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The Italian Merck Case

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Factual and regulatory background

Regulation 1768/92¹ created supplementary protection certificates (hereinafter, ‘SPCs’) for medicinal products (hereinafter, “pharmaceuticals”) protected by patents. SPCs afford the same exclusive rights as those conferred by patents once these expire and may be granted for a maximum of five years.² Italy enacted similar legislation in 1991, the most salient difference between both texts being that, pursuant to Law No. 349/91,³ holders of Italian patents for pharmaceuticals could be granted supplementary protection for a maximum period of 18 years after the expiration of the patent. Following the enactment of Regulation 1768/92, SPCs granted by the Italian authorities were brought in line with the period provided for in that text. However, pharmaceuticals for which supplementary protection was sought in the lapse between the adoption of Law No. 349/91 and Regulation 1768/92 (around 400 products) continued to enjoy the protection provided for in the former text.⁴ Several steps were taken by the Italian authorities to progressively reduce the length of protection granted to these products.

Article 3(8) of Decree-Law No. 63/02 provided that the length of protection for such pharmaceuticals was to be reduced by one year in 2002 and by two years in the subsequent years until the length of protection was in line with that granted at Community level.⁵ Law No. 112/02,⁶ which converted Decree-Law No. 63/02 into Law, chose a different—and slightly more complicated—system. Protection for SPCs granted prior to the entry into force of Regulation 1768/92 was to be reduced by six months (as opposed to one or two years) every year starting on 1 January 2004. At the same time, Law No. 112/02 put in place a system of voluntary licences so as to allow the exploitation of the pharmaceutical by third parties. Voluntary licences were intended for export towards third countries where protection (either through patents or through SPCs) was no longer afforded for the pharmaceuticals in question. Details concerning the granting procedure were left to a Ministerial Decree.⁷ According to the latter text, if the SPC holder and the third party would fail to agree, the competent minister would designate a Conciliation Commission to act as a mediator between the parties. If the Conciliation Commission would fail to reach a satisfactory outcome, the file would then be submitted to the National Competition Authority (Autorità Garante della Concorrenza e del Mercato, hereinafter, “NCA”). The provisions of Law No. 112/02 and the Ministerial Decree were subsequently included in the Industrial Property Code, enacted as Legislative Decree No. 30/2005.⁸

Opening of proceedings

In November 2002, Dobfar, a chemical company based in Italy, requested a licence from Merck for the manufacture and sale in third countries outside the Community of *Imipenem*

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

² *Ibid.*, Article 14(1): “The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community reduced by a period of five years”.

³ Legge 19 ottobre 1991, n. 349, GU [1991] n. 258.

⁴ Pursuant to Article 20 of Regulation No 1768/92, the maximum period of five years “[...] shall not apply to certificates granted in accordance with the national legislation of a Member State before the date on which this Regulation enters into force or to applications for a certificate filed in accordance with that legislation before the date of publication of this Regulation [...]”.

⁵ Decreto-legge 15 aprile 2002, n. 63, GU [2002] n. 90.

⁶ Legge 15 giugno 2002, n. 112, GU [2002] n. 139.

⁷ Decreto 17 ottobre 2002, n. 253, GU [2002] n. 253.

⁸ Decreto Legislativo 10 febbraio 2005, n. 30, GU [2005], n. 52.

Cilastatina, the active ingredient of a sub-family of antibiotics (*carbapenems*) that was protected by an SPC. As Merck refused to grant a voluntary licence, a Conciliation Commission was set up in accordance with the procedure laid down in Article 3(8) of Law No. 112/02 in October 2003. During the conciliation procedure, Merck made it clear that it did not intend to grant a voluntary licence. More precisely, Merck argued that *Imipenem Cilastatina* was a complex product, the manufacture of which required the use of proprietary know-how. Merck also invoked safety reasons to justify its refusal to grant a licence. Following continued disagreement between the parties, the file was sent to the NCA, which decided to open proceedings against Merck for an alleged breach of Article 82 EC in February 2005.⁹

In its decision to open proceedings, the NCA found that the end-product, i.e. *carbapenems*, probably constituted a market of its own, as this sub-family of antibiotics is particularly powerful and therefore distinctively suited for the treatment of some types of infections. The relevant product market was further subdivided on the basis of the commercial channel through which the product reached end-users. Thus, the NCA identified (a) a market for the commercialisation of *carbapenems* via pharmacies as well as (b) a market for the commercialisation of *carbapenems* via hospitals. The relevant geographic market was found to be national in scope.

Whereas it was acknowledged in the decision that AstraZeneca was a strong competitor in the market for the commercialisation of carbapenems via Italian hospitals, the same was not true as regards commercialisation via Italian pharmacies. In the latter market, the NCA found that Merck's market share amounted to 100%, considering both the products marketed by the company itself and via its Italian licensees (Sigma Tau). The same was true in other countries where Merck's active ingredient was no longer protected by SPCs, such as Spain (for commercialisation both via hospitals and pharmacies) or France (via hospitals). More importantly, the NCA took the view that Merck's alleged dominant position could not be challenged as a result of the institutional and technological barriers to entry in place in the said market. According to the NCA, the active ingredient used by AstraZeneca was an inferior product in that it was only administered intravenously. Therefore, the NCA concluded that entry in the relevant product market by producers of generic pharmaceuticals was dependent upon access to *Imipenem Cilastatina*.

In this context, the refusal to licence opposed by Merck was found to be likely to give rise to an abuse under Article 82 EC. In particular, it was held in the decision that Merck's behaviours aimed at artificially extending the length of its exclusive rights in several Member States. More precisely, the NCA claimed that the grant of a licence would have allowed Dobfar (or other generic producers) to undermine Merck's dominant position more easily in those countries (such as France and Spain) where protection for the active ingredient under SPCs had expired. Moreover, the behaviour was not considered to be objectively justified, insofar as Merck's position in the Italian market would have remained unaffected by Dobfar's activities.

Interim measures decision

In the light of these findings, the NCA decided to take interim measures—a possibility that was hinted at in the decision to open proceedings—in June 2005.¹⁰ The interim measures decision was adopted in accordance with Articles 5 and 8 of Regulation 1/2003¹¹ and followed accordingly the requirements laid down in the Camera Care line of case law, that is, (a) a *prima facie* breach of competition law; (b) the risk of a serious and irreparable damage to competition (*periculum in mora*).

⁹ Autorità Garante della Concorrenza e del Mercato, decision n. 14078 of 23 February 2005, *Merck – Principi Attivi*, Case A364.

¹⁰ Autorità Garante della Concorrenza e del Mercato, decision n. 14388 of 15 June 2005, *Merck – Principi Attivi*, Case A364 ("the interim measures decision").

¹¹ Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, OJ [2003] L 1/1. Article 5 of Regulation 1/2003 deals with the "Powers of the competition authorities of the Member States"—which include the power to accept "commitments" and order "interim measures"—and Article 8 of the same Regulation codifies the Camera Care line of case law described above.

As regards the *prima facie* breach of Article 82 EC, the NCA upheld the market definition and the finding of dominance established in the previous decision. It then moved on to examine in closer detail the alleged abusive behaviour on the part of Merck. Interestingly, when examining the abusive nature of the refusal by the latter to grant a licence in the light of previous cases rendered under Article 82 EC, the NCA relied on the *obiter dictum* of the *Oscar Bronner* case,¹² but not on the ECJ ruling in *IMS Health*, which was probably its closest precedent, considering both that it was delivered in 2004 and that it concerned the refusal to grant a licence on an intellectual property right.¹³ The NCA took indeed the view that, absent any objective justification, a refusal by a dominant company to grant a licence for a resource that is deemed essential for penetrating a market amounts to an abuse within the meaning of Article 82 EC. In the NCA's view, the conditions laid down in *Oscar Bronner* were most likely met in the case at hand. First of all, Merck's behaviour seemingly lacked objective justification. Most notably, the NCA recalled that Dobfar always made it clear that it would export the product towards countries outside the EEA so as to avoid jeopardising Merck's intellectual property in Italy as a result of the application of the exhaustion doctrine.¹⁴

Concerning the supposed indispensability of the licence, the NCA based its arguments on the idea that for a chemical company based in Italy, such as Dobfar, a licence is indispensable for the manufacture of a product still covered by intellectual property rights. In this same vein, it was pointed out that Dobfar could not have reasonably been expected to move its manufacturing facilities from Italy to third countries in order to freely manufacture the product. The NCA went as far as to regard Dobfar as an "indispensable manufacturing source", since producers established in third countries where the active ingredient was no longer protected proved unable to compete with Merck in the market for *carbapenems*. In these circumstances, the dominant company's behaviour prevented competition from developing in countries where the absence of regulatory barriers allowed in principle for it, with the subsequent harm to consumers.

The requirements laid down in *IMS Health* were not identical to those sketched in the *obiter dictum* in *Oscar Bronner*. In addition to the conditions set out in the latter, the ECJ required in the former that the refusal opposed by the dominant undertaking prevents the marketing of new product for which there is a potential consumer demand.¹⁵ However, and according to the NCA, this—more stringent—line of case law was not relevant in the present case, considering that the licence would have been granted for sale in third countries where protection by intellectual property rights was no longer afforded.

The risk of a serious harm to competition was equally established by the NCA. According to the decision, a delay in the entry of generic manufacturers could have definitive effects for competition in the market. Based on economic research, the NCA pointed out that, following expiration of intellectual property rights, pharmaceutical companies tend to price their products at a level that discourages new entry by generic manufacturers.

In the light of these conclusions, the NCA ordered Merck to grant a licence to Dobfar for the manufacture of the products in question in exchange of "reasonable" royalties, as provided for in Article 200 of the Industrial Property Code.¹⁶ However, the NCA did not allow Dobfar to sale the active ingredient to generic producers, but just to stock it before a final decision is reached.

Decision upheld on appeal

¹² Case C-7/97, *Oscar Bronner*, [1998] ECR I-7791.

¹³ Joined Cases C-241/91 P and C-242/91 P, *Magill*, [1995] ECR I-743.

¹⁴ It must be recalled that should a licence have been granted for export towards Community countries, Merck's intellectual property rights in Italy would have been exhausted in accordance with the *Merck v Stephar* line of case law. See the interim measures decision, paragraphs 132 et seq.

¹⁵ See paragraph 54 of the *Magill* case: "The appellants' refusal to provide basic information by relying on national copyright provisions thus prevented the appearance of a new product, a comprehensive weekly guide to television programmes, which the appellants did not offer and for which there was a potential consumer demand. Such refusal constitutes an abuse under heading (b) of the second paragraph of Article 86 of the Treaty".

¹⁶ Article 200 of the Italian Industrial Property Code concerns the procedure for the grant of voluntary licences originally provided for in the Ministerial Decree mentioned above, see supra note 7.

Merck challenged the interim measures decision before the Tribunale Amministrativo Regionale del Lazio (hereinafter, "TAR"), which dismissed the action on 3 March 2006.¹⁷ By that time, the SCP over *Imipenem Cilastatina* already came to expiration (this happened on 30 January 2006). The decision bears some importance from a procedural perspective, in that the TAR confirmed the power of the NCA to adopt interim measures.¹⁸ From a substantial point of view, the TAR upheld the NCA's finding that the application of Article 82 EC in the present case did not require the stringent conditions laid down in *IMS Health*; the reasons behind that finding being, again, that Dobfar intended to market its product in countries where the active ingredient was no longer protected.

Commitments proposed in November 2006

The proceedings were closed by a decision of the NCA on 21 March 2007¹⁹ following formal acceptance of the commitments presented by Merck in November 2006. This is one of the first occasions where the NCA has made use of its newly granted powers to close proceedings in competition proceedings through commitments granted by the parties in accordance with Article 5 of Regulation 1/2003.²⁰ In these proceedings, Merck presented commitments regarding the licensing of a different active ingredient, known as *Finasteride*.

In its decision of 15 November 2006,²¹ the NCA acknowledged the commitment taken by Merck to grant a royalty-free licence, from 1st July 2007 until the expiration of the SCP (to take place in on 1 July 2009), for the manufacture, import or promotion in Italy of a specific product containing 5 mg. of *Finasteride* (hereinafter, the "product"), which is a formula indicated for the treatment of some prostate diseases. More precisely, Merck committed (a) not to block imports of *Finasteride* if intended for the manufacturing of the product by the licensee importing the product or another licensee; (b) not to oppose the production of *Finasteride* in Italy if aimed at manufacturing the product or export towards third countries within the Community where protection under intellectual property rights no longer exists and (c) not to oppose acquisition of *Finasteride* by a licensee from another licensee for manufacture and/or sale in Italy. In the NCA decision to close proceedings (decision of 21 March 2007) a new commitment was added. The company committed not to exercise other intellectual property rights to block manufacturing from third parties.

There are strong doubts as to whether the present proceedings were done in accordance with the Italian Industrial Property Code. In the presentation of the sample licence agreement proposed by Merck,²² the NCA considered that commitments regarding *Finasteride* simply aimed at replicating the situation that would have existed with *Imipenem Cilastatina* if Merck had granted a licence to Dobfar in the first place. There are however some reasons to believe it is not the case. First of all, voluntary licences granted under the Italian Industrial Property Code were not royalty-free. Secondly, such licences were careful not to undermine the existence of the SCP in Italy, whereas the royalty-free licence at stake jeopardises the very existence of the exclusive right.

Comments

Among cases dealing with the application of Article 82 EC to a refusal to licence intellectual property rights, the present case probably stands out as a *sui generis* one. The very first question that arises is whether the recourse to Article 82 EC was at all necessary in the

¹⁷ Tribunale Amministrativo Regionale Lazio, decision of 3 March 2006, n. 341.

¹⁸ The TAR confirmed that Article 5 of Regulation 1/2003 has direct effect and prevails over contradicting national legislation.

¹⁹ Autorità Garante della Concorrenza e del Mercato, decision n. 16597 of 21 March 2007, *Merck – Principi Attivi*, Case A364.

²⁰ Commitment decisions, whereby the competition authority closes proceedings against an undertaking or a group of undertakings following commitments offered by these, are one of the most prominent tools in the hands of authorities in post-modernisation competition law. The Italian Competition Act was modified in September 2006 so as to make these new powers stem explicitly.

²¹ Autorità Garante della Concorrenza e del Mercato, decision n. 16130 of 15 November 2006, *Merck – Principi Attivi*, Case A364.

²² Available at <http://www.agcm.it>.

present case. As a matter of fact, Law No. 112/02 did not require the NCA to examine disagreements regarding voluntary licences in the light of competition law principles. It simply provided that the NCA would play a role as a mediator between the parties in the case of a persistent disagreement between the parties. In the light of a literal interpretation of that provision, one could have concluded that the NCA could have made Merck and Dobfar reach a satisfactory compromise thanks to its unique expertise, and this without applying Article 82 EC. In reality, it is not rare that a competition or a regulatory authority is called upon to mediate between two parties or to supervise a deal. For instance, Spanish Law No. 21/1997,²³ concerning sporting exhibitions, appointed the Spanish NCA as a mediator in disputes between broadcasters regarding access to news excerpts of games. This had the consequence of adding new competences to the Spanish NCA, which were included in the 1989 Competition Act²⁴ to the existing ones, without however requiring this body to rely on competition law to rule on disputes brought in accordance with Law No. 21/1997. Likewise, the Italian regulatory authority for telecommunications was called upon by the Commission to supervise the respect by the parties of the conditions imposed by the latter in the NewsCorp/Telepiù merger.²⁵

In any event, it stems from the different decisions that the outcome of the case (i.e. an obligation to license) was somewhat predetermined by the provisions of Law No. 112/02. As a consequence, the application of the refusal to supply line of case law by the NCA is unconvincing in several respects. First of all, it is unclear that a licence was truly indispensable for competition to take place in those markets where the active ingredient was no longer protected by intellectual property rights. If access to the input was indeed free, there were by definition alternative ways in which it could have been accessed. Secondly, the reasons why the conditions laid down by the ECJ in its *obiter dictum* in *Oscar Bronner* are preferred over those set out in *IMS Health* and *Magill* are definitely unconvincing. The right to license an SPC for manufacture in the country of protection is a prerogative of the right holder and exists regardless of whether the same protection is afforded in third countries. Accordingly, there is no valid reason why the more stringent conditions of the *IMS Health* did not apply in the present case.

It is interesting to note that this case somehow confirms the idea that the obligation to license intellectual property rights under Article 82 EC tends to arise in cases where protection for such rights is “weak”. Even though the question was never explicitly acknowledged by the ECJ, the fact that programme listings only qualified for protection by copyright in Ireland and United Kingdom within the Community certainly played a role in the *Magill* case.²⁶ Likewise, the question of whether the “brick structure” at stake in the *IMS Health* case qualified for protection under copyright was a contentious issue throughout the whole procedure.²⁷ The same can be said with regard to the *British Horseracing Board* case.²⁸ The *Merck* case is in some ways comparable to *Magill*, insofar as in both cases the application of Article 82 EC was partly provoked by the disparities concerning protection for intellectual property rights within the Community. In *Merck*, the length of SPCs granted under Law No. 349/91 prior to the entry into force of Regulation 1768/92 put some right holders in a unique position, which would inevitably create tensions. What is more, the case arose as a result of the efforts made by the Italian government to bring its legislation in line with the Community one.²⁹

²³ Ley 21/1997, de 3 de julio, reguladora de las Emisiones y Retransmisiones de Competiciones y Acontecimientos Deportivos, BOE [1997] n. 159.

²⁴ Ley 16/1989, de 17 de julio, de Defensa de la Competencia BOE [1989] n. 170. The consolidated version of the Act is available at <http://www.tdcompetencia.es/html/legislacion/index.asp?codigo=3>.

²⁵ Commission decision of 2 April 2003, *NewsCorp/Telepiù*, OJ [2004] L 110/73.

²⁶ See the *Magill* case, supra note 13 and Govaere, *The Use and Abuse of Intellectual Property Rights in EC Law*, Sweet & Maxwell, 1996, pp. 149-150.

²⁷ See for instance references in Jones and Sufirin, *EC Competition Law – Text Cases and Materials*, Oxford University Press, 2004 (2nd Edition), p. 503.

²⁸ See Court of Appeal of England and Wales, 2 February 2007, *Attheraces v British Horseracing Board*, Case No: A3/2006/0126, available at <http://www.bailii.org/ew/cases/EWCA/Civ/2007/38.html>.

²⁹ Likewise, it is alleged that following the harmonisation of the conditions of protection of databases in Europe, the divergences that became apparent in the *Magill* case would no longer arise. See for instance Strowel and Declaye, *Droit d'auteur et numérique*, Bruylant, 2001, pp. 324-325.

In a different vein, it seems that the NCA has taken advantage of the *Merck* case to legislate on SPCs “through the back door”. It must be pointed out in this regard that the NCA opened parallel proceedings against GlaxoSmithKline on 23 January 2005 relying on a very similar set of facts.³⁰ Moreover, the commitments presented by Merck regarding *Finasteride* go clearly beyond what was allowed under Law No. 112/02 and, unlike the case of the latter, amount in practice to the elimination of the SPCs in Italy. It must be recalled that Law No. 112/02 was a timid and insufficient effort to bring Italian legislation in line with Regulation 1768/92—action proposed in the Decree Law No. 63/02 was much firmer—and it would seem that the NCA is being called upon to do what the Italian legislator proved unable to. If this is so, it must be stressed that the instrumentalisation of competition law is undesirable and may come at the price of a more than dubious application of such provisions, like in the case at hand.

³⁰ Autorità Garante della Concorrenza e del Mercato, decision n. 14070 of 23 February 2005, *Glaxo – Principi Attivi*, Case A363. The proceedings were closed when GlaxoSmithKline accepted to grant a licence on the conditions laid down by the NCA, see Autorità Garante della Concorrenza e del Mercato, decision n. 15175 of 8 March 2006, *Glaxo – Principi Attivi*, Case A363.



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