Bulletin

BusinessLawFirm
kochański zięba rapala & partners

LAWYERS NEWSLETTER JUNE 2012

Intellectual Property & Life Science

Katarzyna Zbierska
Partner, Legal Counselor
k.zbierska@kochanski.pl
+48 660 765 923

Amendment of the Reimbursement Law with respect to incentives and contracting concerning reimbursed products

On 14 June 2012 the Polish Sejm (Parliament) adopted an amendment to the contentious Law on medical activity of 15 April 2011, which also amends other legal acts, including the no less contentious Law of 12 May 2011 on the reimbursement of medicinal products, foods for special nutritional uses and medical devices ("Reimbursement Law"). The President of Poland signed the amendment on 27 June 2012, so that it can enter into force on 30 June 2012.

The amendment concerns the disputed Arts. 49, 50, 52 of the Reimbursement Law, which provide i.a. for a prohibition of any incentives (i.a. in the form of advertising) concerning reimbursed products, as well as strict rules on contracting reimbursed products, in particular making such contracts dependent upon other services or applying inconsistent terms and conditions. According to the amended Reimbursement Law:

- the list of incentives, incentive providers and incentive recipients have been limited (providers - manufacturers, wholesalers, pharmacies and pharmacists; recipients - beneficiaries and "authorized persons") so that it no longer cover e.g. companies or non-profit organizations wanting to make a donation to a hospital concerning reimbursed products. Nevertheless, there are still some incentives for doctors prohibited under the Reimbursement Law (e.g. sponsoring of conferences, advertising gifts) which, based on other provisions are allowed;
- the prohibition on making the conclusion of an agreement concerning reimbursed products dependent on the specific service/s of the other party has been limited only to services unrelated to the subject of the agreement concerning reimbursed products (as opposed to "any services" in the initial wording of the provision);

- respective changes on penal sanctions for infringement of the incentive prohibition have been made in order to adjust the scope of persons obliged to observe the above prohibitions (though penal sanctions refer now to applying "inconsistent" and not "materially inconsistent" contractual terms and conditions, which broadens the scope of the sanction).

Unified Patent Court – the President of the European Council proposes seat of the UPC

As the German newspaper *Handelsblatt*[1] informed on 28 June 2012, the President of the European Council Herman van Rompuy proposed that the seat of the Unified Patent Court ("UPC") should be placed in Paris, whereas some "specialized clusters" of the court should be located in London and Munich. The London branch will specialize in pharmaceutical and biotechnology cases, whereas the Munich branch will deal with cases concerning automotive industries and court administrative issues. Telecom cases will be decided in Paris.

The split of the court operation into three countries has been highly disputed, among others in Germany, whose courts decide most patent cases in the European Union ("EU"). Some believe that such a solution is inefficient; however, a compromise allows work on the UPC to proceed further, in particular because it was one of the major outstanding points on the way to finalizing the unitary patent and litigation package ("Package"). The debate in the European Parliament over the contentious package, which has been subject to severe criticism in Poland, has been rescheduled for 3 July 2012. Although the entire endorsement process over the package by respective EU institutions and national bodies must still take its full course, it appears that the UPC project has entered into the advanced stage.

Entry into force of revised Guidelines for Examination of the European Patent Office – the issue of stem cell patenting

On 20 June 2012 the European Patent Office published revised Guidelines for Examination in the European Patent Office[2] ("Guidelines") which have been amended with respect to contentious patentability requirements of stem cells. The revised wording of the Guidelines reflects conclusions

[1] *EU-Patentgericht geht nach Paris*, Handelsblatt, 27 June 2012, available at http://www.handelsblatt.com/politik/international/standortentscheidung-eu-patentgericht-geht-nach-paris/6805690.html (last visited 28 June 2012)

[2] *Guidelines for examination in the European Patent Office*, available at http://www.epo.org/service-support/publications/procedure/guidelines-2012.html (last visited 28 June 2012)

from the ruling of the Court of Justice of the European Union (CJEU) in the "*Brüstle*" case C-34/10[3] referred to by the German Federal Court of Justice, which concerned the notion of "human embryo" and the scope of general unpatentability of human embryos for industrial or commercial purposes. The CJEU decided in particular that:

- the exclusion from patentability concerning the use of human embryos for industrial or commercial purposes set out in Article 6(2)(c) of Directive 98/44[4] also covers the use of human embryos for purposes of scientific research, with only use for therapeutic or diagnostic purposes (which is applied to the human embryo and is useful to it) being patentable;

- Art. 6(2)(c) of Directive 98/44 excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place, and even if the description of the technical teaching claimed does not refer to the use of human embryos.

The revised Guidelines now specify that a claim directed to a product, which at the filing date of the application could be exclusively obtained by a method which necessarily involved the destruction of human embryos from which the said product is derived, is excluded from patentability even if said method is not part of the claim. The point in time at which such destruction takes place is irrelevant.

The Guidelines will most likely be disappointing for rapidly developing biotech companies. The practical facet of the Guidelines and the CJEU's ruling in the "*Brüstle*" case is that it will be important to demonstrate before the EPO that a biotech invention involving a human embryo does not exceed the unpatentability threshold (in particular with respect to "exclusively obtained" and "destruction" elements). It appears that so-called adult stem cells and human induced pluripotent stem cells should still be patentable, though it will be interesting to see how the EPO applies the revised Guidelines in practice.

[3] Judgment of the Court of Justice of the European Union of 18 October 2011, C-34/10, *Olivier Brüstle v. Greenpeace eV*, available at www.curia.europa.eu (last visited 28 June 2012)
[4] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, available at www.europa.eu

Some new statistics on SPC for medicinal products in Europe

Using this opportunity the Bulletin would like to draw your attention to recently published statistics concerning SPCs granted in the EU, prepared over many years by Ms Alice de Pastors, Conseil en Propriété Industrielle to Cabinet de Alice de Pastors[5]. As we can see from the statistics, most SPCs were filed for in the period of 1991-2011 in France, Italy, the United Kingdom, Germany, Belgium, the Netherlands, Austria and Sweden. Poland is a country indicated as one with the lowest number of SPCs filed out of the aggregate number of 14;620 filed between 1991 and 2011 in Europe, though there are countries with less SPCs filed in this period: Romania, Slovakia, Latvia, Lithuania, Iceland and Bulgaria).

78 per cent of SPC applications filed in Poland between 2007 and 2011 are still pending (among others an SPC application for *sitagliptin* referring to Merck's patent EP 1412357 accompanied with a negative-term marketing authorization based on the CJEU's ruling in the "MSD" case C-125/10 of 8 December 2011), whereas 10.2 per cent of SPC applications were refused, which ranks Poland in the "high-refusal" position. Interestingly, there has been a pediatric extension granted in Poland for *caspofungin*. As to the leaders of SPC applicants, one needs to mention: Novartis and GSK which head the rankings with over 250 SPC applications filed, as well as Bayer, Sanofi, BMS, Janssen and AstraZeneca which filed 100-150 SPC applications. Most SPC applications concerned antineoplastic, anti-infective and cardiovascular medicinal products.

A mistake/ a misprint in the patent description concerning biotech invention – how to amend it?

In the recently published reasoning to its ruling of 1 March 2012 (case no. II GSK 86/11) the Polish Supreme Administrative Court ("SAC") decided that the necessity to use an expert opinion in order to determine a mistake, or a misprint, in a patent description concerning a biotechnology invention does not exclude that such a mistake or a misprint may be corrected.

The case concerns an appeal filed by Ajinomoto Co. Inc. which in 2001 obtained a patent in Poland (PL181614) for the invention concerning "*DNA coding for an Escherichia-derived*

[5] Alice de Pastors, *Latest news on medicinal product SPCs in Europe*, available at the SPC Blog, http://thespcblog.blogspot.com/2012/05/latest-news-on-medicinal-product-spcs.html (last visited 28 June 2012)

dihydrodipicolinate synthase, a bacterium including DNA coding for a dihydrodipicolinate synthase and a process for producing L-Lysine", which was the subject of cancellation proceedings before the Polish Patent Office ("PPO") due to alleged insufficient disclosure of invention. In 2009 the patent owner requested that the PPO correct an obvious mistake in a patent description by replacing numbers: 487 with 513, and 597 with 623. The PPO refused to make such changes in the patent description explaining that it is not allowed to change erroneous chemical formula in the procedure prescribed for "correcting obvious mistakes".

In the PPO's view there are only two types of corrections which can be made, i.e. corrections which do not affect the subject of the invention (until a final decision on granting a patent has been issued), and obvious mistakes in a patent description (after the final patent decision has been issued). The first type of correction requires expert knowledge in order to ensure that the subject matter of invention disclosed in the patent application has not been changed. The other type of correction may concern only obvious mistakes or misprints which are easily identifiable in the wording for a layman, without an expert opinion.

On appeal the District Administrative Court ("DAC") in Warsaw upheld the PPO's decision due to the fact that the requested correction would require an expert opinion and could lead to a change of the scope of the patent protection granted, whereas any corrections may refer only to editorial aspects. Furthermore, a patent description is an integral part of a decision on the granting of a patent, thus a change of a patent description would result in a change of the decision on the granting of the patent.

The SAC repealed the DAC's ruling and returned it to the DAC for reconsideration. The SAC explained that even if it is necessary to use an expert opinion to determine whether there is a mistake in a patent description drafted in a specialist language referring to a particular field, this does not exclude such a mistake from being corrected. A patent description is addressed to persons skilled in the art who, as opposed to a laymen, may easily identify the mistake. If patent descriptions drafted in advanced specialist language could not be corrected, the correction procedure as prescribed in Polish Industrial Property Law would be unavailable in practice. Additionally, the SAC stated that a patent description is not an integral part of the decision on the granting of a patent, though it remains closely connected with such a decision.

Ruling of the CJEU in the "Caronna" case C-7/11 of 28 June 2012 on the requirement to obtain authorization for the wholesale of medicinal products by a pharmacist authorized for the retail sale of medicinal products

On 28 June 2012 the CJEU issued a ruling concerning the interpretation of Art. 77(2)[6] of Directive 2001/83/EC[7] in the case referred to by an Italian court concerning an Italian pharmacist who is authorized for the retail sale of medicinal products, but also dealt with the wholesale of medicinal products without having additional authorization for such wholesale. In the CJEU's view this must be interpreted as meaning that the requirement to obtain authorization for the wholesale distribution of medicinal products is applicable to a pharmacist who, as a natural person, is also authorized under domestic law to operate as a wholesaler in medicinal products.

A pharmacist who is also authorized under domestic law to operate as a wholesaler in medicinal products must satisfy all the requirements imposed on applicants for, and holders of, authorization for the wholesale distribution of medicinal products in Art. 79 to 82 of the Directive. However, that interpretation cannot, of itself and independently of any law adopted by an EU member state, give rise to, or aggravate, liability in criminal law on the part of a pharmacist who has engaged in activities as a wholesale distributor in medicinal products without the requisite authorization.

Warsaw, 29 June 2012

Kochański Zięba Rapala & Partners Sp.J.
Plac Piłsudskiego 1, 00-078 Warsaw
tel. +48 22 326 9600
fax +48 22 326 9601
www.kochanski.pl

[6] *"Where persons authorized or entitled to supply medicinal products to the public may also, under national law, engage in wholesale business, such persons shall be subject to the authorization provided for in paragraph 1."*

[7] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Commission Directive 2009/120/EC of 14 September 2009, available at www.europa.eu