

**Comments in response to Consultation of European Commission's Directorate General for  
Competition on procedural and jurisdictional aspects of EU Merger Control**

**Q.18-22 Jurisdictional criteria based on value of the transaction**

**1. Introduction**

1.1 (...).

1.2 (...).

1.3 We appreciate the desire of the European Commission (the "Commission") to ensure that it has the tools necessary to address and remedy any negative competitive effects arising from transactions. However, we disagree with the proposal for jurisdictional criteria based on transaction value and believe no changes are required to the ECMR.

1.4 As detailed below:

- We do not believe that there is any enforcement gap which would require the envisaged modification of the current Merger Regulation: given both the market transparency (in the pharmaceutical sector) and the legal tools the Commission already has available today under Articles 101 and 102 of the Treaty to investigate and/or challenge a transaction that has fallen beyond the reach of the EU Merger Regulation, a transaction value threshold is in fact not needed;
- However, should the Commission nevertheless pursue the contemplated reform, it is crucial that the Commission's jurisdiction is based on clear cut and objective criteria requiring a material local nexus. Indeed, while objective in theory, transaction value thresholds are anything but straightforward in their practical application. Hence, clear cut and objective criteria requiring a material local nexus would be necessary to ensure that only transactions that are likely to have a significant impact on competition within the EU would be caught by the revised Merger Regulation. Indeed, this need for a material local nexus is highlighted by the OECD, the ICN and reflected in the current EU Merger Regulation;
- A transaction value threshold would raise the risk of violating the fundamental principle of proportionality (set in Article 5 of the Treaty) as it would create unnecessary and significant transaction costs as well as administrative burden for little added benefit, as reflected by the challenges encountered under the U.S. HSR pre-merger notification regime;
- A transaction value threshold would in any event not cover pure pipeline acquisitions as such transactions do not qualify as "concentrations" under the Merger Regulation (defined in the Consolidated Jurisdictional Notice as an acquisition of control over assets which "*constitute the whole or a part of an undertaking, i.e. business with a market presence, to which a market turnover can be clearly attributed*"); and
- Lastly, a transaction value threshold would have adverse unintended consequences for biotech funding.

## **2. The lack of enforcement gap: the Commission already has sufficient tools and visibility**

- 2.1 Changes to the EU Merger Regulation jurisdictional thresholds should be premised on a demonstrable, substantial need for increased enforcement activity reflected in a sufficient volume of cases, rather than exceptional cases (or theoretical, exceptional cases). No such coverage gap exists, and indeed neither the pharmaceutical cases nor the Facebook/WhatsApp transaction that are mentioned as examples by the Commission<sup>1</sup>, illustrate any gap: quite to the contrary they demonstrate that the system currently in place is robust and fit for its purpose.
- 2.2 Hence, as concerns the pharmaceutical cases, it is notable that in each case to date where the Commission has identified competitive issues involving pharmaceutical products in development, the problematic overlaps identified have been but one component of a larger transaction that included drugs already on the market and producing turnover.<sup>2</sup> Given the substantial risk of development failure in pharmaceuticals, it is far from clear whether these transactions would have happened if not for the fact that the targets also had products already available on the market (and thus generating turnover which in turn triggers merger control).
- 2.3 For example, AbbVie's acquisition of Pharmacyclics in 2015 was not a pure pipeline transaction as Pharmacyclics' Imbruvica was approved in the U.S. for certain indications by February 2014, and was also already approved in nearly 50 other countries at the time the transaction closed.<sup>3</sup> Moreover, the transaction was filed with the U.S. Federal Trade Commission (the "FTC"), which allowed the transaction to close just over two months after the HSR notification was filed, without the issuing of a Second Request. Similarly, Shire's acquisition of Dyax was notified to the US agencies, which granted early termination of the HSR waiting period.<sup>4</sup> In Novartis/GSK Oncology, the portfolio included eleven currently marketed pharmaceuticals and two pharmaceuticals from GSK's early-stage clinical 'pipeline'.<sup>5</sup> That transaction also formed part of a three-part inter-conditional transaction whereby GSK has agreed to acquire sole control over Novartis' vaccine business (excluding the influenza business) and GSK and Novartis have agreed to establish a joint venture combining GSK's consumer healthcare business and Novartis' Over-the-Counter business. So, there was no risk that the Commission would not have an opportunity to review the deal, including the pipeline aspects thereof. Thus, none of these transactions is an example of a potentially problematic transaction falling beyond the reach of the Commission and therefore using them to justify the implementation of a transaction value threshold would be "fixing" a problem that doesn't exist.
- 2.4 In the same manner, unlike many of the jurisdictions that have adopted a transaction value threshold, it is simply not the case that transactions that do not have a community dimension necessarily escape antitrust scrutiny in Europe. Member State merger control rules and referral mechanisms under the EU Merger Regulation continue to apply. Indeed, Facebook/WhatsApp

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<sup>1</sup> The Facebook/WhatsApp case is mentioned in Question 14 of the Questionnaire and AbbVie's acquisition of Pharmacyclics is mentioned in Question 14 of the Questionnaire.

<sup>2</sup> E.g. Case No. COMP/M.7326 – Medtronic / Covidien at ¶ 3 (in approving the transaction, the Commission described Covidien as currently "active in the development, manufacturing and sale of a diverse range of medical devices and supply products"); Case No. COMP/M.7559 – Pfizer / Hospira at ¶ 4 (in approving the transaction, the Commission described Hospira as "a global provider of injectable drugs and infusion technologies, with a broad portfolio of generic, branded and biosimilar medicines for humans).

<sup>3</sup> Press Release, AbbVie Completes Acquisition of Pharmacyclics (May 26, 2015), <http://www.prnewswire.com/news-releases/abbvie-completes-acquisition-of-pharmacyclics-300088494.html>.

<sup>4</sup> Early Termination Notice, Shire plc/Dyax Corp. (Dec. 2, 2015), <https://www.ftc.gov/enforcement/premerger-notification-program/early-termination-notices/20160333>.

<sup>5</sup> Case No. COMP/M.7275 – Novartis / GlaxoSmithKline Oncology Business.

demonstrates the efficacy of this system as the case was ultimately referred to the Commission by three Member States<sup>6</sup>.

- 2.5 Moreover, it also bears noting that the Commission itself has sufficient tools under Articles 101 and 102 today to address harm that might arise from transactions that may fall outside the EU Merger Regulation and Member State merger control rules today. Indeed, the potential applicability of these provisions is reflected in the fact that pharmaceutical companies, as a matter of practice conduct antitrust evaluations of all potential transactions, regardless of whether they trigger merger thresholds in Europe or elsewhere.
- 2.6 The capacity of these tools to address purported competition issues arising from pharmaceutical transactions not triggering the notification thresholds is further reinforced by the fact that these deals are almost always announced via press release from the parties – therefore, the Commission (and more generally the market) is fully informed of them. Moreover, due to the regulatory requirements involved in drug development, detailed information about the status of clinical development efforts is publicly available.
- 2.7 Despite the transparency in the pharmaceutical sector – both with respect to the status of development efforts and transactional activity, which is almost always announced by the parties via press release given how important the information is for shareholders (for the acquirer) and for future funding prospects (for the target) – the Commission has yet to identify emblematic examples of potentially problematic pharmaceutical transactions that have “fallen through the cracks”. Hence, the fact that the Commission has never exercised the authority it has under Articles 101 and 102 to investigate and/or challenge a transaction that has fallen beyond the reach of the EU Merger Regulation lends support for the conclusion that the EU Merger Regulation is functioning effectively as currently designed.

### **3. Importance of establishing a local nexus**

- 3.1. Transaction value-based thresholds raise significant jurisdictional questions. As the OECD has noted, transaction value tests, on their own, are “unsuitable” for determining whether a given transaction “will have an impact on a specific jurisdiction.”<sup>7</sup> Indeed, the OECD explains that jurisdictions using this criterion do not apply it on their own, but instead couple it with “rules requiring the transaction to have local effects, and exemptions that take into account local turnover or assets.”<sup>8</sup>
- 3.2. A transaction value-based threshold would also be inconsistent with guidance issued by the International Competition Network (“ICN”). In its Recommended Practices for Merger Notification Procedures, the ICN explains that “[m]erger notification thresholds should...incorporate appropriate standards of materiality as to the level of ‘local nexus’ required,

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<sup>6</sup> We note, further, that this was a transaction between two U.S. companies both based in California and the fact that despite this it was eventually subject to the Commission’s review (through the referral procedure) is, if anything, a sign of how well the EU merger regime functions.

<sup>7</sup> Local Nexus and Jurisdictional Thresholds in Merger Control, Working Party No. 3 on Co-operation and Enforcement, Organization for Economic Co-operation and Development (14-15 June 2016), ¶ 53, [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/WP3\(2016\)4&docLanguage=En](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/WP3(2016)4&docLanguage=En).

<sup>8</sup> *Id.* at ¶ 54.

such as material sales or assets levels within the territory of the jurisdiction concerned.”<sup>9</sup> (such recommendation reflecting *a fortiori* the need to have a local nexus to start with).

- 3.3. The EU Merger Regulation likewise reflects the importance of establishing a local nexus in that it states that “[t]he scope of [its] application should be defined according to the geographical area of activity of the undertakings concerned and be limited by quantitative thresholds in order to cover only those concentrations which have community dimension.”<sup>10</sup>
- 3.4. However, even where transaction value-based thresholds are combined with other rules, it is far from clear that it is possible to design objective rules that ensure a sufficient local nexus is present without sacrificing legal certainty. This challenge has already been recognized by many stakeholders in the context of the Bundeskartellamt’s consideration of such a value-based threshold. Nevertheless, incorporating a local nexus rule is critical to ensuring that unnecessary transaction costs and use of agency resources are not incurred without a sufficient corresponding enforcement benefit.
- 3.5. As indicated above, a local nexus rule must provide sufficient legal certainty to parties, as this is critical in enabling businesses to understand their obligations and, in turn, operate effectively. A local nexus rule requiring the presence of material assets and/or sales of the acquirer and target is typically a more reliable and objective metric.
- 3.6. However, in the pharmaceutical sector, legal uncertainty will even remain when using material assets for a local nexus rule if it is intended to be applied to acquisitions of targets solely or predominantly involved in research and development (“R&D”). Regardless of whether or not the geographic scope of a proposed transaction is worldwide, the location of operations associated with pharmaceutical R&D (e.g. clinical trials, laboratories, IPRs) does not necessarily correlate with where a product will ultimately be commercialized.
- 3.7. Indeed, unless the targeted disease is focused in a particular geographic region or a contract expressly determines where a drug will be commercialized, it is not obvious that R&D is tethered to a particular geography nor is the location of R&D activities determinative of the subsequent geographic scope for commercialization. Commercialization plans for a drug in development can, and do, change significantly right up to the last minute, depending upon trial results and regulatory considerations. Therefore, further guidance on the application of such a local nexus rule to pharmaceutical R&D deals (potentially on a case by case basis) would be necessary to provide sufficient legal certainty to parties.

#### **4. The risk of a disproportional response in violation of Article 5 of the Treaty (as reflected by the challenges of U.S. HSR pre-merger notification regime)**

- 4.1. A local nexus rule requiring the presence of material assets or sales of the acquirer and target is more consistent with the founding principles underlying the EU Merger Regulation. The cornerstone of the EU Merger Regulation is the principle that merger control rules should not go beyond what is necessary in order to achieve their main objective – namely, ensuring that competition in the common market is not distorted. Therefore, any change to be introduced to this regulation should be bound by the principle of proportionality.

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<sup>9</sup> International Competition Network, Recommended Practices for Merger Notification Procedures, at I.B (Comment 1), <http://www.internationalcompetitionnetwork.org/uploads/library/doc588.pdf>.

<sup>10</sup> Council Regulation (EC) No. 139/2004 of 20 January 2004 on the control of concentrations between undertakings (the EC Merger Regulation) at ¶ 9.

- 4.2. Implementing a transaction value threshold would not be a proportional response consistent with Article 5 of the Treaty given the low likelihood of significant competition concerns arising from deals that meet the transaction value threshold, but would not otherwise be caught by the EU Merger Regulation.
- 4.3. In this respect, experience from the U.S. Hart-Scott-Rodino pre-merger notification regime suggests that transaction value-based thresholds present significant challenges for parties and agencies alike, without creating significant benefits from a regulatory perspective to counterbalance these challenges.
- 4.4. Firstly, such a test would likely capture a significant number of transactions compared to the current turnover threshold. For example, according to data provided in the U.S. agencies' Hart-Scott-Rodino annual report for fiscal year 2015, "[o]ver the past three years, the percentage of reportable merger transactions valued at more than \$500 million has steadily increased," with more than 588 being reported in FY2015 alone.<sup>11</sup>
- 4.5. Based on the U.S. example, there is scant evidence that capturing a much higher number of transactions would increase the likelihood of reviewing any transactions that raise significant competitive concerns. Indeed, the U.S. agencies reported 86 transactions in fiscal year 2015 where the acquired entity reported no sales (and which would therefore not have been notifiable under a pure turnover threshold test), only one of which resulted in the issuance of a Second Request.<sup>12</sup>
- 4.6. The Commission should further consider the substantial resources that would be required for it to deal with such a change. Here again, looking at the experience of the U.S. agencies, on top of the additional resources required to review these additional filings from a substantive perspective, the U.S. agencies have also had to devote significant resources merely to respond to questions regarding how the size-of-transaction rules should be applied. The Premerger Notification Office ("PNO") of the FTC has a full-time staff of ten, including six staff attorneys that respond directly to questions from parties considering their filing obligations.<sup>13</sup>
- 4.7. This volume of questions and clarifications is in many ways not surprising because although transaction value may at first blush appear to be a readily attainable, quantifiable metric, in many cases determining the value of a transaction is anything but a straight-forward exercise. A primary example of this are transactions where all or part of the consideration takes the form of milestone payments, earn-outs, or other types of contingent payments. Structuring payments this way is particularly common in the acquisition of drug development candidates, where the

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<sup>11</sup> Notable trends in merger review: inside the HSR Annual Report, Federal Trade Commission (Aug. 12, 2015), <https://www.ftc.gov/news-events/blogs/competition-matters/2015/08/notable-trends-merger-review-inside-hsr-annual-report>.

<sup>12</sup> Hart-Scott-Rodino Annual Report Fiscal Year 2015, Bureau of Competition of the Federal Trade Commission and the Antitrust Division of the Department of Justice, at Table IX, <https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-bureau-competition-department-justice-antitrust-division-hart-scott-rodino/160801hsrreport.pdf>.

<sup>13</sup> FTC Premerger Notification Office Contact Information, <https://www.ftc.gov/enforcement/premerger-notification-program/contact-information>. In fiscal year 2015 alone, the PNO reported responding to "**thousands of telephone calls and emails**" from parties considering their filing obligation (Hart-Scott-Rodino Annual Report Fiscal Year 2015, *supra* n.12 at 3. <https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-bureau-competition-department-justice-antitrust-division-hart-scott-rodino/160801hsrreport.pdf> (emphasis added). Indeed, a simple search of so-called "informal interpretations" issued by the PNO staff in response to these questions returns well over 300 "hits" for the phrase "size of transaction" alone, and this does not take into account interpretations provided by the staff to parties who requested that they not be published online. These figures from the HSR experience may in fact significantly understate the volume of inquiries that can be expected in the EU

value ultimately transferred is subject to substantial uncertainty given the high rate of failure experienced in pharmaceutical development. Thus, transaction values can change materially in short periods of time depending on the success of the development efforts.

- 4.8. Additionally, for transactions that are global in scope (or otherwise involve multiple countries), the size of a transaction itself says nothing about the likelihood of effects in any particular country or region. For this reason, transactions involving foreign assets and/or issuers are treated according to separate rules under the HSR process. The application of these rules in the context of a specific transaction also regularly prompts consultation with the PNO.
- 4.9. In this respect, many of the criticisms leveled with respect to market share notification thresholds likewise apply to transaction value thresholds. Although market share thresholds ensure that an appropriate local nexus exists, they are not an objectively quantifiable metric in many cases (as is the concern with transaction value thresholds). As the ICN explained in its Recommended Practices for Merger Notification Procedures, “[m]arket share-based tests and other criteria that are more judgmental...are not appropriate for use in making the initial determination as to whether a notification is notifiable.”<sup>14</sup> Just as market share thresholds require filing parties to make judgments regarding the relevant geographic and product markets in order to assess their filing obligations, transaction value thresholds necessarily involve judgments regarding the determination of the value of a transaction (for filing purposes) whenever a portion of the consideration takes the form of a contingent payment, particularly where the payment is conditioned on the occurrence of circumstances beyond the control of the parties (e.g., the success or failure of clinical trials).
- 4.10. If a consultation mechanism is not set up by the Commission to address this, parties would be unlikely to have sufficient legal certainty and could (in order to avoid being exposed to a gun jumping procedure and/or fine) err on the side of notifying all transactions that could conceivably meet the transaction value threshold, thereby pulling resources away from transactions that are more likely to raise competition concerns.
- 4.11. This would also impose substantial burdens and costs on filing parties, particularly in light of the fact that the preparation of Form CO notifications under EU Merger Regulation is often significantly more demanding than HSR filings.

## **5. Threshold question on meaning of “concentration” under EU Merger Regulation**

- 5.1. Because the Commission has highlighted the pharmaceutical sector in its explanation of the consultation, we note that there is an important threshold question on the meaning of “concentration” under the EU Merger Regulation that arises with respect to pharmaceutical R&D deals. A transaction value-based threshold would only be engaged if the transaction is a “concentration” under the EU Merger Regulation.
- 5.2. According to the Consolidated Jurisdictional Notice, an acquisition of control over assets can “only” be considered a concentration “if those assets constitute the whole or a part of an undertaking, i.e. business with a market presence, to which a market turnover can be clearly

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<sup>14</sup> Recommended Practices for Merger Notification Procedures, *supra* n.9

attributed.”<sup>15</sup> Therefore, the transfer of market turnover is currently the “only” way in which a concentration may arise.

- 5.3. The exclusive focus of the Consolidated Jurisdictional Notice on the actual turnover associated with the assets that are being transferred seems to reflect the fact that customers are the hallmark of a business, and examining whether a transfer of assets carries with it a transfer of customers is a clear way of distinguishing a transfer of business that is potentially subject to the EUMR from a transfer of “mere” or bare “assets”<sup>16</sup>.
- 5.4. When a pipeline drug is acquired on its own, there is no market turnover which can be attributed to the assets and, therefore, no market presence. The most that such assets give is the chance, with investment, to obtain some turnover, often many years in the future. The fact that pharmaceutical companies are willing to pay to acquire these “chances” (despite the high failure risk associated to them) does not mean that these assets should be treated as “market presence” or as “turnover” – it only reflects that pharmaceutical companies (like any company in an innovative industry) are willing to invest in the future and to take risks. Hence, potential “future” turnover is not relevant for the purposes of assessing whether the transaction is a concentration for EUMR purposes.
- 5.5. A pipeline drug is a particularly high risk investment and may never be approved for sale. In order to generate sales from the acquisition of a pipeline drug, the acquirer faces the massive task (and investment) of designing clinical trials, obtaining approvals for the protocols, recruiting patients, making arrangements with consulting physicians, establishing equipment and procedures for analyzing the results, presenting the analysis to the regulatory authorities, dealing with pharmacovigilance and, if all goes well, obtaining a marketing authorization. In fact, the Commission has in the past stated that even in the case of Phase III trials, over 50% are unsuccessful.<sup>17</sup> Hence, in the pharmaceutical industry, however promising a product may seem, it simply cannot be assumed when, or indeed if, such product will ever reach the market. Indeed, on average, only one or two of every 10,000 substances synthesized in laboratories will ever succeed at all stages of development and reach the market.
- 5.6. Indeed, while it goes without saying that the drug development candidates that are the subject of these transactions reflect “market potential,” it is indeed just that—potential, which is, even in the best of circumstances and the latest stages of development (i.e. Phase III clinical trials), just as likely to amount to nothing as it is likely to result in a product actually making it to market; a competition authority would likely not be best placed to assess whether there are real and effective prospects for such drugs to ever enter the market in the future. The considerable

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<sup>15</sup> Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No. 139/2004 on the control of concentrations between undertakings (2008/C 95/1), ¶ 24, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:095:0001:0048:EN:PDF>.

<sup>16</sup> It is worth noting in this respect that paragraph 10 of the previous version of the Consolidated Jurisdictional Notice referred to “a business to which a market turnover can be clearly attributed”. The final Consolidated Jurisdictional Notice, published after consultation in 2008, added the words “with a market presence”, thus emphasizing the importance of an actual turnover of a business present on the market.

<sup>17</sup> Case COMP/M.1846 Glaxo Wellcome / SmithKline Beecham, ¶ 70. Studies have concluded that compounds targeting certain indications are particularly unlikely to make it through to market from early stages of development. For example, one study found that oncology drug development candidates have just a 6.7% chance of receiving approval from the U.S. Food & Drug Administration. Success rates for oncology candidates in Phases II and III remain low, with phase success rates of 28.3% and 45.2%, respectively. The article explains that “[o]ncology is a particularly challenging disease area in which to achieve phase 3 success” because the FDA “requires overall survival as the primary endpoint in most pivotal oncology studies.” Hay et al, *Clinical development success rates for investigational drugs*, 32 NATURE BIOTECHNOLOGY 40 (January 2014).

uncertainty involved is demonstrated by the fact that there is no evidence that even drugs in late stages of development have any impact on the price of drugs already available in the market.

- 5.7. Lastly, under the EU Merger Regulation, a “concentration” arises only if there is an acquisition of “control of the whole or parts of one or more other undertakings”.<sup>18</sup> An “undertaking” has been defined by the Courts as a natural or legal person engaged in “economic activity”.<sup>19</sup> The Courts have also stated consistently that “any activity consisting in offering goods or services on a given market is an economic activity.”<sup>20</sup> The acquisition of a pipeline drug does not involve the acquisition of assets that are used to offer goods or services on a market; this will (at best) only occur many years in the future.

## **6. Unintended consequences for biotech funding**

- 6.1. Lastly, and in addition to all of the above, this proposal also has a practical impact on the parties to these transactions, including in the biotechnology field where start-up biotech companies depend on the ability to close transactions quickly in order to share the risk of drug discovery and clinical development, and to secure funding that will be used to support further innovation and development efforts.

## **7. Conclusion**

- 7.1. While the current test of an actual market presence to which a turnover can be clearly attributed is simple, objective and easy to apply, we are concerned that a move away from that test would move the Commission away from legal certainty and into a framework of arbitrary case-by-case assessment. Furthermore, such a move would not be a proportional response given the low likelihood of significant competition concerns arising from deals that could meet a transaction value threshold, but would not otherwise be caught by the EU Merger Regulation.

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<sup>18</sup> Art. 3(1)(b).

<sup>19</sup> Case C-41/90 *Höfner and Elser v. Macrotron* [1991] ECR I-1979 and Case T-319/99 *Fenin v. Commission* [2003] ECR II-357.

<sup>20</sup> See, e.g. Case C-113/08P *SELEX Sistemi Integrati v. Commission* [2009] ECR I-2207 at ¶ 69, citing previous case law.