Merck Sharp and Dohme Limited – Principi Attivi
(Italian Competition Authority (ICA), Case A364, Decision n° 14388, Bulletin n° 23/2005, 15 June 2005)

Prepared by UNCTAD's Intellectual Property Unit[1]

Summary

This case concerned an active ingredient for antibiotics whose patents had expired in most of European markets but not in Italy. The patent holder, Merck & CO. Inc. (Merck Sharp & Dohme; hereinafter "MSD") refused to grant a license requested by an Italian company, ACS Dobfar S.p.A. (hereinafter "Dobfar"), for the production and export of the active ingredient to countries where there was no patent protection. The Italian Competition Authority (hereinafter "ICA") held that MSD's refusal had the effect of creating an exclusive right on products in countries in which the patents had already expired and that this conduct was capable of causing serious and irreparable damage to competition, hindering market entry of generic producers. Consequently, the ICA ordered a compulsory license as an interim measure allowing Dobfar and any other producer in Italy to manufacture and export the active ingredient.

The facts

MSD held a patent on Imipenem/Cilastatina, an active ingredient for antibiotics used in the treatment of certain infectious diseases, which had expired in most countries. In Italy however, the active ingredient was still protected by a supplementary protection certificate that effectively prolonged the life of the patent beyond the patent term. In 2002, the Italian chemical-pharmaceutical company Dobfar, with the assistance of the Italian Ministry of Industry as mediator, unsuccessfully sought a voluntary license from MSD for manufacturing the product in question.[2] Dobfar had requested the license to manufacture Imipenem/Cilastatina in Italy for export to generic manufacturers of antibiotics in countries where Imipenem/Cilastatina no longer enjoyed any intellectual property protection. As required under Italian law, the case was sent to the ICA for consideration upon failure of the Ministry-mediated negotiations.

The legal issues

When considering *ad interim* measures, the ICA applying EU law (i.e. Article 82 of the Treaty establishing the European Community[3]) analyzed first the question of whether MSD was dominant in the relevant market. Here, it focused on the fact that Imipenem/Cilastatina was an active ingredient needed for the production of certain antibiotics, rather than on just the market for the ingredient itself, and concluded that MSD was indeed dominant in numerous national markets of EU countries**.** Once the ICA had established MSD as dominant, it considered the

[1] See original summary *in* UNCTAD, Development Dimensions of Intellectual Property in Indonesia: Access to Medicines, Transfer of Technology and Competition, United Nations, New York and Geneva, 2011, p. 40-41, available at https://unctad.org/system/files/official-document/diaepcb2011d6_en.pdf.
[2] The mediation procedure is provided for under Italian law (Law 112/2002 and Ministerial Decree of 17 October 2002).
[3] Now Article 102 of the Treaty on the Functioning of the European Union.

question of whether MSD abused its dominant position by refusing to issue Dobfar a voluntary license to manufacture the active ingredient for export to generic manufacturers of antibiotics in countries where Imipenem/Cilastatina no longer enjoyed any intellectual property protection.

The ICA provided an analysis of why MSD's refusal should be considered abusive, including the following aspects:

1) The active ingredient is essential for the production of generics by MSD's competitors, and Dobfar is an indispensable supplier for the competitors; by refusing to license to Dobfar, MSD was impeding competition in national markets where the active ingredient was no longer protected (either by patent or extension certificate).
2) There was an unjustified refusal to license by MSD, in order to exclude competition by generics using the essential facility; and
3) "The refusal to deal by MSD has been used not to preserve the economic exploitation of the IP right, but to maintain, in fact, the exclusive rights on the active ingredient in countries in which the undertaking no longer has any exclusive right of exploitation."[4] This was so because Dobfar had no real possibility of delocalizing production abroad, where the patent had already expired.

Points of significance

- In March 2007, the ICA came out with a decision finalizing the *ad interim* order forcing MSD to grant a license to Dobfar to produce Imipenem/Cilastatina.[5]
- While it is not entirely clear whether the decision relies more on the "essential facilities doctrine"[6] or a "refusal to deal"[7] analysis in determining abuse of dominance by MSD, some academics note that this decision is noteworthy because the ICA made its decision taking into consideration a refusal affecting markets outside the territory of exclusivity (Italy).[8] Favorable consideration was given to the fact that there was a need to protect competition by potential manufacturers in a secondary market where there was no IP protection over the active ingredient, which was considered to be an essential facility, and particularly those markets of other EU countries where Imipenem/Cilastatina was already off-patent. The analysis is in line with how the EU generally views secondary markets under its competition legislation.

---

[4] English translation of para. 137 of decision Provvimento 14388 A364, as contained *in* Coco, R. and Nebbia, P., 2007, "Compulsory licensing and interim measures in Merck: a case for Italy or for antitrust law?", *Journal of Intellectual Property Law & Practice*, 2(7): 454.

[5] Provvedimento 16597. A364 *Merck – Principi Attivi* in *Boll*. 11/2007.

[6] The essential facilities doctrine originates from US antitrust case law and has been applied in many countries. The essential facilities doctrine has put a limit to the former general rule that a firm has no obligation to deal with its competitors. There are strict requirements to the doctrine, i.e. an abuse is likely, if the following apply: 1) control of the essential facility by a monopolist; 2) competitors' reasonable inability to duplicate the essential facility; 3) a refusal to grant the use of the facility to the competitor; and 4) the feasibility of providing the facility in the absence of any justifications for denying access. *United States v. Terminal Railroad Association*. [1912] 224 US 383.

[7] Refusal to deal generally refers to agreements that restrict, or are likely to restrict, by any method the persons or classes of persons to whom goods or services are sold or from whom the goods or services are bought. See, for example, Section 4-d of India's Competition Act.

[8] Coco and Nebbia (fn. 5, above), p. 455.

- The case is unique in that it involved EU issues, and could also be seen as testing the level of protection conferred by an Italian extension certificate, which extends the period of exclusivity beyond the term of the patent.[9] In any event, it appears that the ICA took pains to ensure that its decision was consistent with existing EU antitrust cases[10] and relevant competition laws, without being seen as overreaching.
- In *IMS Health GmbH v NDC Health GmbH* the European Court of Justice (CJEU) further elaborated on the conditions under which the refusal by a dominant firm to license an IP right on a product indispensable for competition may constitute an abuse of dominance.[11]
- According to the submission of Italy to the 131st OECD Competition committee meeting on 5-7 June 2019 concerning a similar case under its jurisdiction:

  > "The very specific circumstances of the case are characterized, above all, by the absence of any trade-off between competition and [intellectual property rights] since the access to the [active pharmaceutical ingredients] would not have hindered the possibility to recoup costly investments in R&D in the export markets where [intellectual property rights] were absent."[12]
- The TRIPS Agreement in Article 31 (k) authorizes WTO Members to waive certain procedural requirements (i.e. prior negotiations with the patent holder; predominant supply of the domestic market) where a compulsory license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive.

Key words: Competition, essential facility, abuse of dominance, patent, refusal to license, compulsory license.

Available (in Italian) at:
https://www.agcm.it/dotcmsCustom/getDominoAttach?urlStr=192.168.14.10:8080/41256297003874BD/0/5D12F9D21F9201DEC125702700351A82/$File/p14388.pdf

[9] *Ibid.*
[10] The ICA distinguished existing precedents by the European Court of Justice (today: Court of Justice of the European Union, CJEU) on the interface between IP and competition on the grounds that the refusal affected markets outside the zone of exclusivity. These precedents appear to require, *inter alia*, that the refusal to license the product in question impedes the appearance of a new product for which potential demand exists. See C-241 and 242/91 *Radio Telefis Eireann & others v. Commission* [1995] ECR I 743; C-148/01 *IMS Health GmbH v. NDC Health GmbH* [2004] ECR I 5039, among others. CJEU case law confirms, however, that when considering the relationship between IP and competition, the essential function and the specific subject matter of the IP rights at issue must be considered. See 15/74 *Centrafarm BV v. Sterling Drug Inc.* [1974] ECR 1147.
[11] See the summary in this database. The CJEU in that context did not refer to the term "essential facility".
[12] See OECD, Licensing of IP rights and competition law – Note by Italy, DAF/COMP/WD(2019)5, 2019, para. 26, available at: https://one.oecd.org/document/DAF/COMP/WD(2019)5/en/pdf.