Document	**LSR 2018 S. 248**
Auteur(s)	**Valérie Junod, Damiano Canapa**
Titre	**The Impact of Misleading Information on Competition Law**
Commentaire d'arrêt	**C-179/16**
Pages	**248-254**
Publication	**Life Science Recht - Juristische Zeitschrift für Pharma, Biotech und Medtech**
Editeur	**Philippe Fuchs, Andri Hess, Michael Isler, Valérie Junod, Michael Noth, Andreas Schöllhorn**
ISSN	**0031-9688**
Maison d'édition	**Stämpfli Verlag AG**

Competition Law

The Impact of Misleading Information on Competition Law

CJEU C-179/16 of January 23, 2018

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I. Introduction

The “Avastin-Lucentis” saga began around 2007.[1] It played out as follows: the medicine Avastin (International Nonproprietary Name [INN] bevacizumab) was first approved in 2004 as an injectable biologic drug against various cancers.[2] It was developed by Genentech (completely owned by Roche since 2009) and marketed by Roche. The other medicine, Lucentis (INN ranibizumab), was first authorized in 2006 as an injectable biological drug against wet age-related macular degeneration (AMD).[3] It was

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1 See generally in Switzerland: Valérie Junod, Avastin – Lucentis: Un médicament à tout prix? CGSS 2009 n° 42–43, p. 43–74. Also David Lock, Avastin and Lucentis: a guide through the legal maze, 349 British Medical Journal (BMJ) h1377 of April 1, 2015; Deborah Cohen, Why have UK doctors been deterred from prescribing Avastin? 349 BMJ h1654 of April 1, 2015; Jean-Yves Nau, Avastin et Lucentis sont dans un bateau, Revue Médicale Suisse p. 1636 (2012).

2 In the European Union, the EMA delivered the marketing authorization in January 2005.

3 In the European Union, the EMA delivered the marketing authorization in January 2007. Several years later (2011), another drug – Eylea – was approved against AMD; it is not at issue here. Not promising stem cell treatments are discussed; Abi Rimmer, Patients

also developed by Genentech, but the drug is marketed in most countries by Novartis, based on a licensing agreement. The saga finds its roots in the fact that bevacizumab/Avastin and ranibizumab/Lucentis are two very closely related molecules. Doctors realized early on that they could use a small dose of bevacizumab (instead of the standard dose of ranibizumab) for their patients suffering from AMD,[4] as the effects are essentially the same.[5] Such a use is, of course, off-label, since Avastin has never been approved against AMD.[6] However, the price advantage makes such off-label use very attractive for patients paying out-of-pocket and for private or public insurance schemes: the small dose of reconditioned bevacizumab comes at

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an inexpensive price (less than CHF 100[7]) compared to the official price of Lucentis (reimbursed in Switzerland at CHF 1,067, public price).

In Italy, the national health authorities first (2007–2012) decided to reimburse for off-label use of Avastin-bevacizumab.[8] This generated financial losses for both Novartis, which was selling less or little of Lucentis, and for Roche, which was receiving less in licensing royalties from Novartis, given that the few additional sales of off-label Avastin would not be enough to offset the losses on Lucentis.

To deter off-label ophthalmologic use of Avastin, Novartis and Roche – allegedly (if one relies on the decision of the Autorità Garante della Concorrenza e del Mercato [Italian Competition Authority, AGCM] and on the judgment of the Court of Justice of the EU) – embarked between 2011 and 2014 in a scheme to propagate false and misleading

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with severe wet AMD regain vision after stem cell treatment, 360 BMJ (2018).

4 Off-label use of Avastin apparently began even before Lucentis was put on the market. Para. 27 of the judgment at issue.

5 See, e.g., Karina Berg et al., Ranibizumab or Bevacizumab for Neovascular Age-Related Macular Degeneration According to the Lucentis Compared to Avastin Study Treat-and-Extend Protocol, Two-Year Results, Presented at: the American Academy of Ophthalmology Annual Meeting, October 2014, Chicago, Illinois. Manuscript no. 2015-866; Michael T. Andreoli et al., Feasibility and efficacy of a mass switch from ranibizumab (Lucentis) to bevacizumab (Avastin) for treatment of neovascular age-related macular degeneration, Digit J Ophthalmol. 2015; 21(3): 1–17; Guohai Chen et al., Bevacizumab versus Ranibizumab for neovascular age-related macular degeneration: A Meta-analysis of Randomized Controlled Trials, Retina: February 2015 – Volume 35 – Issue 2 – p 187–193; Maureen G Maguire et al., Serious Adverse Events with Bevacizumab or Ranibizumab for Age-Related Macular Degeneration: Meta-analysis of Individual Patient Data, Ophthalmology Retina, Volume 1, Issue 5, 375–381. Also Deborah Cohen, Doctors are cleared to prescribe cheaper drug for wet AMD, 360 BMJ (2018).

6 The label, also called summary of products characteristics only states that Avastin is to be used against certain cancers. The summary of product characteristics (SPC) is approved by the drug agency, here in the European Union the European Medicines Agency or EMA. See art. Articles 8(3)(j) and 11 of Directive 2001/83/EC as well as Articles 6(1), 9(4), 10 and 13(3) of Regulation 726/2004, see also European Medicines Agency, Scientific guidelines with SmPC recommendations, EMA/813125/2012 rev. 4, (2017), at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/01/WC500137039.pdf; European Commission Notice to Applicants, Guideline on summary of product characteristics (SmPC), September 2009, at http://ec.europa.eu/health/files/eudralex/vol-2/c/smpc_guideline_rev2_en.pdf.

7 See, e.g., V. Blandeau et al., 3PC-029, Calculation of annual economic impact of manufacturing avastin® syringes in the age-related macular degeneration treatment in our hospital, Eur J Hosp Pharm 2018;25:A37.

8 In Italy, Avastin was reimbursed in the AMD indication starting May 2007. Lucentis was only included in the Italian list of reimbursed products in December 2008. However, Avastin continued to be reimbursed off-label until October 2012. See para. 28–31 of the judgment at issue.

information about the dangers (i.e., adverse reactions) of such use.[9] In a context of scientific uncertainty, these undertakings claimed (allegedly) falsely that the ophthalmologic use of Avastin-bevacizumab could harm patients.[10] This was meant to bring about a decrease in Avastin's off-label sales and an increase in Lucentis' sales.[11]

In 2014, the AGCM fined Roche (Italy) € 91 million and Novartis (Italy) € 92 million,[12] ruling that the conduct of these undertakings, which resulted in a sharing of the market, constituted a restriction of competition by object, contrary to art. 101 TFEU.[13] This decision was confirmed by the Tribunale amministrativo regionale per il Lazio (Italian Regional Administrative Court).[14] Following the appeal by Roche and Novartis, the Consiglio di Stato (Italian Council of State) referred several questions to the Court of Justice of the EU. By judgment of January 28, 2018, the Grand Chamber of the Court essentially confirmed the position held by the Italian authorities.[15]

The present article presents the key aspects of this judgment and complements this presentation by a critical assessment of five key points. The conclusion suggests improvements as to how labels should be kept up-to-date.

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9 To be more precise, the AGCM concluded that "the arrangement [between Novartis and Roche] was intended to produce and disseminate opinions which could give rise to public concern regarding the safety of Avastin when used in ophthalmology and to downplay the value of scientific opinions to the contrary". The agreement also aimed to facilitate the "amendment of the summary of Avastin's characteristics that were pending before the EMA and […] the sending of a subsequent formal communication sent to healthcare professionals both initiated by Roche", para. 32 of the judgment at issue. For the Court of Justice of the EU, the arrangement between Novartis and Roche aimed "to create an artificial differentiation between [Avastin and Lucentis] by manipulating the perception of the risks associated with the [off-label] use of Avastin […] through the production and dissemination of an opinion which, based on an 'alarmist' interpretation of available data, could give rise to public concern regarding the safety of certain uses of Avastin and influence the therapeutic choices of doctors, and by downplaying any scientific knowledge to the contrary", para. 89 of the judgment at issue. Furthermore, the parties aimed "to disclose to the EMA information that could exaggerate the perception of the risks associated with that use in order to obtain the amendment of the summary of Avastin's characteristics and to be granted leave to send healthcare professionals a letter drawing their attention to such adverse reactions", Id. para. 90.

10 Para. 32 *cum* 92 of the judgment at issue.

11 Id at para. 33. The cost increase for the Italian budget was estimated at € 45 million just for 2012.

12 Decision of February 27, 2014 of the AGCM, available at http://www.agcm.it/concorrenza/intese-e-abusi/open/41256297003874BD/AF96880B5B6A7C6FC1257C9F0053DDF3.html. See also the court case summary by Silvia Pietrini in the law review Concurrences N° 2-2014. also Luca Arnaudo, The Strange Case of Dr. Lucentis and Mr. Avastin. The Italian Competition Authority Fines Roche and Novartis for Collusion (July 2014). European Competition Law Review, Vol. 35, No. 7, pp. 347–351, July 2014, available at SSRN: https://ssrn.com/abstract=2428126 or http://dx.doi.org/10.2139/ssrn.2428126.

13 Para. 22, 32 of the judgment at issue.

14 Tribunale amministrativo regionale per il Lazio, Case 12168/2014, Judgment of November 5, 2014, available at https://www.giustizia-amministrativa.it/cdsavvocati/faces/provvedimentiRic.jsp?_afrLoop=1025317733571445&_afrWindowMode=0&_adf.ctrl-state=s9b7rp46i_194. See also the case summary by Silvia Pietrini in the law review Concurrences N° 1-2015.

15 See also the court case summary by Alain Ronzano in Concurrences 1-2018.

II. The Judgment

A. Main Findings

1) The Court first had to assess the definition of the relevant product market.[16] In Article 101 TFEU-cases, the only aim of this definition is "to determine whether the agreement in question is capable of affecting trade between Member States and has the object or effect of preventing, restricting or distorting competition within the internal market".[17] The Court started by underscoring that illegally manufactured or illegally sold drugs are usually *not* substitutable

with drugs sold legally.[18] However, in the present case, Avastin was not released on the market illegally: a marketing authorization ("MA") existed for the treatment of tumorous diseases. The problem was rather whether a product used off-label could be included in the relevant product market.[19]

Pursuant to EU law, an off-label drug (e.g., Avastin) is sold and distributed legally to the extent that the pharmacist and the physician comply with the rules on off-label repackaging, and on off-label prescribing, respectively. For off-label repackaging, no authorization is required when this action is carried out by healthcare professionals, solely for retail supply.[20] Physicians are entitled to prescribe off-label if they believe that their patient's medical condition calls for this specific medicinal product "for which there is no authorized equivalent on the national market or which is unavailable on that market".[21] Interestingly, the Court stated that compliance with these rules is not to be verified by national competition authorities, but only by medicines/health agencies.[22] If such an agency has indeed examined compliance, the competition authority must "take account of the outcome of that examination".[23] By contrast, when no such examination exists, as in the present case, the competition authority has the discretion to include this off-label in the relevant market, because of "the state of uncertainty surrounding the lawfulness of the repackaging and the prescription".[24]

To sum up, the relevant market can include a product used by physicians off-label (here Avastin) in addition to the drug sold within-the-label (here Lucentis), when the first product is actually being used for the same therapeutic indication as the second, making both products substitutable[25]. For the Court, this conclusion was buttressed by the fact that prescribing doctors exercise direct control over off-label use of prescription drugs, while being guided by health considerations in favor of their patients.[26]

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16 The relevant product market "comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products' characteristics, their prices and their intended use". In addition, supply substitutability may also be taken into account when its effects are the same to those of demand substitutability; European Commission, Commission Notice of 9 December 1997, on the definition of relevant market for the purposes of Community competition law ("Notice on the definition of relevant market"), [1997] O.J. C372/5, para. 7, 20.

17 Para. 49 of the judgment at issue.

18 Id. para. 52. We do not know a situation where the issue has arisen, especially in the pharmaceutical context. However, one could think of a situation where a generic is sold in violation of intellectual property rights. The question would be whether this "illegal" generic could form part of the relevant market with the original patented product.

19 Id. para. 54 and 55.

20 Id. para. 58 and 59.

21 Id. para. 56 and 57

22 Id. para. 60.

23 Id. para. 61.

24 Id. para. 62–64.

25 Id. para. 67.

26 Id. para 65.

2) Secondly, the Court had to analyze whether the anticompetitive agreement meant to deter third parties from using Avastin off-label fell outside of the scope of application of Article 101(1) TFEU, because it would be ancillary to the licensing contract binding Roche and Novartis.[27]

An anticompetitive restriction is held to be *ancillary* to a main agreement, which is not anticompetitive, when dissociating the restriction from the main agreement "is not possible […] without jeopardising its existence and aims".[28] That a licensing contract would be "more difficult to implement or even less profitable" without the anticompetitive restriction "cannot be deemed to give that restriction the objective necessity which is required in order be classified as ancillary".[29]

In the present case, the EU Court noted that the anticompetitive agreement at issue did not aim to limit the autonomy of the contractual parties themselves, "but rather the conduct of third parties, in particular healthcare professionals", whom Roche and Novartis wanted to dissuade from using Avastin in place of Lucentis.[30] Moreover, it found that this second course of conduct was agreed upon several years *after* the conclusion of the licensing contract[31] and that it was meant to decrease the use of Avastin and to augment the use of Lucentis, with a view to making the license more lucrative.[32] Consequently, the second agreement between Roche and Novartis, which was meant to deter off-label use of Avastin, could *not* be qualified as an ancillary and necessary part of their Lucentis' licensing agreement, but fell well within the scope of application of Article 101 TFEU.[33]

3) The Court then reached the main finding of the case: an agreement between competitors to disseminate to professionals, to authorities and to the public, in a context of scientific uncertainty, misleading information related to adverse reactions resulting from the off-label use of a legally sold pharmaceutical product constitutes a restriction of competition *by object* under Article 101(1) TFEU, when implemented in order to artificially partition the market and thus reduce competitive pressure.[34]

Such a qualification is not to be decided lightly, but is reserved "to certain types of coordination between undertakings which reveal", "by their very nature" a serious degree of harm to "the proper functioning of normal competition".[35] This was stressed in 2014 by the Court of Justice in case Groupement des cartes bancaires (CB) v Commission.[36] Such a qualification

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27 Id. para. 68.

28 Id. para. 70.

29 Id. para. 71.

30 Id. para 72.

31 Id. para. 73.

32 Id. para. 74.

33 Id. para 75: that certain conduct designed "to render more profitable the exploitation by Novartis of the technology rights over Lucentis granted to it by Genentech cannot mean […] that that conduct is to be regarded as objectively necessary for the implementation of the licensing agreement at issue".

34 Id. para. 95. As a consequence, the competition authority no longer needs to assess the effect of the agreement on the market, id. para. 94.

35 Id. para. 78.

36 Court of Justice, Judgment in *Groupement des cartes bancaires (CB) v European Commission,* C-67/13P EU:C:2014:2204, para. 50–52: "certain types of coordination between undertakings can be regarded, by their very nature, as being harmful to the proper functioning of normal competition […] Consequently, it is established that certain collusive behaviour, such as that leading to horizontal price-fixing by cartels, may be considered so likely to have negative effects, in particular on the price, quantity or quality of the goods and services, that it may be considered redundant, for the purposes of applying Article 81(1) EC, to prove that they have actual effects on the market […] Where the analysis of a type of coordination between undertakings does not reveal a sufficient degree of harm to competition, the effects of the coordination should, on the other hand, be considered and, for it to be caught by the prohibition, it is necessary to find that factors are present which show that competition has in fact been prevented, restricted or distorted to an appreciable extent".

must rest on an assessment of the arrangement's content, objectives and economic and legal context,[37] this context being dependent on the assessment of the nature of the goods affected.[38] In the pharmaceutical sector, "the impact of EU rules on pharmaceutical products" must thus be taken into account.[39] These rules require, among other things, that the MA holder provides the public authorities with any new information that "might entail the variation of the information required for issuance of the MA"[40] and that the he must make sure "that information to the public is presented objectively and is not misleading".[41] In other words, the MA holder must keep track of any adverse events linked with its own products and report them faithfully.

In the present context, dissemination, by Roche and Novartis, of joint information about adverse reactions of Avastin could not be viewed as being part of their common pharmacovigilance obligations, since such obligations only rest on the MA holder (here Roche) – and not on its competitor (here Novartis). Hence, the finding that such dissemination might pursue other goals than pharmacovigilance.[42] In addition, information is to be held as misleading if it does not meet "the requirements of completeness and accuracy" laid down in pharmaceutical law, notably Regulation 658/2007; it is thus misleading if meant to confuse the EMA and the EU Commission (about the adverse effects of Avastin's off-label use). More generally, the Court also held as misleading the action of emphasizing to the public – "in a context of scientific uncertainty" – the possible risks of off-label use of Avastin, after the EMA had decided that the section of the SPC regarding adverse reactions was not to be amended in the manner requested by Roche and Novartis.[43]

4) Finally, the arrangement decided between Novartis and Roche was not eligible for an exemption under Article 101(3) TFEU, as disseminating misleading information can never be regarded as "indispensable" to satisfy the procompetitive goals of Article 101(3) TFEU.[44]

Because of this, the exemptions of the Commission Regulation 772/2004 on technology transfer agreements[45] (which was replaced by Regulation 316/2014[46] on May 1, 2014) could not enter into consideration either.[47] It is true that companies selling competing products – i.e. competing undertakings – are generally allowed to enter in a licensing agreement.[48] As explained in Recital 9 of the Regulation, however, the benefit of block exemptions is limited to agreements which are assumed to satisfy the conditions of Article 101(3) TFEU. No block exemption is thus available for agreements that, directly

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37 Id. para. 79.

38 Id. para. 80.

39 Id. para. 80.

40 Article 16(2) Regulation No 726/2004; para. 82 of the judgment at issue.

41 Article 106a amended Directive 2001/83; para. 82 of the judgment at issue.

42 Id. para. 91.

43 Id. para. 92. The EMA only agreed to a "Special warnings and precautions for use".

44 Id. para. 98. According to the wording of Article 101(3), the conditions for an exemption are that the agreement must contribute "to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit" and that it "does not impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives" nor "afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question".

45 Commission Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements, [2004] O.J. L 123/11.

46 Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements, [2014] O.J. L93/17.

47 Para. 99–100 of the judgment at issue.

48 Regulation 772/2004 was governed by the maxim "If it is not forbidden, it is permitted", cf. Richard Whish/David Bailey, Competition Law, 7th ed., Oxford 2012, p. 783.

or indirectly, in isolation or in combination with other factors, have, as in the present case, as their object the allocation of markets or customers (Article 4(1)(c) of Regulation 316/2014).[49]

B. Critical Assessments

What is one to think of this judgment? We have the following five comments:

1) The Court of Justice of the EU reached the conclusion that a product sold within-the-label by one party and another product used off-label for the same indication by another party can both belong to the same relevant product market. In the present case, this conclusion is convincing, since there is ample clinical evidence showing that Avastin works well against AMD. The number of clinical studies supporting the substitutability is quite remarkable: many other

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drugs are commonly used off-label, yet they are seldom the subject of clinical trials for these off-label uses.

This brings forth the following questions: would the Court reach the same verdict should an off-label be less well scientifically established? In that context, should the verdict be based only on the actual behavior of the prescribing physicians, or should a minimum of supporting scientific evidence be required? The answer would be of particular relevance, for example when a pharmaceutical company denies occupying a dominant position by claiming that the relevant product market should also include other drugs used off-label.

2) The Court clearly stated that it is for national *health* authorities and national courts to assess whether an off-label use complies with the rules that govern pharmaceutical matters. Where such results exist, the competition authority must “take account” of this conclusion to determine substitutability.[50] That is reasonable. However, when there is no such conclusion from health authorities, which is likely to be the case in most instances, the competition authority can reach its own decision as to substitutability (between off-label and on-label products). One wonders whether such a decision might cause adverse effects from a public health perspective, for example if, ultimately, it influences medical practices or insurance practices. One could imagine, for example, insurance companies starting to privilege the reimbursement of cheaper off-label products, once the competition authority has held the products to be substitutable.

3) In the pharmaceutical sector, deciding whether a given piece of medical or scientific information is correct, or rather false or misleading, can be difficult. The answer may depend on the proper interpretation of multiple studies, which may yield contradictory results. Summarizing the resulting data to convey it, in an appropriately brief format suitable for to health professionals is difficult, because conclusions very much depend on the specific context (e.g., age or gender of patient, comorbidities, or comedications). Moreover, new studies may continuously produce new knowledge so that “state of the art” medical knowledge is a moving target. Individual risk preferences may also influence the way a given information is weighted, with the added difficulty that the factors to be weighted are not always comparable (e.g., benefits, risks, costs, ease of access).[51]

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49 Several exceptions to this rule were foreseen in Article 4(1)(c)(i)–(vii) (now Article 4(1)(c)(i)–(iv) Regulation 316/2014): the agreement whereby Roche granted licensing rights to Novartis on Lucentis could, for example, have contained a clause whereby Roche would have undertaken not to sell Lucentis in a certain territory. However, this licensing agreement related to Lucentis’ rights could not encompass a competing product sold by Roche (here Avastin). In other words, Regulation 772/2004 could not apply to a different product (Avastin) for which no licensing right would have been granted.

50 Id. para. 60, 67.

51 See e.g., Liana Fraenkel Incorporating Patients’ Preferences into Medical Decision Making, Medical care research and review (MCRR) 70.1 p. 80S–93S (2013). Lisa Rosenbaum, The Paternalism Preference — Choosing Unshared Decision Making, 373 NEJM p. 589–592(2015); A Edwards/G Elwyn, I. Understanding risk and lessons for

The propagation of misleading information affects the process of competition as it influences the conduct of consumers (and/or, in the pharma sectors, prescribers and insurers). In the present judgment, the Court held that misleading information disseminated following an agreement between two competing companies is a restriction of competition "by object" under Article 101(1). This characterization appears correct, as the parties' goal was indeed the allocation of customers, i.e., a sharing of markets.[52] In other words, the agreement aimed "to create an artificial differentiation between […] medicinal products by manipulating the perception of the risks associated with the use of Avastin for the treatment of those diseases through the production and dissemination of opinions which, based on an 'alarmist' interpretation of available data, could give rise to public concern regarding the safety of certain uses of Avastin and influence the therapeutic choices of doctors, and by downplaying any scientific knowledge to the contrary".[53]

However, would every agreement to disseminate incorrect information be prohibited? Apparently, awareness by the companies of the falsehood or of the misleading character is not a requirement: the Court solely explains that such information must not be disseminated in a context of *scientific uncertainty.* Hence, in such a context, even an agreement regarding the propagation "in good faith" of misleading information could fall afoul of competition law. The potential impact of this judgment is thus significant.

4) Even though in the present case the Court did not have to examine the lawfulness of Novartis's and Roche's conduct with regard to Article 102 TFEU, which prohibits the abuse of a dominant position, the impact of the judgment at hand could be even more important in this context. Indeed, companies regularly hold a dominant position with respect to each of their best-selling new (patent-protected) medicines[54] and the violation of advertising laws by pharmaceutical companies is a recurrent occurrence, as we know

clinical risk communication about treatment preferences, BMJ Quality and Safety 10(1), p. i9–i13(2001); Lynn Frewer et al., Understanding patients' preferences for treatment: the need for innovative methodologies, BMJ Quality and Safety 10(1), p. i50–i54 (2001); Mart Oude Egbrink/Maarten Ijzerman, The value of quantitative patient preferences in regulatory benefit-risk assessment, Journal of market access and health policy (2014).

52 Article 101(1)(c) TFEU; see also Richard Whish/David Bailey (Fn. 48).

53 Id. para. 89.

54 In itself, the holding of a patent does not create a dominant position. Patents, indeed, do not exclude competition: they only exclude the use of the right that is so protected, see e.g. Hanns Ullrich/Andreas Heinemann, in Ulrich Immenga/Ernst-Joachim Mestmäcker (eds), Wettbewerbsrecht: Band 1 EU/Teil 2: Kommentar zum Europäischen Kartellrecht, 5 edn, Munich 2012, Immaterialgüterrecht paras 21–23. However, in the pharmaceutical industry, there are only one (or perhaps two) products in a given therapeutic class at the time of the launch of an innovative new drug (NCE; new chemical entity). It is only over-time that new entrants will offer additional medicinal products in that given class. Therefore, the odds of holding a dominant position with respect to an innovative new product is actually high in that industry.

from various publications.[55] If, in addition to the sanctions based on health (pharmaceutical)[56] and on unfair competition laws, dominant companies had to face competition law penalties, the financial impact would be powerful.

While the EU Court has not yet been asked to review a "denigration" case, this Lucentis-Avastin affair comes quite close to the issue. Thus, the possible consequence of this judgment for pharmaceutical companies that hold a dominant position is not to be taken lightly. Denigrating remarks regarding a competitor's product by a pharmaceutical company holding a dominant position, to promote its sales and dampen the sales of the competitor, has in fact already been found to constitute an abuse of a dominant position in France.[57] Besides, one could imagine a situation where a dominant undertaking, which would commercialize two competing products, would, through the dissemination of misleading information, create an artificial differentiation between these two products and thus artificially segment the market; this could lead, as in the present case, to favoring the sales of the most expensive product at the expense of consumers.

5) In the present case, Novartis and Roche were not only conveying information to prescribing physicians, but also to public authorities. In the United States, trying to convince a public authority to take a certain decision is protected under the petitioning doctrine (the so-called "Noerr–Pennington" doctrine).[58] In other words, such conduct (if in good faith) cannot be sanctioned under competition law. A first assumption underlying this doctrine is that persons must be free to speak as they see fit to the authorities (freedom of speech guaranteed by the First Amendment). A second

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55 See, e.g., Satabdi Chatterjee et al., An analysis of the warning letters issued by the FDA to pharmaceutical manufacturers regarding misleading health outcomes claims. Pharmacy Practice (Internet) 2012 Oct-Dec;10(4):194–198. In the United States, FDA warning letters are available from https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/%20WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm. In the United Kingdom, measures taken by the (private) Association of the British Pharmaceutical Industry (ABPI) based on its Code of Practice for the Pharmaceutical Industry are available at http://www.pmcpa.org.uk/cases/Pages/default.aspx.

56 See Commission Regulation (EC) No 658/2007 of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council.

57 See, in the case of Sanofi/Plavix/Teva, the judgment of the French "Cour de cassation" of October 18, 2016 (15-10.384) at http://www.autoritedelaconcurrence.fr/doc/cass_13d11.pdf, following the judgment of the Paris "Cour d'Appel" of December 18, 2014, available at https://www.economie.gouv.fr/files/files/directions_services/dgccrf/boccrf/2015/15_02/arret_ca_18122014_sanofi.pdf, following the May 2013 Decision 13-D-11, available at http://www.autoritedelaconcurrence.fr/pdf/avis/13d11.pdf; also Décision no 17-D-25 of December 20, 2017 in the case of Johnson & Johnson/Janssen-Cilag/Ratiopharm/Durogesic/Fentanyl, see http://www.autoritedelaconcurrence.fr/pdf/avis/17d25.pdf .

Moreover, in January 2017, the French *Cour de cassation* had confirmed the application of Article 101 in a case of pharmaceutical denigration involving Schering Plough/Reckitt Benckiser/Arrow/Subutex, available here *http://www.autoritedelaconcurrence.fr/doc/cass_subutex13d21.pdf* (following a judgment of March 2015 of the Paris "Cour d'appel", available at http://www.autoritedelaconcurrence.fr/doc/ca_subutex_13d21.pdf, following the decision 13-D-21 of December 18, 2013, available at http://www.autoritedelaconcurrence.fr/pdf/avis/13d21.pdf). See also David Tayar, Spreading Misleading Information on a Competitor's Product as an Abuse of a Dominant Position: a French Pharmaceutical Story?, (2014) 5(9) Journal of European Competition Law & Practice, 631.

58 See Abiel Garcia, Noerr-Pennington and reverse payment agreements: A match not made in heaven, 67 57 Rutgers University Law Review 755 (2015); Franklin Liu, Weaponizing citizen suits: Second Circuit revises the burden of proof for proving sham citizen suits in Apotex v. Acorda Therapeutics, 58 Boston College Law Review 147 (2017).

assumption is that public authorities are able to defend themselves against potentially misleading information.

The present judgment does not comment this doctrine at all, which is not explicitly recognized under EU law. European Competition authorities, however, have already found that an abusive filing may constitute a violation of Article 102 TFEU.[59] The Court of Justice ruled that the notification of wrong information to the patent office could constitute a violation of "competition on the merits"[60] which is prohibited by Article 102 TFEU.[61] In that context, while the Court did not reconsider the objective character of the abuse of a dominant position, it explained that the sole provision of misleading information to the authority was not sufficient, in itself, to lead to a sentence, but that a potential anti-competitive effect was needed.[62] As for the intention to provide wrong information, while it was not seen as a necessary condition for an abuse, it also had to be taken into account when assessing the circumstances of the case at hand.[63]

The reasoning of the Court in *AstraZeneca* appears correct: in our view, providing misleading information to an authority should not be exempt from competition law scrutiny. It also appears correct that the concept of abuse remains an objective concept in the

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case of the submission of misleading information: a dominant undertaking must be prohibited from using methods that do not come within the scope of competition on the merits, and that have an actual or potential anti-competitive effect.[64] The provision of misleading information may indeed, as already seen, influence the competitive process. Against this background, factors like the intention to provide wrong information, or the presence or absence of a subsequent intervention to rectify the information wrongly issued,[65] are elements that must be taken into account.

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59 European Commission, Decision of 15. 06. 2005, Case COMP/A. 37.507/F3 – AstraZeneca, O.J. 2006 L 332/24; General Court, Case T-321/05 AstraZeneca v. Commission [2010] ECLI:EU:T: 2010:266; ECJ, Case C-457/10 P AstraZeneca v. Commission [2012] ECLI:EU:C:2012:770. See also under the decision of December 20, 2017, from the French Autorité de la concurrence in the case Janssen-Cilag/Durogesic (17-D-25). See further the comment by Alain Ronzano in the law review Concurrences 1-2018.

60 On this aspect, see Rupprecht Podszun, Can Competition Law Repair Patent Law and Administrative Procedures? AstraZeneca, (2014) 51 CML Rev. 281, 293

61 ECJ, Case C-457/10 P AstraZeneca v. Commission [2012] ECLI:EU:C:2012:770, para. 75, 93, 98–99.

62 Id. at para. 112.

63 General Court, Case T-321/05 AstraZeneca v. Commission [2010] ECLI:EU:T:2010:266, para. 356–359; ECJ, Case C-457/10 P AstraZeneca v. Commission [2012] ECLI:EU:C:2012:770, para. 99.

64 Same opinion: Andreas Heinemann, Abusive filing of IP rights, in: Duncan Matthews/Herbert Zech, Research Handbook on Intellectual Property and the Life Sciences, 2017 Cheltenham, 468, 473–475.

65 Which was not the case in AstraZeneca, cf. ECJ, Case C-457/10 P AstraZeneca v. Commission [2012] ECLI:EU:C:2012:770, para. 88.

66 In certain cases, off-label sales of a drug have been exceeded the on-label sales. See, e.g., Christine Fukada et al. Prescribing Gabapentin off Label: Perspectives from Psychiatry, Pain and Neurology Specialists. Canadian Pharmacists Journal: CPJ 145.6 (2012): 280–284.e1. PMC. Web. 4 May 2018; Joshua Wallach/Jospeh Ross, Gabapentin Approvals, Off-Label Use, and Lessons for Postmarketing Evaluation Efforts. 319(8) JAMA p. 776–778. doi:10.1001/jama.2017.21897 (2018); Michael Steinman et al., Narrative review: the promotion of gabapentin: an analysis of internal industry documents. Ann Intern Med 2006;145:284–293.

III. Conclusion

Off-label use of medicine is a “tricky” issue. It has the potential to both harm and benefit patients. In many contexts (e.g., cancer care, pediatric care), patients are being helped by off-label treatments.[66] Some of these off-label uses have become standard, even though the label has never been correspondingly updated.

For the industry, off-label use is also viewed as both a risky and attractive proposition. In the past, many companies have been punished – mostly in the United States – for off-label promotion. The U.S. government has imposed heavy fines for seeking federal reimbursement for off-label prescriptions that pharmaceutical companies had induced among physicians.[67] Yet, the payoff from such sales may – at least in some instances – have offset the fines inflicted.[68]

Somewhat ironically, this is the first time that pharmaceutical companies have been fined for the reverse conduct: trying to discourage off-label use. Prima facie, it may seem a wise approach for companies to encourage physicians to abide by the approved label.[69] However, this ceases to be true when scientific studies strongly suggest that the off-label use is in the therapeutic interests of patients. In such a case, a company insisting on compliance with the label by using inaccurate arguments can mislead health professionals and patients. Such conduct affects competition and thus carries heavy legal consequences if it results from an agreement between undertakings or if it yields an abuse of dominant position.

More generally, and even though not within the scope of the judgment, the case indirectly raises the thorny issue of label update. Under current pharmaceutical law, the therapeutic indication can only be expanded if the MA holder applies for such a change. This change cannot be initiated by the health agencies (e.g., the EMA). Even if scientific studies demonstrate beyond a doubt that a drug can be used for a wider indication, for a new population, for a longer duration, the medicines agencies cannot impose the corresponding change. Thus, in many medical areas, drugs’ labels are outdated, while practitioners rely on more recent medical guidelines. This situation is far from ideal since off-label prescriptions can be fraught with uncertainty, notably with respect to patient liability and social reimbursement.

It should therefore be asked whether now is the time to grant health agencies the authority to force a label extension. A possibility would be to have a separate section of the label/SPC containing the extension decided by the public agencies.[70] This solution

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67 See e.g., U.S. Department of Justice, Justice Department Announces Largest Health Care Fraud Settlement in Its History, Pfizer to Pay $ 2.3 Billion for Fraudulent Marketing, press release of September 2, 2009, at https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history; Centers for Medicare & Medicaid (CMS), Off-Label Phar maceutical Marketing: How to recognize and report it? At https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/off-label-marketing-factsheet.pdf; John Bentivoglio et al., Recent Settlements Suggest Off-Label Cases Aren’t Extinct, Skadden publication (2017), available at https://www.skadden.com/-/media/files/publications/2017/08/recentsettlementssuggestofflabelcasesarentextinct.pdf .

68 See e.g., Aaron S. Kesselheim et al., False Claims Act prosecution did not deter off-label drug use in the case of Neurontin, Health Aff (Millwood). 2011 Dec;30(12):2318-27. doi: 10.1377/hlthaff.2011.0370; Kevin Outterson, Punishing Health Care Fraud — Is the GSK Settlement Sufficient? 367(12) New England Journal of Medicine (NEJM) p. 1082–1085 (2012), see https://www.nejm.org/doi/full/10.1056/NEJMp1209249.

69 One should also add that pharmaceutical companies invest a lot of time and money in clinical studies precisely to offer patients drugs that have been well tested. When this process is circumvented, the outcome may be unfair (from an unfair competition law perspective) and/or dangerous (for a public health perspective).

70 Compare also with the recent addition in the Swiss Therapeutic Products Act of Article 67a, whereby off-label pediatric use is to be reported in a separate database held by the Federal Office for Public Health (also the new articles 41 and 42 of the Ordinance on medicinal products; RS 812.212.21).

would address not only the competition law issues discussed here, but also enhance the legal security to the benefit of stakeholders.