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The Italian Council of State rules on the issue of dominant firms' duty to supply essential information beyond the requirements of sector regulation (BCS)

Italy, Unilateral practices, Abuse of dominance, Essential facility, Access to information, Judicial review, Pharmaceutical

Italian Council of State (Consiglio di Stato), 11 January 2013, n° 548, BCS

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Italy's highest administrative court handed down an important ruling on the issue of the dominant firms' duty under Article 102 TFEU to grant their competitors access to essential information when sector regulation encourages such a disclosure. By its judgment of 11 January 2013, no. 548 (the "*BCS* judgment"), the Italian Council of State court upheld the decision of the Italian Antitrust Authority ("IAA") in the *A415 - Sapec Agro / Bayer-Helm*case [1], which had imposed a fine of over EUR 5 million on two companies of the *Bayer Group, Bayer Cropscience AG* and *Bayer Cropscience Ltd* ("*BCS*"). The Council of State, giving final judgment on the matter, reversed an earlier decision by the Latium Regional Administrative Court that had annulled the IAA Decision at first instance [2].

1. The IAA Decision.

Following a complaint by a competitor, the IAA had launched an investigation against *BCS* for an alleged abuse of dominant position in the Italian market for fosetyl-based fungicides for the treatment of grapevine downy mildew. The IAA found that *BCS* had put in place a complex strategy to refuse certain competitors, members of the European Union Fosetyl-Aluminium Task Force ("the Task Force"), access to the results of two toxicological studies on the effects of fosetyl, which, under sector regulation, were necessary to obtain the renewal of marketing authorizations for generic fungicides based on that active ingredient. According to the IAA, *BCS*'s conduct had resulted in the withdrawal of 26 marketing authorizations, the exclusion of the Task Force from the relevant market, an increase in *BCS*'s market share from 45% to 50-60%, a rise in average prices of fosetyl-based fungicides of about 25%, and a reduction in the sales of those fungicides of about 3% [3].

2. The substantive test applied by the Council of State.

To review *BCS*'s conduct, the Council of State applied a substantive test that seems to conflate the refusal to license and essential facilities doctrines as articulated by EU courts. Just like the Court of Justice did in *Microsoft* [4], the Council of State assessed whether: i) the dominant firm's input was indispensable to operate in a given market; ii) the refusal eliminated effective competition in that market; iii) the refusal prevented the appearance of a new product; iv) the refusal was not objectively justified. However, following the Court of Justice's approach in *Oscar Bronner* [5], the Council of State broke down the first prong of the test into two sub-prongs, i.e. the non-duplicability and the non-substitutability of the input controlled by the dominant firm.

3. Indispensability of the input.

In *Oscar Bronner* the Court of Justice checked whether the same input (i.e. a nationwide home-delivery scheme) could neither be duplicated by access-seekers nor be substituted with alternative inputs [6]. In the *BCS*judgment, instead, the Council of State looked at two different inputs: first, it established whether the studies on fosetyl were duplicable by the Task Force, second, it determined whether fosetyl could be replaced by other active ingredients for the production of downy mildew fungicides.

The duplicability of the studies carried out by *BCS* proved a particularly controversial issue, both in the proceedings before the IAA and before Italian administrative courts. In order to avoid duplicative testing on vertebrate animals, sector regulation encouraged the sharing of test results among competitors and laid down a consultation and arbitration procedure to that end. Nonetheless, because of *BCS*'s obstructionist and dilatory tactics [7], the Task Force and *BCS* did not manage to reach an agreement on access to the fosetyl studies. While the Lazio Regional Administrative Court took the view that sector regulation merely discouraged the duplication of existing studies [8], the Council of State upheld the IAA's claim that replication of the experiments carried out by *BCS* was prohibited, thus making access to those test results indispensable [9].

The Council of State's assessment of the substitutability of fosetyl with other active ingredients marks a clear divergence from the EU case law. While in *Oscar Bronner* the Court of Justice clearly stated that the existence of "less advantageous" substitutes ruled out the indispensable character of a given input [10], the Council of State found that the fosetyl studies were indispensable even though alternative solutions would have allowed the Task Force companies to continue to operate in the relevant market [11], albeit without "maintaining their current position and role" [12]. To paraphrase a well-known commentary to the *Microsoft* case, the Council of State embraced a doctrine of "convenient facilities", rather than of "essential" ones [13].

4. The elimination of competition.

In its decision against *BCS*, the IAA provided a detailed analysis of the effects of *BCS*'s conduct on that firm's market share, on the Task Force, and on the prices and sales of fosetyl-based fungicides [14]. On the contrary, the Council of State simply averred that *BCS*'s behaviour, in view of its clear repugnancy with competition rules and its openly anti-competitive intent, had to be considered illegal "irrespective of a finding of the existence … of harm to competition" [15].

That finding, which implies a *per se* ban on some unilateral practices similar to that applying to agreements restricting competition "by object" under Article 101 TFEU, not only appears at odds with the effect-based reform of Article 102 TFEU advocated by the Commission for the last ten years [16], but also deviates from the more conservative case law of the Court of Justice, according to which the elimination, even potential, of effective competition is one of the prongs that must be met for a refusal to license claim to succeed [17].

5. The obstacle to the introduction of a new product.

The prong in question constitutes the *raison d'être* of the antitrust prohibition on refusal to license: the encroachment on the IP rights of the dominant firm and the reduction of incentives to innovate resulting from the imposition of a duty to license are only justified if obtaining that license enables other firms to introduce new products or services, which the dominant firm does not offer and for which there is a potential demand [18]. As explained in *IMS Health,* this is not the case if the license-seeker "intend[s] to limit itself essentially to duplicating the goods or services already offered on the secondary market by the owner of the intellectual property right" [19]. Yet, in the instant case it was undisputed that the Task Force had requested access to *BCS*'s studies to obtain the renewal of their marketing authorizations for generic fosetyl-based fungicides, i.e. products already offered on the market and entirely equivalent to *BCS*'s own fungicides [20].

Admittedly, the prong concerning the obstacle to the introduction of a new product had been significantly watered down by the Court of First Instance in its judgment in *Microsoft,* where it stated that the refusal to license may constitute an abuse of dominant position even if it merely has a negative impact on the incentives to innovate for the dominant firm's competitors [21]. However, while the Commission had provided ample evidence of the effects of Microsoft's refusal on its competitors' investment in innovation (for example, by comparing their investment behaviour before and after the refusal) [22], the IAA merely claimed that the development of new-generation fungicides would have been "likely" if the Task Force had been allowed to remain on the market [23].

The Council of State, in turn, espoused an even broader understanding of the obstacle to the introduction of a new product prong, by taking the view that, from the perspective of the Task Force, the renewal of existing marketing authorizations for their generic fungicides was "equivalent to obtaining a marketing authorization for a new product" [24]. This approach, which unduly expands the notion of "new product", seems to deprive the prong in question of all practical significance and may substantially chill innovation in industries, such as pharmaceuticals and plant protection products, where interactions between antitrust and IP law are manifold and frequent [25].

6. The absence of objective justifications.

In the course of the proceedings before the IAA, *BCS* had pleaded that its refusal to grant access to the studies was necessary to protect its IP rights [26]. The Court of First Instance had already rejected a similar justification in *Microsoft,* noting that, if the mere fact of holding IP rights could in itself constitute an objective justification, refusal to license could never be contrary to Article 102 TFEU [27].

In the proceedings before the Latium Regional Administrative Court, therefore, the analysis of possible justifications had also extended to *BCS*'s allegations of negligence on the part of the Task Force in taking the steps laid down by sector regulation to obtain access to the test results. The Council of State, however, eventually ruled that the purported negligence of *BCS*'s competitors did not "erase the anticompetitive character" of the dominant firm's conduct [28].

7. Conclusions.

The prerogative of the holder of an IP right to exploit it to its own exclusive advantage is the very subject-matter of that exclusive right [29], which the legal system acknowledges and upholds to reward the creation of original works and the development of innovative technologies [30]. The imposition of a compulsory license, even in return for a reasonable price, leads to a reduction in the incentives to innovate both for the right holder (by discouraging further investment in research) and for its competitors (by sanctioning *free-riding*), thus harming consumer welfare in the long run [31]. For this reason, EU courts, and even more so their American counterparts, [32] have proved rather cautious in imposing licensing obligations on dominant firms, by requiring evidence either of the "exceptional circumstances" outlined in *Magill, IMS Health* and *Microsoft* [33] or of "certain abusive conduct" such as that described in *Volvo* and *Renault* [34].

The Council of State in the *BCSjudgment took the opposite perspective, by characterising the duty to share essential information with competitors as a corollary of the "special responsibility" borne by all dominant firms, subject to requirements that appear a watered-down version of the Microsoft prongs. [35] In particular, by espousing an overly broad understanding of the "new product" prong, the Council of State appeared willing to forego the dominant firm's incentives to innovate without requiring any proof of countervailing potential innovation by access-seekers. [36]*

The Council of State's assessment of the facts of the case might have been influenced by the fact that *BCS* had maliciously circumvented the procedure laid down by sector regulation for the sharing of test results, thus eventually leading the Task Force to carry out its own experiments. Nevertheless, while the existence of a regulatory duty to deal might lower the burden of proof required for the imposition of an obligation to supply under Article 102 TFEU, [37] the use of competition law to fix the loopholes in sector regulation by requiring a conduct that regulation merely sought to encourage appears a bridge too far, as it may undermine legal certainty and chill innovation thereby harming consumers in the long run.

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[1] IAA Decision no. 22558 of 28 June 2011, *A415 - Sapec Agro / Bayer-Helm*, in *Bulletin* no. 26/2011 (the "*BCS* Decision"). See also **P. L'Ecluse**, *The Italian Competition Authority fines a leading chemical company €5 M for refusal to grant access to research data (Bayer CropSciences)*, 5 juillet 2011, e-Competitions, N°41101.

[2] Latium Regional Administrative Court, Judgment of 21 March 2012, no. 4403 (the "*BCS* Trial Judgment"). *See also* **Valerio Mosca**, *The First Instance Administrative Tribunal of Lazio quashes the decision of the Competition Authority which had found an alleged abuse of dominant position by*

a crop science compagnie consisting in the refusal to grant access to certain essential studies protected by IP rights (Bayer CropScience), 16 mai 2012, e-Competitions, N°48547.

[3] See *BCS* Trial Judgment, paras 296-300.

[4] See Case T-201/04, *Microsoft Corp. v. Commission,* ECR p.II-03601, ("*Microsoft*") para 324; *See also* Joined Cases C-241/91 P and C-242/91 P,*RTE and ITP v. Commission,* ECR p.I-743, ("*Magill*"), paras 53-56; Case C-418/01, *IMS Health GmbH v. NDC Health GmbH, ECR* p. I-05039, ("*IMS Health* "), para 37.

[5] See Case C-7/97, *Oscar Bronner,* ECR p. I-07791, ("*Oscar Bronner*"), paras 41-47.

[6] See *Oscar Bronner,* paras 43-46. *See also* **Communication from the Commission** -Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings (*OJ C 45, 24.2.2009, p. 7-20->* http://eur-lex.europa.eu/LexUriServ...]), para 83.

[7] During the investigation, the IAA found a BCS corporate document entitled "How we made Fosetyl-Al a difficult target for generic companies." *See BCS* Decision, paras 132-135.

[8] See *BCS Trial Judgment*, para 3.1.2.

[9] See *BCS* Decision, paras 269-283; *BayerCropscience* para IV.C.Ia.

[10] See *Oscar Bronner,*para 43. *See also IMS Health,*para 28.

[11] See *BCS* Decision, para 285

[12] Ibid., para 286.

[13] Cf. D. Ridyrard, Compulsory Access Under EC Competition Law - A New Doctrine of "Convenient Facilities" and the Case for Price Regulation, in European Competition Law Review, 2004, p. 670 et seq..

[14] See *BCS* Decision, paras 288, 294-300.

[15] See *BCS* Judgment, para IV.c.4a. In para IV.c.5a, however, the Council of State noted that harm to competition did in fact take place in the instant case.

[16] See*, e.g.,* speech delivered on 23 October 2003 by the Director General of DG Competition Philip Lowe at the Fordham Corporate Law Institute; "An economic approach to Article 82", report presented in July 2005 by the Economic Advisory Group on Competition Policy; Discussion Paper on the application of Article. 82 to exclusionary abuses, published in December 2005 by DG Competition; and Article 82 Guidance, paras 19-22.*See also* A. Ezrachi, *The Commission's Guidance on Article 82 EC and the Effects Based Approach: Legal and Practical Challenges* in Ezrachi A. (ed.) *Article 82 EC: Reflections on its Recent Evolution,* Hart Publishing, Oxford , 2009, p. 56 et seq.

[17] See *Magill*, para 56; *IMS Health,*paras 40-47; *Microsoft,*paras 561-563.

[18] See Opinion of AG Tizzano, Case C-418/01, *IMS Health*, *ECR* p.I-05039, para 62.

[19] See *IMS Health*, para 49.

[20] See G. De Stefano, *Tough Enforcement of Unilateral Conduct at the National Level: Italian Antitrust Authority Bayer and Pfizer Sanctions for Abuse of Dominant Position (aka Ruling AstraZeneca and Essential Facility Doctrine in Italian Sauce),* in *Journal of European Competition Law & Practice,* 2012, p. 6.

[21] See *Microsoft,*para 659.

[22] See Commission Decision of 24 March 2004 no. 2007/53/EC, *COMP/C-3.37.792 - Microsoft, OJ* 2007 L 32, p. 23, paras 693-708 and 782.

[23] See *BCS* Decision, para 288.

[24] See *BCS* Judgment, para IV.c.3a

[25] See, *generally*, Commission Pharmaceutical Sector Enquiry Final Report, 8 July 2009, available at: http://ec.europa.eu/competition/sec....

[26] See *BCS* Decision, para 289.

[27] See *Microsoft,*para 690.

[28] See *BCS* Judgment, para IV.c.4a.

[29] SeeCase 238/87, *Volvo AB c.Erik Veng (UK) Ltd, ECR* p. 6211, para 8; *Microsoft*, para 691

[30] See S. Calandrillo, *An economic analysis of property rights in information: justifications and problems of exclusive rights, incentives to generate information, and the alternative of a Government-run reward system,* in *Fordham Intellectual Property Media and Entertainment Law Journal,* vol. 9, 1998, pp. 310-316.

[31] See Article 82 Guidance, para 75.

[32] See *Data General Corp. v. Grumman Systems Support Corp.,* 36 F.3d 1147 (1st Cir.1994); *Image Technical Servs., Inc. v. Eastman Kodak Co.,* 125 F.3d 1195 (9th Cir.1997); *In re Independent Service Organizations Antitrust Litigation,* 203 F.3d 1322 (Fed. Cir. 2000). On refusal to deal in general, see also *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP,* 540 U.S. 398 (2004); *Pacific Bell Telephone Co. v.. linkLine Communications, Inc.,* 555 U.S. 438 (2009).

[33] See *Magill,*paras 53-56; *IMS Health,*para 37; *Microsoft*, para 324.

[34] See *Volvo,*para 8.

[35] See*BCS* Judgment, para IVc.

[36] See E. Fox, *Monopolization, Abuse of Dominance, and Refusal to License Intellectual Property*

Competitors to-Do Antitrust Duties Help or Hurt Competition and Innovation? How Do We Know?, in C. Ehlermann and I. Atanasiu (eds.), *European Competition Law Annual 2005: What Is An Abuse Of A Dominant Position?,* Hart, Oxford, 2006, pp. 633 ff.

[37] See **Communication from the Commission**, Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings ; (*OJ C 45, 24.2.2009, p. 7-20*->http://eur-lex.europa.eu/LexUriServ...]), para 82; *See also* Commission Decision of 4 July 2007, *COMP/38.784*, *Wanadoo Espana v. Telefónica, Commission,* para 303; Opinion of Advocate General Mázak in Case C-52/09, *Konkurrensverket v. TeliaSonera AB*, para 58.

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