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Chapter 3

EU MERGER CONTROL IN THE PHARMACEUTICAL SECTOR

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I INTRODUCTION

The combination of relatively stagnant markets in the EU with the foreseen extraordinary growth in the emerging markets[2] is likely to result in further consolidation in the pharmaceutical industry. Regulators will be crucial to this consolidation. This chapter summarises the approach of the European Commission to merger control in the pharmaceutical industry.

II MARKET DEFINITION

Defining the relevant market and the calculation of market shares is necessary to analyse market power and the potential impact of behaviour on competition. In the Commission's words: '[m]arket definition is a tool to identify and define the boundaries of competition between firms. It serves to establish the framework within which competition policy is applied by the Commission. The main purpose of market definition is to identify in a systematic way the competitive constraints that the undertakings involved face.'[3] The calculation of market

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2 According to a report by PricewaterhouseCoopers, the global pharmaceutical industry could be worth nearly $1.6 trillion by 2020 (see PwC, 'The Global Pharmaceutical Market could be Worth Nearly $1.6 trillion by 2020', available at www.pwc.com/gx/en/pharma-life-sciences/pharma2020/market-opportunities-and-outlook.jhtml).

3 See Commission Notice on the definition of relevant market for the purposes of Community competition law, OJ C 372, 9.12.1997, pp. 5–13, at paragraph 2.

shares, by reference to a previously defined market, is an exercise that the Commission considers to provide 'useful first indications of the market structure and of the competitive importance of both the merging parties and their competitors'.[4]

The principles set out in the Commission's Notice on the Definition of the Relevant Market[5] have been applied to the pharmaceutical sector by the European institutions.[6]

i Product market definition for finished dose pharmaceutical products

The Commission has traditionally resorted to different parameters to define relevant markets for finished dose pharmaceuticals.

The European Pharmaceutical Market Research Association Anatomical Therapeutical Chemical Classification (EPhMRA's ATC)

In past years,[7] the Commission has resorted to the EPhMRA's ATC[8] classification, which has been developed for marketing purposes and is the basis for the pharmaceutical sales Intercontinental Medical Statistics database (IMS Health), which provides data that are often used by global pharmaceutical and biotechnology companies for econometric market analysis.[9]

The EPhMRA ATC classifies pharmaceutical products[10] according to their indications and use,[11] distinguishing the following four levels:

a the first level of the code indicates the anatomical main group (i.e., the part of the human body that the medicine intends to address);

b the second level of the code indicates the therapeutic main group (i.e., the main disease groups that the medicine intends to address);

c the third level of the code indicates the therapeutic and pharmacological subgroup (i.e., the different drug actions that will address the disease in question); and

d the fourth level of the code indicates the chemical subgroup.

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4 See Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings, OJ C 31, 5.2.2004, pp. 5–18 (Guidelines on the Assessment of Horizontal Mergers), at paragraph 14.

5 See Notice on the definition of relevant market for the purposes of EU] competition law, OJ C 372, 9.12.1997, pp. 5–13.

6 See, e.g., Case T-321/05 *AstraZeneca v. Commission* [2010] ECR II-2805.

7 See Case COMP/M.5865 – *Teva/Ratiopharm*; Case COMP/M.6613 – *Watson/Actavis*; Case COMP/M.6969 – *Valeant Pharmaceutical International/Bausch & Lomb Holdings*; Case COMP/M.7379 – *Mylan/Abbott* EPD-DM.

8 See 'EphMRA/PBIRG Classification Committee; who we are; what we do 2008', available at www.ephmra.org/user_uploads/ephmra%20who%20we%20are%202015%20final.pdf.

9 IMS Health is a private entity that provides information and services for the healthcare industry (see www.imshealth.com/portal/site).

10 This distinguishes it from the WHO classification system, which classifies substances according to the therapeutic or pharmaceutical aspects and in one class only. The main purpose of the WHO classification is for international drug utilisation research and for adverse drug reaction monitoring.

11 It is therefore possible to find the same compound in several classes, depending on the product, e.g., naproxen tablets can be classified in M1A (antirheumatic), N2B (analgesic) and G2C if indicated for gynaecological conditions only.

The Commission starts its analysis at different levels, often depending on whether the transaction involves producers of originators or generics.

When it comes to originator companies, the Commission's analysis tends to begin at the ATC3 level, which, as indicated in (c) above, groups medicines according to their broad therapeutic and pharmacological indications.[12]

By contrast, in many recent merger cases involving mature genericised markets (i.e., markets involving products with regard to which originators' patent protection has expired and generic companies are offering alternative generic products), the Commission has found classification by molecule (e.g., at ATC4 level) to be more accurate for the purposes of defining the relevant market.[13]

In mergers involving originators and generic producers, the Commission may identify a certain degree of substitutability between the molecules used by originators and generic producers (see Section II.i, Originators, generics and biosimilars, *infra*). In these scenarios, the Commission might take into account the closeness of substitution between these molecules, and consider the generic molecule as being the closest substitute to the ex-originator drug based on the same molecule.[14]

Prescription medicines, over-the-counter (OTC) and dual-status medicines

The Commission has usually defined separate markets for prescription medicines and for OTC or dual-status medicines.[15] This is due to the fact that seriousness of disease (i.e., medical indications or dosage, or both, in some cases), strength of products (including possible side effects and harmfulness if misused), legal framework, marketing, distribution, the medical indications (including their possible side effects), legal framework, distribution and rules on reimbursement of drugs all tend to differ between the two categories of medicines, even when the active ingredients are identical.

Certain variants of a drug with the same active ingredient or brand name are sometimes classified as both OTC and prescription-only, depending on the package size, dosage or 'galenic' form.[16] In these cases, the price of the OTC medicine may be a factor determining whether the patient simply purchases this medicine at his or her own expense

12 See, e.g., Case COMP/M.5253 – *Sanofi-Aventis/Zentiva*, at paragraphs 12 ff; Case COMP/M.5295 – *Teva/Barr*, at paragraphs 10 ff. In the context of originator products, the Commission has sometimes resorted to the EPhMRA ATC4 level (see Case COMP/M.3544 – *Bayer Healthcare/Roche (OTC Business)*, at paragraphs 15–20).

13 See Case COMP/M.6613 – *Watson/Actavis*, at paragraph 7; Case COMP/M.5295 – *Teva/Barr*, at paragraph 18; Case COMP/M.5865 – *Teva/Ratiopharm*, at paragraph 12; Case COMP/M.7379 – *Mylan/Abbott EPD-DM*, at paragraph 13. However, the Commission has sometimes defined markets on the basis of the molecule level or group of molecules that are interchangeable for a wide range of applications (see Case COMP/M.5865 – *Teva/Ratiopharm*, at paragraph 14).

14 See Case COMP/M.7379 – *Mylan/Abbott EPD-DM*, at paragraph 13. This possibility had already been explored in Case COMP/M.5865 – *Teva/Ratiopharm*, at paragraph 13.

15 Ibid, at paragraphs 22 ff.

16 Ibid.

or visits a doctor to obtain a prescription for a reimbursable alternative.[17] Similarly, in some specific circumstances where the status of a drug is not clearly limited to either OTC or prescription, it may not be excluded that these products compete with each other.[18] Finally, the presence of a product or brand in both the prescription and OTC segments may result in it enjoying a stronger market position.[19]

Originators, generics and biosimilars

Broadly speaking, there are two types of pharmaceuticals that aim to offer alternatives to originator drugs: (1) synthetic small-molecule generics; and (2) biosimilar products.

Small-molecule generic products are based on the same active principle as that of their equivalent small-molecule originator drugs and are synthesised by chemical processes. Generic products are produced and offered upon patent expiry of the originator that they aim to reproduce. Small-molecule originators and generic drugs can generally be considered homogeneous products, to the extent that the Commission has recently found that they compete mainly on price, particularly in the case of hospital drugs procured through tenders.[20]

While the Commission's market investigations have often suggested that there may be differences in demand for originators versus generics, this phenomenon has not been found to justify the definition of two separate product markets.[21] According to the Commission, a number of elements indicate that generic medicines based on the same molecule compete in the same product market as the branded originator medicines on which they are based.[22] These elements include:

a the fact that, in order to obtain regulatory approval to market its product, a generic drug manufacturer must demonstrate that its drug is bioequivalent to the originator

17 See Case COMP/M.5253 – *Sanofi-Aventis/Zentiva*, at paragraphs 58–59. For OTC products, the Commission has also recently taken into consideration the classification used in the IMS Consumer Health's OTC Review Reports (see, e.g., Case COMP/M.6280 – *Procter & Gamble/Teva OTC business*, at paragraphs 9 and 11).

18 See Case COMP/M.5778 – *Novartis/Alcon*, at paragraph 14; Case COMP/M.7379 – *Mylan/Abbott EPD-DM*, at paragraph 20.

19 See, e.g., Case COMP/M.1846 – *Glaxo Wellcome/Smithkline Beecham*, at paragraphs 98–113.

20 See Case COMP/M.7559 – *Pfizer/Hospira*, at paragraph 33.

21 See Case COMP/M.5253 – *Sanofi-Aventis/Zentiva*, at paragraphs 25–26; Case COMP/M.7379 – *Mylan/Abbott EPD-DM*, at paragraph 15.

22 See Case COMP/M.5476 – *Pfizer/Wyeth*, at paragraph 19; Case COMP/M.7379 – *Mylan/Abbott EPD-DM*, at paragraph 16; Case COMP/M.7559 – *Pfizer/Hospira*, at paragraph 33. However, generic companies might also compete with products based on other molecules (see Case COMP/M.5865 – *Teva/Ratiopharm*, at paragraph 13; Case COMP/M.7379 – *Mylan/Abbott EPD-DM*, at paragraph 13).

drug[23] (i.e., the generic is bioequivalent in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use, thus working in essentially the same way as the originator in the patient's body);[24]

b the fact that generic versions of originator medicines are often designed by generic producers to be copies of those originator medicines on which they are based (indeed, only bioequivalence can ensure generics the fast route to the market, meaning that they main obtain a marketing authorisation by simply showing that they are bioequivalent to the originator drugs, which thus dispenses them from carrying on the full clinical trials that an originator product would have to do); and

c the applicable regulatory framework, which encourages switching between originator and generic medicines.

Separately, in the past years, growing competition has been observed between originator biological products (biopharmaceuticals) and biosimilar products.[25] Unlike small molecule generics, bio-similars are not exact copies of the originator drugs. However, biosimilar drugs aim to have the same therapeutic mechanism as original patented medicines.[26] According to the guidelines of the European Medicines Agency (EMA), in order to obtain a marketing authorisation for a biosimilar, its manufacturer needs to demonstrate similarity (in terms of quality, safety and efficacy) to a reference biological product.[27]

The Commission has observed that, since the first complex bio-similar was approved in Europe in 2013, the offering of biosimilar products has led to price decreases compared to originator products.[28] Biosimilars are expected to allow wider access by patients to biological drugs and to be an important factor in relieving the financial pressure on healthcare systems. Accordingly, in recent cases the Commission has found that an originator biopharmaceutical and its biosimilar product belonged to the same product market.[29]

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23 Bioequivalence is defined by the European Medicines Agency as the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of action when administered at the same molar dose under similar conditions in an appropriately designed study.

24 As regards competition between generic medicines, generic medicines developed to be bioequivalent of the same originator product, and based on the same molecule, may still have some differentiating elements from one another (e.g., inactive ingredients or impurities). However, these differences have not been found sufficient to define separate markets for two generics falling under the same molecule: see Case COMP/M.5253 – *Sanofi-Aventis/Zentiva*, at paragraph 26.

25 Biopharmaceuticals are originator medicines whose active substance is made by or derived from living organisms.

26 See Case COMP/M.7559 – *Pfizer/Hospira*, at paragraphs 9 and 34–35.

27 See 'Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues' available at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/01/WC500180219.pdf.

28 See Case COMP/M.7559 – *Pfizer/Hospira*, at paragraph 11.

29 See Case COMP/M.7559 – *Pfizer/Hospira*, at paragraph 25, where the Commission found the relevant product market to comprise infliximab pharmaceuticals, including both the

However, competition among biosimilars and biopharmaceuticals may not always be homogeneous. Because of the possible differences between originator biological products and biosimilar products in terms of clinical evidence available on their efficacy and safety, physicians and pharmacists might not necessarily consider originator and biosimilars based on the same biologic molecule to be fully interchangeable, depending on the Member State. This may equally apply to the interchangeability amongst biosimilars based on the same molecule, which are also not identical in their chemical structure and clinical evidence.[30] Accordingly, competition between original biologic products and biosimilar products, as well as between any pair of biosimilar products, may be characterised by a limited degree of substitutability for patients already undergoing treatment, and a high degree of substitutability for new patients.[31]

Biosimilar and small molecule traditional generics

The Commission has also reviewed in detail the distinction between bio-similar products and small molecule traditional generics.[32]

The Commission has identified a number of differences between these types of products, which has sometimes led to their individual assessment:[33]

a the development of biosimilars tends to require considerably longer development periods than synthetic generics;

b the development of biosimilars tends to require higher upfront investments than those required for the development of other generics;

c the development of biosimilars entails a higher risk of failure for research and development (R&D);

d the development and manufacturing of biosimilars requires specific biotech know-how and facilities; and

e the R&D process for biosimilars is closer to the R&D of originator than of synthetic generic drugs requiring, for example, clinical trials.

Galenic formulation

In recent cases that have involved generics, the Commission has investigated whether a difference in the 'galenic' formulation further limits substitutability within or across molecules. The Commission has found this to be the case in a number of cases,[34] to the extent that the launch of a new 'galenic' form may take up to two or three years to appear in the

originator infliximab (Remicade) and infliximab bio-similars.

30 See Case COMP/M.7559 – *Pfizer/Hospira*, at paragraphs 35-38.

31 Ibid.

32 See Case COMP/M.5865 – *Teva/Ratiopharm*, at paragraphs 28 ff.

33 See Case COMP/M. 5865 – *Teva/Ratiopharm*, at paragraph 29; Case COMP/M.5479 – *Lonza/Teva/ JV*, at paragraph 7; Case COMP/M.7559 – *Pfizer/Hospira*, at paragraph 18.

34 See, e.g., Case COMP/M.5865 – *Teva/Ratiopharm*, at paragraphs 16–21 and 39–41: '[...] in this case, different routes of administration of a medicine are, in general, […] not interchangeable. This may also be the case of the dosage and of the pharmaceutical form […].' Lack of substitutability was mainly found for oral syrups, rectal forms, and injectable or parenteral forms (see paragraphs 19, 118, 157, 184, 253–256, 267–268, 279, and 336–340).

market, a period that may exclude supply-side substitutability;[35] and that different routes of administration for a medicine are, in general, designed to serve the needs of different patient groups, and are therefore not interchangeable.[36] In these situations, the reference system for distinguishing between medicinal formulations is the typology of form code (also called the New Form Code (NFC)) used by IMS Health and EphMRA.[37]

Product 'pipelines', innovation and R&D

In accordance with the Commission's general guidance, R&D and product pipelines should be considered in markets and sectors, such as the pharmaceutical sector, where innovation is an important competitive force that may be driven or impeded depending on the particular circumstances of each case.[38] In such scenarios, a full competitive analysis requires that the relevant authority examine those products that have not as yet entered the market, but that are at an advanced stage of development (e.g., advanced R&D pipeline products in Phase III of clinical trials).[39] In a number of cases, the Commission has assessed the impact of transactions in 'pipeline products'.[40] Patents and other IP rights also play an important role in the competitive assessment of current and future markets.[41]

National registration and reimbursement rules

In certain cases, the Commission has taken into consideration the influence of national registration and national reimbursement rules on the prescription behaviour of physicians for the purposes of defining markets.[42]

35 See Case COMP/M.5865 – *Teva/Ratiopharm*, at paragraph 18.

36 See Case COMP/M.7379 – *Mylan/Abbott EPD-DM*, at paragraph 24. For example, the liquid form of certain drugs (such as syrups), has been considered to be mainly designed for paediatric patients

37 See http://www.ephmra.org/New-Form-Codes-Classification.

38 See Guidelines on the Assessment of Horizontal Mergers at paragraph 38.

39 See, e.g., Case COMP/M.1403 – *Astra/Zeneca*, at paragraphs 43 and 44; Case IV/M.1846 – *Glaxo Wellcome/Smithkline Beecham*, at paragraphs 150–216; Case COMP/M.3354 – *Sanofi-Synthélabo/Aventis*, at paragraphs 324–330; COMP/M.5476 – *Pfizer/Wyeth*, at paragraphs 13, 34-38, 65, 87-95, and 99; and Case COMP/M.5999 – *Sanofi-Aventis/Genzyme*, at paragraphs 7, 21, 29, and 38–46. However, in Case COMP/M.7275 – *Novartis/GlaxoSmithKline Oncology Business*, the Commission analysed markets where the parties had ongoing clinical trials at earlier stages, including Phase I and Phase II.

40 See Case COMP/M.5865 – *Teva/Ratiopharm*, at paragraphs 421 ff. Case COMP/M.7275 – *Novartis/GlaxoSmithKline Oncology Business*, at paragraphs 47 ff.

41 See Case No. IV/M.737 – *Ciba-Geigy/Sandoz*, at paragraphs 96-107.

42 See, e.g., Case COMP/M.7275 – *Novartis/GlaxoSmithKline Oncology Business*, at paragraphs 123-124; Case COMP/M.5865 – *Teva/Rationpharm*, at paragraph 90.

Other medicine characteristics

Further segmentation of product markets in the pharmaceutical sector may result from a number of characteristics of medicines (e.g., the medicine's indications and contraindications, their efficacy and side effects, their frequency of administration and period of action).[43]

ii Markets upstream and downstream from finished pharmaceuticals

In addition to the markets defined for finished pharmaceuticals set out above, the Commission has also identified the neighbouring markets, some of which are set out below.

Active pharmaceutical ingredients (API) markets and other raw materials

In its precedents, the Commission has identified separate markets for APIs, which is one of the main raw materials used by pharmaceutical companies for the manufacture of drugs.[44] The Commission has generally found that API markets might be as narrow as each individual API (i.e., the relevant molecule).[45] Sufficient supply-side substitutability may, however, justify the inclusion of a number of APIs in the same relevant product market.[46] However, the following elements might lead to the opposite conclusion:

a demand-side substitutability is unlikely in practice, given that a generic company that produces a specific pharmaceutical product needs to buy the relevant API molecule and lacks the ability to use another alternative API;[47] and

b switching to another API source might require variations in the relevant authorisations. Obtaining these can involve devoting significant resources.[48]

Other raw materials used for the manufacture of pharmaceutical products include: (1) excipients (non-active ingredients used in a final drug dosage form, such as binders, fillers, diluents, lubricants, flavours, solvents sweeteners or preservatives, with *inter alia* lactose, starch, cellulose, magnesium, stearic acid, gelatine, sucrose, talc or sodium); and (2) biopharm ingredients (process chemicals used in biopharmaceutical processes, including buffers and stabilisers – such as amino acids, carbohydrates and polymers).[49]

43 See Case COMP/M.1846 – *Glaxo Wellcome/Smithkline Beecham*, at paragraph 38; Case COMP/M.737 – *Ciba-Geigy/Sandoz*, at paragraph 21; Case COMP/M.5999 – *Sanofi Aventis/Genzyme*, at paragraph 42; Case COMP/M.5865 – T*eva/Ratiopharm*, at paragraphs 161, 232, 242, and 282; and Case COMP/M.1835 – *Monsanto/Pharmacia&Upjohn*, at paragraphs 29–30.

44 See, e.g., Case COMP/M.5865 – *Teva/Ratiopharm*, at paragraphs 393-394; Case COMP/M.7379 – *Mylan/Abbott EPD-DM*, at paragraphs 456 ff.

45 See, e.g., Ibid,. at paragraph 393; Case COMP/M.5295 – *Teva/Barr*, at paragraph 189.

46 See Case COMP/M.6113 – *DSM/Sinochem/JV*, at paragraphs 20–24.

47 See Ibid., at paragraph 19.

48 See Case COMP/M.6278 – *Takeda/Nycomed*, at paragraph 30.

49 See Case COMP/M.7435 – *Merck/ Sigma-Aldrich*, at Section IV.4.

Contract manufacturing of finished dose pharmaceuticals

The Commission has identified a separate upstream market for the contract manufacturing of finished dose pharmaceuticals on behalf of third-party pharmaceutical companies.[50] In the past, the Commission has considered, but ultimately left open, the possibility that this market be further segmented by reference to the function of the pharmaceutical form (e.g., solids, powder, liquids, sterile liquids) or by reference to the conditions of manufacture (e.g., types of APIs involved, toxicity, involvement of a sterile environment, etc.).[51]

Out-licensing

In the out-licensing market, one party (the licensor) out-licenses a pharmaceutical product to one or more third parties (the licensee or licensees)).[52] During the duration of the licence, the licensee will generally buy the finished product (or 'bulk') from the licensor on an exclusive basis and will commercialise the product under its own name, using the marketing authorisation that was licensed to it by the licensor.[53] The Commission has considered a possible narrower segmentation within the out-licensing market for the out-licensing of IPRs for particular APIs or pharmaceutical products, or both.[54]

Other upstream markets

The Commission has identified other separate markets, such as input markets for substances required for the production of APIs;[55] and dosage delivery mechanisms.

Markets downstream from finished pharmaceuticals

Pharmaceutical companies reach distributors and end users through different distribution channels characterised by very different competitive dynamics. The Commission has thus far defined the following separate markets in the pharmaceutical industry distribution value chain:

a pre-wholesale services;[56]

b wholesale services;[57]

50 See Case COMP/M.5865 – *Teva/Ratiopharm*, at paragraphs 408 ff; Case COMP/M.6258 – *Teva/Cephalon*, at paragraph 145. This definition excludes the manufacturing of API (see Case COMP/M.5953 – *Reckitt Benckiser/SSL*, at paragraphs 57–62; Case COMP/M.6613 – *Watson/Actavis*, at paragraph 123; See Case COMP/M.7379 – *Mylan/Abbott EPD-DM*, at paragraphs 463–465.

51 See Case COMP/M.5953 – *Reckitt Benckiser/SSL*, at paragraphs 57–62; Case COMP/M.6613 – *Watson/Actavis*, at paragraph 123.

52 See Ibid., at paragraph 122; Case COMP/M.5865 – *Teva/Ratiopharm*, at paragraph 408.

53 See Case COMP/M.6613 – *Watson/Actavis*, at paragraphs 118 ff.

54 Ibid, at paragraphs 120 and 121.

55 See Case IV/26.911 – *Zoja/CSC-ICI*.

56 See Case COMP/M.6044 – *Alliance Boots/Andreae-Noris Zahn*, at paragraphs 6 ff.

57 See Case COMP/M.4301 – *Alliance Boots/Cardinal Health*, at paragraphs 10 ff. This activity has been distinguished from the direct distribution of manufacturers to customers (e.g., retail pharmacies, hospitals); see Case COMP/M.5865 – *Teva/Ratiopharm*, at paragraphs 450–452.

c hospitals;[58]
d pharmacy retail;[59] and
e home care.[60]

III GEOGRAPHIC MARKET DEFINITION

i Finished pharmaceuticals

The Commission has consistently found geographic markets for finished pharmaceutical products to be national. However, when the Commission has taken into consideration the future presence of a particular pharmaceutical company in a specific market by reference to its pipeline products, R&D or patents, the Commission has tended to find wider geographic markets (EEA-wide or worldwide). This is due to the fact that R&D tends to occur on a multinational and, often, global scale.[61]

ii Markets upstream of finished pharmaceuticals

Upstream markets have generally been found to be at least EEA-wide or worldwide in scope, regardless of whether they concern the sale of APIs,[62] contract manufacturing[63] or out-licensing.[64]

IV COMPETITIVE ANALYSIS IN THE PHARMACEUTICAL SECTOR

i Preliminary considerations

Whether the Commission considers that a transaction in the pharmaceutical industry raises competition concerns is likely to depend on the nature of the business activities and nature companies involved in the concentration. For example, mergers between two originators active in the same markets may raise traditional horizontal concerns. Mergers between originators and research firms might affect competition in the current and future relevant product markets, particularly if both companies have competing late-stage pipeline products or the transaction could result in a decrease in overall R&D.

58 See Case COMP/M.7323 – *Nordic Capital/Ghd Verwaltung*, at paragraph 39; Case COMP/M.5805 – *3i/Vedici Groupe*; Case COMP/M.5548 – *Barclays/RBS/Hillary*; Case COMP/M. 4367 – *APW/APSA/Nordic Capital/Capio*; Case COMP/M.4229 – *APHL/L&R/Netcare General Healthcare Group*; Case COMP/M.4788 – *Rozier/BHS*.

59 See Case COMP/M.2432 – *Angelini/Phoenix/JV*; Case COMP/M.2573 – *A&C/Grosspharma*, at paragraphs 11 and 12; and Case COMP/M.5865 – *Teva/Ratiopharm*, at paragraph 452.

60 See Case COMP/M.7323 – *Nordic Capital/Ghd Verwaltung*.

61 For future markets, see Case COMP/M.5865 – *Teva/Ratiopharm*, at paragraph 422.

62 Ibid, at paragraph 396.

63 See Case COMP/M.6613 – *Watson/Actavis*, at paragraph 124; Case COMP/M.6278 – *Takeda/Nycomed*, at paragraphs 20 and 21.

64 See Case COMP/M.6613 – *Watson/Actavis*, at paragraphs 120 and 121; Case COMP/M.5865 – *Teva/Ratiopharm*, at paragraph 396; Case COMP/M.5295 – *Teva/Barr*, at paragraph 190; and COMP/M.6278 – *Takeda/Nycomed*, at paragraph 19.

Different competition concerns may arise when a concentration involves one or more generic producers. Generic companies not only compete among each other in the development of biosimilar and molecule generics of originator pharmaceuticals; they also compete with originator pharmaceuticals after the expiration of the relevant patent.

ii Key competitive drivers in the pharmaceutical markets

To date, competition concerns in notified cases have focused on potential restrictions arising from direct overlaps in the relevant market or markets. In addition, the competitive assessment is likely take into consideration innovation and other aspects of dynamic competition, the effects of regulation and reimbursement schemes on competition and the commercialisation stage of the relevant products. The Commission has focused its analysis on the different competitive drivers of the pharmaceutical markets.

Innovation and product differentiation

The Commission tends to consider innovation to be of critical importance for the pharmaceutical sector. In the Commission Communication accompanying the Pharmaceutical Sector Inquiry, the Commission highlighted the significant R&D efforts of originator companies and other stakeholders (e.g., research companies) in order to innovate.[65] Current Competition Commissioner Margrethe Vestager seems to have embraced this by indicating that the Commission's 'focus on investment and innovation in merger control is also clear in the pharmaceutical sector', although when pharmaceutical companies announce a merger the Commission needs to 'carefully balance the benefits of pooling their resources with the potential negative impact of eliminating an innovator'.[66]

In a number of cases, the Commission considered the potential risks that a concentration entails for the development of pharmaceuticals and innovation, both in relation to originators (e.g., when developing new pharmaceutical products or variants)[67] and to generic manufacturers (e.g., when developing biosimilars).[68] Similarly, the Commission has also taken into account the potential impact of competition exerted by 'pipeline' products (i.e., the competition that products might face from other products not yet released on the market) when reviewing certain transactions.[69] This is due to the fact that, if the adequate conditions are met (e.g., those regarding the pharmacological characteristics and therapeutic use), pipeline products might be actual or credible future competitors of existing products. In assessing pipeline competition, the Commission has focused on instances where one merging

65 See Communication from the Commission – Executive Summary of the Pharmaceutical Sector Inquiry Report and Pharmaceutical Sector Inquiry – Final Report (both of 8 July 2009).

66 See speech of 15 June 2015, 'The State of the Union: Antitrust in the EU in 2015-2016', available at: https://ec.europa.eu/commission/2014-2019/vestager/announcements/state-union-antitrust-eu-2015-2016_en.

67 See, e.g., Case COMP/M.5661 – *Abbott/Solvay Pharmaceuticals*, at paragraph 119; Case COMP/M.5502 – *Merck/Schering-Plough*, at paragraph 38.

68 See Case COMP/M.5865 – *Teva/Ratiopharm*, at paragraphs 421 ff.

69 See Case COMP/M.5502 – *Merck/Schering-Plough*, at paragraph 38.

party is planning to enter a market with a new product within a period of two years, and the merging other party (or the parties combined) has a market share of 35 per cent or more on any possible market definition where the pipeline products and existing products overlap.[70]

Intellectual property rights (IPRs) are also a key element in the promotion of innovation. The pharmaceutical industry invests heavily in R&D and tends to rely on IPRs to protect innovation, and to manufacture or distribute its products, or both (e.g., through out-licensing). In recent cases, the Commission analysed the potential effects of transactions on R&D, for example by decreasing the merging parties' incentives to further investigate, or by obstructing the licensing of patents for R&D.[71] Such an exercise presents the potential pitfall, from an analytical perspective, of the different approaches of economists to the relationship between market structure and innovation.[72]

As occurs in other markets, product differentiation can also play an important role in determining the competiveness or closeness of competition between different pharmaceuticals. For example, originators might enjoy a better position in the market as a result of the publication of clinical trial evidence (e.g., as regards the efficacy or safety profile of a product) or where their products are well known to end users (e.g., as a result of branding advertising).

Authorisation, price and reimbursement conditions

The Commission sometimes finds that pharmaceutical markets present rigid pricing and entry conditions.[73]

The sale of prescription medicines is generally regulated in the EU and is often subject to reimbursement conditions from the social security systems of the Member States. As a result, the use of prescription medicines may rely heavily upon the national authorisations and guidelines that doctors and medical staff use for their prescription; and upon the extent to which the financial burden is ultimately borne by the affected Member State (or private health insurances, or both) in question.

As previously indicated, the impact that authorisation procedures, pricing and reimbursement conditions have on consumption levels for certain pharmaceutical products is such that these elements have been used in a number of Commission precedents to exclude products from the relevant market despite therapeutic indications being identical.[74] In addition, price regulation and reimbursement schemes in the Member States are likely to be of crucial importance when analysing the ability of a merged entity to increase prices

70 See COMP/M.6258 – *Teva/Cephalon*, at paragraphs 81 and 129; COMP/M.6613 – *Watson/Actavis*, at paragraphs 110–111; Case M.7379 – *Mylan/Abbott EPD-DM*, at paragraph 450.

71 See Case COMP/M.7275 – *Novartis/GlaxoSmithKline Oncology Business*, at paragraph 105; Case COMP/M.5476 – *Pfizer/Wyeth*, at paragraphs 91 and 93.

72 See Teece, DJ, *Dynamic Capabilities and Strategic Management: Organizing for Innovation and Growth*. Oxford University Press, 2011.

73 See, e.g., Case COMP/M.7275 – *Novartis/GlaxoSmithKline Oncology Business*, at paragraph 62.

74 Ibid, at paragraphs 123–124; Case COMP/M.5865 – *Teva/Rationpharm*, at paragraph 90.

post-transaction in markets for prescription medicines.[75] Reimbursement schemes that encourage generic competition may also be taken into account when determining whether a transaction leads to competition concerns.[76]

Generic and biosimilar competition

The existence of competitive constraints from generic manufacturers can be of great importance in determining whether a concentration will give rise to competition concerns. Broadly speaking, after the expiry of the relevant patent, generic pharmaceutical companies are in competition with one another and with originator companies.[77] In general, generic companies focus on price competition and tend to invest less in branding and advertising, given the limited importance attributed by them to differentiating their products from originator products. In addition, in a number of countries, regulatory substitution rules and mechanisms will ensure generic market penetration with limited promotional activities being needed. Finally, in a majority of countries in the EU, the entry of a generic product may trigger price reductions, as a result of which demand tends to shift away from originators.

In assessing competition between originator and generic companies, the Commission considers, *inter alia*, the asymmetries in their respective product offerings or market focuses to assess whether the two products are closely competing.[78]

Competitive dynamics for OTC products

OTC medicines are subject to different competitive dynamics than those indentified for prescription medicines. Indeed, the sale of OTC products is usually significantly less subject to reimbursement regulations or to the prescription guidance of doctors, which shifts the decision-making role to pharmacists and end users. As a result, the success of OTC medicines tends to rely on (consumer-focused) advertising, innovation (often in the form of customisation to suit user preferences) and branding strategies. Generic OTC medicines sometimes exert significant competitive constraints on branded OTC medicines, although the ultimate impact of such constraints will ultimately depend on the brands and products in question.[79]

Non-horizontal effects

Concentrations between pharmaceutical companies can lead to competition concerns where the parties are active in markets that are upstream, downstream or adjacent of one another

75 Ibid, at paragraph 65, where a number of factors were cited in support of the view that prices in all the affected countries for many medicines in mature generic markets were upwardly inflexible or could only be increased with difficulty.

76 See, e.g., Case COMP/M.5295 – *Teva/Barr*, at paragraphs 186 ff.

77 Ibid, at paragraphs 184–185.

78 See Case COMP/M.5253 – *Sanofi-Aventis/Zentiva*, at paragraph 484, regarding generic and generic differentiation; Case COMP/M.6258 – *Teva/Cephalon*, at paragraph 12, regarding originator and generic differentiation.

79 See Case COMP/M.6280 – *P&G/Teva OTC Business*, at paragraph 20; Case COMP/M.3751 – *Novartis/Hexal*.

(e.g., APIs and finished dose pharmaceuticals, or IPR holders and licensee manufacturers).[80] For example, based on Commission's practice, out-licensing may result in vertically affected markets where: (1) one merging party (company A) is active on a downstream market for the manufacturing of a specific finished dose pharmaceutical; (2) the other merging party (company B) is active upstream as a licensor and contractor of another manufacturer downstream (company C); and (3) the combined market share of the merging parties and of the sub-contracted licensee (companies A, B, and C) on the downstream market exceeds 25 per cent.

As with other non-horizontal mergers, the importance of this type of concerns will depend on the market presence and power of the merging parties in the relevant upstream and downstream markets, and their ability and incentive to leverage this presence into other markets to foreclose competing companies.[81]

iii Remedies and commitments in merger control

The history of EU merger control in the pharmaceutical sector is characterised by the absence of prohibition decisions. However, the Commission has accepted commitments proposed by the merging parties primarily during Phase I investigations. As regards Phase II investigations, cases have been completed with commitments decisions mainly in the related but separate medical devices industry.[82]

Where the Commission has identified concerns that result from the horizontal overlap created by a concentration, it has traditionally required the divestiture of entire product lines or businesses, or both, to eliminate a significant part of the parties' overlap in a problematic (geographic or product) market.[83] The appropriateness and suitability of the assets, IPRs, licences, supplies, personnel, customer lists or proposed buyer will be key in determining the acceptance of any proposed divestitures, in particular where the divested business risks are not being considered as a stand-alone entity by the Commission but rather as part of a larger business that, when severed from the entity, could have limited viability, competitiveness and ability to innovate post-transaction.[84] Where necessary, the Commission might require

80 For vertical concerns see, e.g., Case COMP/M.6258 – *Teva/Cephalon*, at paragraphs 133 ff and Case COMP/M. 3493 – *Yamanouchi/Fujisawa*. For conglomerate concerns see, e.g., COMP/M.5999 – *Sanofi-Aventis/Genzyme*, at Section 4.6.

81 See, e.g., Case COMP/M.5253 – *Sanofi-Aventis/Zentiva*, at paragraphs 511 ff; Case COMP/M.6258 – *Teva/Cephalon*, at paragraphs 133 ff.

82 See, e.g., Case COMP/M.3687 – *Johnson & Johnson/Guidant*; Case COMP/M.6266 – *Johnson & Johnson/Synthes*; and Case COMP/M.7265 – *Zimmer/Biomet*.

83 See, e.g., Case COMP/M.3544 – *Bayer Healthcare/Roche (OTC Business)*, at paragraphs 57 ff, regarding divestitures of product lines; Case COMP/M.3751 – *Novartis/Hexal*, at Section 6, regarding divestitures of sale and marketing rights; Case COMP/M.4314 – *Johnson & Johnson/Pfizer Consumer Healthcare*, at paragraphs 138 ff, regarding the divestiture of assets (e.g., inventories, clinical data, trademarks); Case COMP/M.4779 – *Akzo/ICI*, at paragraphs 53 ff, regarding the divestiture of a shareholding in a joint venture. See also Case COMP/M.5253 – *Sanofi-Aventis/Zentiva*, at paragraphs 550 ff; Case COMP/M.5295 – *Teva/Barr*, at paragraphs 205 ff; Case COMP/M.7379 – *Mylan/Abbott EPD-DM*, at Section 5.

84 See, e.g., Case COMP/M.6851 – *Baxter International/Gambro*, at paragraph 564 and 571 (where the merging parties proposed an up-front buyer). For the need to ensure supplies and

that the notifying party enter into agreements with the divestiture buyer prior to clearance in order to ensure that the latter will be committed to carrying out R&D investments and launches of pipeline products.[85]

Given the complexity of the pharmaceutical sector, the Commission has sometimes required that the divestiture of product lines or businesses be supported with the provision of technical assistance in the production, sale and marketing of the pharmaceutical product.[86] Sometimes, to facilitate the market entry and sustained competitiveness of third parties, the Commission has required the divestiture of a product line to be supplemented with the divestiture of a distribution business.[87]

Insofar as the merger control review of the Commission is limited to the EEA market or markets where it identifies competition concerns, the Commission has accepted where appropriate divestitures of global businesses combined with an exclusive license-back clause to the merging parties for non-EEA markets.[88] In such cases, where the notifying party also reserves for itself certain decision-making rights related to the output of the divested business (e.g., product development, clinical trials), these should be limited so as to not to give to it joint control on these aspects of the business.[89]

In other circumstances, the Commission has accepted licensing arrangements as an alternative to divestitures where, for instance, the proposed divestiture would hinder ongoing research or it would be impossible due to the nature of the business.[90]

In addition, to the extent that the competitive concerns related to the grant of exclusive rights or licences to other competing entities, the Commission has accepted commitments to, dilute or remove altogether minority shareholding relationships and other contractual arrangements (e.g., turn exclusive licensing relationships into non-exclusive relationships, limiting supply agreements).

V CONCLUSIONS

While the substantive analysis of mergers in the pharmaceutical sector might not be fundamentally different from that carried out in other innovation-intensive regulated industries, it presents the following particularities:

a the market definition process is characterised by the use of a range of different analytical tools to identify relevant markets. The Commission has a well-established

licences in the medical devices sector, see Case COMP/M.7326 – *Medtronic/Covidien* and Case COMP/M.7265 – *Zimmer/Biomet*; Case COMP/M.7379 – *Mylan/Abbott EPD-DM*, at paragraphs 472 ff. and 485.

85 See Case COMP/M.7275 – *Novartis/GlaxoSmithKline Oncology Business*.

86 See, e.g., Case COMP/M.4314 – *Johnson & Johnson/Pfizer Consumer Healthcare*, at paragraphs 139 and 140.

87 See Case COMP/M.5778 – *Novartis /Alcon*, at paragraphs 291 ff.

88 See Case COMP/M.7559 – *Pfizer/Hospira*, at paragraph 297.

89 See Case COMP/M.7559 – *Pfizer/Hospira*, at paragraph 310.

90 See Case COMP/M.2972 – *DSM/Roche Vitamins*. See also Commission Notice on remedies acceptable under Council Regulation (EC) No. 139/2004 and under Commission Regulation (EC) No. 802/2004, C 68, 02.03.2001, p. 3, at paragraph 29.

approach to market definition on the basis of the EPhMRA ATC classification, nuanced by reference to other competitive drivers such as the distinction between OTC and prescription drugs and, where applicable, between originators and generics;

b actual competition is analysed mainly on the basis of observed overlaps in the relevant market or markets. In addition, the competitive assessment becomes more complex as the Commission takes into consideration innovation and other aspects of dynamic competition, the impact of regulation and reimbursement schemes, and the commercialisation stage of the relevant products; and

c where concerns arise deriving from horizontal overlaps, the Commission is not reluctant to require divestitures, emphasising the need for the divested business to constitute a viable stand-alone business.

Appendix 1

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Pablo Figueroa is a Spanish qualified lawyer and member of the Brussels Bar, based in the Brussels office of Gibson, Dunn & Crutcher, and has more than 10 years of experience working in mergers and acquisitions.

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