Court of Justice of the European Union
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Press and Information

Judgment in Case C-414/11
Daiichi Sankyo Co. Ltd, Sanofi-Aventis Deutschland GmbH v DEMO
Anonimos Viomikhaniki kai Emporiki Etairia Farmakon

The Agreement on Trade-Related Aspects of Intellectual Property (TRIPs) [1] falls within the exclusive competence of the European Union

A patent granted before the entry into force of the TRIPs Agreement for the process of manufacture of a pharmaceutical product does not, after its entry into force, cover the actual invention of the product

Daiichi Sankyo Co. Ltd obtained a national patent in Greece in 1986 for levofloxacin hemihydrate, a chemical compound used as an active ingredient in antibiotic treatments, in particular in an original medicinal product called Tavanic. It granted a licence to Sanofi-Aventis Deutschland GmbH to distribute it in Greece, under an authorisation to place it on the market granted by the competent Greek authorities in 1999. The application for the patent sought protection for the product (the active ingredient) and its process of manufacture. The protection conferred by the patent, which was due to expire on 20 June 2006, was extended by a supplementary protection certificate (SPC) [2] for five years, to 2011.

In 2008 and 2009 DEMO AE obtained authorisations in Greece to place on the market a generic medicinal product called Talerin, which also had the active ingredient levofloxacin hemihydrate.

In those circumstances Daiichi Sankyo and Sanofi-Aventis asked the Polimeles Protodikio Athinon (Court of First Instance, Athens) to order DEMO to cease all marketing of Talerin or any other medicinal product with the active ingredient levofloxacin hemihydrate.

The Greek court explains that the main proceedings have to determine whether the SPC held by Daiichi Sankyo from 2006 to 2011 – in other words, in the period during which DEMO was preparing to market the medicinal product containing the pharmaceutical product – covered the invention of the pharmaceutical product or only the invention of its process of manufacture.

If the protection under the SCP covers the product, the fact that Tavanic and Talerin have the same active ingredient would mean that DEMO infringed Daiichi Sankyo's patent. If, on the other hand, the protection covers only the process of manufacture, the fact that Tavanic and Talerin have the same active ingredient would only raise the presumption that the generic medicinal product was manufactured on the basis of the process protected by the SPC. In that case, it would be sufficient for DEMO to rebut that presumption by showing that that medicinal product was manufactured by a different process.

Greece ratified the Convention on the Grant of European Patents (EPC) in 1986, but it was only from 1992, on the expiry of a reservation previously expressed, that Greece also recognised the patentability of pharmaceutical products. [3]

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[1] Agreement on Trade-Related Aspects of Intellectual Property, constituting Annex 1C to the Agreement establishing the World Trade Organisation (WTO), signed at Marrakesh on 15 April 1994 and approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ 1994 L 336, p. 1).

[2] Under Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1).

[3] Convention on the Grant of European Patents (EPC), signed at Munich on 5 October 1973.

In that context, the national court essentially asks the Court of Justice whether a patent obtained following an application claiming the invention both of the process of manufacture of a pharmaceutical product and of the pharmaceutical product as such, but, because of that reservation, granted only for the process of manufacture, must none the less, by reason of the TRIPs Agreement and from the date of its entry into force, be regarded as also covering the invention of the pharmaceutical product.

It also asks to what extent the TRIPs Agreement, which was concluded by the Community and the Member States by virtue of shared competence, still falls within the competence of the Member States.

In today's judgment, the Court of Justice starts by observing that **since the Treaty of Lisbon the common commercial policy** – which is within the context of the European Union's external action and relates to trade with non-member countries – **also concerns the commercial aspects of intellectual property**. [4] If a European Union act is intended to promote, facilitate or govern international trade, it falls within the common commercial policy.

The rules in the TRIPs Agreement have a specific link with international trade. The agreement itself forms part of the liberalisation of international trade, and its objective is to strengthen and harmonise the protection of intellectual property on a worldwide scale and to reduce distortions of international trade in the territory of the Member States of the WTO. **The agreement therefore now falls within the field of the common commercial policy and the exclusive competence of the European Union**.

The Court goes on to note that – according to the actual wording of the TRIPs Agreement – any invention, whether a product or a process, which is new, involves an inventive step and is capable of industrial application is patentable, provided only that it belongs to a field of technology. Pharmacology belongs to such a field and the invention of a pharmaceutical product is therefore capable of being patented.

Moreover, in accordance with the European Union regulation, [5] the protection conferred by the SPC was subject to the same limitations as those affecting the protection conferred by the basic patent.

The reservation, permitted by the EPC, under which medicinal products were not patentable in Greece from 1986 to 1992, applied by analogy to national patents, such as that of Daiichi Sankyo. Similarly, the rule that the effect of the reservation continues throughout the term of the patent [6] was also applicable by analogy to national patents. Consequently, Daiichi Sankyo's national patent and its SPC were of no effect as regards the invention of the pharmaceutical product, notwithstanding the patentability of pharmaceutical products in Greece from 1992.

Consequently, while **the TRIPs Agreement** obliges the Member States of the WTO to make it possible to obtain patents for pharmaceutical products, it **does not oblige them to regard patents which were granted solely for processes of manufacture of those products as covering**, after the entry into force of that agreement, **the inventions of those products as such**.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

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The full text of the judgment is published on the CURIA website on the day of delivery.

[4] Article 207(1) TFEU.
[5] Articles 4 and 5 of Regulation No 1768/92.
[6] Article 167(5) of the EPC.

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