

D YOUNG & CO

PATENT

NEWSLETTER *no.56*

December 2016

In this issue:

Undisclosed disclaimers 03

New Enlarged Board of Appeal referral

Warner Lambert v Actavis 04

Second medical use patent invalid but broad interpretation of Swiss form claims confirmed

Raytheon 06

On-demand instantiation in a high-performance computing system

Supplementary protection certificates 07

Eligibility of a protein-bound drug

Petitioning for “the right to be heard” 08

Additional guidance

Also Hospira v Genentech (Herceptin formulation patents), the patentability of plants in Europe & the USPTO two step test for eligible subject-matter

Patent litigation

Expedited cases and more on numerical limits

Full Story Page 02

STOP PRESS UK Government to ratify Unified Patent Court (UPC) Agreement regardless of Brexit. UK ratification has already been approved by Parliament. UK and German ratification are required as necessary conditions for commencement of the UPC Agreement. The UPC and unitary patent (UP) are back on track to commence during 2017. Read more at www.dyoung.com/upandupc. Email your questions or comments to up@dyoung.com.



With this newsletter we send our best wishes for a joyful and successful 2017 to all our colleagues and clients around the world.

As readers will note from the stop press overleaf, 2016 closes with what may be for some a surprising announcement from the UK Government that it will ratify the Unified Patent Court (UPC) Agreement. We expect the New Year will bring new opportunities and challenges as the UPC and unitary patent (UP) progress to commencement, and on a broader stage, as the UK's plans for Brexit develop. As ever, we offer our assurance that we continue to represent our clients' interests in these complex and sometimes controversial matters.

Finally, news that our latest book 'EPO Board of Appeal Decisions' has published. You can read more about it on page 12 of this newsletter.

Editor:
Anthony Albutt



Events



11 January 2017

IPAN plant science patents, London UK

Aylsa Williams will speak about the evolving field of patenting plants at this Intellectual Property Awareness Network event, hosted by CIPA.

18-20 January 2017

Rothamsted Open Innovation Forum, Harpenden UK

Aylsa Williams and Garreth Duncan will take part in this event promoting collaboration for the development of innovations addressing global food and nutrition security challenges.

www.dyoung.com/events

Subscriptions



subscriptions@dyoung.com
Sign up for our email newsletters.

Read online and view previous issues:
www.dyoung.com/newsletters

Follow us



LinkedIn: dycip.com/dymlinkedin
Twitter: @dyoungip

Litigation

Patent litigation Expedited cases and more on numerical limits

In our October 2016 newsletter we commented on patent litigation in the UK in the light of Brexit. As we noted there, UK patent litigation proceedings have a strong reputation for quality, which will endure, and real efforts are being made to improve costs and efficiency.

Speed and flexibility in the UK

The recent case of Napp Pharmaceutical Holdings Limited v Dr Reddy's Laboratories (UK) Limited and Sandoz Limited [2016] EWCA Civ 1053 highlights two other highly user-friendly aspects of UK patent litigation: speed and flexibility. This case is an excellent illustration of both as it proceeded extremely quickly thanks to active and flexible case management by the courts.

The action was commenced on 19 February 2016, and included an application for a preliminary injunction. The court at first instance, recognising the commercial urgency involved, ordered an expedited trial to be heard in early June, that decision in turn leading to an undertaking by the defendants not to launch a product before determination of the claim (which removed the need for an injunction itself, which can require a substantial application to the court). The first instance court found in favour of the defendants but gave leave to appeal, extending the interim relief (undertaking) pending that appeal. In turn, the Court of Appeal heard the case at the beginning of August, and gave its oral decision (rejecting the appeal) on 02 August 2016. The case therefore went from commencement to final determination on appeal in less than six months. This is a very good illustration of the flexibility and speed with which the UK courts can operate.

Numerical limits revisited

Substantively speaking, the case involved further consideration of the meaning of numerical limits in patent claims. We reported a review of UK case law in our August 2015 newsletter, in particular the case of Smith & Nephew v ConvaTec [2015] EWCA Civ 607. That case reiterated the basic point that, as with all claim limitations, the overriding approach is purposive construction, such that the meaning of the limitation must be derived

from an objective assessment of what the patentee was intending to mean by using it.

In this case, the claim involved numerical limits or ranges of "10%", "10% to 15%" and "about 10%". The defendants had argued that as each limit was expressed in terms of whole numbers, each should be interpreted as including figures that conventionally round to these as the nearest whole number. The patentee on the other hand argued that a broader interpretation should apply *inter alia* because each element was expressed in steps of 5% in the patent itself. The patentee contended that in the claim therefore 10%, for example, could cover amounts up to 15%.

The first instance court had disagreed with this approach, finding for the defendants. The Court of Appeal agreed. The Court of Appeal noted that patent claims were not supposed to be a puzzle game in which the skilled person must theorise as to what degree of precision was intended. A patentee who wanted to cover a range of 7.5% - 12.5%, for example (which the defendant argued would be within the meaning of 10%), could easily have said so expressly in the claim.

On this basis, the Court of Appeal confirmed that the figures in the claims were indeed expressed to the nearest whole number and therefore "10" meant "9.5 - 10.5". The court also agreed with the judge at first instance that the addition of the word "about" merely added a slightly more generous degree of imprecision to the meaning of "10%" than would be allowed with rounding conventions. In this case, "about 10" meant "9 to 11%".

Author:
Richard Willoughby



Useful links

'UK patent litigation in the light of Brexit', Richard Willoughby, October 2016:
www.dyoung.com/article-brexipatentlitigation

Napp Pharmaceutical Holdings Limited v Dr Reddy's Laboratories (UK) Limited and Sandoz Limited [2016] EWCA Civ 1053:
<http://dycip.com/ewcaciv20161053>

Smith & Nephew v ConvaTec [2015] EWCA Civ 607: <http://dycip.com/ewcaciv2015607>

Undisclosed disclaimers

New Enlarged Board of Appeal referral

New questions have been referred to the EPO Enlarged Board of Appeal regarding the allowability of disclaimers. Typically, when a claim is amended to overcome a prior art objection additional features are added to narrow the scope of the claim, ie, a positive limitation is provided. However, in some circumstances this is not possible, and it is necessary to add a negative limitation, a disclaimer, to exclude some subject-matter from the scope of the claim.

Amendments to patent applications must comply with Article 123(2) EPC, specifically they must not contain subject-matter which extends beyond the content of the application as filed. Any amendment must be directly and unambiguously derivable from the application as filed.

How disclaimers are considered in the context of Article 123(2) EPC has previously been reviewed by the Enlarged Board of Appeal in decisions G 1/03 and G 2/10.

Enlarged Board of Appeal decision G 1/03

G 1/03 held that a disclaimer which is not disclosed in the application as filed, referred to as an “undisclosed disclaimer”, may be allowable in certain circumstances, namely in order to:

- a. restore novelty by delimiting a claim against state of the art under Article 54(3) EPC, ie, another European patent application that was filed earlier than, but not published until after, your application
- b. restore novelty by delimiting a claim against an accidental anticipation from a document in an unrelated technical field; and
- c. disclaim subject-matter which, under Articles 52 to 57 EPC, is excluded from patentability for non-technical reasons.

Thus G 1/03 provided some exceptions to the general principle that an amendment must be directly and unambiguously derivable from the application as filed.

T 437/14 concerns EP1933395 relating to phosphorescent organometallic compounds



Enlarged Board of Appeal decision G 2/10

Subsequent decision G 2/10 related to disclaimers, but in this case disclaimers of subject-matter that was originally disclosed in the application as an embodiment of the invention, so-called “disclosed disclaimers”.

In G 2/10 the Enlarged Board held: “An amendment to a claim by the introduction of a disclaimer disclaiming from it subject-matter disclosed in the application as filed infringes Article 123(2) EPC if the subject-matter remaining in the claim after the introduction of the disclaimer is not, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person using common general knowledge, in the application as filed.”

As pointed out in point 4.3 of this decision, this has now become the ‘gold standard’ for assessing any amendment for its compliance with Article 123(2) EPC.

Board of Appeal decision T 437/14

In recent Board of Appeal Decision T 437/14, the Board noted that if the ‘gold standard’ mentioned in G 2/10 is to be applied to any amendment, there is a potential conflict with the allowability of undisclosed disclaimers in accordance with G 1/03. Therefore, the following questions were referred to the Enlarged Board of Appeal:

1. Is the standard referred to in G 2/10 for the allowability of disclosed disclaimers under Article 123(2) EPC, ie, whether the skilled person would, using common general knowledge, regard the subject-matter remaining in the claim after the introduction of the disclaimer as explicitly or implicitly, but directly and unambiguously, disclosed in the application as filed, also to be applied to claims containing undisclosed disclaimers?
2. If the answer to the first question is yes, is G 1/03 set aside as regards the exceptions relating to undisclosed disclaimers defined in its answer 2.1?
3. If the answer to the second question is no, ie, if the exceptions relating to undisclosed disclaimers defined in answer 2.1 of G 1/03 apply in addition to the standard referred to in G 2/10, may this standard be modified in view of these exceptions?

We shall be monitoring the outcome of this case with interest. The possibilities for amendment of European patent applications will be restricted if the Enlarged Board of Appeal decides that undisclosed disclaimers are no longer available.

Author:
Catherine Keetch



Warner Lambert v Actavis

Second medical use patent invalid but broad interpretation of Swiss form claims confirmed

The Court of Appeal has decided the latest instalment of the pregabalin second medical use litigation between Warner-Lambert (part of Pfizer) and Actavis (and other generics manufacturers) in the UK. Readers may recall that this case has featured in our August and October 2015 newsletters, which reported the Court of Appeal's decision on preliminary applications for an interim injunction and a strike-out of part of Warner-Lambert's case, and the substantive decision at First Instance. Readers may also recall a distinct difference of opinion between Lord Justice Floyd in the Court of Appeal and Mr Justice Arnold in the Patents Court as to the meaning and application of Swiss Form claims, as a matter of both direct and indirect infringement.

Background

Pregabalin is sold by Pfizer as Lyrica® for three labelled indications: epilepsy, generalised anxiety disorder and neuropathic pain. The basic patent, which disclosed the epilepsy and anxiety indications, expired in 2013, after which generics manufacturers prepared to launch generic pregabalin with a 'skinny label' omitting the neuropathic pain indication which is the subject of the patent below. Some also took further steps to inform pharmacists and health professionals that the drug was not to be prescribed for the treatment of pain.

The claimed invention

The patent in suit, EP 0 934 061 (as centrally limited at the European Patent Office - EPO), was directed to pregabalin for the treatment of pain. Two claims were alleged to be infringed, claims 1 and 3. Claim 1 was a Swiss form claim to the "use of [pregabalin] for the preparation of a pharmaceutical composition for treating pain". Claim 3 was limited to treating neuropathic pain.

The issues in the case

There were three principal issues in the case: validity (in particular, insufficiency); amendment; and infringement. The Court of Appeal upheld Arnold J on the first two issues, but disagreed with him (as it had at the interim stage) on the third.

Insufficiency

The insufficiency attack centred on whether

Pregabalin is sold for epilepsy, generalised anxiety disorder and neuropathic pain



the animal tests disclosed in the patent in suit were sufficient to render it plausible that pregabalin would work (a) for the treatment of pain generally (claim 1) and (b) for all kinds of neuropathic pain (claim 3).

The requirement that the application as filed makes the invention 'plausible' has been raised before both the EPO and national courts under the headings of insufficiency, inventive step and industrial applicability. Generally, the plausibility requirement is aimed at preventing speculative claiming and avoiding the grant of a monopoly over a field of endeavour in which the inventor has made no contribution.

The Court of Appeal confirmed that the plausibility requirement for the purposes of sufficiency is not the same as that for inventive step: for the purposes of sufficiency, the specification did not have to provide

enough information that rendered the claimed invention "obvious to try with a reasonable expectation of success", which concerns inventive step. On the contrary, plausible speculation that fell short of providing any such expectation of success would be enough for sufficiency. It is a low threshold test: the claim will not be seen as speculative when the inventor provides a reasonably credible theory as to why the invention will or might work. Data can be produced later either to support or rebut plausibility, although the court made it clear that such data could not be filed in order to establish plausibility itself. The specification itself must do that much.

Equally however, the Court of Appeal confirmed that plausibility must be established across the breadth of the claim. On the evidence, the animal tests related to inflammatory pain and could also support a claim to peripheral

➤ **Case details at a glance**
Jurisdiction: England & Wales
Court: Court of Appeal (Civil Division)
Parties: Warner-Lambert Company LLC (appellant) and Generics (UK) Limited (trading as Mylan), Actavis Group PTC EHF, Actavis UK Limited and Caduceus Pharma Limited (respondents) and the Secretary of State for Health (intervener).
Citation: [2016] EWCA Civ 1006
Date: 13 October 2016
Full decision: <http://dycip.com/ewcaciv20161006>

neuropathic pain, but there was no unifying characteristic for all of the types of pain that were claimed and/or for which the animal studies provided plausible support. Accordingly, only the claims for which the animal models provided a plausible model were sufficient.

This was essentially the end of the matter as regards claim 1 (treatment of pain generally) but not claim 3, which as noted above was to neuropathic pain. On this issue, two kinds of neuropathic pain were relevant – central and peripheral. The expert evidence was such that while the animal models were good enough to support a claim to the treatment of peripheral neuropathic pain, the same could not be said of central neuropathic pain. Warner-Lambert therefore sought to argue that the claim as properly construed was limited to peripheral neuropathic pain, an argument rejected by both the Patents Court and the Court of Appeal.

Accordingly, the Court of Appeal upheld the judge's finding of insufficiency of both claims 1 and 3. The court ruled that the fact that pregabalin had subsequently been authorised for central neuropathic pain could not justify a claim that was speculative when it was made.

Amendment

At first instance, having lost on sufficiency of claim 3 and seeing in the judgment that a claim limited to peripheral neuropathic pain would have been sufficient, Warner-Lambert sought a post-judgment amendment to make this limitation. There is a consistent line of authority in the UK that post-judgment amendments are permissible to the extent they delete invalid claims, but not where they involve re-writing existing claims. The reasoning is simple – such an amendment should be brought early enough in the case to allow all issues relating to it, including inventive step, novelty and allowability, to be addressed. Inventive step and novelty in particular have to be considered at trial because expert evidence may well be required. The UK courts will not allow amendments that would require a second trial.

Warner-Lambert argued that because the sufficiency of a claim limited to peripheral neuropathic pain had been decided by the judge the amendment should be

allowed. They further argued that Actavis's case on sufficiency had not been made clear until late in the proceedings, and they had been prejudiced as a result.

The judge had rejected these arguments, and he was upheld by the Court of Appeal. At trial, Warner-Lambert had clearly argued the point as a matter of claim construction. Accordingly they had been sufficiently aware of the issue. A conditional amendment could have been sought at the commencement of the trial if desired, to cover the situation that their construction was wrong, but it wasn't. Further, while sufficiency may have been addressed at trial, this did not mean that other aspects had been. In particular, the court noted that Actavis's approach on inventive step may have differed if faced with the proposed amended claim.

In the light of this and previous case law (Nikken v Pioneer [2005] and Nokia v IPCOM [2011]), the Court of Appeal upheld the judge's refusal to allow a post-judgment amendment, as an abuse of process.

Infringement of Second Medical Use Claims (Swiss Form)

As the claims that were alleged to be infringed had been found invalid, it was not necessary for the Court of Appeal to render a decision on infringement. However, in light of the difference of opinion between Arnold J and the Court of Appeal on both direct and indirect infringement, Floyd LJ took the opportunity to reiterate his views.

On direct infringement, Floyd LJ repeated his view that the words "for the treatment of..." in Swiss form claims imported an objective intention as to the ultimate use of the medicament, rejecting once again the 'subjective intention' test of the lower court. Accordingly, where a manufacturer knows or can reasonably foresee that the medicament will be used for the patented use, there is *prima facie* infringement. That intention can be negated where the manufacturer takes all reasonable steps within his power to prevent that use. The court did not give guidance on what "all reasonable steps within his power" might entail but the message seems to be clear enough: reliance on a 'skinny label'

alone will not be enough and positive steps must be taken to try prevent the drug from being used for the patented process.

As for indirect infringement, a cause of action rejected by Arnold J as essentially unarguable, Floyd LJ explained his view as previously expressed at the interim stage. Arnold J had decided that because there was no downstream act of manufacture and bearing in mind Swiss-form claims are process claims, there could be no supply of means relating to that invention by the upstream manufacturer. Floyd LJ noted instead however that "preparation" for the purposes of a Swiss-form claim can include a packaging step and/or a labelling step, the latter potentially being carried out by a (downstream) pharmacist. Accordingly, the supply by the original manufacturer could fall within the indirect infringement provisions of the Patents Act 1977.

Conclusion

This judgment leaves four clear points to bear in mind.

1. While the test of plausibility for sufficiency is not the same as for inventive step, the patent itself must contain sufficient information to make the claimed invention plausible across its breadth: if it does not, later-generated data may not remedy this defect.
2. Re-writing amendments post judgment is unlikely to be possible in the UK: always consider a conditional amendment before trial if arguing a crucial point of claim construction.
3. The relevant intention for direct infringement of second medical use claims is an objective one, viewed from the point of the manufacturer.
4. Swiss form claims can be infringed indirectly based on downstream preparatory steps.

Authors:

Garreth Duncan & Richard Willoughby 

Useful links

Nikken v Pioneer [2005] full decision:
<http://dycip.com/nikkenvpioneer>

Nokia v IPCOM [2011] full decision:
<http://dycip.com/nokaviipcom>

Raytheon

On-demand instantiation in a high-performance computing system

On the 22 June 2016 the Technical Board of Appeal issued its decision (T 1742/12) regarding an appeal concerning the selection of closest prior art when it is ambiguous as to which document is closest to the claimed arrangement.

In this case, the appellant (Raytheon) had filed an application which was rejected by the examining division for lack of inventiveness with respect to D1.

Raytheon appealed against the decision of the examining division on the grounds that the document selected as the closest prior art was inappropriate, as it was not intended for the same purpose as the claimed system.

Raytheon cited several earlier decisions in support of their appeal (including T 254/86 and T 606/89) which each suggested that D1 would not be allowable as the closest prior art.

Raytheon also noted that decisions, such as T 21/08, have come to differing conclusions as to whether D1 would be allowable as the closest prior art, and in view of this discrepancy requested that questions be referred to the Enlarged Board of Appeal; this request was refused by the Board of Appeal.

The Board of Appeal found that the approaches of T 21/08 and T 967/97 were correct in finding that if the skilled person had a choice of several workable routes which might lead to the invention (ie, if several different documents could reasonably be used as a basis for assessing inventiveness), then the problem-solution approach should be assessed with respect to each of these routes. Several further decisions were cited that also supported this reasoning, and as such it was considered that the findings of T 967/97 and T 21/08 were not isolated outcomes as was suggested by the appellant.

While the Board of Appeal did agree that

This application generally related to high performance computing (HPC) systems



the intended purpose of an invention (both of the claimed invention and a cited prior art document) is relevant when assessing inventive step, a difference between the purposes of the two documents does not preclude the use of the prior art in assessing the inventiveness of the claimed invention; that is, unless the difference is so large that it is inconceivable that the skilled person would consider modifying the earlier arrangement to arrive at the claimed arrangement.

The Board of Appeal instead found that it was only necessary to determine whether it would be obvious to modify the prior art to provide the features of the claimed arrangement; the closest prior art should be considered to be the disclosure from which it would be most obvious to derive the claimed arrangement, not necessarily the one that has the most similar intended use.

The Board of Appeal further stated that that an inventive step objection does not become invalid simply because another document has been established as the closest prior art; this is clearly unreasonable, and could lead to situations in which the person skilled in the art could be disadvantaged by having a greater knowledge of existing arrangements. Therefore

the introduction of a new document, D6, which was suggested as the closest prior art by the appellant is not taken to be prejudicial to the inventive step argument based upon D1.

In the appeal it was held that D1 was a suitable document upon which to base an inventive step argument, and that D1 rendered the independent claims of each of the main and first three auxiliary requests invalid for a lack of inventiveness. The application was referred back to the examining division for further processing on the basis of the fourth auxiliary request.

Summary

The Technical Board of Appeal found that when the selection of the closest prior art is not clear-cut, and the skilled person has several routes by which they could derive the invention starting from different documents, inventive step should be assessed with respect to each of these documents. If any of the routes are deemed to be obvious, then the claims should be rejected for a lack of inventive step regardless of which document is initially identified as the closest prior art.

Author:
Ryan Lacey



Supplementary protection certificates

Eligibility of a protein-bound drug

➤ Case details at a glance
Decision level: UKIPO
Applicant: Abraxis BioScience LLC
Citation: BL O/410/16
Date: 26 August 2016
Full decision: <http://dycip.com/bl041016>

Supplementary protection certificates (SPCs) are available in Europe to extend the effective protection available to eligible products. To qualify, a product must be covered by a basic patent; must not be the subject of an earlier SPC; and must have been granted the first authorisation to place it on the market as a medicinal product (Article 3 of the SPC Regulation).

Background

An SPC application was filed for albumin-bound paclitaxel nanoparticles (nab-paclitaxel). The SPC Regulation defines a product as “the active ingredient or combination of active ingredients of a medicinal product” (Article 1(b) of the SPC Regulation). However, the examiner objected that the only active ingredient in nab-paclitaxel is paclitaxel, an established anti-cancer drug with earlier marketing authorisations (eg, for Taxol®). Therefore, the marketing authorisation for nab-paclitaxel was not considered the first authorisation for the product. Consequently, it was held that the application did not comply with the SPC Regulation.

The applicant objected that nab-paclitaxel is a single active ingredient, and therefore eligible for SPC protection. In response, the examiner offered a hearing, and set out two questions:

1. Does nab-paclitaxel constitute a new active ingredient?
2. If not, should an SPC nonetheless be granted in light of Neurim Pharmaceuticals v Comptroller General of Patents C-130/11 [2009] (Neurim)?

Purpose of the SPC Regulation

Pharmaceutical research is often the subject of regulatory delays and significant financial costs. On account of this, the SPC Regulation intends to provide further protection to compensate the time and money invested in drug development.

The applicant argued that an SPC for nab-paclitaxel met the purpose of the SPC Regulation, and that the case was analogous to Generics UK Ltd v Daiichi Pharmaceutical Co Ltd EWCA Civ 646 [2009] (Daiichi). In Daiichi, an SPC was granted for a single enantiomer of a racemic antibiotic with earlier

marketing authorisations, because it was considered inventive over the racemate.

Despite similar circumstances, the hearing officer found that the facts of the cases were not comparable. Daiichi concerned two different forms of a single molecule, whereas nab-paclitaxel comprised two different molecules. Nevertheless, the hearing officer agreed that obtaining an SPC for nab-paclitaxel case may not be inconsistent with the purpose of the SPC Regulation, and proceeded to consider the examiner’s questions.

A new active ingredient?

To answer the examiner’s first question, the hearing officer initially considered the activity of nab-paclitaxel at the cellular level.

Based on evidence supplied by the applicant, the hearing officer accepted that nab-paclitaxel is more effective than paclitaxel for the treatment of some tumours. The hearing officer also accepted that nab-paclitaxel is more effective at crossing cell membranes, and that it is transported as a single unit.

However, the hearing officer required a closer inspection of nab-paclitaxel’s activity. At the molecular level, the hearing officer held that nab-paclitaxel is not a single “active ingredient”. Instead, nab-paclitaxel is made up of two distinct components - paclitaxel and albumin.

Accordingly, the hearing officer considered whether nab-paclitaxel might be eligible as a “combination of active ingredients”. The hearing officer held that, although nab-paclitaxel had improved efficacy over paclitaxel, the albumin component merely behaves as a carrier, and does not have its own therapeutic effect.

In Massachusetts Institute of Technology C-431/04 [2006] (MIT), the CJEU decided that a “combination of active ingredients” does not include combinations of substances where only one has its own therapeutic effects.

The applicant argued that the facts in the cases were different, because the MIT excipient breaks down and does not enhance the active ingredient’s efficacy in vitro, whereas nab-paclitaxel enters the cell as a single unit.

However, in MIT, the CJEU had acknowledged that excipients may influence the efficacy of an active substance. The hearing officer understood from this that carriers that enhance an active ingredient’s efficacy cannot themselves be considered “active ingredients” unless they have therapeutic activity alone. With this in mind, the hearing officer determined that MIT was applicable, and that nab-paclitaxel is not a “combination of active ingredients”.

Should an SPC be granted in light of Neurim?

The applicant submitted that nab-paclitaxel is a new application of paclitaxel, and is consequently entitled to SPC protection following Neurim (reviewed in our July 2012 newsletter). However, the hearing officer held that the new application must be a new therapeutic application for Neurim to apply. Nab-paclitaxel did not have a different therapeutic application to paclitaxel. As such, the hearing officer did not consider Neurim to affect the SPC eligibility of nab-paclitaxel. As a result, nab-paclitaxel was not considered to be a new product under the SPC Regulation. Therefore, the marketing authorisation for nab-paclitaxel was not considered the first authorisation for the product.

Consequently, the SPC application was refused.

The applicant lodged an appeal on 13 September 2016. We will keep you informed of developments in this matter.

Author:
Laura Jennings



Useful links

‘Sheep don’t follow authorization – CJEU decides on Neurim SPC application, Garreth Duncan, 24 July 2012: www.dyoung.com/article-neurimspc0712

Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents, C-130/11): <http://dycip.com/c-13011>

Generics UK Ltd v Daiichi Pharmaceutical Co Ltd and Daiichi Sankyo Co Ltd, EWCA Civ 646 [2009]: <http://dycip.com/ewcavic6462009>
Massachusetts Institute of Technology C-431/04 [2006]: <http://dycip.com/c-43104>

Petitioning for “the right to be heard” Additional guidance

Decisions of the European Patent Office (EPO) may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments (Article 113(1) EPC). As discussed below, decision R2/14 provides further guidance on when parties to an appeal may have a case for asserting that there has been a violation of their ‘right to be heard’ and requesting the case to be re-opened.

Case law has established that the right to be heard according to Article 113(1) EPC is an important procedural right intended to ensure that no party is caught unaware by grounds and evidence in a decision turning down the request on which that party has not had the opportunity to comment (R 3/10). It is well established case law that this requirement includes the party’s right to have relevant submissions and arguments considered and fully taken into account in the written decision in a manner that enables the party to understand, on an objective basis, the reasons for the decision (R 19/10, R 23/10, R 8/11, R 17/11, R 15/12, R 13/12 and R 19/12).

Any party to appeal proceedings adversely affected by the decision of the Board of Appeal may file a petition for review of the decision by the Enlarged Board of Appeal (Article 112a(1) EPC). One of the grounds for the petition is that a fundamental violation of the right to be heard under Article 113 EPC occurred.

In R2/14 the proprietor filed a petition against the written decision of the Board of Appeals (T 1627/09) asserting that the decision was not reasoned and that the right to be heard had been violated.

Background to R 2/14

Claim 1 of the Main Request and the Auxiliary Request in T 1627/09 concern a purified protein having desaturase activity in which the claim contained a mistake in the sequence such that the protein does not have the required desaturase activity.

At first instance, the EPO Opposition Division revoked the patent essentially for non-compliance with enablement requirements

(Articles 83 and 100(b) EPC). In brief, the reasoning behind this decision was that there was an undue burden on the skilled person to identify which variants (falling under the “at least 60% identity” language in the claims) had desaturase activity.

The proprietor appealed the decision. In the appeal, the proprietor argued that the opponent had not discharged the burden of proof and there was no undue burden of proof on the skilled person. In the written proceedings leading up to the oral proceedings, the opponent commented in detail on this point. The matter was discussed at oral proceedings.

In its written decision, the Board of Appeal acknowledged that the skilled person could have carried out each of the steps for recloning the gene in isolation but asserted that it is the **combination** of necessary steps which creates an undue burden on the skilled person.

The proprietor then filed a petition in which two complaints against the decision were raised:

- i. the Appeal Board had not explained in the written decision why it did not accept the proprietor’s arguments; and
- ii. the Appeal Board’s written decision was based on facts and arguments that had not been heard and it had not reasoned its conclusion.

Decision of the Enlarged Board of Appeal

The first complaint

During the appeal process, the proprietor had referred to a specific document to support the assertion that the claims are enabled. This document is not referred to in the Board of Appeal decision. The Enlarged Board of Appeal noted that the teachings in the document did not go beyond what had been disclosed in the patent and the document had merely been used by the proprietor to support factual and legal arguments.

The Enlarged Board of Appeal held that a separate discussion of a document does not necessarily indicate that the Appeal Board had not taken it into account. The Enlarged Board of Appeal held that based on the first complaint by

itself, the right to be heard had **not** been violated.

The second complaint

The Enlarged Board of Appeal noted that the Appeal Board did not mention explicitly or implicitly in the written decision the facts or the sequence of arguments which led it to arrive at the conclusion that the combination of required steps imposed an undue burden on the skilled person.

The Enlarged Board of Appeal held that it has to assume that a violation of the right to be heard under Article 113(1) EPC has occurred if:

- it cannot establish the reasons for the decision are based on facts and considerations on which both parties to the appeal proceedings had an opportunity to comment; or,
- in the event that the parties had been given an opportunity to comment, it cannot establish that the parties’ relevant submissions and arguments were considered and fully taken into account when taking the decision.

In R 2/14, the Enlarged Board of Appeal held that the petition was allowable and the decision under review should be set aside and proceedings before the Appeal Board re-opened.

Practical points for parties to an appeal

Petitions for review by the Enlarged Board of Appeal are confined to procedural defects. Substantive matters (eg, novelty, inventive step or enablement) leading to the Board of Appeal decision are **not** reviewed by the Enlarged Board of Appeal. The Enlarged Board of Appeal needs to set a decision aside before substantive matters will be reviewed by the Board of Appeal.

If you receive a written decision from a Board of Appeal which contains reasons that you did **not** have the chance to comment on **or** your submissions were **not** considered and taken into account, then you could file a petition to the Enlarged Board of Appeal that your right to be heard has been violated. If the petition is successful, the decision will be set aside and the case will be re-opened.

Author:
Stephanie Wroe



Hospira v Genentech Herceptin formulation patents still obvious

➤ Case details at a glance

Decision level: Court of Appeal (Civil Division)

Jurisdiction: England and Wales

Parties: Hospira UK Limited (claimant/
respondent) and Genentech, Inc
(Defendant/Appellant)

Citation: [2016] EWCA Civ 780

Date: 12 & 13 July 2016

Full decision: <http://dycip.com/2016ewcaciv780>

In July this year, the Court of Appeal handed down a decision in *Hospira v Genentech* [2016] EWCA Civ 780 which upheld the decision by Birss J in November 2014 to revoke the two Herceptin formulation patents for obviousness and added matter.

Herceptin and trastuzumab

Herceptin is an important breast cancer drug and contains a monoclonal antibody active ingredient known as trastuzumab. At the priority date there were two general approaches to formulating antibodies such as trastuzumab: one was to produce a ready-to-use liquid formulation and the other was to produce a lyophilized (freeze-dried) formulation which can be made up into a sterile solution for use.

The two patents filed by Genentech were EP 1 516 628B and EP 2 275 119B. Both concerned lyophilised formulations of trastuzumab and were essentially based on choosing certain excipients for the formulation. The excipients chosen were trehalose as the lyoprotectant, histidine as the buffer, and polysorbate 20 as the surfactant.

Decision at first instance

At first instance Birss J found that both patents were obvious over a pair of documents (Carter) which disclosed that trastuzumab was in phase II clinical trials for breast cancer as a liquid formulation. Birss J held that a skilled team of a clinician and a formulator reading Carter in light of their common general knowledge (CGK) would have been motivated to produce a lyophilized version of trastuzumab, and the claimed formulation was simply the result of a necessary and routine screening programme to find a satisfactory combination of excipients. Histidine was an obvious buffer candidate for the pH range at which trastuzumab was most stable, and polysorbate 20 was an obvious surfactant candidate. For the lyoprotectant, Birss J held that trehalose would have been on a list of possible candidates and any concerns about toxicity and regulatory approval did not make testing trehalose inventive.

Herceptin is a breast cancer drug containing antibody formulation trastuzumab



Hospira v Genentech on appeal

On appeal Genentech's main argument was that Birss J had erred in principle to accept Hospira's case that the claimed invention was obvious because it could be reached by the application of routine approaches using CGK. Genentech argued that formulating proteins was difficult and unpredictable, that there were no pointers in the CGK or prior art to the claimed formulation and that the formulation had a beneficial effect in terms of stability. There was nothing to provide the skilled person with the necessary fair expectation of success.

Genentech also submitted that the judge had misapplied the distinction between "would" and "could" and with reference to EPO jurisprudence, argued that the possible inclusion of something in a programme for testing in order to see if it works but without any expectation of success did not establish obviousness.

In the lead judgement by Floyd LJ, however, the appeal was dismissed.

Floyd LJ agreed that the skilled team knew that lyophilised formulations of proteins had been successfully made before, and that the three types of excipient (buffer, surfactant and lyoprotectant) were all part of the formulator's common general knowledge and

were being used for their known purposes. There was nothing inventive in the screening approach and no evidence that trastuzumab presented any special formulating problems.

In dismissing the appeal Floyd LJ also considered the "could-would" argument put forward by Genentech. Floyd LJ noted that there was no need to establish "**in every case that the skilled person would necessarily have arrived at the precise combination claimed. The skilled person may be faced with a range of obvious possibilities, making it statistically unlikely that he will settle on any one of them. They will all be obvious**".

In this case, the screening methods were part of the CGK, the tests involved were routine, the excipients were CGK and there was no *a priori* reason why a successful lyophilised formulation could not be made. Floyd LJ held that the team may have had a reasonable degree of confidence that the screening methods would produce a formulation that will work but to require them to be able to predict in advance which would be the successful combination is **wholly unrealistic**. There was no invention in embarking on a screening process to pick out the "good from the bad".

Author:
Rachel Bateman

The patentability of plants in Europe Interpreting the Biotech Directive

In March 2015, the Enlarged Board of Appeal at the European Patent Office (EPO) decided in G 2/12 (Broccoli II) and G 2/13 (Tomatoes II) that the exclusion to patentability of essentially biological processes (Art. 53(b) EPC) must be interpreted narrowly and thus the exclusion did **not** extend to the patentability of any products resulting from such processes *per se*.

This decision was intended to provide legal certainty for would-be proprietors of such technologies. However, the fact that this opened the possibility for the protection of plants obtained by classical breeding and selection under both patents and the separate rights conferred by Plant Variety Rights (PVRs) has led to much speculation about its potential impact on the plant breeding industry as a whole. In particular, while PVRs are specific to protecting a new variety, the infringement of these rights are limited by what is known as a 'breeders' exemption' (where a plant breeder would not infringe a PVR if the activity is for the creation of a new variety). Such an exemption does not exist in many national laws relating to patents.

On December 2015, the European Parliament adopted a resolution¹ for the European Commission to clarify the interpretation of what is commonly known as the 'Biotech Directive'² as regard the scope of the exclusion to essentially biological processes (Art. 4) and access to biological materials (Art. 12 and 13). It should be noted that while the EPO acts independently from the EU, the Biotech Directive is incorporated into the implementing regulations of the European Patent Convention (EPC)³.

The Commission notice

On 08 November 2016, the European Commission issued its comments on the Biotech Directive⁴. In a document longer than the Directive itself, it concluded *inter alia* the exclusion under Art. 4 to essentially biological processes (the wording of which is mirrored in Art. 53(b) EPC)⁵ intended to include within its scope products resulting from those processes. Under this interpretation, plants formed from classical breeding and selection would not be patentable in Europe. The Commission in particular focussed on the

A plant breeder will not infringe a PVR if the activity is for the creation of a new variety



legislative history and evolution of what is now Art. 4 of the Directive from its first proposal in 1995, which did include a reference to plants produced by essentially biological processes.

Of interest, the relationship to Art. 3 of the Directive also drew a divergent opinion, compared to that of the EPO in G 2/12. The EPO focussed on Art. 3(1), which essentially allows the patentability of biological products provided they meet the basic requirements of patentability; in the Board's opinion, this necessarily limited the scope of exclusion under Art. 53(b) EPC. The Commission referred instead to Art. 3(2), which specifically recited the patentability of biological material "produced by a technical process", stating that an essentially biological process could not be a technical one.

Divided opinions

It should be noted that dissent against the EPO decisions of March 2015 is not new. France, as recently as 08 August 2016, adopted an amendment to its code de la propriété intellectuelle (CPI) to specifically exclude products obtained by essentially biological processes⁶. This follows the legal provisions already present in both Germany⁷ and the Netherlands⁸. Thus, it was already questionable if validated European patents directed towards plants produced by crossing and selection (ie, an essentially biological process) would be valid in these countries.

The Chartered Institute of Patent Attorneys (CIPA) in the UK also expressed its opinion in a position paper of July 2016. In particular, it focussed on the fact that legislation which would have come into effect upon introduction of the Unified Patent Court Agreement (UPCA) would have provided a breeders' exemption in UPCA-contracting states⁹. Thus, as far as Intellectual Property Rights would still allow breeders to carry on their activity, it was perceived that the UPCA would at least

Notes

1. European Parliament resolution of 17 December 2015 on patents and plant breeders' rights (2015/2981(RSP))
2. Directive 98/44/EC
3. Rule 26(1) EPC; OJ EPO 1999, 101
4. Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (2016/C 411/03)
5. G 2/12, Reason VII.4(3)
6. L. 611-19 CPI
7. § 2a Patentgesetz
8. Art. 3 Dutch Patent Act
9. Art. 27(c)

introduce a degree of harmonisation within the European Patent system. In this regard, CIPA saw no reason to alter the present legislation or the precedence set by G 2/12 and G 2/13.

Following the result of the EU Referendum in the UK, there has been a substantial delay in ratification of the UPCA. This would appear to place a higher short-term importance on national laws and how they deal with the conflicting opinions of the EU and the EPO. Time will tell if other EPC-contracting states will follow France and introduce its own exclusion to products derived from biological processes.

As far as the EPO itself is concerned, given that G 2/12 and G 2/13 were decided primarily upon the Enlarged Board's interpretation of the EPC, there is arguably no reason for it to change its tone in light of the Commission's notice – Art. 164(2) EPC provides that the EPC prevails in case of any conflict with its implementing regulations (which includes the Biotech Directive).

If access to plant breeding material is the primary concern, providing a plant breeders' exemption in national laws appears to be a much more convenient solution than casting doubt on the legal fiction of exclusions to patentability. Indeed, it was the UK's intention to directly implement the breeders' exemption once the UPCA came into force. Perhaps linked to the debate over the patentability of plants are the somewhat arduous requirements to obtain a compulsory licence under Art. 12 of the Directive, which the Commission has also noted to merit further analysis.

It remains to be seen how this area develops, and whether the EU will begin the torturous process of amending the Biotech Directive.

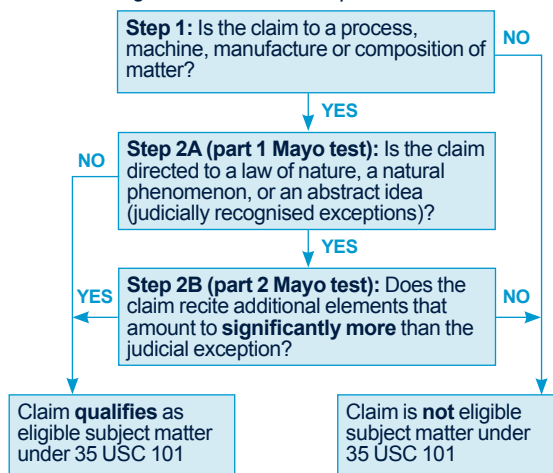
Authors:

Aylsa Williams & Feng Rao



Eligible subject-matter USPTO two-step test

➤ Figure 1: USPTO two-step test



Under US patent practice, laws of nature, natural phenomena and abstract ideas are not patentable. In recent years, several key decisions by the US Supreme Court (namely: Mayo, Myriad and Alice) have led to the development of a ‘two-step eligibility test’ by the USPTO and a toughening of what will be considered patent eligible subject-matter under US patent law (35 USC §101).

In brief, the Mayo case concerned a method for optimising the therapeutic efficacy of a specific drug; it was held that the level of the drug and its efficacy was a natural law and that the steps in the method were not sufficient to transform the claim as they described routine, conventional activity. The Myriad case concerned the identification of BRCA genes associated with an increased risk of breast cancer; it was held that the isolated sequences encoding a naturally-occurring gene were not patent eligible - in effect, this case reversed the USPTO’s previous practice of allowing patents to naturally isolated substances as long as they were ‘isolated’ from nature and met with patentability requirements. In the Alice case it was held that claims directed to a computer-implemented electronic servicer for facilitating financial transactions were an abstract idea and ineligible for patent protection.

Based on these cases, the two-step eligibility test has been developed by the USPTO (see figure 1). If a claim is considered to be directed to a law of nature, a natural phenomenon or an abstract idea then the examiner must consider if the additional elements in the claim amount to **significantly more** than the exception. If an additional element (or combination of elements) is **not** routine or conventional in the field then it should be considered as ‘significantly more’ and, thus, the claim is directed to patent eligible subject-matter.

The USPTO has issued guidelines together with examples of what falls within and outside this test. Most recently, in May 2016 the USPTO issued long-awaited examples for diagnostic methods.

Referrals to the US Supreme Court

The case of Ariosa Diagnostics, Inc v, Sequenom, Inc concerned a diagnostic test to measure cell-free foetal DNA (cffDNA)

in maternal plasma and serum. This test allows for prenatal diagnosis of foetal DNA without sampling from the foetus or placenta thus avoiding risks such as miscarriage. This test was considered to be a significant scientific breakthrough. However, the Federal Court upheld the patent to be ineligible because cffDNA is a natural phenomenon and the methods used to test for it do not themselves represent anything beyond routine, conventional steps. Notably, Circuit Judge Linn in his concurring opinion stated that: “The new use of the previously discarded maternal plasma to achieve such an advantageous results is deserving of patent protection. . . . But for the sweeping language in the Supreme Court’s Mayo opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible”. Many commentators felt that this comment would lead to a review of the case and the two-step eligibility test by the Supreme Court. Disappointingly, the US Supreme Court declined to accept the case for review.

Four further patent eligibility cases (Genetic Tech, Jericho, Associate and Trading Technologies) were recently put before the US Supreme Court for consideration. Disappointingly, in October 2016 the US Supreme Court announced that it would not review any of these cases.

Some clarification of the two-step eligibility test

Rapid Litigation Management Ltd v, CellzDirect Inc is one case in the life sciences field which has provided some clarification with regard to the two-step eligibility test.

The claims in this case concerned methods of producing multi-cryopreserved hepatocytes. The District Court had held that the discovery that hepatocyte cells were capable of surviving multiple freeze-thawing cycles was patent ineligible subject-matter because it is a law of nature and that the inventors had simply reapplied a well-understood freezing process.

The Federal Court held that “[t]he inventors certainly discovered the cells’ ability to survive multiple freeze-thaw cycles, but that is not where they stopped, nor is it what they patented. . . . They employed their natural

discovery to create a new and improved way of preserving hepatocyte cells for later use”.

The Federal Court looked at the two-step eligibility test and held that at step 1 it is not enough to merely identify a patent-ineligible concept underlying the claim; it must be determined whether that patent ineligible concept is what the claim is directed to.

Further at step 2, if it **improves** an existing technological process then it is sufficient to **transform** the process into an inventive application of the patent-ineligible concept. Under step 2, the elements must be viewed “**both individually**” and “**as an ordered combination**”. A new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made. The Federal Court also pointed out that patent eligibility does not turn on the ease of execution or obviousness of the application – these questions are examined under separate provisions.

The impact

The USPTO issued a memorandum in July 2016 confirming that neither Rapid Litigation Management Ltd v, CellzDirect Inc nor Ariosa Diagnostics, Inc v, Sequenom, Inc altered the subject-matter eligibility guidance.

Under the guidance recently issued in May and November 2016, the USPTO confirmed that the two-step eligibility test is to be used.

Examiners must, nevertheless, support a rejection with reasoned rationale and identify any elements beyond the patent ineligible subject-matter and explain why the additional elements taken individually and as a combination do not result in the claim as a whole amounting to more than the judicial exception. Examiners should not require applicants to model their responses and claims to an allowable example of patent eligible subject-matter in the guidance. Nevertheless, when faced with such an objection, applicants may find it useful to point out how their case is similar to such an example. The recent November memorandum from the USPTO... *[continued overleaf]*

D YOUNG & CO INTELLECTUAL PROPERTY

And finally...

Eligible subject-matter USPTO two-step test

[continued from page 11]...

cautions examiners to not use non-precedential decisions unless the application uniquely matches the facts at issue in the decision and, thus, the memorandum may be useful in overcoming rejections of claims which are only tenuously similar to non-precedential decisions; the USPTO's website concerning subject-matter eligibility indicates whether or not a decision is precedential. This recent memorandum alludes to a forthcoming update to the subject-matter eligibility guidance.

Conclusions

- Expect the USPTO to issue further guidelines.

- The US Supreme Court seems satisfied with how subject-matter eligibility is being dealt with by the lower courts. Therefore it may be some time before the US Supreme Court takes on any 'patent ineligible' case for review and issues further guidance.
- It remains a tough environment for applicants who find themselves facing an eligible subject-matter objection from the USPTO and it seems that this will be the case for some time yet.

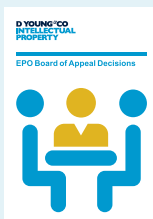
Author:

Stephanie Wroe



EPO Board of Appeal Decisions D Young & Co publishes synopsis of important EPO decisions

We are pleased to announce the publication of our EPO Board of Appeal Decisions book. The decisions, which have been selected on the basis of many years of experience in arguing cases before the European Patent Office, are often cited or relied upon by the EPO or parties to opposition or appeal proceedings. The case extracts



provide a flavour of some of the legal principals adopted by the EPO when considering patent matters and have a general applicability for those practicing patent law.

For further information please see www.dyoung.com/news-epodecisionsbook.

Contact details

London
Munich
Southampton

T +44 (0)20 7269 8550
F +44 (0)20 7269 8555

mail@dyoung.com
www.dyoung.com

This newsletter is intended as general information only and is not legal or other professional advice. This newsletter does not take into account individual circumstances and may not reflect recent changes in the law. For advice in relation to any specific situation, please contact your usual D Young & Co advisor.

D Young & Co LLP is a limited liability partnership and is registered in England and Wales with registered number OC352154. A list of members of the LLP is displayed at our registered office. Our registered office is at 120 Holborn, London, EC1N 2DY. D Young & Co LLP is regulated by the Intellectual Property Regulation Board.

Copyright 2016 D Young & Co LLP. All rights reserved. 'D Young & Co', 'D Young & Co Intellectual Property' and the D Young & Co logo are registered trade marks of D Young & Co LLP.

Contributors

Partner, Patent Attorney
Editor

Anthony Albutt
aja@dyoung.com
www.dyoung.com/anthonyalbutt



Partner, Patent Attorney
Aylsa Williams

aaw@dyoung.com
www.dyoung.com/aylsawilliams



Partner, Patent Attorney
Garreth Duncan

gad@dyoung.com
www.dyoung.com/garrethduncan



Partner, Solicitor
Richard Willoughby

rww@dyoung.com
www.dyoung.com/richardwilloughby



Associate, Patent Attorney

Stephanie Wroe
sfw@dyoung.com
www.dyoung.com/stephaniewroe



Associate, Patent Attorney

Rachel Bateman
reb@dyoung.com
www.dyoung.com/rachelbateman



Associate, Patent Attorney

Catherine Keetch
cak@dyoung.com
www.dyoung.com/catherinekeetch



Technical Assistant

Laura Jennings
lej@dyoung.com
www.dyoung.com/laurajennings



Technical Assistant

Feng Rao
fxr@dyoung.com
www.dyoung.com/fengrao



Technical Assistant

Ryan Lacey
rjl@dyoung.com
www.dyoung.com/ryanlacey

