

NON-CONFIDENTIAL

European Commission
Directorate-General for Competition
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BELGIQUE/BELGIË
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Vera Pozzato, Policy Officer, A.1.

4 June 2024

Dear Ms Pozzato, dear Mr Kadar,

REQUEST FOR ADDITIONAL GUIDANCE ON EXCLUSIONARY ABUSES IN THE EUROPEAN COMMISSION'S FUTURE GUIDELINES ON THE APPLICATION OF ARTICLE 102 TFEU

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1. INTRODUCTION

Medicines for Europe welcomes the European Commission's plan to adopt guidelines on the application of Article 102 TFEU (the "Guidelines") as the members of Medicines for Europe frequently face several types of potential abuses of a dominant position from other companies active within the pharmaceutical industry.

While the European Commission's existing guidance on the Commission's enforcement priorities in applying Article 102 TFEU to abusive exclusionary conduct by dominant undertakings (the "Guidance") provides valuable insights on certain types of conduct, Medicines for Europe considers that the inclusion of additional guidance on Article 102 TFEU in the Guidelines would be beneficial to limit anti-competitive conduct in the internal market.

Indeed, members of Medicines for Europe have often encountered uncertainties concerning the interpretation and application of the existing guidance, in particular when dealing with conduct of (potential) competitors. The current lack of accessible information on when certain types of conduct may infringe Article 102 TFEU has in particular been apparent in relation to the frequent abuses of the regulatory framework surrounding the pharmaceutical industry where anti-competitive conduct is a frequent occurrence from dominant companies.

The effectiveness of antitrust enforcement in supporting the swift market entry of generics and biosimilars is also explicitly recognised by the European Commission in its report "Update on competition enforcement in the pharmaceutical sector (2018-2022)".¹

Medicines for Europe consequently wishes to express its interest in having additional guidance from the European Commission included in the Guidelines.

This submission is structured as follows:

- A section briefly outlining the pharmaceutical industry and the special nature of this industry, including an overview of the role of Medicines for Europe and its members;
- An introduction to the background for requesting more comprehensive guidance on the application of Article 102 TFEU; and
- A description of the types of potentially abusive conduct that Medicines for Europe's members in particular request to be included in the Guidelines.

¹ Report from the Commission to the Council and the European Parliament - Update on competition enforcement in the pharmaceutical sector (2018-2022), page 23.

We would be grateful for an opportunity to discuss this request further in a meeting with your services at your convenience.

2. EXECUTIVE SUMMARY

Medicines for Europe respectfully requests the European Commission to include guidance specifically addressing the currently not-included concerns of the pharmaceutical sector, either in a chapter specifically on the pharmaceutical industry or in chapters concerning the types of conduct frequently faced by Medicines for Europe's members in the Guidelines.

In particular, Medicines for Europe requests additional guidance on the following topics to be included:

- The notion of **competition on the merits**, in particular in relation to the placing of obstacles to entry or the use of other blocking measures to prevent the growth of competition, especially when conduct complies with other regulatory rules
- Guidance on the notion of **patent thickets** and **divisional patents**, i.e. types of misuse of a regulatory system (in this case a patent system).
- Guidance on the notion of **disparagement**
- Guidance on the notion of **product hopping**

In relation to the requested guidance, it is in particular noted that these types of conduct are highlighted as areas of focus for the European Commission in its report "Update on competition enforcement in the pharmaceutical sector (2018-2022)".²

Consequently, Medicines for Europe considers that issuing Guidelines that are **comprehensive** and **clear** to all stakeholders in the pharmaceutical industry when covering these topics will lead to greatly increased effective competition in this crucial industry.

3. THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry plays a crucial role in public health, innovation, and the overall economic landscape of the European Union. Thus, the state of competition plays a crucial role not only for the competitors within the market but also for several other important parts of society, including government spending on health care.³

As a market, the pharmaceutical industry is characterized by unique market dynamics, including the high costs associated with research and development, the significance of intellectual property rights – and of special importance for this submission – the influence of regulatory frameworks on the market and competition between the market participants herein, which will be described in more detail below.

3.1 The role in the European pharmaceutical industry of the members of Medicines for Europe

Medicines for Europe began over 20 years ago with the goal of representing the emerging generic industry, and later growing to include biosimilar medicines to its portfolio. Medicines for Europe's members now supply over 67% of all medicines in Europe, and over the last ten

² Report from the Commission to the Council and the European Parliament - Update on competition enforcement in the pharmaceutical sector (2018-2022), page 23-28.

³ In 2020, EU Member States spent between 5.8% and 12.8% of their GDP on health expenditures.

years, generic medicines have increased access to medicines by over 100% in 7 key therapeutic areas. For the treatment of high blood pressure alone, almost 50 million patients are taking generics each day, and 20 million people across Europe are now being treated for diabetes with generics.

Of special significance for the purposes of this submission is that Medicines for Europe represents developers of *generics* and *biosimilars*, which generally compete with *originators*.

As your services are aware, *Generics* are medicines with the same qualitative and quantitative composition in active substance and the same pharmaceutical form as a product by an originator which already possesses a marketing authorisation (i.e. the “reference product” on whose clinical data the generic relies after its period of data exclusivity has expired).

Biosimilars are medicines that are highly similar to another biological medicine already on the market in the EU and are therefore in general terms interchangeable and can be used instead of its reference medicine (or vice versa).

For biosimilars it is especially noteworthy that these are generally subject to higher barriers to entry than generics and more prone to being excluded from the market via non-price competition, primarily due to the inherent differences that exist between all biological medicines (unlike for generics). Additional guidance to prevent anti-competitive conduct from originators of biologicals is therefore potentially of greater significance for biosimilars than for generics.

Due to both generics and biosimilars treating the same diseases as the reference medicine, these are in competition with the originator’s medicines and therefore play a fundamental role in promoting pharmaceutical innovation and ensuring the affordability, sustainability and accessibility of healthcare systems in the EU. Indeed, the entrance of generics and biosimilars in a market in particular leads to significant price competition,⁴ thus benefitting patients and national healthcare systems.

3.2 The competitive landscape in the pharmaceutical sector is heavily impacted by the existence of regulations on market exclusivity

As it is well-known to your services, the pharmaceutical industry is characterised by originator companies being granted various types of exclusivities (primarily patents, regulatory exclusivity and Supplementary Protection Certificates) to market specific medicines. Competitive pressure on originators therefore usually only arises following the expiry of these exclusivity periods after which generic medicines and biosimilars are allowed to enter the market.

To postpone the entry of competition, originators often devise and implement a multitude of strategies to artificially extend the granted exclusivity on certain medicines beyond the period for which it was originally intended, i.e. artificially extending the duration of a monopoly.

It is practices having this as their purpose, which Medicines for Europe in particular considers necessitating additional guidance on the application of Article 102 TFEU.

⁴ On average, prices fall by 40% in the period after generics enter the market, as the price of generics is on average 50% below the initial price of the corresponding originator’s product (Copenhagen Economics, Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe, Final Report, May 2018)

This said, Medicines for Europe believes that such additional guidance would equally be applicable to many other sectors of the economy, thus only increasing the need for such additional guidance.

4. BACKGROUND FOR REQUESTING ADDITIONAL GUIDANCE ON THE APPLICATION OF ARTICLE 102 TFEU

Medicines for Europe recognises that competition law, including Article 102 TFEU, is a versatile enforcement tool, being pan-European, allowing for both behavioural remedies and deterring fines.

However, while Medicines for Europe continues to consider Article 102 TFEU to be of paramount importance for ensuring effective competition in the pharmaceutical sector, as it has been so far, by being applied to several delaying strategies implemented by dominant companies, the current Guidance is insufficient for the pharmaceutical sector and other industries subject to significant regulation.

This can for example be seen from the fact that the National Competition Authorities of the Member States and the European Commission have adopted 26 intervention decisions just in the period 2018-2022 with more than 30 ongoing investigations.⁵

Some of the conduct targeted with these intervention decisions has only been possible to implement by dominant companies because of the particularities of the pharmaceutical sector, i.e. this industry being subject to a comprehensive regulatory framework covering significant aspects of the commercial conduct by market participants in the industry.

Indeed, the members of Medicines for Europe frequently face practices that hinder or delay the market entry of generics and biosimilars and thereby the resulting increase in consumer choice and price competition. Examples of these types of conduct will be provided below.

Medicines for Europe considers that the extent of such conduct could be greatly mitigated via issuing Guidelines that are **comprehensive** and **clear** to all stakeholders in the pharmaceutical sector and beyond and **effective**. Issuing such comprehensive guidelines will assist stakeholders with considering potentially **overlooked matters**, thus prompting immediate action against this.

The inclusion of such guidance in the Guidelines would especially be appropriate as the application of Article 102 TFEU continues to be necessary in addition to the regulatory framework to ensure effective competition in the pharmaceutical industry. Indeed, it is recognised by the European Commission and National Competition Authorities that "*antitrust enforcement supports swift market entry of cheaper medicines*,"⁶ i.e. generics and biosimilars, and that measures to fully exploit the savings generated by the generic and biosimilar competition are primarily outside the scope of the general pharmaceutical legislation.⁷

⁵ Report from the Commission to the Council and the European Parliament - Update on competition enforcement in the pharmaceutical sector (2018-2022), page 11.

⁶ Report from the Commission to the Council and the European Parliament - Update on competition enforcement in the pharmaceutical sector (2018-2022), page 32.

⁷ Staff Working Document, IMPACT ASSESSMENT REPORT, *Accompanying the documents* Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC, section 2.1.

Indeed, the general pharmaceutical legislation often increases the possibility of abuses of dominance, thus further increasing the need for the application of Article 102 TFEU.

In brief, Medicines for Europe primarily considers that more comprehensive guidance on the application of Article 102 TFEU would be beneficial to competition in the pharmaceutical industry as it would:

- Promote legal certainty for dominant companies;
- Facilitate compliance for all market participants (in an already complex industry with significant compliance costs);
- Enable the European Commission to address evolving market practices and overlooked competition issues, in particular by providing guidance on the notion of “*competition on the merits*” in a highly regulated industry;
- Ensure consistency in enforcement practices across the EEA; and
- Assist with levelling the playing field for market participants and mitigate the resource asymmetry between dominant companies and the usually less resourceful competitors (in the case of the pharmaceutical sector, the developers of generics / biosimilars).

Providing more comprehensive Guidelines would therefore ultimately promote a competitive environment that benefits consumers, lowers public spending and fosters economic growth.

In this regard, Medicines for Europe notes that one of the primary goals of the Pharmaceutical Strategy for Europe is to increase accessibility and affordability for healthcare systems and patients in the EU,⁸ which would be greatly increased by facilitating earlier market entry of generics and biosimilar medicines.

4.1 Current case-law and guidance is insufficient for companies to determine when certain types of conduct fall outside the notion of “*competition on the merits*”

While the European Commission and the European Court of Justice have on several occasions found that certain conduct taking place within the pharmaceutical sector constituted infringements of Article 102 TFEU, the scope of application of Article 102 TFEU remains unclear in relation to several types of conduct.

In relation to this, Medicines for Europe as a general note notes that the European Commission defines anticompetitive foreclosure as a situation where the conduct of the dominant undertaking “*adversely impacts an effective competitive structure thus allowing the dominant undertaking to negatively influence, to its own advantage and to the detriment of consumers, the various parameters of competition, such as price, production, innovation, variety or quality of goods or services*”.⁹

This has more recently been described by the European Court of Justice as follows:

“In addition, conduct may be categorised as ‘abuse of a dominant position’ not only where it has the actual or potential effect of restricting competition on the merits by excluding equally efficient competing undertakings from the market(s) concerned, but also where it has been

⁸ Pharmaceutical Strategy for Europe 2020, page 9.

⁹ Policy Brief, Issue 1, March 2023, p. 5 and Guidance on Enforcement Priorities, para. 19.

proven to have the actual or potential effect – or even the object – of impeding potentially competing undertakings at an earlier stage, through the placing of obstacles to entry or the use of other blocking measures or other means different from those which govern competition on the merits, from even entering that or those market(s) and, in so doing, preventing the growth of competition therein to the detriment of consumers, by limiting production, product or alternative service development or innovation (see, to that effect, judgment of 30 January 2020, Generics (UK) and Others, C-307/18, EU:C:2020:52, paragraphs 154 to 157).”¹⁰

As the above is a key concept within possible misuses of regulatory systems, as this conduct may often constitute placing obstacles to the entry of competition, Medicines for Europe respectfully submits that an elaboration by the European Commission on *inter alia* what the “*placing of obstacles to entry or the use of other blocking measures*” entails in relation to misuses of regulatory frameworks would be beneficial.

This is in particular relevant for assessing conduct which does not infringe other regulatory rules governing the conduct in question.

In brief, Medicines for Europe finds that the market would benefit greatly from additional guidance on the notion of “*competition on the merits*” and how to formulate a coherent legal test for abuse, *inter alia* in contexts where conduct by a dominant is also impacted by regulatory requirements.

Examples of such types of conduct where the notion of “*competition on the merits*” remains unclear will be provided below.

4.2 The effects-based approach is not always the appropriate threshold to apply to the pharmaceutical sector

Medicines for Europe has noted that the European Commission in its Policy Brief states that “*an overly rigid implementation of the effects-based approach could set the bar for intervention at a level that would render enforcement [...] unduly burdensome or even impossible.*”¹¹

Medicines for Europe considers that the pharmaceutical sector is a prime example of this need to deviate from the effects-based approach in specific cases as it would otherwise render enforcement impossible. This is especially the case as several of the types of conduct faced by members of Medicines for Europe often allow dominant companies to foreclose entry of *any* competition, thus preventing the growth of competition, whether the relevant competitors are *as efficient* or not.

Moreover, if competition law is to support the additional policy objectives mentioned in the Policy Brief, such as *fairness, consumer welfare, innovation* and *a level-playing field*, it is necessary that the legal test for a finding of abuse is not restricted to an *as-efficient-competitor* test.

Consequently, the Guidelines should specify in which cases it is relevant to rely on other tests than the AEC-test for establishing an abuse of a dominant position. In this regard, Medicines for Europe considers that it should be considered to include specific references to the types of abuse mentioned below in section 5.

¹⁰ Case C-333/21, *European Superleague Company*, para. 131.

¹¹ Policy Brief, Issue 1, March 2023

4.3 More comprehensive Guidelines will benefit competition in several (regulated) industries

While Medicines for Europe naturally primarily possesses extensive knowledge of examples of anti-competitive conduct taking place within the pharmaceutical sector, Medicines for Europe considers that the benefits mentioned above will be applicable to a wide array of regulated industries.

This would in particular include industries where IP rights are essential or where the commercial conduct of market participants is otherwise heavily impacted by other types of sector regulation, as “misuses of the regulatory framework” is likely to be a common occurrence in many such industries to deviate from competition on the merits.

5. SPECIFIC TYPES OF ABUSES TO BE INCLUDED IN THE GUIDELINES

As can be seen from the above, Medicines for Europe considers that more comprehensive Guidelines would be beneficial to competition in the pharmaceutical industry.

In particular, Medicines for Europe considers that more clear enforcement practices against conduct preventing innovation or limiting patent choice is necessary.

To assist your services with assessing which types of conduct that currently appears to be overlooked by market participants and enforcers relative to the damage they inflict upon effective competition, Medicines for Europe will in this submission provide information on the types of conduct, which Medicines for Europe considers are in most need of additional guidance. These types of conduct include:

- Patent thickets
- Divisional patents
- Disparagement
- Product hopping

The first two types of conduct concern the use of certain rights and privileges conferred upon dominant companies under the patent framework governing regulated industries to block the entry of competition. For good measure it is, however, noted that the effects on effective competition of disparagement and product hopping may also increase significantly when this is combined with (mis-)use of such rights.

Where applicable, Medicines for Europe has for each of these types of conduct included a brief analysis of existing case law to assist your services with implementing more specific guidance.

5.1 Patent thickets

Originators are known to file multiple “follow-on” patent applications to further extend the patent protection of medicines. The consequence of this is that an extensive “thicket” of patents is formed around a medicine. This thicket acts as a barrier to entry for generics and biosimilars as each granted patent must be revoked if a competitor is to bring its product to market without risking that this will lead to significant financial and time burdens.

The background for this strategy is twofold as originators either hope that:

- At least one of the numerous “follow-on” patent applications will be granted and create years of legal uncertainty until the patent is finally revoked, the patent being enforced nationally during this period until revocation.
- Developers of generics and biosimilars will be dissuaded from challenging the patents as this would incur significant legal costs and often involve time-consuming litigation in multiple jurisdictions.

Medicines for Europe is aware of at least one example where a European competition authority has challenged such a patent thicket, namely *Boehringer Ingelheim and Almirall (COPD)*.¹² In this case the European Commission investigated a case where Boehringer Ingelheim had filed for several unmeritorious patents over three types of combination of active substances with a new active substance developed by Almirall for treating chronic obstructive pulmonary disease (COPD), which would block the entry of competing medicines.

This matter was, however, settled by the parties, thus allowing the European Commission to end its investigation into the conduct without issuing a decision on this conduct.

The use of patent thickets continues to be a common practice in the pharmaceutical industry within the EEA. The common occurrence of this conduct has also been noted by the European Commission in its Pharmaceutical Sector Inquiry,¹³ in which it is stated that:

“Filing numerous patent applications for the same medicine (forming so called “patent clusters” or “patent thickets”) is a common practice. Documents gathered in the course of the inquiry confirm that an important objective of this approach is to delay or block the market entry of generic medicines.

In this respect the inquiry finds that individual medicines are protected by up to nearly 100 product-specific patent families, which can lead to up to 1,300 patents and/or pending patent applications across the Member States (...)

When the number of patents and in particular of pending patent applications is high (patent clusters), this can lead to uncertainty for generic competitors – affecting their ability to enter the market. Statements in internal documents collected in the context of the sector enquiry point at the awareness by patent holders that some of their patents might not be strong.”¹⁴

Medicines for Europe has also in **Appendix A** provided an overview of examples of current patent thickets that are likely to be unmeritorious for the aforementioned reasons.

5.1.1 Recommendations for inclusion in Guidelines

As the use of patent thickets continues to be a common practice in the pharmaceutical industry within the EEA, Medicines for Europe considers that it is necessary that guidance on the legal standard for when this type of conduct may infringe Article 102 TFEU is issued.

In particular, Medicines for Europe considers that the European Commission must include guidance as to the extent to which the use of patent thickets would be considered as “*placing of obstacles to entry or the use of other blocking measures.*” While no case law on this is publicly available, Medicines for Europe considers that a high number of patent applications and patents related to specific medicines serves as a useful initial indicator for finding an abuse

¹² https://ec.europa.eu/commission/presscorner/detail/en/IP_11_842

¹³ European Commission, Final Report: Pharmaceutical Sector Inquiry (2009).

¹⁴ European Commission, Final Report: Pharmaceutical Sector Inquiry (2009), page 201.

of dominance, absent objective justifications for applying patent clusters by the originator (even where this is allowed under patent rules).

The need for additional guidance from the European Commission on this type of conduct is particularly necessary in light of the common occurrence of this conduct coupled with the current lack of guidance for market participants as the only investigation into this was closed without a publicly available decision.

5.2 Divisional Patents

A second instrument used by originators is the filing of "divisional patent" applications, most prominently before the EPO where the majority of patent applications in the pharmaceutical sector are filed.

Divisional patent applications, which are foreseen under patent law as a legitimate way to split an (initial) parent application,¹⁵ cannot extend beyond the scope of the earlier application nor the protection period. But they can extend the examination period by the patent office, as the examination of divisional applications continues even if the parent application is withdrawn or revoked, which adds to the legal uncertainty for developers of generics or biosimilars.

This is in particular the case as no limitations exist for new divisional applications and since applicants may file as many divisional applications as they wish, without any justification required. A European patent application may give rise to multiple divisional applications, which, themselves, may give rise to multiple divisional applications leading to several generations of divisional patent applications.

Divisional patents are considered to have the same date of filing as the parent, i.e. they are considered protected retroactively from the filing date of the parent patent, but will be subject to new examination procedures and, if granted, new opposition periods independently from the outcome of the parent application.

This allows companies currently holding patents to “*play the divisional patent game*”, i.e. undertaking certain divisional strategies in procedures before the EPO to create legal uncertainty for generic/biosimilar medicine developers seeking to launch competitor products, with subsequent generic/biosimilar delayed launch. This can manifest itself in the practice of:

- 1) filing cascades of divisional patent applications, with each divisional patent application filed subsequently, at different times, all related to the same weak parent application and claiming in slightly different ways the same product or invention, salami-slicing second medical uses or trying to block any alternative option to design around the claims of the parent application;
- 2) defending such divisional patents in EPO opposition proceedings;
- 3) enforcing such divisional patents in national courts, incl. via preliminary injunctions; and

¹⁵ E.g. in a case where multiple inventions were originally disclosed in a single application instead of separate applications.

- 4) blocking P&R¹⁶ procedures for generics/biosimilars (*unlawful* patent linkage);¹⁷
- 5) blocking the product entry at customs (without a court order, again constituting unlawful patent linkage); and
- 6) eventually, strategically withdrawing any earlier patent from the family, just before it is due to be adjudicated by the Opposition Division or Technical Board of Appeal of the EPO, to avoid a decision confirming it is invalid.

In engaging in either of these practices, the patent applicant, can maintain legal uncertainty by keeping a series of divisional patent applications pending for an extended period of time, so that even when a parent patent is invalidated before a patent office or court, there will still be a divisional patent application covering substantially the same subject matter, replicating the legal uncertainty.

The uncertainty is even higher, with increased risk of patent infringement, in scenarios where a patent thicket has been generated and divisional applications are filed from numerous secondary patents, subsequently used to block or delay regulatory or administrative approvals of generic and biosimilar medicines (ie. patent linkage).

While there may be valid and objective reasons to withdrawing a divisional patent, certain fact patterns (large-scale patent thickets with accompanying divisional applications, withdrawals for typographic reasons rather than substantive differences or at specific time points in the opposition process) may indicate an originator is instead attempting to avoid subjecting its IP to proper scrutiny.

All this results in:

- 1) undue prolongation of the enforceable life of invalid patents
- 2) unnecessary and costly oppositions and litigation against multiple members of the same patent family;
- 3) delayed generic/biosimilar entry, as the launch is blocked by the granting of injunctions and/or costs of litigation; and
- 4) a risk for potential damages to be awarded by a national court, even if the divisional patent is later revoked in national proceedings or at the EPO.

Medicines for Europe also notes that despite the apparent attractiveness of the Unified Patent Court (UPC), most originator companies have chosen to opt out of the UPC at least parts of their portfolios to enable them to continue to pursue an anti-competitive strategy of applying for patents across multiple jurisdictions.

To provide one among several examples, the Italian national competition authority has previously fined Pfizer € 10.7m for misusing divisional patents. In this case, the original patent for Pfizer's glaucoma drug Xalatan (EP 0 364 417) was set to expire in September 2009.

¹⁶ Pricing and Reimbursement

¹⁷ Patent linkage refers to the practice of linking the granting of marketing authorisation, the pricing and reimbursement status or any regulatory approval for a generic medicinal product, to the status of a patent (application) for the originator reference product (Pharmaceutical Sector Inquiry, page 130). While the status of a patent (application) shall not be used as an argument for refusing, suspending or revoking marketing authorisation, this is nonetheless frequently combined with divisional patents and patent thickets to block P&R procedures.

However, Pfizer filed for, and obtained, a divisional patent (EP 1 225 168) followed by an SPC and paediatric extension. The Italian competition authority found evidence that the sole purpose of the strategy was to delay the onset of generic competition in the Italian market. Pfizer's strategy had successfully managed to extend the duration of its monopoly by seven months until May 2010, which cost the Italian Health service an additional €14 million. The Italian Council of State confirmed this decision on appeal in 2014 and the Italian Supreme Court further confirmed this in January 2024.

5.2.1 Recommendation for inclusion in Guidelines

Due to the common nature of this type of conduct, Medicines for Europe considers that it would be beneficial to include additional guidance on this type of conduct in the Guidelines.

To provide additional clarity on the application of Article 102 TFEU, Medicines for Europe considers that it should be specified in what cases applications constitute a part of the “divisional game” and thus not competition on the merits.

This could for example include cases where originators:

- Submit applications without an explanation as to why the new application differs from the previous application and overcomes the problem(s) of the earlier application(s).
- Do not provide legally or commercially justifiable reasons for withdrawing an application (e.g. withdrawals for typographic reasons rather than substantive differences).
- Delay the filing of a divisional application unreasonably.
- Apply for large scale patent thickets with accompanying divisional applications.
- Withdraw the application at specific time points in the opposition process.
- Otherwise are aware they will not receive a patent as a result of the application (i.e. cases where originators have as their intent to misuse the divisional patent system).

In this regard, it is particularly noted that while the European Patent Convention and its Implementing Regulations allow the above types of conduct, which strongly indicate the existence of “divisional games”, these may constitute infringements of Article 102 TFEU.

5.2.2 Examples from Medicines for Europe

For a recent example of this, please refer to **Appendix B**, which is [CONFIDENTIAL].

Moreover, please refer to **Appendix C**, which [CONFIDENTIAL].

5.3 Disparagement

Disparagement and/or denigration (hereinafter referred to as “disparagement”) is a joint term for two types of competition law infringements; namely

- 1) The false or misleading criticism of a competitor's product towards purchasers of products in order to influence the purchasing patterns or habits of consumers; and
- 2) The provision of false or misleading information to public authorities.

While the concept of disparagement as an abuse infringing Article 102 TFEU is well-established in Europe, specific guidance on the legal standard for establishing an abuse at an EU level is not yet available.¹⁸

Initially, Medicines for Europe notes that of particular relevance to the understanding of the term disparagement is the body of French case law on disparagement under Article 102 developed by the French competition authority, the Autorité de la Concurrence, which has been upheld on appeals in two instances in France, namely the Cour d'appel de Paris and the Cour de Cassation.¹⁹ In relation to the former type of disparagement, it can be seen *inter alia* from this significant body of national case that the relevant elements of illegal disparagement infringing Article 102 TFEU exists, when the following elements are present:

- 1) There is disparagement of a competitor's product with a view to obtaining a commercial advantage.
- 2) A link between the dominance and the disparagement has to be established.
- 3) The statements put forward in the market by the dominant company are not based on objective findings or verified assertions.
- 4) The commercial statements are liable to influence the structure of the market.

Moreover, the issue of influencing public authorities has previously been dealt with in great detail by the European Court of Justice in the *AstraZeneca* case²⁰ and has also been helpfully pointed to in the national body of case law from the Cour d'appel de Paris. In these cases of particular interest for this submission it has been held that submitting misleading information to public authorities, which is liable to lead them into errors in the granting of exclusive rights, constitutes an abuse of a dominant position.

Nonetheless, Medicines for Europe considers that specific guidance on the concept of disparagement in relation to the application of Article 102 TFEU to both types of disparaging conduct will be important.

¹⁸ Medicines for Europe is aware of the ongoing investigation into Vifor Pharma in case AT.40577 related to disparagement where the market testing period for the commitments proposed by Vifor Pharma has recently expired (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C_202402877).

¹⁹ See e.g. the decisions by the French Autorité de la Concurrence in the following cases: (1) Décision no. 07-D-33 du 15 octobre 2007 relative à des pratiques mises en oeuvre par la société France Télécom dans le secteur de l'accès à l'Internet à haut débit ("France Telecom"); (2) Décision no 07-MC-06 du 11 décembre 2007 relative à une demande de mesures conservatoires présentée par la société Arrow Génériques ("Arrow Génériques"), upheld on appeal to the cour d'appel de Paris on 5 February 2008 and the Cour de Cassation on 13 January 2009; (3) Décision no. 09-D-14 du 25 mars 2009 relative à des pratiques mises en oeuvre dans le secteur de la fourniture de l'électricité ("GEG"), upheld on appeal to the cour d'appel de Paris on 23 March 2010; (4) Décision no 09-D-28 du 31 juillet 2009 relative à des pratiques de Janssen-Cilag France dans le secteur pharmaceutique ("Janssen-Cilag France"); (5) Décision no 10-D-32 du 16 novembre 2010 relative à des pratiques mises en oeuvre dans le secteur de la télévision payante ("Groupe Canal Plus"); (6) Décision no 13-D-11 du 14 mai 2013 relative à des pratiques mises en oeuvre dans le secteur pharmaceutique ("Sanofi-Aventis"), upheld on appeal to the cour d'appel de Paris on 18 December 2014 and the Cour de Cassation on 18 October 2016; (7) Décision no 13-D.21 du 18 décembre 2013 relative à des pratiques mises en oeuvre sur le marché français de la buprenorphine haut dosage commercialisée en ville ("Schering-Plough"), upheld on appeal to the cour d'appel de Paris on 26 March 2015 and the Cour de Cassation on 11 January 2017.

²⁰ Case C-457/10 P, *AstraZeneca AB and AstraZeneca plc*.

While this is relevant for a multitude of industries, national case law demonstrates that this type of conduct in particular impacts the pharmaceutical sector.²¹

In relation to this, Medicines for Europe further notes that the potential inclusion of a prohibition against “*advertising that aims to highlight negatively another medicinal product*” as currently set out in the proposal to the EU pharmaceutical reform will not suffice to mitigate the issues faced by the members of Medicines for Europe. Indeed, the scope of such a prohibition needs to both be wider and more adaptable to the relevant circumstances in question, thus likely requiring that this conduct continues to primarily be subject to competition law.

Moreover, Medicines for Europe notes that this is currently in particular a common type of conduct for originators to apply against the marketing of biosimilars (both at a general level against biosimilars as a concept and against individual medicines).

5.3.1 Disparagement may be a part of a strategy of vexatious litigation

While vexatious litigation has previously been recognised as a potential abuse by the European Courts,²² Medicines for Europe considers that the bar to prove this should be lowered in cases where the vexatious litigation is combined with a dominant company providing misleading information either to the relevant authorities or the courts as this greatly amplifies the anti-competitive effects of either of these types of conduct on effective competition.

5.3.2 Recommendations for inclusion in Guidelines

Due to the abundance of examples of disparaging conduct that members of Medicine for Europe face when attempting to introduce new medicines to the market, Medicines for Europe consider that the pharmaceutical market (and other industry sectors) would benefit greatly from simply having this included as an example of a type of conduct that the European Commission enforces rigorously.

Moreover, the Guidelines should list the four conditions mentioned above to ensure that it is clear to all market participants and reinforces when disparaging conduct infringes Article 102 TFEU.

In addition, the Guidelines should explicitly state that before a decision on infringement of a patent, no authority should act upon a statement by the patent holder but only consider its relevant laws and regulations to follow, since any patent infringement is to be decided only by the competent courts and not by any other authority. Nor should an authority be party to patent infringement proceedings, which should be conducted exclusively by the involved commercial parties.

Further, any statements of IP holders to authorities should be made publicly available in order to ensure a fully transparent procedure. There should be no confidential correspondence between an IP right holder and an authority about infringement of the IP right by a company bringing into the market a generic or biosimilar medicine.

²¹ Similarly to Article 102 TFEU, the existence of this type of conduct as a harmful type of conduct for effective competition has also been recognised by the European Court of Justice, which has previously stated that “*given the characteristics of the medicinal products market, it is likely that the dissemination of such information will encourage doctors to refrain from prescribing that product, thus resulting in the expected reduction in demand for that type of use.*” (Case C-179/16, *Hoffman la Roche and others v Autorita Garante della Concorrenza e del Mercato* (2018), para. 93.)

²² See e.g. Case T-111/96, *Promedia*

5.3.3 Examples from Medicine for Europe

Several members of Medicine for Europe have faced a multitude of examples of disparaging conduct from dominant companies attempting to ensure that generics or biosimilars cannot enter the market.

Broadly speaking, these can be divided into cases where the dominant company has either put forward statements not based on objective findings or verified assertions concerning either

- i. the effectiveness or side-effects of the generic or biosimilar medicine; or
- ii. information to distributors concerning the commercial risks that they would run by distributing a product that would infringe their patent; or
- iii. statements made to authorities and commercial partners (distributors, wholesalers, pharmacies, doctors, hospitals) that a generic/biosimilar product is infringing a patent and will not be available anymore, including threats that the authorities or commercial partners will be held liable for patent infringement and damages and therefore they should not add the product in P&R or medicinal availability lists or use or sell the generic/biosimilar product.

For a recent example of this, please refer to **Appendix C** (section 2), which [CONFIDENTIAL] and **Appendix D**, which provides [CONFIDENTIAL].

5.4 Product hopping

“Product hopping” refers to the introduction by originators of modified versions of pharmaceuticals or second-generation pharmaceuticals and the strategies used to switch patients from an original product to a follow-on product that benefits from further patent protection.

This may include the complete removal from the market of the original formulation because it is nearing the expiry of relevant patent rights. The removal effectively forces all patients to switch to another notionally “improved” formulation, for example, the introduction of a tablet in place of a capsule, that happens to be patent protected for a longer duration.

The second-generation product may be more expensive, thus leading to an immediate increase in profits. The first-generation product may be withdrawn entirely, forcing clinicians to prescribe the more expensive second-generation product (“a hard switch”). Alternatively, the market for the first-generation product may be left to atrophy, whilst all marketing and promotional spend is focused on moving sales on to the second-generation product (“a soft switch”).

This is a commonly occurring phenomenon in the pharmaceutical industry. Indeed, this happened to 40% of samples, which had lost exclusivity from 2000 to 2007 in the review conducted by the European Commission for its 2009 report.²³

The European Court of Justice has already in the *AstraZeneca* case found that product hopping may constitute an infringement of Article 102 TFEU, as it found that:

“the preparation by an undertaking, even in a dominant position, of a strategy whose object it is to minimise the erosion of its sales and to enable it to deal with competition from generic products is legitimate and is part of the normal competitive process,

²³ European Commission, Final Report: Pharmaceutical Sector Inquiry (2009), page 367.

provided that the conduct envisaged does not depart from practices coming within the scope of competition on the merits, which is such as to benefit consumers.”²⁴

In this instance, the European Court of Justice found that the deliberate deregistration of the market authorisation along with providing misleading information to the patent offices or other authorities was designed to hinder the introduction of generic products and parallel imports and therefore could not be considered competition on the merits. Moreover, internal documents evidenced AstraZeneca's underlying intent and failed to demonstrate its arguments at trial that it had legitimate reasons for deregistration.²⁵

5.4.1 Recommendations for inclusion in Guidelines

Similarly to disparagement, Medicines for Europe consider that due to the abundance of examples of such conduct that the members of Medicine for Europe face when attempting to introduce new medicines to the market, the pharmaceutical market would benefit greatly from simply having this included as a type of conduct against which the European Commission enforces rigorously.

Moreover, the Guidelines should clearly describe in what way the legal standard for establishing that this type of abuse of a regulatory framework can be considered to deviate from competition on the merits.

5.4.2 Examples from Medicine for Europe

For an example of product hopping by an originator, please refer to **Appendix E**, which is [CONFIDENTIAL].

6. CONCLUDING REMARKS

In light of the above, we respectfully request the European Commission to include guidance on the following specific types of conducts related to the abuse of dominance under Article 102 TFEU in the future Guidelines:

- The notion of **competition on the merits**, in particular in relation to the placing of obstacles to entry or the use of other blocking measures to prevent the growth of competition, , especially when conduct complies with other regulatory rules
- Guidance on the notion of **patent thickets** and **divisional patents**, i.e. types of misuse of a regulatory system (in this case a patent system)
- Guidance on the notion of **disparagement**
- Guidance on the notion of **product hopping**

We appreciate the European Commission's commitment to promoting fair competition, and we are confident that your consideration of our request will contribute to the ongoing refinement of competition law in the European Union.

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²⁴ Case C-457/10 P, *AstraZeneca AB and AstraZeneca plc*, para. 129.

²⁵ Case C-457/10 P, *AstraZeneca AB and AstraZeneca plc*, para. 130; para. 136.

We remain at your disposal for any questions or comments regarding the above.

Yours sincerely,

Sergio Napolitano
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Medicines for Europe