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Développements récents en Europe en droit de la concurrence appliqué au secteur pharmaceutique

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Excessive pricing cases in the pharmaceutical industry: Economic considerations and practical pitfalls

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Recent developments in antitrust pharma sector: The Aspen case by the Italian Competition Authority

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ABSTRACT

The authors of this On-Topic focus on the latest developments in the pharmaceutical sector. According to Ms Thill-Tayara, author of the first contribution and lawyer at Dechert Paris, if the competition agencies' activism is partly motivated by the need to limit the expenses of national health insurances systems, this has led competition authorities to use and enforce legal concepts which may seem difficult to implement in such a specific sector. In the second article, Mr. De Coninck, economist at CRA Bruxelles, highlights the main conceptual difficulties with excessive pricing cases, and argues that such cases should be limited to truly exceptional circumstances. He discusses the numerous practical difficulties in determining whether a price can be considered as excessive, and the main pitfalls to avoid. Ms Alessandra Tonazzi, the last contribution's author, and member of the Italian Competition Authority, focuses on the investigation by the Italian Competition Authority, concluded with an infringement decision in September 2016, into the prices charged by Aspen for a number of cancer drugs. She stresses that the Aspen case shows some of the features that many economists and lawyers would recognize as justifying an antitrust intervention.

Ce dossier réunit 3 contributions sur les développements récents dans le secteur pharmaceutique. Pour Me Thill-Tayara, avocate chez Dechert Paris et auteur de la première contribution, si l'activisme des autorités de concurrence est motivé, au moins en partie, par le besoin de limiter les dépenses des systèmes nationaux d'assurance maladie, il conduit toutefois les autorités à devoir manier des concepts juridiques qui sont a priori difficiles à appliquer dans ce secteur si spécifique. Dans le second article, M. De Coninck, économiste chez CRA Bruxelles, souligne les principales difficultés conceptuelles des cas de prix excessifs, et avance que de tels cas devraient être limités à des circonstances exceptionnelles. Il aborde ensuite les nombreuses difficultés pratiques de la détermination du prix excessif et les principaux écueils à éviter. Mme Alessandra Tonazzi, auteur de la dernière contribution et membre de l'Autorité italienne de la concurrence, met l'accent sur l'enquête menée par l'Autorité italienne, ayant abouti en septembre 2016 à la décision d'infraction d'Aspen. Elle précise ensuite que cette affaire a pu être perçue comme appelant une intervention antitrust.

Développements récents en Europe en droit de la concurrence appliqué au secteur pharmaceutique

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1. Si le secteur pharmaceutique a toujours fait l'objet d'une vigilance de la part des autorités de concurrence, l'actualité européenne de ces dix-huit derniers mois a été particulièrement riche en enseignements[1]. On constate en effet une volonté manifeste des autorités de concurrence d'intervenir sur de nouvelles probléma-

* Article écrit avec le concours de Sophie Pelé, Romain Maulin et Simon Hetsch.

1 D. W. Hull et M. J. Clancy, The application of EU Competition Law in the Pharmaceutical Sector, *Journal of European Competition Law & Practice*, 2017, vol. 8, nº 3, et également disponible à l'adresse suivante : https://academic.oup.com/jeclap/article-abstract/8/3/205/3054202/The-Application-of-EU-Competition-Law-in-the?redirectedFrom=fulltext. V. égal. Anticompetitive practices in the pharmaceutical sector: An overview of EU and national case law, 14 juin 2017, *e-Competitions Bulletin Pharma & Anticompetitive practices*.

tiques, dont certaines paraissaient jusqu'ici en dehors de leur sphère de compétence naturelle, car concernant le prix des produits pharmaceutiques (I.), la validité des brevets (II.) ou encore les débats scientifiques que peuvent susciter certains médicaments (III.).

2. Si l'on manque encore du recul suffisant pour apprécier les conséquences de ces développements récents pour le secteur pharmaceutique, ils semblent toutefois annonciateurs d'un besoin de redéfinition des compétences et expertises respectives des différentes autorités intervenant dans le secteur pharmaceutique, en particulier les autorités de fixation des prix, les autorités de santé ou encore les offices de brevets et leurs juridictions de contrôle.

I. La pratique de prix excessifs dans le viseur des autorités de concurrence européennes

3. La pratique de prix excessifs[2] a, sur la période récente, attiré l'attention d'un certain nombre d'autorités de concurrence dans plusieurs États membres de l'Union européenne (1.), mais également celle de la Commission européenne ("Commission") (2.).

1. Une pratique qui commence à faire l'objet d'une action de la part des autorités nationales de concurrence

4. Le cas italien – *Aspen*[3]. L'autorité de la concurrence italienne ("AGCM") a sanctionné Aspen pour avoir abusé de sa position dominante en pratiquant, à compter de 2014, des prix excessifs sur ses produits anticancéreux commercialisés en Italie.

5. À l'origine de cette affaire, Aspen a, en 2009, acquis auprès de GlaxoSmithKline un certain nombre d'anticancéreux. Aspen a ensuite engagé des négociations avec l'Agence du médicament italienne ("AIFA") afin d'obtenir, à compter de 2014, une revalorisation de leurs prix.

6. L'objectif officiellement invoqué par Aspen était de (i) procéder à un alignement des prix pratiqués en Italie avec ceux en vigueur dans d'autres États membres afin de juguler les importations parallèles et (ii) récupérer une partie des sommes engagées au titre de ses obligations de pharmacovigilance. Au cours de cette négociation, Aspen a notamment menacé d'interrompre la commercialisation de ses produits en Italie à défaut d'une revalorisation significative des prix. Au final, cela a permis à Aspen de pratiquer une augmentation de prix variant, selon les produits concernés, de 300 à 1 500 %.

7. L'AGCM a sanctionné ces pratiques en imposant une amende de 5,2 millions d'euros à Aspen, sanction entièrement confirmée le 14 juin 2017 par le tribunal administratif du Lazio[4].

8. L'analyse de la décision italienne permet de constater que l'AGCM a manifestement cherché à faire du neuf avec de l'ancien, puisqu'elle s'est appuyée sur le test de prix excessifs utilisé pour la première fois en 1978 au niveau européen dans l'affaire *United Brands*[5], preuve que les prix excessifs ne sont que rarement sanctionnés par les autorités de concurrence. Rappelons que, dans cette affaire concernant le prix des bananes, la Cour de justice de l'Union européenne ("CJUE") avait dégagé un test en trois temps pour apprécier si les prix en question pouvaient être qualifiés d'abusifs au sens de l'article 82 (a) du traité CE, devenu depuis 102 TFUE[6]. Ainsi, pour qu'un prix soit considéré comme excessif, il est nécessaire de procéder à :

- une comparaison entre le prix de vente du produit et son prix de revient, comparaison d'où se dégage la marge bénéficiaire[7] ;
- l'appréciation d'une éventuelle disproportion excessive entre le coût effectivement supporté et le prix effectivement réclamé[8] ;
- l'appréciation de la question de savoir si un prix est inéquitable "*soit au niveau absolu, soit par comparaison avec les produits concurrents*"[9].

2 Parmi une littérature abondante sur ce sujet, v. en particulier OCDE, Table ronde sur les prix excessifs, octobre 2011, disponible à l'adresse suivante : http://www.oecd.org/competition/abuse/49604207.pdf ; D. S. Evans et J. A. Padilla, Excessive Prices: Using Economics to Define Administrable Legal Rules, *Journal of Competition Law and Economics*, 2005 et rapport de l'autorité suédoise de la concurrence intitulé *The Pros and Cons of High Prices*, 2007, disponible à l'adresse suivante : http://www.konkurrensverket.se/globalassets/english/research/the-pros-and-cons-of-high-prices-14mb.pdf (v. en particulier la contribution de N. Whal, Exploitative high prices and European competition law – a personal reflection, pp. 47-64).

3 AGCM, décision du 29 septembre 2016, A480 – *Incremento Prezzo Farmaci Aspen*, disponible à l'adresse suivante : http://www.agcm.it/concorrenza--delibere/concorrenza-istruttorie/download/41256297003874BD/A2E0FDDC46C947B5C1258051003331BD.html?a=p26185.pdf. Les produits en question sont les suivants : Alkeran (melphalan), Leukeran (chlorambucil), Thioguanin (thioguanine) et Purinethol (mercaptopurine).

4 Lazio court dismisses Aspen's appeal against Italian excess-pricing decision, *Mlex*, 14 juin 2017. Ce jugement est disponible à l'adresse suivante: https://www.giustizia-amministrativa.it/cdsintra/cdsintra/AmministrazionePortale/DocumentViewer/index.html?ddocname=5E2RMFWDI3OQYIG55NPXXHKHMU&q=aspen.

5 CJUE, 14 février 1978, *United Brands c/ Commission*, aff. 27/76.

6 L'AGCM s'est livrée à une analyse économique approfondie afin d'examiner (i) la différence entre les coûts de production et les nouveaux prix pratiqués par Aspen pour ses produits Cosmos, en concluant que cette différence était significative et (ii) si cette différence significative pouvait être justifiée, ce que l'AGCM a rejeté.

7 Précité note 5, , § 251.

8 *Ibid.*, § 252.

9 *Ibid.*

9. S'agissant de ce dernier critère, l'avocat général Nils Wahl a récemment précisé, dans ses conclusions présentées le 6 avril 2017 dans le cadre de l'affaire *AKKA/LAA*[10], qu'un prix ne saurait être considéré excessif qu'à la double condition qu'il se situe "*de manière significative et persistante au-dessus du prix de référence*"[11].

10. D'ailleurs, selon lui, "[i]*l n'est nullement besoin d'appliquer* [l'article 102, deuxième alinéa, sous a)[12]] *dans un marché libre et concurrentiel : en l'absence de barrières à l'entrée, des prix élevés devraient normalement attirer les nouveaux entrants. Le marché s'autocorrigerait en conséquence*"[13]. Il sera donc intéressant de voir la réponse de la CJUE au regard du récent regain d'intérêt pour cette incrimination dans le secteur de la santé.

11. Le cas britannique – *Pfizer/Flynn Pharma*[14]. À la suite d'une plainte du ministère de la Santé[15], Pfizer et Flynn Pharma ("Flynn") se sont vu reprocher, par la Competition and Markets Authority ("CMA"), d'avoir abusé de leur position dominante respective sur les marchés de la fabrication et de la distribution de la phénytoïne sodique au Royaume-Uni.

12. À l'origine de cette affaire, Pfizer a, en 2012, cédé pour un euro symbolique à Flynn, laboratoire spécialisé dans l'acquisition et la valorisation de produits pharmaceutiques en fin de vie[16], ses autorisations de mise sur le marché ("AMM") pour l'Epanutin[17] au Royaume-Uni, tout en continuant à fabriquer le principe actif (phénytoïne sodique) mais en concédant les droits exclusifs pour l'approvisionnement au Royaume-Uni à Flynn.

13. Dès le début de la prise en charge de la commercialisation, Flynn a "débrandé"[18] le médicament afin de pouvoir le vendre sous sa propre marque (Phenytoin Sodium Flynn Hard Capsules), lui permettant ainsi d'en fixer le prix librement. Parallèlement, Pfizer a augmenté significativement son prix de vente à Flynn, en l'occurrence entre 780 et 1 600 % du prix auquel Pfizer le vendait auparavant. Flynn a également, de son côté, procédé à une augmentation, comprise entre 1 000 et 1 520 % du prix de vente aux grossistes et pharmaciens. Au total, il en est résulté pour le patient une augmentation comprise entre 2 300 et 2 600 %, ce qui, en 2013, a généré un surcoût de l'ordre de 54 millions d'euros[19] pour le National Health Service ("NHS").

14. Au-delà de l'importance de la hausse des prix, analysée en l'espèce au regard de la jurisprudence *United Brands*[20], la CMA s'est fondée sur un ensemble d'éléments et pièces dont elle disposait, pour la plupart[21] à la suite de demandes de renseignements[22] extensives adressées aux deux laboratoires.

15. La CMA a aussi considéré, se fondant sur des documents préparatoires à la conclusion de l'accord entre Pfizer et Flynn[23], que l'un des aspects clés de la négociation a porté sur le fait que la cession des AMM sur l'Epanutin permettrait son *debranding* et, *in fine*, de significatives hausses de prix au bénéfice respectif des parties, tout en protégeant Pfizer des risques réputationnels pouvant résulter des hausses de prix à venir[24].

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10 Conclusions de l'avocat général Nils Wahl présentées le 6 avril 2017 dans l'affaire C-177/16.

11 *Ibid.*, § 106.

12 Sont abusives, au sens de l'article 102 (a) TFUE, les pratiques consistant à "*imposer de façon directe ou indirecte des prix d'achat ou de vente ou d'autres conditions de transaction non équitables*".

13 Conclusions de l'avocat général Nils Wahl présentées le 6 avril 2017 dans l'affaire C-177/16, § 4. Il précise toutefois qu'"[i]*l peut en être autrement sur des marchés où il existe des barrières juridiques à l'entrée ou à l'expansion et, notamment, sur ceux où il existe un monopole légal. En effet, il peut y avoir des marchés qui, en raison de leurs caractéristiques particulières, ne fonctionnent pas efficacement lorsqu'ils sont ouverts à la concurrence. Ainsi, un gouvernement peut avoir des raisons politiques légitimes à limiter la concurrence sur un marché spécifique, sacrifiant ainsi l'efficacité économique au profit d'autres objectifs publics*".

14 CMA, 7 décembre 2016, *Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*, case CE/9742-13, disponible à l'adresse suivante : https://assets.publishing.service.gov.uk/media/594240cfe5274a5e4e00024e/phenytoin-full-non-confidential-decision.pdf.

15 La décision de la CMA fait également état de plaintes provenant de plaignants individuels et de "*Clinical Commissioning Groups*", notion définie de la façon suivante dans la décision : « [C]*linical Commissioning Groups* (…) *are responsible for providing and funding health services in their local areas*".

16 CAT, *Jugdment on interim relief*, 19 janvier 2017, *Flynn Pharma v. CMA*, case No. 1274/1/12/16 (IR), § 6. Selon la CAT, au moment des faits, la demande pour les capsules de phénytoïne sodique était en déclin dans la mesure où les patients nouvellement diagnostiqués comme étant atteints d'épilepsie se voyaient prescrire des traitements plus récents et comportant moins d'effets secondaires. Toujours selon le CAT, la patientèle utilisant les capsules de phénytoïne sodique était limitée à 48 000 patients, soit approximativement 10 % des patients anglais atteints d'épilepsie (§ 7).

17 Le médicament ayant été mis sur le marché pour la première fois en 1938.

18 La pratique de *debranding* consiste, pour un laboratoire pharmaceutique, à cesser de vendre son médicament sous nom de marque, et d'en lancer une nouvelle version générique. Cette pratique permet de se libérer du système des prix négociés avec le National Health Security applicable aux seuls produits sous nom de marque, pour basculer dans la catégorie des produits génériques censés se faire concurrence sur les prix, sans intervention de la puissance publique.

19 Par comparaison aux dépenses d'assurance maladie pour l'Epanutin représentant seulement 2,3 millions d'euros l'année précédente, la CMA indiquant également que le surcoût pour le NHS a également été de 45,6 millions d'euros en 2014 et de 40 millions d'euros en 2015 (§ 1.19).

20 CJUE, 14 février 1978, *United Brands c/ Commission*, aff. 27/76. V. not. L. Zanon Di Valgiurata, Price Discrimination under Article 86 of the EEC Treaty: The United Brands Case, *International and Comparative Law Quarterly*, pp. 36-58, 1982, W. Bishop, Price Discrimination under Article 86: Political Economy in the European Court, *The Modern Law Review*, pp. 282-295, 1981, P. Orianne, L'apport de l'arrêt "Chiquita" au droit communautaire de la concurrence, Journal des tribunaux, pp. 85-92, 1979 et P. Delannay, *Revue trimestrielle de droit européen*, pp. 294-302, 1978.

21 Au titre des pièces particulièrement incriminantes, relevons qu'au § 3.216, la CMA fait état d'un document interne à Pfizer en ces termes : "[M]*y other concern is just an ethical one—the top line looks great, however this would increase the price of phenytoin capsules to the NHS drastically and to be frank, doesn't feel right* (…) *Pfizer appears to have grappled with this particular concern on a number of occasions but ultimately decided to proceed with genericizing Epanutin (by partnering with Flynn rather than with [Company A])*."

22 La décision précise que Pfizer et Flynn ont respectivement reçu six et cinq demandes de renseignements (§ 2.56).

23 CMA, 7 décembre 2016, *Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*, case CE/9742-13, §§ 3.252 à 3.261.

24 *Ibid.*, § 1.15:"*A key feature of the negotiations between Pfizer and Flynn concerning Pfizer's divestment of its Epanutin Mas was that genericisation would provide the basis for a significant increase in the prices of phenytoin sodium capsules. Indeed, the evidence suggests that one of the key reasons Flynn was introduced into the supply chain was for it to be the focus of any adverse reaction to the price increases and therefore to mitigate the risk of Pfizer suffering reputational damage*."La CMA reproduit également un document transmis par Flynn à Pfizer lors des négociations en ces termes :"*On potential reputational damage ('pharmaco-political fall-out'), Flynn proposed that it 'carries this risk'. That is, that Flynn would front any reputiational damage*"(§ 3.279).

16. Selon la CMA, la reprise des AMM par Flynn n'a finalement que très légèrement modifié la *supply chain*, les capsules restant fabriquées par Pfizer en Allemagne et délivrées directement au Royaume-Uni à un intermédiaire autre que Flynn. Le rôle de Flynn se limitait donc uniquement à la passation des commandes et à la fixation des prix[25].

17. La CMA considère également que Pfizer et Flynn ont délibérément cherché à exploiter une faille dans le système réglementaire britannique s'agissant de la régulation des prix des produits pharmaceutiques à la suite de leur *debranding*[26]. Le comportement est jugé d'autant plus grave que l'Epanutin était suivi par approximativement 48 000 patients au Royaume-Uni, sans possibilité de le substituer sous peine de risques graves pour la santé des personnes épileptiques[27], faisant ainsi de Flynn un "*partenaire obligatoire*" pour la NHS[28], au sens de la jurisprudence *Hoffmann-Laroche*[29].

18. La CMA s'est ensuite attachée à établir le caractère à la fois excessif et inéquitable des prix respectivement pratiqués par Pfizer et Flynn. Après avoir admis qu'à ce jour il existe peu de précédents permettant de définir ce qu'est un prix excessif[30] et, s'agissant plus particulièrement du secteur pharmaceutique, qu'aucun benchmark ne permet de déterminer la marge pouvant être légalement appliquée par Flynn aux prix de fourniture facturés par Pfizer, la CMA constate toutefois que les très significatives hausses de prix ne résultent pas, en l'espèce, d'un quelconque changement significatif dans les coûts de production supportés par Pfizer, ni d'une quelconque innovation provenant de Pfizer ou Flynn, ou encore du moindre nouveau risque lié à l'Epanutin[31].

19. Après avoir analysé le taux moyen de rentabilité au Royaume-Uni de Pfizer pour d'autres produits que l'Epanutin (compris entre 0 et 5 %[32]) et de Flynn (compris entre 5 et 19 %[33]), le taux de rentabilité autorisée au titre du système de régulation volontaire des prix du NHS, en l'occurrence 6 %[34], mais également le taux de rentabilité d'autres laboratoires pharmaceutiques (compris entre 16,4 et 25,1 %[35]), la CMA considère comme excessifs au sens de l'article 102 TFUE :

– les prix pratiqués par Pfizer, dans la mesure où ils intègrent, par rapport aux coûts de production, une marge comprise entre 29 % (pour les capsules de 25 mg) et 690 % (pour les capsules de 300 mg)[36] ; et

– les prix pratiqués par Flynn, dans la mesure où, par rapport au coût d'approvisionnement auprès de Pfizer, ils intègrent une marge comprise entre 31 % (pour les capsules de 100 mg) et 133 % (pour les capsules de 25 mg)[37].

20. Sur la base de ces éléments, la CMA a sanctionné ces pratiques, d'une part, en imposant à Pfizer et Flynn une amende globale de 100,9 millions d'euros[38] et, d'autre part, en leur enjoignant de baisser leurs prix respectifs dans un délai maximal de quatre mois. Flynn a toutefois demandé la suspension de cette injonction au motif, notamment, qu'elle ne précisait aucune fourchette de réduction de prix à appliquer, la rendant de ce fait impossible à mettre en œuvre[39]. Le Competition Appeal Tribunal ("CAT") a refusé de faire droit à cette demande par jugement du 19 janvier 2017[40].

21. L'appel sur le fond de la décision sera, quant à lui, examiné le 30 octobre 2017.

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25 CMA, 7 décembre 2016, *Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*, case CE/9742-13, § 1.14.

26 La décision décrit cet aspect aux §§ 3.149 à 3.195 et précise que ce qui n'était alors qu'un projet de loi, intitulé Health Service Medical Suppliers (Costs) Bill, a été présenté au parlement en septembre 2016 afin de permettre à l'avenir de contrôler également les prix pour les médicaments ne relevant pourtant pas du régime volontaire de fixation des prix. Ainsi que le relevait la CMA, "[i]*f enacted, this Bill will change the UK's pharmaceutical price regulation framework in several aspects. These include: (i) making drugs outside of a voluntary scheme subject to statutory regulation even if the licence holder is a member of a voluntary scheme; and (ii) requiring licence holders to provide cost and other financial information to the DH upon request*", § 3.157. Après avoir été approuvé par les deux chambres, ce texte est entré en vigueur le 27 avril 2017 et vient désormais compléter les dispositions du National Health Service Act de 2006. Plus d'informations sont disponibles à l'adresse suivante : http://services.parliament.uk/bills/2016-17/healthservicemedicalsuppliescosts.html.

27 CMA, 7 décembre 2016, *Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*, case CE/9742-13, §§ 1.6 et 1.7: "[P]*henytoin sodium has a narrow therapeutic index ('NTI') and non-linear pharmacokinetics. These characteristics mean that even small changes to the dose delivered to the circulation can give rise to a disproportionate change in the level of the drug in the body. These characteristics can give rise to the risk of therapeutic failure and toxic side effects, such as seizures which may have life-changing implications*" et "[t]*hese potentially significant risks have resulted in clinical guidance, including guidance published by the National Institute for Health and Care Excellence ('Nice'), in October 2004 and January 2012, and by the Medicines and Healthcare Products Regulatory Agency ('MHRA'), in November 2013, recommending that patients who are stabilized on a particular manufacturer's phenytoin sodium capsule should be maintained on that manufacturer's product and should not be switched to another manufacturer's capsule. This principle is referred to as 'Continuity of Supply' in the Decision and I adopt it here also.*"

28 CMA, 7 décembre 2016, *Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*, case CE/9742-13, § 5.327.

29 CJUE, 13 février 1979, *Hoffmann-La Roche c/ Commission*, aff. 85/76, § 41.

30 CMA, du 7 décembre 2016, *Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*, case CE/9742-13, § 5.340.

31 *Ibid.*, § 5.271.

32 *Ibid.*, § 5.89.

33 *Ibid.*, § 5.187.

34 *Ibid.*, § 5.205. La CMA précise d'ailleurs qu'il s'agit d'un chiffre "cible" que peu de laboratoires atteignent en pratique.

35 *Ibid.*, § 5.103.

36 *Ibid.*, § 5.125.

37 *Ibid.*, § 5.128.

38 Respectivement de 95,1 millions d'euros pour Pfizer et 5,8 millions d'euros pour Flynn Pharma.

39 CAT, *Jugdment on interim relief*, 19 janvier 2017, *Flynn Pharma v. CMA*, case No. 1274/1/12/16 (IR), § 40, (a)(i)(ii) et (iii) : "*Flynn makes four broad claims regarding the harm it will suffer by implementing the directions: (a) First, Flynn says that the Directions are not capable of sensible implementation by Flynn because they are vague and unworkable. (i) The Decision does not specify a rate that Flynn should use or indicate the scale of the price reductions required. Paragraph 1(d) of the Directions leaves open the question of the appropriate rate of return. It is unclear whether prices set at costs plus 6% would be considered excessive. (ii) Flynn considers that a rate of return based on a 6% ROS may not be economically viable depending on the level of Pfizer's input price reduction, (iii) Flynn cannot prepare Step Two of the Directions because it does not know what price Pfizer will set*". Précisons également que Pfizer n'a, quant à elle, pas demandé la suspension de l'injonction de baisse des prix.

40 Ce jugement est disponible à l'adresse suivante : http://catribunal.org.uk/files/1274_Flynn_Judgment_CAT_1_190117.pdf. Une retranscription de l'audience de plaidoiries est également disponible à l'adresse suivante : http://www.catribunal.org.uk/files/1274_Flynn_Transcript_CMC_170117.pdf.

2. La Commission se saisit également des pratiques tarifaires mises en œuvre par Aspen

22. Le 15 mai 2017[41], la commissaire à la concurrence Margrethe Vestager a annoncé l'ouverture d'une enquête sur les pratiques tarifaires du laboratoire Aspen concernant les mêmes anticancéreux que ceux en cause dans l'affaire italienne[42].

23. Aspen aurait, dans "*certains États membres*", eu un comportement analogue à celui adopté en Italie vis-à-vis de l'AIFA, menaçant de retirer les produits anticancéreux en cause[43] et mettant même, "*dans certains cas*", sa menace à exécution.

24. L'approche adoptée aujourd'hui par la Commission peut sembler singulière tant elle a systématiquement, par le passé, considéré que les questions tarifaires en matière pharmaceutique relevaient de la compétence exclusive des États membres. C'est du reste ce qui l'avait conduite, en 2014, à refuser d'ouvrir une enquête au sujet des pratiques tarifaires du laboratoire Gilead concernant le Solvadi, indiqué dans le traitement de l'hépatite C[44].

25. L'ouverture d'un nouveau cas Aspen soulève également un certain nombre de questions dans le cadre du Réseau européen des autorités de concurrence, qui suppose une application décentralisée du droit de la concurrence, c'est-à-dire une compétence des autorités nationales de concurrence, sauf les hypothèses où la Commission est objectivement l'autorité la mieux placée pour traiter d'un cas. En l'espèce, il est permis de s'interroger sur les raisons ayant conduit la Commission à se saisir d'un cas qui a, du moins en partie, déjà été traité par une autorité nationale de concurrence.

26. La suite qui sera donnée par la Commission à cette affaire permettra sans doute d'éclairer sur les motifs qui l'ont conduite à agir ainsi.

27. Plus généralement, la question se pose de savoir si les autorités de concurrence ne se dirigent pas de plus en plus vers un interventionnisme les faisant sortir de leurs rôles en imposant, dans le cadre d'un contrôle *ex post*, aux laboratoires pharmaceutiques ce qu'elles estiment être un "*juste*" prix[45]. En effet, d'une part, elles veillent à ce que les politiques commerciales des laboratoires pharmaceutiques n'aboutissent pas à un prix trop bas qui serait, lui aussi, susceptible de constituer un abus au sens de l'article 102 TFUE, comme l'illustre la récente notification de griefs adressée par la CMA au laboratoire MSD[46]. D'autre part, elles surveillent désormais le plafond supérieur des prix pratiqués par les laboratoires. Dès lors, les autorités de concurrence ne risquent-elles pas d'agir en régulateur des prix des produits pharmaceutiques dont la fixation relève, depuis l'origine, d'autorités sectorielles[47] ?

II. Les pratiques de *pay-for-delay* à la suite de l'arrêt *Lundbeck**

28. Le 8 septembre 2016[48], le Tribunal de l'Union européenne ("Tribunal") a confirmé en tous points la décision adoptée par la Commission le 19 juin 2013[49], par laquelle celle-ci a sanctionné, sur le fondement de l'article 101 § 1 TFUE, les accords transactionnels conclus entre Lundbeck, d'une part, et quatre laboratoires génériques, d'autre part, d'une amende globale de 145,9 millions d'euros[50]. Ces accords transactionnels visaient à retarder le lancement des génériques du traitement phare de Lundbeck contre la dépression, à base de citalopram.

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41 Comm. eur., communiqué IP/17/1323 du 15 mai 2017, Pratiques anticoncurrentielles : la Commission ouvre une procédure formelle d'examen sur les pratiques tarifaires d'Aspen Pharma concernant des médicaments contre le cancer, disponible à l'adresse suivante : http://europa.eu/rapid/press-release_IP-17-1323_fr.htm.

42 Auxquels s'ajoute toutefois le Busulfex (busulfan).

43 Chlorambucil, melphalan, mercaptopurine, tioguanine et busulfan.

44 En témoigne la réponse donnée par la commissaire à la concurrence Margrethe Vestager le 22 décembre 2014 à une question posée par les parlementaires Soledad Cabezón et Michèle Rivasi, à la suite de la décision de la Commission de ne pas ouvrir une enquête à l'égard de potentielles pratiques de prix excessifs mises en œuvre par le laboratoire Gilead s'agissant de son traitement contre l'hépatite C, le *Solvadi* : "*En vertu de l'article 168, paragraphe 7, du TFUE, les États membres sont compétents pour les services de santé et les soins médicaux, et notamment les ressources qui leur sont affectées. Chaque État membre peut donc prendre des mesures visant à réguler ou à influencer les prix dans ces secteurs. C'est la raison pour laquelle le processus de fixation des prix, auquel participent les fabricants de produits pharmaceutiques et les systèmes de soins de santé, est généralement conduit au niveau national, ce qui permet aux États membres d'exercer leur pouvoir de négociation. À la connaissance de la Commission, la France et d'autres États membres ont conclu – ou sont en voie de conclure – avec Gilead des accords limitant les prix pratiqués.*" Cette réponse est disponible à l'adresse suivante : http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=P-2014-008636&language=FR.

45 Sur ce point, il convient de noter que, lors de la présentation du rapport annuel pour 2016 de l'Autorité française de la concurrence, la Présidente Isabelle de Silva a indiqué l'ouverture imminente d'une enquête sectorielle dans le secteur de la santé. Invitée à préciser le périmètre de cette enquête, elle indiquait: « [n]*ous souhaitons poursuivre* [l'effort engagé pour les besoins de la rédaction de l'avis n°16-A-24 du 14 décembre 2016 relatif au fonctionnement de la concurrence dans le secteur des audioprothèses] *avec une enquête sectorielle plus large à l'échelle de tout le secteur de la santé, en regardant divers sujets : le sujet des pharmacies, le sujet des achats hospitaliers notamment, le sujet des laboratoires de biologie, donc regarder toute une série de secteurs pour voir, à chaque fois, s'il est possible d'insuffler davantage de concurrence pour une meilleure efficacité parce que le but c'est toujours que le patient in fine en bénéfice et que l'on puisse diminuer les dépenses de santé* ». Son interview est disponible à l'adresse suivante : https://www.radioclassique.fr/radio/emissions/matinale-de-radio-classique/l-invite-de-l-economie/.

46 Communiqué de presse de la CMA du 23 mai 2017, disponible à l'adresse suivante : https://www.gov.uk/government/news/cma-issues-provisional-decision-in-relation-to-drug- firms-pricing.

47 À ce titre il est intéressant de noter qu'au paragraphe 46 du jugement du CAT du 19 janvier 2017, *Flynn Pharma Limited c/ CMA*, la CMA elle-même considère que son rôle n'est pas de réguler les prix. C'est d'ailleurs un argument qu'elle a utilisé devant le CAT pour répondre à Flynn Pharma, qui lui reprochait de ne pas lui avoir donné suffisamment d'indications quant au niveau de prix à respecter afin d'éviter qu'il ne soit excessif.

* Pour une analyse détaillée de cet arrêt, v. notre analyse disponible à l'adresse suivante : https://info.dechert.com/10/7366/october-2016/2016-10-04-arret-lundbeck-fr(1).asp.

48 Trib. UE, 8 septembre 2016, *Lundbeck A/S et Lundbeck Ltd c/ Commission*, aff. T-472/13.

49 Comm. eur., déc. du 19 juin 2013, *Lundbeck*, aff. AT.39226.

50 Amende d'un montant de 93,7 millions d'euros pour Lundbeck (montant confirmé en appel) et une amende cumulée de 52,2 millions d'euros pour les quatre laboratoires génériques.

29. Cet arrêt était très attendu, car le Tribunal était, pour la première fois, amené à juger l'approche adoptée par la Commission en matière de *pay-for-delay*, sachant par ailleurs que cette approche avait été reprise dans des décisions rendues postérieurement (*Fentanyl*[51] et *Servier*[52]) et pourrait l'être également dans l'affaire *Teva*[53].

30. Deux points posaient notamment question dans le raisonnement adopté par la Commission : (i) l'existence d'un rapport de concurrence potentielle entre Lundbeck et les laboratoires génériques et (ii) la qualification de restriction par objet des accords litigieux en dépit de leur caractère nouveau.

31. Le Tribunal a tout d'abord validé le raisonnement de la Commission consistant à considérer que Lundbeck et les laboratoires génériques en cause étaient des concurrents, à tout le moins des concurrents potentiels, au sens de l'article 101 TFUE. Selon le Tribunal, la simple existence d'un brevet ne permet pas d'exclure toute concurrence dans la mesure où les laboratoires génériques peuvent soit en contester la validité, soit lancer un produit générique en prenant le risque de s'exposer à une action en contrefaçon.

32. S'agissant de la restriction par objet, le Tribunal, tout comme la Commission, assimile les accords en cause à de classiques accords de répartition ou d'exclusion de marché, qui sont, au regard de leur nocivité intrinsèque, considérés comme constitutifs d'une infraction par l'objet[54]. Le Tribunal se fonde en particulier sur la jurisprudence *BIDS*, par laquelle la CJUE avait jugé, dans le contexte spécifique des surcapacités affectant la filière bovine en Irlande et d'un plan de rationalisation visant à ramener le nombre de transformateurs de 20 à un chiffre compris entre 4 et 6, que l'accord par lequel les "*restants*" indemnisent financièrement les "*sortants*" du marché avait un objet anticoncurrentiel au sens de l'article 101 TFUE[55].

33. La portée réelle de l'arrêt *Lundbeck*, actuellement sous pourvoi[56], doit toutefois d'ores et déjà être quelque peu relativisée, le Tribunal ayant pris le soin de confirmer que l'approche retenue par la Commission n'avait pas pour objectif "*de fixer des normes juridiques généralement applicables*"[57] et que, partant, tous les règlements amiables en matière de brevets ne seront pas tous forcément contraires à l'article 101 TFUE. Des éclaircissements sur ce point sont par ailleurs attendus dans une autre affaire de *pay-for-delay* qui devrait prochainement connaître son épilogue : l'affaire *Servier*, dans laquelle le Tribunal doit rendre son arrêt dans les prochaines semaines[58]. Cette affaire *Servier* présente cependant plusieurs singularités par rapport à l'affaire *Lundbeck* puisque la Commission a, pour la première fois, eu recours à la notion de "*stratégie d'exclusion unique et continue*"[59] pour sanctionner non seulement des transactions en matière de brevets mais aussi l'acquisition de la technologie d'un concurrent. Ce faisant, elle s'est fondée tant sur l'article 101 que sur l'article 102 du TFUE.

34. Ces affaires montrent que la Commission n'hésite désormais plus, certes sur la base de pièces incriminantes saisies chez Lundbeck[60] ou Servier[61], à porter sa propre appréciation sur la validité des brevets objets de la transaction, sans estimer devoir s'en remettre au jugement des autorités et juridictions spécialisées[62].

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51 Comm. eur., déc. du 10 décembre 2013, *Fentanyl*, aff. AT.39685.

52 Comm. eur., déc. du 30 septembre 2016, *Perindopril (Servier)*, aff. AT.39612 (dont une nouvelle version de la décision a été publiée le 17 mai dernier, disponible à l'adresse suivante : http://ec.europa.eu/competition/antitrust/cases/dec_docs/39612/39612_12449_3.pdf).

53 Comm.eur, communiqué de presse IP/17/2063 du 17 juillet 2017, La Commission européenne adresse une communication des griefs à Teva concernant un accord de type « pay-for-delay », disponible à l'adresse suivante : http://europa.eu/rapid/press-release_IP-17-2063_fr.htm.

54 Comm. eur., Guidance on restrictions of competition "by object" for the purpose of defining which agreements may benefit from the De Minimis Notice, 25 juin 2014, disponible à l'adresse suivante : http://ec.europa.eu/competition/antitrust/legislation/de_minimis_notice_annex.pdf.

55 CJUE, 20 novembre 2009, *Competition Authority c/ Beef Industry Society Ltd (BIDS)*, aff. C-209/07.

56 Les moyens au soutien du pourvoi de *Lundbeck* sont disponibles à l'adresse suivante : http://eur-lex.europa.eu/legal-content/fr/TXT/PDF/?uri=uriserv%3AOJ.C_.2017.030.01.0025.01.FRA.

57 Trib. UE, 8 septembre 2016, *Lundbeck A/S et Lundbeck Ltd c/ Commission*, aff. T-472/13, § 415.

58 Pour rappel, la Commission a sanctionné en juillet 2014 une pratique de *pay-for-delay* en imposant à Servier une amende d'un montant de 331 millions d'euros pour avoir conclu des accords avec des laboratoires génériques afin, selon la Commission, de retarder leur entrée sur le marché. Au moment où nous rédigeons cet article, les audiences de plaidoiries, qui se sont tenues du 6 au 9 juin 2017, viennent de se terminer. L'essentiel des débats s'est notamment concentré sur les points suivants : (i) la position dominante de Servier sur le marché du périndropil, (ii) la notion de concurrence potentielle, (iii) la qualification des accords en cause comme étant des restrictions de concurrence par objet, (iv) le moment choisi par la Commission pour analyser les effets des pratiques en cause (au moment de la conclusion des accords litigieux) et, enfin, (v) le montant de l'amende et, en particulier, son caractère disproportionné.

59 Comm. eur., déc. du 9 juillet 2014, *Perindopril (Servier)*, (version publiée le 17 mai 2017), § 2774 et section 8.4.1. La Commission précise que "[l]*e schéma de comportement de Servier a combiné une acquisition de technologie et cinq accords de règlement amiable consécutifs et a servi principalement à éliminer les sources proches de concurrence. Que ceci ait constitué une stratégie d'exclusion unique et continue est confirmé par un certain nombre d'éléments de l'époque*" (§ 2774). La Commission relève en particulier qu'"[i]*l existe des preuves documentaires montrant que Servier a acquis la technologie Azad (qui contournait avec succès le brevet '947 sur la forme alpha) afin d'entraver l'entrée des génériques plutôt que pour tirer des gains d'efficacité de la technologie acquise. En effet, le préambule de l'accord Azad du 9 novembre 2004 contient un exposé explicite des intentions de Servier : ' Servier souhaite renforcer le mécanisme de défense de ses propres formes alpha, bêta et gamma de périndopril et a décidé d'acquérir la demande de brevet et son savoir-faire'. Cela confirme que l'intérêt de Servier dans l'acquisition de la technologie Azad n'était pas d'améliorer ses procédés de production (comme indiqué a posteriori dans le cadre de la présente enquête), mais d'ajouter la demande de brevet d'Azad à son ' mécanisme de défense', qui ne peut avoir été conçu que pour se défendre contre l'entrée des génériques.*"

60 Trib. UE, 8 septembre 2016, *Lundbeck A/S et Lundbeck Ltd c/ Commission*, aff. T-472/13, § 119 : "[l]*l ressort également des évaluations internes de Lundbeck d'août et de septembre 2003 émises dans le contexte du litige Lagap, que celle-ci* [Lundbeck] *avait elle-même considéré qu'il y avait entre 50 % et 60 % de risques que son brevet sur la cristallisation puisse être déclaré invalide en cas de contentieux.*"

61 Commission, décision du 9 juillet 2014, *Perindopril (Servier)*, (version publiée le 17 mai 2017), § 122 : " [U]*n document de l'époque fait apparaître que, parmi les 23 brevets de procédés (concernant les voies de synthèse, principalement), 21 étaient qualifiés en interne par Servier de ' brevets de barrage' ou ' brevets de papier'. Trois de ces 21 brevets de procédé étaient de surcroît décrits comme n'impliquant pas la moindre activité inventive (' activité inventive zéro')*."

62 Sur ce point, l'un des arguments développés par Lundbeck dans le cadre du quatrième moyen présenté à l'appui de son pourvoi tient au fait que "[l]*a conclusion du tribunal selon laquelle Lundbeck doutait de la validité de ses brevets est entachée d'une erreur de droit, d'une erreur manifeste d'appréciation des preuves et d'une motivation contradictoire (…) le Tribunal a commis une erreur de droit en jugeant que les éléments de preuve datant d'après la conclusion des accords, mais qui toutefois dans de nombreux cas étaient antérieurs à l'expiration des accords, ne peuvent pas être décisifs pour examiner si les entreprises de génériques étaient des concurrents potentiels de Lundbeck. Les documents comprennent des preuves scientifiques de ce que les entreprises de génériques et leurs fabricants d'API ont violé les brevets de Lundbeck, des décisions des juridictions nationales accordant des injonctions préliminaires et d'autres formes de mesures provisoires à Lundbeck contre des produits de citalopram basés sur des IPA utilisés par certaines entreprises de génériques et la confirmation par l'Office européen des brevets de la validité du brevet de cristallisation de Lundbeck sur tous les aspects pertinents dont la Commission avait remis en cause la force.*"

III. Les pratiques s'inscrivant dans le cadre d'un débat scientifique avec les autorités de santé

35. La première incursion des autorités de concurrence dans ce domaine revient à l'Autorité de la concurrence française (l'"Autorité") et a concerné les pratiques de dénigrement de génériques. La problématique est désormais bien connue : en tant qu'opérateur dominant, le laboratoire pharmaceutique, bien qu'astreint à d'importantes obligations de pharmacovigilance, dispose surtout de la responsabilité particulière de présenter, aux professionnels de santé, des informations à la fois exhaustives et objectives.

36. Si la période récente n'offre que peu d'actualités sur ce sujet en dehors de la confirmation par la Cour de cassation, par un arrêt du 18 octobre 2016[63], de la décision *Plavix*, elle illustre toutefois le fait que les autorités de concurrence semblent désormais tout à fait disposées à examiner des pratiques s'inscrivant dans le cadre d'un débat scientifique, y compris lorsqu'un sujet n'a pas encore été définitivement tranché par la communauté scientifique.

37. Ainsi, le 27 février 2014, l'AGCM a sanctionné les laboratoires Roche et Novartis pour s'être entendus afin d'empêcher l'utilisation d'Avastin – fabriqué par Roche et bénéficiant d'une AMM pour le traitement de nombreux cancers – dans le traitement de la dégénérescence maculaire liée à l'âge (DMLA), indication pour laquelle le Lucentis – fabriqué par Novartis et commercialisé à un prix significativement plus important qu'Avastin – bénéficiait d'une AMM.

38. La proximité du mode d'action des deux médicaments a conduit certains ophtalmologistes à utiliser Avastin "*hors-AMM*" ("*off label*") dans le traitement de la DMLA, essentiellement pour des considérations budgétaires[64]. Cette utilisation supposait un reconditionnement par l'ophtalmologiste réalisant l'injection.

39. Afin d'encadrer les risques générés par une telle utilisation hors-AMM, Roche a demandé et obtenu de l'European Medecines Agency ("EMA") qu'elle modifie le résumé des caractéristiques du produit ("RCP") d'Avastin afin de préciser que son médicament n'avait pas été formulé pour une injection intravitréenne.

40. Or, selon l'AGCM, par cette démarche, Roche et Novartis se sont entendues, au sens de l'article 101 TFUE, pour créer ou, du moins, entretenir une différenciation artificielle entre deux produits pouvant intervenir dans le traitement d'une même pathologie, en l'occurrence la DMLA. Elles se sont, respectivement, vu imposer des amendes de 90,6 millions d'euros et 92 millions d'euros[65]. L'AGCM va donc plus loin que la jurisprudence *AstraZeneca*[66], sanctionnant la seule transmission d'informations inexactes ou trompeuses aux autorités de santé.

41. Après avoir été déboutées en appel[67], Roche et Novartis ont formé un pourvoi devant le Conseil d'État italien, qui a sursis à statuer, afin de soumettre cinq questions préjudicielles à la CJUE[68]. Ces questions préjudicielles soulèvent un certain nombre de points cruciaux relatifs à l'interaction entre le droit de la concurrence et d'autres droits tels que le droit de la propriété intellectuelle, ou le droit réglementaire applicable au secteur pharmaceutique[69], et qui pourraient, en fonction de la réponse qu'y apportera la CJUE, avoir des conséquences importantes sur les modalités d'action des autorités de concurrence.

42. Deux des cinq questions préjudicielles ont ainsi précisément porté sur le point de la concurrence potentielle entre deux laboratoires n'intervenant pas directement sur le même marché de produits, problématique que l'on retrouvait déjà dans l'arrêt *Lundbeck*[70] :

– Existe-t-il un rapport de concurrence, au sens de l'article 101 TFUE, entre un laboratoire pharmaceutique n'opérant sur le marché du donneur de licence qu'en raison d'un accord de licence ?

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63 Cass. com., 18 octobre 2016, n° 15-10.384.

64 Précisons qu'en France, le Conseil d'État a jugé que l'Avastin hors-AMM pouvait constituer une alternative aux spécialités Lucentis et Aylea, notamment en cas d'échec thérapeutique, CE, 24 février 2017, 1re et 6e ch. réunies, n° 392459.

65 AGCM, déc. du 27 février 2014, I 760, *Roche-Novartis/Farmaci Avastin Lucentis*, disponible à l'adresse suivante : http://www.agcm.it/concorrenza/concorrenza-delibere/download/41256297003874BD/AF96880B5B6A7C6FC125 7C9F0053DDF3.html?a=p24823.pdf. Pour un commentaire de cette décision, v. égal. L. Arnaudo, The Strange Case of Dr. Lucentis and Mr. Avastin. The Italian Competition Authority Fines Roche and Novartis for Collusion, *European Competition Law Review*, vol. 35, n° 7, pp. 347-351, juillet 2014, disponible à l'adresse suivante : https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2428126.

66 CJUE, 6 décembre 2012, *AstraZeneca c/ Commission*, aff. C-457/10 P, § 93 : "[O]*r, force est de constater que, comme le Tribunal l'a jugé aux points 493, 495, 507, 598, 599, 608 et 609 de l'arrêt attaqué, le comportement constant et linéaire de AZ, tel que résumé ci-dessus, qui était caractérisé par la communication aux offices des brevets de déclarations fortement trompeuses ainsi que par un manque manifeste de transparence notamment quant à l'existence de l'autorisation technique française et par lequel AZ a délibérément tenté d'induire les offices des brevets ainsi que les autorités judiciaires en erreur afin de préserver le plus longtemps possible son monopole sur le marché des IPP, était étranger à la concurrence par les mérites*." Sur ce point, v. égal. L. Arnaudo, The Strange Case of Dr. Lucentis and Mr. Avastin. The Italian Competition Authority Fines Roche and Novartis for Collusion, *European Competition Law Review*, vol. 35, n° 7, pp. 347-351, juillet 2014, disponible à l'adresse suivante : https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2428126 "[S]*uch infringement has been perpetrated by means of ' classical' direct relationships among undertakings in order to share product markets, with no involvement of the sectorial agencies: to be clear, the Italian decision should not be read in the wake of the EU AstraZeneca case on regulatory gaming*."

67 Tribunal administratif régional du Latium, jugement du 5 novembre 2014.

68 CJUE, *F. Hoffmann-La Roche AG, La Roche SpA, Novartis AG and Novartis Farma SpA c/ Autorità Garante della Concorrenza e del Mercato*, aff. C-179/16.

69 Les questions sont disponibles en français à l'adresse suivante : http://eur-lex.europa.eu/legal-content/FR/TXT/?uri=uriserv:OJ.C_.2016.222.01.0004.01.FRA&toc=OJ:C:2016:222:FULL.

70 Sur ce sujet, v. not. le dossier spécial paru dans *Concurrences* n° 2-2017, pp. 24-50, The *Lundbeck* case and the concept of potential competition.

– Existe-t-il un rapport de concurrence entre deux produits disposant de la même indication thérapeutique, mais dont l'un a une autorisation de mise sur le marché alors que l'autre est vendu hors-AMM ?

43. Les conclusions de l'avocat général, Henrik Saugmandsgaard Øe, sont attendues fin septembre 2017[71]. Les réponses qui seront apportées par la CJUE à ces questions risquent, en particulier, d'avoir un impact sur la suite que pourrait donner l'Autorité au dossier concernant les deux laboratoires, qui avaient également fait l'objet d'opérations de visite et saisie en France le 9 avril 2014[72].

Conclusion

44. L'année 2016 et le début d'année 2017 montrent que le secteur pharmaceutique est toujours particulièrement surveillé par les autorités de concurrence européennes avec un interventionnisme probablement plus marqué que dans d'autres secteurs économiques compte tenu des répercussions sanitaires et financières de certaines pratiques (par exemple en matière de prix excessifs) sur les patients et les systèmes nationaux d'assurance maladie.

45. S'il est prématuré de tirer de véritables enseignements de ces affaires, dont la plupart sont encore en cours, les entreprises pharmaceutiques ont d'ores et déjà la confirmation qu'une validation de leur action par une autorité sectorielle de santé ne les prémunira pas d'une éventuelle poursuite de la part d'une autorité de concurrence.

46. Il semble par ailleurs acquis aujourd'hui que les autorités de concurrence ne se limiteront plus à une simple vérification de l'absence de manipulation des autorités de régulation *via* la diffusion d'informations délibérément trompeuses (jurisprudence *AstraZeneca*) mais procéderont à des appréciations toujours plus qualitatives concernant notamment la robustesse d'un brevet et les chances de succès d'une action en contrefaçon, les demandes de modification du RCP ou encore le juste niveau de prix.

47. Mais où se situe la limite à l'action des autorités de concurrence à cet égard ? ■

71 Roche, Novartis appeal of Italian drug-collusion ruling heard at EU court, *Mlex*, 3 mai 2017.

72 Aut. conc., communiqué de presse du 9 avril 2014, La rapporteure générale de l'Autorité de la concurrence confirme que des opérations de visite et saisie inopinées ont été réalisées le 8 avril 2014 dans le secteur de la commercialisation de traitements contre la DMLA, disponible à l'adresse suivante : http://www.autoritedelaconcurrence.fr/user/standard.php?id_rub=591&id_article=2335. Ces opérations de visite et saisie ont été validées par un arrêt de la chambre criminelle de la Cour de cassation (rendu suite à un pourvoi formé par Novartis) en date du 26 octobre 2016, nº 15-83.477. Les inspections en Italie ayant, quant à elles, eu lieu le 14 février 2013.

Excessive pricing cases in the pharmaceutical industry: Economic considerations and practical pitfalls

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1. Both national competition authorities and the European Commission have recently shown a new interest in pursuing excessive pricing cases in the pharmaceutical sector. The European Commission's launch of an investigation into the pricing of five cancer drugs by Aspen pharmaceuticals is the most recent case in this area. The UK authority already has two such cases, one against Pfizer and Flynn on the pricing of anti-epilepsy drug phenytoin and one against Actavis on the pricing of hydrocortisone tablets, while the Italian Competition Authority has already fined Aspen on the same conduct.

2. Economists have long questioned whether high prices, in the absence of other abuses, call for competition policy intervention. In section I, we briefly summarise the arguments that have been developed in this context. Section II argues that the pharmaceutical sector is an industry that is particularly ill-suited for intervention on excessive pricing grounds. Section III then discusses some of the practical pitfalls to avoid in determining whether prices can in fact be considered excessive.

I. Excessive pricing cases should be exceptional

3. In our view, the goal of antitrust should be to protect the competitive process and not to prevent high prices as such, since high prices are necessary to reward investment, and act as a signal to attract further investment and entry. As Carlton and Heyer (2008)[1] note, "*an essential element of antitrust policy is to allow firms to capture as much of the surplus that by its own investment, innovation, industry or foresight, the firm has itself brought into existence*," and antitrust enforcement should therefore focus on conduct that extents market power, rather than on conduct that merely extracts surplus. This view is consistent with US antitrust enforcement, which does not consider excessive prices as an abuse.

4. Even in jurisdictions where excessive prices are considered an antitrust violation, as in Europe, competition authorities have traditionally shied away from launching excessive pricing investigations, particularly when there is no other element of abuse,

* While the authors have been advising Flynn in the UK excessive pricing investigation, all views expressed in this article are strictly personal and are not meant in any way to represent the views of Flynn or of any other client.

1 D. W. Carlton and K. Heyer, Extraction vs. Extension: the basis for formulating antitrust policy towards single firm conduct, *Competition Policy International* 4 (Autumn): 285–305.

such as exclusion.[2,3] The general reluctance by investigating authorities to launch excessive pricing cases stems from the fact that such cases raise a number of practical and conceptual challenges. Conceptually, as dominance is not in itself an abuse, charging a monopoly price should not be considered abusive. As highlighted by Advocate General Nils Wahl, "*it would seem natural to expect a monopolist to charge the monopoly price. Interfering with such a pricing policy would be tantamount to interfere with dominance as such.*"[4] High prices, and potentially very high prices, are therefore no ground in themselves to justify antitrust intervention: additional—and very specific—conditions are necessary to establish an excessive price case.

5. As part of the modernization of European antitrust, the Commission rightly decided to focus its enforcement priorities on exclusionary rather than excessive prices,[5] and an interesting debate took place among economists and policymakers to determine under what specific circumstances excessive price cases could be justified.

6. In particular, Röller[6] proposed a logically consistent and very limited role for excessive pricing cases in Europe, i.e., to cover "gap cases" that would otherwise not be caught under Article 102 TFEU. Gap cases arise because Article 102 only applies to dominant firms, so exclusionary conduct that "*leads to a dominant position*" is not caught under Article 102; there is thus a possibility that a non-dominant firm would gain a dominant position through exclusionary means without infringing Article 102, and would subsequently exploit its gained dominance by imposing excessive prices. This approach can be extended to cases where dominance was not obtained on the merits, such as previously state-owned monopolies, recognizing also that sectoral regulators are better placed to fix prices than competition authorities.

7. Röller therefore proposed a cumulative five-condition test for the use of Article 102 in respect of exploitative conduct:

- There are significant entry barriers;
- The market is unlikely to self-correct;
- No (structural) remedy is available;
- There is no regulator or there is a regulatory failure; and
- The exploitative abuse stems from acquiring a dominant position as a result of an exclusionary abuse.

8. Similarly, Motta and de Steel[7] proposed a cumulative three-condition test:

- High and non-transitory barriers to entry leading to a super dominant position. According to the authors the threshold should be higher than the existence of mere dominance or super dominance. These are cases where the dominant or super dominant position is unlikely to be challenged by potential entrants.
- The super-dominant position is due to current/past exclusive/special rights or to un-condemned past exclusionary anticompetitive practices. To ensure that excessive pricing cases do not reduce incentives to invest and innovate, the position of dominance should not have been earned by business acumen, past risky investments or effort.
- No sector-specific regulator has jurisdiction to solve the matters. If an industry-specific regulator exists, which is likely in industries in which the previous two conditions hold, then the regulator is more suitable to intervene in questions of excessive pricing.

9. The cumulative aspect of the proposed tests is essential: high barriers to entry and the unlikeliness of the market to self-correct are a necessary but not sufficient condition to justify intervention. The restriction to cases where dominance was not obtained on the merits (legal monopoly or past exclusionary behaviour) is necessary, as is the absence of (a more efficient) regulatory solution. Except if these specific conditions are met, it is not socially optimal to intervene.

10. Even in cases where dominance was not obtained on the merits, but through historical state intervention, excessive pricing intervention is not automatically justified. As Evans and Padilla[8] point out, many incumbents in the telecoms and energy sector in Europe invest significant amounts on infrastructure in competition with entrants. They find that consumers are generally better off without intervention in industries where innovation and investment play a key role and that intervention should

2 For example, in the *Napp* case, where Napp was accused of charging excessively low (exclusionary) prices in the hospital segment and excessively high prices in the community segment for its sustained release morphine tablets, Vickers explained that "*the OFT explicitly viewed Napp's pricing policy as a whole and in the appeal case went on to say that it would not wish to maintain excessive pricing abuse if the pricing to the hospital segment was not judged to be exclusionary.*" J. Vickers, How Does the Prohibition of Abuse of Dominance Fit With the Rest of Competition Policy?, Paper for the eighth annual EU competition law and policy workshop at the European University Institute, Florence, 6 June 2003.

3 According to the opinion of Advocate General Nils Wahl, intervention on the basis of excessive pricing alone has been generally limited to regulated industries. Opinion of Advocate General Wahl, delivered on 6 April 2017, following a request for a preliminary ruling by the Latvian Supreme Court on the conditions under which the rates set by the Latvian collecting society AKKA/LAA are excessive under Article 102.

4 N. Wahl (2007), Exploitative high prices and European competition law – a personal reflection, in Konkurrensverket – Swedish Competition Authority (ed.), *The Pros and Cons of High Prices*, p. 51.

5 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, 2009.

6 L. H. Röller (2007), Exploitative Abuses, in Ehlermann and Marquis (eds.), *European Competition Annual 2007: A reformed Approach to Article 82*.

7 M. Motta and A. de Streel (2007), Excessive Pricing in Competition Law: Never say Never?, in Konkurrensverket – Swedish Competition Authority (ed.), *The Pros and Cons of High Prices*, p. 14.

8 D. S. Evans and A. J. Padilla (2004), Excessive Prices: Using Economics to Define Administrable Legal Rules, *CEMFI Working Paper* No. 0416.

be limited to situations where the dominant firm enjoys a legal monopoly and where the excessive prices charged by the legal monopoly may prevent the launching of new products in adjacent markets.[9]

11. In any case, enhancing static efficiency through antitrust intervention aimed at curbing excessive prices, at the possible cost of dynamic efficiency, would be short-sighted. Even if, taking an *ex-post* perspective, it may be tempting for a competition authority to impose lower prices, this may be misguided from an *ex-ante* perspective given the chilling effect of such intervention on investment. This consideration calls for extreme caution in pursuing excessive price cases, which is further reinforced by a competition authority's inferior ability to regulate prices, compared to a sector-specific regulator.

II. The pharmaceutical sector is ill-suited to excessive pricing cases

12. The conditions set out above are generally not met in the pharmaceutical industry.

13. Firstly, the pharmaceutical sector is a dynamic industry, where innovation is key in the successful introduction of new products. The role of patent protection is exactly to provide incentives to firms to engage in risky R&D activities by rewarding them with a period of protection during which they can earn higher profits. Antitrust intervention for excessive prices in the pharmaceutical industry would therefore limit the rewards for innovation, with a likely outcome of limiting the introduction of new, and potentially life-saving drugs. Dominant positions enjoyed by pharmaceutical companies have been achieved on the merits, and are normally not the result of previous state monopolies or exclusionary conduct. There is thus no reason to prevent firms which have ahieved dominance through competitive means to reap the rewards for their investments and innovation.

14. Secondly, following the end of the patent protection period, there are generally few barriers to entry as generic manufacturers can generally enter the market swiftly, with strong price effects. Although smaller product markets may attract fewer generic entrants, and generic entry may be less swift in some cases, one can generally expect that high prices would then make such entry more profitable.[10]

15. Thirdly, pharmaceuticals is an already heavily regulated sector. If there is regulatory failure, is competition policy the right tool to address this? In cases where there are other elements of abuse, such as exclusionary behaviour, competition policy may be the right instrument, but if the concern is purely one of pricing, then it is less clear that competition policy is the correct tool to use. Regulating prices is not an easy task as it requires deep industry knowledge, which may not be available to more generalist enforcers such as competition authorities. This is the reason why most industries that require price regulation have specialised regulators responsible for enforcing it. Additionally, price regulation is burdensome; it cannot be implemented with a one-off decision, but requires significant resources to monitor adherence, which could be onerous for busy competition authorities.

16. The Commission generally recognizes the importance of rewarding innovation, and therefore has not shown any indication that it would intervene to curb high prices for new and innovative drugs. For example, the European Commission has so far declined to open an investigation into allegations of excessive pricing for Hepatitis C drugs on the basis that it was a rapidly moving therapeutic area with several new medicines in advanced stages of development.[11]

17. The Commission and national authorities thus appear to draw a distinction between expensive but innovative medicines, on the one hand, and old off-patent medicines that experience significant price increases, on the other hand. Indeed, recent cases focus on older molecules, where price increases have been observed, and for which there are allegedly high barriers to entry.

18. However, in our view, the mere observation of high price increases and barriers to entry are not sufficient to justify intervention. Indeed, such cases do not fall under the realms of legal monopolies or past exclusionary conduct. If, in exceptional circumstances, the specific market conditions are such that they should be treated as natural monopolies, sector-specific regulation appears better placed to solve the issue than antitrust policy.

9 For an extensive overview and discussion of the economic screens proposed to minimise the costs of excessive pricing investigations, *see* in particular F. Jenny, Abuse of Dominance by Firms Charging Excessive or Unfair Prices: An Assessment (September 11, 2016). Available at SSRN: https://ssrn.com/abstract=2880382.

10 For example, Kanavos finds that the size of the market is an important determinant of the likelihood of generic entry. P. Kanavos (2014), Measuring performance in off-patent drug markets: a methodological framework and empirical evidence from twelve EU Member States, *Health Policy*, Volume 118, Issue 2, pages 229-241. Similar findings have also been made in other empirical papers. *See*, for example: P. Danzon and M. Furukawa M. (2011), Cross-National Evidence on Generic Pharmaceuticals: Pharmacy vs Physician-Driven Markets, *NBER Working Paper* No. 17226; E. Glowicka, S. Lorincz, E. Pesaresi, L. Sauri Romero and V. Verouden (2009), Generic Entry in prescription medicines in the EU: Main Characteristics, Determinants and Effects. Available at http://ec.europa.eu/dgs/competition/economist/prescription_medicines.pdf; L. Magazzini, F. Pammolli and M. Riccaboni. (2004), Dynamic Competition in Pharmaceuticals: Patent Expiry, Generic Penetration, and Industry Structure, *European Journal of Health Economics* 5: 175–182.

11 Commissioner Vestager's responses to parliamentary questions (P-008636/2014 and 000261/2015).

19. Abstracting from the more normative question of whether authorities should investigate excessive pricing cases in the pharmaceutical sector, we now turn to the practical pitfalls of excessive pricing cases in the context of pharmaceuticals.

III. Determining whether prices are excessive: Practical pitfalls

20. Once an authority has decided to open an investigation into excessive pricing, the first consideration is what framework to use to assess whether prices are excessive. In excessive pricing cases enforcers will typically examine the level of prices relative to costs and assess whether prices or profits are excessive usually by comparing these to appropriate benchmarks.[12] From a practical perspective, establishing what an appropriate benchmark is in each case is far from an easy task. For example, in industries characterised by significant investments and innovation, as in the pharmaceutical sector, or economies of scale, competitive prices can be expected to be well above the marginal costs of production. Additionally, even if an appropriate benchmark is found, establishing whether prices or profits are above, at or below the benchmark is not straightforward as it may depend on the way costs are measured and on the method used to allocate common costs. Thirdly, from a conceptual and practical point of view, establishing when prices are excessive, i.e., by how much do prices or profits need to be above the benchmark to be considered excessive, is inevitably a matter of judgement. There is therefore no set rule or guidance to determine when prices or profits can be considered excessive.

21. These challenges imply that enforcers are likely to make incorrect judgements when investigating excessive pricing cases, i.e., there will be cases where prices are considered excessive when in fact they are not (Type I errors) and cases where prices are not considered excessive when they are (Type II errors). Type I errors entail costs to consumers in the medium to longer term as *ex-post* intervention reduces companies' incentives to invest and innovate. In the pharmaceutical sector, where research and development is essential in ensuring new life saving treatments are discovered and brought to the market, the social costs of Type I errors could be particularly significant.

12 The legal framework for analysing whether prices are excessive was originally set out in the *United Brands* case, where the European Court of Justice proposed the following test, sometimes referred to as the "United Brands test."*"The questions therefore to be determined are whether the difference between the costs actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products."* Judgment of the Court of 14 February 1978, *United Brands Company and United Brands Continentaal BV v. Commission of the European Communities – Chiquita Bananas*, case 27/76.

22. Leaving aside the conceptual shortcomings of excessive pricing cases, there are thus also a number of practical pitfalls to avoid in determining whether a price is in fact excessive. We highlight below some of the traps that competition authorities should avoid in this respect.[13]

1. Defining markets too narrowly

23. In order to build an excessive prices case, authorities first have to establish dominance. They may be tempted to do so by defining very narrow markets, so that the shares of the company under investigation appear very high. In extreme cases, an authority may consider that a market could be defined just on the basis of a molecule, the form, and even exclude generic competitors from the market. While such approaches do indeed lead to high computed shares, these are, however, not indicative of dominance.

24. Authorities may point out that some customers are somehow captive, which would justify such an approach of excluding generic competitors if customers do not switch between drugs of different manufacturers, due, e.g., to a drug's narrow therapeutic index. However, in the absence of price discrimination at the customer level, such market definitions based on customer subgroups are flawed as producers' prices also reflect competition that they face for non-captive customers (e.g., for new customers not yet treated).

2. "You know it when you see it"

25. Competition authorities officials have on some occasions referred to US Supreme Court Justice Steward's "*you know it when you see it*" statement regarding the difference between hard-core pornography and obscenity. However, adopting such an approach in order to identify excessive pricing cases would be very problematic.

26. Beyond the pure arbitrariness of such a test, the issue with such an approach is that it provides no guidance to firms as to when they may be infringing competition law. It is important to think of the impact of competition policy beyond a specific case under review, but also in terms of the behaviour modification that it imposes on firms more generally. If firms are afraid that they may be infringing competition law, they may choose to price below the socially optimal level, with potential negative effects for investment and innovation. In the pharmaceutical industry, this would be particularly worrying given the importance of rewarding investment in life-saving drugs.

13 Some of the practical limitations of excessive price cases have been known for long, such as the difficulty of cross-country price comparisons highlighted in *United Brands*, which we are not repeating here. For further reference, *see*, e.g., D. Geradin, The Necessary Limits to the Control of ' Excessive' Prices by Competition Authorities – A View from Europe, *Tilburg University Legal Studies Working Paper*. Available at SSRN: https://ssrn.com/abstract=1022678.

27. Moreover, the lack of specific guidance on when prices or profits can be considered excessive creates additional uncertainty for companies, as they cannot be sure whether their pricing infringes or not. This uncertainty can create a chilling effect on investment particularly in dynamic sectors such as pharmaceuticals, where the success of R&D is already inherently uncertain.

3. Arbitrary cost plus method

28. There may be a temptation for competition authorities to determine whether a price is excessive based on whether the price exceeds cost plus a certain arbitrary percentage (so-called "cost-plus" approach). The CMA in its recent decision on the pricing of Phenytoin relied on such a "cost-plus" approach and used a 6% ROS as a reasonable return on the basis that it is the allowable return-on-sales (ROS) under the Pharmaceutical Price Regulation Scheme (PPRS).[14] Such a crude approach is particularly misguided in our view, as it is bound to lead to a high number of Type I errors. Indeed, there is no common return on sales that could be deemed reasonable across the board. Returns are highly product-specific, and therefore whether a return is truly out of the ordinary can only be determined by comparisons with similar benchmark products.

4. Not considering a variety of benchmarks

29. Whether a price is out of the ordinary can only be determined by comparison to a wide range of benchmarks. Indeed, even for similar products, it is not abnormal to observe quite different returns. In other words, even for products that are relatively similar on many dimensions and which are not considered excessively priced, one can observe a range of prices and returns. A finding that returns are higher compared to a single benchmark is no indication that they are excessive, as this would lead to too many Type I errors. It is only when the returns of a product are way out of line compared to all comparison products that this could be an indication that prices are excessive.

30. According to Advocate General Wahl in his recent opinion, in order to minimise the risk of Type I errors investigating authorities should "*strive to examine a case by combining several methods*" of determining whether prices are excessive and that it is of utmost importance for the authority to consider other indicators that may corroborate or conversely cast doubt on the results of that method.[15]

5. Using an average calculated over a portfolio of products as a benchmark

31. While it is essential to compare the observed price (or margin) to a range of comparable products, care should be taken when comparing a single price to the average calculated over a portfolio of products. This is because an average hides a wide variation in prices and profits: comparing a single product to an average may thus not be informative as to whether the single product's price or profitability is excessive.

32. For example, it is well known that in the pharma industry some drugs are "hits" and other are not. The very essence of conducting risky investments and having a portfolio of pipeline products is that some will be successes and others will be failures. Some projects may even lead to losses, bringing the average profit measure down.

33. Rather than focusing on averages over a portfolio, it is thus more meaningful, if the data are available, to look at the distribution of returns over comparable products and to then observe whether the product in question is at odds with the observed distribution. That is, the price of an observed product may well be above the average of a portfolio of drugs, but as long as there are comparable benchmark products with similar price/profitability, there is no ground for finding an excessive price.

6. Using a competitive benchmark for a dominant firm

34. Another common mistake is to compare prices of a dominant firm to a competitive benchmark. By definition, a competitive product is not an appropriate benchmark for determining whether a price by a dominant firm is excessive. Indeed, pricing close to marginal cost would not be expected for a product that has significant market power, even if prices were not excessive. Being dominant is certainly not an abuse in itself, and hence it cannot be considered infringing for a dominant firm to price above a competitive level (otherwise, the pricing by all dominant firms would be considered abusive). An appropriate benchmark should thus operate under similar competitive conditions as the product investigated for excessive prices.

7. Relying on insufficiently comparable benchmarks

35. It is important that the benchmark used is sufficiently comparable to the product under investigation. In particular, care should be taken to compare products that have relatively similar cost structures. Indeed, the profitability of a product that e.g. has significant sales and promotional efforts could be different to the profitability of a second product that has limited such activities, and hence not provide an appropriate benchmark for this second product.

14 CMA Decision *Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*, case CE/9742-13.

15 Opinion of Advocate General Wahl, delivered on 6 April 2017, following a request for a preliminary ruling by the Latvian Supreme Court on the conditions under which the rates set by the Latvian collecting society AKKA/LAA are excessive under Article 102.

36. Yet, competition authorities are sometimes tempted to use vastly different products as comparators, which may lead to serious errors in their assessment. For example, comparing returns of generic and branded drugs is inappropriate to establish excessive prices, as generic and branded drugs have different business models, are at very different points of their life cycles, which in turn typically implies different competitive conditions, marketing expenditures and so on.

8. Rejecting meaningful benchmarks because they might themselves be excessive

37. Authorities may also be tempted to reject comparisons showing that a product is not priced excessively in comparison to another similar product on the basis that this other product should itself be considered as being priced excessively. Such an approach would be particularly ill-suited if the authority has not opened an investigation into excessive prices for that other product. Indeed, in such a case, there is no way for the company under investigation to know that the benchmark it used was not appropriate. The situation would be different, of course, if the competition authority had already adopted a decision that the comparable product's price was excessive (or at least publicly opened an investigation), in which case the investigated company could reasonably know it should not use it as a benchmark.

9. Reverse cellophane fallacy

38. One of the traps that authorities can easily fall into is to compare the price of the investigated product with the price of a regulated product. This could be for example the case where a drug increases its price (potentially very significantly) once it is no longer subject to a previously applicable regulation. In such a case, the price before the increase would not provide a proper benchmark, as it is not determined by the market but set exogenously at low levels (which may even be loss-making for the manufacturer).

39. This phenomenon has been described as a "reverse cellophane fallacy."[16] Under the reverse cellophane fallacy, the reference price is not appropriate as it does not correspond to competitive market conditions, but rather than being too high (as in the cellophane fallacy), the reference price is too low.

40. Most recent pharmaceutical excessive pricing investigations involve old, off-patent products that experienced significant price increases since they became generic. Comparing the prices of these products to their pre-generic regulated levels would not be appropriate if the regulated prices were loss making or very low due to regulation. In countries such as the UK where profits are regulated on a portfolio of products under the PPRS framework, the profits on a single product may be very low but compensated by higher profits on other products. In fact companies under this framework may choose to price their older products at lower levels in order to be able to set higher prices on their newer products and still remain within the regulated profit limit. Choosing the low profit product as a benchmark would therefore be inappropriate, as a loss making or artificially low price is clearly not the right benchmark.

10. Focusing on high percentage price increases

41. Percentage increases of several thousand percent are headline grabbing, but provide a poor guide of whether a price is excessive. Indeed, for the reason mentioned above, the previous price may not provide a meaningful benchmark. But even further, high price increases in percentages are often associated with low absolute numbers. Indeed, if a pill used to cost cents, even a high percentage price increase will represent a limited amount in euros, which may actually be needed to ensure a sufficient profitability to incentivise companies to keep providing the drug. Therefore, high percentage price increases in themselves provide no indication of whether a product is priced at an excessive level.

11. Using accounting instead of economic measures of return on capital

42. It may appear practical for authorities to use accounting measures of profitability, as such measures are readily available. However, as is well-known,[17] such measures may be misleading. In economic terms profitability of an investment is assessed in terms of net present value, taking into account revenues over the product's life cycle. Accounting measures in contrast regard profitability at a point in time, where the value of assets is based on accounting rules.

43. To compute the economic rate of return, information is required on the cash flows generated over the lifetime of the investment as well as the value of the investments. This approach is, however, often impractical in excessive pricing cases, which typically concern limited time periods. Alternative profitability measures are therefore used by competition authorities, such as the Return on Capital Employed (ROCE), The formula of the ROCE is *ROCE(%)*= Return on Sales (ROS). The formula of the ROS is *ROS (%)*= profit contributions.

16 D. J. Aron and D. E. Burnstein, Regulatory Policy and the Reverse Cellophane Fallacy (December 4, 2010), *Journal of Competition Law and Economics*, Vol. 6, Issue 4, pp. 973–994, 2010. Available at SSRN: https://ssrn.com/abstract=1171292.

17 *See*, e.g., the classic article by F. M. Fischer and J. J. McGowan, On the Misuse of Accounting Rates of Return to Infer Monopoly Prices, *American Economic Review*, 1983, Vol. 73 No. 1, pp. 82–97.

Profit contribution is computed by subtracting from revenues those costs that can be directly attributed to the product in question (COGS, sales and promotion, distribution costs, amortisation of product specific investments, etc.). as well as gross margin measures.

44. For instance, the ROCE measures profits relative to the value of the assets used to generate them. Estimating the value of the assets used to generate profits can present the authorities with a number of challenges.

45. The first challenge relates to the difference between accounting and economic value of the assets. Most companies book their fixed assets at historical cost, which bears no resemblance to the cost of replacing the asset with a modern equivalent (this is called the "Modern Equivalent Asset (MEA) approach" to measuring assets), particularly if the asset is old. In cases where the assets are old and mostly depreciated but still have a useful life, an adjustment needs to be made to the accounting value of the assets. The MEA approach measures the cost of replacing the assets with a modern equivalent and is the preferred approach. However, many fixed assets do not have active trading markets that would enable an easy evaluation of the cost to replace the asset with a modern equivalent.

46. The second challenge relates to the measurement of intangible assets, such as patents, licences and know-how, which are an important part of the assets of pharmaceutical companies. The accounting treatment of intangible assets rarely corresponds to the true economic value of the asset, which in itself is hard to measure. In accounting, internally generated IP is treated as an expense and does not appear in the balance sheet. Therefore in such cases an adjustment is required to recognise these R&D expenditures as assets. In the case of externally acquired IP, the accounting method is to value the asset at the historical purchase cost, amortized over a certain period. However, the amortization schedule used in accounting may not reflect the economic depreciation of the asset, where the net value of the asset is equal to the present value of the future cash flows it would bring. In both cases, adjustments need to be made to the accounting value of the intangible assets, which are not straightforward.

47. The third challenge involves the estimation of capital employed for specific products. Excessive pricing cases usually involve specific products. In multi-product firms, such as pharmaceutical companies, it can be challenging to allocate certain common fixed assets (manufacturing plants, machinery, office buildings, etc.) to particular products.

48. Last, the ROCE method is not appropriate to use in asset light businesses, e.g., in cases where the product is merely being distributed by a company. In such cases a measure such as the ROS (%), gross margins or product contributions may be more appropriate to use. Though computationally less problematic, these measures are not without difficulties. For example, when using a ROS (%) measure, common costs are required to be allocated, so the allocation issues are relevant here too.

12. Improper allocation of common costs

49. In many of the profitability measures, with the exception of profit contributions and gross margins, authorities need to estimate the net profits earned by the products under investigation. Whereas it is straightforward to measure sales revenues and direct costs at a product level, indirect or common costs need to be allocated, and the allocation method needs to be considered carefully.

50. Allocating common costs on the basis of sales revenues without further adjustment could be inappropriate in excessive pricing cases, as a disproportionate amount of the common costs would be allocated to the products under investigation. On the other hand, allocating common costs on the basis of volumes is not ideal either in cases of multi-product firms with heterogeneous volumes, which is characteristic of most pharmaceutical firms. In situations where the allocation of common costs is not straightforward, ideally authorities should test the robustness of their findings under a range of alternative cost allocation methods and also under a range of profitability measures.

13. Using WACC as a benchmark to determine excessive prices

51. Having arrived at a preferred profitability framework, the authorities would then need to choose an appropriate benchmark against which to compare the profitability of the investigated products. This is far from an easy task. A ROCE measure of profitability is sometimes compared against the WACC of the business. However, finding that a ROCE of a product is higher than the WACC does not automatically imply that returns are excessive. The WACC is the minimum return that investors would expect in order to undertake an investment. A ROCE can be higher than the WACC due to a number of procompetitive reasons, such as higher efficiency, successful innovation, cyclical factors or even just luck.

Given the inherent uncertainties of the product development and commercialisation process, *ex-post* realised profitability may very well turn out to be higher than expected *ex ante* (and conversely). Therefore, a comparison against the WACC is not in itself informative on whether profits are excessive.

14. Ignoring the role of regulation

52. Finally, antitrust intervention for excessive prices begs the question of why regulatory intervention would not be more adapted if there are true market failures that need to be addressed. Competition authorities have,

time and again, repeated that they do not see themselves as price regulators. Indeed, competition authorities are not well placed to fix and monitor prices, given their lack of industry expertise and the need for continuous intervention. Second-guessing sector-specific regulation therefore does not, in our view, constitute desirable antitrust policy.

IV. Conclusion

53. This short article has highlighted the conceptual difficulties with excessive prices cases. In our view, in light of both these difficulties and the high probability and cost of errors in such cases, competition authorities should simply not run cases resting on excessive prices alone. At the very least, excessive pricing cases should be limited to truly exceptional circumstances. And we find that the pharmaceutical sector is particularly ill-suited for running excessive price cases.

54. But when competition authorities decide to nonetheless pursue such cases, they should in any case be extremely cautious about how they determine whether prices are excessive. In particular, we have highlighted some of the numerous practical difficulties in determining whether a price can be considered as excessive, and the main pitfalls that authorities should (hopefully) avoid. ■

The *Aspen* case by the Italian Competition Authority

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I. Introduction

1. In recent years we have observed an increasing attention on competition concerns in the pharmaceutical sector.[1] Antitrust authorities around the world conducted a number of studies[2] and investigations on practices adopted by pharmaceutical companies. The investigations, in particular, focused on anti-competitive practices that could delay or undermine entry of generic medicines upon expiry of patent protection for the originators. Exclusionary practices assessed by competition authorities took a range of different forms, from refusal to license, to abuse of regulatory procedures, to pay-for-delay or reverse settlement agreements.[3]

2. Competition policy in this sector raises difficult issues, as antitrust enforcement should not undermine the incentives for the development of new drugs, by discouraging investment, innovation and risk-taking behaviour. Typically, most of the competition cases in the pharmaceutical sector have focused on the tension between the legitimate reward to innovation, granted to pharmaceutical companies that invest in R&D, and the illegitimate use of intellectual property rights to create barriers to entry for competitors.

While competition authorities recognize that rewarding innovation and protecting dynamic competition is an objective of competition policy and that competition policy and IP protection are complementary in fostering innovation, their enforcement action aims at preserving a competitive process ensuring access to medicines to the highest number of patients at the lowest possible price, by preventing illegitimate conducts excluding competitors.

3. More recently, antitrust authorities in Europe have adopted decisions or launched investigations that shift the focus from exclusionary to exploitative practices—namely, in the form of unfair prices. This contribution will focus on the latter, in particular with reference to the investigation by the Italian Competition Authority (the "Authority" or the "ICA") into the prices charged by Aspen for a number of cancer drugs that concluded with an infringement decision on September 29, 2016.[4]

II. The interventions by the ICA in the pharmaceutical sector

4. The ICA has been particularly active in recent years in the pharmaceutical sector and this should not come as a surprise in light of the importance of the sector, not only economically but also in terms of access to healthcare and medicines and impact on public expenditure.[5]

5. The cases assessed by the ICA have mainly dealt with exclusionary conducts by pharmaceutical companies holding licences for active principles aimed at delaying entry of generic firms.[6] In two cases, concluded in 2006 and 2007 respectively, the Authority assessed Merck's and

* The views expressed in this article are those of the author and do not necessarily reflect the official opinion of the Italian Competition Authority.

1 *See* the OECD Competition Committee discussions, in particular the 2009 Roundtable on Generic Pharmaceuticals and the 2014 Roundtable on Competition Issues in the Distribution of Pharmaceuticals, whose proceedings are available at: http://www.oecd.org/competition/generic-pharmaceuticals-competition.htm.

2 *See*: European Commission, Pharmaceutical Sector Inquiry, Final Report, July 2009. Since then, the Commission has been monitoring patent settlements between originator and generic companies and publishes annual reports, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry.

3 *See Competition and Patent Law in the Pharmaceutical Sector. An international Perspective*, G. Pitruzzella and G. Muscolo (eds.), Wolters Kluwer, 2016.

4 Italian Competition Authority, case A480 – *Incremento prezzo farmaci Aspen*, decision No. 26185, published in Bulletin No. 36/2016.

5 In Italy, in 2015, the expenditure for drugs amounted to 28.9 billion euros, 76% reimbursed by the National Health System. *See*: AIFA, National Report on Use of Medicines in Italy, available at: http://www.aifa.gov.it/sites/default/files/OsMed_2015_Eng.pdf.

6 Enforcement in this sector was complemented with advocacy interventions that have pointed out the regulatory restrictions to generic entry, suggesting reforms that might facilitate the diffusion of generic pharmaceuticals and foster competition in the pharmaceutical industry. In March 2011, the ICA issued an opinion (opinion AS819) against a draft law intended to exclude the principle of therapeutic equivalence for biosimilars. This position was confirmed in an opinion sent to some public healthcare administrations in May 2013 (opinion AS1049), where the ICA reiterated that therapeutic equivalence between original biotech products and biosimilars should be adopted as a general principle in public procurement. More recently, the ICA (AS1312 of Nov 2016) highlighted competition concerns with regard to a provision which denied the possibility to include in the same lot therapeutically equivalent medicines but with different active ingredients.

Glaxo's refusal to grant licences to chemical companies for the production of API's (Imipenem Cilastatin and Sumatriptan Succinate) to be supplied to generic companies in European countries, where all patents on those products had already expired.[7]

6. In 2012, the *Pfizer* case touched the borders between competition and IP rights.[8] The ICA questioned Pfizer's strategy of artificially extending patent protection from September 2009 to July 2011 by means of requiring a divisional patent and additional supplementary protection certificate (SPC) rights. The ICA did not question Pfizer's application for a divisional patent as such, but the timing of the request and the fact that its only purpose was to enable the company to request an SPC in Italy. No new product was released by Pfizer, who also put in place a complex "dissuasive" strategy against new entrants, issuing warnings to the generic producers, resulting in litigation and claims for damages in case of commercialization of generic drugs before the new deadline of patent protection. Entry of generic drugs was delayed, resulting in an increased expenditure for the Italian NHS estimated at approximately 14 million euros. The reasoning of the Authority was that the general strategy and the related request for the patent were not linked to innovation, which is a key element in assessing these cases. The Authority's analysis was based on the effects of the exclusionary conduct. The higher administrative court, in upholding the decision, maintained that the question at stake was not how the patent had been obtained, but the way a legitimate right under IP law had been exercised in the specific circumstances of the case. It should be underlined that the circumstances of this abuse were very specific. Therefore, a similar assessment should be limited to those cases in which the misuse of the patent system clearly does not contribute to consumer or social welfare because it does not legitimately promote innovation to the benefit of consumers but is solely intended to illegitimately restrict competition.

7. In the *Roche-Novartis* case,[9] the ICA tackled a collusion that did not involve generic medicines, but mirrored conducts typically aimed at stifling generic competition. Namely (in the Authority's opinion, the two parties to the proceedings), the two companies tried to steer sales from a cheaper off-label product (Avastin) to a new and more expensive on-label drug (Lucentis) by participating in an anti-competitive agreement in the market for ophthalmic drugs used to treat some serious vascular eyesight conditions, including age-related macular degeneration. In the ICA's view, this was part of an artificial product differentiation plan developed in order to favour the commercial performance of Lucentis, from which both Roche and Novartis took advantage. In fact, Roche collected significant royalties from the sales of Lucentis, which had been developed by its subsidiary Genentech, while Novartis directly gained from the sales of Lucentis. The ICA imposed on Roche and Novartis fines totalling €90.5 million and €92 million respectively.[10]

8. More recently, as mentioned above, the ICA adopted a decision fining the Aspen pharmaceutical group for the infringement of Article 102(a) TFEU for unfair pricing in the market for some cancer drugs whose price increases ranged up to 1,500%. In particular, in September 2016 the Authority fined the Italian subsidiary of South African pharmaceutical company Aspen €5.2 million for abusing its market power over four cancer drugs.

III. Excessive prices in the pharmaceutical sector

9. The *Aspen* case carried out by the ICA does not appear isolated, as antitrust authorities in Europe recently seem to have been focusing on cases in the pharmaceutical markets that deal with pricing behaviour. In December 2016 the UK CMA fined Pfizer and Flynn Pharma for charging excessive prices to the NHS for an anti-epilepsy drug[11] and provisionally found that Actavis UK had infringed competition law by charging the NHS for hydrocortisone tablets.[12] More recently the European Commission launched an investigation into Aspen Pharma's pricing practices for cancer medicines: "*The European Commission has announced that it will investigate information indicating that Aspen has imposed very significant and unjustified price increases of up to several hundred percent. The Commission has information that, for example, to impose such increases, Aspen has threatened to withdraw the medicines in question in some Member States and has actually done so in certain cases*."[13]

10. These recent developments are, in a certain respect, noteworthy given the very few cases of excessive prices that authorities have dealt with in the past. They are, however, not entirely surprising, as access to healthcare and medicines is at the centre of the public debate, especially at a time when the economic crisis and its consequences in terms of cuts to public expenditure and welfare have raised troubling questions on how to better address healthcare accessibility. The role of competition authorities with respect to their ability to intervene on

7 Italian Competition Authority, case A363 – *Glaxo-Principi Attivi*, decision No. 15175 of 8 February 2006, published in Bulletin No. 6/2006. Italian Competition Authority, case A364 – *Merck-Principi Attivi*, decision No. 16597 of 21 March 2007, published in Bulletin No. 11/2007.

8 Italian Competition Authority, case A431 – *Ratiopharm/Pfizer*, decision No. 23194 of 11 January 2012, published in Bulletin No. 2/2012.

9 Italian Competition Authority, case I760 – *Roche-Novartis/Farmaci Avastin e Lucentis*, decision No. 24823 of 27 February 2014, published in Bulletin No. 11/2014.

10 A preliminary judgment in front of the European Court of Justice is currently pending: *see* case C-179/16, available at: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:62016CN0179&from=EN.

11 *See* the UK CMA press release of December 7, 2016, available at https://www.gov.uk/government/news/cma-fines-pfizer-and-flynn-90-million-for-drug-price-hike-to-nhs.

12 *See* press release of December 16, 2016, available at: https://www.gov.uk/government/news/pharmaceutical-company-accused-of-overcharging-nhs.

13 *See* the European Commission press release of May 15, 2017, available at: http://europa.eu/rapid/press-release_IP-17-1323_en.htm.

excessive prices has been part of this public debate. Even before the opening of the *Aspen* case by the European Commission, Commissioner Vestager had remarked in a speech that, under specific circumstances, with respect to unjustified price increases of certain medicines "*there might be times when competition rules need to do their bit to deal with excessive prices*."[14]

11. The debate over spiking prices of drugs has been heated in Europe but it has not spared the US. Situations involving significant price increases (the *EpiPen* and *Turing* cases) have been brought to the attention of the US antitrust authorities.[15] However, the US legal framework is different from the European one and it appears that absent any form of collusion or attempt to monopolize, there is no basis in US antitrust law to sanction excessive prices.[16]

12. The difficulties—both theoretical and practical—in assessing antitrust cases on excessive prices are well known. When is a price excessive, or more precisely "unfair" as provided by Article 102(a) of the EU Treaty? Standard economic theory predicts that the profits associated with excessive prices will attract entry thus bringing prices down to competitive levels.[17] In presence of market failures, regulation is generally considered a better alternative. Moreover, establishing at what level a price can be considered excessive entails a very difficult evaluation. It is not surprising, therefore, that the European Commission has been cautious in bringing such cases and that the European courts have been very strict in clarifying the conditions under which the imposition of high prices by a dominant firm may infringe competition law.

Most economists and lawyers would agree on at least some conditions that are necessary (but not sufficient) to bring an excessive price case against a dominant firm: (1) high and non-transitory barriers to entry leading to a monopoly or near monopoly; (2) this (near) monopoly being due to current or past exclusive or special rights; (3) no effective means to eliminate the entry barriers; and (4) no sector regulator being competent (or sufficiently powerful) to regulate the excessive prices.[18]

13. The European case law has clarified the steps that a rigorous analysis should follow when assessing whether the prices charged by a dominant firm can be deemed excessive. In *United Brands* and subsequent decisions the courts have clarified that to establish that a price is unfair under point (a) of Article 102 of TFEU it is necessary to demonstrate that the price charged by the dominant company has no reasonable economic value with respect to the product or service supplied.[19] In order to make this evaluation a two-step analysis is required, first showing that there is a significant difference between the price charged by the dominant company and the price it would have charged had there been competition in the relevant market, then assessing whether the excessive price is unfair, examining possible justifications and legitimate reasons for the charged price.

14. One way to look at the analysis on excessive prices is to make a comparison between the sale price and the cost of production. Given the difficulty in assessing costs and economic values of products and services, a number of different methodologies have been suggested by the courts. These include a comparison across competitors (price charged by dominant player versus price charged by non-dominant player), comparison of the price of the same product or service across time or in other geographic markets. Since no single method is in itself conclusive it has been suggested that, when possible, the analysis should be conducted combining different methods.[20] This has been the approach that has been followed by competition authorities[21] and suggested by the economic literature.[22]

15. Whatever the benchmark, the threshold price, which guarantees a satisfactory margin, cannot be too close to the benchmark price for reasons of legal certainty since it could be difficult for a dominant undertaking to estimate in advance this threshold price. There are other elements that the courts suggest as part of the analysis, such as: condition of entry in the relevant market, role of a sector regulator and countervailing power of powerful buyers, as all these factors might undermine the ability to charge excessive prices. The lack of reliable data or the complexity of the analysis cannot justify a superficial or inconclusive assessment.

16. The unfairness of the excessive prices should then be checked against the possible justifications: a price might be excessive but not unfair if there are reasonable explanations. For example, a number of legitimate reasons may justify why a dominant player prices a given product or service above the benchmark/competitive price: cost of production (and what about x-inefficiency?) or consumer perception (i.e., willingness to pay). This evaluation can be made on the price itself (there can be very specific

14 Speech, Protecting consumers from exploitation, Chillin' Competition Conference, Brussels, 21 November 2016 available at: https://ec.europa.eu/commission/commissioners/2014-2019/vestager/announcements/protecting-consumers-exploitation_en –.

15 *See*, for instance, CPI article, US: Sanofi files antitrust suit against Mylan over EpiPen, April 4, 2017, available at: https://www.competitionpolicyinternational.com/us-sanofi-files-antitrust-suit-against-mylan-over-epipen.

16 For a different view, *see* F. M. Abbott, Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health (January 19, 2016), *UC Irvine Law Review*, Vol. 6, Issue 3, Spring 2017, Forthcoming; FSU College of Law, *Public Law Research Paper* No. 787; FSU College of Law, Law, *Business & Economics Paper* No. 16-4. Available at SSRN: https://ssrn.com/abstract=2719095.

17 *See* 2011 OECD Roundtable on Excessive Prices, available at http://www.oecd.org/competition/abuse/49604207.pdf.

18 M. Motta and A. de Streel, Excessive Pricing in Competition Law: Never say Never? in Konkurrensverket – Swedish Competition Authority (ed.), *The Pros and Cons of High Prices*, 2007.

19 Case 27/76 – *United Brands Company v. Commission* [1978] ECR 207.

20 Opinion of AG Wahl delivered on 6 April 2017 – case C 177/16, available at: http://curia.europa.eu/juris/document/document.jsf?text=&docid=189662&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=267756.

21 Decision of the Director General of Fair Trading No Ca98/2/2001, 30 March 2001, Napp Pharmaceutical Holdings Limited and Subsidiaries (Napp), available at: https://assets.publishing.service.gov.uk/media/555de4bf40f0b669c4000169/napp.pdf.

22 *See* 2011 OECD Roundtable on Excessive Prices, available at http://www.oecd.org/competition/abuse/49604207.pdf

hypothesis where the firm charges a price for a product or service it has not delivered) or in comparison with similar products or services. In terms of burden of proof, it is for the dominant player to justify the difference between its actual price and the benchmark(s).

IV. The *Aspen* case by the ICA

17. The ICA, in line with other European competition agencies, has taken in the past very few decisions of infringement on excessive prices.[23] However, in the specific circumstances of the *Aspen* case, the prices charged by the dominant firm were deemed unfair using a variety of methodologies and assumptions favourable to the defendant, in consideration of the absence of reasonable justifications for increases ranging between 300% and 1,500% with respect to the initial prices and in view of the strategy adopted by the dominant firm to put pressure on the regulator to approve the price increase. The infringement of Article 102(a) TFEU consists in the imposition of excessive and unfair prices, through the adoption of an aggressive strategy during the negotiations with the Italian Pharmaceutical Regulator (AIFA), based on the threat of discontinuing the supply of the drugs on the Italian market if the increases were not approved. The Authority closed the investigation with an infringement decision and imposed fines for an amount of 5.2 million euros.

18. The case concerned a portfolio of antineoplastic drugs that Aspen had bought from GSK in 2009 (internally referred to as "the Cosmo package"). The Authority began its investigation in 2014 after a consumer association and media reports had claimed that the National Health System (NHS) was experiencing shortages in the provision of the cancer drugs.

The patent for these drugs had long expired but they were still used in the treatment of severe blood cancers. In Italy the price for these drugs was entirely reimbursed by the NHS (the drugs being classified as so-called "A class" drugs). Although a patent was no longer pending on the Cosmos drugs there was no entry by generics given the small size of the markets and the fact that entry costs may exceed expected profits.

19. In order to better understand the conduct it is useful to briefly recap the regulatory framework on pricing of drugs in Italy. The Italian NHS grants total reimbursement for drugs that are deemed essential for the patients. The price of these drugs is defined through a negotiation process between the pharmaceutical companies and the AIFA. The revision of an approved price (renegotiation) is admitted, under condition of the companies proving a documented change in production costs. However, an increase in general expenses or common costs not directly related to the specific drug will not be accepted as a reason for a request of price increase.

20. At the end of 2013, Aspen submitted to the AIFA an initial request for reclassification of the Cosmos drugs from the so-called "A class" (where the price for the patient is totally reimbursed by NHS) to the so-called "C class" (where the companies are free to set the price and drugs are not reimbursed). The AIFA rejected the request for reclassification, considering the drugs "essential" since they lacked any therapeutic alternative for certain categories of patients. In October 2013 Aspen and the AIFA entered into a negotiation for new reimbursement prices for Cosmos drugs since the price applied in 2013 dated back to the time of the first marketing authorization (1950s and 1960s). In March 2014, the negotiation ended with AIFA's approval of new A class prices for Cosmos drugs, accepting the prices increase submitted by Aspen. The outcome of the negotiation was influenced by the threat, advanced by Aspen, of leaving the Italian market if the regulator did not accept the price increases.

21. In the following paragraphs I will describe the steps of the analysis that led to the infringement decision by the ICA. The initial part of the analysis focused on the definition of the relevant markets and on the assessment of Aspen dominance. The ICA defined four relevant product markets at ATC5 level (molecule level): markets of drugs based on the active ingredients mercaptopurine, tioguanine, melphalan and chlorambucile. The assessment was based on the absence of therapeutic alternative to Cosmos drugs in Italy for certain group of patients in specific phases of their illness. Other authorized drugs for the treatment of the same pathologies (based on different active ingredients) were not considered substitutable, because of their formulation for infusion (hospital use) while Cosmos products were available in tablets and used for home therapy; in addition, the other drugs presented more severe side effects. The independent experts contacted by the ICA affirmed that they were therapeutically irreplaceable and the experts committed by Aspen also confirmed that there were no alternative products for specific diseases and for the frailest patients (children and old people).

22. Aspen was the only company active in the relevant markets, so no effective competition undermined its monopoly. Although there were no patent barriers, no entry was observed: the scarce sales volume at the new prices (in the range of 5–10 M€) reduces the incentives to enter in the markets, with the subsequent risk of not recovering the entry costs). For similar reasons, Aspen monopoly position was not disciplined by any potential competition as there was no pending request for the introduction of the generic version of the drugs.

23. Other considerations relevant for the assessment of the dominance concerned the demand side. Being lifesaving drugs, their derived demand from patients is completely inelastic. This also implies that price negotiations

23 The ICA has a legal basis on excessive prices both in the national law (Article 3 a) L. 287/90) and when applying article 102 of the EU Treaty. *See* cases: A306 – *Veraldi/Alitalia* (airlines), 2001; A376 – *ADR/tariffe aeroportuali* (handling), 2008; A 377 – *SEA/tariffe aeroportuali* (handling), 2008.

occurred in a situation of asymmetric bilateral monopoly where the supplier has higher bargaining power: in fact, the AIFA's objective is to keep the lifesaving drugs in Italy in class A as a drug reimbursed by the NHS, but if no agreement is reached with the pharmaceutical company, the drugs would be automatically moved in the class C, on charge of the patients.

24. The analysis of the ICA on the prices was conducted in two steps: first an assessment of the excessiveness of the new prices charged by Aspen with respect to costs, then an analysis of unfairness. The ICA used different methodologies and assumptions in analyzing whether the prices could be deemed excessive in line with the criteria established by the European case law, which favours the application of more than one methodology. In particular, using a gross margin test, the ICA calculated the difference between *ex-ante* prices and direct costs. The resulting gross margin in percentage of sales was compared to the total indirect costs in percentage of sales to conclude that prices before the increase already granted a margin in line with Aspen average gross margin; therefore, percentage price increase ranging between 300% and 1,500% of initial prices led to an unreasonable excess of prices on the economic value. With the second method—cost plus method—the ICA calculated the difference between prices and a comprehensive measure of costs including direct costs plus a portion of indirect costs plus a reasonable rate of return on sales (ROS).[24]

The analysis allowed to conclude that new prices applied by Aspen generated an excess in percentage of cost plus, ranging from 100% to almost 400%.[25]

25. After concluding for the existence of an unjustified excess of prices on costs, the ICA considered case specific elements to evaluate the general unfairness of prices applied by Aspen. All the elements considered by the Authority pointed to the absence of any economic justifications for such price increases: first and foremost, there was no justification based on the innovative efforts and no R&D expenditure was documented by Aspen. Other elements considered were that: pre-existing prices already granted a gross margin in line with Aspen average; Cosmos drugs did not need medical promotion and they were not directly produced by Aspen; there was no increase in production or distribution costs; similarly, the Authority ascertained the absence of any non-cost related factor leading to an improvement in quality or in the level of service to the NHS or patients. In addition, the nature of the drugs (antineoplastic) and the absence of substitutes resulted into an inelastic demand: there was no possibility for patients to shift to alternative medical lifesaving treatment (high-level willingness to pay).

26. To sustain its exploitative conduct, Aspen put pressure on the AIFA in several ways: it requested a reclassification of its drugs from A class to C class, mindful of the AIFA's impossibility to accept this request since Aspen drugs are essential medicines for the treatment of cancers; and, it threatened to withdraw the drugs from the Italian market if the AIFA did not accept the proposed prices. Furthermore, during the negotiations with AIFA, a shortage of its drugs in the Italian distribution system was observed despite the absence of any production problems: according to the ICA, this artificial shortage, generated through Aspen Europe-wide stock allocation mechanism, was aimed at influencing the AIFA decision-making process.

27. The ICA final decision ascertained the infringement and imposed a cease and desist order; however, the decision did not tell Aspen what prices to set and how to set them since it is for Aspen to charge prices which are compatible with EU and Italian competition law, i.e., which have a reasonable relationship with the economic value of the products. In the decision, Aspen was also required to inform the Authority, within sixty days from the decision date, of the actions adopted to comply with the ICA decision. Aspen requested interim measures, which were rejected by the Italian courts and appealed the ICA decision (the case is pending). In the meantime, Aspen refused to comply with the decision and delayed the renegotiation with the AIFA: therefore, in March 2017 the Authority has opened a proceeding for non-compliance.[26] The Regional Administrative Court of Lazio (the first instance judicial review Court) recently upheld the Authority's decision and the 5 M€ fine, confirming the legal assessment and economic methodology applied to the case[27].

24 Different assumptions on the rate of return on sales were used in the calculation (13%, the average ROS of the sector, or 15–20%, the specific Aspen group ROS) and the inclusion of the trademarks purchasing costs: ROS 13%: excess between 100–150% and 350–400%; ROS 13% + trademarks: excess range between 100–150% and 300–350%; ROS 15–20%: excess range between 100–150% and 250–300%; ROS 15–20% + trademarks: excess range between 50–100% and 200–250%.

25 These percentages are well above those that have been considered "abusive" in previous cases (e.g., *Deutsche Post*: 25%; *Albion Water ii*: 46%).

26 Italina Competition Authority, A480B – *Incremento Prezzo Farmaci Aspen-Inottemperanza*, decision No. 26432, published in Bulletin No. 10/2017.

27 T.A.R: decision. 8945, 26 July 2017.

V. Conclusions

28. Are these new developments in the pharmaceutical sector part of a new trend? The specificities of each case play a relevant role in the assessment and there are very good reasons, outlined above, for competition authorities to be cautious in engaging in these cases. However, at least in Europe, when certain circumstances recur, the possibility of an antitrust intervention should not be excluded. The *Aspen* case shows some of the features that many economists and lawyers would recognize as justifying an antitrust intervention: a situation of monopoly due to a past exclusive right, with no likelihood of entry; no regulator with the ability to curb the significant price increase unjustified by any innovative effort or change in costs. There might not, and perhaps should not, be a trend, but it is difficult to deny that there was a case. ■

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