimate-3 phosphate synthesis, an invention causing glyphosate (a herbicide) tolerance in soy plants.

Monsanto's invention results in genetically modified plants. A large part of the soy beans from these plants are used for the extraction of oil. After oil extraction, the residual parts of the soy beans are then further processed into soy meal, which is used as cattle feed.

The defendants purchased soy beans in Argentina (where there was no patent protection), the beans being grown from plants carrying one of the genes disclosed in the patent. The beans, grown in Argentina, were imported by the defendants into the Netherlands as processed soy meal.

The patent claims include claims directed to isolated DNA sequences, a recombinant DNA molecule, a method of producing genetically transformed herbicide-tolerant plants.

Monsanto has argued that intact DNA molecules are residually present in soy meal imported into Europe and that its European patent is therefore infringed under the national patent laws in Europe.

One of the counter arguments of the soy meal importers is that on the basis of Article 9 of the "Biotech Directive" (Directive 98/44/EC on the legal protection of Biotechnological Inventions) the scope of protection of Monsanto's patent does not extend to situations where the DNA molecules, if present at all, are residually present and are incapable of performing any function whatever, least of all the function for which the patent was granted, i.e. creating glyphosate tolerance.

Article 9 of the Biotech Directive states: "The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function."

The District Court of The Hague gave its (interim) judgment on March 19, 2008, referring the case to the ECJ for their interpretation of Articles 8 and 9 of the Biotech Directive. In its more recent 24 September 2008 decision the District Court of The Hague (having heard the parties' observations in respect of the draft questions included in its March 2008 decision) finalised the questions for the ECJ.

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EDITORIAL

As we come to the end of another year it is time to reflect on another year gone by. As you will see from this edition of the Patent Newsletter, the Courts have been busy in the latter part of 2008. This edition of the Newsletter includes updates on the patentability of software related inventions, including a recent referral to the Enlarged Board of Appeal of the EPO in respect of computer program inventions. For those of you who are interested in patenting polymorphs and/or plant biotechnology we have articles which bring you the latest developments in these fields.

In addition to this bumper packed edition of the Newsletter – we also enclose an added extra in the form of a Supplement which considers how much data are required for patentability of an invention in respect of European patents in light of recent Court decisions.

We hope you enjoy this edition of the Newsletter and wish you all Season's Greetings and a prosperous and happy New Year!

CAN THERE BE ABSOLUTE PROTECTION FOR DNA PATENTS?

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THE QUESTIONS REFERRED TO THE ECJ

The District Court decided that it cannot clearly ascertain whether "classic" absolute product protection would apply for DNA molecules on the basis of national patent laws and that their scope of protection is unrelated to any function or expression of characteristics within the meaning of the Biotech Directive, particularly Article 9. It will effectively ask the ECJ whether, under the present circumstances of the case, the scope of protection of DNA patents is governed exclusively by the Biotech Directive.

In addition the questions seek clarification as to whether or not it makes any difference if the patent was applied for and granted before the Biotech Directive was adopted.

THE MONSANTO PATENT AND THE BIOTECH DIRECTIVE

The Monsanto case has demonstrated how the different implementation of the Biotech Directive in different Courts within Europe has the potential to create different results around Europe.

In each action brought by Monsanto the facts of the case were the same.

In Spain, the court held that the Biotech Directive applied, and importing soy meal did not infringe on Monsanto's patent because the inserted gene, even if present, was not performing its function (needed according to Article 9) because to perform its function, it would need to be transcribed into mRNA and then translated into an amino acid sequence. In the UK in Monsanto Technology LLC v Cargill International SA & Anor before the High Court, it was held in October 2007 that the Biotech Directive did not apply because the application for the patent was made before July 28, 2000, i.e. before the date that the Biotech Directive was implemented. The decision was, therefore, based purely on existing case law and claim construction. This decision is being appealed by Monsanto. The UK Court held that the product claims had not been infringed. Although some DNA sequences survived the manufacturing process and were present in the allegedly infringing meal, they fell outside the scope of the claims as the term "isolated" was construed to mean DNA sequences that had been removed from a genome and were in a form ready for further processing. As the gene sequence in the soy meal was not isolated within this meaning, the importation of soy meal into the UK did not infringe on Monsanto's patent.

The Dutch Court also adopted the construction of the word "isolated" as used before the UK Court and as a result, found non-infringement. For the claims not restricted by the word isolated, the Dutch court has asked the ECJ to clarify the scope of Article 9 and to which patents the Biotech Directive applies.

While the three results above were ultimately the same, the reasoning of the different courts was not consistent and thus could lead to divergent results on a different fact pattern.

THE BIOTECH DIRECTIVE & ITS IMPLEMENTATION IN DIFFERENT JURISDICTIONS IN EUROPE

When implemented, it was hoped that the Biotech Directive would clarify the patent position of biotechnological inventions in Europe.

The Biotech Directive has now been implemented throughout Europe; however there is some suggestion that it may not be used consistently.

Typically for patentability, the industrial application of the gene sequence must be disclosed in the patent application but not necessarily within the claim. Hence, the Biotech Directive arguably allows *per se*, or product-based, protection for a gene sequence that has been isolated from its natural environment.

There is a potential limitation to *per se* protection contained within the Biotech Directive in Article 9 thereof (recited in full above).

The wording of the Biotech Directive has been preserved in the UK and so could allow *per se* protection for genes in certain circumstances. As no cases have yet been decided or are due to be decided under the Biotech Directive, the UK's approach is yet to be seen.

When transposing the Biotech Directive into their national legislation, France and Germany have provided for a purpose-bound protection, i.e. a restriction of the patent so that only the specific use disclosed in the patent application can be claimed, as regards to inventions concerning material isolated from the human body (France) and human/primate gene sequences (Germany).

Hopefully the decision of the ECJ in the Monsanto case will resolve some of the differences in implementation of the Biotech Directive across member states.

Inconsistent implementation and interpretation of the Biotech Directive by different member states might affect the outcome of future litigation relating to biotech patents. Thus, the choice of jurisdiction may be important to the success of an action brought in Europe under a biotechnology patent.

AYLSA WILLIAMS

FOUR QUESTIONS CONCERNING COMPUTER PROGRAM INVENTIONS

In a letter dated 22 October 2008, the President of the EPO, Alison Brimelow, has referred four questions concerning the treatment of computer program inventions to the EPO Enlarged Board of Appeal. This referral is now pending under the reference G03/08 (see www.epo.org/patents/appeals/pending.html).

The first question concerns whether claims can be directed specifically to a computer program if there is a corresponding allowable method and/or system claim. The referral draws attention to the EPO Board of Appeal decisions T1173/97 (which first allowed computer program claims at the EPO) and T424/03. The latter decision is part of the more recent EPO case law that has downplayed the exclusion of Article 52(2) EPC. According to the referral, this has led to the position where "overcoming the exclusion for programs for computers ... [has] become a formality". However, the referral is perhaps slightly disingenuous here, since it completely ignores Article 56 EPC. T424/03 specifically requires technicality to be taken into consideration under Article 56 EPC, and hence the overall bounds of patentability have not been altered in practice.

The second question asks whether the use of a computer in a claim specifically overcomes the computer program exclusion of Article 52(2) EPC, or whether a further technical effect is also needed. The referral cites two decisions, namely T1173/97, which first introduced the requirement for a further technical effect, and T258/03, which interprets Article 52(2) EPC and Article 56 EPC in the same general manner as T424/03.

The third question asks whether a claimed feature must cause a technical effect on a physical entity in the real world in order to contribute to the technical character of the claim, and if so, can the physical entity be a computer. Whereas the first two questions are aimed primarily at claim format, the third question appears to be more broadly concerned with the boundaries of patentability. It cites two cases, T163/85 and T190/94, as supposedly requiring a technical effect on a real world entity, and two cases, T125/01 and T424/03, where this was apparently not required. The referral argues that "on the reasoning of the latter decisions [T125/01 and T424/03], it would appear that an inventive step could be based on a programmer's choice of elementary programming constructs (tables, loops, subroutines, objects) ... It is therefore difficult to contemplate which aspects or effects of a computer program could fall within the exclusion". However, if the computer program exclusion were not present, it could be argued that the ordinary interactions between any computer program and a machine would necessarily bestow technicality. The impact of the computer program exclusion can therefore be seen in the requirement for a "further technical effect (emphasis added)", as per T1173/97, over and above these ordinary interactions.

The fourth question asks whether programming a computer necessarily involves technical considerations, and if so, do all the programming features contribute to the technical character. A particular focus of the fourth question is on the skills to be attributed to the skilled person. According to T833/91, T204/93 and T769/92, it is considered that a programmer's activity is excluded by Article 52(2) EPC, whereas T1177/97 and T172/03 regard a programmer as a person of skill in the art. This question again seems to go to the heart of whether computer-implemented inventions are patentable under the EPC. The fourth question rather assumes a clear separation between the roles of engineer and programmer, but in reality there is often no such separation. For many engineering projects, the programmers are also the engineers (and *vice versa*).

The legal basis for the referral under Article 112(1)(b) EPC requires there to be different decisions from two Boards of Appeal. However, the referral does nothing to dispel the impression that current EPO law and practice regarding the computer program exclusion is actually reasonably settled. For example, the referral has to go back some 10 years to find a divergent decision (and even longer in the case of the fourth question), and certainly, recent decisions and practice all appear to be in conformity with one another. Indeed, only last year, Alain Pompidou, the previous president of the EPO, refused to make a referral on the same issue to the Enlarged Board of Appeal, arguing that there were insufficient differences in decisions from the Boards of Appeal. In these circumstances, it is entirely possible that the Enlarged Board of Appeal might declare the referral inadmissible, and therefore refuse to give an opinion.

Overall there has been mixed reaction to the referral. In some quarters it has been welcomed as an opportunity to clarify the law, although on the negative side, the referral casts a cloud over the current, settled EPO practice in this area. This may cause a significant period of uncertainty until the Enlarged Board of Appeal issues its opinion (this is likely to take at least a year or two).

SIMON DAVIES

PATENTING POLYMORPHS - THE EPO APPROACH

In the highly competitive environment that is the pharmaceutical industry, the expiry of patents covering blockbuster drugs and the shortage of new drug candidates mean that the need exists now, more than ever, for innovator companies to manage and extend the life cycle of existing products. A common way to extend the exclusivity of a product is to protect new crystalline forms of the drug. Patent protection for a new crystalline form of a compound can be extremely valuable, for example, if the new form possesses a desirable physical property, such as improved stability, or if it is an unavoidable component of a commercial drug product, so that the competition is postponed whilst third parties try to work around to avoid infringement. Increasingly, this has also become an important strategy for generic companies vying to keep their competitors off the market for as long as possible.

The existence of different crystalline forms of a compound – so-called "polymorphism" - arises from the ability of molecules to "pack" into different arrangements within the crystal lattice. Crystal packing of compounds can be influenced by process parameters such as crystallisation temperature, the presence or absence of particular solvents, and crystallisation times. Moreover, during crystal formation, solvent molecules may be incorporated into the crystal structure, giving rise to solvated crystalline forms, which may themselves be polymorphic. In contrast, amorphous (i.e. non-crystalline) forms of compounds do not form an ordered arrangement of molecules. The term "polymorphism" typically extends to different crystalline forms of a chemical compound, as well as to solvated/hydrated forms and amorphous forms of the same compound.

Polymorphic forms can be distinguished by techniques such as X-ray diffraction (XRD), infra-red absorption spectroscopy (IR), thermogravimetric analysis (TGA), solid state nuclear magnetic resonance (ss-NMR) and differential scanning calorimetry (DSC). Polymorphic forms of compounds can also be characterised according to crystal morphology – e.g. plate- or needle-shaped crystals.

Whilst not all compounds exhibit polymorphism, it is true to say that many compounds do exist in different polymorphic forms. Polymorphic forms of the same compound may exhibit different chemical and physical properties – for example, melting point, solubility, dissolution rates and density. In a pharmaceutical product, these differences can affect the properties of the drug (e.g. bioavailability), or may influence the suitability of the compound for formulating (e.g. handling characteristics such as flowability and compressibility, and stability). It follows that the discovery of new crystalline forms is an important and valuable part of the drug development and product life cycle management process.

The EPO's practice in respect of claims to crystalline forms has evolved with time and over recent years it has tightened its approach to the allowance of such claims. Important considerations in view of the EPO's current practice in respect of polymorph applications are discussed below.

Where an invention relates to a crystalline form of a known compound, and the compound is disclosed in the prior art as an amorphous solid, or an oil, it is possible to obtain a broad claim to "crystalline compound X." Similarly, if the prior art discloses only crystalline forms of a compound, it is possible to obtain a claim to "amorphous compound X." A more typical scenario is where the crystalline forms of a compound are already known in the prior art. Here, since crystalline forms are typically distinguished by virtue of differences in experimental parameters (e.g. by the techniques mentioned above), the first consideration in drafting claims to a new polymorphic form is the selection of a suitable set of experimental parameters with which the crystalline form can be characterised and distinguished over the prior art (see e.g., EPO Board of Appeal Decision T0885/02, where it was held that the IR peaks listed in the claims did not effectively distinguish over a prior art form). Only the minimum essential parameters should be included to ensure a broad claim scope. This may involve a certain amount of educated judgement. For example, the selection of peaks in an XRD pattern that are unique to a particular crystalline form can only be made with knowledge of the XRD patterns of prior art forms. Clearly the recitation of the fewest possible peaks is the best strategy for obtaining the broadest protection, but this also leaves the claim more vulnerable to attack. It is not possible to predict whether the selected peaks will be sufficient to distinguish over prior art uncovered after filing. It is therefore essential to include in the patent application a raft of other parameters (e.g. alternative and secondary XRD peaks, XRD peak intensities, IR absorption bands, and DSC thermograms) that can be relied on to provide basis in the event that amendment is needed in view of prior art.

The use of experimental parameters to characterise a polymorph can present problems of reliability and variability in the analytical technique. For example, differences may arise from the instrumentation, sample preparation, and atmospheric conditions. Thus, the parameters used to define a new polymorphic form should be reliable, clear and unambiguous in order to meet the requirement of sufficiency and clarity (Articles 83 and 84 EPC). It is therefore essential to include in the patent application the specific experimental conditions used to obtain the measurement, e.g. the wavelength of the X-ray source in the case of XRD, the disc material in the case of IR, and the heating rate in the case

of DSC. The absence of such essential experimental details for characterising a crystalline form can give rise to an incurable objection of insufficient disclosure.

Another special feature of polymorphic forms is that, in some cases, tight control of experimental conditions is necessary in order to ensure that a particular polymorph is formed. For example, the presence or absence of water may mean the difference between the formation of a hydrate or an anhydrous form, and in the case of the former, the amount of water in the crystallisation process may additionally affect the number of water molecules that are incorporated into the crystal lattice (e.g. hemihydrate, monohydrate, sesquihydrate, dihydrate, etc). Thus, in order to meet the requirements of sufficient disclosure, it is essential that the application describes the experimental conditions used to produce the new polymorph as precisely as possible. Further, the processes for making the new form should be distinguishable from any prior art processes.

If only general process details are disclosed in the application and these are essentially identical to a prior art process, but it is indicated in the application that a different polymorph is obtained, this may lead not only to a problem of lack of novelty of the process claims, but to an incurable lack of sufficiency of the polymorph claims. Thus, details of process features and conditions that are likely to affect the nature of the polymorph formed (e.g. temperature, solvent quantities and proportions, seeding step, heating or cooling rates, water content, etc.) should be included in the patent application to provide scope for amendment should new prior art come to light. On the subject of sufficient disclosure, if a particular seed crystal is required in order to initiate the formation of the claimed crystalline form, and a process for obtaining the requisite seed crystals is not disclosed or known in the art, then this can lead to an insufficient disclosure, which cannot be rectified (EPO Board of Appeal Decision T1066/03; a more lenient approach was adopted in T0939/93).

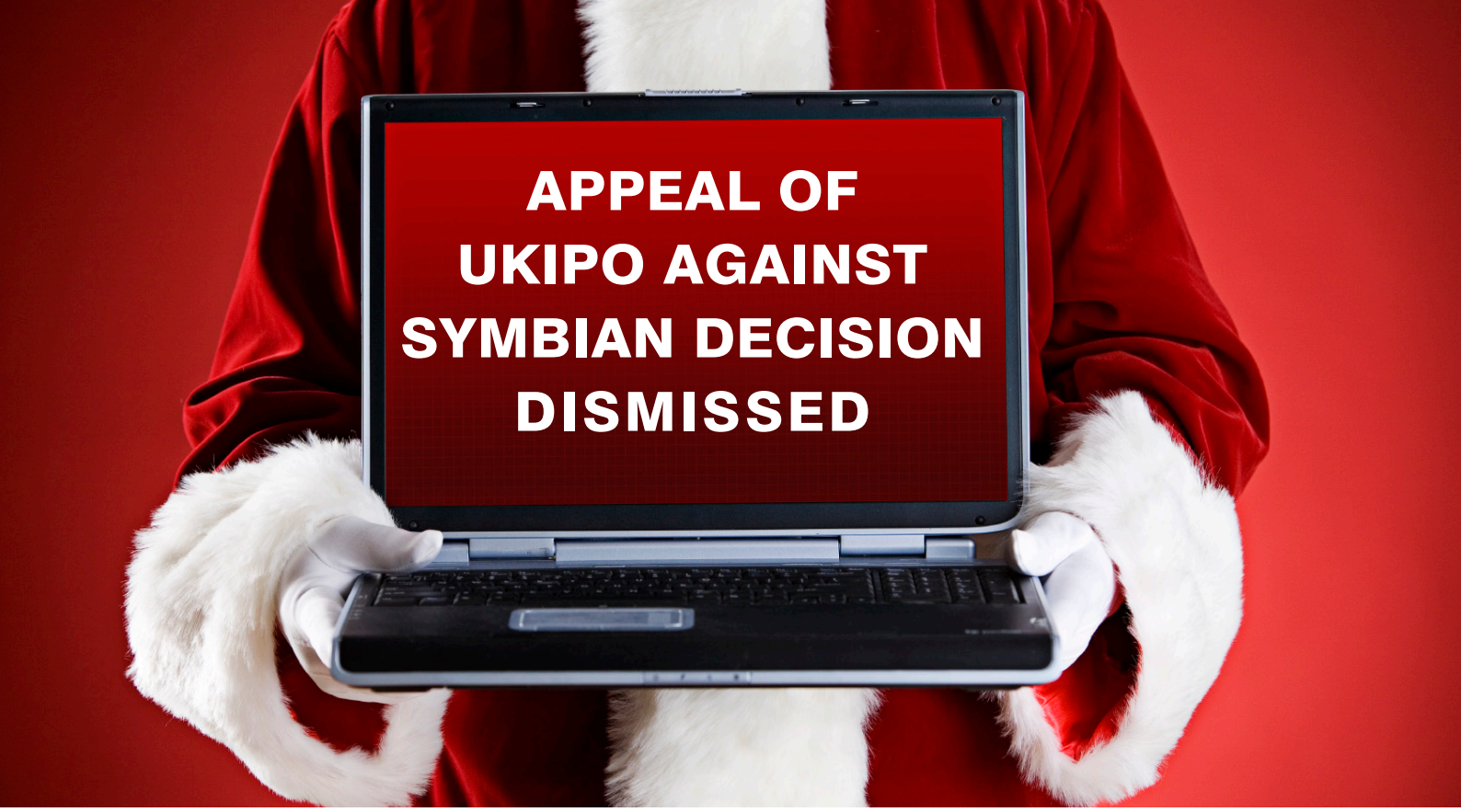
The assessment of novelty (Article 54 EPC) can also present a challenge in polymorph cases. Owing to the fact that characterisation of different crystalline forms is typically reliant on its internal structure, the problem of inherent disclosures can arise when assessing novelty. This is particularly the case where the prior art discloses the same compound and a similar crystallisation procedure or solvent. The onus may then be on the applicant to demonstrate that the prior art process does not inherently give rise to the same polymorph. Indeed, much of the litigation involving polymorph patents has involved allegations that a prior art process inevitably produces the form claimed in the patent in suit – for example, a published process for making an anhydrous crystalline form may also produce small quantities of a hydrate, or the anhydrous form may convert over time to the hydrate. In this case, although the prior art is silent on the existence and characterisation of the hydrated form, it is nevertheless considered to be disclosed. For this reason, it is prudent to include in any polymorph application, numerical ranges for the purity of the new polymorphic form in order to provide basis for amendment (note that relative terms such as "substantially pure" are unlikely to provide useful basis for amendment, since these typically fall foul of the requirement of clarity under Article 84 EPC).

A common obstacle with patent applications claiming new crystalline forms is fulfilment of the requirement of inventive step under Article 56 EPC. It is here, particularly, that the EPO has tightened its criteria for allowance of claims to new crystalline forms. The EPO's current approach to assessing inventive step for polymorph claims starts from the assumption that polymorph screening experiments are a routine part of the drug development process. This has the effect that new polymorphic forms of known compounds are considered to represent an alternative compound to achieve the same technical effect (i.e. medical use), so that an inventive step is not normally acknowledged.

The EPO's approach raises an interesting point because on the one hand, it is presently not possible to predict whether any given compound exhibits polymorphism (and if so, to what extent), yet on the other hand, when a polymorph is found, the EPO automatically considers that the new form is obvious, unless it can be shown to possess advantageous properties compared with the closest prior art form. Thus, it is becoming standard practice for the applicant claiming a new polymorphic form to be required to demonstrate the existence of an unexpected effect by the provision of comparative data. Whilst these data need not be provided in the application, the drafting of polymorph applications should take into consideration the eventual likelihood that comparative data may be required in order to satisfy the requirements of Article 56 EPC. For example, it is good practice to provide a discussion of the potential advantages of the claimed polymorphic forms, at least in general terms, so that the description provides support for later-filed experimental data showing an advantage.

In summary, protection of polymorphic forms of compounds, especially drug products, is becoming increasingly important for both innovator and generic companies. As more polymorphs for commercial drug products are discovered, the crowded patent landscape is likely to lead to an increase in litigation of these patents, both in EPO opposition proceedings and national revocation actions. In view of this, drafting to maximise the claim scope whilst ensuring a complete and sufficient disclosure of the new polymorph form is essential so as to facilitate prosecution of the application and to ensure that the eventual patent can stand up to the scrutiny of litigation proceedings.

KIT WONG



On 8 October 2008, the UK Court of Appeal handed down its much anticipated judgement in the matter of Symbian Ltd v Comptroller General of Patents [2008] EWCA Civ 1066.

This case was an appeal by the UKIPO against a decision of the High Court between the parties, which was in turn an appeal by Symbian Ltd against a decision of the UKIPO to refuse UK patent application GB0325145.1, on the ground that the alleged invention was excluded from patentability by Section 1(2) of the Act [1].

In the High Court, Mr Justice Patten had overturned the UKIPO's decision to refuse, allowing Symbian's appeal. The UKIPO took issue with this decision and strongly attacked Patten J's decision, alleging that it failed to follow the established case law [2]. The UKIPO therefore appealed the High Court's decision, which is the appeal decision now discussed.

As readers active in this field may well be aware, the UKIPO has in recent times taken a very negative approach to examination of patent applications for inventions which can be implemented in software. The UKIPO maintains that its approach is based upon the previous decision of the Court of Appeal in Aerotel [3], despite the wisely accepted fact that although the Aerotel decision considered itself only to be a restructuring of the test for patentability rather than a change in the test per se, the UKIPO underwent a step change in attitude to computer implemented inventions after Aerotel.

In the Decision, the Court of Appeal (the bench including Law Lord Lord Neuberger as well as Court of Appeal patents specialist Jacob LJ and Court of appeal judge Maurice Kay LJ) made a number of key determinations which are expected to affect the practice of the UKIPO in future, as well as setting the tone for future court decisions.

On the widest matters, the Court cautiously affirmed its earlier position in Actavis [4] that it can (but is not bound to) depart from its own precedent where there is a settled position in the body of EPO Board of Appeal decisions that is contrary to that earlier precedent of the Court. In the decision, Lord Neuberger stated at paragraph 36:

> *"Given that there are decisions of this court and of the Board which relate to the ambit of the computer program exclusion in art 52, the right basis for assessing that ambit in this court should be as follows: if the judgements in the Court of Appeal cases give tolerably clear guidance which would resolve the issue on this appeal, then we should follow that guidance, unless it is inconsistent with clear guidance from the Board, in which case we should follow the latter guidance unless satisfied that it is wrong."*

This appears to set out clear guidance as to the ambit of the Acatvis principle of departing from precedent.

Applying this principle to the present case, the Court took the approach of reverting to the analysis used in early precedent of the Court in Merrill Lynch [5] and Gale [6] and that used by the Boards of Appeal in Vicom [7] and two IBM Corp. cases [8]. In so doing, the Court avoided the analysis used in Aerotel which (although stated therein to be a rephrasing of the previous analysis) has caused so much difficulty in recent times, and was the basis for the UKIPO's refusal of the application in this case.

Considering the *"program for a computer" "as such"* exclusion of section 1(2) of the Patents Act 1977, a number of important points were made by the Court.

The Court started by confirming that, following Section 130(7) of the Act, the effect of this exclusion is to be considered in parallel with and provided with the same effect as the equivalent exclusion in Article 52(1) EPC. It was this determination that lead to the above-mentioned discussion of the Actavis principle of departing from precedent.

The Court also held that the computer program exclusion embodied in Section 2(1) of the Act is one of substance rather than form and gave a number of key points of guidance on this issue.

Lord Neuberger, giving the decision of the Court, states at paragraph 48

> *"[t]he mere fact that what is sought to be registered is a computer program is plainly not determinative. Given that the Application seeks to register a computer program, the issue has to be resolved by answering the question whether it*

reveals a "technical" contribution to the state of the art", continues at paragraph 54 with *"the fact that the improvement may be to software programmed into the computer rather than hardware forming part of the computer cannot make a difference"* and then re-emphasises the issue at paragraph 56 *"[t]o say "oh but that is only because it is a better program – the computer itself is unchanged" gives no credit to the practical reality of what is achieved by the program"*.

Lord Neuberger concludes his discussion by holding, at paragraph 58:

> *"Therefore, it must mean, consistently with Vicom and the two IBM Corp. cases, that a technical innovation, whether within (as in the last-mentioned cases) or outside the computer will normally suffice to ensure patentability (subject of course to the claimed invention not falling foul of the other exclusions in art 52(2))"*.

The Court has clearly aimed to remove a large part of the uncertainty surrounding the computer programs exception; Lord Neuberger states at paragraph 51,

> *"we should try to follow previous authority, we should seek to steer a relatively unadventurous and uncontroversial course, and we should be particularly concerned to minimise complexity and uncertainty"*.

The Court of Appeal refused the UKIPO the right of further appeal, the UKIPO has the option to apply to the House of Lords for permission to appeal, but it appears very unlikely that the House of Lords would grant such leave, not least due to the presence of Lord Neuberger on the bench in the Court of Appeal.

The result of the decision appears to be directly counter to the UKIPO's present position, discussed above, of refusing even to fully examine almost every application of an invention which can be implemented using a computer. We are therefore hopeful that the practice of the UKIPO will shortly be modified to coincide more often with the approach taken by the EPO.

Lord Neuberger does comment (paragraph 61) that it is

> *"inevitable that there will be cases where the EPO will grant patents in this field when the UKIPO should not"*

and repeats earlier calls by the UKIPO judiciary for proper dialog and cooperation between the national offices and the EPO. Whether the offices will heed this call remains to be seen.

DAVID MELDRUM

NOTES

[1] Patents Act 1977
[2] UKIPO press release
[3] Aerotel Limited v Telco Limited; Macrossan's Application (2007) RPC 7, (40)
[4] Actavis UK Ltd v Merck & Co Inc (2008) EWCA Civ 444
[5] Merrill Lynch's Application (1989) RPC 561
[6] Gale's Application (1991) RPC 305, 323
[7] Vicom/Computer-related invention T0208/84, (1987) 2 EPOR 74
[8] IBM Corp./Data processor network (1988) T06/83, (1990) EPOR 91 and IBM Corp./Computer-related invention (1988) T115/85, (1990) EPOR 107

PPH PROGRAMME BETWEEN THE EPO AND THE USPTO

The Patent Prosecution Highway (PPH) pilot programme commenced on 29 September 2008, for a period of one year ending on 29 September 2009. Notice will be published if the PPH pilot programme is terminated for any reason before 29 September 2009.

The aim of the PPH is to leverage fast-track patent examination procedures already available at both Offices, to allow applicants to obtain corresponding patents faster and more efficiently. The Offices hope that the PPH will permit each Office to exploit the work previously done by the other Office and reduce duplication. In turn the hope is that the initiative will reduce the examination workload and improve patent quality.

REQUIREMENTS FOR REQUESTING PARTICIPATION IN THE PPH PILOT PROGRAMME BEFORE THE EPO

In order to be eligible to participate in the PPH pilot programme, the following conditions must be met:

(1) The EP application is a Paris Convention application validly claiming the priority of one or more applications filed with the USPTO.

(2) The USPTO application(s) has at least one claim determined by the USPTO to be patentable/allowable. The applicant must submit a copy of the patentable/allowable claims from the USPTO application(s).

(3) All of the claims in each EP application for which a request for participation in the PPH pilot programme is made must sufficiently correspond, or be amended to sufficiently correspond, to the patentable/allowable claims in the USPTO application(s). Claims will be considered to sufficiently correspond where, accounting for differences due to claim format requirements, the claims are of the same or similar scope. The applicant is also required to submit a claims correspondence table in English. The claims correspondence table must indicate how all of the claims in the EP application correspond to the allowable claims in the USPTO application(s).

(4) Examination of the EP application for which participation in the PPH pilot programme is requested has not begun.

(5) The applicant must file a request for participation in the PPH pilot programme.

(6) The applicant must submit a copy of all the Office actions (which are relevant to patentability) for each of the USPTO application(s) containing the allowable claims that are the basis for the request.

(7) The applicant must submit copies of all the documents cited in the USPTO Office action and translations thereof in one of the EPO official languages except for European patents or published European patent applications.

PROSECUTION UNDER PACE

Once the request for participation in the PPH pilot programme has been granted, the EP application will be processed in an accelerated manner under PACE.

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OUT AND ABOUT

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7-11 DECEMBER 2008
Louise Holliday will be attending IBC's 19th Annual Antibody Engineering Conference.

PHARMACEUTICAL PATENT LIFECYCLES MANAGEMENT CONFERENCE
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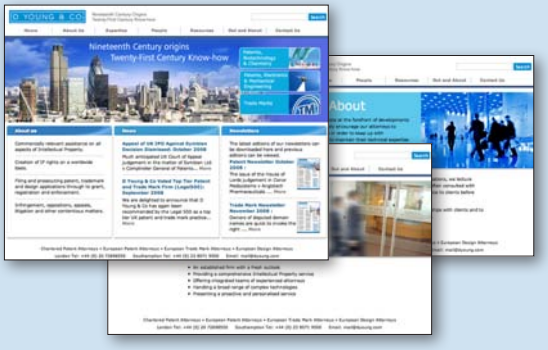

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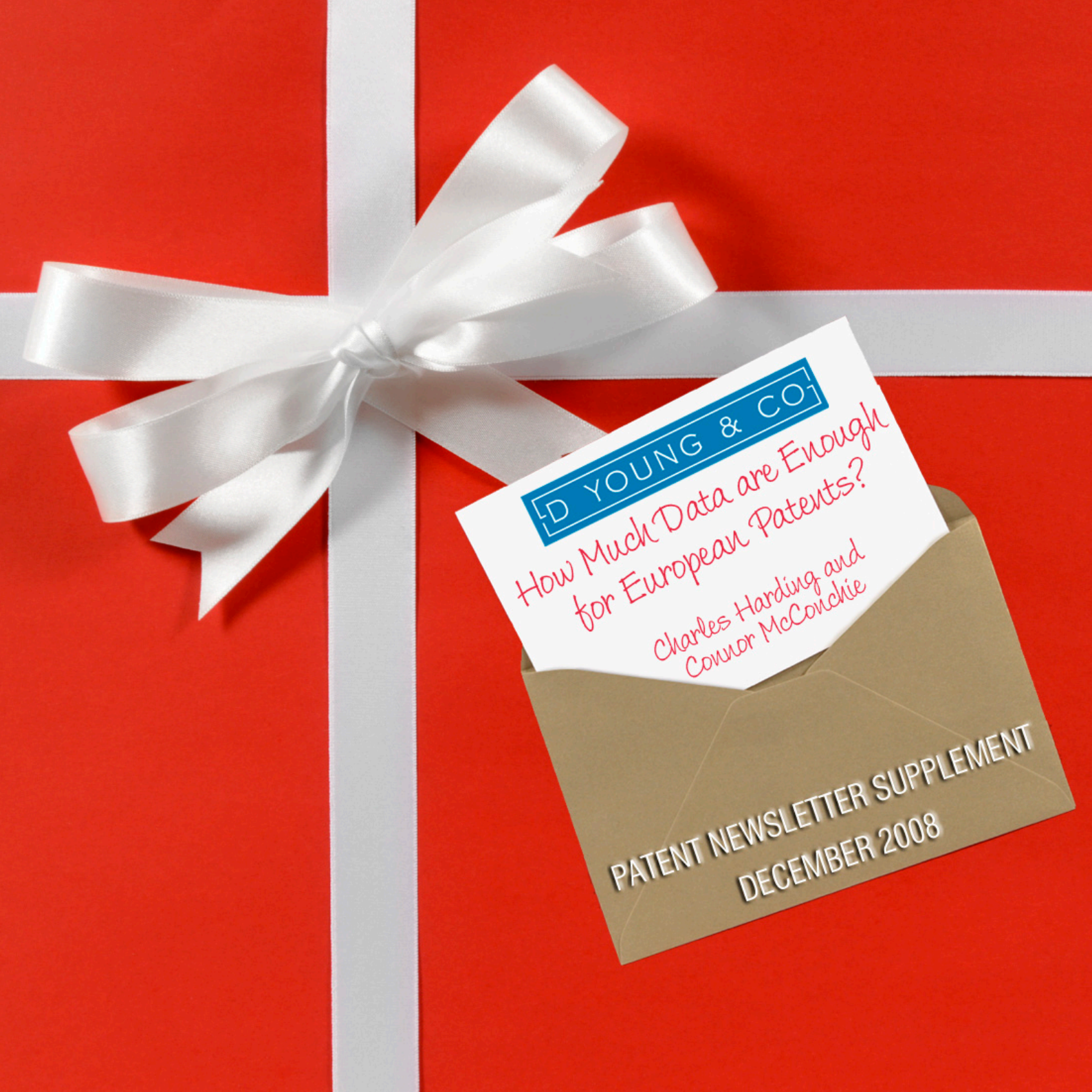

D YOUNG & CO
How Much Data are Enough for European Patents?
Charles Harding and Connor McConchie
PATENT NEWSLETTER SUPPLEMENT
DECEMBER 2008

HOW MUCH DATA ARE ENOUGH FOR EUROPEAN PATENTS?

THE INTERPLAY OF SCIENTIFIC DATA AND PATENTABILITY

The trade off between the interests of the commercial world and those of the public is well established in the patent system: the patent must disclose the invention to such an extent that the public can put it into practice. In return, the applicant obtains a defined period of legal monopoly in respect of the invention.

As the rewards for obtaining a dominant patent can be huge, there is often a surge to be the "first out of the blocks" in the race to the Patent Office. However, recent decisions of the UK Courts and the EPO Boards of Appeal have shown that making a very quick start can be a serious risk.

HOW MUCH IS ENOUGH?

It has always been considered to be advisable to include in a patent application data which support the inventive concept of the invention in question. However, as it has been pointed out on a number of occasions, neither the UK Act nor the EPC (in both its original and recently revised formats) specifically requires the presence of experimental data or worked examples.

In view of this lack of legislative guidance, applicants have been forced to argue their case in legal proceedings before the authorities in EPO opposition or appeal proceedings, or in national infringement and revocation proceedings.

As a result, applicants often ask:

> *"What is the minimum amount of information that a patent application must provide at the filing date in order to obtain a valid legal monopoly?"*

The answer to this is not straightforward.

In fact, the amount of data (if any at all) may differ depending on a number of factors, including the nature of the invention itself and the common general knowledge in the technical field. The amount of data required might also differ for the various patentability criteria that must be satisfied in order to achieve grant. It is this last point that has been relevant in a number of important decisions of the UK Courts.

The recent rulings of Justice Kitchin in the Patents Court in *Eli Lilly & Company v Human Genome Sciences Inc [2008] EWHC 1903 (Pat), 31 July 200 (Lilly)* and that of the House of Lords in *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc & Others [2008] UKHL 49, 9 July 2008 (Conor)* have laid down important principles on the requirement of data. However, these decisions rule primarily on two "distinct" criteria for patentability - *viz* industrial application and inventive step. Furthermore, the conclusions for each criterion appear to differ subtly.

Accordingly, when drafting the application is there scope for reconciling the data requirement for each of the criteria? Or must the patentee assess the requirement for inventive step and industrial applicability individually?

To answer this question one must look at the two cases in a little detail.

Conor Medsystems Inc. v Angiotech Pharmaceuticals Inc, and others, 2008

In a very important ruling from the House of Lords [1], delivered largely by Lord Hoffmann, the threshold for

inventive step attacks based on the "obvious to try" approach appears to have been raised. However, it may be that this ruling could have more subtle implications which possibly reach beyond inventive step.

Although the main independent claim in this case was for a stent coated with taxol, it was claim 12 (which was dependent on claim 1) directed to a stent for treating or preventing recurrent stenosis, which was at issue.

In coming to the conclusion that the subject matter of claim 12 was not obvious, Lord Hoffmann stated:

> *"But there is in my opinion no reason as a matter of principle why, if a specification passes the threshold test of disclosing enough to make the invention plausible, the question of obviousness should be subject to a different test according to the amount of evidence which the patent presents to justify a conclusion that his patent will work".*

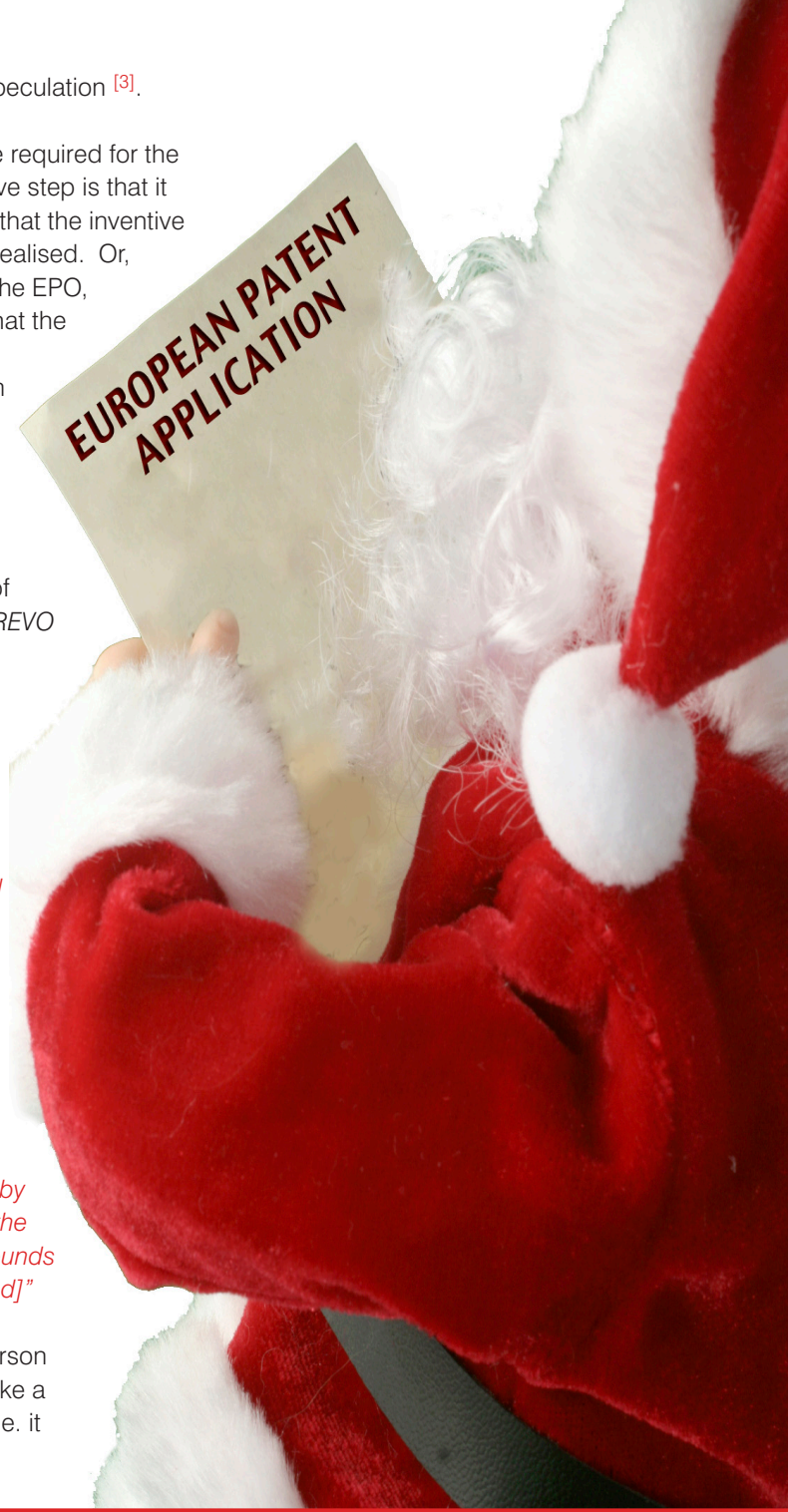
Indeed, Lord Hoffmann went on to emphasise that for the purposes of inventive step of a product (such as in claim 12), patent law does not require that an application demonstrates that an invention actually works [2]; if it did not work, it may well be invalid for lack of sufficiency. However, Lord Hoffmann did stress that such situations were in contrast with situations where the invention is mere speculation [3].

All that seems to be required for the purposes of inventive step is that it would be plausible that the inventive concept has been realised. Or, in the language of the EPO, that it is plausible that the solution solves the problem in question (T 1329/04). Indeed, this requirement of plausibility seems to be in line with the leading Board of Appeal case of *AGREVO (T 0939/92)*.

As noted by Lord Hoffmann, the Board of Appeal said:

> *"… [A] technical effect which justifies the selection of the claimed compounds must be one which can be* ***fairly assumed*** *to be produced by substantially all the selected compounds [emphasis added]"*

Thus, the skilled person must be able to make a "fair assumption", i.e. it



must be plausible from the point of view of the skilled person that the inventive concept has been realised.

Eli Lilly and Co. v Human Genome Sciences, Inc.

It has been widely acknowledged that this decision has given much needed guidance on the interpretation of Section 4 of the UK Patents Act, especially with regard to those inventions having a biotechnological slant.

Although all the claims were found invalid, claim 1 at issue was as proposed to be amended by HGS and is as follows:

> *An isolated nucleic acid molecule comprising a polynucleotide sequence encoding a neutrokine-a polypeptide wherein said polynucleotide sequence is selected from the group consisting of:*
>
> *(a) a polynucleotide sequence encoding the full length neutrokine-a polypeptide having the amino acid sequence of residues 1 to 285 of SEQ ID NO:2; and*
>
> *(b) a polynucleotide sequence encoding the extracellular domain of the neutrokine-a polypeptide having the amino acid sequence of residues 73 to 285 of SEQ ID NO:2.*

In formulating the decision, Justice Kitchin made numerous references to relevant decisions of the EPO [4], as well as to leading decisions of the US Courts, viz Brenner v Manson 383 U.S. 519 (1966) [5] and US Court of Appeals for the Federal Circuit in Fisher v Lalgudi (2005) 04-1465, 09/619,643 [6].

Of the EPO Board of Appeal decisions referred to by the Judge, the most relevant issue seems to be the requirement for a disclosure to be **"immediate"** in the sense that it is directly derivable from the description, if it is not already obvious from the nature of the invention or from the background art.

EPO Board of Appeal decision *T 0898/05* explains that the expression "profitable use" should be understood in the sense of *"immediate concrete benefit"*.

EPO Board of Appeal decision *T 0870/04* found that the only practicable use disclosed in the application was to use the invention to ascertain further knowledge about the invention itself – i.e. the immediacy requirement was not met.

Thus, both of these EPO Board of Appeal decisions appear to place an onus on the applicant to make a disclosure which requires nothing more from the public, other than to apply the common general knowledge.

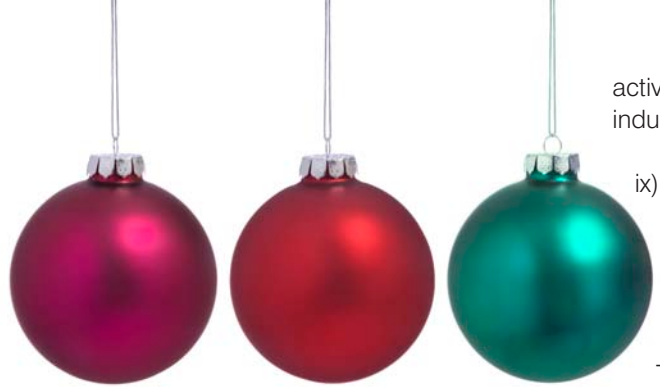
The Judge's analysis of the position in Europe, the US and the UK was summarised in a series of important principles concerning the requirements for industrial applicability:

i) [7] The notion of industry must be construed broadly;

ii) [8] The capability of industrial exploitation must be derivable by the skilled person [9] from the description read with the benefit of the common general knowledge;

iii) [10] The description must disclose a practical way of exploiting the invention in at least one field of industrial activity;

iv) [11] (a) There is a sound and concrete basis for recognising that the contribution could lead to practical application in industry, (b) there is a need to disclose in definite technical terms the purpose of the invention and how it can be used to solve a given technical problem, and (moreover) (c) there must be a real prospect of exploitation which is derivable directly from the specification, if not already



obvious from the nature of the invention or the background art;

v) [12] (a) A speculative indication of possible objectives that might or might not be achievable by carrying out research is not sufficient, and (b) it should not be left to the skilled person to find out how to exploit the invention by carrying out a research programme;

vi) [13] The purpose of granting a patent is (a) not to reserve an unexplored field of research for the applicant, and (b) not give the patentee unjustified control over others who are actively investigating in that area and who might eventually find ways actually to exploit it;

vii) [14] If a substance is disclosed and its function is essential for human health then the identification of the substance having that function will immediately suggest a practical application [15];

viii) [16] Using the claimed invention to find out more about its own activities is not in itself an industrial application; and

ix) [17] It is no bar to patentability that the invention has been found by homology studies using bioinformatics techniques.

These principles are said by the Judge to be:

"consistent with the Directive and with the approach adopted by the US courts … that in return for his monopoly the patentee must make a full disclosure of his invention, including a practical use to which it can be put".

In his concluding paragraphs, Justice Kitchin said:

"The Patent is invalid for lack of industrial applicability, insufficiency and obviousness. Whatever the merit of the discovery of Neutrokine-a, ***the specification contains no more than speculation about how it might be useful. It does not teach the person skilled in the art how to solve any technical problem and its teaching as to the range of applications of Neutrokine-a is implausible.*** *Moreover, the claims to therapeutic and diagnostic products are insufficient in any event."*

"This was a field in which many researchers were active. The application was filed at a time when rapid advances were being made in terms of the public availability of gene sequences and how they might be searched. Not surprisingly, other teams found Neutrokine-a soon after the priority date. Perhaps anticipating this, ***HGS filed its application very promptly. But in doing so it failed to disclose how the protein might be used and it required a research programme to make good this deficiency. HGS secured broad protection over an unexplored technical field without providing an adequate compensating benefit to the public."***

It is unlikely to be in dispute that the HGS application disclosed a practical use to which the invention can be put (in fact, it disclosed many practical uses). What was in dispute however, was whether the offering of this practical use was merely "speculation" or, in the alternative, whether it could be considered to be something more – such as something which the skilled person would be convinced by and indeed attempt.

The Judge decided in this case that the mere identification of a protein, without anything more, was not sufficient to establish that an industrial application of the inventive concept had been disclosed. For some commentators, this may well be in line with the "immediate" criteria of the Board of Appeal cases mentioned above.

However, does this approach sit with

the "plausible" requirement espoused in *Conor* as well as the number of EPO cases concerning the data required for the assessment of inventive step? Indeed, despite referring to *Conor*, there does not appear to have been an analysis by the Judge of whether or not the performance of the invention in one of the disclosed practical uses was at least "plausible".

PLAUSIBLE YES...BUT NOT WITHOUT AN UNDUE BURDEN?

Setting the principles from *Lilly* and *Conor* side by side, it would appear that for an application to disclose enough information to meet the requirements of industrial applicability, there must be sufficient information present to allow an immediate (in the sense of EPO Board of Appeal decision *T 0898/05*) practical use to be derived, whilst for an inventive step to be acknowledged, only sufficient information in order to render the inventive concept at least plausible should be present.

Is it the intention of the UK courts and the EPO Boards of Appeal that more information is required to satisfy the industrial applicability criterion than inventive step?

To some this may seem to be particularly harsh, particularly considering that it is well established that industrial applicability is to be given a broad interpretation (see the first limb of the criteria laid out above). However, if the standard was considered to be in line with that for inventive step (i.e. at least plausible), the applicant may err on the side of caution and include as many applications as possible, because the person skilled in the art would no doubt think it at least plausible that the invention could be made or used in at least one of them.

Of course, such an approach may be risky. In this respect, Judge Kitchin was not particularly impressed about the large range of applications disclosed in the HGS patent [18].

Also, in a valuable addition to the decision in Conor, Lord Walker noted that the patent specification in suit contained so much information that the inventive concept *"nearly got lost"* [19].

Thus, perhaps Judge Kitchin considered that whilst it was plausible that the invention could be made or used in at least one of the disclosed practical uses this could not be proved without an undue burden being placed on the skilled person.

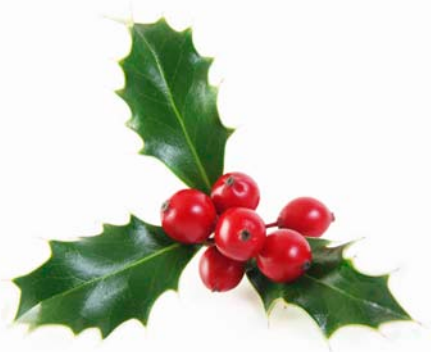
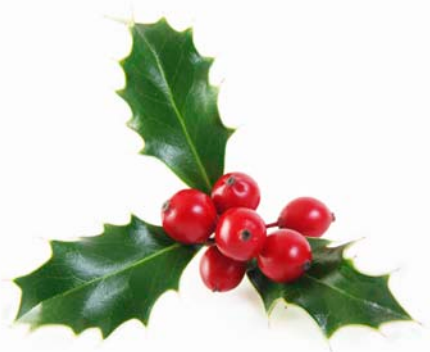
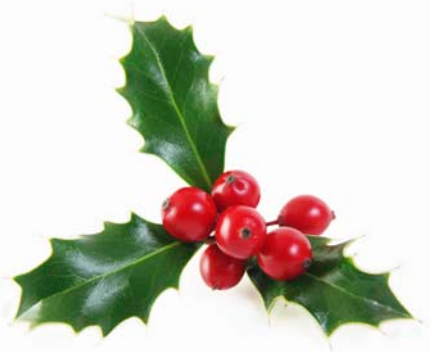
OK THEN, HOW MUCH IS ENOUGH?

It is important to point out that, in all cases, the provision of supporting data in an application is invaluable. Thus, the preferable route is likely to be that of a "belt and braces" approach.

However, it is understood that in some situations time is of the essence and the need to beat the competitors to the patent office is paramount. In these situations, it appears that in order to secure a valid UK patent, sufficient information which satisfies as closely as possible the nine principles mentioned by Judge Kitchin is needed.

IN THE FUTURE?

Looking to the future, perhaps what is required for all patentability criteria is the presence of sufficient information in the application as filed to ensure that the invention as defined in the claims is at least plausible without placing an undue burden on the skilled person to confirm it.

NOTES

[1] This is highlighted by Lord Neuberger of Abbotsbury in paragraph 55 when he says:
"I have had the benefit of reading in draft the opinions of my noble and learned friends Lord Hoffmann and Lord Walker of Gestingthorpe. I agree with them that this appeal should be allowed. **Although the decision represents a significant development in United Kingdom patent law, and we are differing from the views of highly experienced Judges in that field**, I do not think there is anything that I can usefully add to the reasons given by Lord Hoffmann, or to the additional remarks of Lord Walker, with both of whom I entirely agree."

[2] Lord Hoffmann at paragraph 19:
"In my opinion, however, the invention is the product specified in a claim and the patentee is entitled to have the question of obviousness determined by reference to his claim and not to some vague paraphrase based upon the extent of his disclosure in the description. ***There is no requirement in the EPC or the statute that the specification must demonstrate by experiment that the invention will work or explain why it will work.*** *As the Dutch court said (at paragraph 4.17): "... it is not required in the view of the court that experimental data concerning such use of taxol stents in humans and the actual prevention of restenosis be included in the patent to further substantiate [the claim]."*"

[3] In paragraphs 29 and 30, there is stated:
"It is true that ***a patent will not be granted for an idea which is mere speculation****, unsupported by anything disclosed in the specification. Article 84 of the EPC says that the claims must be "supported by the description" and this requirement is reproduced in section 14(5)(c) of the 1977Act. So in Re Prendergast's Applications [2000] RPC 446, the applicant attempted to patent the use of two known pharmaceuticals to treat--*
"battle fatigue, combat stress reaction, post-traumatic stress disorder in civilian and military emergency situations, neurological symptoms associated with chemical warfare and nausea associated with chemical or biological warfare.""
"The specification contained no information whatever to support the claim that the products in question would have any effect on these ailments. Neuberger J upheld the Comptroller's rejection of the claim on the ground that it was not supported by the description."

[4] For example, reference was made to T0338/00; T0604/04; T0870/04; T0898/05; T1452/06 and the Decision of the Opposition Division in the ICOS Corp case {OJEPO (2002) page 293 etc.}

[5] In the famous case of Brenner v Manson 383 U.S. 519 (1966), the Court held:
"The basic quid pro quo contemplated by the Constitution and by Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point -- where specific benefit exists in currently available form -- there is insufficient justification for permitting an applicant to engross what may be a broad field."

[6] In the HGS case, the Judge further referred to and quoted from the US cases as follows:
"The rationale presented herein, having been drawn from principles set forth by the Supreme Court in Brenner, applies with equal force in the fields of chemistry and biology as well as in any scientific discipline. In Brenner, the Supreme Court was primarily concerned with creating an unwarranted monopoly to the detriment of the public: "Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public... This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something "useful", or that we are blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But ***a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. [A] patent system must be related to the world of commerce rather than to the realm of philosophy****."*
"Here, granting a patent to Fisher for its five claimed ESTs would amount to a hunting license because the claimed ESTs can be used only to gain further information about underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of Fisher's research effort, but only tools to be used along the way in the search for a practical utility. Thus, while Fisher's claimed ESTs may add a noteworthy contribution to biotechnology research, our precedent dictates that the '643 application does not meet the utility requirement of § 101 because ***Fisher does not identify the function for the underlying protein-encoding genes. Absent such identification, we hold that the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent.***""
"This conclusion contains a powerful citation from the decision of

the Supreme Court in Brenner. ***In return from his monopoly the patentee must disclose how his invention can be used. A patent is not a hunting licence to find a use for the claimed product. It is a reward for the successful conclusion of the search."***

[7] T0870/04; Chiron vs Murex [1996] RPC 535; T0898/05

[8] T0604/04

[9] This can be held to be a team of people – as evidenced by Lord Hoffmann's comments in paragraph 281:
"Materially, I have accepted in paragraphs [31]-[32] that it is a team including or with access to a bioinformaticist."

[10] T0870/04

[11] T0898/05

[12] T0870/04; T0898/05; T0338/00

[13] T0870/04; T0898/05

[14] T0870/04

[15] This may not be the case where the function of that substance is not known or is incompletely understood.

[16] T0870/04

[17] T0898/05

[18] See, for example, the statements made in paragraphs 100 etc. For convenience, paragraphs 132 to 134 are presented below:
These very long lists are again not supported by any data or in vitro or in vivo studies.
Finally the Patent contains various examples which primarily relate to the expression of Neutrokine-a.
Conclusion as to the teaching of the Patent
Overall, the Patent contains extravagant and sometimes contradictory claims. By way of illustration, it suggests in paragraph [0123] that Neutrokine-a inhibits immune cell function and in paragraph [0143] that antagonists of Neutrokine-a also inhibit immune cell function. There is nothing by way of experimental evidence to support the claims made and I accept Professor Saklatvala's evidence that the idea that Neutrokine-a and antagonists to Neutrokine-a could be used to treat the extraordinary range of diseases identified was fanciful. He found it hard to believe that anyone could seriously suggest on the basis of no experimental data at all that that Neutrokine-a was the answer to so many conditions, from treating cancer to treating worms. In my judgment the skilled person would come to the conclusion that the inventors had no idea as to the activity of Neutrokine-a when drafting the Patent. It teaches the skilled person nothing useful about its activity other than that Neutrokine-a is another member of the TNF ligand superfamily.

[19] At paragraph 53:
"The European Patent Office focuses on the need for an invention to solve a particular technical problem: see for instance AGREVO, Case-T0939/92, paras 2.4 to 2.4.2. So far as the focus was on stents, there was a particular technical problem, clearly highlighted in the "Holy Grail" paper published in 1993. ***The specification, fairly construed, did put forward a taxol-eluting stent as the answer to this problem. But that teaching had to be disentangled from so much extraneous matter that it nearly got lost.***

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