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EU Commitments in Pharmaceutical Mergers & Acquisitions

Merging Parties' Guidelines on the Notification of Complex Concentrations

Towards a Fairer System

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ABSTRACT

Commitments under the EU merger control have been used as the tool to balance the preservation of fierce competition in the single market and the positive impact of M&A activity both in Europe and worldwide. Infrequently, the complex competitive analysis of concentrations results in the finding of serious doubts as to the compatibility of the transaction with the common market. In order to solve the Commission's concerns, it is for the notifying parties to submit acceptable commitments which entirely and effectively eliminate all impediments to competition. The adequacy of remedies and other aspects of the procedure influencing the negotiation of commitments, and the notification procedure of complex mergers in general, are of core relevance to precisely advise merging parties.

The present thesis clarifies the current practice of commitments in M&A, in particular, in the pharmaceutical sector, the most advisable strategies for merging entities on the preparation and during the notification procedure and lastly, this paper identifies practical problems and suggests potential improvements. The analysis firstly examines the regulatory framework of commitments and therefore Regulations, Guidelines and Notices are addressed. Secondly, the Commission's approach and the study of its decisions, with great focus on the specificities of the pharmaceutical industry. Thirdly, the notifying parties' perspective in relation to the difficulties or ease given by the Commission and the desirable enhancements. And finally, the examination of the law, the decisions and the approach of all players involved lead to the finding of some of the best practices for merging parties, together with potential developments for the upcoming years.

KEYWORDS

EU Merger Control. European Commission. Notifying parties. Notification Procedure. Complex concentrations. Competition concerns. Commitments. Divestiture. Negotiation of remedies. Business strategies. Pharmaceutical sector. Pharmaceutical Mergers & Acquisitions.

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Lund, Sweden. May 2016.

Cristina Muíño Palomar

ABBREVIATIONS

AIP	Active Ingredient Pharmaceuticals
ATC	Anatomical Therapeutic Chemical classification
DG	Directorate-General
EC	European Community
EEA	European Economic Area
EphMR	European Pharmaceutical Market Research Association
EU	European Union
EUMR	European Union Merger Regulation
FTC	Federal Trade Commission
ICN	International Competition Network
M&A	Mergers and Acquisitions
MS	Member State
NACE	Statistical Classification of Economic Activities
OTC	Over the counter drugs (non-prescribed)
PBIRG	Pharmaceutical Business Intelligence and Research Group
Rx	Prescribed drugs
SIEC	Significant Impediment to Effective Competition
TFEU	Treaty of Functioning of the European Union
US	United States of America

1. INTRODUCTION

1.1. Background

Competition policy in the Union protects fair competition in the single market to, among other aims, create incentives for firms to be more efficient in order to stay ahead of rivals, thereby ensuring the development of higher quality, lower prices, wider choice and innovation, ultimately benefiting European customers.[1] In this context, companies are attracted to join forces in order to increase their competitive position both in the Union and global markets. Although the transactions' economic benefit is not discussed, some concentrations might undermine competition, usually by creating or strengthening a dominant player. Under these circumstances, the European Commission is enhanced by the Treaties to control that concentrations do not significantly impede effective competition in the single market or a substantial part of it.[2]

The EC Merger Regulation from 2004 developed merger control in the Union to favour those transactions in line with dynamic competition and growth of European industry and to forbid operations which will harm European consumers by eliminating or weakening the competitive process in the market.[3] Mergers and acquisitions with a European dimension, usually assessed by reference to turnover above certain thresholds, are subject to the prior notification obligation.[4] Once all the necessary information is provided by the notifying parties,[5] the Commission assesses, within the time limits, 25 to 35 days for Phase I, and 90 to 125 for Phase II, the compatibility of the concentration with the single market.[6]

While most of the mergers investigated by the Commission do not raise competition concerns, around 5 to 8% of notified reorganisations are found to impede effective competition. The Commission has pro-

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[1] DG for Communication, *The European Union explained: Competition*, European Union, November, 2014, pages 3 and 8.

[2] Consolidated Version of the Treaty on the Functioning of the European Union, 2012/C 326/01, of 13 December 2007, article 3(1)(e) and 119.

[3] Council Regulation 139/2004 of 20 January 2004 on the control of Concentrations between Undertakings (hereinafter, EUMR), Recital 4.

[4] See in relation to concentrations with Community dimension, EUMR, article 1(2), and to the effect of the obligation of prior notification, EUMR, art. 4.

[5] Annex I of EUMR and Commission Regulation (EC) No 802/2004 (hereinafter, the Implementing Regulation), Form CO relating to the notification of a concentration pursuant to Regulation 139/2004 (hereinafter Form CO).

[6] EUMR, article 10.

hibited a merger in really few cases and in the large majority competition concerns are solved through remedies offered by the parties, either at Phase I or Phase II of the investigation.[7]

Acknowledged the rare circumstances under which commitments have to be suggested, with respect to the pharmaceutical sector, data indicates a slightly different picture.[8] First of all, the approval of adequate remedies in the pharmaceutical sector has been proven to be more effective than in other industries. Since the EUMR entered into force, no transaction has been prohibited and only one case under the NACE code C.21 has gone into the Phase II of the investigation.[9] On the other hand, the rate of cases subject to commitments points out a significantly higher level of intervention. Such scene evidences that, since the early 1990s, the consolidation of the sector has been driven by mergers and acquisitions of the largest firms. Hence, the Commission has been required to balance human health improvements through joint forces and the protection of the competitive process across the Union and towards global markets.[10] As exemplified along the following lines, commitments in the pharmaceutical sector are inevitably influenced by the demand for safe, effective, innovative and affordable medicines in Europe.[11]

1.2 Purpose and Research Questions

This thesis is aimed at examining EU commitments in M&A, in particular, in the context of the pharmaceutical sector. The purpose is to offer a clearer view of the current practice of commitments under the EU merger control in order to assist merging parties and to investigate required improvements to the process.

Although greater clarification of the commitments' legal framework might also be welcomed, there is a wide amount of Guidelines and decisions for understanding the Commission's assessment. However, regarding the difficulties that notifying parties face in the negotiation and acceptance of commitments, the information cannot be easily obtained. The importance of confidential business information and the

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[7] White Paper, *Towards a more effective EU merger control,* 9th July, 2014, para. 6.

[8] Concluded from the European Commission Merger Case Search, 22 % of the notified reorganisations under the NACE code C.21 are subject to commitments.

[9] Case No COMP/ M. 5046 - *Friesland Foods/ Campina.*

[10] Charles River Associates, *Innovation in the Pharmaceutical Sector,* 8 November, 2004, pages 104 to 120.

[11] Communication from the Commission. *Executive Summary of the Pharmaceutical Sector Inquiry Report*, 8 July, 2009.

lack of details in the Commission's decisions regarding the actual negotiation process with the notifying parties makes it difficult to fully understand the process of identifying adequate commitments.

The focus is on concentrations in the pharmaceutical industry which some might argue to be even more complex and urgent, taking into account the importance of long-term R&D and innovation in the sector, in connection with the fierce competition from elsewhere outside the Union and the enormous repercussion on the health of the citizens of Europe.[12]

In order to achieve the purpose, the following research questions will be addressed:

1. *What is the current EU practice of commitments, in particular, in pharmaceutical M&A?*

   In relation to this question, the research will examine the regulatory framework of commitments and analyse the Commission's approach in order to clarify the negotiation and approval of commitments.

2. *What are the most advisable practices for future notifying parties?*

   The second question aims to identify the most convenient strategies in the notification process, and particularly, the negotiation of commitments in order to offer guidance for potential merging parties.

3. *What are the potential improvements to the EU practice of commitments?*

   The adequacy of commitments and the current negotiation process of remedies will be scrutinised in order to find potential improvements. Among others, the proportionality of the remedies or the need for greater transparency and wider international cooperation will be assessed.

[12] Opinion of the European Economic and Social Committee on the 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: *Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector,* COM (2008) 666 final, 2009/C 318/14.

1.3 Methodology

This thesis combines the legal traditional method and a qualitative method to provide a practical overview of commitments in pharmaceutical Mergers and Acquisitions. The dogmatic and traditional method is used to describe and analyse the current practice of commitments in the European Union and to establish the present state of the law. Conclusions will be based on regulations, notices, guidelines, decisions and academic articles. The descriptive and analytical research gained through this method are influenced by politics and economics. The assessment of the EU merger control and the Commission's approach cannot avoid the inclusion of social and political circumstances affecting the Union and the development of the internal market.

The qualitative method is used to interview international lawyers with the greatest experience in the notification procedure of M&A. The collection of the data given by the practitioners is aimed at identifying the most advisable strategies for the notifying parties and other aspects of the process, thus, contributing with a practical perspective to this research.

The qualitative method consisted of standardised open-ended interviews. The content of the interviews is structured in the ten questions included in *"Annex I"*. The questionnaire was asked in a defined order and in a set manner to ensure no variation between interviews. The questions have been distributed in advance to every practitioner involved and the telephone discussions were conducted under the same procedure during the month of March until the middle of April.[13]

"Annex II" includes a list of the ten leading international law firms selected. The order of the list is random as all the included firms are of the highest reputation. EU Competition experts in those firms were approached in the order prescribed by the list until a total of six interviews were reached. The practitioners were interviewed according to their willingness to respond. Therefore, in case of the delays or negative answers, the next one included on the list was contacted.

The sample size of six interviews has been decided taking into account the nature and design of this study along with the following grounds. Firstly, the purpose of this qualitative method was never to reach the largest number of practitioners, rather contact those with the greatest experience in order to

[13] L. A. Burke and M. K. Miller, *Phone Interviewing as a Means of Data Collection: Lessons Learned and Practical Recommendations.* Forum: Qualitative Social Research, Vol. 2 Nº 2, 2001 and D.W. Turner, *Qualitative Interview Design: A Practical Guide for Novice Investigators.* The Qualitative Report Vol. 5 Nº 3, 2010.

obtain an overview of the highest quality legal advice given to merging parties. Hence, the number of six of some of the leading international law firms in Europe has been considered enough by this writer to reach the level of saturation. The outcome of the interviews determined the adequate amount of sample data required to exemplify an accurate picture of the current situation of commitments.[14] Secondly, the choice of six interviews has been settled anticipating potential misfortunes in the performance of certain interviews within the months of March and April, as well as other practical limitations, together with the possibility of not obtaining positive responses from all ten different law firms included in *"Annex II"*.[15]

"Annex III" includes the list of respondents who contributed to the Survey, together with a brief explanation of their extensive knowledge in the area subject to this research. The short mention of the lawyers' areas of expertise is intended to indicate, according to the selecting criteria used to determine the targeted interviewees, their suitability to achieve definite and careful results. The answers given by the practitioners are not directly linked to the particular respondent or to their corresponding law firm, thereby ensuring more open discussions. Consequently, the practitioners have been named A, B, C, D, E and F and the random letter allocated to each lawyer does not respond to the order of the Annex.

"Annex IV" contains the transcripts of the six interviews performed. The transcripts are aimed at allowing the reader to test himself the practical information under which this thesis has been based, in particular but not exclusively, in respect of Chapter 4. Only comments risking the anonymity of the respondents have been excluded from the transcripts and the information included is the complete source obtained from the contact with the lawyers.

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[14] L. Webley, *Qualitative Approaches to Empirical Legal Research, Academia*, Chapter 38 of The Oxford Handbook of Empirical Legal Research, Oxford, OUP, 2010.

[15] R. Edwards and J. Holland, *What is a Qualitative Interviewing?* Bloomsbury Academy, 2013, pages 7 and 65 to 67.

1.4 Delimitations

Firstly, the assessment of the EU merger control is asserted in the light of the current practice and limited to concentrations in Europe, thus, international comparative merger control laws are not investigated. Only mergers with a European dimension notified directly to the Commission are assessed, setting aside the circumstances where the referral notifications come into play.

Secondly, the focus is located on the negotiation of commitments and therefore on transactions raising competition concerns and notified by the merging parties in order to yet obtain clearance. Provided vertical and conglomerate mergers are not likely to raise competition concerns, this thesis exclusively analyses horizontal overlaps given they are the most common and harmful to free competition.

Thirdly, the study examines the negotiation procedure and the assessment of adequate remedies. The analysis does not include post-clearance matters such as the implementation of obligations and conditions annexed to the commitments, potential appeals before the EU Courts or infringement proceedings.

Fourthly, although many of the aspects that aim to be clarified through this research could be applicable to other sectors, or in general to concentrations, the study focus on the pharmaceutical industry and consequently, no mention to the particularities of other industries is included.

1.5 Terminology

Commitments and Remedies: Although commitments and remedies may have distinct meanings in the general language, the two concepts are understood equally for the purposes of this thesis and used indistinctly. Remedies in the context of EU merger control relate to those modifications applied to a concentration, where competition concerns are found by the Commission, in order to render the transaction compatible with the single market. The notion of commitments refers to those remedies suggested by the notifying parties subject to be implemented after clearance, unlike measures which modify the transaction prior to a Commission's decision. Thus, where the Commission considers that the commitments submitted by the parties solve competition concerns, the concentration will be approved subject to conditions and obligations in the implementation of such commitments. Provided that remedies might be seen as a wider category which includes commitments, for the purposes of this thesis, where referring to

remedies, the research relates to the limited concept of those modifications suggested by the parties in order to clear the transaction subject to conditions.[16]

Merging parties and Notifying parties: These expressions refer to the undertakings under whom the notification obligation relies on accordance with Article 4 of the EUMR. For the purposes of this thesis, these terms tend to cover all situations irrespective of the specific notifying entities of the concrete case, i.e, acquirer, merging parties, bidder…

Parties: In line with the delimitations of this thesis, the reference to parties is limited to the notifying parties. Therefore, other involved actors, that is, those part of the proposed concentration other than the notifying parties such as the seller and the undertaking which is the target of the concentration, or third persons such as customers, suppliers and competitions provided sufficient interest within the meaning of Article 18(4) EUMR are excluded from the meaning of "parties" unless clearly clarified.[17]

Pharmaceutical Sector or Drugs Industry: These terms are solely used to refer to the NACE code C.21, including the manufacture of basic pharmaceutical products and pharmaceutical preparations. Hence, other activities related to Life Sciences, the Healthcare Sector or the Biotechnological Industry and thus falling outside C.21.1, C.21.0, C.21.2 and C.21.2.0 are not included in this thesis.

[16] Commission Notice on Remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004, (hereinafter, the Notice on Remedies), para. 5.

[17] Implementing Regulation, article 11.

2. COMMITMENTS UNDER THE EU MERGER CONTROL

2.1 Primary and Secondary Law

2.1.1 Treaty provisions

Commitments under the EU Merger Control are aimed at solving competition impediments and therefore at ensuring that the transactions authorised will not contradict the objectives pursued by the common commercial policy in the Union. On that line, as established in Articles 3, 119(1) and (2), and 120 of the TFEU, the economic policy in the internal market, and thus, the concentrations approved by the Commission, shall be in accordance with the principle of an open market economy with free competition. Hence, where the Commission determines that a transaction risks competition, the authorisation should be subject to commitments capable of remedying the obstacles to competition previously identified.

2.1.2 Council Regulation (EC) No 139/2004

Commitments under the EU Merger Control refer to those modifications intended to solve competition concerns and agreed vis-à-vis between the Commission and the notifying parties in order to render a concentration compatible with the internal market. According to the principles settled by the EUMR, commitments submitted by notifying parties should be proportionate to the competition concern identified by the Commission and entirely eliminate it.[18] In that context, pursuant to Article 2(1), concentrations within the scope of the EUMR will be assessed in order to determine whether they are compatible with the common market, thereby identifying when commitments are required.

As established under Article 6(1), the Commission shall initiate proceedings where a concentration raises serious doubts to significantly impede competition in the common market or in a substantial part of it. The Commission will assess the compatibility of the notified transaction having regard to the structure of all affected markets, the actual and potential competition from undertakings located either within or beyond the Community and the market position of the undertakings concerned. In case the Commission finds obstacles to effective competition through that assessment, in particular as a result of the creation or strengthening of a dominant position, the concentration shall be declared incompatible unless modifi-

[18] EUMR, recital 30.

cation by the parties, both before and after the initiation of proceedings, render the concentration compatible with the internal market.[19]

The assessment of commitments might influence the time limits established under Article 10 of the EUMR in order to allow for sufficient time for the analysis and market testing of the commitments offered. Consequently, Phase I shall be extended from 25 working days at most to 35 working days, starting the day after the receipt of the notification or after the information is complete, where the undertakings concerned offer commitments pursuant to Article 6(2) EUMR. With regard to the Phase II, the 90 working days limit shall be increased following commitments under Article 8(2) in the event that commitments have been offered less than 55 working days after the initiation of proceedings.[20]

In case the commitments suggested by the parties are considered to entirely solve the competition concerns identified by the Commission, conditions and obligations will be attached to the decision in order to ensure that the undertakings concerned comply and implement the commitments effectively.[21] In the case of failure to fulfil a condition attached to the decision, the approval does not materialise and consequently, if implemented, the transaction will be treated as a non-notified concentration implemented without authorisation. In the case of breaching an obligation, the Commission should be able to revoke the decision and as a consequence for both cases, impose appropriate financial sanctions.[22]

2.1.3 Commission Regulation (EC) No 802/2004

The Commission, empowered by Article 23 EUMR, laid down the consecutive regulatory framework with regard to the procedure and time limits for the submission and implementation of commitments pursuant to Article 6(2) and 8(2) EUMR under the Implementing Regulation.[23]

One original and ten copies of commitments, together with an electronic copy, indicating the confidential information and its reasons, as well as a non-confidential version, are to be submitted by the parties

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[19] With regard to concentrations incompatible with the internal market, EUMR, Article 2(3). In respect of clearance following modifications, EUMR, articles 6(2) and 8(2).

[20] In relation to the start of time limits, Article 10(1). To the effect of the extension of time limits, EUMR, Recital 35, Article 10(1), second paragraph, and 10(3).

[21] EUMR, recital 31, articles 6(2) and 8(2).

[22] To the effect of infringements of conditions and obligations, EUMR, recital 31, articles 8(4)(b), 8(5)(b), 8(6)(b) and 8(7). For the appropriate financial sanctions, EUMR, article 14(2).

[23] Implementing Regulation, recital 17 and chapter VI.

not later than the 20 working day from the receipt of the notification in case of commitments pursuant to Article 6(2), and not more than the 65 working days in case of commitments under Article 8(2) EUMR.

Among the Annexes attached to the Implementing Regulation, the Form RM relates to the necessary information for the submission of remedies in order to allow the Commission to examine whether those commitments are capable of preventing significant impediments to effective competition. That information includes the description of commitments, the conditions for implementation, the suitability to remove competition concerns and non-confidential summaries. In case of divestiture, a detailed description of the divested business and the impact of the commitments, as well as the grounds for a suitable purchaser and the time-framework for implementation must be enclosed.[24]

Ultimately, the regulatory framework for commitments establishes that the notifying parties are responsible for proposing suitable commitments to remove the Commission's competition concerns within the time limits established under Article 19 of the Implementing Regulation. Consequently, the transparency of the procedure is of major importance where expecting the parties to propose acceptable commitments. The Commission should grant the possibility of pre-notification contacts and maintain open discussions regarding practical and legal problems in the examination of the concentration. Even more, pursuant to Article 17, where requested by the parties, the access to the file after the Statement of Objections shall be granted in order to protect the rights of defense of the undertakings.[25]

2.2 Notices and Guidelines

2.2.1 Commission Notices

2.2.1.1 Commission Notice on Remedies

The Notice on Remedies settles the general principles applicable to remedies acceptable to the Commission, the different types of commitments and the requirements for their proposal and implementation. The Commission retains the burden of proof concerning those concentrations that effectively impede competition, however, it is for the notifying parties to formulate appropriate remedy proposals to elimi-

[24] Implementing Regulation, Annex IV, Form RM relating to the information concerning commitments submitted pursuant to article 6(2) and 8(2) EUMR, introduced by the Implementing Regulation (hereinafter, Form RM).

[25] Implementing Regulation, recital 11 and article 17; See also EUMR, recital 42 and articles 17(3) and 20.

nate the identified competition concerns. Similarly, merging parties are responsible for providing all necessary and detailed information to the Commission for the assessment of the commitments offered and their suitability to remove any significant impediment to effective competition.[26]

Albeit the Commission is not legally authorised to unilaterally impose commitments, it should communicate the competition concerns to the parties to allow them to formulate adequate remedies.[27] On that line, appropriate commitments shall eliminate competition concerns entirely and effectively, together with the certainty of being implemented in a short period of time and the ability to be monitored.[28]

Commitments of structural nature are preferable under the EUMR, mainly because once implemented, they do not require further monitoring. However, other commitments are also capable of being accepted in exceptional circumstances where their outcomes are at least as effective as divestiture. Behavioral remedies consist of future behavior such as committing to not raise prices, to not reduce supply, to decrease product ranges or to the removal of brands.[29]

Although divestiture is considered to be the benchmark of the Merger Regulation, other structural remedies might also be acceptable to the Commission. Structural remedies should ensure with the requisite degree of certainty that the new commercial structures will be sufficiently workable and lasting. Moreover, they should allow an effective implementation as to ensure that the significant impediment to free competition will not materialise.[30]

With regard to the more acceptable commitments, and having regard to the pharmaceutical sector, the Commission Notice points out in paragraph 38 that, where the competition concerns arise from a market position held due to technology or IP rights, for instance, a patented molecule, an originator drug or a high-tech therapy, it is preferable to remedy competition concerns by divesting such technology due to the fact that it eliminates a lasting relationship between the merged entity and its competitors. However, the Commission may accept licensing agreements as an alternative to divestiture where, for instance, the divestiture would impede efficient or on-going research.

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[26] Notice on Remedies, para. 6.

[27] *idid*, paras. 6 to 11 and 85. See Case T-310/01 *Schneider Electric v Commission*, ECLI:EU:T:2002:254, paras. 442 to 444.

[28] Notice on remedies, paras. 9 and 13.

[29] *ibid*, paras. 13 to 15, 61, 66 and 69.

[30] In relation to the preference for structural remedies, *ibid*, paras. 17, 22 and 61 and seq. In respect of the requisites for eliminating competition concerns, *ibid*, para. 10.

In the case of divestiture, the Commission finds stand-alone businesses to be more appropriate. Nonetheless, the principle of proportionality in relation to the competition concerns implies the possibility of accepting carve out and reverse carve outs. The business to be divested shall be viable, if operated by a suitable purchaser, to compete effectively with the merging entity on lasting basis. For the business to be viable, all assets and personnel, as well as other essential functions such as facilities, R&D and other technology to meet the on-going needs, should be included in the divestiture. Additionally, it may sometimes be necessary to include assets related to markets where the Commission did not find competition concerns in order to guarantee the creation of an effective competitor in the affected market.[31]

Under the assessment of a viable business, the assets of the future purchaser will not be taken into account, unless there is already a specific purchaser. More commonly, the Commission confers a fixed time limit to the parties in order to find a suitable purchaser after approval. On the contrary, where the identity of the purchaser is crucial for the viability of the business, parties might be required to enter into a binding agreement with a suitable purchaser during the notification procedure, the so-called fix-it-first buyer. On the other hand, the Commission may sometimes consider up-front buyer solutions necessary to confer clearance. In such case, the parties, instead of entering into a binding agreement prior approval, commit not to implement the proposed concentration unless and until they have entered into a binding agreement with a purchaser approved by the Commission. In any case, a suitable purchaser must be able to exercise an active competitive force, independent of and unconnected to the merging entity.[32]

The Notice establishes in the same line the procedure and time limits for the submission and implementation of commitments. In relation to Phase I, the Commission should inform the notifying parties of its serious doubts before the deadline, not later than the 20 working day. Such deadline is aimed at conferring the Commission sufficient time to consult the commitments with the Authorities of MSs and, when considered appropriate, also with third parties in the form of market test in order to certainly conclude that the remedies proposed will entirely and effectively eliminate competition concerns. With regard to Phase II, the Commission will assess whether the commitments suggested solve all concerns raised in the Statement of Objections. Additionally, the Notice points out the lack of obligation of the Commission to accept remedies after the legal deadline, 65 working day, and the exceptional circumstances under which it may accept to do so.[33]

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[31] See for stand-alone business and carve outs, *ibid*, paras. 32 and 35. In respect of a viable business, paras. 23 to 28.

[32] *ibid*, paras. 47 and 48. To the effect of the different mechanisms for establishing a suitable purchaser, paras. 50 to 57.

[33] In relation to the deadline in Phase I, *ibid*, para. 78. For the required information, *ibid*, paras. 79 and 82. To the effect of the Commission's assessment of commitments, *ibid*, paras. 80 to 83.With regard to Phase II, *ibid*, para. 88 to 94.

2.2.1.2 Commission Notice on the definition of the relevant market

The guidance given by the Commission in relation to the definition of the relevant market cannot be disregarded taking into account that it is the criteria and evidence under which the Commission relies upon to conclude that a concentration significantly impedes competition. The Notice aims at increasing the transparency of Competition policy, in particular, regarding Merger Control. A better anticipation of the Commission's competition concerns is expected to help companies and their advisors in their own internal decision-making when contemplating, for instance, acquisitions, mergers or joint ventures.[34]

On that line, the delineation of the market is essential to identify the need for remedies and submit appropriate commitments. Further analysis on the relevant product and geographic market is asserted under the subsequent Chapter as a result of the relevance of those definitions to find adequate commitments and due to the specific features of the pharmaceutical sector in this regard.

Some provisions of the Notice are remarked above due to the particular interest they bring to this study, without the aim, on the contrary, of disregarding the other criteria settled for defining the market.[35] Firstly, the Notice acknowledges the possible differences on the scope of markets when assessing concentrations, where the analysis is essentially prospective, from an analysis of a past behavior deemed by Articles 101 and 102 of the TFEU.[36] Secondly, the product dimension depends very much on the characteristics and specificities of the industry, factors which will be observed in the Commission's practice regarding the pharmaceutical sector in Chapter 3.[37] Finally, the geographic markets are carefully assessed in the light of continuing the process of market integration, where geographic markets tend to be broader and legislative barriers isolating national markets from each other have been removed. Such point is worth mentioning due to the national legislative weight of the pharmaceutical sector, as exemplified under Section 2.3.[38]

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[34] Commission Notice on the Definition of the Relevant Market for the Purposes of Community Competition Law, 97/C 372/03 (hereinafter, Notice on the Relevant Market) paras. 2, 4 and 5.

[35] *ibid*, paras. 7, 8, 9, 13 to 31.

[36] *ibid*, para. 12.

[37] *ibid*, para. 25.

[38] *ibid*, para. 32.

2.2.1.3 Commission Notice on the access to the Commission file

The identification of adequate commitments and the predictability of the Commission's approach is directly influenced by the access to the file that the parties have during the negotiation procedure.

The Commission Notice on the access to the Commission file provides the right to the parties to acquaint themselves with the information included in the Commission file to ensure that they can effectively express their views, thereby protecting their rights of defense. The file in a competition investigation consists of all documents which have been obtained, produced or assembled by the DG for Competition during the investigation, with the exception of internal documents, business secrets of other undertakings or other confidential information. The documents excluded from the file, in particular, the internal documents, cannot be incriminating or exculpatory and cannot be part of the evidence under which the Commission will rely on its assessment.[39]

As stated in paragraph 28 of the Notice, and in accordance with Article 18(1) and 18(3) of the EUMR and 17(1) of the Implementing Regulation, the notifying parties will be given access to the file upon request at every stage of the procedure following the Commission's Statement of Objections.[40]

2.2.2 Best Practice Guidelines

2.2.2.1 Best practices on the conduct of merger proceedings

The Best Practice Guidelines aim at promoting the spirit of cooperation between the Directorate-General for Competition and the legal and business community, advising frank and open discussions throughout the procedure in order to enhance the efficiency, transparency and predictability of the investigations.

The Guidelines emphasise the importance of pre-notification contacts, giving the opportunity to discuss the intended concentration informally and in confidence. Pre-notification contacts favour the greater preparation of the information required and avoid declarations of incompleteness, but more importantly

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[39] The Commission Notice on the rules for access to the Commission file in cases pursuant to Articles 81 and 82 of the EC Treaty, Articles 53, 54 and 57 of the EEA Agreement and Council Regulation (EC) No 139/2004 (hereinafter, Notice on the access to the file), paras. 8 and 10. To the effect of documents excluded, *ibid,* paras. 12 to 20.

[40] *ibid*, paras. 26 and 28.

to this study, those contacts facilitate the identification of competition concerns at an early stage.[41] The extent of the pre-notification depends on the complexity of the transaction but the Guidelines suggest that contact should be initiated at least two weeks before notification. Notifying parties are advised to involve legal advisers and business representatives at this stage with the aim of having early fruitful discussions sharing a good understanding of the business and the functioning of the markets in question.[42]

In the context of the notification procedure, the DG Competition will provide guidance to the parties as to the general appropriateness of commitments. Such guidance can be given in the state of play meetings aimed at exchanging information. In relation to remedies, the state of play meeting before the expiry of 3 weeks into Phase I ensures that notifying parties will be aware of the serious competition doubts in order to prepare the formulation of commitment proposals before the deadline of the 20 working day. In the same line, the state of play included within 2 weeks after the decision of opening the Phase II of the investigation facilitates the understanding of the Commission's concerns and the identification of the commitments required to obtain approval.[43]

In addition to the access to the file after the Statement of Objections, the DG Competition provides notifying parties with the opportunity of reviewing and commenting key documents consisting in substantive submissions of third parties or market studies.[44]

2.2.2.2 Best practice guidelines: Commission's Model texts

The Commission recognises that timing is crucial where merging parties reach the remedies stage and therefore the standardised model of Divestiture Commitments and Standard Trustee Mandate are aimed at relieving the notifying parties of the time and resource consuming negotiation of all standard terms. The Best practice guidelines, apart from pursuing that parties concentrate more on the actual substance and implementation of commitments, are intended to increase transparency and legal certainty.[45]

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[41] DG COMP, *Best Practices on the conduct of EC merger proceedings,* of 20 January, 2004. paras. 5, 6, 7, 16, 19 and 20.

[42] *ibid*, para. 5 to 11, 16, 19 and 20.

[43] *ibid*, para. 33, 40 to 46.

[44] *ibid*, para. 45

[45] DG COMP, *Best Practice Guidelines: The Commission's Model Texts for Divestiture Commitments and the Trustee Mandate under the EC Merger Regulation* (hereinafter Model Texts) of 5 December, 2013. Paras.1, 2, 5 and 6.

Since the implementation of commitments falls outside the scope of this thesis, comments concerning the Standard Trustee Mandate will be suppressed. However, attention is given to the importance of following the Model text to provide all the necessary information concerning the substance and the effective implementation of commitments in order to obtain the Commission's approval.

In relation to the Standard Model for Divestiture Commitments and Standard Commitments, Section A establishes the definitions of the terms used throughout the Commission Model Text. Section B is intended to define the divestment business and the procedure under which is to be implemented. The description of the divestiture should contain in detail the schedule to the commitments and the specific assets, personnel and key personnel to be included. Section C deals with related commitments to maintain the viability, marketability, and competitiveness of the divestment business, as well as the preservation of independence from the merging entity. Section D consists of the provisions relating to the suitable purchaser, section E, the duties and obligations of both types of trustees and section F, the review clause.[46]

2.2.3 Guidelines

The Commission has published further Guidelines on the assessment of horizontal and non-horizontal mergers on the control of concentrations between undertakings.[47] With regard to horizontally affected markets, the combined market share of the merging parties and the HHI levels are the starting point to compare the competitive conditions that would result from the notified merger with the conditions that would prevail without the merger. In order to determine the likelihood that the merger will result in anti-competitive effects on the market, either through non-coordinated or coordinated effects, the Commission assesses, in the absence of countervailing factors, the ability of the parties to increase prices, reduce output, choice of quality of goods and services, diminish innovation, or otherwise influence the parameters of competition.[48]

Taking into consideration the importance of improving the standards of living in the EU, special mention is required with respect to efficiencies as a countervailing factor. In particular, in sectors such as the

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[46] *ibid*, paras. 7, 15, 18, 21, 25, 27 to 34.

[47] Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings, 2004/C 31/03, (hereinafter, HMG) and Guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings, 2008/C 265/07.

[48] In relation to the comparative merger assessment, HMG, paras. 8 and 9; In respect of market shares and concentration thresholds, Section III; To the effect of anti-competitive effects, Section IV; For countervailing factors, Section V, VI and VII.

pharmaceutical industry where the development of technical and economic progress have an enormous impact on consumers, specifically, on the health of European patients. The Commission Guidelines on horizontal mergers provides the possibility of finding that efficiencies generated by a merger are likely to counteract the adverse effects which the merger might otherwise have. In that context, the Commission is in a position to conclude on the basis of sufficient evidence that a concentration is compatible with the internal market where the efficiencies generated are likely to enhance the ability and incentives to act pro-competitively as long as those efficiencies fulfil the cumulative conditions of benefiting consumers, being merger-specific and verifiable.[49]

2.3 Pharmaceutical framework

The assessment of pharmaceutical concentrations is inevitably affected by the sector features. This section intends to provide with a brief overview of the specificities likely to influence the finding of adequate commitments.

The European Commission has repeatedly expressed its concerns, together with the Member States, of ensuring the competitiveness of the industry, the sustainable financing of the national health care systems for an aging European population, and ultimately, the access to innovative, safe and affordable medicines for EU citizens.[50]

Firstly, the large national regulatory framework in the industry often divides drug markets along national lines, leading to a more complex integration of pharmaceuticals in broader markets. As a result of the national legislative weight, the European Commission, the Member States and stakeholders are called to cooperate, among other aims, to increase transparency in the industry, grant better access to medicines and foster valuable innovation likely to generate therapeutic and clinical benefits, quality of life developments and other socio-economic improvements.[51]

The Commission acknowledges that in recent years, the consolidation of the sector has been intensified through concentrations amongst large originator companies, acquisitions of generic and biotech compa-

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[49] *ibid,* paras. 76 to 88.

[50] Communication from the Commission. *Executive Summary of the Pharmaceutical Sector Inquiry Report*, 8 July, 2009.

[51] High Level Pharma Forum, *Final Conclusions and Recommendations of the Pharmaceutical Forum*, Final Report 2005-2008, pages 2, 12, 75, 100 to 103; Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP), Advises from the Meetings on 27 January 2015, 6 May 2015, 20 October 2015 and 10 March 2016.

nies by originators or mergers and acquisitions between the generic industry. On the other hand, the introduction of novel medicines and generic launch as a consequence is on the decline. Similarly, most of the R&D investment has gradually been relocated from Europe to the US and Asia. In such context, the EU merger control cannot disregard the key role of innovation and R&D and the weight of intellectual property rights in the industry.[52]

The substantive assessment of commitments should be aligned with the common set of guiding principles, thus, the Commission shall exclusively allow the consolidation of the sector where the concentration is in accordance with dynamic competition and the remaining market structures are likely to foster innovation. Accordingly, remedies are requested where the post-merger entity will be in a position to decrease its R&D paths or its investigation efforts because of low constraint forces in the market. Similarly, commitments should not undermine on-going research driven by the notifying parties. On that line, the Commission's assessment, taking into account this context, pursues continuity of the parties' R&D activities after clearance. Divestment of assets, licensing agreements or other facilities contracts should guarantee that the merging parties are still in a position to contribute to their previous research or that, on the contrary, other players in the market will effectively develop those innovative drugs.[53]

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[52] Opinion of the European Economic and Social Committee on the 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: *Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector,* COM (2008) 666 final, 2009/C 318/14.

[53] L. Hancher and W.Sauter, *A dose of competition: EU antitrust law in the pharmaceutical sector,* TILEC DP 2015-2017, September, 2015. In respect of R&D continuity, Notice on Remedies, para. 38.

3. EUROPEAN COMMISSION'S APPROACH

3.1 Pharmaceutical overview

Traditionally, the pharmaceutical sector has been less likely to rise competition concerns from a merger perspective. The industry is relatively fragmented taking into account that there is a large number of players and none of them currently have more than 10% of global shares by revenue. On the other hand, and unless the merger represents delays in generic entry, the existence of numerous patent-protected drugs imply that concentrations may not be detrimental to competition. Firstly, if there was no competition in the market prior to the merger as a result of legal monopolies and secondly, if competition is likely to be restored after the expiration of the patent. On the contrary, the Commission has been found to intervene more often in pharmaceutical mergers. The question arising is therefore what reasons lead to a higher demand of modifications in pharmaceutical reorganisations.[54]

Under the NACE Code C.21, since 1990, 137 concentrations were notified, 30 of which were approved subject to commitments and 2 withdrawn. Numbers after the EUMR came into force show that the Commission has maintained a rate of between 21 to 22% of transactions requiring commitments, being more than double in comparison to other sectors. 21 transactions out of 91 notified cases needed remedies.[55] Is the Commission stricter clearing pharmaceutical concentrations? Do those concentrations involve larger multinational companies with greater horizontal overlaps?

Firstly, and equivalently to other sectors, the Commission's merger assessment focuses on avoiding Type Errors II but trying not to impose undue burdens on the merging parties. The substantive analysis of mergers in the pharmaceutical sector is not fundamentally different from the one carried out in other innovation-intensive regulated industries. Nonetheless, it presents several specificities in relation to the market definitions, the weight of high technology or regulatory barriers to entry and the even stronger preference for stand-alone divestitures of packages of drugs.[56]

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[54] G. Duhs and M. Mahmood, *Pharmaceutical Mergers: Changes in the Regulatory Landscape,* Pharmaceutical Technology Europe, Industry Insider, January, 2015, pages 10 and 11.

[55] Concluded from the European Commission Merger Case Search, NACE Code C.21.

[56] F. Have, J. Martinez and E. Demertzi, *The European Commission's Pharmaceutical Merger Control Practice: An Overview of the State of Play*. World Competition 39 no. 1, 2016, pages 86 and 94.

Moreover, the growth of the drugs industry has been driven by large mergers. This can be observed in the decisions given that most of them are subject to the same multinational players. In that context, the Commission, taking into account the strategic role of the sector in Europe, carefully assesses the likelihood that those big concentrations will raise serious doubts. Moreover, pharmaceutical companies tend to have diverse drug portfolios and therefore it is usual that concentrations include a large number of affected markets. Consequently, despite the fact that remedies are often required, commitments represent a small proportion of the business taking into account the size of the transactions.[57]

Additionally, although prohibition decisions do not occur often in any sector, it is still worth mentioning that the Commission has not prohibited any transaction within the drugs industry. Looking at the Commission's practice throughout 25 years, although not common, some transactions have been forbidden as it recently happened in *Deutsche Börse/ NYSE Euronext* or *Ryanair/ Aer Lingus*. On the contrary, pharmaceutical concentrations have always obtained the Commission's clearance and even more, since the EUMR came into force only one case has been subject to an in-depth investigation.[58]

3.2. Identification of competition concerns

A concentration which would significantly impede effective competition, in the common market or in a substantial part of it, in particular as a result of the creation or strengthening of a dominant position, shall be declared incompatible with the common market unless remedies are submitted. As confirmed by the EU Courts, the need for commitments can only be addressed once the Commission has clearly clarified and communicated to the parties the identified threat to competition. Therefore, the Commission carefully defines the affected markets and drives the SIEC test to decide whether the transaction raises serious doubts as to its compatibility with the internal market.[59]

The Commission's concerns result in over 80 per cent of the cases from horizontal overlaps whereas only 6 per cent of concentrations raise serious doubts due to purely vertical situations.[60] Even more, the anti-competitive effects identified during the competitive assessment have been non-coordinated appro-

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[57] *ibid.*

[58] To the effect of recent prohibition decisions, M.6166 - *Deutsche Börse/ NYSE Euronext* and M.6663 - *Ryanair/ Aer Lingus III*. In respect of the only pharmaceutical case subject to Phase II, M. 5046 - *Friesland Foods/ Campina.*

[59] D. Hoeg, *European Merger Remedies Law and Policy*, Hart Publishing, 2014, page 35. See also Case T-310/01, *Schneider v Commission,* paras. 442 to 444.

[60] D. Hoeg, *European Merger Remedies Law and Policy*, Hart Publishing, 2014*,* para. 36

ximately in the 84 per cent of cases, while only 14 per cent of commitments were aimed at collective dominance. In such context, the analysis is limited to horizontal overlaps and more attention is given to single dominance situations.[61]

This section asserts some of the pharmaceutical specificities with regard to market definitions and the competitive assessment, directly affecting the need for remedies. In particular, and following the Commission's findings, the section differentiates between finished dose pharmaceuticals and future products. Firstly, finished dose pharmaceuticals are essentially drug products in the form in which they are marketed for use. Secondly, future products, also known as pipelines, relate to the drugs that a pharmaceutical company holds, either under discovery or under research and development.

In addition, the Commission has considered under certain circumstances active ingredients, contract manufacturing and out-licensing of pharmaceuticals to be separate markets from the downstream of finished dose drugs. The serious doubts arisen from these activities are usually in vertically affected markets and therefore their assessment is excluded in accordance with Section 1.4.[62]

3.2.1 Finished dose pharmaceuticals

3.2.1.1 Definition of the relevant market

The relevant market under which the Commission assesses a given competition issue is established by the combination of the product and the geographic market. Hence, the specificities of the market delineation of finished dose pharmaceuticals refer to both their product and geographic scope.[63]

A) Relevant Product Market

The Commission includes within the definition of the relevant product market, the interchangeable molecules, drugs and therapies, or suitable by the consumer, by reason of the medicines' characteristics,

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[61] DG COMP, *Merger Remedies study, Public Version,* October, 2005, pages 20 and 21.

[62] F. Have, J.T. Martinez and E. Demertzi, *The European Commission's Pharmaceutical Merger Control Practice: An Overview of the State of Play,* World Competition 39, no. 1, 2016, pages 108-112. For AIPs, see M.5253 - *Sanofi-Aventis/ Zentiva*, para. 179 et seq. or M.5865 - *Teva / Ratiopharm*, para. 393 et seq.; For contract manufacturing, see M.5953 - *Reckitt Benckiser / SSL*, para. 57 et seq. or M.7379 - *Mylan / Abbott EPD-DM,* paras. 463 to 465; For outlicensing of pharmaceuticals, *Teva/ Ratiopharm,* para. 408 et seq. or *Mylan / Abbott EPD-DM,* paras. 466 to 468.

[63] Notice on the Relevant Market, para. 9

their prices and their intended use.[64]

In the pharmaceutical context, the definition of the relevant market is influenced by the interplay between the therapeutic and the economic substitution. The Commission acknowledges that drugs with the same intended use or therapeutic application may still differ in terms of price and reimbursement status, medical prescription or patient preferences, consumption indications or other relevant attributes.[65] Where that is the case, the relevant product markets might be differentiated and only those drugs significantly constraining each other's market power should fall under the same definition.[66] The ATC classification, the distinction between OTC and prescribed medicines and the Commission's approach to generic and originator drugs are included below as some of the aspects which influence the assessment of horizontally affected markets in the pharmaceutical sector.

A.1) ATC Classification

According to the Commission's decisions, pharmaceuticals may be subdivided into therapeutical classes by reference to the European Pharmaceutical Market Research Association Anatomical Therapeutical Chemical Classification. The ATC classification is divided according to the pharmaceuticals' indications and used down to four different levels.[67]

The Commission generally uses the third ATC level as the starting point to investigate the relevant product markets, dividing medicines in terms of their therapeutical indication, i.e., their intended use. However, the Commission acknowledges the appropriateness of carrying out assessments at other ATC levels, or a mixture thereof, where the market indicates that the competition constraints faced by the undertakings differ from the third ATC category.[68] In fact, the recent Commission's practice evidences that competition issues arise more often at the molecule level, at the ATC4 or on the basis of a group of molecules.[69] Consequently, the ATC4 class, referring to the chemical group such as molecule class, formu-

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[64] *ibid*, para. 7.

[65] F. Have, J.T. Martinez and E. Demertzi, *The European Commission's Pharmaceutical Merger Control Practice: An Overview of the State of Play,* World Competition 39, no. 1, 2016, page 87.

[66] Case COMP/A.37.507/F3 - *AstraZeneca,* para. 370.

[67] European Pharmaceutical Market Research Association, *Anatomical Classification Guidelines,* 2016; EphMRA and PBIRG, *Classification Committee, Who we are What we do,* 2015.

[68] M.3751 - *Novartis/ Hexal,* para. 2; M.5295 - *Teva/ Barr*, para. 10 and 11; *Sanofi-Aventis/ Zentiva,* paras.12 to 16.

[69] M.5865 - *Teva/ Radiopharm*, paras. 12 to 14.

lation or mode of action, or the molecule level, according to medicines based on the same active pharmaceutical ingredient, have been frequently found by the Commission to be a more appropriate indicator. to delineate the market.[70]

On the contrary, the third level, therapeutic or intended use, has also been found to efficiently define the competition forces between drugs in numerous cases.[71] As an illustrative example, in the acquisition of SSL by Reckitt, the Commission in order to delineate the market of analgesics attended to the ATC3 classification, N2B, including all non-narcotic and anti-pyretics analgesics. The Commission, in its subsequent competitive assessment, took into account the combined market share of analgesic drugs falling within N2B, Reckitts' drug *Nurofen* (ibuprofen-based product) and SSL's drugs, *Syndo*l and *Paramol* (paracetamol-based product). Despite the fact that competition concerns were not found due to the strong presence of credible competitors in all segmented markets, this case can easily exemplify the impact on the Commission's outcome of the different levels of the Anatomical Classification. Meaning that, in case the Commission would have found the molecule level to be more appropriate, ibuprofen-based and paracetamol-based drugs would have been assessed separately and therefore, Reckitt's market share with regard to *Nurofen* will not have been incremented by SSL's market share in relation to *Syndol* and *Paramol* because of not sharing the same active ingredient.[72]

The Commission undertakes market investigations with regard to the demand and supply substitutability in order to decide which ATC level is the adequate to determine the scope of drugs exercising competition restraints to each other. For example, in *Teva/ Barr*, the demand-side substitutability indicated that the majority of hospitals did not consider switching to drugs based on a different molecule even if the price of the molecule increased significantly. Accordingly, the Commission concluded that the assessment could not only focus on the ATC3 classification but also on the molecule level.[73]

The Commission, although heavily relying on the ATC classification, acknowledges that therapeutically interchangeable drugs may still differ in terms of economic substitutability, for example, with regard to price and reimbursement status, mode of action, consumer preferences and other relevant attributes. As a

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[70] M.3544 - *Bayer Healthcare/ Roche*, para. 20; M.6613, *Watson/ Actavis*, para. 7; or *Teva/Barr,* para. 18.

[71] *Sanofi-Aventis/ Zentiva*, para. 55 to 59, 106, 109… or *Bayer Healthcare/ Roche*, paras. 21 to 23.

[72] To the effect of the relevant product market of analgesics, *Reckitt Benckiser/SSL*, paras. 17 to 19; To the effect of the Commission's competitive assessment, *Reckitt Benckiser/ SSL* paras. 67 to 73.

[73] *Teva/ Barr*, paras. 14 and 15.

result, the Commission often leaves open the relevant market because no ATC category or other indicators lead to an accurate result of the product market's scope.[74]

A.2) OTC and Prescription drugs

Over the counter drugs and Rx pharmaceuticals have been considered by the Commission as separate markets, even if the active ingredients are identical. However, the Commission still conducts the assessment on a case-by-case basis to test the adequacy of the distinction. Factors supporting such division relate to their different medical indications, legal framework or marketing and distribution conditions.

In short, OTC pharmaceuticals are advertised to the general public, meaning that consumers make their own choice, whereas advertising of prescribed drugs is restricted in most Member States. Doctors have an essential intervention in the choice of Rx pharmaceuticals and therefore marketing strategies target prescribers instead of patients. With regard to the legal framework of pricing and reimbursement practices, the price of prescribed drugs is influenced by the public health care system which reimburses completely or partially the purchase price. On the other hand, OTC drugs allow a more conventional market definition exercise because prices are often not regulated and purchases are in most cases not reimbursed, leading therefore to a higher price elasticity of demand.[75]

A.3) Originator and generic drugs

According to the Commission's view, originator and generics belong to the same relevant product market. Generics can efficiently substitute originator drugs after patent expiry, especially if the regulatory system encourages switching. Generic drugs are developed, authorised and marketed depending on the effectiveness and reliance of the copy of an innovator drug. In regulatory approval procedures, a generic drug manufacturer has to demonstrate that the generic version of the originator drug is biologically equivalent to the innovative drug in quality and purity terms. The originator drug and the generic copies are based therefore on the same molecule and consequently, each other's closest competitors.[76]

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[74] With regard to the same relevant market, *AstraZeneca*, para. 370. In respect of open ATC delineations, *Sanofi-Aventis/ Zentiva*, paras. 37, 42, 46 54, 66, 70, 83, 102 and 120; or M.7275 - *Novartis/ GlaxoSmithKline*, paras. 201 to 216

[75] *Novartis/ Hexal*, para.3; *Bayer Healthcare/ Roche* paras. 13 and 14; *Sanofi- Aventis/ Zentiva*, paras. 21 to 24 and *Teva/ Barr*, paras. 12 and 13. In respect of price competition, see *Teva/ Radiopharm*, para. 62 et seq.

[76] *Teva/ Barr,* paras. 14 and 16; *Sanofi-Aventis/ Zentiva*, para. 25 and *Teva/ Radiopharm,* para. 12.

B) Relevant Geographic Market

Relevant geographic markets are defined as the area in which the undertakings concerned are involved in the supply and demand of drugs or treatments, in which the conditions of competition are sufficiently homogeneous and which can be distinguished from neighbouring areas because the conditions of competition are appreciably different in those areas.[77] The Commission has consistently considered that the geographic market for pharmaceutical products, including generics, is national in its scope, as competition between pharmaceutical companies still takes place predominantly at the national level. The results of the market investigation should confirm this finding from a supply-side perspective (competitors) and from a demand-side perspective (customers).[78] However, it is unlikely that the Commission accepts, even if certain wholesalers may source products internationally, that demand and prices for finished dose drugs do not vary substantially from one country to another.[79]

3.2.1.2 Competitive assessment

The substantive test applicable to EU mergers analyses whether the concentration post-merger will significantly impede effective competition, in particular, by creating or strengthening a dominant position. The assessment is conducted asserting the market position of the parties, their economic and financial power, the alternatives available to suppliers and users, the legal or other barriers to entry, the supply and demand trends for the relevant goods and services, the interests of the intermediate and ultimate consumers or the development and economic progress created through the merger.[80]

Once the Commission delineates the horizontally affected markets, the competitive assessment has as the starting point the combined market share of the notifying parties. With regard to horizontal overlaps, the Commission presumes that combined market share below 25%, either in the common market or in a substantial part of it, are not liable to impede competition. As a result of the narrow definitions in the pharmaceutical sector, a large number of drugs often exceed those thresholds. To this end, since *Novartis/ Hexal*, the Commission classifies the horizontally affected markets under three different groups in order to filter the products where competition concerns are more likely to raise, i.e., Group 1 of the clas-

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[77] Notice on the Relevant Market, para. 8.

[78] *Teva/Barr,* para. 19 and *Novartis/ GlaxoSmithKline*, para. 217.

[79] *Sanofi-Aventis/ Zentiva*, paras. 28 to 30.

[80] HMG, para. 24 et seq.

sification.[81] The first Group relates to those products with a combined market share of over 35% post-merger and an increment of 1% through the merger. Group 2 of drugs refers to those products with a combined market share of 35% and an increment of less than 1% and Group 3 includes products with a joint market share below 35%. The Commission has adopted the classification on numerous occasions, for example, in *Teva/ Barr*, the combined market share of the two generic pharmaceutical companies in excess of 35% raised serious doubts in relation to 11 countries and 7 different drug markets. On the other hand, the Commission, after taking into account that third parties did not indicate any significant impediment to competition with regard to drugs falling within Group 2 and 3 excluded those markets from the competition concerns and only drugs under Group 1 were asserted.[82]

Additionally, the Commission introduced the Group 1 "plus" in *Novartis/ Alcon* in order to investigate in more detail markets where the parties have a combined market share of below 35% but only one competitor remains on the market and markets with a joint market share of over 35% and an increment of less than 1% if the party with the small increment is a recent entrant.[83]

Subsequently, the Commission has to determine whether the combined market share is an accurate indicator of the market power held by the parties and whether the post-merger entity will be in a position to prevent competition. The ability to raise prices or reduce supply, the strength and number of competitors, the capacity constraints or the substitutability between parties' products are some of the factors which determine whether the transaction raises coordinated or non-coordinated effects. The latter effects relate to the ability of the post-merger entity, for example to increase prices, irrespective of the responses of its competitors. For instance, the higher degree of substitutability between the merging firms' products will be an indicator that the parties will be in a position to raise prices significantly. Conversely, the existence of close substitutes remaining in the market after the merger points out still fierce competition.[84]

With regard to coordinate effects, the Commission addresses the likelihood that the post-merger entity and the other players in the market will be in a position to coordinate their behavior. For example, the elimination of a player through a merger in high concentrated markets is likely to lead to coordinated practices between the remaining firms. However, in the pharmaceutical context, the Commission's subs-

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[81] S. Zuehlke and J. Komossa, *A review of recent pharmaceutical mergers,* mlex MAGAZINE, AB Extra - Pharmaceutical Mergers, January - March, 2011, pages 3 to 5. See in addition cases *Teva/Barr,* para. 21 and *Teva/ Radiopharm,* para. 48.

[82] *Teva/Barr*, para. 23 and 29.

[83] M.5778 - *Novartis/ Alcon*, paras. 25 and 26.

[84] HMG, para. 24 et seq. See also *Teva/ Radiopharm,* para. 12 or *Bayer Healthcare/ Roche*, paras. 45 and 53.

tantive assessment generally excludes coordinated effects. The pharmaceutical regulatory framework, for instance, the pricing policies, together with the intrinsic instability of innovation-intensive markets, make unlikely collusive understanding in the drugs industry. Thus, the Commission's analysis in the drugs industry is typically limited to single dominance situations.[85]

Provided that the transaction significantly impedes competition, unless countervailing factors such as buyer power, new entries or efficiencies counteract the harmful effects previously identified, remedies will be required in order to obtain clearance. Despite the fact that the Commission asserts countervailing factors as part of the substantive analysis, the decisions illustrate a greater weight of buyer power and new entrants analysis compared to the most residual place of efficiencies.[86] As an example of the countervailing power of the demand, the concentration will not be likely to prevent competition if the position held by national purchasers, such as national health care systems, counteract powerful sellers and achieve also post-merger favourable purchasing terms from them.[87]

The entry analysis refers to the existence of barriers to entry, regulatory barriers, ownership of intellectual property rights or the need for high investment particularly in technology markets such as the drugs industry. This part of the substantive test can be used as a defense where there is clear evidence that the dominant position created or strengthened through the merger will only be temporary due to the high probability that other competitive forces will quickly enter into that market, eroding the initial competition concerns. For instance, the Commission has found in previous cases that the existence of new entrants which were already active in neighbouring product and geographic markets might eliminate the risk to competition. In relation to product markets, players active in closely related therapeutic areas are likely to become a competitive constraint taking into account the higher probability of adding new molecules to their already settled portfolio. In respect of geographic markets, being already active in another EEA country implies that the competitor has nearly all infrastructures, facilities or distribution networks required.[88] On the contrary, the Commission has not been convinced by this argument where there were still significant barriers to entry such as market authorisations, organisation networks or registrations

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[85] HMG, para. 39 et seq. and F. Have, J.T. Martinez and E. Demertzi, *The European Commission's Pharmaceutical Merger Control Practice: An Overview of the State of Play,* World Competition 39, no. 1, 2016, pages 96 to 98.

[86] In respect of the barriers to entry, M.6851 - *Baxter International/ Gambro*, paras. 85 to 88; M.7559 - *Pfizer/ Hospira*, paras. 74 to 79; *Reckitt Benckiser/ SSL*, paras. 83 and 84; *Teva/ Barr*, paras. 24 to 27; *Teva/ Radiopharm*, paras. 54 to 57. To the effect of buyer power, *Baxter International/ Gambro*, paras 88 to 90. To the effect of efficiencies, *Teva/ Radiopharm*, paras. 58 to 61.

[87] G. Duhs and M. Mahmood, *Pharmaceutical Mergers: Changes in the Regulatory Landscape,* Pharmaceutical Technology Europe, Industry Insider, January, 2015, pages 10 to 11.

[88] *Bayer Healthcare/ Roche*, paras. 45 and 47.

for reimbursement. The Commission exclusively considers that new entrants can constrain the position of the merged entity where sufficient proof is provided of its likelihood within a short period of time.[89]

3.2.2 Future markets

3.2.2.1 Definition of the relevant market

A) Relevant product market

The Commission's assessment incorporates future product markets in those markets where innovation is an important competitive force. Therefore, in the pharmaceutical sector, the relevant product market includes the analysis of those R&D or pipeline products which have not yet entered the market but that are at an advanced stage of development to be qualified as a concrete potential constraint. In relation to generic pipelines, the Commission usually includes them in the competitive assessment when there is a maximum of two years until launch or 1.5 years if the product is already sold in another EEA country. With regard to biosimilars, when they are at preclinical stage and in respect of an originator pipeline, the Commission ordinarily asserts pipelines on Phase III of Clinical Trials.[90] However, cases such as *Teva/ Radiopharm* and *Novartis/ GlaxoSmithKline* have shown that the Commission might, in addition, comprise drugs at earlier stages of development.[91]

With reason of the intrinsic uncertainty of asserting products which do not exist yet, the Commission decides to leave the definition of the product market open even more often. In any case, the delineation of the pipelines market will take into account the characteristics of the future products and the indications for which they will be likely to apply.[92]

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[89] *Sanofi-Aventis/ Zentiva,* paras. 210 to 216 or *Bayer Healthcare/ Roche*, para. 55.

[90] P. Figueroa and A. Guerrero, *EU Merger Control in the Pharmaceutical Sector, The Merger Control Review*, Sixth Edition, Law Business Research, Chapter 2, 2015, page 25. See in that regard M.1846 - *Glaxo Wellcome/Smithkline Beecham,* paras. 150 to 216 and M.5476 - *Pfizer/Wyeth,* paras. 13, 34-38, 65, 87 to 95, and 99.

[91] F. Have, J.T. Martinez and E. Demertzi, *The European Commission's Pharmaceutical Merger Control Practice: An Overview of the State of Play,* World Competition 39, no. 1, 2016, Page 105. In respect of generic pipelines, M.6258, *Teva/ Cephalon,* para. 80; In relation to biosimilar future drugs, T*eva/ Radiopharm*, paras. 426 and 427; For early originator pipelines, *Teva/ Radiopharm,* para. 432; and *Novartis/ GlaxoSmithKline,* paras. 84, 99 and 104.

[92] *Novartis/GlaxoSmithKline,* paras. 26, 27 and 68.

B) Relevant geographic market

The scope of the geographic market regarding pipeline products is decided according to the R&D area and consequently, the Commission has considered those markets to have a global dimension or at least to be EEA-wide.[93]

3.2.2.2 Competitive assessment

The competitive assessment asserts the likelihood that drugs under development will grow into effective competitive forces. Pipeline products will normally only be considered in the competitive assessment if the parties either have two competing pipeline products (pipeline to pipeline) or when one party (or both) has (have) a market share of 35% or more in any market on which the other party plans to enter with a new product (pipeline to market).[94] Moreover, competitors' pipelines might, in addition, be assessed as a countervailing factor in the case of being capable to effectively restore competition in a short period of time.[95]

With regard to the pipeline to pipeline cases, the Commission is moving towards the presumption of harm. The Commission considers that overlaps between the parties on R&D paths are likely to influence the post-merger, facilitating cost savings by eliminating the investment in one of the pipelines.[96]

In relation to the pipeline to market situations, competition concerns raised for example when one of the merging parties has a developed version of a generic drug and the other holds patent protection for the originator. For example, in *Teva/Cephalon*, the Commission had serious doubts regarding Teva's pipeline of Cephalon's innovator drug. The Commission considered that the decision of Teva to abandon the launch of the generic version eliminated the closest and only competitor of Cephalon's drug. Teva was the only player authorised to enter the market three years before the expiration of the patent by reason of a previous patent settlement between the merging parties, hence, the post-merger situation was likely to extend the single dominance of Cephalon and prevent new generic entries.[97]

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[93] *ibid,* para. 32.

[94] *Teva/ Radiopharm*, paras. 421 and 424; and *Novartis/ GlaxoSmithKline*, para. 47.

[95] *Novartis/ GlaxoSmithKline*, paras. 51 and 78.

[96] *Teva/ Radiopharm,* paras. 32, 421 and 439, *Novartis/GlasxoSmithKline*, paras. 47, 57 to 59,76, 82, 83, 89, 91, 104 to 112.

[97] *Teva/ Cephalon*, paras.93 to 127.

3.3 Acceptable commitments

Once the Commission has established serious doubts to competition, the parties can voluntarily decide whether they wish to submit commitments. In reality, the Commission informally indicates to the parties what is broadly needed, for instance, provisions such as additional assets, up-front buyers or fit-it-first clauses are usually explicitly required by the Commission and subsequently submitted by the parties. All the same, only remedies capable of rendering the merged entity compatible with the single market shall be accepted.[98] As confirmed by the EU Courts, the Commission has a considerable margin of discretion in that assessment, especially when it involves exercises of an economic nature. In any case, it is the sole responsibility of the Commission to establish whether or not a concentration, as modified by the remedies, significantly impedes effective competition.[99] This section asserts the required conditions for adequate commitments, the different types of remedies and the necessary requisites for divestiture.

3.3.1 Conditions for acceptable commitments

Remedies should be proportionate to the competition concern and entirely eliminate it. Moreover, commitments must be comprehensive and effective from all points of view, as well as capable of being implemented effectively within a short period of time. With regard to the requisite of entirely and effectively eliminating the threat to competition in a proportionate manner, the Commission compares the market structure in the absence of commitments with the effects to competition of a clearance decision subject to remedies. The Commission will approve the proposal of commitments only where it can be concluded, with the requisite degree of certainty, that it will be possible to implement and that the new commercial structures, in case of divestiture remedies, will be sufficiently workable and lasting to ensure that the significant impediment to competition will not materialise.[100] For instance, uncertainty in respect of the implementation can result from difficulties finding a suitable purchaser or concerns regarding the unavoidable degradation of the viable business.[101] In order to determine the effectiveness of the remedies, commitments cannot be too complex or difficult to monitor. The Commission may, therefore, reject

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[98] D. Hoeg, *European Merger Remedies Law and Policy*, Hart Publishing, 2014, pages 35 to 40.

[99] *ibid;* To the margin of discretion, C-202/06 P - *Cementbouw Handel & Industrie v Commission,* ECLI:EU:C:2007:814, para. 53. For modifications demanded by the Commission, *Sanofi-Aventis/ Zentiva,* para. 550, 552 and Section B4(f) of Commitments.

[100] Notice on Remedies, para. 10; T-210/01 - *General Electric v Commission*, ECLI:EU:T:2005:456, paras. 555 and 612; and D. Hoeg, *European Merger Remedies Law and Policy*, Hart Publishing, 2014, page 57.

[101] T- 177/04 - *easyJet v Commission*, ECLI:EU:T:2006:187, para. 197.

them on the grounds that if their implementation cannot be effectively monitored, commitments will be limited to mere declarations of intent, thereby diminishing or eliminating their effects.[102]

Once the parties submit the commitments, the Commission should, therefore, assert whether it can be concluded with the requisite degree of certainty the capability of the remedies to entirely eliminate the threat of competition. In such context, the Commission must fully inform the Competent Authorities of the Member Sates in order to express their views on any commitment proposals in Phase I and II.[103]

Likewise, when appropriate, the Commission may consult third parties, such as suppliers, customers, and competitors, to verify the factual information submitted by the parties and the adequacy and effectivity of the proposed commitments having into account the third parties' insight in the markets involved. The market testing consists of a questionnaire regarding the adequacy of commitments, together with a non-confidential version. Aspects such as the interest of third parties in buying assets or the difficulties to find a suitable purchaser, the viability of the divested business or the need to include additional assets to create an effective competitive force, among many others, will provide the Commission with a more diverse overview of the market structures prior and after remedies. The market test is usually conducted right after the submission of commitments. Taking into account the time constraints, especially with regard to Phase I, only limited and clear-cut modifications will be possible to introduce following the market feedback. The EU Courts have recognised the importance of testing the remedies in the market as part of the Commission's investigation, nevertheless, the Commission is not obliged to drive the market testing and hence commitments proposals can be rejected without consulting third parties when they are found manifestly insufficient to solve the Commission's serious doubts.[104]

The Commission relies on the market test to conclude that remedies suggested in Phase I are likely to eliminate impediments to competition or to decide whether to open an in-depth investigation. In the case of remedies submitted during Phase II of the procedure, the Commission likewise decides whether the commitments satisfy the competition concerns or the transaction shall be prohibited. Although it is usual to observe mentions to the market test in the Commission's decisions, in connection with the Section 2.2.1.3 Commission Notice on the Access to the Commission file, merging parties have no access to the

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[102] Notice on Remedies, para. 13 and 14; See also *easyJet v Commission,* para. 186 and *EDP v Commission*, para. 72.

[103] EUMR, art. 19 (1).

[104] Notice on Remedies, para. 80; D. Hoeg, *European Merger Remedies Law and Policy*, Hart Publishing, 2014, pages 59 to 64 and Directorate for Financial and Enterprise Affairs Competition Committee, *Remedies in Merger Cases, European Union,* Working Party No. 3 on Co-operation and Enforcement, 28 June, 2011, paras. 55 to 60.

data obtained through the market test. Nonetheless, summaries are forwarded to them and the key documents obtained are discussed with the case-team during the meetings.[105]

In case the remedies are accepted, the removal of competition links shall not be transitional. The parties shall for a period of 10 years after the effective date of clearance not acquire direct or indirect influence over the whole or part of the divested business unless the Commission previously found that the market structures have changed to such an extent that remedies are no longer necessary.[106]

3.3.2 Types of commitments

Acceptable remedies can be classified into two different categories, structural and behavioral. The Commission generally distinguishes between divestiture type of commitments, other structural remedies, and behavioral remedies. Divestitures imply changes in the ownership of property rights in the market and they have represented in the previous years over the 70 per cent of cases involving commitments.[107]

On the other hand, there are other types of structural remedies which the parties might submit and the Commission subsequently accept when considered equally effective. Under such category, the Commission has accepted access remedies such as granting interoperability or access to infrastructure, networks, essential inputs, key technology or IP rights on non-discriminatory terms.[108] Access-type remedies are ordinarily defined after the approval due to the need of taking into account the particular situation of potential beneficiaries. Therefore, it is necessary to include straightforward obligations that will facilitate the effective monitoring. Moreover, dispute settlement mechanisms and fast track arbitration procedures are usually provided to avoid that the commitments do not meet the legal standards, meaning that those remedies should ensure actual, sufficient and timely entry of new competitors.[109]

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[105] *ibid.*

[106] Model Texts, Standard Model for Divestiture Commitments, Sec. B, para. 5; To the effect of cases following that wording, *Bayer Heathcare/ Roche,* Section. B of Commitments, para. 2 (2); *Teva/ Cephalon,* Section. B of Commitments, para. 5.

[107] C. Esteva Mosso, *EU Merger Control: The big picture.* Sixth Annual GCR Conference,12 November, 2014, page 7.

[108] Directorate for Financial and Enterprise Affairs Competition Committee, *Remedies in Merger Cases, European Union*, Working Party No. 3 on Co-operation and Enforcement, 28 June, 2011, paras. 8, 9, 10, 23, 24, and 29.

[109] A. Italianer, *Legal certainty, proportionality, effectiveness: the Commission's practice on remedies.* Charles River Associates Annual Conference, 5 December, 2012, page 7. In respect of access remedies, DG COMP, *Merger Remedies study, Public Version,* October, 2005, pages 114 to 121.

Looking at the Commission's practice in the pharmaceutical sector, horizontal impediments to competition have been mainly solved through the divestment of drugs, pipelines or other assets and behavioral commitments have been disregarded and not usually proposed. Howbeit, the Commission has accepted that both divestiture remedies and other structural remedies can effectively and entirely remedy competition concerns under the same circumstances. For instance, in *Novartis/ GlaxoSmithKline*, the Commission accepted the crown-jewel suggested by the merging entity. The alternative commitments included the option to ensure the development of the clinical trial programme through a joint cooperation with a suitable partner and in the alternative, the divestiture of the programme to a suitable purchaser. The players in the market only reached an agreement implying the modification of property rights and consequently, divestiture was the only option that complied with the Commission's concerns and the business interests of the other players involved in the agreement. However, it is worth mentioning that although the Commission accepts the possible effectivity of non-divestiture remedies, a crown jewel commitment assures that, in case the non-divestiture commitment is inefficient, the parties would otherwise be able to divest a viable business and thus meet the Commission's concerns.[110]

Behavioral remedies are accepted only under rare circumstances and more commonly in the context of vertical and conglomerate overlaps. Those commitments relate to the obligation to behave in a particular manner commonly established through contractual relationships between the merging parties, the Commission and the beneficiary of such particular conduct. Although the Commission has exceptionally accepted behavioral commitments to solve competition concerns in horizontally affected markets, approval of conduct remedies in the drugs market is even more infrequent.[111]

In addition, despite non-divestiture remedies are sometimes not sufficient to completely restore the competitive forces in the market, behavioral remedies or other structural commitments are repeatedly included in the commitments to extend the scope of the divestiture. For instance, access to facilities, supply transitional agreements, use of market authorisations and licenses of IP rights have been submitted in the proposal of commitments to strengthen the safeguarding of free competition by the divested business.[112]

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[110] *Novartis/ GlaxoSmithKline*, para. 296. In respect of crown jewels, Notice on Remedies, paras. 22 and 23 and DG COMP, *Merger Remedies study, Public Version,* October, 2005, page. 52.

[111] D. Hoeg, *European Merger Remedies Law and Policy*, Hart Publishing, 2014, Pages 43 to 45. In respect of behavioral remedies to solve horizontal concerns, M.5669 - *Cisco/Tandberg,* para.157 et seq. and 163 in particular.

[112] *Teva/ Barr,* para. 209; *Bayer Heathcare/ Roche,* para. 59; *Teva/ Cephalon,* paras. 156, 157 and 160; and *Sanofi-Aventis/ Zentiva*, para. 552.

3.3.3 Divestiture

As a result of the general prevalence of divestiture, particularly in the pharmaceutical sector, this section focuses on the required conditions for effectively removing all competition concerns through divestiture commitments. The divested activities must consist of a viable business that, if operated by a suitable purchaser, can compete effectively with the merged entity on a lasting basis. Normally, the divestiture consists of an existing stand-alone business and it must contain all the assets necessary for its operation and all the personnel currently employed.[113] In case the divestment of a separate business division is not available, the carve out of certain assets integrated into one or more of the parties' businesses is a satisfactory alternative. Likewise, divestitures of selected assets complimenting the purchaser's area of activities, license arrangements or re-branding exercises are other remedies that render transactions compatible with the single market. The distinct scope of the divestiture is determined on a case-by-case basis. While some mergers might require the divestiture of standing alone business of all field therapies, other competition concerns may be solved through the divestment of a sole pipeline drug.[114]

Following the Divestiture Model Text structure, Section B, C and D are developed below due to their more problematic character and interest to the purpose of this thesis. Section B refers to all the assets to be divested in order to constitute a viable business. In particular, all tangible and intangible assets (including IPRs), all licenses, permits and authorisations issued by any governmental organisation for the benefit of the divestment business, all contracts, leases, commitments and customer orders of the divestment business, all customer, credit and other records of the divestment business and personnel.[115] In relation to the personnel, despite the scope depends on the specific working of the business, the transfer of key personnel usually enhances the success of the divested business. In addition, the issues related to the transfer of know-how or other intangible assets are less problematic when the key personnel possessing the know-how have been transferred with the divested business.[116]

In line with the divestiture of a viable business, Section C establishes the standard Related Commitments, meaning those commitments required to maintain the viability, marketability, and competitive-

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[113] Notice on Remedies, para. 46; DG COMP, *Merger Remedies study, Public Version,* October, 2005, page 23; and Directorate for Financial and Enterprise Affairs Competition Committee, Working Party No. 3 on Co-operation and Enforcement: *Remedies in Merger Cases, European Union*, June, 2011, para. 12.

[114] *Teva/ Barr,* para. 206 compared to *Novartis/ GlaxoSmithKline,* para. 283.

[115] Standard Model for Divestiture commitments, Section B, Assets to be included. See, for instance, *Teva/ Barr,* para. 207.

[116] DG COMP, *Merger Remedies study, Public Version,* October, 2005, pages 43 and 82.

ness of the divestment business. In particular, parties undertake not to take any action that might have a significant adverse impact or alter the nature and scope of activity of the divestment business, as well as to make available sufficient resources for the development of the divestment business, on the basis and continuation of the existing business plans. To this end, it is common to find in Section B of the decisions the inclusion of transitional agreements between the parties and the purchaser during a start-up phase. Temporary supply agreements, technical assistance, manufacturing agreements or other transitional services, although creating a temporary dependence of the purchaser on the parties, might be necessary to ensure the successful implementation and competitiveness of the divested business.[117]

Likewise, Section D sets up the relevant provisions in terms of finding a suitable purchaser. The purchaser shall be an existing or potential competitor in the position to effectively compete with the concentration. The purchaser shall be independent of and unconnected to the merging entity, have financial resources, expertise, and incentives required to maintain and develop the divested business as an active competitive force.[118] In many cases, the viability of the divested business has been considered to depend to a significant extent on the purchaser. For instance, divestitures with a really limited scope might only become viable with a purchaser which could bring in very specific assets and skills to the operation.[119]

The Commission has previously considered necessary that a certain group of drugs should be divested to a single purchaser in order to ensure that the purchaser will be in a position to effectively compete. In the drugs industry, it is common that the Commission requires that the purchaser has already experience in the area. For instance, in *Teva/ Barr,* the oncology experience of the purchaser for the oncology drugs was indicated as a key factor and consequently the parties modified the commitments to include the criterion of an existing presence in oncology therapies in the EEA. In addition, with regard to both oncology and non-oncology drugs, the reduced size of the divested business required single purchasers. However, a single purchaser might in other cases be an impediment to aggressively market all drugs. For example, in *Sanofi-Aventis/ Zentiva*, separate groups of products were divested to different purchasers to ensure that all the purchasers had incentives to effectively compete in the market.[120]

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[117] *ibid*, page. 44. In respect of related commitments, *Mylan/ Abbot EPD-DM*, Section C of commitments, para. 8 or *Sanofi-Aventis/ Zentiva,* Section C of Commitments, para. 5. To the effect of transitional agreements, *Sanofi-Aventis/ Zentiva,* Section B of Commitments, para. 4(f) or *Mylan/ Abbot EPD-DM*, Section B of Commitments, para. 6(g).

[118] Standard Model for Divestiture Commitments, Section C, para. 17; To the effect of a suitable purchaser, Notice on Remedies, para. 48.

[119] DG COMP, *Merger Remedies study, Public Version,* October, 2005, page 99.

[120] S. Greenaway, E. Jakab, D. Johansson and J. Kundan, *Recent Commission Merger Control Decisions in the Pharmaceutical Sector: Sanofi-Aventis/Zentiva and Teva/Barr,* Competition Policy Newsletter 2009.

4. NOTIFYING PARTIES' PERSPECTIVE

4.1 Overview of the current EU practice

This section offers the notifying parties' perspective of the notification procedure and remedies in particular. The comments included below have been extracted from the responses of question 1, in respect of the identification of competition concerns, question 2 for the predictability of the Commission's approach and question 8 in relation to the impact of the procedure and the remedies on the transaction.

4.1.1 Identification of competition concerns

Provided most cases, around 80 per cent of concentrations, do not raise competition concerns, the preparation, pre-notification and notification procedure might not point out any impediment to effective competition and the transaction might be cleared without further difficulties. With regard to the more complex cases, all practitioners agree that the notification should be prepared within weeks, or even months, in order to identify all possible competition concerns before starting the procedure. It has been emphasised that the precise function of legal advisors is to identify potential impediments in advance given that commitments might have an impact in the manner under which the deal is structured.

As pointed out by practitioner D, the identification of competition concerns may vary depending on the closeness with the client and his business. In relation to well-known clients, the identification takes place at a really early stage due to the deep understanding of the business and the markets involved. On the other hand, practitioners might take some time understanding new clients' business and consequently identifying competition impediments in those areas. In any case, it is very rare that the Commission surprises the notifying parties with the finding of serious doubts.

Under extraordinary circumstances where competition concerns are not identified before the pre-notification contacts, practitioners referred to the procedural stages where the Commission clarifies its concerns. The Commission, although not formally, communicates its concerns by indicating some problematic areas, for instance, with regard to drugs belonging to Group 1. Once the notification procedure is started, around day 15, a working meeting is arranged where the Commission shares the serious doubts regarding the compatibility with the single market. Although the need for discussion implies the demand of commitments, the Commission requests before the meeting more information with regard to the con-

flicted markets, pre-warning the type of remedies needed. In that meeting, in case it is not yet clear, the Commission explains all competition problems with the aim of allowing the submission of suitable commitments before the day 20.

4.1.2 Predictability of the Commission's approach

Through the assessment of past decisions in alike cases, it can be surely anticipated that the Commission will assert the narrowest market definition and analyse all potential competition concerns thoroughly. Lawyers confirm a great predictability of the remedies capable of satisfying the Commission's concerns. However, clients might not be willing to compromise the deal to that extent and the predictability of the Commission's approval regarding the commitments suggested is not that easily foreseen. The parties, regardless their interests are in line with the Commission's most likely outcome, drive an independent assessment in order to defend the rationale of the transaction and the least intrusive remedies.

Lawyer D pointed out that the practical difficulty of predicting adequate commitments more in line with the client's interest results from the Commission's practice of testing the remedies in the market after being suggested by the parties. The predictability of the information provided by competitors, suppliers or consumer might be tougher than the Commission's approach itself.

Practitioner E explained the different degree of anticipation depending on the type of remedies. Structural commitments are highly predictable once the Commission's serious doubts are clarified whereas, in case competition concerns do not result from market overlaps or too high market shares, the predictability of adequate behavioral remedies is more complex.

The practitioners experienced in the pharmaceutical sector remark the good understanding of the analytical framework and the Commission's approach. The adequate preparation of a concentration commonly guarantees a great predictability of outcomes to clear the transaction in Phase I. The respondents emphasised the greater simplicity to identify competition concerns and suitable commitments in the drugs industry. Commonly, significant impediments to competition result from the overlap of several drugs in a certain geographic market, resulting in too high market shares. Thus, the divestiture of those drugs is a pretty straightforward remedy in comparison with the difficulties observed in other sectors. However, lawyer A commented on some not clear-cut cases where the position taken by the Commission differed from its usual or expected practice. Some examples are the assessment of pipelines in early sta-

ges of development or the requirement of up-front buyers in cases where the Commission decides that the purchaser degree of expertise is of core importance to market certain drugs.

4.1.3 Detriment to the Merger's Rationale

The EU merger control, in particular, the need for remedies, might have an impact on the rationale of the deal. First of all, the transactions which raise the most anticompetitive concerns are not even notified because practitioners advise merging parties of the complex and low chances of clearance, even with commitments. The consensus among practitioners indicates that the most common is that transactions do not rise competition concerns and therefore the merger rationale is not affected by the notification.

On the contrary, players in the market, sometimes, decide not to close certain deals due to the likely need for radical remedies. In those cases, the commitments would have significantly rested the commercial value of the operation. The analysis asserted by the lawyers tends to be conservative and consequently, the remedies are previously measured and priced in within the deal. In the majority of the cases, the commitments are less demanding than the ones which were potentially considered in the preparation. On the other hand, practitioner D pointed out that, although expected commitments will not be commercially sensitive for the deal, the flip side of the coin is the business disadvantage of other market players being aware of the fact that the merging entity is squeezed by the commitments' obligations.

With regard to the pharmaceutical sector, lawyer A acknowledges that the rationale of the transaction is less likely to be affected due to the well-established practice of acquisition and sales of assets outside the context of remedies. Thus, the establishment of certain commitments would not be considered as demanding as in other sectors taking into account the settled use of the same type of operations.

The EU merger control infrequently detriments the initial interest of the concentrations. However and under rare circumstances, the rationale of the transaction is compromised where the deal has to be abandoned. Notified transactions might be withdrawn, as lately happened in *Mondi/ Walki Assets*,[121] where the large impact on the business by the required commitments left the deal no longer commercially sensitive. Additionally, the negotiation procedure might conclude with a prohibition decision, examples could be the recent cases *Ryanair/ Aer Lingus* or *Deutsche Börse/ NYSE Euronext*, where for instance the market did not allow suitable commitments acceptable to the Commission.

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[121] M.7566 - *Mondi/ Walki Assets* (NACE C.17.12 and C.22.22, withdrawn at Phase II after submitting remedies).

4.2 Business strategies

The information provided below has been collected through question 1 and 5 of the survey in relation to the first and second subheadings, preparation and pre-notification. The third section, negotiation procedure, includes responses extracted from the interview questions 5, 6 and 7.

4.2.1 Preparation

The previous assessment of potential competition risks takes place with generous time in advance, weeks or months before any contact has been made with the Commission, not only in relation to the notification procedure but also with regard to the negotiation of the deal. All practitioners consider that the preparation is of vital importance, especially in respect of the client's interest in negotiating the conditions of the deal having into account the possible losses suffered by potential commitments.

The relevant role of preparation does not only respond to the importance of legal certainty where closing a deal but also results from the tight time limits of the procedure. In the undesirable context that the preparation has not foreseen the need for remedies with sufficient advance, the time limits will have a real impact on the negotiation procedure. The submission of all required information, the autonomous assessment of remedies or the discussion with the Commission may be in that case severely restricted.

The preparation required varies depending on the specific concentration. While some transactions will be subject to benefit from the simplified procedure, the more complex cases require greater time and information. The practitioners emphasised the extreme importance of ex-ante assessment in order to identify the potential competition problems and potential remedies, together with all relevant arguments to defend the transaction before the Authorities on due time. The preparation of documents will include dynamic assessments or economic reports supporting the still fierce competition in the affected markets in order to argue clearance without commitments.

4.2.2 Pre-notification

Pre-notification contacts with the Commission are of special interest in order to engage in early discussions regarding the controversial aspects of the transaction. The pre-notification part of the procedure is not affected by time limitations and consequently varies depending on the complexity of the concentration. In that regard, practitioner F pointed out that, despite the on-going debate concerning the delay of

the notification procedure by prolonging the pre-notification contacts, such extension might also be in the interest of the notifying parties who, by the pre-notification contacts, minimise the risk of running out of time to introduce all necessary arguments during the procedure. Although parties might try to push the discussions with regard to controversial affected markets, the Commission is usually reluctant to express concrete competition concerns at this stage. In any case, as advised by practitioner C, during pre-notification, the focus should rely on gathering all the required information to complete the notification as soon as possible.

4.2.3 Negotiation procedure

According to all practitioners' view, the best strategies to negotiate commitments before the European Commission are designed by the client's interest in line with the nature and the rationale of the deal. The initial strategy is always to clear the transaction without commitments, or with the least remedies. However, many transactions show the unavoidable need for commitments to satisfy the Commission's doubts. In such context, the strategy for the proceedings depends, among other factors, on the importance of time and the impact of the commitments on the transaction.

Some practitioners, for instance, E and F, highlighted the relevance of the time limits affecting the negotiation of commitments. Others, such as A and C, consider that the deadlines are only relevant with regard to the submission of commitments before the day 20 or 65 and do not influence the nature and type of remedies submitted. Following that argument, commitments are prepared with a lot of time in advance due to the extensive data required and given certain transactions have notification obligations with numerous reviewing agencies. Thus, the different phases of the negotiation do not vary the content of the remedies submitted since the commitments are ordinarily designed in advance.

On the other hand, every practitioner, although to a different extent, mentioned that time limits influence the structure under which the negotiation of remedies is driven. The interest in fast approval might result from numerous reasons such as the variable market circumstances, financial matters, pressure from other parties involved in the deal and many other commercial factors. Where the client is interested in a quick authorisation, taking into consideration the extremely short time to negotiate in Phase I, E and F indicated that larger commitments should be submitted to avoid Phase II. In case the aim is to obtain a faster clearance, notifying parties should try to discuss competition problems and potential remedies as soon as possible, at least informally. On the contrary, if the client is not sensitive to the timing but to the divest-

ment of certain company's assets, the merging entity should offer commitments progressively, being aware that approval will be delayed due to the discussion of more convenient remedies.

According to E's experience, if time is not a priority, the following reasons explain that it might be worthy to further discuss the remedies, in particular, in relation to those grey areas especially sensitive for the profitability of the deal. Firstly, the Commission usually expresses more competition concerns than the actual impediments requiring remedies at the end, and secondly, during the last days of the investigation, the Commission usually yields and it does not have the same determination than in the starting days.

Touching upon the structure of the negotiations, lawyer C stressed the careful assessment of the costs of going into Phase II of the investigation. Starting an in-depth investigation could generate negative messages to the employee confidence or the investment community, having an impact on the company share prices. Moreover, other Competition regulators might as a result consider that the deal raises more concerns than the ones assessed by them and thus, might open in the same line a complete investigation. In that assessment, the chances of winning the arguments and the sensitive character of the remedies potentially required should also be included in order to balance the overall value of the deal and the impact of prolonging the approval or implementing larger commitments.

In addition, E illustrated that the time limits are the factor which influences the negotiation the most in relation to the pressure variation between the notifying parties and the Commission. At the beginning of the process, the pressure relies upon the company which will try to avoid the second phase of the procedure. Although in-depth investigations imply larger workload for the Commission, the negative impact of Phase II is bear by the notifying parties. Once Phase II has started, and in the last days particularly, the pressure on the Commission is heavier. A prohibition decision is not ideal for the Commission and consequently, it will only occur under extraordinary circumstances. First of all, the Commission's objectives are in accordance with approving transactions as long as they are compatible with the single market but even more, a prohibition decision is likely to be subject to appeal before the EU Courts and the Commission is probably not interested in having its discretion limited by the Courts review.

With regard to the manner in which to structure the negotiations before the Commission, according to A, D and E's experience, it does not occur that often that the Commission rejects the commitments suggested and forces the parties into a second round of remedies. However, even when the commitments pro-

posed do not require major changes, there will always be specificities to negotiate, such as matters concerning market authorisations, manufacturing facilities or the conditions for suitable purchasers.

On that line, several lawyers, D, E and F, referred to the need of taking into account that the Commission always requires improvements to the remedies suggested, therefore, it is important not to reveal everything that the client is willing to give away from the beginning. This might be problematic if the time is crucial for the transaction. In that case, it is essential to have open debates with the Commission from early stages in order to solve all serious doubts effectively within the time limits. On the other hand, according to B and C' practice, the best strategy, irrespective of timing as a factor, is to disclose all possible issues as early as possible in order to ensure sufficient time for informed discussions.

4.3 Improvements

The comments included in the sections below have been collected through the assessment of question 10 in respect of power balance, question 3, 4 and 10 for the transparency section, question 9 and 10 with regard to efficiencies and innovation and question 10 in relation to international cooperation.

4.3.1 Power balance

Several practitioners have pointed out the sometimes excessive burdens allocated to the merging parties, especially, in relation to the excessive data to be disclosed in the Form CO or in the Form RM. In particular, lawyer B emphasised that there is no real power balance between the notifying parties and the Commission. For instance, with regard to the length of the procedure, the Commission might delay the pre-notification contacts by requesting further information or declare the notification incomplete once the procedure has started. The lack of certainty on the time required to consider the notification complete or to obtain approval may be really stressing from a commercial point of view. Accepting the Commission is in charge of the procedure, many at the business side feel that the Commission is not really sensitive to the costs of preparing all the information or the losses resulted from postponing the authorisation. Few days delay in large transactions can cost millions and even the failure of the deal, therefore, the business world awaits greater comprehension from the Commission in this regard.

4.3.2 Transparency

Three aspects regarding transparency concerns will be included as a result of the practitioners' comments. Firstly, matters concerning the access to the investigation file, secondly, the cooperative and open dialogues with the case-teams and thirdly, the wider publication of the Commission's documents with regard to the practice of commitments.

4.3.2.1 Access to the Commission file

In relation to the either problematic or understandable lack of access to the file before the Statement of Objections, the practitioners' opinion dissent. According to D and F, this context questions the transparency and the rights of due process of the procedure whereas A and E consider that a good balance of both parties' interests is maintained and that the information is offered to the parties by different means. With regard to the practitioners who have pointed out the insufficient access to the file, especially in comparison with the more satisfactory access to National Competition files in some MSs, the transparency concerns especially result from the fact that the Commission heavily relies on the market test to decide whether to clear a transaction or to open the Phase II of the investigation. Under the current regulatory framework, the legal obligation to access to the file only applies after the Statement of Objections, however, as F suggested, nothing prevents the Commission from including in its guidelines a greater procedural transparency. The access to the file from the beginning will avoid that the transparency of the procedure will merely rely upon the cooperative character of the case-team handling the case.

Other arguments raised by the practitioners who consider the current access to the file insufficient are that, even where the access to the file is granted in Phase II, notifying parties are too busy answering the Commission's questions in that stage as being in the last phase of the investigation squeezed by the time periods. Therefore, parties suggest that the access to those documents should be granted as soon as the Commission gets them in order to promote fairer negotiations and to ensure that all parties involved can have a thorough understanding of the competition concerns. In addition, in-depth investigations are unusual and most cases are cleared in Phase I, i.e. without access to the Commission file.

The practitioners defining the Commission as transparent stated that, although access to the file is not granted, oral feedback is conferred to the parties after the market test is conducted in respect of the comments obtained. As indicated by E, given that notifying parties cannot test the data themselves, one problem might be that they do not have another choice than to trust the case-team and its interpretation

of the results. Even A and E accept that the access to the file is desirable because it is acknowledged that the access to the market test from the Phase I will increase the fairness of the procedure and the equality of arms of the parties. Additionally, despite the Commission's practice of reviewing and discussing key documents with the parties is generally considered satisfactory, the lack of access to the file can be especially problematic where the case-team or the case-manager are reluctant to share information.

4.3.2.2 Cooperative and open discussions

Another aspect to improve in relation to the transparency of the EU merger procedure and with regard to the right to due process relates to the cooperative and open dialogues to identify competition concerns and as a consequence, adequate commitments. All practitioners mentioned the variability of frank discussions between one case-team and another, relying upon the case-manager handling the approval. While some case-teams are open in the discussions regarding the remedies required to solve the serious doubts, others are more reluctant to discuss the problems and they will only do so in the state of play meeting before the deadline for the submission of commitments.

A, B and E accentuated the transparency and cooperative atmosphere granted by the Commission. Albeit dependent on the case-team, the most usual is to encounter a frank environment for sharing information and finding solutions. With regard to the pharmaceutical sector, A suggested that the higher predictability of adequate commitments results in more open dialogues than in other sectors.

On the other hand, according to C and D's view, given that the parties have to propose commitments before being tested in the market to decide upon their suitability, the openness of the dialogues is thereby restricted. As commented by D, the position of the Commission, limited under time constraints, is not easy bearing in mind the need to conduct the market test in order to ensure an objective assessment. However, more open dialogues in advance, before testing the commitments in the market, would be beneficial for both parties. Such context will assimilate the scene to private negotiations where both parties discuss their interest in favour of a win-win compromise. A more active role by the Commission in the negotiation by including what is considered necessary and avoidable will help the parties to suggest adequate commitments likely to pass the market test.

A, E and D pointed out the convenience of formally discussing the remedies from the start of the notification. The Commission firstly defines the markets and the problematic areas, and only once it has acquired a clear position, it initiates formal discussions of remedies. From the notifying parties' perspect-

ive, especially with regard to those operations affected by time pressures, a parallel assessment would be preferable to allow discussions of commitments throughout all Phase I and not only limited to the last 15 to 20 days. To this effect, A, after comparing the situation with the practice five years ago, considers that the Commission is on the right path of improving to guarantee earlier informed discussions of remedies.

4.3.2.3 Publication of internal documents

C pointed out that, although the Templates and the Model Texts constitute good grounds for understanding the present demands, the publication of more extensive documents of previous decisions to share a clearer understanding of the Commission's approach will improve the current practice.

4.3.3 Efficiencies and Innovation

Although practitioners recognised the important role of efficiencies and innovation in the market of drugs, those arguments are not often tried due to their low success. Consequently, efficiencies and innovation defenses have little weight in the process and there is still a long way to go before having them properly scrutinised. In the current practice, as exemplified by E, the arguments to defend the clearance of a transaction usually relate to the definition of product or geographic markets, barriers to entry or the compensatory force of the demand. Economic studies in that regard are usually the most successful given that a broader market implies lower market shares and consequently a shortened divestiture.

As pointed out by B and C, although efficiencies and innovation do not play a role in the negotiation of commitments, they are always present in the procedure as one of the questions of the Form CO. Pursuant to the assessment of the concentration, innovation and efficiencies can favour the parties, for example, in case a competitor holds a pipeline product subject to entering in the market and contain the strength of the concentration. Or, on the contrary, they can be considered an impediment to competition where the R&D paths horizontally overlap between the merging parties. The practitioners experienced in the pharmaceutical sector underlined the role of innovation within the substantive analysis of many cases, for instance, *Pfizer/ Hospira* or *Novartis/ GlaxoSmithKline*. A commented in respect of the latter case that the Commission should take into account in the assessment of pipelines in earlier phases of development the difficulties of divesting assets that from a commercial perspective have no certainty of effectivity or success.

The overall objective of both parties, the merging entity and the Commission, is that innovation will not be negatively affected. The Commission's focus is to ensure continuity both from the seller's side of assets and from the purchaser's perspective. Consequently, it is not desirable to detriment through the commitments the ability of the seller to innovate in the areas not affected by the serious doubts, especially, with regard to R&D companies where the separation of assets might be complex. Several mechanisms can be applied to solve those competition doubts, for instance, the divestiture of an intellectual property right (but conferring a narrow license to the seller for the use in markets where there are no competition concerns) or the license by the purchaser of technology, granting assistance in relation to R&D in the transitional process.

4.3.4 International Cooperation

A defined the cooperation between different Regulatory Authorities of Merger Control around the world as the greatest challenge of the current practice. The finding of an international common framework to deal with remedies in a coordinated manner would mean a real improvement. Notifying parties often suffer the difficulties of having notification procedures before four or five different Competition Authorities with distinct time limits, requirements and approaches to the deal. Consequently, the greatest development to decrease the burdens on notifying parties would be to facilitate the combination of those procedures.

5. ANALYSIS AND SUGGESTIONS

5.1 Overview of the current EU practice

The findings related to the First Research Question, *What is the current EU practice of commitments, in particular, in the pharmaceutical sector?,* conclude in the light of the remarks included below that the EU merger control, particularly, the practice of commitments, is generally considered satisfactory. In view of the large number of unproblematic operations, around 93% since the Merger Regulation came into force in 1990, it is important that the administrative costs are kept as low as possible.[122] The wide amount of Guidelines, White Papers and Notices, together with the introduction of Simplifying packages, evidence the willing of the Commission to move towards a more effective system, with greater legal certainty, in order to diminish the burdens on the parties. Thus, although practical problems have been identified during this thesis and potential improvements are suggested along this chapter, the efforts of all parties involved during the notification procedure lead to continuous developments.

In general, the Commission is reluctant to prohibit transactions, hence, the priority of EU Merger Control is not to interfere on the commercial practices within the single market but to protect free economy. The Commission cooperates with the merging parties to find solutions aimed at rendering the transaction compatible with the internal market. The remedies suggested by the parties and subsequently approved by the Commission should be proportionate to the competition concern and entirely eliminate it. Meaning that commitments have been used as the tool to balance the protection of effective competition in the single market and the preservation of the positive impact of M&A for restructuring and investment.

From the notifying parties' perspective, this study shows a high predictability of the competition concerns and the Commission's demands in respect of commitments. The assessment of the Commission's previous decisions allows the merging parties to structure the deal in accordance with the expected remedies. Although depending on the cooperative character of the case-team, the Commission and the parties usually engage in fruitful and successful discussions regarding the serious doubts to competition and the need for commitments.

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[122] C. Esteva Mosso, *EU Merger Control: The big picture.* Sixth Annual GCR Conference,12 November, 2014, page 4.

In any case, the Commission communicates the impediments to competition, at the latest, in the state of play meetings before the deadlines for submitting commitments, either at Phase I or II, in order to allow the parties to propose adequate commitments. Albeit concerns have been expressed in relation to the transparency of the procedure and the desirable discussion of remedies in earlier stages of the process, the residual rate of concentrations subject to commitments, withdrawn notifications or prohibited transactions indicate the efficiency of the system.

In the pharmaceutical context, despite many concentrations demand remedies to not significantly impede competition, the notifying parties and the Commission have easily reached prompt suitable commitments. In this regard, several factors have influenced the Commission's decisions. Firstly, M&A of the large pharmaceutical companies have been used as the mechanism to conduct the development and consolidation of the sector. Horizontal overlaps have been therefore usual and extensive and parties have been aware and predisposed to divest part of the assets involved in the transaction to remedy threats to competition. Hence, structural commitments, and especially divestiture in order to dilute combined market shares, have been the most definitive and safe solution to entirely remedy the Commission's concerns. Secondly, the usual purchase and sale of assets within the drugs sector outside the context of commitments have ensured likewise the effectivity of those remedies under the EU merger control. Lastly, the transparency of the sector with regard to market authorisations, patented drugs or reimbursement requests among others, facilitates a more open assessment of merging parties' activities and competitors' areas of business, simplifying to a greater extent the understanding of the likelihood of anti-competitive effects.

On the other hand, concerns have been often expressed in relation to the insufficient regard by the Commission to the large costs of delays in approval for big transactions or to the commercial losses of in-depth investigations. The Commission has been found to mainly focus on avoiding Type Errors II whereas ignoring the risks of imposing undue burdens on merging parties or the hazard of Type Errors I.

The constant clearance of pharmaceutical M&A during the Phase I confers however a positive message to the drugs business community. As previously stated, *Friesland/ Campina* is the only example of a complete investigation after the EUMR entered into force. Several factors of such decision emphasise the low probability for future pharmaceutical merging parties of facing an in-depth investigation. Firstly, in *Friesland/ Campina,* the first commitments were submitted pursuant to Article 8(2) of the EUMR, therefore during the Phase II. One of the reasons for explaining the opening of an in-depth investigation

is that no solution for the competition concerns was suggested during the Phase I. Additionally, the concentration involved the NACE categories C.21.1 but also C.10.4, C.10.5, C.10.51 and A.01.41. The markets affected by the serious doubts concerned the procurement of raw milk, fresh diary products and cheese, more in line therefore with the categories C.10.5, C.10.51 and A.01.41. Thus, apart from the fact that one specific decision will not generate conclusions applicable to all drugs sector, these circumstances may indicate that the case was not really representative of the pharmaceutical reality.

Although the general picture suggests a skilled framework, as stated by the Deputy Director-General for Mergers at the DG Competition, Mr. Carles Esteva Mosso, one of the positive features of EU merger control is the ability to periodically question its rules and principles and come up with ways of improving them.[123] Accordingly, it is a responsible exercise to evaluate the system in order to examine whether there is still room for enhancement. For instance, interesting discussions may arise from the assessment of aspects such as the correct delimitation of the affected markets, the adequate combined market share thresholds, the sufficient substantive assessment of innovation or other countervailing factors, the procedural burdens on merging parties, the scope of the Simplified Procedure, the balance and transparency of the negotiations, the proportionality and effectivity of the remedies or the promotion of the industry and the protection of fierce competition through the EU Merger Control.

5.2 Guidelines on the notification of complex concentrations

This section addresses the Second Research Question, *What are the most advisable practices for future notifying parties?,* and briefly summarises some of the most convenient strategies in order to offer guidelines for future merging parties.

Notifying parties might vary their approach towards the notification depending on their interest and personal preferences, however, merging parties are advised to take into account several relevant factors to obtain a prompt and successful clearance.

First of all, in order to achieve the most beneficial business outcome for the transaction under the EU current merger practice, notifying parties are encouraged to drive an ex-ante assessment of the concentration and prepare the notification with generously sufficient time. The complex market reality and the thorough economic assessments conducted by the Commission, together with the time constraints of the

[123] C. Esteva Mosso, *EU Merger Control: The big picture.* Sixth Annual GCR Conference,12 November, 2014, page 9.

procedure, show the enormous importance of having an extensive comprehension of the markets and serious competition doubts prior to the negotiation of the deal and the pre-notification contacts.
On one hand, the early study of the concentration confers to the merging parties the sufficient time to collect all the required information for a complete notification, as well as all to provide evidence for supporting wider affected markets, strong remaining competitive forces or new potential entrants, ultimately, the compatibility of the transaction with the single market, either before or after modifications. On the other hand, the prompt analysis of the impediments to competition likely to be found by the Commission allow merging parties to price in the deal the potential losses resulting from the procedure, and more in particular, from the remedies. Where the notifying parties rightly assert in advance all possible costs resulting from the potential need for large commitments, it is unlikely that the Commission's demands will leave the transaction no longer commercially sensitive.

Through the assessment of the well-established regulatory framework, notices, guidelines and decisions, merging parties, concretely, their advisors, are in the position to predict the Commission’s findings. Although the practitioners might still seek market evidence in order to claim a more permissive clearance, the merging parties should take into account all possible fortuitous related to the notified concentration. In particular, regarding the pharmaceutical sector, many aspects of the industry have been remarked through this thesis with the aim of offering a greater understanding of the features that affect the definition of the market, the competitive assessment and the acceptance of commitments.

The merging entity is advised to assert, firstly, the delineation of product and geographic markets and the substantial assessment of finished dose drugs, future products, AIPs, contract manufacturing and out-licensing. In relation to the ATC classification for drugs, the evidence submitted should support one level of the classification or another depending on the overlaps between the parties. For instance, using the example provided under Section 3.2.1.1 in relation to *Reckitt Benckiser/ SSL*, in case both parties are active in the market of paracetamol and ibuprofen-based products, the economic evidence should support the ATC3 level if their combined market share is lower in relation to the broader market of analgesics included under N2B. On the contrary, if one party holds a position in the ibuprofen-based drugs market and the other in the paracetamol-based products market, the assessment at the molecule level will remove the horizontal overlap between the parties because of the different active ingredient of their portfolio drugs. In any case, it is important to carefully assess the distinct levels of the classification in order to ensure that no competition concerns raise from any available definition. In the same line, differences between originator and generics, OTC and Rx drugs, or other factors such as pricing and reimbursement

policies, galenic formulations or mode of action should not be disregarded to apply, alike the Commission, the interplay between therapeutic and economic substitution.

In respect of future products, the notifying parties' assessment of their pipelines should not be limited to drugs under Clinical Trial III but also at earlier stages of development. Merging parties should take into account that the Commission is moving towards the presumption of harm where R&D paths between the parties overlap. Therefore, the merging entity should be in a position either to evidence the preservation of innovation and fierce competition in future markets or be ready to remedy those overlaps by commitments, most likely the divestiture of the pipeline drug.

The competitive assessment has proved a strong reliance on the combined market share and therefore parties are advised to locate their efforts in defining markets which will result in more diluted joint shares to move drugs from Group 1, where competition concerns are more likely to arise, to Group 2 or 3. The assessment of effective competitive constraints obviously depends on a case-by-case basis. However, it can be observed a stronger success of arguments such as the still strong competitive forces in the market or new likely entrants over efficiency or innovation gains post-merger. Notably, the industry of drugs facilitates a more transparent assessment of those aspects, for instance, due to the possibility of asserting the competitors' areas of activities through the record of IP rights, drugs under Clinical trials, market and distribution authorisations or reimbursement registrations. Hence, merging parties are encouraged to benefit from the possibility of a more open assessment in the industry.

In relation to the commitments, once the competition impediments are identified, the predictability of the remedies capable of satisfying the Commission's concerns is fair. The parties should provide all information required by the Form RM or discuss with the Commission the dispense of certain data. Moreover, they should use the Template for Commitments facilitated by the European Commission, concretely the Standard Model for divestiture commitments and Standard Trustee Mandate or otherwise explain the deviation from the pertinent Model Texts.[124]

Furthermore, the merging entity is advised to take into account that the approval of more permissive remedies requires time and effort. In short, the parties should balance the interest of a faster clearance and the impact of large commitments in order to structure the submission of remedies to the Commission.

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[124] Form RM, Introduction in respect of information waivers, and Section 3 for the deviation from Model Texts.

With reference to the procedure, it should be emphasised the importance of pre-notification contacts and openness during the negotiations. In respect of the early discussions with the Commission, even before submitting a complete notification, it is advisable that merging entities include their lawyers and advisors to guarantee prompt, informed and productive discussions.

Although practitioners have pointed out different strategies, in general, it can be concluded that it is in the best interest of notifying parties to be cooperative and open regarding the complications which arise from the deal. The Commission will anyway thoroughly assess all plausible markets to the narrowest scope and every possible threat to competition, therefore, hiding competition concerns in the dialogues with the case-team will not result in more beneficial outcomes. Being collaborative in the discussions with the Commission will favour a faster approval and a more cooperative atmosphere in the finding of solutions adequate to the Commission's serious doubts and to the merging parties' commercial interests.

5.3. Improvements

The improvements introduced below are expected to answer the Third Research Question, *What are the potential improvements to the EU practice of commitments?*, particularly, in respect of the substantive analysis of complex transactions and commitments, together with the procedural aspects of the notification. Most suggestions are directed to avoid Type Errors I and decrease the burdens on the notifying parties. Some of the desirable enhancements are accompanied by possible solutions whereas others are merely raised acknowledging the complexity of taking a short-cut or concluding with one only right or wrong response. The areas analysed include the existent administrative burdens, the need for greater transparency, the assessment of efficiencies and innovation, the proportionality of commitments, the strong reliance on the market test and the expected progress in terms of international cooperation.

5.3.1 Administrative Burdens

Taking into consideration the minimal rate of prohibition decisions or concentrations subject to an in-depth investigation, the notification before the Commission is still a cumbersome process. Even with regard to the concentrations rising competition concerns and requiring commitments, the Commission establishes excessive burdens on the notifying parties while having into account, for instance, the amount of information required by the Form CO or the Form RM.

Although the Commission has made efforts towards the simplification of the procedure, the question is whether those amendments are enough. The Commission introduced Model Texts to relieve notifying parties of the heavy demands both in terms of time and resources of negotiating the standard terms for commitments. Likewise, the Model Texts aimed at increasing transparency and legal certainty as a result of consistency across cases.[125] Provided the practitioners, C in particular, stressed the ease conferred by the standardised templates for commitments, their experiences evidence that, in fact, the largest burdens relate otherwise to the information requirements and the length of the negotiations.

The Form CO requires to provide data of all plausible alternative product and geographic market, needless to mention the Commission's practice of delineating markets to the narrowest definition, thereby demanding notifying parties to disclose an extremely onerous amount of information. The conferral of data is not limited to those relevant markets where, according to the parties' pre-assessment or the expected Commission's analysis, there is a likelihood of harm or remedies' demand. Plausible markets suggest a broader interpretation, not limited to alternative product and geographic definitions assessed by the Commission in previous decisions. This might be considered especially problematic provided the already wide understanding of affected markets by the Commission due to the narrow substitutability delineations. For instance, with regard to the pharmaceutical industry, it is not sufficient to submit information regarding the product markets according to the ATC3, and parties are also required to provide data of the classification at the molecule and ATC4 level. Or, in relation to OTC drugs and Rx medicines, originator and generics, galenic form splits, contractual manufacturing or AIPs.[126]

From the notifying parties' perspective, taking into account that the notification is not completed until all necessary information is provided, the pressure to disclose data regarding all hypothetical market definitions, sometimes not economically realistic, may extend the length of pre-notification contacts and lead transactions under economic and timing constraints to undesirable and uncertain commercial outcomes.

As accentuated by B, this scenario, together with the uncertainty of time required to obtain approval, evidences the lack of power balance in the procedure and the excessive pressure allocated on the parties by the Commission. Taking into account the administrative burdens and costs of collecting data, both regarding the Form CO and the submission of commitments, and the negative impact of delaying appro-

[125] Model Texts paras. 5 and 6.

[126] P. Citron, *EU merger control: New measures aimed to reduce administrative burden,* Kluwer Competition Law Blog, 9 December, 2013; Baker & McKenzie, *The Devil in the Detail: European Merger Regulation Reforms Increase Burdens for Merging Parties*, Baker & McKenzie's Global Antitrust and Competition, December, 2013; and G.Bushell, *Mama Mia, Here We Go Again,* Kluwer Competition Law Blog, 23 September, 2014.

vals, the Commission should carefully assess the unfortunate effects of discouraging M&A and doing business in Europe. While a concentration might impede free competition in a certain market may foster pro-competitive effects and growth in another. Hence, the Commission should continue its efforts to decrease the inconveniences to M&A activity during the notification procedure. Particularly, the concept of plausible alternative markets should be narrowed down and information waivers, where appropriate, should be more commonly given. In addition, in relation to both the extension of pre-notification contacts or declarations of incompleteness once the procedure has started, the Commission should be extremely sensitive to the burdens imposed thereby on the notifying parties.[127]

5.3.2 Greater cooperation and Transparency

Although it is acknowledged that the notification procedure is usually cooperative, sometimes, the parties or the case managers are reluctant to share information. A greater cooperation in the analysis of concentrations and the assessment of commitments is beneficial for both the merged entity and the Commission. The parties will achieve a better understanding of the Commission's serious doubts and the features of the remedies required and therefore submit adequate commitments. The Commission will then also obtain more acceptable proposals, decreasing the risk of refusing packages of commitments and prohibition decisions.

In relation to a greater cooperative environment, from the business side, a more parallel assessment of the competition concerns and the necessary remedies would be welcomed. In the current practice, the Commission firstly clarifies the competitive effects of the transaction and subsequently communicates potential problematic areas to the parties to allow the submission of remedies. Merging parties consider that the simultaneous assessment would contribute to seize the mutual efforts of the case-team and the parties in the finding of consensual solutions.

On the other hand, the Commission's methodology under EU merger control is comprehended taking into account the time constraints to reach a decision. Anyhow, it is nevertheless interesting to appreciate that the Commission and the notifying parties could be more effective working as a single team since, at the end of the day, they both expect the clearance of the transaction without contradicting the EU regulatory framework and practice.

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[127] J. Bellis, P.Elliott and J. Acker, *The current state of EU merger Control System: Ten areas where improvements could be made*, Fordham Competition Law Institute, 2012.

In addition, the Commission, and in particular, the EU merger control are in general terms transparent. Although the access to the file is only granted after the Statement of Objections, collaborative case managers share the data contained in the Commission's investigation through other means. Thus, the rights of defense of the parties and the legal certainty are nonetheless protected. However, and in connection with a more parallel approach of the substantive analysis and the commitments, the access to the file from the beginning of the notification would facilitate the parties' understanding.

Repeatedly, although the time limits push the Commission towards a more individual assessment, the access to the investigation file does not mean that the parties will be in a position to express complaints subject to delay the Commission's decision. According to this view, such access would only ensure a higher capability of answering the Commission's serious doubts in a more informed and accurate manner. Consequently, despite the Notice on the access to the Commission file only recognises that right after the Statement of Objections, the Commission is in the position to introduce the extension of such right in further Guidelines.[128]

Likewise, in accordance with the Section 5.3.5, Market test of commitments, the possibility to access the actual documents of the market survey, with the obvious exception of those containing business secrets, would increase the transparency of the Commission's decision-making. In this context, and irrespective of the future extension of the right to access to the market test, the publication of Guidelines on how the Commission weights the data collected in the market test will, apart from proving the objective assessment driven by the case-teams, increment the transparency and legal certainty. Although the published decisions make references to the results of the market tests, there is little information about the actual process, the questions asked or the responses received. Taking into account that the Commission heavily relies on the market test to reach a decision, it is especially unfortunate that an official policy has not been expressed as to how the information obtained is assessed.[129]

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[128] Suggestion introduced by Lawyer F.

[129] O. Bretz and K. Schallengerg, Clifford Chance Paris, *Market Tests of Remedies: A practitioners' view,* 2013.

5.3.3 Efficiencies and Innovation

Efficiencies and innovation concerns will be approached in respect of the competitive assessment of the transaction and the adequacy and suitability of remedies. Firstly, as part of the merger substantive analysis, efficiencies are asserted either as a factor rising or countervailing serious doubts. The analysis of the Commission's decisions, in particular, in the pharmaceutical sector, points out that efficiencies are not given in practice enough weight in comparison to other countervailing powers, in particular, the existence of new entrants. More often, the Commission considers that the efficiency gains leave the post-merger entity being too efficient as to prevent competition. The market power gained through the merger efficiencies may therefore require the submission of remedies.

Although some concentrations might enjoy in the immediate post-merger context some dominance, that does not necessarily mean that competition in the market will be distorted. Such context can create an incentive for competitors to compete more aggressively and also achieve greater efficiencies which may conclude in the growth and development of the industry. Consequently, the role of efficiencies should be subject to further discussions in order to clarify whether its current position fully protects fierce competition and the pro-competitive effects of M&A activity, not only in short terms but in the long run.[130]

Following the same line of argument, and acknowledging the importance of protecting innovation in high-tech markets such as the pharmaceutical sector, the likelihood of harm where independent R&D programs overlap cannot be straightforwardly assumed. Careful analysis is required with regard to the incentives that the post-merger entity will have to invest or its ability to develop the drugs under Clinical Trials more efficiently after the merger.[131] Especially, in relation to pipelines under early stages of development and the unavoidable uncertainty around them, the Commission's test should not take for granted that the pipeline will enter into the market. Despite the benefits of assessing those drugs where there is a degree of certainty of real harm, the Commission should take into account the low rate of launching, for instance, only 10 to 15 % of pipelines under Phase I, and 30 % of drugs under Phase II. The complexity

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[130] R. Snelders and S. Genevaz, *Merger Efficiencies and Remedies,* International Competition Legal Guides, Merger Control, 2006.

[131] G. Bushell, *Veering off the well-trodden path? European Merger Control and the Pharmaceutical Industry*, Kluwer Competition Blog, 2015. With regard to the Chairman Muris's statement in Genzyme/ Novazyme.

however relies on the intrinsic difficulty of predicting through economic studies or empirical research the significant likelihood that a pipeline will grow into a competitive force.[132]

In the light of acceptable commitments, both efficiencies and innovation should also be taken into account to ensure that commitments do not undermine the economic or technical progress. When a concentration generates efficiencies in one market but anti-competitive effects in another, the remedies to solve competition concerns should not threat efficiency gains nor the effective development of the research. On that line, the design of commitments, in accordance with the Notice on Remedies, paragraph 38, should include licensing agreements where the divestiture is likely to impede on-going research. Despite divestiture is considered more adequate due to the fact that it eliminates a lasting relationship between the merging entity and its competitors, the Commission should assert the adequate position of the merging entity and the suitable purchaser to innovate. Thus, in case the carve out of R&D paths prevents the maintenance of resources to develop other products, commitments should avoid that competition concerns are remedied at the cost of technical progress.

The respondents to the Survey, principally A, acknowledge that the Commission, in order to accept the necessary assets subject to divestiture, the conditions for a suitable purchaser or other related commitments, assesses that innovation will not be negatively affected. Hence, the analysis of efficiencies and innovation in the design of commitments is satisfactory in comparison to the importance given to them under the substantive assessment. However, caution should be taken in relation to the divestiture of early pipelines where the effective development from the purchaser's side and the potential negative impact of the transfer are hardly monitored. Unfortunately, it is still soon to assert for instance whether the outcome in *Novartis/ GlaxoSmithKline* has ensured that the purchaser effectively develops the two investigational skin cancer treatments, B-Raf and MEK inhibitors, or if, on the contrary, the divestiture undermined their viability.

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[132] T. Lorca Morales, *Merger Control in the Pharmaceutical Sector and the Innovation Market Assessment. European Analysis in Practice and differences with the American Approach,* Documento de Trabajo Serie Política de la Competencia Nº 25/2008, 2008, pages 18 to 26; and G. Bushell, V*eering off the well-trodden path? European Merger Control and the Pharmaceutical Industry,* Kluwer Competition Law Blog, October, 2015.

5.3.4 Proportionality of commitments

The commitments suggested and approved by the Commission shall be proportionate to the competition concerns identified. Consequently, the Commission shall accept the least restrictive remedies when there are several alternatives. The EU Courts, confirming the discretionary margin of the Commission's economic analysis, have recognised that the Commission might accept commitments submitted by the parties even when they are broader than the competition concerns, unless they are entirely unnecessary. That conclusion is based on the assumption that parties should not be limited to propose commitments aimed strictly at restoring the pre-merger situation. It is up to the notifying parties to consider which remedies solving competition concerns are the most convenient to them.[133]

Although the Commission has acknowledged in previous cases that the remedies proposed by the parties were disproportionate and unnecessary to the narrow competition concerns, the general circumstances around the notification procedure suggest that, despite not patently disproportionate, commitments go often beyond what is necessary to strictly meet the competition demands.[134] The main concern is whether those larger remedies respond to the parties' business strategies or to the economic and procedural pressure of obtaining approval.

In addition, even though the responsibility of submitting commitments relies on the parties, the negotiation process points out that, in reality, the Commission informally indicates to the parties what is broadly needed in order to obtain an approval decision. In particular, it is a well-known fact for the parties involved in negotiations with the Commission that provisions such as additional assets, up-front solutions or fix-it-clauses are usually, albeit informally, required by the Commission and subsequently submitted by the parties. Therefore, the question is not only whether the notifying parties submit proportionate remedies but also whether the Commission has proportionate demands.[135]

First of all, the strong prevalence of divestiture and the exceptional character of behavioral remedies causes that, parties do not often submit future conduct commitments. The preparation of commitments proposals does not only require time but it is also economically costly. Accordingly, notifying parties submit, within the limits of their commercial preferences, the commitments more likely to be accepted

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[133] D. Hoeg, *European Merger Remedies Law and Policy*, Hart Publishing, 2014, pages 54 to 57. See also *Cementbouw Handel & Industrie v Commission*, para. 307.

[134] *ibid.* and *Glaxo Wellcome/SmithKline Beecham*, para. 221.

[135] D. Hoeg, *European Merger Remedies Law and Policy*, Hart Publishing, 2014, pages 38 to 40.

and do not often include different packages of possible commitments. Therefore, the higher probability of success of structural remedies and standing-alone business results in the minor role of behavioral commitments and carve outs. The logical prevalence of divestiture in sectors such as the drugs industry where competition concerns ordinarily result from too high market shares does not set aside possible proportionality concerns. The list of assets included in the divestiture or the increasingly frequent up-front buyer provisions question in addition whether all those conditions, despite conferring greater security to the elimination of competition concerns, are necessary for the viability of the divested business.

Secondly, the time constraints affecting the procedure strengthens the proposal of extensive remedies. The notifying parties, especially where timing is crucial for the success of the transaction, might offer larger commitments in order to obtain a faster clearance.

Thirdly, and according to some practitioners' view, the Commission is less determined in relation to the serious doubts at the end of Phase II of the notification. If the Commission is more likely to accept more limited remedies at the end of the procedure, does that mean that the notifying parties convince the Commission of lesser threats to competition or higher effectivity of commitments? or on the other hand, does it mean that, if the parties would have aimed at a quick clearance, the larger commitments requested by the Commission during the Phase I would have been disproportionate to the competition harm? Those questions are, according to this view, especially relevant in the light of the pharmaceutical sector where concentrations are mostly cleared in Phase I. Acknowledging that one of the aspects favouring that efficiency is a greater legal certainty in the sector, another important factor is that those concentrations are composed by large pharmaceutical companies and are nonetheless million euro contracts, therefore, it is assumed that timing is usually crucial. Hence, does it mean that those transactions could be cleared with less demanding commitments, and therefore proportionate if the parties would not be concerned with an early approval?

In respect of the proportionality of the Commission's demands with regard to the parties' proposal of remedies, it is worth mentioning that several practitioners, for instance, E or F, recognised that the first commitments proposed never obsolete what the client is willing to compromise as it is well-known that the Commission will always express further requests. On the contrary, the Secretary-General Mr. Alexander Italianer has stated that the negotiation of remedies is certainly not a bargaining process. However, taking into account that at first notifying parties submit narrower commitments and the Commission

expresses larger competition concerns than the ones remaining at the end, it seems that, if not a bargaining process, the procedure has in practice a really similar nature.[136]

Although the varied circumstances affecting the case-by-case analysis impede establishing a general answer, it is worth reflecting around the two sides of the proportionality of commitments to ensure that the EU merger control moves towards a fairer system. Firstly, the proportionality of the commitments the parties submit, either due to their business interests or because of the excessive burdens imposed on them, and secondly, the proportionality of the finding of serious doubts and the amendments required by the Commission in relation to the initial proposal of remedies.

5.3.5 Market test of commitments

The commitments proposed by the parties should be market-tested when appropriate. The Commission's practice evidences that the market test of remedies is generally appropriate and systematically conducted, thereby ensuring effective consultation and third parties' right to be heard. Market surveys target a number of pre-selected commercially interested players with the aim of both, verifying the factual information provided by the notifying parties and assessing the workability and effectiveness of the proposed commitments. While third parties' views might support a more efficient analysis of the factual evidence, for example, in relation to the product and geographic market features, it is questionable to what extent they can play a role with regard to the competitive assessment of the post-merger situation.[137]

First of all, the third parties approached are not economist or specialists unlike the case-team members and the notifying parties' advisors. Secondly, those third parties do not have a complete picture of the merger context. Although the questionnaires are distributed with a summary of the relevant context affecting the transaction, they cannot be found to be at the same level of knowledge as the actual parties involved. Furthermore, the customers, competitors or suppliers included in the specific targeted groups have their own commercial agenda. Parties' competitors might express the need for more extensive

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[136] A. Italianer, *Legal certainty, proportionality, effectiveness: the Commission's practice on remedies.* Charles River Associates Annual Conference, 5 December, 2012, page 2.

[137] Notice on Remedies,para. 80; O. Bretz and K. Schallengerg, Clifford Chance Paris, *Market Tests of Remedies: A practitioners' view,* 2013

commitments due to their interest, for instance, to acquire some of the notifying parties' assets or weaken the position of the merged entity in the market.[138]

In the recent prohibition decision *Deutsche Börse/ NYSE Euronext*, the parties requested the rejection of all parties' competitors comments due to their subjective approach. The Commission dismissed the argument, and in line with its previous statements, considered that its careful, critical and objective assessment is not distorted by third parties' submissions. The Commission has in other occasions confirmed its awareness of the possibility that some competitors might aim to enlarge the scope of the remedies. However, since the notifying parties are always invited to comment on the results obtained, the Commission supports that the market test allows a more complete study of the future merger effects.[139]

On the other hand, the concerns regarding the risks of heavily relying on the market test remain. It is understandable the reluctance of notifying parties to accept that economic evidence can be extracted from the intrinsically biased competitors' comments. In particular, taking into account that there is little guidance on how the Commission weights the submissions of competitors and the notifying parties' responses to them. Besides, if the commitments agreed between the Commission and the parties must satisfy the market test, assuming that means third parties' interests, the danger is to convert commitments in complaisance solutions, avoiding third parties appeals but disregarding the effective elimination of competition concerns and the proportionality of commitments.[140]

Altogether, it remains doubtful how the market test, although helpful for scrutinising factual information, can accurately conclude whether new market structures will restore free competition or whether a divested business will effectively compete in the market. Even more importantly, the test applied by the Commission to weight the comments obtained is largely unknown. Thus, the concerns expressed in the lines above could possibly be disregarded with the publication of guidelines on how to objectively and carefully analyse third parties' responses.

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[138] O. Bretz and K. Schallengerg, Clifford Chance Paris, *Market Tests of Remedies: A practitioners' view,* 2013.

[139] *ibid.*

[140] D. Hoeg, *European Merger Remedies Law and Policy*, Hart Publishing, 2014, pages 59 to 64.

5.3.6 International Cooperation

A considers cooperation between Competition Authorities around the world as the greatest challenge for the future. Notifying parties' burdens are considerably increased when taking into account the growing number of mergers having an international dimension and requiring approval in several jurisdictions. The Commission and other Competition Authorities are making constant efforts towards a more efficient cooperation. In particular, the Commission has signed bilateral agreements as well as Memorandas of Understanding with numerous jurisdictions. Even more, the case-teams have some form of cooperation with other agencies in at least half of the cases in an in-depth investigation. For instance, with special regard for the pharmaceutical study, the cooperation in *Novartis/ GlaxoSmithKline* between Canada, China, Australia, Brazil, Pakistan, and the Federal Trade Commission in the US allowed a greater understanding of the healthcare competitive landscape in the respective jurisdictions in order to find compatible and non-conflicting remedies.[141]

However, larger cooperation is still needed, especially taking into account the importance of compatible procedural and substantive assessments. In that regard, it is worth noting the initiatives made by the International Competition Network, the conclusions extracted from its work groups and the advice introduced in its practical guides.[142] On that line, cooperation is considered beneficial, not only for the notifying parties in terms of decreasing the burdens on the procedure, but also to third parties and Competition Authorities in order to reduce unnecessary duplication of work, gaps information and inconsistent outcomes. The need and utility of cooperation are defined on a case-by-case basis but Competition Authorities are always encouraged to coordinate even before the beginning of the procedure and especially, in the determinative moments of the notification process such as before the opening of an in-depth investigation or the approval of remedies.

In order to have an effective cooperation, procedural timing should be aligned to such an extent that would allow meaningful communication at key decision-making.[143] In relation to the substantive assessment, Competition Authorities are expected to engage in informed discussions regarding market definition, theories of harm or potential remedies. With regard to commitments, cooperation may even re-

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[141] D. Hoeg, *European Merger Remedies Law and Policy*, Hart Publishing, 2014, page 68; and M. Vestager, *Merger review: Building a global community of practice,* ICN Merger Workshop, Brussels, 24 September, 2015.

[142] ICN, *Recommended Practices for Merger Notification Procedures; Recommended Practices for Merger Analysis; Merger Remedies Review Project;* or *Practical Guide to International Enforcement Cooperation.*

[143] ICN, *Practical Guide to International Enforcement Cooperation in Mergers,* pages 2, 5 and 6.

sult in globally-addressed remedies where the impact of the transaction is similar in the different jurisdictions. For instance, cooperation on divestitures of the same business might allow, where convenient, a consistent scope of the assets divested, common trustees and monitors, or the same suitable purchaser. Irrespective of the distinct anti-competitive effects, remedies established under one jurisdiction may have consequences in another. Agencies should therefore work together to avoid conflicting remedies or inconsistent obligations imposed on the parties, as well as to minimise the implementation difficulties.[144] The cooperation between the Commission and other Authorities has influenced the outcome of numerous cases. Many of the non-standard provisions under the EU merger control, meaning those not included in the Model Texts, are originated from coordination with other agencies. For instance, the vast majority of fix-it-first, up-front buyer and crown jewel provisions stem from EU-US cooperation.[145]

Although Authorities can still cooperate without the collaboration of the merging entity, the Commission encourages undertakings to facilitate international cooperation. Notifying parties are requested to submit, together with the Form CO, a list of those jurisdictions outside the EEA where the concentration is subject to regulatory clearance under merger control rules. On that line, it is worth noting that it is on the parties' benefit to contribute to procedural and substantive symmetries. The lack of coordination may result in delays or incompatible obligations, ultimately disfavouring their own commercial interests.[146]

Regarding the procedural aspects, merging parties are encouraged to file notifications or remedy proposals taking into account the different stages and time limits of the reviewing agencies. With reference to the substantive analysis, the consent of the notifying parties is requested in most jurisdictions, such as under the EU merger control, in order to share confidential information with other Authorities. Thus, the merging entity can facilitate informed and fruitful discussions by conferring confidentiality waivers. For instance, the Commission emphasises the importance of sharing relevant information between different agencies as to have effective joint discussions and to that aim, a model waiver can be found at the DG Competition website.[147] Nevertheless, caution is advised in cases involving purely local or regional markets since joint analysis could unfortunately result in more burdensome requests by certain Authority.[148]

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[144] *ibid*, pages 10 to 12.

[145] D. Hoeg, *European Merger Remedies Law and Policy*, Hart Publishing, 2014, page 70.

[146] ICN, *Practical Guide to International Enforcement Cooperation in Mergers,* pages 6, 8 and 12.

[147] Form CO, page 8 and ICN, *Waivers of confidentiality in merger investigations, Appendix D, European Commission confidentiality waiver.*

[148] G. Bushell, *The one-handed European Merger Simplification Project?* Kluwer Competition Law Blog, 11 June, 2013

6. CONCLUSIONS

Under the EU Merger Control, concentrations with a European dimension are subject to the prior notification obligation. The Commission shall therefore decide upon their compatibility with the single market. In case the Commission observes through this assessment obstacles to competition, the transaction shall only be authorised if modifications introduced by the parties, pursuant to Articles 6(2) of the EUMR during Phase I of the procedure, or 8(2) in the case of an in-depth investigation, remedy effectively and entirely the competition concerns.

Consequently, the Commission shall communicate to the parties any significant impediment to effective competition identified as to allow them to propose commitments to yet obtain clearance. On that line, serious doubts shall be shared with the parties at the latest in the state of play meetings before the deadlines to submit commitments, 20 day for Phase I and 2 weeks after the opening of a complete investigation in Phase II to clarify the content of the Statement of Objections. Once the remedies proposed by the parties are proved to solve all competition concerns, the Commission clears the transaction subject to conditions and obligations to ensure an effective implementation of commitments.

According to the EUMR, and more in detailed under the Notice on Remedies, commitments should be proportionate to the competition concern and entirely eliminate it. Furthermore, commitments shall be possible to implement and be effective on a lasting basis. Accordingly, the regulatory framework and practice of commitments evidence the strong prevalence of structural remedies, and divestiture in particular. That preference is based on the higher degree of certainty and minor monitoring requirements of modifying market structures. However, behavioral commitments might be acceptable under exceptional circumstances provided their equivalent effectivity compared to divestiture.

In relation to the pharmaceutical sector, the consolidation of the sector and the recent promotion of growth have been conducted through mergers and acquisitions. In that context, the Commission's assessment has been inevitably influenced by the features of the sector. With regard to commitments, this study proves a greater interventionism by the Commission in pharmaceutical concentrations but also a better predictability and an adequate acceptance of commitments. Even with more emphasis than in other sectors, most of the Commission's serious doubts have been solved through the divestiture of certain subsidiaries, assets, drugs or pipelines. Accordingly, the design of commitments focuses on assuring that the divested business will effectively compete in the market and constraint the merging entity. To this

end, aspects such as all the necessary assets to be included, the removal of competition links with the merging entity or the finding of a suitable purchaser will be determinative to obtain approval.

The assessment of pharmaceutical concentrations, concretely those causing horizontal overlaps, differentiates between finished dose pharmaceuticals and future products. Correspondingly, the Commission's definition of product and geographic markets is affected by the varied competitive constraints in those delineations. In relation to the affected product markets, the Commission examines the interplay between the economic and therapeutic substitutability using as the starting point the ATC classification. With regard to geographic markets, the large national regulatory framework of finish dose drugs results in national markets whereas future products are usually considered worldwide or at least EEA-wide.

The competitive assessment of pharmaceutical M&A is based on the general theories of harm, mostly non-coordinated competitive effects due to the variability of high-tech sectors. It is worth noting that due to the often higher market shares, the Commission divides the drugs into three different groups based on the combined market share and the increase caused by the merger. On that line, drugs falling under Group 1 are problematic in competition terms whereas medicines under Group 3 are not likely to rise serious doubts.

Given the importance of a deep understanding of the businesses involved, the assessment of concentrations in the drugs industry varies extensively depending on the parties' area of activities. The analysis is influenced by the different features of overlaps between originator and generic companies, among generics or with players operating in AIPs or other related markets. The influence of IPRs, market authorisations, pricing and reimbursement policies or innovation complicate the finding of clear-cut outcomes.

Provided an overall picture of the EU practice of commitments, the most advisable conduct for the notifying parties obviously depend on the nature of the concentration and the rationale of the deal. However, and irrespective of particular interests, notifying parties are advised to drive an early ex-ante assessment aimed at structuring the deal according to the potential costs or losses resulting from the required commitments. For instance, if notifying parties take into account the likely need for the divestiture of a subsidiary, the acceptance of such remedy during the procedure will not have a negative impact on the deal. Even more, large preparation is required to successfully meet all Commission's demands during the procedure. The extensive amount of information required under the Form CO and the Form RM require nonetheless time and resources. A correct preparation avoids in the same line unnecessary delays,

benefiting in last instance the commercial interest of a prompt implementation of the deal. The parties' pre-assessment should not disregard the narrowest product market definitions, according to not only ATC3 but also ATC4 and the molecule level, or the most limited geographic markets to the national level, the early assessment of future products, or the classification of combined market share groups.

Taking the pharmaceutical sector as an example, the sector evidences prompt clearances subject to divestiture commitments during Phase I of the procedure. However, it is acknowledged that, in general, the submission of commitments extensively depends on the importance of timing for the success of the deal and on the commercial harm of divesting certain assets.

With regard to the procedure, merging parties are encouraged to engage in informed discussions during the pre-notification contacts with the Commission. Firstly, in order to submit all necessary information and get the procedure started but also with regard to early discussions of the competition concerns and the possible remedies. Although the Commission is reluctant to formally discuss remedies in this phase, notifying parties can achieve a greater understanding of problematic areas during these fruitful discussions. Being open and cooperative during the procedure in relation to the threats to competition and to the more convenient commitments would contribute to a fairer outcome of the case.

Bringing to criticism the developments during these twenty-five years, the EU Merger Control, and the practice of commitments in particular, can be awarded in terms of efficiency and success. Although Commission's investigations are usually adequate to prevent dominance positions, some borderline cases suggest the need to focus also on avoiding Type Errors I. Most mergers do not harm competition and have a positive impact on the economy by reducing costs and increasing efficiency, therefore, the Commission shall only intervene to prevent those concentrations creating or enhancing the merged firm's ability to distort competition either unilaterally or through coordinated conducts with its competitors.[149] Those anti-competitive effects are known to increase prices, reduce quality and prevent innovation, ultimately disfavouring consumers. However, a too protectionist approach might additionally have a negative impact on the competitiveness, growth and development of EU markets. With special regard to the pharmaceutical industry, the larger investment in R&D in the recent years has anyway resulted in a decreasing number of newly registered drugs, and even more, Europe does only receive a residual propor-

[149] ICN, *Recommended Practices for Merger Analysis,* Working Group Comments, April, 2008, page 2.

tion of that investiture. Therefore, the Commission's thorough and careful analysis is called to balance all interests involved.[150]

The identification of competition concerns by the European Commission, and therefore the need for remedies, has been considered in certain cases to be too intrusive and strict. The Commission's narrow market definitions, resulting in higher joint shares, together with the sometimes straightforward presumptions of harm, imply that the Commission is in a position to easily prove serious doubts as to the compatibility of the transaction with the common market. Without the aim of underestimating the importance of protecting fierce competition and its benefits for the single market and the society, the notification procedure has been found sometimes to impose needless barriers to M&A activity.

Accordingly, the EU merger control should be yet improved. Some of the practical problems identified have been connected to possible solutions whereas some others have been merely introduced for further debate. Concrete suggestions have been considered with regard to less demanding requirements in terms of information disclosure, further publication of guidelines on the market tests of commitments, larger access to the Commission file and a more active coordination with other Competition Authorities.

The practitioners' view indicated that the cooperation in the notification from the Commission's side should be improved. In particular, in relation to the transparency of the procedure, the existence of open discussions with the case-teams and the parallel assessment of competition doubts and remedies. The current notification procedure still imposes excessive administrative burdens on the notifying parties, and especially taking into account the importance of timing in the business world, the Commission should be more collaborative in terms of information waivers and early discussions of commitments in the procedure.

The access to the Commission file even before the Statement of Objections would facilitate an advanced and closer understanding between the case-team and the parties, thereby avoiding the proposal of insufficient commitments or the opening of in-depth investigations. On the other hand, with regard to those sectors such as the pharmaceutical industry where most cases are cleared under Phase I, the access to the file would grant a better assessment of the evidence under which the Commission relies to conclude that the transaction rises serious doubts. In addition, although most case-teams are open to fruitful discus-

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[150] Opinion of the European Economic and Social Committee on the 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: *Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector,* COM (2008) 666 final, 2009/C 318/14.

sions, some others are reluctant to share information before reaching a determinative position. The pressure imposed on the parties as a result of non-cooperative case-teams could be amended by granting the access to the file. Despite the Commission's strict time constraints are acknowledged, the access to the file should not lead to delays in the investigation but to more productive discussions in order to acquaint solutions convenient to both, the Commission and the notifying parties.

On the other hand, the complex delineations of the markets or the likelihood of anti-competitive effects heavily rely on a case-by-case basis, thus, particular enhancements extensively vary on the sector, the type of concentration and the markets affected. Hence, substantive improvements are only suggested in respect of a more careful assessment of efficiencies, innovation and the proportionality of commitments.

With regard to efficiencies and innovation, the Commission's decisions under the NACE C.21 category point out the usual assessment of pipelines. In this context, the Commission is encouraged to be especially sensitive when bringing to the examination products at earlier stages of development. The intrinsic uncertainty of drugs at Phase I or II of Clinical Trials cannot be disregarded assessing the likelihood of growing into a competitive force. The Commission should also take into account that the implementation of divestitures of early pipelines might jeopardise the development of the product or be problematic in terms of finding a suitable purchaser. In addition, the design of remedies should carefully conclude that the divestiture of certain assets will not prevent the merging entity's ability to innovate in the future.

In relation to the proportionality of remedies, the Commission should not only focus on the modification of market structures but also on the efficient restoration of competition forces. Therefore, the strong prevalence of divestiture is unfortunate given that behavioral or non-divestiture commitments might be under certain circumstances equally efficient. Likewise, although it is the parties' responsibility to submit proportionate remedies, the Commission should be more comprehensive regarding the economic pressure of the tight time limits of the procedure in connection with the commercial losses of clearance delays.

Overall, the regulatory framework and the Commission's practice in the notification procedure, in particular of commitments should be awarded as solid and adequate. However, the self-assessment of the still practical difficulties is essential to develop, in line with the previous 25 years, towards a more efficient EU merger control. Thus, the Commission and all the other players involved are called to cooperate to improve the remaining and complex questions of the current practice, moving thereby towards a fairer system.

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ANNEX I - INTERVIEW CONTENTS

1. Do you usually identify competition concerns in the pre-notification contacts or in the earlier stages of Phase I?

2. Do you easily predict the Commission's approach in relation to the necessary commitments?

3. To what extent do you have access to the investigation file during the process?

4. How cooperative and open is the dialogue with the Commission to identify acceptable commitments?

5. What is your business strategy when negotiating commitments?

6. Does the Commission usually approve the first commitments you suggest?

7. Do the time limits influence the commitments you submit?

8. Do the commitments often compromise the initial interest of the concentration?

9. To what extent efficiencies or innovation defenses play a role in the negotiation of commitments?

10. If any, which improvements do you consider necessary in the current practice of commitments?

ANNEX II - CONTACTED LAW FIRMS

1. Linklaters
2. Cleary Gottlieb Steen & Hamilton
3. Uría Menéndez
4. Norton Rose Fulbright
5. Baker & McKenzie
6. Vinge
7. Garrigues
8. Cuatrecasas, Gonçalves Pereira
9. Mannheimer Swartling
10. Freshfields Bruckhaus Deringer

ANNEX III - RESPONDENTS TO THE SURVEY

1. ***Mr. Niklas Maydell*** is an associate at ***Cleary Gottlieb Steen & Hamilton*** in the Brussels Office. His broad area of expertise focuses on EU Competition law, in particular, on Merger Control in the EU and worldwide. In addition, Mr. Maydell has extensive experience in a wide number of industries, including pharmaceuticals.

2. ***Mr. Antonio Guerra Fernández*** is a partner at ***Uría Menéndez,*** in the Madrid Office. Mr. Guerra Fernández is known for having the greatest understanding, together with other areas of practice, of European Competition Law, advising companies and associations in all types of proceedings before the European Commission.

3. ***Mr. Jonas Koponen*** is a partner at ***Linklaters*** in the Brussels Office. Mr. Koponen is Global Head of Linklaters Competition/ Antitrust Practice. He is an international competition lawyer with the largest experience in complex transactions together with extensive practice in the healthcare industry, among other sectors.

4. ***Mr. Victor Sand Holmberg*** is an associate at ***Mannheimer Swartling*** in the Brussels Office. As part of the EU and Competition Law Department, his area of practice covers the EU Merger Control, in particular, with regard to notification proceedings before the Swedish Competition Authority and the European Commission.

5. ***Mr. Gavin Bushell*** is a partner at ***Baker & McKenzie*** in the Brussels Office. His area of practice focuses on EU Competition law and Merger Control. Mr. Bushell has the widest experience in all aspects of merger transactions, together with an extensive knowledge of the pharmaceutical industry.

6. ***Mr. Pär Remnelid*** is a partner at ***Vinge,*** in the Brussels Office. His expertise cover, among other fields, European Union and Competition & Regulatory Law. Mr. Remnelid is recognised for having the greatest understanding of the legal and business world by Directories such as Legal 500.

ANEX IV - INTERVIEW TRANSCRIPTS

PRACTITIONER A

1. **Do you usually identify competition concerns in the pre-notification contacts or in the earlier stages of Phase I?**

In the pharmaceutical sector, there is a good understanding of the analytical framework. Thus, where taking into account that only one case since the EUMR came into force went into Phase II, there is a message that competition concerns and solutions to solve them are highly predictable. One particular aspect of the pharmaceutical sector is that very frequently, even outside the context of mergers, companies deal with each other with regard to relatively small tangible or intangible assets. The acquisition and sales of assets take place even without the need of establishing remedies, therefore, there is a well-established practice in doing deals. Applying that practice and experience into the remedies needs makes it possible to find ways of doing deals which are sufficiently firm to allow the Authorities to consider that such way of doing the deal can be an effective remedy.

If you do the preparation well in the drugs industry, it is possible to have a pretty good predictability of outcomes, avoiding then Phase II. A lot of the M&A activity in the pharmaceutical sector takes place in the US because much of the R&D and product development is there, the FTC is extremely experienced and they have influence other Authorities, including Europe. In Europe, there are many deals happening too but not with the same flow as in the United States. Between Europe and the US, in many deals, there are similar ways of identifying the problem and the solution. Consequently, competition concerns are anticipated to the notification procedure, which means that they have been predicted before even pre-notification and Phase I. Actually, clients try to price the remedies in the deal, thus, it is necessary to take into account the possible most demanding commitments.

2. **Do you easily predict the Commission's approach in relation to the necessary commitments?**

In most situations, it is easy to predict the Commission's approach. In particular, in some of the recent cases, there can be found some remedies in the borderline such as in the case *Novartis/ GlaxoSmithKline* where there was required to divest a pipeline asset at an early stage of development. That is one of the cases where the Commission went beyond of its current practice. Pipeline assets can be developed with some other company but the right to market it will be held by one of the merging parties. What it should be taken into account by Authorities, in respect of early stages of pipeli-

ne assets, is that it might not be that easy to divest that asset, simply because there is uncertainty from the commercial perspective of effectivity, price and success of the asset since it is still in an early phase of development and all those aspects are not yet proven. So, the lack of enough data in relation to an early pipeline might not be only a complication from a theoretical perspective to identify the value and potential competition concerns that that asset might raise but also in the practice, it could be hard to be sold.

In relation to finding an adequate buyer, sometimes, it might not be easy. There are different ways to deal with this problem. The FTC practice is that there has to be an upfront buyer in every situation and the deal cannot be closed unless the FTC approves the buyer, thus, there will always have certainty that the buyer is a good buyer. The practice in Europe is slightly different. The standard practice is that you will agree on the remedy with the Commission which will be incorporated in the decision and the parties will have five or six months to close the deal after the decision has been made and to implement the remedy (find the buyer, negotiate the deal and come back to the Commission which will approve the buyer in order for the parties to implement the remedy). However, the Commission, of course, wants, before giving approval, to test whether there is a number of potential buyers which look credible or whether there is already a short list of buyers with whom the seller has been already under negotiations and so on. The Commission requires some degree of certainty that there is a decent pool of good candidate buyers to avoid the situation that there are no buyers for the assets. It has not happened that candidates are not found, however, sometimes, the implementation period has had to be extended so that the seller will have more time to negotiate with the buyer.

Sometimes, the Commission will require also an upfront buyer where the drugs at hand require that the buyer is an expertise in that market. From the notifying parties' perspective, it is a plus to be in the situation where there is no need for having experience in the area to compete effectively after buying that asset with the seller. Certainly, all Agencies will want to ensure that are clear standards set up for what is a good buyer. If the potential number of buyers is small, the Commission will require an upfront buyer because otherwise they will not be comfortable accepting that remedy.

3. To what extent do you have access to the investigation file during the process?

The access to the investigation file is not granted until Phase II. However, after the market test, the parties obtain oral feedback and in case there have been some important submissions by third parties, the Commission will discuss them with the notifying parties to check on the arguments and evidence. There could be some situations where it can be frustrating not acceding to the file. However, in most of the cases, the Commission's practice in reviewing and discussing key documents with the

parties works well and the lack of access to the file is not a big issue because there is a pretty good balance of both parties' interests in the process.

4. **How cooperative and open is the dialogue with the Commission to identify acceptable commitments?**

The Commission is cooperative and open to finding solutions. Since there is a high predictability in the pharmaceutical sector with regard to adequate commitments, the dialogue is sometimes better than in other sectors. However, it is a matter of time and how soon you can start discussing commitments. The Commission mainly focuses on getting its own understanding of the market life, competition concerns and then on finding solutions. Thus, some cases take some time to be developed whereas in others it is easier to clarify what is the situation. The sooner you get to the point of clarity, the sooner you can have an informed discussion concerning remedies. However, in some other cases where it is more complex to identify concerns, you can also have informal discussions with the Commission regarding potential problems and solutions. Comparing the current situation with 5 or 6 years ago, nowadays, it is easier to have earlier discussions than previously.

5. **What is your business strategy when negotiating commitments?**

The purpose is always the best outcome for the client. That is, of course, the least remedies as possible or as close to the expected remedy because of predictability. In situations where the client has made an analysis of price and within that price has introduced the costs or losses of the potential commitments into the deal price, it is important to get as close as possible to those expectations. The strategy is defined by the client since it is its business and its deal. The strategy will be supporting the business objective.

6. **Does the Commission usually approve the first commitments you suggest?**

Yes, this question is also connected with predictability. Where the remedy is proposed formally, such remedy has been prepared as much as possible, thus, there will be a great understanding between the notifying parties and the case-team about what are the core aspects of the remedies and then, the market test might introduce some changes to the remedy.

7. Do the time limits influence the commitments you submit?

Remedies cannot be prepared during the running of Phase I, only very simple remedies can be done in that phase. Commitments are always prepared with a lot of time in advance because the information which is required nowadays implies a lot of preparation. The collection of data for the notification has to start long before contacting the Commission. Also, many of these deals are fought with many different Authorities and many issues will be discussed with several Authorities and not only with the Commission. Consequently, the formal time period in Phase I does not influence the nature of the commitments proposed because the preparation of those remedies starts long before.

8. Do the commitments often compromise the initial interest of the concentration?

The initial interest of the concentration is not often compromised. Parties want to prepare the deals with time in order to avoid surprises. Therefore, the established practice that exists helps to predict the outcomes and then the anticipation of the commitments which will be included is taken into account where assessing the interest of the concentration.

9. To what extent efficiencies or innovation defenses play a role in the negotiation of commitments?

The overall objective of both parties, the Commission and the notifying parties is that innovation will not be negatively affected. From the Authorities' perspective, they want to see continuity from the buyer's side, not only in relation to the market products but also in relation to the innovation, thus, there might be necessary to transfer R&D resources. Additionally, from the selling side from which the assets are carved out, it is not desirable to detriment the ability of the seller to innovate in other areas. Especially, finding solutions with regard to R&D companies which cannot separate some of its assets can be harder. Solutions for that can be to sell the patent to the buyer but getting a license back for a narrow use in some therapies where there is no competition concern. Or the other way around, the seller divests assets problematic for competition but maintains the necessary know-how and the technology which are licensed to the buyer. The seller will license then the patent to the buyer, giving him also some assistance during the transfer of technology. It depends on a case-by-case basis what the Commission is more likely to accept, either divesting the patent and obtaining a license for the seller's use of that technology in some other related areas free of competition concerns or

licensing technology to the buyer of a certain business line where such technology remains under the seller's assets.

10. If any, which improvements do you consider necessary in the current practice of negotiating commitments?

The big challenges in the current practice and for the years ahead concern the coordination between the different agencies of merger control in the world. An important challenge for Authorities and also merging parties internationally is to find a common framework of how to do remedies that could work in a coordinated way. It can be an absolute nightmare to deal with four or five different Agencies, especially when they have different experiences and procedures. The greater challenge for Competition Authorities is to cooperate internationally. In relation to the possible solutions to achieve such challenge, the ICN is working in a project on how to decide merger remedies at the international level at the annual meeting which will take place in April.

PRACTITIONER B

1. Do you usually identify competition concerns in the pre-notification contacts or in the earlier stages of Phase I?

Competition concerns are identified in advance due to their importance for the negotiation of the actual deal. A buyer will not be willing to go through an acquisition if it is not likely to be approved by the Commission. Competition concerns are identified therefore long before even a letter of intention is sent, the deal is negotiated or signed. Usually, the preparation of the notification starts weeks, or even months, before contacting the Commission for pre-notification proceedings. The pre-notification begins with the draft of the Form CO where all competition concerns can be already identified, especially in relation to the question based on the draft Form CO the Commission will then ask.

2. Do you easily predict the Commission's approach in relation to the necessary commitments?

The Commission's conclusions might not be easily predicted, however, what can be predicted is that the Commission will scrutinise very thoroughly the transaction and be sure that competition concerns are analysed in-and-out. The Commission is very feral is its assessment and the narrowest definition of the market is always asserted in order to conclude there are no impediments to competi-

tion. Where predicting the Commission's assessment, it is possible to be sure that the analysis has taken into account the narrowest definition of the market, even though in the Commission's decisions is established that the market is not required to be delineated since there are no concerns.

3. **To what extent do you have access to the investigation file during the process?**

The access to the file is not granted until the Statement of Objections. Where mergers do not raise competition concerns, therefore, the access to the file is not granted. In relation to the access after the merger has been cleared, the access is not usually requested as it is not found necessary.

4. **How cooperative and open is the dialogue with the Commission to identify acceptable commitments?**

It depends on the case-team handling the case in the Commission, the type of merger and so on. The Commission is the one controlling the procedure, they can decide that the notification is not complete or that they require further information which can be a really heavy burden. A good cooperation usually exists, however, the Commission is definitely in charge of the procedure.

5. **What is your business strategy when negotiating commitments?**

The main strategy is to be very honest and clear in relation to the competition concerns identified and also answering all the questions put by the Commission since not replying to them can become really problematic for the parties.

6. **Does the Commission usually approve the first commitments you suggest?**

In the same line as the submission of the Draft CO, the Commission and the parties work from the first drafts filed but the Commission will have questions with regard to what has been submitted, parties can be requested to develop certain points and to provide with more information, even in relation to markets where competition concerns have not been found.

7. **Do the time limits influence the commitments you submit?**

The time limits can be really important because the parties cannot close the deal before they have

received authorisation. Therefore, that can be really relevant for the buyer, the seller or both. The timing is thus of great importance, that is the reason why the notification procedure is planned a lot before is submitted because once the notification is filed, the clock starts ticking.

8. Do the commitments often compromise the initial interest of the concentration?

The notification procedure itself does not compromise the initial interest of the concentration, with the exception of the possible impact of the timing of the transaction. On the other hand, where commitments are involved, that will absolutely be likely to compromise some interests involved in the transaction because they will imply a modification of the deal.

9. To what extent efficiencies or innovation defenses play a role in the negotiation of commitments?

Efficiencies are included as one of the questions of the Form CO and therefore, they are always brought up to the assessment. However, where the cases do not raise competition concerns, the role they played and their relevance can be questioned. In more complex cases, where the merger could be raising doubts in certain markets, the efficiencies will be of greater importance than in non-problematic cases.

10. If any, which improvements do you consider necessary in the current practice of negotiating commitments?

In general, DG Competition conducts a very sophisticated analysis compared to many national competition authorities in Europe. The only remark I can have on the procedure is that there is really no power balance between the notifying party and the Commission. Even though the Commission is aware of the scheduled date of the notification (you indicate the date you are planning to submit the filing in your "team allocation request" which is the first thing you submit to the Commission to notify the intention of initiating the notification procedure), the Commission can very well declare a few days before the scheduled submission that they need more information and that they will declare the submission incomplete before they have received it. In practice, the Commission will see to that they have all possible information even before the clock starts ticking (30 days). The Commission will, therefore, refuse to declare the submission complete before they are satisfied. It can be very stressful for the parties not knowing exactly when they can file and when the 30 days starts counting.

As I said before, timing can be crucial from a business point of view because of a multitude of reasons. In short, a few days delay in a large transaction can cost millions (or it can even mean that the transaction fails). When it comes to problematic mergers that go into phase 2, the parties must be even more stressed. Briefly, I think that many at the business side feel that the Commission does not take into account the costs of delays due to the notification.

PRACTITIONER C

1. **Do you usually identify competition concerns in the pre-notification contacts or in the earlier stages of Phase I?**

Normally, the Commission does not raise concerns in the pre-notification phase. It depends on how long the pre-notification takes and also on the facts. In the pharmaceutical sector, there will be usually a 2 or 3 months period of pre-notification where the parties share information with the case-team. The data includes the drugs forming Group 1, 2 or 3 at the national level. During this process, there is a bit of a discussion why none of the markets should raise competition concerns. At first, there might be, for example, 30 products within Group 1, those with combined market share of over 35% port-merger and an increment of 1% but that in some of those products the market share does not reach over 40% and there are still strong restraints in the market by other players, or for example the regulatory factors in the country where prices are regulated and therefore there is no option to raise them after the merger, among many other aspects. After this discussion, there might be still some markets subject to competition concerns, however, it is not likely that the Commission will communicate that during the pre-notification. Thus, in the pre-notification, parties are focus on giving as much information as possible in order to file and get the clock started, being sure that they have not missed anything in terms of overlaps, pipelines, portfolios, upstream markets, components or ingredients, manufacturing, etc. Usually, the same day or the day after the notifying parties file, the Commission share its concerns. It can happen that they do so before the file but it is not common. Before day 15, and any day after, it is when after the market testing, commitments start to be discussed. The parties will push the process to discuss them as early as possible. However, it usually happens on those dates of the investigation. Frequently, in relation to all markets involved, the parties might have really good arguments to disregard the competition concerns in some but there will be still others which may remain problematic and might need to be solved through remedies. If they indicate the meeting is not required, it means that you do not have an issue with the approval of the transaction. Although the arrangement of the meeting consequently brings bad news, parties get a

pre-warning of the problems pretty quickly. The request for more information and questions, which the parties should respond immediately, in relation to the results of the market test, indicate to the parties the direction the Commission is taking.

2. **Do you easily predict the Commission's approach in relation to the necessary commitments?**

About day 15, a working meeting will take place. The deadline for submitting the remedies is day 20, therefore, the parties are interested in having that meeting really early, because if there are concerns you do not have many days to discuss them and suggest the adequate commitments. The Commission never indicates the need for a remedy. However, they will share the areas where they found competition concerns, sharing a list of the drugs and national markets which consider to be controversial and explain why. The Commission will explain competition concerns such as the lack of competition strength in the market by other players, in situations where, for example, the merging parties are the closest competitors without a substitutable drug on the market, as well as in the case that a traditional pharmaceutical company acquires a generic company who would have been the most likely competitor to enter into that market. Therefore, the Commission will state, that in case the parties do not propose a solution for those impediments to competition, they will be opening Phase II of the investigation.

3. **To what extent do you have access to the investigation file during the process?**

Of course, there will be telephone contacts with the case manager but they will not be telling you very much about the concerns. They are quite nervous about giving information away. The case manager is usually the person in charge of sharing the feedback, however, sometimes they might try to hint the reasons for finding competition concerns in certain areas and the parties will have to push them in order to understand the reasons for such impediments to competition in relation to a particular drug in a particular country. The case manager may share and discuss with the parties the conversation they had with competitors, consumers or other players in the market. There are meetings or telephone contacts but there is no access to the file and the actual information.

4. **How cooperative and open is the dialogue with the Commission to identify acceptable commitments?**

It is not open at all. First of all, because it is for the notifying parties to put the remedies on the table.

There is a template from prior cases which has been accepted and can be used, usually as a starting point. The template includes marketing authorisations, royalty free licenses, IP rights, the relevant books and materials, customer orders, transference of Key Personnel, etc. The draft is submitted after acknowledging the Commission's concerns, after the 15 day meeting, but before the deadline (Day 20) in order to receive Commission's feedback. So, usually, the parties submit a draft to the Commission around day 18 and after hearing comments, the commitments will be formally submitted Day 20th the latest, before midnight.

If the market investigation proves that the proposed commitments addressed the concern, will be usually accepted, although usually improved or specified. However, there is no need for much of a dialogue of how to improve them. There are always points that need to be discussed, for example, limitations on market authorisations in relation to not being used outside the geographic markets where the remedy is imposed or other conditions imposed on the potential purchaser (need of having a market footprint in the market where the product is given), etc.

There is a possibility that, either in the Commission's first look or after the market investigation, the Commission might find that the commitments are not sufficient, for example, it might be that they require also manufacturing facilities, the economic basis on which those facilities are given or so on. You can end up being in a thorough discussion and of course, the deadlines push out. Phase I is only 25 to 35 working days but the actual period to negotiate is from around the 20 to the 31 or 32 because around day 33 they need to be finalising the paperwork and putting it through the process of getting discussed and approved by the Commission, including the consultation and legal service.

5. What is your business strategy when negotiating commitments?

The best strategy is to put the issues very upfront, and as early as possible. It is important to be thinking about the data that will be required. Also, it is important to be sure that you do not wait until day 15 where you get the bad news for preparing remedies. Thus, working on remedies should start before, mainly because it takes a lot of time to collect all the information required and to draft all the necessary documentation for proposing remedies.

6. Does the Commission usually approve the first commitments you suggest?

No, there is always improvements or tricks. Even if they approve the basic model, you always end up having a bit of a discussion about what is included, even in relation to the language used, for example, the Commission does not usually like where the text diverges from the Standard Commit-

ments Text or commitments which have not been accepted in previous cases.

7. Do the time limits influence the commitments you submit?

The timing does not have an impact on the shape of the remedies. The time influences in relation to when you submit them and develop them. The two main concerns are, firstly, meeting the 20 working days deadline because otherwise you will get into Phase II of the investigation. If the party does not submit adequate remedies the day 20, at midnight, or after such submission, the Commission still finds serious concerns, the concentration will be investigated in Phase II in-depth. The other factor refers to the jurisprudence of the Court in Luxembourg, according to it, the Commission cannot accept entire remedies after day 20. So, anything that they accept after that date has to be improvements to what has been submitted. Therefore, the notifying parties have to be sure that whatever they put on the table before the day 20th is capable of being improved if they get further concerns. The remedies might not influence the type of commitments suggested. However, timing is a commercial factor which influences the process in different manners. Generally, clients, in the light of the commercial assessment, want to get the transaction cleared as soon as possible in Phase I, either with or without remedies. If the parties decide to take the risk of going into Phase II, there are several factors which have to be taken into account.

Firstly, the timing impact. Usually, cases do not get out of Phase II quickly. Few cases get closed after 5 or 6 weeks in the second phase where parties might not be able to agree in a remedy, and they might take extra time. The majority of cases once in Phase II, they take long time to be cleared. Secondly, going into Phase II might generate quite negative messages to other people, such as the investment community which may believe there is a problem with the deal, having a negative impact on company share prices and investment or employee confidence. On the other hand, it might also have an impact with regard to other regulators around the world that the notifying parties may be dealing with. Normally, a concentration is not only notified to one Authority, and usually depending on the facts, it is necessary to notify several agencies. The regulators will watch each other, if you go into Phase II in one jurisdiction, that might raise concerns in another because they might consider that, maybe, they should be looking at something else in your case and putting you consequently into Phase II in that jurisdiction too. Therefore, it is a commercial consideration of what is the price of going into Phase II. Aspects such as the high or low chances of winning the discussion, the cost of implementing the remedy in relation to the overall value of the deal, the impact of prolonging the approval.

8. Do the commitments often compromise the initial interest of the concentration?

The majority of cases do not compromise the initial interest of the concentration. However, it sometimes happens. In most transactions, that is not the case, especially in pharmaceutical concentrations because the remedies are quite discrete. There can be cases however where the commitments cover a very large part of the business and leave the deal no longer commercially sensitive, for example, a really old case is the acquisition Busch by Interbrew where the Commission authorised the transaction but require the divestment of Busch, thus, the commitments did not represent an interesting commercial outcome. Therefore, there is the need to balance to what extent the rationale of the deal is affected and in case the initial interest is compromised, the deal will be dropped as it recently happened in *Mondie / Walki Assets* which was finally withdrawn in Phase II of the investigation.

9. To what extent efficiencies or innovation defenses play a role in the negotiation of commitments?

Efficiencies and innovation defenses do not play a major role in the negotiation of commitments, they rather affect the substantive assessment before you get to the discussion of remedies. The Commission will take into account innovation in Phase I. Innovation can be assessed as a factor favouring the parties, for example, where a competitor holds a pipeline product subject to entering in the market and constrain the strength of the concentration. On the other hand, innovation can also work as an impediment to competition where the R&D paths horizontally overlap between the merging parties. That scene has occurred recently in cases such as *Novartis/ GlaxoSmithKline*, where the Commission has not looked only into products in the third phase of Clinical trials but also in the second one. The Commission assesses the transactions in the light of innovation by examining the potential reduction of R&D assets comparing the pre-merger and the most likely post-merger context. The parties would be competing and processing the research therapeutical programs in parallel but, as a result of the merger overlap, resources spent in that area of investigation are likely to decrease. Innovation is a concern and it can be observed in many cases, as in the recent merger of *Pfizer/ Hospira* where the Commission had concerns in relation to the continuation of the research after the merger of certain drugs which were being developed by one of the parties. Those concerns will be solved through remedies, and in this case, the remedies will not solve current overlaps but future ones. Same applies to efficiencies, both will be quantified in the substantive assessment in order to clarify what the effects of the mergers might be after clearance.

10. **If any, which improvements do you consider necessary in the current practice of negotiating commitments?**

In relation to the adequacy of remedies, the commitments included in the Template constitute good solutions to competition concerns. Clarity in relation to the publication and understanding of previous decisions might be welcomed, otherwise, the template is quite clear regarding the current practice of acceptable commitments.

PRACTITIONER D

1. **Do you usually identify competition concerns in the pre-notification contacts or in the earlier stages of Phase I?**

Yes, it depends on a case-by-case basis. Especially, if there is a client you know very well, together with his business and market shares, then, it is very often that you identify the competition concerns very early in the process, even before you start the pre-notification and the contacts with the Commission. On the other hand, if you don't know the client before, it might take some time to understand his business and to identify potential competition problems. However, it is very rare that you get surprised by the Commission's concerns. Competition concerns are generally identified quite early. It is not always that the identification of problems is right, however, the Commission gives indications during the pre-notification process and it might also get quite clear during the meetings in the earlier stages of Phase I. For example, it can occur that the Commission is really demanding during the pre-notification regarding the content of it but then it expresses that the transaction doesn't raise impediments to competition. As advisors, the aim is to identify those concerns as early as possible because they might have an impact on the manner under which the deal is structured.

2. **Do you easily predict the Commission's approach in relation to the necessary commitments?**

The scenario where commitments are needed does not happen that often. It is easy to predict which commitments the Commission will be happy with, however, it might be that there is something you do not want to offer because it is too much. What is sometimes a bit problematic from a practical point of view, it is that the Commission first wants the notifying parties to suggest the commitments and after, it conducts the market test in order to check whether they are appropriate, consequently, open discussions are difficult since the Commission will accept or not the commitments depending

on the market tests made after proposing the remedies. The Commission might be willing to discuss the form of commitments, which kind of agreement and so on but at an earlier stage they might not be happy to discuss in detailed the commitments the parties should suggest. In general, it is desirable that there will be more informal and open discussions with the Commission but also it is connected to the case at hand.

3. To what extent do you have access to the investigation file during the process?

The access to the investigation file is granted very late in the process, after the Statement of Objections in Phase II, stage of the investigation which is very unusual since concentrations are usually cleared or withdrawn before of getting into Phase II. National filings are so much easier to get. During meetings, the Commission might let you know that its investigation has revealed that there is a problem and you can discuss it with the case-team but the access to the file is not granted in the earlier phases. In Phase II, although you get access to the investigation file, the parties are also really busy in answering to all the Commission's questions. The access to those documents from the moment the Commission gets them will highly facilitate the parties' understanding.

4. How cooperative and open is the dialogue with the Commission to identify acceptable commitments?

It depends on the case-team and the case handler. There are usually not so open because they want first to receive a proposal and after do the market test.

5. What is your business strategy when negotiating commitments?

It depends on the client's interest, on the reasons to acquire or merge with another company or on the rationale of the transaction. Of course, you have to fight for that with the Commission. Sometimes, it could be easy to satisfy the Commission, for example, when it is not so important for the interest of the concentration to divest some part of the business. You never reveal everything, and it is on a case-by-case basis and the purpose of the client to do the transaction. Sometimes, it could be worthy to fight the interest the whole way but it usually never happens because it takes too long to go through the whole process. Some other times, it is necessary to compromise and then the parties should find commitments which will not damage the deal too much because otherwise although the remedies submitted will meet the Commission's demands, the transaction will not be longer worthy

and the client may decide to cancel the deal.

6. **Does the Commission usually approve the first commitments you suggest?**

The Commission usually approves or disapproves and it is not that often to go to a second round of commitments. It is 50% of cases where the Commission approves the commitments suggested at first. Sometimes, it is easier to predict what the Commission will approve than to obtain approval because the client might not be willing to give up so much.

7. **Do the time limits influence the commitments you submit?**

There have been cases where you have not identified that you need commitments very early in the process and then, the time limits influence very much. Also, it is possible to prolong Phase I if you offer commitments. If you are in a real hurry to close the deal, you should offer the commitments very early in the process. Moreover, the time matters in relation to other circumstances, for example, the client might be under time pressure to obtain clearance quickly for instance in an acquisition where several purchasers are included and there is a need to structure the transaction with the seller.

8. **Do the commitments often compromise the initial interest of the concentration?**

It happens. Sometimes, we have identified the concerns that the Commission will have in the process and there are deals which have not been done because of the need to offer radical commitments. But it also happens that the concentration does not raise any problems. It is not so common but it happens. In addition, another problem is that, when submitting the commitments to the Commission, you might get squeezed because everyone knows you have a commitment you have to fulfil.

9. **To what extent efficiencies or innovation defenses play a role in the negotiation of commitments?**

In general, it is a very hard to defend a case by efficiencies or innovation defenses. It is possible to use them, however, it has not been successful in practice and therefore, it is not often tried.

10. If any, which improvements do you consider necessary in the current practice of negotiating commitments?

Where offering a commitment, it would be really nice if the Commission could say to the parties that they need to include or to exclude this to meet its competition concerns. Sometimes, you offer the commitments and then you see what the Commission thinks, thus, a very useful improvement would be to have more discussions in advance with the Commission in order to have an open dialogue. On the other hand, the position of the Commission is also understood when thinking that they are under time constraints and they need to test the commitments in the market. However, if the dialogue will be more open in relation to what is needed, the negotiation will be more similar to negotiations between two private parties where you can discuss which interests you can compromise. The Commission should, of course, be objective in his assessment and that is not always easy.

PRACTITIONER E

1. Do you usually identify competition concerns in the pre-notification contacts or in the earlier stages of Phase I?

In complex transactions in competition terms, therefore, where it is predictable that the Commission or any other National Competition Authority will conduct a substantive analysis under which risks to competition are likely to be found, the identification of competition concerns is conducted at a really early stage. In fact, that assessment is conducted even before starting any pre-notification contacts. In numerous occasions, before concluding the deal. The parties will often not be willing to agree to the terms of the deal (or even to continue with it) until the risk to competition and likely remedies that the Commission will most probably request are not clarified. The internal analysis of competition threats driven by the company, together with its lawyers, is conducted at a really early stage, thus, not only in relation to the notification procedure but also with regard to the actual negotiation of the agreement with the other party.

2. Do you easily predict the Commission's approach in relation to the necessary commitments?

In the majority of cases, the Commission's approach regarding remedies is easily predicted. Structural commitments or divestitures have a high level of predictability. From the moment that the Commission identifies risks to competition, the remedies which will be required to solve those concerns

are generally predictable. When competition threats are not based on structural concerns but behavioral as a result for instance that those threats are due to the nature of the market and not to the addition of market shares, it is more complicated to predict the adequate remedies for the Commission and it is necessary to discuss explicitly efficient solutions. Behavioral remedies are consequently harder to predict and to negotiate with the Commission.

3. To what extent do you have access to the investigation file during the process?

The market tests clarifies the existence of competition concerns or the efficiency of the remedies through consumers, competitors or suppliers' comments. The access to those documents is not granted during the pre-notification and the Phase I. The market test might also be performed in other moments of the procedure, for instance, in relation to a suitable buyer in the divestiture of certain assets. What the Commission confers is the possibility to discuss in a meeting with the case-team the results. There is no access to the specific responses of those third parties but the case-team communicates the conclusions obtained to the parties and the interpretation the Commission has extracted from their comments. At this stage, it is necessary to trust the accuracy of the information facilitated by the Commission, together with its interpretation of the situation. It is a sensitive moment of the procedure because both parties, the Commission and the notifying parties, do not have equality of arms. Obviously, for the parties, it will be beneficial to have access to the results obtained in the market test, however, under the current parties the access to the Commission file is only granted in Phase II where such access is complete.

4. How cooperative and open is the dialogue with the Commission to identify acceptable commitments?

It depends on the case-team and on the transaction. In general, the Commission is transparent and thus cooperative and open. It is true that during the Phase I of the procedure, the Commission tends to identify or express larger competition concerns than the ones actually remaining at the end, especially in relation to grey competition areas. Once the threats to competition are clarified, the Commission is open to discussing the serious doubts arising from the transaction with the parties and it is again where the importance of timing plays an important role.

5. What is your business strategy when negotiating commitments?

In relation to the interaction with Competition Authorities, either the Commission, the National Authority or any other international reviewing agency, the contacts depend on the clients' strategy. There are transactions where the priority for the client is to obtain a prompt authorisation and there are others where the priority is to save factories or assets from divestiture, meaning that the focus is on avoiding remedies. In the first case, the interest relies on discussing with the Commission as early as possible all potential problems to competition together with the need for remedies, even in an informal manner (During the pre-notification phase, the Commission does not discuss remedies formally but competition concerns are transferred to the parties through the dialogue). This strategy results from the need to agree on remedies in a prompt stage for obtaining authorisation during the Phase I of the procedure. On the other hand, when the client or the deal are not sensitive to the timing but to the losses resulting from the likely remedies, the negotiation with the Commission will delay the approval. In this case, the notifying party will play with the time limits in its favour and therefore discuss the remedies with less pressure.

On that line, when time is the priority, the client has to be willing to offer more remedies that the ones which will be required in case to be willing to go to the Phase II and use the time limits until the end. If time is not the priority, the remedies offered will be the least as possible being aware of the need to discuss them throughout an in-depth investigation and submit commitments little by little. If time is not a priority, it is worthy to discuss the commitments until the end of the procedure, not in relation to all aspects of the deal but concerning those grey areas most sensitive to the clients' interest from the point of view of the profitability of the transaction. This is because in the last days of the procedure, the Commission yields and it does not have the same determination regarding competition concerns as it had during the Phase I.

6. Does the Commission usually approve the first commitments you suggest?

The Commission accepts the first commitments suggested but it does not approve them as final because it usually considers those initial remedies to be insufficient. The first package of remedies proposed in the initial phase does not commonly include everything the parties are willing to offer and thus, it is rare that the Commission considers those remedies to solve entirely and efficiently the threat to competition. Even when the aim is to clear the transaction during Phase I, the remedies submitted by the notifying parties do not exhaust all commitments the parties are willing to take.

7. Do the time limits influence the commitments you submit?

Time limits are absolutely determinant. Firstly, the manner under which the remedies is negotiated differs depending on the clients' time pressure to obtain clearance. Additionally, the time limits vary the pressure on the parties. It could be said that at the beginning of the procedure, the pressure relies on the notifying parties which will try to avoid the opening of an in-depth investigation. On the other hand, for the European Commission, even though the workload might be larger, it is not as relevant as for the notifying parties to go to the Phase II of the procedure. Once in Phase II, and especially in relation to the last days, the pressure on the Commission increases since a prohibition decision is not the ideal outcome mainly because of two reasons. Firstly, for the Commission will rather approve transactions subject to commitments than prohibiting concentrations. And secondly, a prohibition decision is likely to be appealed before the EU Courts and that makes possible that the Courts will supervise the Commission's practice and discretion.

8. Do the commitments often compromise the initial interest of the concentration?

In the majority of the cases, the commitments do not compromise the transaction's rationale. In case the remedies will compromise the profitability of the deal, the concentration will not be concluded. However, in complex concentrations, it can happen that remedies end up being more or less harmful to the clients' interest. It depends on the specific case, however, the analysis of lawyers together with their clients tend to be conservative. Consequently, cases where the authorisation requires fewer remedies than the ones which have been weighted in the pre-assessment occur more often than cases where the commitments required are larger than the ones predicted.

9. To what extent efficiencies or innovation defenses play a role in the negotiation of commitments?

It depends on the affected markets but in general, efficiencies and innovation arguments have little weight and are not usually successful. The most relevant arguments are the definition of markets, either product or geographic, barriers to entry or the demand compensatory power. Economic studies play an important role to argue fewer barriers to entry or broader geographic markets, therefore, diluting the combined market share and as a consequence decreasing the need for divestiture.

10. If any, which improvements do you consider necessary in the current practice of negotiating commitments?

As a first improvement, it would be a responsible exercise that the formal discussion with the Commission in respect of remedies will start from the beginning of the negotiation. Currently, the Commission prefers to define markets, problematic areas, and when its position is clear, then it opens the formal negotiation of remedies. From the notifying parties' perspective, a parallel assessment of competition concerns together with remedies from the first contacts would be really beneficial, especially, in those transactions especially sensitive to time pressure. The parallel assessment will decrease that pressure on the parties and allow them to have more time to discuss commitments, because otherwise, and under the current practice, the time is limited to the 15 or 20 days, or even less. As a second suggestion, the access to the market test from the first phase of the procedure in order to allow that the parties and the Commission are not on equality of arms and that both are in a position to discuss the results of the market test and the necessary remedies to solve the concerns raised by third parties' comments.

PRACTITIONER F

1. **Do you usually identify competition concerns in the pre-notification contacts or in the earlier stages of Phase I?**

Mergers and Acquisitions discussed refer to the more complex cases since 80% of M&A are cases which do not generate competition issues and that are even subject to the Simplified procedure. In the more complex cases, long before the notification, it is extremely important in the ex-ante assessment to assert the potential impediments to competition and the possible remedies. The aim is still to obtain clearance without commitments but it is important to prepare all the arguments and predict the competition problems before starting the procedure, having regard to its tight time limits. Concretely, that is why competitive concerns discussions are engaged in the pre-notification contacts with the Commission. The notification procedure can take from 4 to 7 months in complex cases. There is an on-going debate regarding the extension of time limits in merger procedure due to the extensive period of pre-notification contacts. However, it is sometimes forgotten that it is also in the interest of the notifying parties who, by the pre-notification contacts, minimise the risk of running out of time to introduce all necessary arguments to obtain approval.

2. **Do you easily predict the Commission's approach in relation to the necessary commitments?**

After the reception of a case, the Commission's approach is easily predicted by assessing precedents or past decisions similar to the concentration at hand. Although the competition concerns that the Commission will find are predictable, it is necessary to drive an independent assessment in order to support the client's interest and the compatibility of the merger with the single market. Such assessment will consist of, for example, competitive dynamics assessments or economic informs. In the pharmaceutical industry, the notification procedure, identification of competition concerns and suitable commitments is not different compared to other sectors. One specific feature is that, in comparison with other industries such as the airlines or stock markets, in the pharmaceutical sector is typically easier to solve competition concerns. This is because impediments to competition in the pharmaceutical sector occur where several drugs overlap in some markets obtaining too high market shares. Thus, it is quite simple to find suitable commitments by divesting some of those drugs. Actually, taking into account the high level of action in the pharmaceutical sector in M&A, there has been only one case since the EUMR entered into force that has gone to the Phase II and therefore showing that the offer and acceptance of suitable commitments are simpler than in other industries.

3. **To what extent do you have access to the investigation file during the process?**

The access to the file is not granted which raises important transparency concerns in relation to the EU merger procedure. The right to access to the Commission file is only granted after the Statement of Objections, meaning that until Phase II the notifying parties cannot observe the Commission's assessment. This is particularly problematic because the Commission heavily relies on what they call market casting which is the feedback obtained in the market from competitors, suppliers, customers, etc. This situation leaves the clearance of the transaction only in the Commission's hands since the parties cannot access the documents containing the test of the suggested commitments in the market. The lack of transparency complicates the procedure for the notifying parties and questions the rights of due process.

4. **How cooperative and open is the dialogue with the Commission to identify acceptable commitments?**

The dialogue with the Commission depends a lot on the case manager handling the case. There are

some who are really open and explain frankly the competition concerns precisely while others are more reluctant to closely discuss the problems raised by concentrations and will only do so once started the Phase I of the procedure. This situation is particularly problematic in relation to the tight time limits. This brings again the concern of transparency and due process under the EU merger control which does not fulfil the expected standard from an institution such as the Commission.

5. **What is your best business strategy when negotiating commitments?**

The business strategy in negotiating commitments depends on a case-by-case basis. Firstly, it depends on the rationale of the transaction and on how much the client is willing to give away. Sometimes, merging parties are happy to commit assets but what matter to them it is the time spent in the procedure. There are several reasons for that, the client might be interested in a quick transaction before the market circumstances vary or due to financing matters, many deals are financed by loans and from the business perspective, some commitments do not matter that much as the delay on time. Of course, instructions are always to fight the clearance without commitments as hard as possible, however, that is a question of every case at hand and the interest of the particular client.

6. **Does the Commission usually approve the first commitments you suggest?**

The first commitments suggested are never accepted. This is a matter of negotiating, even where the commitments suggested meet all the possible competition concerns, the Commission will always ask for improvements. It is important to be aware of this for not obsoleting what the client is willing to compromise from the beginning in order to suggest, after a couple of round of negotiations, the commitments you were willing to submit in the first place.

7. **Do the time limits influence the commitments you submit?**

The time limits influence the commitments submitted. In particular, if the aim is to obtain clearance in Phase I, 35 working days, is extremely short to negotiate with the Commission, so, you usually end up having to offer larger commitments in Phase I that you would have had if you would have the time to go to Phase II. Sometimes clients do not have the time to go to Phase II and you should advice them that they will have to be prepared to offer more commitments.

8. **Do the commitments often compromise the initial interest of the concentration?**

The cases which raise the most anticompetitive concerns are not even notified because merging parties are advised not to since those transactions will not be approved even with commitments. And as well there are other transactions that simply do not allow suitable commitments to offer, there are cases such as Ryanair or Deutsche Börse merger cases where they were no suitable commitments that could attract the Commission's concerns. In these kind of situations, the rationale of the transactions is of course affected since the concentrations have to be abandoned.

9. **To what extent efficiencies or innovation defenses play a role in the negotiation of commitments?**

Efficiencies should play a bigger role than in the current practice. On the other hand, efficiencies and innovation arguments are increasing their importance but there is still a long way to go for having efficiencies properly included in the assessment.

10. **If any, which improvements do you consider necessary in the current practice of negotiating commitments?**

The key improvements are the ones related to the more procedural transparency. The Commission should be under an obligation to grant the access to the file, in particular, due to the importance of market feedback. On that line, the Commission would guarantee a fairer approach to the negotiation of commitments. Under the current rules, the Commission is not obliged to do it but nothing stops the Commission from introducing greater Guidelines to state its will to improve the current practice and increase transparency granting the parties access to the file from the beginning. There are around 3 or 4 meeting in pre-notifications, depending on the complexity of the case and as well in Phase I around 3, and in those meetings discussions are established with the case-team but without having access to the investigation file. Consequently, there is no access to the actual documents where the Commission relies on for finding competition concerns or adequate commitments. Thus, transparent information is not granted to the parties and it depends on the cooperative character of the teams involved in those meetings.