Bulletin

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Intellectual Property Law – SPECIAL EDITION

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The Polish Supreme Administrative Court applies the definition of a "product" in the light of the CJEU's judgments in the *"Medeva"* and *"Georgetown"* cases and Polish principles on patent claim construction

In its recently published reasoning to the judgment of 14 February 2012, the Polish Supreme Administrative Court ("SAC") explains the grounds for upholding the judgment of the District Administrative Court in Warsaw ("DAC"), which ruled that the decision of the Polish Patent Office ("PPO") on renouncing to grant an SPC for an antiretroviral product was correct.

Merck & Co., Inc applied for an SPC for an antiretroviral product ("Atripla") based on Polish patent PL 176679, which encompassed a new compound I or II and one nucleoside analog. The PPO stated that the basic patent concerned a product consisting of two active ingredients, whereas an SPC application concerned a product consisting of three active ingredients: *efavirenz*, *emtrycitabine* and *tenofovir dizoproxil*. The PPO decided that the product cannot be identified in the basic patent and *tenofovir dizoproxil* is a nucleotide analog whereas the subject matter of the basic patent is nucleoside analog. Since the patent claims do not refer to nucleotide analog or nucleoside analog prodrugs, the PPO decided that *tenofovir dizoproxil* does not fall within the claims of the basic patent. As a result, the PPO refused to grant an SPC.

Merck challenged the argumentation raised by the PPO that patent claims, in particular in the case of inventions in the field of chemistry, may not be construed literally. Furthermore, the basic patent also covers products which consist of three active ingredients since the second ingredient specified in the patent claims has a functional character, thus encompasses any compounds which are biologically active. Claim construction applied by the PPO excessively limits the scope of the patent protection. The PPO does not take into account that patent protection encompasses not only ingredients indicated in the claims but also additional features, thus any combination of such ingredients may be considered a product qualifying for an SPC.

According to Merck the claim no. 1 of the basic patent specifies a combination of ingredients having a formula I or II (in this case – *efavirenz*) with nucleoside analog being a reverse-HIV-transcriptase inhibitor (in this case nucleoside analog is: *emtricitabine* and *tenofovir disoproxil fumarate*). The claim does not refer only to one nucleoside analog since nucleoside analog reverse-HIV-transcriptase inhibitor concerns a group of compounds defined functionally. When editing patent claims a singular is commonly used, which however does not limit patent protection just to a single solution. The application of a nucleotide analog in combination which, after administration to a patient, transforms into a nucleoside analog falls into claim no.1 of the basic patent. The nucleotide analog is a nucleoside analog prodrug and is an equivalent to the solution covered by the basic patent.

The DAC upheld the PPO's decision and decided that the claims of the basic patent concern a combination of active ingredients to prevent HIV infection characterized by that it is a combination of a formula I or II or pharmaceutically acceptable salts of formula I or II, with a nucleoside analog being a reverse-HIV-transcriptase inhibitor. According to the DAC, the basic patent covered only a two-ingredient combination: a combination of formula I or formula II with a nucleoside analog reverse-HIV-transcriptase inhibitor. The three-ingredient product being a combination of *efavirenz*, *emtricitabine* and *tenofovir dizoproxil* does not fall within the patent claims. One cannot derive from a teaching of the patent that it should cover more than two active ingredients. Neither do patent claims contain any "nucleotide analog" or "nucleoside analog prodrugs". As a formula I, a formula II, their salts or nucleoside inhibitor one may use different compounds expressed by a particular formula or a functional name, though there will always be only two ingredients. *Tenofovir dizoproxil fumarate* is an additional active ingredient which renders the product new comparing to that included in the basic patent, beyond its scope of protection.

Merck appealed the DAC's verdict to the SAC which dismissed the appeal. According to the SAC, the scope of protection of the basic patent is determined by its claims. The Patent description and drawings should support claim construction, however, these are claims which are decisive when determining the scope of the patent protection. This means that claims should be construed literally and only what one can construe based on a patent document has a meaning. There is no basis to construe patent claims to the extent which a patent applicant did not take care of himself and seek protection which extends over the literal meaning of claims. This applies also to equivalents. It is important to remember that patent protection is not only a privilege for a patent owner but a limitation for others which should not encroach upon patent monopoly. Therefore, there must be and are limits of patent protection and this case has indicated this precisely.

Granting an SPC over a product which is not entirely protected by the basic patent would in fact be contrary to Art. 3a of Regulation 1768/92. The SAC referred at this point to the judgments of the Court of Justice of the European Union of 24 November 2011 in cases C-322/10 ("*Medeva*") and C-422/10 ("*Georgetown*"), in which the CJEU held that Art. 3a of the Regulation precludes the PPO from granting an SPC to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the SPC application. Art. 3b of the Regulation does not preclude the PPO from granting an SPC for a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent relied on where the medicinal product for which the marketing authorization is submitted in support of the SPC application contains not only that combination of the two active ingredients (in the "*Georgetown*" case, C - 422/10 – "*that active ingredient*"), but also other active ingredients. As a result, the material patent law has not been infringed in this case when determining scope of protection of the basic patent.

According to the SAC, the subject matter of the basic patent is: a combination of two active ingredients, where active ingredient I is a particular compound I or II or their salt, and active ingredient II is a functional compound - nucleoside analog being a reverse-HIV-transcriptase inhibitor. Therefore, the second active ingredient must be from a group of nucleoside analog reverse-HIV-transcriptase inhibitors, however, one cannot derive from the claims of the basic patent that the combination may include two different nucleoside analogs, i.e. include a third active ingredient being another nucleoside analog. The basic patent did not encompass a combination of three active ingredients: *efivarenz* (compound indicated expressly in the patent claims), *emtricitabine* (nucleoside analog), *tenofovir dizoproxil fumarate* (nucleotide analog which transforms in a human body into another nucleoside analog). As a result, an SPC could not be granted for such a product which extends over the literal meaning of patent claims of the

basic patent and thus does not meet the requirements under art. 3(a) of Regulation 1768/92.

The Court of Justice of the European Union declares that the Republic of Poland infringed Art. 6 of Directive 2001/83

Based on an action of the European Commission ("Commission"), the European Court of Justice of the European Union ("CJEU") ruled on 29 March 2012 in the case C-185/10 that the Republic of Poland failed to fulfill its obligations under Art. 6[1] of Directive 2001/83 of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use by keeping in force Art. 4 of the Polish Pharmaceutical Law of 6 September 2001 as amended by the act of 30 March 2007 ("PPL"). Art. 4 of the PPL allowed the placing on the Polish market without national authorisation of medicinal products imported from outside Poland which have the same active substances, the same dosage and the same pharmaceutical form as those having obtained a marketing authorisation in Poland, provided that, in particular, the price of those imported medicinal products is competitive in relation to the price of products having obtained such authorization.

Basis of the Commission's action

According to the Commission, Directive 2001/83 does not provide for the possibility of placing medicinal products on the market having regard to their "competitive" price when they have not obtained the authorisation referred to in Art. 6 of Directive 2001/83, issued by the national authorities or in accordance with the centralised procedure provided for in Regulation no 726/2004. Art. 5(1) of Directive 2001/83 makes it possible to derogate for a particular medicinal product from the requirement to have a national marketing authorisation where the medicinal product is supplied on account of a specific individual order and has to be imported due to its unavailability on the national market. Nevertheless, it does not justify a derogation based on financial reasons. The possibility offered by Polish legislation was not limited to the import of medicinal products necessary in the course of treating specific problems which affect certain patients, but concerned in particular, medicinal products used for treating persons who cannot leave their place of care, so that the derogation at issue was capable of relating to patients of an entire hospital sector or to wholesale marketing.

Furthermore, Art. 4(3a) of the PPL did not refer to the medical opinion in an individual case, but only to "*the requirement … expressed by a health insurance doctor*". Thus, this provision did not authorize the import of solely a limited quantity of a medicinal product such as to cover only individual needs, but the import on a larger scale of medicinal products the price of which is "competitive" in relation to that of medicinal products available on the national market. Art. 4(3a) of the PPL allowed the placing on the Polish market without authorisation issued by the national authorities of both foreign equivalent medicinal products which are less expensive, i.e. generic medicinal products and identical medicinal products marketed in other countries at lower prices

[1] "*No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EC) No 726/2004 [of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p.1)], read in conjunction with [Regulation No 1394/2007].*"

than those on the Polish market. In this case, it was only the criterion of the lowest price which allowed the prohibition set out in Art. 4(3)(2) of the PPL to be lifted.

Position of the Republic of Poland

Poland argued that Art. 4 of the PPL allows, under well-defined conditions, some medicinal products to be imported in the context of the procedure of "targeted importation", which is compliant with the derogation provided for in Art. 5(1) of Directive 2001/83. Additionally, the Commission overlooked the conditions which arise from an overall analysis of Art. 4 of the PPL because it focused solely on the competitive nature of the price. The application of the exception in Art.4 of Directive 2001/83 is contingent on the conditions specified in the PPL[2].

Furthermore, Polish legislation provides for supplementary conditions that are stricter than those set by Art. 5(1) of Directive 2001/83 for the importation of medicinal products containing the same active substance or substances and the same dosage and having the same form as medicinal products which have obtained marketing authorisation. In principle, Art. 4 of the PPL excludes the possibility of importing such medicinal products unless their price is competitive in relation to the price of the medicinal product which has obtained a marketing authorisation and on condition that:
(i) the requirement expressed by a health insurance doctor has been confirmed by a consultant in the medical sector concerned, and
(ii) the minister with responsibility for health-related matters has expressly decided to authorize the import.
Art. 5(1) of Directive 2001/83 does not lay down a condition of unavailability of a medicinal product on the national market in the sense of the lack of an "equivalent" registered medicinal product. The derogation provided for in Article 4(1) of the PPL from the requirement that a marketing authorisation be obtained is based not on the lower price of the medicinal product abroad but on the need to import a medicinal product where it is necessary for the purpose of saving the life or safeguarding the health of a patient, which satisfies the condition of fulfilling special needs set out in Art. 5(1) of Directive 2001/83.

A decision to import a medicinal product in the context of health insurance can be dictated by financial considerations, namely by the need to ensure the financial stability of the national health insurance system. According to Art.168(7) of the Treaty on Functioning of the European Union, EU law does not detract from the power of the Member States to organise their social security systems and to adopt measures intended to govern the consumption of pharmaceutical products in order to promote the financial stability of their health-care insurance schemes. Art. 4(3) of Directive 2001/83 is not to affect the powers of the EU member states' authorities either as regards the setting of

[2] – that the use of the medicinal product is necessary for the purpose of saving the life or safeguarding the health of a patient,
– that the medicinal product the import of which is envisaged is marketed in the foreign country and, for that purpose, has a current marketing authorisation;
– that the basis for the import of the medicinal product is the requirement of the hospital or the doctor treating the patient;
– that that requirement is confirmed by a consultant in the medical sector concerned;
– that pharmacies, wholesalers and hospitals engaging in the commercial sale of those medicinal products maintain a register for that purpose;
– that the requirements governing the safety of the application of the medicinal products are satisfied;
– that the normal procedure to authorise the placing on the market provided for in the PPL, that is to say a marketing authorisation, need not be applied having regard to the limited nature of the import (paragraph 4 a contrario);
– that as regards the medicinal product which is intended to be imported, the Minister of Health has not refused marketing authorisation, or? refused to extend the duration of its validity or revoked authorisation (paragraph 3(1)).

prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.

Furthermore, Art. 4(3a) of the PPL is used in rare and exceptional cases and the basic criterion for authorizing the import of a medicinal product is the safety of the patient and the concern of guaranteeing him a real possibility of obtaining the treatment which is necessary for his survival or health. The competitive nature of the price of that treatment in relation to that of equivalent medicinal products registered in Poland only constitutes a supplementary condition. In a situation where a number of patients have only limited financial means, the importation of an equivalent but less expensive medicinal product is the only possibility of treating those persons, even of saving their life, and this certainly satisfies the condition concerning the need to "fulfil special needs" provided for in Directive 2001/83.

The CJEU's judgment and its reasoning

In the reasoning to its judgment, the CJEU stated that the principle aim of Art. 6 of Directive 2001/83 is to eliminate hindrances to trade in medicinal products between the EU member states and protect public health, though there are some derogations from that general rule. In this case, the only derogation referred to in Article 5(1) of Directive 2001/83 is relevant. Under this provision, an EU member state may exclude from the directive's scope, in order to fulfil special needs, medicinal products supplied in response to a "bona fide unsolicited order", formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility. Implementation of the derogation under Art. 5(1) of Directive 2001/83 is conditional on fulfilment of a set of cumulative conditions to be interpreted strictly, and must be exercised exceptionally, only if necessary taking the specific needs of patients into account in order to preserve the practical effect of the marketing authorisation procedure.
The derogation under Art. 5(1) of Directive 2001/83:
(i) can only concern individual situations to meet the needs of the patient,
(ii) in which the doctor considers after an actual examination of his/her patients on the basis of purely therapeutic considerations that the patient's state of health requires that a medicinal product be administered
(iii) for which there is no authorised equivalent on the national market or which is unavailable on that market.
Where medicinal products which have the same active substances, the same dosage and the same form as those which the doctor providing treatment considers that he must prescribe to treat his patient(s), are already authorised and available on the national market, there cannot in fact be a question of "special needs". Financial considerations cannot lead to the recognition of the existence of such special needs capable of justifying the application of the derogation provided for in Art. 5(1) of Directive 2001/83.

In principle, Art. 4(3)(2) of the PPL excludes the import, without a marketing authorisation, of medicinal products which contain the same active substance or substances and the same dosage and have the same form as medicinal products having obtained such authorisation in Poland. However, Art. 4(3a) introduces an exception to that rule, based not on the actual unavailability of the medicinal product authorised on national territory, but on the "competitive" price, i.e. the lower price, of the equivalent medicinal product (not necessary to meet special medical needs). The exception provided for in Art. 4(3a) of the PPL does not satisfy the conditions required in order to benefit from the derogation provided for in Art. 5(1) of Directive 2001/83. Art. 4(3a) of the PPL

allows such placing on the market where certain other conditions are satisfied, hence it does not merely impose stricter conditions, but creates an exception to the prohibition on placing on the market in circumstances not provided for in Art. 5(1) of Directive 2001/83.

EU law does not frustrate the power of the EU member states to organise their social security systems and to adopt provisions intended to govern the consumption of pharmaceutical products in order to promote the financial stability of their health-care insurance schemes (e.g. set prices of medicinal products and the level of reimbursement), as long as the EU member states comply with EU law in exercising that power. Art. 5(1) of Directive 2001/83 is not concerned with the organisation of the health-care system or its financial stability, but is a specific derogating provision, which must be interpreted strictly, applicable in exceptional cases where it is appropriate to meet special medical needs. Therefore, Art. 5(1) of Directive 2001/83 cannot be relied on to justify a derogation from the requirement for a marketing authorisation for reasons of a financial nature.

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