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Editorial

Here in the UK the weather has been the main diversion from Brexit negotiations. Issues relating to SPCs appear to be the hot topic for our attorneys and just as we go to press the CJEU has issued its decision in Teva v Gilead which has failed (again) to provide clarity to "protected by a basic patent in force" (see http://dycip.com/giliead). Similarly the proposed "manufacturing waiver" raises more questions than it answers. Meanwhile, some clarity from the Boards of Appeal on documents not admitted at first instance may be welcome relief for all. Perhaps it is the heat getting to everyone. Have a relaxing summer!

Editor:
Neil Nachshen

Events

27 September 2018
EPO Automotive & Mobility, Chicago US
Anton Baker presents "Win-win solutions: Tips for drafting successful applications for Europe".

25-27 October 2018
AIPLA Annual Meeting, Washington, US
Solicitor Antony Craggs will be attending AIPLA's annual meeting in October.

08 November 2018
CIPA Life Sciences Conference, UK
We will be attending the CIPA Life Sciences conference in November.

15 October 2018
Chemistry Means Business, UK
Garreth Duncan and Rachel Bateman will be attending this London-based conference.

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SPCs

Supplementary protection certificates
EU proposes SPC manufacturing waiver

The European Union is proposing a change to its regulations on supplementary protection certificates (SPCs) for medicines. The change will allow medicines which are protected by SPCs in EU countries to be manufactured in the EU for export to non-EU countries where the product is not under patent or SPC protection.

> The change in the law is proposed to come into force in 2019 and is good news for the EU generics and biosimilars industry, but concerns have been raised as to how it may work in practice.

SPCs extend the term of patents for medicinal and plant protection products which require regulatory approval before they can be put on the market. SPCs expire 15 years from the date of the first marketing authorization in the EU, the term being capped at 5 years from the expiry date of the basic patent. The value of SPCs to the innovator pharmaceutical industry is immense, as the term of the SPC is typically when the product achieves its peak sales.

SPCs were introduced in the EU in the early 1990s, and since then many other countries, including the US, Japan, South Korea, Russia and Australia, have adopted similar legislation to provide patent term extension for pharmaceutical products. However, this has not been adopted worldwide: many major countries, including China and India, still do not have any form of patent term extension. Canada introduced SPCs in September 2017, but the term of Canadian SPCs is capped at two years from the expiry date of the basic patent.

The EU considered this difference put EU generics and biosimilars manufacturers at a disadvantage compared with competitors outside the EU, on two grounds.

1. SPCs prevent manufacturing the protected product inside the EU, even for export to countries where SPC protection for the product does not exist or has expired.
2. SPCs were considered to delay the entry of EU manufacturers into the EU market, as they cannot build up EU production capacity until the SPCs have expired.

Neither of these restrictions apply to manufacturers located in non-EU countries with no SPCs or expired SPCs. There was concern that this disparity may cause some pharmaceutical manufacturing to relocate outside the EU.

The European Commission has reacted to these concerns by proposing a change to the medicines SPC Regulation.

> Importantly, the law on eligibility for SPCs and the term of SPC protection will remain unchanged.

However, the proposed change will exempt from SPC protection acts of making the product for the exclusive purpose of export to third countries; or any related act that is strictly necessary for that making or for the actual export itself. The proposed change does not affect SPCs for plant protection products, so the manufacturing exemption will not apply to these products.

> To ensure that SPC-protected medicines manufactured in the EU for the purposes of export are not diverted back into the EU market, the proposal is accompanied by a series of safeguards to avoid this and ensure transparency.

Companies intending to start manufacturing for export purposes will be obliged to give the regulatory authority in the member state of manufacture at least 28 days' prior notification, and the information contained in that notification will be made public.

The manufacturer will also be required to affix the logo shown below to the packaging of SPC-protected products for export outside the EU. Finally, manufacturers will be required to inform third party contractors that the product is subject to SPC protection and that any marketing inside or re-import into the EU will infringe the SPC.

The proposed changes have raised concerns with the innovator pharmaceutical industry, in particular as to how a breach of any of the conditions would be enforced. There are no provisions in the amended Regulation for the EU or member states to take action against companies which breach the exemption, meaning that the burden will likely fall on the SPC holder to sue such companies for infringement. Obtaining evidence of a breach may be difficult in countries which have limited disclosure for litigation.

> Importantly, the proposed exemption will only affect SPCs granted on or after the change to the new Regulation comes into force.

In view of this, many SPC applicants are attempting to accelerate examination of their SPC portfolios throughout the EU, so they are granted before the changes come into force. Although this may be difficult in the UK in view of the backlog of SPC applications before the UK IPO, we are working with SPC agents around the EU to accelerate examination where possible. Please contact your usual D Young & Co adviser if this would be of interest.

Author:
Garreth Duncan

Admissible documentation

T 2026/15 Admissibility of documentation at the Board of Appeal

T 2026/15 concerns the question of admissibility of a document, particularly when moving from a department of first instance to the Board of Appeal.

In this case, the applicant had filed a main request and a first auxiliary request in response to the summons to oral proceedings before the examining division. The examining division refused to admit the first auxiliary request under Article 137(3), which allows the examining division to refuse to give their consent to an amendment made after a response to a Rule 70a or Rule 161 communication has been made.

> In this case, however, the examining division provided multiple pages of arguments as to why the first auxiliary request could not be admitted – addressing issues such as clarity.

During appeal, the applicant insisted that the Board of Appeal consider the first auxiliary request. The Board of Appeal agreed. Moreover the Board of Appeal stated that the examining division had clearly taken the first auxiliary request into account despite saying that it was "not admitted". In particular, the document had been thoroughly analysed, with only two of the reasons made by the examining division having been made "prima facie". The first auxiliary request had therefore been implicitly considered. Indeed, the Board of Appeal noted that only after a request has been admitted can it be considered on its merits. In contrast, this is not the case where admission is refused because refusal to admit is carried out in order to bring examination to a close.

According to the Rules of Procedure of the Board of Appeal (RPBA), the Board of Appeal must take into account everything presented with the grounds of appeal, but do have the power to hold inadmissible as anything that was not admitted in the first instance. Therefore, in this case, with the first auxiliary request having been implicitly admitted, the Board of Appeal was in fact obliged to consider the first auxiliary request. The rules permitting them to hold the first auxiliary request inadmissible were not applicable.

The Board of Appeal also noted that it was undesirable for the examining division to have control over the applicant's options for appeal, and thus it was not desirable for an examining division to be able to actively prevent the Board of Appeal from considering a request. Furthermore, the Board of Appeal noted that the end result of whether the examining division had refused to admit the request or whether they had (as the Board decided) implicitly admitted the request, but refused it, were the same – the request was not granted. Therefore, there was nothing to be gained by depriving the applicant of the opportunity to appeal and put forward the first auxiliary request.

This latter point is good news for applicants, who want the best chance to try and get an application granted.

> In particular, this latter statement from the Board of Appeal is encouraging as it suggests that Boards of Appeal may be dissuaded from wanting to deprive applicants of having every chance to get an application granted.

It is also clear that simply because the examining division says that a document is not admitted does not necessarily make it so. One must instead consider the examining division's approach to the document and consider whether it has been analysed in substance (leading to an implicit admission of the document, despite any declaration to the contrary).

Author:
Alan Boyd

Supplementary protection certificates & parallel imports
Pfizer Ireland Pharma, Operations Support Group v Orifarm

Since 2000, the European Union has expanded from 17 to 28 member states. The integration of those states has given rise to a number of issues in the field of intellectual property.

With regard to supplementary protection certificates (SPC), one issue which has arisen is whether the holder of an SPC could prevent the import of a product into an existing member state from a new member state where it could not have been given patent protection in the new member state before accession.

In Pfizer Ireland Pharmaceuticals, Operations Support Group v Orifarm GmbH (Case C-681/16), the Court of Justice of the European Union has addressed this question, answering broadly in the affirmative.

Pfizer was the owner of an SPC covering the protein etanercept based on European patent No 0 939 121 and the marketing authorisation for Enbrel. In October 2012, the German Patent and Trade Mark Office granted a paediatric extension of the SPC to August 2015 under Regulation No 1901/2006.

Pfizer manufactured Enbrel in Germany and marketed it in several other countries for the treatment of arthritis. Orifarm operated as a parallel importer of medicinal products.

In 2012 Orifarm notified Pfizer of its intention to carry out parallel imports mainly from Estonia and Latvia and, from February 2015, from Bulgaria, the Czech Republic, Hungary, Poland, Romania, Slovakia and Slovenia. Pfizer objected.

The Acts of Accession of new member states contain certain exemptions to the free movement of goods between the new member states and existing member states, referred to as the 'Specific Mechanisms'. The Act of Accession of 2003 reads as follows:

"… the holder… of a patent or supplementary protection certificate … filed in [an existing] Member State at a time when such protection could not be obtained in one of the … new Member States for that product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the import and marketing of that product in the [existing] Member State ..."

SPCs and parallel imports: Pfizer's SPC covering the protein etanercept

It was common ground between the parties that "on the date on which the application for the basic patent was filed, namely 31 August 1990, it was impossible to obtain equivalent protection for the product at issue in the main proceedings in all of the new Member States in question and that, on the date on which the application for the SPC at issue was filed, namely 26 June 2003, it was possible to obtain protection of that product by means of an SPC in all those new Member States, with the exception of Croatia."

In June 2015 Pfizer brought proceedings before the Landgericht Düsseldorf (Regional Court, Düsseldorf, Germany) for infringement of the SPC. Orifarm argued that the specific mechanisms were inapplicable on the ground that on the date of the filing of the application for the SPC at issue, equivalent protection should have been obtained in the new member states in question. In that regard, it submitted that the basic patent and the SPC must be considered separately. The Landgericht Düsseldorf referred the issue to the Court of Justice of the European Union asking four questions.

The first and second questions boiled down to asking the precise date in respect of which the level of protection in the importing member state and the level of protection in the exporting states should be compared for the purpose of applying the specific mechanisms (for example, the filing date of the basic patent, publication date of the basic patent or filing date of the SPC). The CJEU, following the Advocate General's opinion, held that this should be the date of filing the basic patent.

The third and fourth questions were directed towards whether the specific mechanisms must be interpreted as applying to the paediatric extension. Here the CJEU held that"… it cannot be inferred from the fact … that the provisions establishing the specific mechanisms do not expressly mention the SPC extension and that Regulation No 1901/2006 was not part of the EU acquis at the time when the Acts of Accession of 2003 and 2005 were concluded, that that extension does not come within the scope of those mechanisms."

Author:
Antony Craggs

Renewal reminders
Obligations on applicants

This European appeal concerns obligations on applicants regarding renewal reminders from an agent such as an IP firm.

Two reminders were sent to the applicant's executive (Mr Taylor – Head of Science) prior to a renewal fee becoming due. Two further reminders were sent after this date, within the six month grace period.

The renewal fees remained unpaid and consequently a loss of rights was received by the agent.

Each of the reminders was sent by post and marked as being of particular urgency ("renewal notice", "final renewal notice", "important – overdue renewal fees").

The applicant made a request for re-establishment stating that during the period in question, Mr Taylor had been required to cover the vacant role of Technical Manager, and this necessitated a great deal of travel. During this period, the reminders from the agent had been received and placed in a "junk" pile for Mr Taylor to check. However, this never happened.

The request for re-establishment was refused and the applicant appealed.

> The Board of Appeal noted that the requirement to take "all due care" lies first and foremost with the applicant. If the applicant appoints an agent, this duty extends to the agents, but it does not replace the applicant' duty of care, which remains.

The Board of Appeal noted that the agent did appear to have taken all due care by having sent a number of reminders (appropriately marked as urgent).

The Board of Appeal also felt that in this particular situation, there was nothing to require the agent in the absence of instructions to pay for the renewal fees out of their own pocket to keep the application alive.

Meanwhile, the Board of Appeal stated that the applicant had not shown a duty of care since no precautionary measures were taken to prevent a prolonged interruption in communication. Mail had been checked by an "unknown person" indicating that no instructions had been given at all. Furthermore, in the space of nine months, despite Mr Taylor being in the office at various points, the "junk" pile was never checked.

The Board of Appeal noted the case law relating to the excusable isolated mistake in an otherwise satisfactory system (J5/80). However, they noted that this related to an assistant in the role of agent. It therefore did not extend to an applicant and did not extent to a non-assistant (following R18/13). The Board of Appeal noted that Mr Taylor could not be considered to be an assistant in any event, because an assistant performs routine tasks and in Mr Taylor's case, no supervision occurred.

In summary, it is important for applicants to remember that the EPO places obligations on the agent and the applicant to have a duty of care towards their applications.

> Although a good agent will be able to anticipate deadlines and warn applicants in good time of such deadlines, agents may be unable to act without explicit instructions from the applicant.

It is therefore essential that applicants keep lines of communication open and take specific measures to prevent interruptions in communication with their agents.

Author:
Alan Boyd

Unitary patent and Unified Patent Court
Latest news

Following the announcement from the UK Government on 26 April 2018 that ratification of the UPC Agreement has taken place; a government white paper has now been released entitled "The future relationship between the United Kingdom and the European Union".

Brexit and the UPC

In this white paper the UK Government highlights the importance of intellectual property, and indicates that they intend "to explore staying in the (Unified Patent) Court and unitary patent system after the UK leaves the EU".

To do this the white paper states that the UK will "work with other contracting states to make sure the Unified Patent Court Agreement can continue on a firm legal basis".

Such statements are positive and hopefully mean that the necessary negotiations can take place so that the UK can remain a participating state of the UP and UPC when the new system comes into effect.

UPC Agreement incompatible with Hungary's Fundamental Act

Outside of the UK, the Hungarian Constitutional Court has declared the Unified Patent Court Agreement incompatible with Hungary's Fundamental Act.

This means that the Hungarian Government will need to amend the Act before being able to ratify the UPC agreement. Whilst such amendment is possible, it remains to be seen how the Hungarian Government will proceed.

How do I find out more?

Bookmark our UP & UPC website page to keep up to date on this subject: **www.dyoung.com/knowledgebank/up-upc**.

Author:
Rachel Bateman

Do the facts speak for themselves? When written and verbal decisions at oral proceedings differ

T2374/16 concerns a situation in which the written decision of oral proceedings before the opposition division differed from the verbal decision given at the end of the oral proceedings.

According to the announcement that was orally made at the end of the oral proceedings, and the reasoning for the decision that was issued, the opposition division intended to maintain the application on the basis of the claims of the first auxiliary request. However, according to the actual written decision, and the opposition Druckexemplar, the patent was maintained based on the main request (with some of the description pages amended).

Both the proprietor and the opponent appealed.

The proprietor submitted that a simple mistake had occurred, which could be corrected under Rule 140 EPC if both parties withdrew their appeal. According to the proprietor, this would not prejudice the rights of any third parties because the appeal had a suspensive effect on the decision of the opposition division and so the granted claims were in effect. The proprietor also noted that, in any event, referring the case back to the opposition division would have the same effect as correcting their decision under Rule 140.

The opponent submitted that a clear procedural violation had occurred because the decision had not been sufficiently reasoned.

The Board of Appeal opened by considering whether the proprietor was entitled to appeal, since there was a question as to whether they had been adversely affected. The proprietor successfully argued that they were adversely affected by having been made to amend their summary of invention – an action that was not part of their main request.

Although the Board of Appeal agreed that the appeal was therefore admissible, this argument seems to have been used to conclude that the decision must be overturned. In particular, the Board of Appeal noted that the text of the Druckexemplar did not correspond with any request made by any party. Consequently, it could not be maintained. The Board of Appeal did consider the proprietor's comments regarding third party rights and a predictable outcome occurring in subsequent opposition proceedings. However, the Board of Appeal noted that they cannot make decisions based on developments that may or may not happen, but only on the actual facts that were before it. The Board of Appeal therefore ruled that the decision was overturned and the case had to be remitted back to the opposition division to be re-heard.

> Clearly this case emphasises the importance that should be placed on checking that the decision and the reasons for the decision (as well as the Druckexemplar and the orally presented decision) all match. A discrepancy between these could be sufficient for a case to be remitted back to first instance.

The Board of Appeal disagreed that the outcome of such remittance was inevitable. In particular, the Board of Appeal noted several possibilities that could change the outcome – an intervention might be filed, the opposition might be withdrawn, or the opposition division might be persuaded differently on the day of oral proceedings. This was therefore not sufficient to prevent remittance.

It is also noteworthy that the proprietor's own arguments for admissibility appear to have been used against them. In particular, in noting that they had not achieved their main request due to the description pages needing amendment, the Board of Appeal was able to argue that the resulting Druckexemplar did not correspond to any submitted request and so had to be overturned. This underscores the importance of thinking through the consequences of particular lines of argument – in this case, it seems doubtful that anything positive could have been gained by the proprietor actively appealing the decision rather than merely acting as a party as of right during the opponent's appeal.

The written and verbal decisions at the oral proceedings differed

Author:
Alan Boyd

Confidentiality clubs
TQ Delta v Zyxel Communications

Case details at a glance
Jurisdiction: United Kingdom
Decision level: High Court (Chancery Division)
Parties: TQ Delta LLC and Zyxel Communications UK Limited, Zxyel Communications A/S
Citation: [2018] EWHC 1515 (Ch)
Date: 13 June 2018
Full decision: dycip.com/zyxel-confidentiality

Pre-action or specific disclosure (discovery) of earlier patent licences is, in certain types of cases, becoming increasingly common in English patent litigation.

One area of contention is often the confidentiality regime which applies to those earlier licences being disclosed. In particular, there is often a question as to whether disclosure of the confidential information should be limited to 'external eyes' only (namely, legal representatives, experts and the court, but not the party).

The reasons for such a limitation will vary case by case. Usually, the disclosing party expresses concern that the other side will gain a commercial advantage in licence negotiations with it and others; conversely, the 'receiving' party explains that it cannot give meaningful instructions to its legal representatives without seeing the documents.

Mr Justice Carr has now given guidance on this issue in TQ Delta LLC v Zyxel Communications UK Ltd.

Here, TQ Delta brought a claim for infringement of two patents for DSL broadband technology. It reasoned that these were 'essential' in that the relevant ITU Recommendations could not be practiced without infringement of the patents. Zyxel defended the action and counterclaimed, challenging the validity of the patents, and seeking a declaration of non-essentiality. It also raised issues relating to reasonable and non-discriminatory licences and remedies (RAND).

Zyxel sought disclosure from TQ Delta and it fell to the parties to agree a confidentiality agreement. TQ Delta sought to distinguish between confidential and highly confidential information, with the latter only to be disclosed on an external eyes only basis. Zyxel objected. It fell to the court to determine the issue.

Mr Justice Carr, giving judgment, declined to order an external eyes only tier, reasoning as follows:

Should disclosure of confidential information be limited to 'external eyes' only?

"... It is exceptional to limit access to documents in the case to external eyes only ... The problems with an external eyes only tier, which TQ Delta contended should extend to previous licences for the portfolio granted by TQ Delta and its predecessor in title, were summarised by [counsel for Zylex] in the following terms, with which I agree:

1. Zyxel would potentially be precluded from hearing and understanding the arguments and evidence on RAND licence terms being advanced by TQ Delta.
2. The Zyxel lawyers would have to construct arguments and put together evidence without any input from their clients.
3. Zyxel would not be able to see, let alone approve, the arguments being advanced by their lawyers or the evidence being drafted by their experts.
4. The proceedings would be bedevilled on Zyxel's side by the constant need for their lawyers to monitor what Zyxel could be told about the case and which documents being prepared for the case they could be shown.
5. It would be impossible to take informed instructions as to whether to accept any Part 36 or other offers made by TQ Delta in the course of proceedings.
6. It would be practically impossible for Zyxel to have an informed discussion with their lawyers about the appropriate terms of any Part 36 offer to be made by them.
7. Zyxel would be substantially excluded from the trial, having to sit outside while the debate took place in the courtroom."

Mr Justice Carr emphasised that the above did not preclude the parties from agreeing the contrary, from the parties redacting non-relevant information from documents, and to limiting the number of people within the receiving party who could see the information.

Author:
Antony Craggs

And finally...

Webinar catch up

European biotech patent case law
Webinar update

In our July 2018 patent biotech webinar, we provided an update on important recent decisions from the EPO Boards of Appeal.

T 239/16

Could an information leaflet and consent form distributed to prospective participants in a clinical trial be prejudicial to the patentability of a second medical use claim? This case highlights the all-important need to consider the timing of filing a patent application in order to balance the plausibility of the claimed medical use with a potentially prejudicial disclosure. The rarity of the condition to be treated, the availability of a pre-clinical model for that condition and the structural similarity of the compound to known drugs for the same indication are all considered as factors in determining the presence or absence of an inventive step.

T 282/12

The Board of Appeal concluded that, for consistency, the concept of partial priority must also apply in assessing which application is the "first application" in relation to a priority claim. Based on this concept, a disclosure in a priority application that encompasses alternative subject matter may be conceptually divided into parts, and hence earlier filings by the same applicant may be considered to be the "first application" for any of those parts that they disclose, thus invalidating the priority claim. The impact of this decision on filing strategies should be carefully considered: addition of alternative subject matter to the scope of an existing application (for example, by extension of a range) might not give rise to a new priority date for the whole scope.

T 1931/14

Under which circumstances would the preamble of a method claim ("method for doing X") be interpreted as a limiting feature of the method? The Board of Appeal concluded that in the context of a method claim, it is important to differentiate between different types of purpose claimed, namely those that define the application or use of a method, and those that define an effect arising from the steps of the method and implicit therein. If the purpose defines the specific application of the method, certain additional steps are required which are not implied by or inherent in the other remaining steps defined in the claim, and without which the claimed process would not achieve the claimed purpose.

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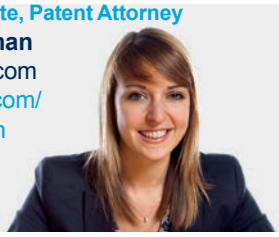

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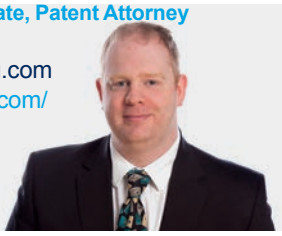

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