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QUESTION A

APPLICATION OF COMPETITION LAW IN THE PHARMACEUTICAL SECTOR

BELGIUM

National Reporter

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¹ The content of this report does not necessarily reflect the position of Van Bael & Bellis or its clients. Responsibility for the information and views expressed lies entirely with the author.

1. Introduction

This report analyses in what way the application of the Belgian competition rules is affected by the specific characteristics of pharmaceutical products and markets. Sub-questions discussed include (i) whether pharmaceutical products receive differentiated legal treatment under Belgian competition law; (ii) whether any differentiated enforcement mechanisms exist; (iii) the interaction of pharmaceutical intellectual property protection and competition law; and (iv) whether there is shared practice on budgetary and other public interest considerations.

This report will not rigidly follow the structure of the International Rapporteur's questionnaire. In particular, there will be a stronger emphasis on the few relevant Belgian competition cases in the pharmaceutical sector, which often clarify several of the sub-questions raised in the questionnaire.

The report will first briefly describe the Belgian legal framework (*see*, Section 2 below).

Second, the issue of market definition in the pharmaceutical sector will be addressed (*see*, Section 3 below).

Third, the report will discuss *intra*-brand competition in the pharmaceutical sector, and parallel trade in particular (*see*, Section 4 below).

Fourth, the report will address *inter*-brand competition in the pharmaceutical sector, focusing on generic entry in particular (*see*, Section 5 below).

Finally, a brief conclusion will be formulated (*see*, Section 6 below).

2. Legal Framework

The Belgian competition rules are laid down in Book IV of the Code of Economic Law of 28 February 2013² (**CEL**). The rules, as well as their application, are heavily based on EU competition law. Articles IV.1 and IV.2 **CEL** repeat in near-identical terms the principles laid down in Articles 101 (anti-competitive agreements) and 102 (abuse of dominance) of the Treaty on the Functioning of the European Union (**TFEU**).

Article IV.1 **CEL** provides as follows:

“**Art. IV.1.** §1. Without the need for a prior decision to that effect, all agreements between undertakings, decisions by associations of undertakings and concerted practices which have as their object or effect the

² Code of Economic Law of 28 February 2013 (*Wetboek van economisch recht van 28 februari 2013/Code de droit économique du 28 février 2013*), *BS/MB* of 29 March 2013, p. 19975.

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appreciable prevention, restriction or distortion of competition on the Belgian market concerned or a substantial part thereof are prohibited, and in particular those which:

- 1° directly or indirectly fix purchase or selling prices or any other trading conditions;
- 2° limit or control production, markets, technical development, or investment;
- 3° share markets or sources of supply;
- 4° apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- 5° make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

§2. Any agreements or decisions prohibited pursuant to this Article shall be automatically void.

§3. The provisions of paragraph 1 may, however, be declared inapplicable in the case of:

- 1° any agreement or category of agreements between undertakings,
- 2° any decision or category of decisions by associations of undertakings, and
- 3° any concerted practice or category of concerted practices which contribute to improving the production or distribution of goods or to promoting technical or economic progress or which enable small and medium-sized enterprises to strengthen their competitive position on the market concerned or the international market, while allowing consumers a fair share of the resulting benefit, and which do not:

- a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives;
- b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

§4. Natural persons are prohibited from negotiating or making arrangements with competitors in the name and on behalf of an undertaking or an association of undertakings about:

- a) the fixing of selling prices of products or services to third parties;
- b) the limitation of production or sale of products or services;
- c) the allocation of markets.”

Article IV.2 CEL reads as follows:

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“**Art. IV.2.** Without the need for a prior decision to that effect, the abuse by one or more undertakings of a dominant position on the Belgian market concerned or a substantial part thereof is prohibited.

Such abuse may, in particular, consist in:

- 1° directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- 2° limiting production, markets or technical development to the prejudice of consumers;
- 3° applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- 4° making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.”

The Supreme Court ruled that the above provisions should be applied in the light of EU law.³ They are fully applicable to the pharmaceutical sector which, despite its specific characteristics, is not subject to any special competition rules. The same applies under the Belgian merger control rules.⁴

There is in Belgium no specific legislation or guidance on the application of competition law to the pharmaceutical sector. The enforcement of competition law in the pharmaceutical sector is also not different from that in any other economic sectors. This means that the competition rules are enforced by the Belgian Competition Authority (*Belgische Mededingingsautoriteit/Autorité belge de la Concurrence* – the **BCA**), which may intervene either *ex officio* or at the request of a plaintiff, and that the BCA’s decisions can be appealed to the Brussels Court of Appeal.⁵ The civil courts can settle disputes regarding breaches of competition law as well. Contrary to the BCA, the civil courts can also rule on disputes in consumer law matters.

Although the BCA has, over the years, received a few merger notifications in the pharmaceutical sector, it has never prohibited any mergers between pharmaceutical companies or imposed remedies on merging pharmaceutical companies.

3. Market Definition in Pharmaceutical Sector

As is the case under EU competition law, the analysis of an agreement or practice under Articles IV.1 and/or IV.2 **CEL** starts with the definition of the relevant product and geographic markets.

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³ Supreme Court, 9 June 2000, *Arr.Cass.* 2000, p. 354.

⁴ See, Articles IV.6 through IV.11 **CEL**.

⁵ See, **Article IV.79 CEL**. The judgments of the Brussels Court of Appeal can be further appealed, but on points of law only, to the Supreme Court.

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3.1 Relevant Product Market

The relevant product market comprises “all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products' characteristics, their prices and their intended use”.⁶

Applying this definition to the sale of pharmaceutical products, the BCA has adopted a disparate *ad hoc* approach similar to that of the European Commission (the *Commission*) which considers the characteristics of the pharmaceutical sector.

The BCA has noted that it should first be determined whether the product concerned is (i) an approved medicine; (ii) an active substance; or (iii) a pipeline product.⁷

For approved medicines, the third level of the Anatomical Therapeutic Chemical classification system (ATC 3) is generally used as a starting point.⁸ The ATC classification system divides medicines into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties. The system's third level groups medicines in pharmacological/therapeutic subgroups (e.g., the subgroup of “blood glucose lowering drugs, excluding insulins”).

However, the BCA has recognized that, depending on the circumstances, a narrower or broader market definition may be appropriate. In *Bofar*, for instance, the Competition Prosecutor-General found that “the analysis of the relevant markets, as regards therapeutic use and substitutability from the point of view of the prescribing physician, differs clearly from the analysis of the same markets from the point of view of the distribution system to pharmacies”.⁹ Adding that, in the latter situation, “the commercial freedom of companies to substitute one pharmaceutical product by another is nearly inexistent”, the Prosecutor concluded that “it may be necessary to derogate from the existing market definition, at level 3 of the ATC classification, and to apply narrower market definitions such as at levels 4 or 5 of the ATC classification”.¹⁰

⁶ Commission notice on the definition of the relevant market for the purposes of Community competition law, OJ 1997, C372, p. 5, point 7.

⁷ See, Competition Council, Decision No. 2001-C/C-39 of 2 July 2001, *Johnson & Johnson/Alza Corporation*.

⁸ See, for instance, Competition Council, Decision No. 2002-C/C-54 of 9 July 2002 in case CONC-C/C-02/0031, *Advent International Corporation/Viatris*.

⁹ Competition Prosecutor-General, Decision No. 2008-V/M-12-AUD of 26 March 2008 in case MEDE-V/M-07/0038, *Bofar NV v Alcon-Couvreur NV, AstraZeneca NV, Bayer NV, Biogen Idec Belgium NV, Boehringer Ingelheim Comm. V., Bristol Myers Squibb Belgium, Janssen-Cilag Belgium, Pfizer NV and Seroxo Benelux BV*, point 99. The BCA's finding is based on, and refers to, Decision No. 07-D-22 of 5 July 2007 of the French Competition Council.

¹⁰ *Ibid.* The criterion of “substitutability” as applied in competition cases differs from that in comparative advertising cases, where products are found “substitutable” if they are, at least to a certain extent, capable of meeting identical consumer needs. Contrary to what is the case in competition cases, there is thus no room for a supply-side analysis in comparative advertising cases. In the pharmaceutical field, the Belgian courts have ruled several times that an originator reference product and its generics versions are

However, the Prosecutor dismissed Bofar's assertion that there would be a separate product market for each patented medicine.

In other instances, the BCA adopted broader market definitions, such as the market of pharmaceutical wholesalers-distributors (*groothandelaars-verdelers/grossistes-répartiteurs*) or, even broader, the pharmaceutical wholesaling market in general. In *Investipharm Belgium/Alpha Répartition* and in *Febelco/Mauroy Ets.*, the Competition Council held that, for pharmacies, "regular" wholesalers are not a valid alternative to wholesalers-distributors. Contrary to "regular" wholesalers, wholesalers-distributors are indeed subject to public service obligations, including the obligation to (i) maintain a constant stock of pharmaceuticals corresponding to (a) two-thirds of the number of pharmaceuticals that are on the market in Belgium and (b) the average value of the monthly turnover of the preceding year per pharmaceutical; and (ii) be able to supply the pharmaceuticals in case of urgency and, otherwise, within 24 hours after ordering.¹¹ The BCA noted in *Febelco/Mauroy Ets.* that the market could possibly be segmented according to the category of customers as well (pharmacies vs hospitals), but it did not deem it necessary to decide upon this distinction.

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In contrast, in *Source Belgium/Febelco*, the relevant product market was defined more generally as the wholesale market for pharmaceuticals.¹²

The BCA has not yet had the opportunity to define product markets in the active substances and pipeline products spaces.¹³

substitutable, and thus can be compared, as their intrinsic characteristics are by definition comparable. This holds true even if the originator product has more therapeutic indications than the generic product because (i) the comparison made by the generic manufacturer by definition cannot go beyond the indications listed in the patient information leaflet of the generic product; and (ii) both products respond to the same needs for these indications (See, for instance, Brussels Court of Appeal, 26 March 2002, UCB NV and UCB Pharma NV v Eurogenerics NV, Jb. Hand. Med. 2002, p. 80).

¹¹ Competition Council, Decision No. 2005-C/C-9 of 9 March 2005 in case CONC-C/C-05/0006, *Investipharm Belgium SA/Alpha Répartition SA*, point 3.2; Competition Council, Decision No. 2008-C/C-65 of 8 December 2008 in case MEDE-C/C-08/0027, *Febelco CVBA/Mauroy Ets. NV*, point 21. The public service obligations of wholesalers-distributors are legally based on Article 12ter, §1, indent 10 of the Law of 25 March 1964 on medicines (*Wet van 25 maart 1964 op de geneesmiddelen/Loi du 25 mars 1964 sur les médicaments*, BS/MB of 17 April 1964, p. 4206 – the **Law on Medicines**) *juncto* Articles 100 and 101 of the Royal Decree of 14 December 2006 on medicines for human and veterinary use (*Koninklijk Besluit van 14 december 2006 betreffende geneesmiddelen voor menselijk en diergeneeskundig gebruik/Arrêté royal du 14 décembre 2006 relatif aux médicaments à usage humain et vétérinaire*, BS/MB of 22 December 2006, p. 74016 – the **Royal Decree on Medicines**).

¹² President of the Competition Council, Decision No. 2004-V/M-30 of 25 March 2004 in case MEDE-V/M-04/0003, *Source Belgium NV v Febelco CVBA*, point 5.1.1.

¹³ At the European level, *see*, for instance, Commission decision of 9 August 1999 in case IV/M.1378, *Hoechst/Rhône-Poulenc*, Decision on Commission website, point 25 (active substances) and points 26 and 27 (pipeline products); Commission decision of 8 May 2000 in case COMP/M.1846, *Glaxo Wellcome/Smithkline Beecham*, Decision on Commission website, points 70-72 (pipeline products).

3.2 Relevant Geographic Market

The relevant geographic market comprises “the area in which the undertakings concerned are involved in the supply and demand of products or services, in which the conditions of competition are sufficiently homogeneous and which can be distinguished from neighbouring areas because the conditions of competition are appreciably different in those area”.¹⁴

In line with the Commission’s decisional practice, the BCA has consistently found that the relevant geographic market for finished pharmaceutical products is national in scope due to the differences in national health insurance and reimbursement systems, national regulatory systems, prescription behaviour of physicians, etc.¹⁵

In *Investipharm Belgium/Alpha Répartition*, the BCA found that the market of pharmaceutical wholesalers-distributors is national in scope. It noted that, although initially organised at a regional level, the wholesale distribution of pharmaceuticals has clearly evolved to a national structure. The conditions of market access and the prices of medicines are the same throughout the country and all wholesalers-distributors are subject to the same regulatory framework. Moreover, given the small size of Belgium, any wholesaler is able to supply a medicinal product within 1.5 hour after a pharmacist’s ordering.¹⁶ In its subsequent decision in *Febelco/Mauroy Ets.*, the Competition Council found the market of pharmaceutical wholesalers-distributors to be “at most” national in scope.¹⁷

4. Intra-brand Competition –Parallel Trade

The BCA ruled on *intra*-brand competition, and on restrictions to parallel trade in particular, in the *Bofar* case, which is the BCA’s most important case in the pharmaceutical sector in Belgium. As the BCA extensively considered Belgium’s specific regulatory context in this case, the first subsection will describe this context (*see*, Section 4.1 below). Next, the *Bofar* case itself will be discussed (*see*, Section 4.2 below).

4.1 Belgian Regulatory Context

The Belgian pharmaceutical sector is characterised by its (i) extensive and strict price regulation; and (ii) specific distribution system.

¹⁴ Commission notice on the definition of the relevant market for the purposes of Community competition law, OJ 1997, C372, p. 5, point 8.

¹⁵ *See*, for instance, College of Prosecutors [in Competition Matters](#), Decision No. 2007-V/M-25 of 5 October 2007 in case MEDE-V/M-07/0018, *Merck Generics Belgium BVBA, Generics UK v Merck Sharp & Dome BV and MSD Overseas Manufacturing Company*, point 19.

¹⁶ Competition Council, Decision No. 2005-C/C-9 of 9 March 2005 in case CONC-C/C-05/0006, *Investipharm Belgium SA/Alpha Répartition SA*, point 3.2.

¹⁷ Competition Council, Decision No. 2008-C/C-65 of 8 December 2008 in case MEDE-C/C-08/0027, *Febelco CVBA/Mauroy Ets. NV*, point 38.

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4.1.1 Extensive and Strict Price Regulation

In Belgium, the prices of medicines for human use are subject to extensive and strict price regulation. In essence, the price regulation system aims to reconcile the interests of pharmaceutical companies (which need a sufficient prospect of profitability of their investment to bring a medicine to the market) with those of society in general (which expects medicines to be accessible to patients at reasonable prices).

The Minister of Economic Affairs determines on a case-by-case basis the maximum ex-factory price (*i.e.*, the sales price excluding VAT as invoiced by the manufacturer or importer to the wholesaler) of *all* medicines that are marketed for the first time in Belgium, irrespective of whether they are (i) reimbursable or non-reimbursable; (ii) available prescription-only or over-the-counter (OTC), or (iii) innovative or generic. The Minister of Economic Affairs must also approve any requests to increase the approved maximum ex-factory price.¹⁸ In addition, the Minister of Economic Affairs fixed by Ministerial Decree the maximum distribution and dispensing margins applicable to respectively wholesalers and pharmacies as well as the pharmacies' maximum sales prices to the public.¹⁹ The distribution and dispensing margins vary, and their calculation basis differs, depending on whether or not the medicine concerned is reimbursable. For non-reimbursable medicines, a further distinction is made according to whether the medicine concerned is (i) an originator or hybrid medicine or a medicine that was registered on the basis of published scientific literature; or (ii) a generic medicine (including generic versions of reference medicines that were authorised by the Commission).

¹⁸ See, Title 2 (“Price determination of medicines and assimilated products”) of Book V (“Competition and price evolutions”) of the CEL *juncto* the Royal Decree of 10 April 2014 determining the condition of admissibility, time limits and practical formalities of requests to determine the price, requests to increase the price, price notifications and (price) communications of medicines, of objects, appliances and substances assimilated to medicines and of raw materials, as meant in Book V of the Code of Economic Law (*Koninklijk Besluit van 10 april 2014 tot vaststelling van de ontvankelijkheidsvoorwaarden, de termijnen en de praktische modaliteiten voor aanvragen tot prijsvaststelling, aanvragen tot prijsverhoging, prijskennisgevingen en (prijs)meldingen van geneesmiddelen, met geneesmiddelen gelijkgestelde voorwerpen, apparaten en substanties, en grondstoffen, als bedoeld in boek V van het Wetboek van Economisch Recht/Arrêté royal du 10 avril 2014 fixant les conditions de recevabilité, les délais et les modalités pratiques des demandes de fixation de prix, des demandes de hausse de prix, des notifications de prix et des communications (de prix) des médicaments, des objets, appareils et substances assimilés à des médicaments, et des matières premières, tels que visés dans le livre V du Code de droit économique*), BS/MB of 1 July 2014, p. 48786.

¹⁹ Ministerial Decree of 17 June 2014 designating the objects, appliances and substances as meant in Book V of the Code of Economic Law which are assimilated to medicines and determining the maximum prices and maximum margins of medicines and assimilated objects, appliances and substances (*Ministerieel besluit van 17 juni 2014 tot aanwijzing van de met geneesmiddelen gelijkgestelde voorwerpen, apparaten en substanties als bedoeld in boek V van het Wetboek van Economisch Recht en tot vaststelling van de maximumprijzen en maximummarges van de geneesmiddelen en de met geneesmiddelen gelijkgestelde voorwerpen, apparaten en substanties/Arrêté ministériel du 17 juin 2014 désignant les objets, appareils et substances assimilés à des médicaments, visés dans le livre V du Code de droit économique et fixant les prix maxima et marges maxima des médicaments et des objets, appareils et substances assimilés à des médicaments*), BS/MB of 1 July 2014, p. 48811.

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Furthermore, to limit public health expenditures, Article V.11 ~~CEL~~ provides that the King can decide to wholly or partially freeze the prices of all or certain categories of medicines. If the price freeze relates to reimbursable medicines, the Ministers of Economic and Social Affairs must carry out a review, at least once a year, to ascertain if the macro-economic conditions justify that the price freeze is continued.²⁰ In exceptional circumstances, if a pharmaceutical company can demonstrate that this is justified for reasons related to its rate of return, the Minister can derogate from the price freeze.

In addition, price reductions may be imposed for medicines that are already on the market.²¹

There is no special legislation defining excessive or discriminatory pricing in Belgium, differentiating it from “ordinary” excessive or discriminatory pricing cases.

4.1.2 Specific Rules on Sale and Distribution of Pharmaceutical Products

As a general rule, medicines can in Belgium be dispensed to patients by pharmacists only.²² Pharmacists can only acquire medicines for human use from licensed wholesalers (which includes manufacturers of pharmaceuticals) or wholesalers-distributors.²³ To enable pharmacists to meet the needs of their patients, Article 12~~quinquies~~ of the Law on Medicines requires the marketing authorisation holder (*MAH*) and the wholesalers of a medicine to ensure, within the limits of their respective responsibilities, that once the medicine has been placed on the market, it is available on a continuous basis and in sufficient quantities to persons who are entitled to supply pharmaceuticals to the public.²⁴ It is apparent from the explanatory memorandum to Article 12~~quinquies~~ of the Law on Medicines that this provision only requires the MAH and wholesalers to ensure that there is a sufficient supply of medicines to meet the need of patients *in*

²⁰ Since 2009, the prices of reimbursable medicines have been frozen in Belgium.

²¹ See, for instance, system for “old medicines” laid down in Article 69 of the Law of 27 April 2005 concerning the control of the health care budget and containing various provisions regarding health (*Wet van 27 april 2005 betreffende de beheersing van de begroting van de gezondheidszorg en houdende diverse bepalingen inzake gezondheid/Loi du 27 avril 2005 relative à la maîtrise du budget des soins de santé et portant diverses dispositions en matière de santé*), *BS/MB* of 20 May 2005, p. 23686.

²² Article 4, §1 of Royal Decree No. 78 of 10 November 1967 on the exercise of healthcare professions (*Koninklijk besluit nr. 78 van 10 november 1967 betreffende de uitoefening van de gezondheidszorgberoepen/Arrêté royal n° 78 du 10 novembre 1967 relatif à l'exercice des professions des soins de santé – Royal Decree No. 78*), *BS/MB* of 14 November 1967, p. 11881. The exceptions to this general rule are listed at Article 4, §2 of Royal Decree No. 78. In addition, specific rules exist for the dispensing of medicines in hospitals and in institutions such as retirement homes.

²³ Article 3, §2 of the Law on Medicines.

²⁴ See also, Article 72~~bis~~, §1, 1° and 2° of the Coordinated Law of 14 July 1994 regarding the compulsory medical care and sickness benefit insurance (*Wet betreffende de verplichte verzekering voor geneeskundige verzorging en uitkeringen gecoördineerd op 14 juli 1994/Loi relative à l'assurance obligatoire soins de santé et indemnités coordonnée le 14 juillet 1994*, *BS/MB* of 27 August 1994, p. 21524), which requires pharmaceutical companies to ensure that their reimbursable medicinal products (i) are effectively available at the latest from the date on which they become reimbursable; and (ii) remain continuously available thereafter.

Belgium.²⁵ Moreover, manufacturers and wholesalers are obliged to supply medicines to (i) wholesalers-distributors to such an extent as to enable them to carry out their public service obligations (*see*, Section 3.1 above); and (ii) persons who are entitled to supply pharmaceuticals to the public.²⁶ One category of wholesalers is exempt from these supply obligations, namely those wholesalers which are licensed exclusively to export medicines (*wholesalers-exporters*). Contrary to wholesalers-distributors, wholesalers-exporters do not purchase and sell the full range of medicines but only those medicines that can be sold at a profit abroad.

4.2 Consideration of Regulatory Characteristics in Context of Parallel Trade – *Bofar* Case

The BCA extensively considered the above-described characteristics of the pharmaceutical sector (*i.e.*, the sector's price regulation and specific distribution system) in the *Bofar* case.

4.2.1 Background and decision of Competition Prosecutor-General of 26 March 2008

Bofar NV (*Bofar*) is a wholesaler-exporter which does not sell any products on the Belgian market. Its activity consists of purchasing medicines from pharmaceutical companies in Belgium at the price fixed by the Minister of Economic Affairs and exporting them for resale to countries where prices are substantially higher.

In December 2007, Bofar lodged a complaint with the Competition Council against nine pharmaceutical companies which had discontinued or significantly reduced their supplies to Bofar. In its complaint, Bofar argued that this amounted to an infringement of both Articles IV.1 and IV.2 ~~CEL~~ and Articles 101 and 102 TFEU. The defendants' decisions to discontinue or reduce supplies to Bofar allegedly constituted (the first step of) a concerted practice aimed at excluding competition from parallel traders in export markets and ultimately reducing the number of wholesalers-distributors to one per country. In addition, according to Bofar, the defendants would have abused their alleged dominant position by refusing to supply to Bofar and other exporters or by applying a quota system.

In addition to its complaint on the merits, Bofar requested interim measures that would require the pharmaceutical companies to supply Bofar adequately. On 26 March 2008, the Competition Prosecutor-General dismissed Bofar's request for interim measures.²⁷ The Prosecutor ruled that Bofar had failed to

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²⁵ The explanatory memorandum to Article 12*quinquies* provides that “[t]his provision seeks to counter the pernicious effects resulting from parallel imports and parallel exports between Member States which sometimes create a lack of sufficient stocks of a given medicinal product to meet the *requirements of the own market*” (emphasis added) (*See*, Bill of 23 December 2005 revising the pharmaceutical legislation, Parliamentary Documents Chamber of Representatives 2005-06, No. 51-2189/1, p. 42-43).

²⁶ Articles 94(4) and 95, §1 of the Royal Decree on Medicines.

²⁷ Competition Prosecutor-General, Decision No. 2008-V/M-12-AUD of 26 March 2008 in case MEDE-V/M-07/0038, *Bofar NV v Alcon-Couvreur NV, AstraZeneca NV, Bayer NV, Biogen Idec Belgium NV, Boehringer Ingelheim Comm. V., Bristol Myers Squibb Belgium, Janssen-Cilag Belgium, Pfizer NV and Serono Benelux BV*.

establish a *prima facie* infringement of the competition rules, which is one of the conditions to obtain interim measures under Belgian law.

First, the Prosecutor found that Bofar had failed to produce sufficient evidence of a concerted practice. In this regard, he noted that (i) there were considerable differences in how the defendants dealt with orders from wholesalers-exporters (refusal of supply, quota systems, one delivery per wholesaler-exporter, etc.); (ii) the defendants introduced the measures at different times within a timespan of not less than seven years (between 2001 and 2007); and (iii) apart from some form of parallelism, Bofar failed to produce any evidence of concertation or contacts between the defendants regarding their distribution systems.

Second, the Prosecutor held that there was also no evidence of a *prima facie* abuse of a dominant position by the defendants. Addressing first the question of whether there was an abuse, the Prosecutor noted that a refusal to supply by a dominant company is not in itself abusive. A dominant company is entitled to take reasonable steps to protect its commercial interests, provided that such steps are (i) proportionate to the possible harm caused; and (ii) not aimed at strengthening or abusing the company's dominant position.²⁸

Importantly, the Prosecutor continued that, to assess an alleged abuse, regard is to be had to the economic context of the challenged practices. Analysing the specific economic characteristics of the pharmaceutical market, the Prosecutor emphasised the need to take full account of (i) Bofar's status as a wholesaler-exporter; and (ii) the price regulation in the pharmaceutical sector. He ruled that, if pharmaceutical companies cannot freely determine the prices of their products, they cannot be obliged to apply the same conditions of sale to products that are intended exclusively for exportation to other countries where the market conditions are clearly different. The Prosecutor therefore concluded that the refusal by a pharmaceutical company to supply medicines to wholesalers-exporters at the price fixed by the Minister of Economic Affairs, in defence of its commercial interests, does not constitute an abuse of a dominant position. The price regulation in the pharmaceutical sector and Bofar's status as a wholesaler-exporter thus acted as objective justifications for the refusal to supply.²⁹

²⁸ *Ibid.*, points 103 and 104, which refer to the CJEU's seminal *United Brands* judgment (ECJ, case 27/76, *United Brands Company and United Brands Continentaal BV v Commission*, [ECLI:EU:C:1978:22](#)).

²⁹ No similar justification may be available outside the context of parallel trade. See, Liège Court of Appeal, 5 February 2009, *Agim ASBL, Messer Belgium SA, Vivisol B SPRL, Air Products SA, Medigaz SA, Linde Gas Belgium SA and Air Liquide Medical SA v Oxycure Belgium SA*, *Jb. Hand. Med.* 2009, p. 955 (confirmed by Supreme Court, 13 December 2010, *Arr.Cass.* 2010, p. 2972). In this case, several producers/distributors of medical oxygen were found to have infringed Article IV.1 ~~CEL~~ by collectively refusing to supply medical oxygen to a competitor called Oxycure. Oxycure distributed an electrical appliance producing oxygen. However, the appliance needed to be accompanied by a spare bottle of medical oxygen, which Oxycure was not able to produce itself, to guarantee a continuous oxygen supply to the patient in case of, for instance, electricity shortages. ~~The first judge had ordered the petitioners to provide Oxycure with offers for the supply of medical oxygen under the suspensive condition of Oxycure obtaining a wholesale licence for medical oxygen. Instead of complying with this order, the petitioners sent refusal letters to Oxycure. Having regard to the petitioners' refusals to supply and the factual circumstances of the case (including the fact that the petitioners (i) were collectively dominant on the Belgian market for~~

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In reaching this conclusion, the Prosecutor relied on the opinion of Advocate-General (AG) Jacobs in *Syfait I*.³⁰ In his opinion, AG Jacobs rejected the proposition that a refusal to supply by a dominant pharmaceutical company would automatically amount to an abuse of dominance. In his view, a restriction of deliveries in order to limit parallel trade can be justified as a reasonable and proportionate measure in defence of the dominant company's commercial interests. The AG stressed that such a restriction is not aimed at fragmenting the markets but merely responds to the market fragmentation that results from the national price regulation and public service obligations imposed by the EU Member States. Furthermore, a requirement to supply would harm the incentive for pharmaceutical companies to innovate rather than promote either free movement or competition. Moreover, there is no reason to assume that either patients or EU Member States benefit from parallel trade.³¹

4.2.2 Decision on Appeal of President of Competition Council of 2 April 2009

On 25 April 2008, Bofar appealed the Prosecutor's decision of 26 March 2008 to the President of the Competition Council (the *President*), claiming that the Prosecutor had erroneously held that there was no *prima facie* infringement of Articles IV.2 ~~CEL~~/102 TFEU.

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By decision of 2 April 2009, the President dismissed Bofar's appeal.³² The President relied on the CJEU's judgment of 16 September 2008 in *Syfait II*, in which the CJEU had ruled that, although it is permissible for a dominant pharmaceutical company to take reasonable and proportionate steps to protect its commercial interests by limiting parallel exports, that company abuses its dominant position if, in order to put a stop to parallel exports, it refuses to meet "ordinary" orders from wholesalers.³³ Importantly, contrary to Bofar (which, as indicated earlier, is a pure exporter), the wholesaler concerned in *Syfait II* was active on both the domestic market and the export markets. Applying the *Syfait II* principles to the Bofar case, the President

medical oxygen treatments; (ii) were represented by the same counsel; and (iii) sent their refusal letters, of which the content was similar but not identical, to Oxycure on the same date), the Liège Court of Appeal found the petitioners guilty of an unlawful concerted practice. This finding was subsequently confirmed by the Supreme Court. Interestingly, the College of Prosecutors in Competition Matters reached the opposite conclusion in this very same case. Although admitting that there was some parallelism in the companies' behaviour, the College held that there were plausible alternative and competitively acceptable explanations for this parallelism (See, College of Prosecutors in Competition Matters, Decision No. 2010-P/K-45-AUD of 17 November 2010 in case CONC-P/K-04/0055, *Oxycure BVBA v Air Products NV, Medigaz NV, Westfalen BVBA, Air Liquide Medical NV, Messer Belgium NV, Ysfabriek Strombeek NV, Indugas NV, Linde Gas Belgium NV and BTG-GTB BVBA*).

³⁰ As already indicated, the Prosecutor also relied on Decision No. 07-D-22 of 5 July 2007 of the French Competition Council.

³¹ Opinion of Advocate-General Jacobs of 28 October 2004 in CJEU, case C-53/03, *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline plc and GlaxoSmithKline AEVE*, [ECLI:EU:C:2004:673](#), point 100. The CJEU never considered the argumentation of AG Jacobs since it found itself without jurisdiction.

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³² President of Competition Council, Decision No. 2009-V/M-04 of 2 April 2009 in case MEDE-V/M-07/0038, *Bofar NV v Alcon-Couvreur NV and Others*.

³³ CJEU, joined cases C-468/06 to C-478/06, *Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE Farmakeftikon Proionton, formerly Glaxowellcome AEVE*, [ECLI:EU:C:2008:504](#).

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therefore noted that the concept of “ordinary” orders used in *Syfait II* could not be applied to the alleged refusals to supply to Bofar. This is because, in *Syfait II*, the CJEU held that orders are out of the ordinary if, in a given EU Member State, certain wholesalers order pharmaceuticals in quantities which are disproportionate to those previously sold by the same wholesalers to meet the needs of the market in that EU Member State. As this test of what are “ordinary” orders cannot be applied in a case involving refusals to supply to a pure exporter, the President concluded that a dominant pharmaceutical company can reduce the supplies to a wholesaler that is active only on export markets, without abusing its dominant position.

The President also took into account that at least some of the pharmaceutical companies involved in the proceedings had reduced supplies to Bofar out of concern that they would be unable to meet demand in the Belgian market. However, the President stressed that, even in the absence of such supply problems on the domestic market, a dominant pharmaceutical company can protect its commercial interests by limiting parallel trade.

Following the dismissal of its appeal, Bofar decided to withdraw its complaint on the merits.³⁴

5. **Inter-brand Competition – Innovation and Generic Entry**

Since *AstraZeneca*,³⁵ the first abuse of dominance decision in the pharmaceutical sector at the EU level, the Commission’s traditional enforcement focus on *intra*-brand competition was supplemented by an emphasis on *inter*-brand competition.³⁶ In this respect, most attention has been given to competition between originator medicines and generics. This should not surprise considering, amongst others, the increasing number of medicines that have approached or are approaching patent expiry.³⁷

The Commission’s fairly recent focus on restrictions of generic competition presumably explains why there are very few Belgian competition cases on this matter and why the few cases that exist were initiated shortly after the Commission’s initial prohibition decision in *AstraZeneca*. Following a brief, non-

³⁴ See, College of Prosecutors in Competition Matters, Decision No. 2009-P/K-23-AUD of 6 October 2009 in case MEDE-P/K-07/0037, *Bofar NV v Alcon-Couvreur NV, AstraZeneca NV, Bayer NV, Biogen Idec Belgium NV, Boehringer Ingelheim Comm. V., Bristol Myers Squibb Belgium, Janssen-Cilag Belgium, Pfizer NV and Serono Benelux BV*.

³⁵ Commission decision of 15 June 2005 in case COMP/A 37.507/F3, *AstraZeneca*, Decision on Commission website (summary also available at OJ 2006 L 332, p. 24); on appeal: CFI, case T-321/05, *AstraZeneca AB and AstraZeneca plc v Commission*, [ECLI:EU:T:2010:266](#); on further appeal: EGC, case C-457/10 P, *AstraZeneca AB and AstraZeneca plc v Commission*, [ECLI:EU:C:2012:770](#).

³⁶ N. de Souza, Competition in Pharmaceuticals: the challenges ahead post AstraZeneca, Competition Policy Newsletter 2007(1), pp. 39 and 41-42.

³⁷ See, [Figure 41 at page 156 of the Pharmaceutical Sector Inquiry Final Report of 8 July 2009 \(available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf - last date of consultation: 17 May 2016\) for an overview of the number of pharmaceutical substances for which a product lost patent protection and/or data exclusivity in the EU in the period 2000–2007.](#)

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exhaustive overview of some of the regulatory measures to promote generic entry (*see*, Section 5.1 below), I will discuss these few cases (*see*, Section 5.2 below).

5.1 Regulatory Measures Promoting Generic Entry

As many other countries, Belgium has a policy to promote the use of generic medicines with a view to reduce public health expenditure. Generic entry, and use of generics, is promoted in a variety of manners, including the following:

- In addition to providing for a simplified marketing authorisation procedure for generic medicines, Article 6*bis*, §1 of the Law on Medicines provides that “[c]onducting the necessary studies, tests and trials with a view to meeting the conditions and modalities referred to in indents 1 to 7 of this paragraph and all the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates”.
- Generic medicines benefit from a simplified procedure to be included in the list of reimbursable medicinal products.³⁸
- Generic medicines can be included in the list of reimbursable medicinal products, notwithstanding any pending court proceedings against the originator. However, this does not prejudice the outcome of the court proceedings.
- Pursuant to the reference reimbursement system, the reimbursement basis of medicines that go off-patent decreases. Until 1 March 2016, the reimbursement basis of the products belonging to the reference cluster (*i.e.*, the group (“*cluster*”) of medicines containing the same active substance) was reduced in four steps over a period of six years. Since 1 March 2016, this gradual reduction of the reimbursement basis has been replaced by a single, sharp reduction which takes place as soon as the reference cluster is opened (a “*patent cliff*”).³⁹ By reducing the reimbursement level of originator medicines to that of cheaper generics, the reference reimbursement system makes originator medicines more expensive for patients (higher patient contribution). To avoid this, originators generally reduce the price of the originator medicine.

³⁸ *See*, Articles 28 through 34 of the Royal Decree of 21 December 2001 laying down the procedures, time-limits and conditions concerning assistance from the compulsory medical care and sickness benefit insurance towards the costs of pharmaceutical specialties (*Koninklijk Besluit van 21 december 2001 tot vaststelling van de procedures, termijnen en voorwaarden inzake de tegemoetkoming van de verplichte verzekering voor geneeskundige verzorging en uitkeringen in de kosten van farmaceutische specialiteiten/Arrêté royal du 21 décembre 2001 fixant les procédures, délais et conditions en matière d'intervention de l'assurance obligatoire soins de santé et indemnités dans le coût des spécialités pharmaceutiques*), BS/MB of 29 December 2001, p. 45584.

³⁹ This “*patent cliff*” was one of the measures to ensure budgetary durability and predictability foreseen by the “Pact for the Future” (*Toekomstpact/Pacte d'avenir*) which the Minister for Social Affairs and Public Health entered into with the pharmaceutical sector on 27 July 2015.

- Physicians are incited to prescribe the cheapest possible medicine. They can still prescribe more expensive medicines, but must meet certain targets to avoid penalties.
- In case of an International Non-Proprietary Name (INN) prescription, pharmacists must dispense the cheapest product.
- The Pact for the Future of 27 July 2015⁴⁰ provides for the introduction of a system to boost the use of biosimilars during a period of, at most, five years.⁴¹ Implementing this provision, a Covenant was concluded in January 2016 to boost the use of specific biosimilars in hospitals.⁴² The Covenant requires hospital physicians to consider, at least for bio-naïve patients, the use of biosimilar versions of erythropoietin (EPO), filgrastim and infliximab. Should the Covenant not reach its goal, legislative action will be taken to promote biosimilar uptake.

5.2 Belgian Competition Law and Generic Entry

As is the case under EU competition law, intellectual property right holders, including pharmaceutical patent holders, are not immune from competition law intervention in Belgium. For instance, agreements between originator companies and generic companies (e.g., settlement, licensing, co-marketing or co-promotion agreements) could be problematic under Articles IV.1 and IV.2 ~~CEL~~. Likewise, certain life cycle strategies of originator companies to extend the commercial life of their medicines could contribute to generic delay and possibly qualify as an abuse of dominance under Article IV.2 ~~CEL (e.g., "evergreening" and product hopping, litigation against generics for patent infringements, acquisition of secondary patents or supplementary protection certificates)~~.

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Yet, there are very few Belgian competition cases dealing with generic entry. As there has never been a competition law inquiry into the pharmaceutical sector at the Belgian level, there is very little information available on the topic. The only information that is available, including on patent settlements (which are normally confidential), is that published by the Commission in the context of its 2008/2009 pharmaceutical sector inquiry and subsequent annual patent settlement monitoring exercise.⁴³

⁴⁰ ~~In this Pact, the Minister for Social Affairs and Public Health agreed with the Belgian pharmaceutical sector on a significant number of measures in the pharmaceutical field for the period 2015-2018. The Pact aims to stimulate (i) patient access to innovative therapies; and (ii) growth and innovation. At the same time, it stresses the importance of ethical requirements and seeks to ensure budgetary durability and predictability for the next few years.~~

⁴¹ According to the Pact for the Future, the system “should guarantee a minimum uptake in DDD [i.e., Defined Daily Dose] of 20% biosimilars for bio-naïve patients for those medicines where biosimilars exist, and considering the characteristics of the diseases concerned”.

⁴² Covenant on the re-launch of biosimilar medicines in Belgium (*Convenant Doorstart voor biosimilaire geneesmiddelen in België/Convention sur la relance des médicaments biosimilaires en Belgique*).

⁴³ See, Pharmaceutical Sector Inquiry Report of 8 July 2009 and Reports on the Monitoring of Patent Settlements available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/>, (last date of consultation: 17 May 2016).

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The two Belgian competition cases of which I am aware that deal with generic entry are discussed below. They relate to (i) price reductions by an originator company; and (ii) reliance by an originator company on an allegedly invalid patent and supplementary protection certificate (SPC).⁴⁴ In both cases, the generic company's complaints against the originator were dismissed.

5.2.1 Price Reductions by Originator Company – *Docpharma v Eli Lilly Benelux*

The judgment of the President of the Brussels Commercial Court of 20 November 2006 in *Docpharma v Eli Lilly Benelux* illustrates that generic entry could possibly be hindered by an originator's decision to lower the prices of its products.⁴⁵ The generics company Docpharma had filed a cease-and-desist action against Eli Lilly for having cut the price of its antibiotic Ceclor® by 80%. This price cut was a response to new legislation of December 2015 requiring pharmaceutical companies to implement a price reduction on the ex-factory prices of their products corresponding to at least 2% of their Belgian turnover in 2014. The price reduction could be linear or focused on certain specific products. Eli Lilly's price reduction focused on Ceclor® as this was an end-of-life antibiotic of which sales had decreased over the years due to the availability of other antibiotics for the same indication.

Following Eli Lilly's price cut, the authorities had reduced the price and reimbursement basis of Docpharma's generic version of Ceclor®, called Doccefacro, to the same level as that of Ceclor®. This had forced Docpharma's to abandon its production activities of Doccefacro as they had become structurally loss-making.

Docpharma's argumentation before the President of the Brussels Commercial Court was based on both unfair market practices law and competition law. First, it claimed that Eli Lilly had committed an unfair commercial practice by selling at a loss.⁴⁶ The President dismissed this claim. He acknowledged that the general prohibition on sales at a loss was indeed applicable. In this regard, he noted that Eli Lilly could not rely on the December 2015 legislation to justify selling at a loss because that legislation did not impose a specific selling price and did not exempt pharmaceutical companies from other rules such as the prohibition on sales at a loss. However, the President continued that one of the exceptions to the general prohibition on sales at a loss applied, namely that for goods of which the commercial value is significantly reduced due to

⁴⁴ Supplementary protection certificates extend the patent right for a medicinal product for a maximum of five years (to be extended by six months for certain paediatric medicines) to offset for the loss of patent protection that occurs due to the period that elapses between (i) the filing of an application for a patent for a new medicinal product; and (ii) authorisation to place the medicinal product on the market (See, Regulation 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ 2009, L 152, p. 1).

⁴⁵ President of the Brussels Commercial Court, 20 November 2006, *Docpharma SA v Eli Lilly Benelux SA*, *Jb. Hand. Med.* 2006, p. 293; TBM 2007, ed. 1, p. 90.

⁴⁶ Docpharma relied on the then-applicable equivalent of current Article VI.104 ~~CEL~~, which prohibits "any act contrary to fair market practices whereby a company harms or may harm the professional interests of one or more other companies", read in conjunction with the general prohibition on sales at a loss under Belgian consumer law.

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their perishable nature and diminished possibilities for use. He noted that Ceclor® was an end-of-life product, of which Eli Lilly wanted to liquidate its existing stocks. This stock clearance had to take place in winter 2006-2007 considering that (i) Ceclor® was a seasonal product, predominantly sold in winter; (ii) the expiry date of the Ceclor® in stock ranged between 1 June and 1 December 2007; and (iii) it was necessary to commercialise the products at least six months before their expiry date because wholesalers only accept medicines with an expiry date of at least six months.

Second, Docpharma argued that Eli Lilly's price cut for Ceclor® constituted an abuse of a dominant position. The President of the Brussels Commercial Court dismissed this argument as well, noting that Docpharma had failed to provide evidence of Eli Lilly's alleged dominant position. Interestingly, however, the President continued that, even if a dominant position were to be established, there was in any case no abuse. Eli Lilly's goal was not to eliminate Docpharma from the market but to liquidate its Ceclor® stock in the context of the December 2015 legislation. Moreover, Eli Lilly had no plans to re-enter the market after having liquidated its stock. The President thus considered Eli Lilly's practice to be objectively justified, which precluded a finding of abuse of dominance.

The President's judgment illustrates how, by virtue of Article VI.104 CEL, competition law can interplay with consumer law in civil court cases.

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5.2.2 Reliance by originator on Allegedly Invalid Patent and SPC – *Merck v MSD*

The second Belgian case on generic entry relates to an originator's reliance on an allegedly invalid patent and SPC. In 2007, the generics division of Merck filed a complaint and request for interim measures with the Competition Council against the originator MSD in order to stop it from relying on an allegedly invalid patent and SPC for the active substance alendronate, which it marketed under the brand name Fosamax®.⁴⁷ Fosamax® is indicated for the treatment of osteoporosis.

In its request for interim measures, Merck argued that MSD had abused its dominant position by (i) relying on the patent and SPC; and (ii) initiating legal proceedings to prevent competitors from infringing the patent and SPC. The Prosecutor in Competition Matters found MSD to be dominant, irrespective of whether the relevant product market be defined at ATC 3 level, ATC 4 level or, as MSD defended, as the market of medicines for the treatment of osteoporosis.⁴⁸ Accordingly, the exact market definition was left open.

Yet, the Prosecutor failed to see how MSD would have abused its dominant position. The Prosecutor noted that the Competition Council is not competent to declare a patent null and void. Furthermore, a patent holder cannot be denied the right to rely on a patent or to protect this patent against infringements for the

⁴⁷ Prosecutor in Competition Matters, Decision No. 2007-V/M-25-AUD of 5 October 2007 in case MEDE-V/M-07/0018, *Merck Generics Belgium BVBA, Generics UK v Merck Sharp & Dome BV and MSD Overseas Manufacturing Company*.

⁴⁸ It was not in dispute that the relevant geographic market was national in scope.

sole reason that the validity thereof is being challenged. This implies that, as long as the patent has not been declared null and invalid *de jure* by the competent courts, the patent holder is entitled to initiate legal proceedings with a view to safeguarding its patent rights. Hence, the Prosecutor dismissed Merck's request for interim measures.

6. Conclusion

As follows from the above, the pharmaceutical sector is, like any other economic sector, fully subject to the ordinary Belgian competition rules. In my personal opinion, this is how it should be.

This being said, pharmaceutical companies do not operate in a vacuum. When applying the competition rules to pharmaceutical companies, due account must be taken of the fact that they operate in a context where the normal conditions of competition do not prevail. As illustrated above, the pharmaceutical sector is indeed characterised by the presence of diverse, pervasive and often fragmented regulation at both the European and national levels. While some of this regulation may be justified considering the fundamental concerns that are at stake, including public health and the need to protect national budgets, the necessity of some other regulation could be questioned. For instance, I have difficulties in understanding why the rigid Belgian price regulation system applies to both reimbursable *and* non-reimbursable products. At least for non-reimbursable OTC products, the pricing regulation is in my view overly paternalistic. I cannot but believe that the pharmaceutical industry and market forces in general deserve a higher level of trust.

Yet, the current situation is what it is, and the effects and impact of the applicable regulation on pharmaceutical companies and on the pharmaceutical sector in general must in my view be fully considered for the purpose of applying competition law. I am pleased to note that this is what the BCA has done in the *Bofar* case.

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