



WHITE PAPER

**Anatomy of a Failure to Launch:**  
a review of barriers to generic and biosimilar market  
entry and the use of competition law as a remedy

AUTHOR



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# **Anatomy of a Failure to Launch:**

a review of barriers to generic and biosimilar market entry and the use of competition law as a remedy

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## CONTENTS:

1.	<b>INTRODUCTION</b> .....	4
2.	<b>BACKGROUND</b> .....	4
3.	<b>USE OF 'PATENT THICKETS' TO DISCOURAGE COMPETITION</b> .....	10
4.	<b>MISUSE OF THE DIVISIONAL PATENT SYSTEM</b> .....	12
5.	<b>PATENT LINKAGE</b> .....	18
6.	<b>PRODUCT HOPPING</b> .....	23
7.	<b>PREDATORY PRICING / ANTI-COMPETITIVE REBATES</b> .....	28
8.	<b>DENIGRATION IN ORDER TO HARM COMPETITION</b> .....	33
9.	<b>CONCLUSION</b> .....	36

### 1. INTRODUCTION

- 1.1 The purpose of this whitepaper is to examine the evolution of specific barriers to generic and biosimilar market entry in the European Union ("EU") over the last decade with consideration of the application of competition law as a potential remedy<sup>1</sup>.
- 1.2 It provides an updated overview of some of the strategies used to delay generic and biosimilar entry<sup>2</sup> such as:
- 1.2.1 the use of patent thickets, secondary patents and so called 'evergreening' strategies;
  - 1.2.2 the exploitation of the divisional patent system;
  - 1.2.3 the concept of patent linkage, including:
    - (a) what patent linkage is and how the issue of patent linkage is compounded due to the number of secondary patents granted to companies; and
    - (b) the misuse or misdirection of the medicines regulatory framework to, for example, link marketing authorisation grant to patent expiry or activities taken directly against competent authorities seeking to restrain their activities.
  - 1.2.4 the use of 'product hopping' strategies;
  - 1.2.5 the use of predatory pricing strategies; and
  - 1.2.6 the use of misleading statements designed to inhibit competition.
- 1.3 Section 9 sets out our conclusions concerning generic and biosimilar entry into the European market and provides some recommendations designed to address some of the findings.

### 2. BACKGROUND

- 2.1 The European Commission (the "**Commission**") launched a pharmaceutical sector inquiry (the "**Inquiry**") on 15 January 2008 which addressed some obstacles to market entry for prescription medicines for human use. The Inquiry was undertaken as part of the Commission's initiatives "*aimed at providing European patients with safe, effective and affordable medicines*", whilst at the same time stimulating research, innovation and competitiveness in the sector. The launch of the Inquiry followed closely behind a 2008 paper by Medicines for Europe (then the European Generic Medicines Association) (the "**2008 Paper**"), which also considered patent-related barriers to market entry for generic medicines.
- 2.2 The Commission's final report, published in July 2009, (the "**2009 Report**") confirmed the use of various strategies designed to delay the market entry of generic medicines and retain exclusivity for an extended period. For example, such practices included the generation of patent thickets (where there are multiple, overlapping patents that cover a product) and intervention in national approval procedures for generic medicines. It

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<sup>1</sup> Medicines for Europe has consulted with its members in order to elicit some examples of these strategies in action. This has been a useful exercise in order to help understand the prevalence of some of these strategies. We have included a few of the examples in this whitepaper in order to provide some practical illustrations of the strategies discussed. These examples are based on the information provided by members of Medicines for Europe, which contain only limited information and are designed solely to aid understanding.

<sup>2</sup> This whitepaper is not exhaustive and does not cover all issues that may effectively act as barriers to generic and biosimilar market entry, for example vexatious litigation or misrepresentation. Where an issue is not discussed, it should not be interpreted that the issue does not act as a barrier to generic and biosimilar entry.

further noted that other factors, such as the regulatory background, may also play a role in creating delay.

2.3 Since 2009 there has been commentary from EU institutions on the importance of generic medicines entering the market, from the perspective of improved patient outcomes in the EU<sup>3</sup>. With this background, this whitepaper considers the extent to which the issues identified in the 2008 Paper and 2009 Report have been addressed. It also considers whether in the subsequent eleven years any new potential barriers to market entry for medicinal products have arisen and what steps could be taken to eliminate such barriers and deliver prompt patient access to generic and biosimilar medicines in Europe.

### 2.4 **The Pharmaceutical Sector**

2.5 In 2016, the total retail spend on pharmaceuticals in the EU (excluding hospital care) was more than EUR 210 billion, a 5% increase since 2010<sup>4</sup>. In 2017, the EU spent 9.6% of its GDP on healthcare - pharmaceuticals account for approximately 20% of that expenditure<sup>5</sup>. These significant levels of expenditure, combined with the crucial need to provide patients with access to affordable medicines, indicates the vital role played by companies responsible for the timely provision of generic and biosimilar medicines. The importance of this issue has only been emphasised by the Covid-19 crisis.

2.6 Generic and biosimilar products are those products that can enter the market upon loss of exclusivity of the innovator product, be it patent or regulatory exclusivity expiry. Generic and biosimilar medicines play a fundamental role in promoting pharmaceutical innovation and, by introducing competition, ensuring the affordability, sustainability and accessibility of healthcare systems in the EU. Generic and biosimilar pharmaceutical products are fundamental to the reduction of healthcare expenditure in the EU. Generic competition can lower the cost of off-patent products by up to 66%<sup>6</sup> and biosimilar competition can lower the cost of off-patent products by up to 30%<sup>7</sup>. In 2014, generic products led to estimated savings of €100 billion in the EU<sup>8</sup>. Obstacles that prevent or delay generic and biosimilar entry will therefore have significant ramifications on the cost and accessibility of healthcare in the EU.

### 2.7 **The patent system and regulatory framework**

2.8 The Inquiry focussed on the behaviour of undertakings, but also acknowledged that other factors may play a role in creating obstacles to market entry. The 2008 Paper addressed two such factors – the regulatory and patent system.

2.9 The patent system is designed to foster innovation and provide compensation (through the provision of a time-limited monopoly) to companies and individuals for the research and development costs associated with developing patentable inventions. This is particularly important for pharmaceutical innovation – as at 2012, the cost of research

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<sup>3</sup> See, for example: European Council, *Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States* (17 June 2016), paras. 14, 19 and 47

[<https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/>]; and European Parliament, *Resolution of 2 March 2017 on EU options for improving access to medicines 2016/2057(INI)* (2 March 2017), para. 21 [[https://www.europarl.europa.eu/doceo/document/TA-8-2017-0061\\_EN.html](https://www.europarl.europa.eu/doceo/document/TA-8-2017-0061_EN.html)]

<sup>4</sup> European Commission, Organisation for Economic Co-operation and Development, *Health at a Glance: Europe 2018, State of Health in the EU Cycle* (2018), p.140

[[https://ec.europa.eu/health/sites/health/files/state/docs/2018\\_healthatglance\\_rep\\_en.pdf](https://ec.europa.eu/health/sites/health/files/state/docs/2018_healthatglance_rep_en.pdf)]

<sup>5</sup> *Ibid*, p. 46

<sup>6</sup> Ferrario et al, *Strategies to achieve fairer prices for generic and biosimilar medicines*, BMJ, (13 January 2020) p. 1

<sup>7</sup> Deloitte, *2018 Global life sciences outlook*, p. 5

[<https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-ls-outlook-2018.pdf>]

<sup>8</sup> IMS Institute for Healthcare Informatics, *The Role of Generic Medicines in Sustaining Healthcare Systems: A European Perspective* (June 2015), pp. 5 and 8 [[https://www.medicinesforeurope.com/wp-content/uploads/2016/03/IMS\\_Health\\_2015\\_-\\_The\\_Role\\_of\\_Generic\\_Medicines\\_in\\_Sustaining\\_Healthcare\\_Systems\\_-\\_A\\_European\\_Perspective.pdf](https://www.medicinesforeurope.com/wp-content/uploads/2016/03/IMS_Health_2015_-_The_Role_of_Generic_Medicines_in_Sustaining_Healthcare_Systems_-_A_European_Perspective.pdf)]

and development of a new drug was estimated to be USD 1.9 billion<sup>9</sup>. This is investment which may partially be recouped during the 20 year patent monopoly.

- 2.10 Prior to a medicinal product being marketed and sold in the EU, a marketing authorisation ("**MA**") must be obtained. For new active substances, this requires the submission of full pharmacological, toxicological and clinical data. The time required to collate such data often results in a delay between the grant of a patent protecting the product and the grant of the marketing approval for that medicinal product.
- 2.11 In recognition of this delay, where a European Patent protects a medicinal product, up to an additional five years of exclusivity may be obtained through nationally granted Supplementary Protection Certificates ("**SPCs**"). SPCs are intended to compensate patent holders for time that elapses between the grant of a patent and the grant of the regulatory approval referred to above.
- 2.12 When operating as intended, the patent system allows originators to recoup their research and development expenditure and often to generate a significant profit. Generic entrants may then enter the market, providing more affordable medicines to patients, following the creation of competition. The granting of a temporary monopoly right excluding competition represents a carefully balanced trade-off designed to incentivise very significant investments in innovation to the benefit of patients.
- 2.13 Evidence suggests that the patent system is being exploited to artificially extend the duration of the monopoly beyond the period for which it was originally designed. For example, through the exploitation of patent thickets, secondary patents and exploitation of the divisional patent filing system. Patent thickets comprise a multitude of patents which may overlap and protect different aspects of the same product<sup>10</sup>, meaning that those seeking to bring a generic or biosimilar product to market must navigate a congested patent landscape, requiring investment of considerable time and expense.
- 2.14 Secondary patents are those that follow on from patents covering a new compound itself (so-called primary or basic patents). Secondary patents can claim, for example, new formulations of a product or use of the product for new treatments. Naturally, innovations in relation to known products may be patentable; however, there is often a perception that secondary patents are more likely to be held to be invalid than primary product patents.
- 2.15 The European Patent Office's ("**EPO**") 2019 Quality Report (the "**2019 Quality Report**") found that the percentage of patents granted by examiners which were found to be compliant with legal requirements was 76.9%. This demonstrates a marked decrease from 2017 and 2016 levels respectively (and only a marginal increase on 2018 levels), as demonstrated by Figure 13 from the 2019 Quality Report, copied below. Whilst low quality patents may be more susceptible to revocation, invalidating the patent still requires investment of often considerable time and resource. If those investments are not made, generic or biosimilar product entry will be delayed. This is particularly problematic in the pharmaceutical sector, considering the resultant impact on patient access to affordable medicines and the financial cost to healthcare payers of delaying generic and biosimilar entry.

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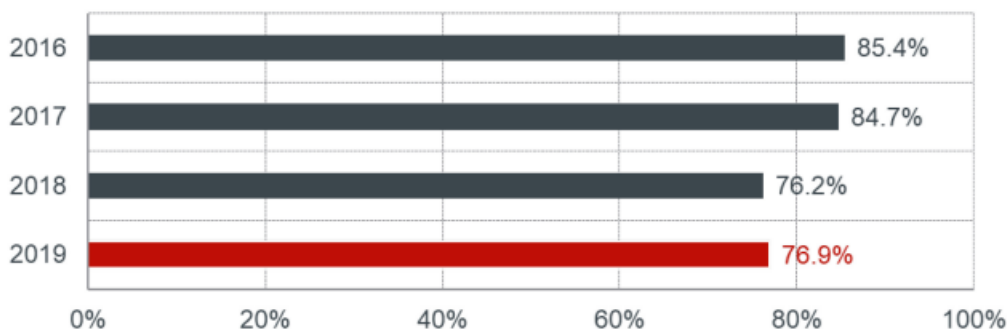
<sup>9</sup> Mestre-Ferrandiz, J., Sussex, J. and Towse, A., *The R&D Cost of a New Medicine*, Office of Health Economics (December 2012), pp. 3 and 6

<sup>10</sup> The patents comprising such thickets may also be used to obtain multiple SPCs covering the same medicinal product.



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Source: EPO

**Figure 13: Percentage of patent grants found compliant by quality audits**

- 2.16 The issue of low quality patents is further exacerbated by the very lengthy timelines of both the grant procedure and subsequent revocation actions either before the EPO or national courts. Both may be used as strategic tools to create and prolong uncertainty for third parties. According to the 2019 Quality Report, by the end of 2019, 95% of all patent grants were delivered in approximately seven years of filing (although it should be noted that the report does not provide data for pharmaceutical patents). The timelines for pharmaceutical patents can be much longer. There are examples where the final decision of the Technical Board of Appeal has been provided more than 16 years after filing. Even after the EPO communicates its intention to grant a patent, the applicant may request further processing of the application multiple times, which again delays grant and continues uncertainty for generic and biosimilar companies.<sup>11</sup> Such lengthy timelines for the grant and subsequent revocation of invalid patents serve to extend the uncertainty for those seeking to bring generic or biosimilar products to market.
- 2.17 Regardless of the quality of the patent granted and the likelihood of it subsequently being found to be invalid, patentees are motivated to seek preliminary injunctive relief, restraining the entry of generic or biosimilar competitors to the market. This is because in some markets there is no obligation to provide a cross-undertaking to compensate the competitor for the time they were wrongly held off the market by the injunction; or in the jurisdictions in which damages would ultimately be payable by the patentee to the competitor, the disparity in profit margins for the two means that unless damages are awarded on a restitutionary basis, the incentive to the patentee in keeping a generic or biosimilar competitor off the market until the patent is ultimately invalidated far exceeds the financial burden which a damages award would likely impose upon the patentee. In considering damage suffered in the scenario of an injunction being granted to restrain generic or biosimilar entry until the patent is ultimately invalidated, it would be remiss not to acknowledge the financial burden suffered by the healthcare payers – for example in the current *Warner-Lambert Company LLC v Actavis Group PTC EHF et al* litigation before the Patents Court in England & Wales, the NHS in England, Wales, Northern Ireland and Scotland are claiming up to £788.4 million in damages suffered as a result of the orders made by the Court in light of the actions taken by Warner-Lambert to enforce a patent which ultimately was found to be invalid.
- 2.18 In France, the practice of the Court awarding provisional damages, together with a preliminary injunction, is liable to discourage generic and biosimilar entrants to the market, even where their assessment is that the blocking patent will ultimately be found invalid. In one case, provisional damages of over €4 million were awarded against a generic manufacturer, following grant of a preliminary injunction. This was so, notwithstanding the Court of Appeal ultimately quashing the injunction (and nullifying

<sup>11</sup> See, for example, the EPO files of EP2792349 A2 and EP3093012 A1 where five communications stating the EPO's intention to grant were communicated but the applicant requested further processing, and EP2965751 A1, where two communications stating the EPO's intention to grant were communicated but the applicant requested further processing.

the award) after finding that the SPC on which the action was based was likely to be invalid<sup>12</sup>. In other cases, provisional damages awards against generics have been much higher, for example €28 million<sup>13</sup> and over €13 million<sup>14</sup>. In contrast quantum of damages awards to generics, in cases where preliminary injunctions have been wrongly granted, is likely to be lower in one example damages in the sum of €3.5 million was awarded to the generic<sup>15</sup>.

- 2.19 The granting of SPCs may also be exploited to create barriers to market entry for generic or biosimilar competitors. A member of Medicines for Europe noted that "*an area of abuse is the manipulation of the SPC system by applying for multiple SPCs for the same product. These SPCs are subject to many national litigations and referrals to the CJEU and in effect create a thicket of unmerited claimed protections which must be litigated for a generic to launch*". Multiple SPCs may be granted for the same product or based upon the same marketing authorisation. The Court of Justice of the European Union ("**CJEU**") recently provided some clarity in confirming that SPCs may not be granted in the case of a new medical use for an existing product<sup>16</sup>; however, uncertainty remains over whether there are some instances where multiple SPCs may nevertheless still be granted. In addition, there is often little by way of published information regarding the SPC grant process, which can create uncertainty for generic and biosimilar companies until the SPC is actually granted.
- 2.20 A further means to extend the duration of the monopoly relating to a product arises in the context of medicines for use in the paediatric population. If the requisite requirements are satisfied, a paediatric extension may be granted, which entitles the SPC holder to an additional six months of exclusivity. In order to be granted a paediatric extension, a PIP (being a research and development programme aimed at generating the data to determine the conditions in which a product may be authorised to treat the paediatric population) must be agreed with the EMA. Whilst studies under the relevant PIP are carried out, competitors will not know whether the paediatric extension will be granted and thus will not have certainty as to the final expiration date of the SPC. Yet further uncertainty may be created in relation to orphan medicinal products (being those products indicated to treat rare conditions for which the patient population is small), where an additional two years of orphan market exclusivity may be obtained upon completion of the paediatric studies. In respect of orphan medicinal products protected by an SPC, a practice has developed of abandoning orphan designations and "electing" for a six month extension to the SPC. Which reward the rights holder will elect for is not clear until that election is made, thereby continuing uncertainty for competitors.
- 2.21 This whitepaper elaborates further on the potential flaws within the European patent system; potential misuse of the same and linkage of the European patent system with the regulatory approval processes. As observed by one member of Medicines for Europe, patent thickets and secondary patent applications "*lead to legal uncertainty, oppositions with the EPO which take too long and sometimes even a number of parallel national litigations*" all of which incur significant time and expense and will ultimately delay generic and biosimilar product entry. Whilst not examined in detail, we note that the additional topics touched on above also create uncertainty and delay in market entry.

<sup>12</sup> *MSD v Mylan*, Tribunal de grande instance de Paris, 7 March 2019, Docket № 17/14664, following the grant of a preliminary injunction and Cour d'appel de Paris, 14 February 2020, Docket № 19/06114, upon the rejection of the preliminary injunction and nullifying of the award.

<sup>13</sup> *Eli Lilly v Fresenius Kabi*, Tribunal judiciaire de Paris, 11 September 2020, Docket № 17/10421, following a finding of infringement on the merits.

<sup>14</sup> *Novartis v Teva*, Tribunal de grande instance de Paris, 7 June 2018, Docket № 16/15196, following the grant of a preliminary injunction.

<sup>15</sup> *Biogaran v. Laboratoires Negma*, Cour d'appel de Paris, 31 January 2014, Docket № 12/05485, following the wrongful grant of a preliminary injunction.

<sup>16</sup> *Santen SAS v Directeur général de l'Institut national de la propriété industrielle*, Case C-673/18



- 2.22 **Concern about generic and biosimilar market entry in the EU institutions**
- 2.23 Intellectual property rights and competition law both share the common goal of promoting innovation and consumer welfare and are expected to act in concert. Article 8(2) of TRIPS<sup>17</sup> specifically recognises the role of competition law where intellectual rights may be subject to abuse: *“Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by rightholders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”*
- 2.24 The 2009 Report examined various barriers to generic market entry and the potential for competition law to address some of the concerns that had been identified. In 2016, the European Council called on the Commission to *“continue and where possible intensify... the monitoring, development and investigation - in cooperation with national competition authorities in the European Competition Network (ECN) - of potential cases of market abuse, excessive pricing as well as other market restrictions specifically relevant to the pharmaceutical companies operating within the EU”*<sup>18</sup>.
- 2.25 Also in 2016, the European Parliament's Committee on Legal Affairs voted for a motion to remind the Committee on the Environment, Public Health and Food Safety that *“the Pharmaceutical Sector Inquiry Report carried out by the Commission in 2009 indicated that... some companies’ abusive practices in connection with patent claims have contributed to delays in the market entry of generic medicines and should be avoided”*<sup>19</sup>.
- 2.26 The Committee on Legal Affairs voted to request that the Committee on the Environment, Public Health and Food Safety adopt the following requests into a motion for a resolution that the EPO and Member States only grant patents on health products *“that strictly fulfil the patentability requirements of novelty, inventive step and industrial applicability as enshrined in the European Patent Convention, and should pay particular attention to ‘evergreening’ [of patents]”*<sup>20</sup>.
- 2.27 These motions and the view of the European Council outlined above were both cited by the European Parliament in its March 2017 *Resolution on EU options for improving access to medicines* (the **“2017 Resolution”**), which stated *inter alia* that the European Parliament *“deplores the litigation cases aiming to delay generic entry”* and finds *“that biosimilar medicines enable increased competition, reduced prices and savings for healthcare systems”*<sup>21</sup>.
- 2.28 In May 2018, the Commission released a report on a study<sup>22</sup> considering the ‘effective protection period’ which best incentivises innovators. The report confirmed the significant benefits of generic competition, including the reduction in the cost of a treatment after the expiry of an originator's protection<sup>23</sup>.
- 2.29 A further report, entitled *Competition Enforcement in the Pharmaceutical Sector*, was published by the Commission in January 2019 (the **“2019 Report”**)<sup>24</sup>. This report reviews how the Commission and national competition authorities have enforced

<sup>17</sup> The Agreement on Trade-Related Aspects of Intellectual Property Rights

<sup>18</sup> European Council, *Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States* (17 June 2017), para. 48 [<https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/>]

<sup>19</sup> European Parliament, Committee on Legal Affairs, *Opinion of the Committee on Legal Affairs for the Committee on the Environment, Public Health and Food Safety on EU options for improving access to medicines* (2016/2057(INI)) (18 November 2020), para. 4 [[https://www.europarl.europa.eu/doceo/document/A-8-2017-0040\\_EN.html#title4](https://www.europarl.europa.eu/doceo/document/A-8-2017-0040_EN.html#title4)]

<sup>20</sup> *Ibid*, para. 10

<sup>21</sup> European Parliament, *Resolution of 2 March 2017 on EU options for improving access to medicines* 2016/2057(INI)) (2 March 2017), para. 21 [[https://www.europarl.europa.eu/doceo/document/TA-8-2017-0061\\_EN.html](https://www.europarl.europa.eu/doceo/document/TA-8-2017-0061_EN.html)]

<sup>22</sup> European Commission & Copenhagen Economics, *Final Report: Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe* (May 2018) [[https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmaceuticals\\_incentives\\_study\\_en.pdf](https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmaceuticals_incentives_study_en.pdf)]

<sup>23</sup> *Ibid* p. 159 [[https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmaceuticals\\_incentives\\_study\\_en.pdf](https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmaceuticals_incentives_study_en.pdf)]

<sup>24</sup> European Commission, DG Comp, *Report from the Commission to the Council and the European Parliament: Competition Enforcement in the Pharmaceutical Sector (2009 – 2017)*, (2019)

antitrust and merger rules in the pharmaceutical sector from 2009 to 2017, in response to concerns by the European Council and Parliament that anti-competitive behaviours may compromise patients' access to affordable and innovative medicines. The report noted that national competition authorities adopted 29 antitrust decisions in the years following the 2009 Report, with total fines imposed exceeding EUR 1 billion.

- 2.30 Recently, on 4 June 2020, the Commission began a consultation to inform a 'roadmap' for building an EU Pharmaceutical Strategy for timely patient access to affordable medicines. This seeks to build a holistic, patient-centred, forward-looking EU Pharmaceutical Strategy which covers the whole life-cycle of pharmaceutical products from scientific discovery to authorisation and patient access, creating "*synergies with relevant EU policies, such as in the areas of research and innovation, industry, competition, environment and chemicals. Coherence will be kept with EU clinical trials and medical devices legislation*"<sup>25</sup>. This again highlights the role that the EU envisages for competition law in promoting improved generic and biosimilar access to the pharmaceuticals market.
- 2.31 Whilst it is evident that competition law can be a powerful tool to seek to promote prompt access to the market for generic and biosimilar pharmaceutical products, this whitepaper evaluates the extent to which, despite the concerns articulated by EU institutions listed above, obstacles to generic and biosimilar entry still exist in the pharmaceutical sector and the further role that competition law can play in overcoming such obstacles.

### 3. USE OF 'PATENT THICKETS' TO DISCOURAGE COMPETITION

- 3.1 As described above, patentees are known to file multiple 'follow-on' patent applications to further extend a product's patent protection. This is done in the hope that at least one of the numerous 'follow-on' patent applications will be granted and survive a litigation challenge. The consequence of this is that oftentimes an extensive 'thicket' of patents is formed around a pharmaceutical product, which may act as a barrier to entry. Attempting to clear the way when faced with multiple patents across multiple jurisdictions is an extremely expensive and time consuming process even if all of the 'follow-on' patents are considered to be relatively weak. The various patents constituting such a 'thicket' may cover the following aspects of a product:
- 3.1.1 the active pharmaceutical substance itself (typically the first patent(s) granted)<sup>26</sup>;
  - 3.1.2 a polymorph (or hydrated) form of the active substance;
  - 3.1.3 a simple salt of the active pharmaceutical substance;
  - 3.1.4 an isomeric form of the API;
  - 3.1.5 a substantially pure form of the API;
  - 3.1.6 an impurity inherent in an already disclosed process of making the compound;
  - 3.1.7 formulations, whether in solution or in solid form;
  - 3.1.8 concentrations in dosage forms;

<sup>25</sup> European Commission, *Communication: Pharmaceuticals – safe and affordable medicines (new EU strategy)* (2 June 2020) [<https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12421-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines>]

<sup>26</sup> This may be a very specific claim to just one molecule, or the particular molecule might be disclosed only as part of a broader family.

- 3.1.9 the use of the product in particular patient groups, or dose adjustments relating to the same;
  - 3.1.10 methods of manufacture and analytical methods;
  - 3.1.11 the use of a product in a method of diagnosis; and/or
  - 3.1.12 second medical use patents (particularly if in a related field to that disclosed in the first patent, or a variation of that dosage regime).
- 3.2 Each granted patent must be revoked if a competitor is to bring its product to market without risk that will incur significant financial and time burden.
- 3.3 Patent thickets, and the low quality and questionably innovative nature of the patents they are constituted of, were identified as a barrier to generic access in the 2008 Paper<sup>27</sup>, which addressed a number of examples of this type of abuse including the medicinal products citalopram, SSRIs, combinations comprising hydrochlorothiazide and perindopril. The Commission also raised the proliferation of patent thickets as an issue in the 2009 Report, finding that "*individual blockbuster medicines [in the EU] are protected by up to 1,300 patents and/or pending patent applications... certain [of these] patent filings occur very late in the life cycle of a medicine*"<sup>28</sup>.
- 3.4 Notwithstanding these findings, the 2019 Report noted that this form of activity continues to take place in the market<sup>29</sup>. It cited the recent example of the dispute between Boehringer and Almirall<sup>30</sup> which demonstrated that the issue of patent thickets persisted in the years after the findings in the 2009 Report were published:
- Boehringer and Almirall (COPD)*
- 3.4.1 In 2011, the Commission closed an antitrust investigation into allegations by Almirall that Boehringer 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). Almirall alleged that these patents would delay/block the entry of its competing medicines. However, ultimately, the parties reached a settlement agreement, allowing the Commission to end its pursuit of the case.
- 3.5 The strategic use of patent thickets continues today. For example, an on-body injector, which is used to administer a product to reduce the risk of infection in patients, is protected by at least 40 patent families relating to the device. The practice of creating a 'thicket' of patents around devices is particularly problematic in the biosimilar space, where it is difficult for biosimilar companies to switch between devices. Such patent thickets, therefore, create uncertainty and may prevent biosimilar companies from launching their products.
- 3.6 A further example of a constructed patent thicket concerns a treatment for idiopathic pulmonary fibrosis, which is protected by 6 different patent families, most of them related to different dosage regimes linked to safety issues indicated in the product labelling of the reference medicinal product. Some of the divisional patents within the different families have been invalidated at the EPO, but the parent patents are currently still in

<sup>27</sup> European Generic Medicines Association (now Medicines for Europe), *Patent-related Barriers to Market Entry for Generic Medicines in the European Union* (May 2008), pp. 12-16 [[http://www.ieis.org.tr/ieis/assets/media/EGA%20-%20QIP\\_Barriers\\_web.pdf](http://www.ieis.org.tr/ieis/assets/media/EGA%20-%20QIP_Barriers_web.pdf)]

<sup>28</sup> European Commission, *Final Report: Pharmaceutical Sector Inquiry* (8 July 2009), p.201

[[https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf)]

<sup>29</sup> European Commission, *Report from the Commission to the Council and the European Parliament: Competition Enforcement in the Pharmaceutical Sector (2009-2017): European Competition Authorities Working Together for Affordable and Innovative Medicines* (2019), pp. 39-40

[[https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/report\\_en.pdf](https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/report_en.pdf)]

<sup>30</sup> *Ibid.*

force. This patent landscape makes it very difficult for third parties to clear the way and launch their own generic or biosimilar product.

#### 4. MISUSE OF THE DIVISIONAL PATENT SYSTEM

- 4.1 The EPO states that *"the usual reason for filing a European divisional application is that the parent application does not satisfy the requirements as to unity of invention... and the applicant wishes to obtain a patent for all the inventions"*<sup>31</sup>. Without the ability to file divisionals, an applicant whose application falls foul of the unity of invention requirement<sup>32</sup> would be precluded from obtaining patents over each separate invention contained within the rejected application. Divisional applications, therefore, represent a useful tool in obtaining protection for one's inventions.
- 4.2 Divisional patent applications are those which derive from an earlier patent application with the earlier application referred to as the "parent". In relation to European Patents, divisionals are provided for by Article 76 of the EPC, which makes clear that the subject matter of any divisional application cannot extend beyond the scope of the earlier application as filed. The advantage of divisional applications is that they are deemed to have the same date of filing (and enjoy any right to priority) as the parent. As a result, anything published between that filing/priority date and the date the applicant applies for a divisional cannot be relied upon to invalidate that patent.
- 4.3 The divisional patent system may be exploited in order to create legal uncertainty for third parties seeking to launch competitor products. A third party can only know what a patent protects after it is granted and the scope of the claims is finalised. A pending patent application creates uncertainty, as the scope of the claims may change throughout the prosecution of a patent presenting an undefined blocking position. The uncertainty this creates is compounded in scenarios where a patent thicket has been generated and divisional applications are filed from numerous secondary patents. The uncertainty manifests in the increased risk of patent infringement issues on launch of the generic or biosimilar product, which can crystallise in either: (i) a litigation risk, which can lead to proceedings being commenced in any and all national courts, which can be costly to defend against; (ii) having the launch blocked by the granting of an interim injunction following launch; or (iii) creating 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 (whether at the Opposition Division or at the Technical Board of Appeal).
- 4.4 Often the primary patent covering the product *per se* has expired but uncertainty remains due to pending secondary patents and their divisional applications that may protect specific attributes of the product, such as, for example, specific indications, patient groups or formulations. Divisional applications may be filed at the EPO any time<sup>33</sup> whilst the earlier parent patent application is pending<sup>34</sup>. If the parent application provides basis, divisional applications could be filed after competitors have lodged applications for marketing authorisation for their products, or even launched the product into the market; in this way, the divisional patents could encompass within their claims the competitor product. The uncertainty this creates can present a significant barrier to generic and biosimilar manufacturers seeking to bring their products to the market.
- 4.5 It is only possible for an opposition before the EPO or a revocation action before a national court to be brought once the patent has been granted, thus those looking to market competitor products are forced to wait a significant period of time to obtain any certainty as to whether their product infringes a patent<sup>35</sup>. Even where the parent patent

<sup>31</sup> European Patent Office, *European Patent Guide: How to get a European patent*, section 5.8.001

<sup>32</sup> I.e. In that the patent relates to more than one invention.

<sup>33</sup> The rules were changed for a short period to require that divisional applications must be filed within 24 months of the first communication by the EPO examining division in relation to the parent, which resulted in a significant increase in the number of divisional applications filed.

<sup>34</sup> Rule 36 (1) Implementing Regulations to the EPC.

<sup>35</sup> In Germany, nullity proceedings cannot be brought before the national courts prior to expiry of the EPO opposition period following grant or where opposition proceedings are pending before the EPO. Due to the bifurcated nature of the

## Anatomy of a Failure to Launch:

a review of barriers to generic and biosimilar market entry and the use of competition law as a remedy

is invalidated before a patent office or court, the risk remains that a patent covering substantially the same subject matter may issue from a related pending divisional application replicating the legal uncertainty. A patentee can choose to maintain the legal uncertainty by keeping a series of divisional patent applications pending for an extended period of time. Every time one patent approaches grant, another may be published and thus restarts the lengthy grant process creating an interminable version of legal 'Whack-A-Mole', as demonstrated by the diagram below. For example, at the EPO, the grant of a divisional application triggers a new opposition deadline (9 months) and a minimum of 4 months is given to the patentee to reply to a notice of opposition. Although acceleration is possible, an opposition does not last less than 1.5 years not including appeal timelines. Currently, companies seeking to challenge a parent and its divisionals have no means to oppose these in one action at the EPO, nor to seek pre-emptive declaratory relief before the EPO to seek to stem the flow of new divisional application filings.

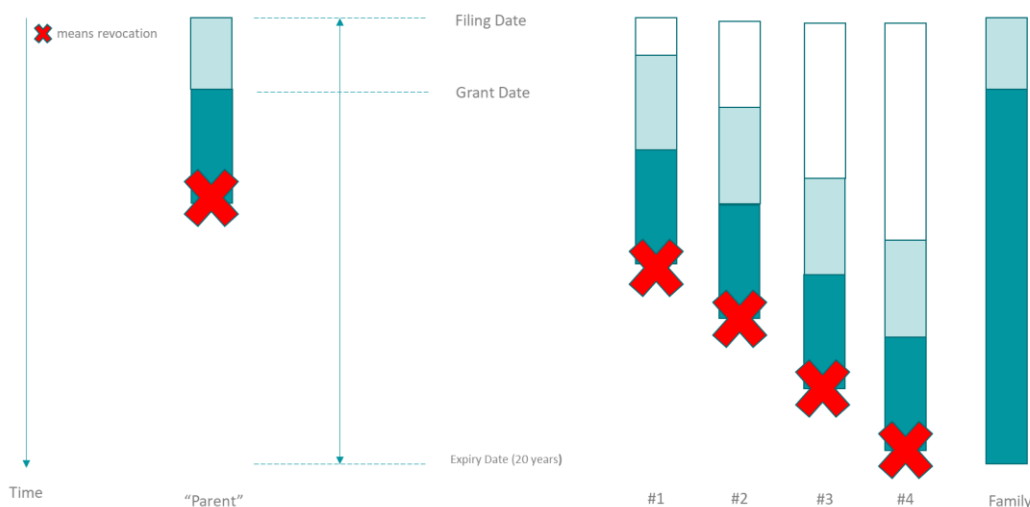


Figure provided by Medicines for Europe.

- 4.6 Furthermore, a practice has developed whereby the divisional patent system is used to frustrate the judicial and administrative procedures inherent in the patent system, thus prolonging the life of patents that may not be able to stand up to judicial scrutiny. This practice, often referred to as the 'divisional game' can involve:
- 4.6.1 **Filing “cascades” of divisional patents**, where each divisional patent is filed at different time periods, most often just before the grant of the previous member of the family (where often the differences between the claims of such divisional patents are immaterial);
  - 4.6.2 **Defending opposition proceedings** in respect of such divisional patents (where often such opposition proceedings can take between 3 and 6 years from initiation of the opposition until final resolution by the Technical Board of Appeal of the EPO);
  - 4.6.3 **Enforcing such patents in national courts**, where such patents can be used in litigation to grant preliminary injunctions against generic competitors who wish to launch at risk in the face of such patents;
  - 4.6.4 **Strategically withdrawing an earlier patent**, just before the point at which the earlier patent from the family is due to be considered by the Opposition Division or Technical Board of Appeal of the EPO, thereby frustrating the

German system, this can create challenges for generic and biosimilar companies in the event that infringement proceedings are brought against them.



judicial process by shielding the patent family from judicial scrutiny<sup>36</sup>. Any new opposition proceedings in respect of later filed divisional patents can then take another 3 to 6 years from initiation of the opposition until final resolution by the Technical Board of Appeal of the EPO.

- 4.7 It is worth noting that some national jurisdictions have adopted local rules designed to prevent a patentee from filing 'cascades' of divisional patents as referred to above. A common solution to prevent late filing of divisional applications is to simply impose a deadline for the filing of any divisional applications that is not dependent on the pendency of the relevant parent patent or its divisionals<sup>37</sup>. This provides a reasonable period of time for any divisional to be sought while limiting the potential for abuse. The EPO attempted a similar approach when Rule 36 of the European Patent Convention (which governs divisional applications) was amended in 2009 to limit the time period within which a divisional application could be filed to two years from the Examining Division's first communication to the applicant (with limited exceptions). However, this led to an initial influx of divisional applications that stretched the EPO's limited resources and, after a consultation and some effective lobbying, the deadline was removed on 1 April 2014.
- 4.8 Some national courts (such as the UK and the Netherlands) have also tried to provide certainty to generic and biosimilar companies in the form of what have become known as 'Arrow declarations'. In effect, this is a declaration from the court that a particular product or process was not new or was obvious at a specific point in time' for example, at the priority date of a relevant patent. Such declarations are able to provide certainty regardless of the number of divisionals filed or granted. However, this practice has been of limited practical use. First, its value may be limited to the specific country in which the declaration is sought. Secondly, when such a declaration is sought, the patent holder may simply withdraw the national designations of the relevant patents and divisional applications and undertake not to designate future divisional applications in the relevant country. Whilst this can provide certainty for that jurisdiction, it does not overcome the uncertainty that generic and biosimilar companies face in other European jurisdictions.
- 4.9 Some countries such as Italy and Germany have a local concept of 'unfair competition'. This principle of law is designed to prevent the illegitimate use of a legitimate right. Again, it is only available in limited jurisdictions and national courts have only been prepared to use this concept in isolated cases<sup>38</sup>.
- 4.10 *Previous examples*
- 4.11 Misuse of the divisional system was identified as an ongoing issue in the 2008 Paper<sup>39</sup>. Medicines for Europe identified examples of the potentially abusive use of divisional patents in relation to Alendronate (Fosamax), Budesonide/formoterol fumarate dihydrate (Symbicort) and Esomeprazole (Nexium).
- 4.12 The 2008 Paper recommended preventing the filing of divisional patents which are essentially identical to the parent application in question, on the basis that double-patenting is prohibited under C-IV, 6.4 of the EPO's *Guidelines for Examination*.

<sup>36</sup> Other instances may involve the applicant filing auxiliary claims that do not satisfy one of the requirements for the grant of a European patent, in order to avoid a reasoned decision on other requirements for the grant of a European patent, which may prejudice the validity of the whole family.

<sup>37</sup> For example, in the UK, if an applicant receives notice of intention to grant the patent, a divisional application may be filed within two months of the date of such notice. Where a notice has not been received, a divisional application must be filed within three months before the expiry of the 'compliance date' of the parent application, being 4 years and 6 months from the priority date/filing date of the parent patent or 12 months after the date on which the first substantive examination report is sent to the applicant (if later). The 'compliance period' for a divisional application is the same as that for the parent, which prevents a 'cascade' of divisional applications being filed.

<sup>38</sup> See, for example, the decision of the Munich District Court "*Verbot des Fallenlassens von Patenten*" on 24 February 2020 (O 1456/20) and the decision of the Consiglio di Stato in relation to *latanprost* on 12 February 2014 (693/214).

<sup>39</sup> Medicines for Europe, *Patent-related Barriers to Market Entry for Generic Medicines in the European Union* (May 2008), p. 14 [[http://www.ieis.org.tr/ieis/assets/media/EGA%20-%20IP\\_Barriers\\_web.pdf](http://www.ieis.org.tr/ieis/assets/media/EGA%20-%20IP_Barriers_web.pdf)]

- 4.13 The Commission also condemned the proliferation of divisional patents in the 2009 Report<sup>40</sup>. It noted that the "*examination of divisional applications continues even if the parent application is withdrawn or revoked, which can add to the legal uncertainty for generic companies*", adding that: "*filing divisional applications for the same secondary patent... can... be used strategically to create further uncertainty and delays for new entrants*".<sup>41</sup>
- 4.14 Furthermore, the Commission's report revealed the extent of this problem at the time. The Commission reported that it had received feedback from the industry showing that "*of the 43 [originator companies]... addressed, eleven... declared that in the period 2000 to 2007 they had filed for divisional patent applications where the corresponding parent application had subsequently been refused or withdrawn*" The Commission elaborated, confirming that "*the numbers of individual divisionals varied between 1 and 30*"<sup>42</sup>.
- 4.15 Current, relevant examples
- 4.16 Despite the recommendations made by both Medicines for Europe and the Commission, a multitude of divisional applications continue to be applied for and granted relating to single medicinal products, to the detriment of potential generic entrants. Last year, the 2019 Report identified this as an ongoing issue a decade on from the 2009 Report.<sup>43</sup> The Commission cited the following examples of such behaviour in the 2019 Report:

*Pfizer (Xalatan)*

- 4.16.1 In January 2011, the Italian national competition authority fined Pfizer €10.7 million for anticompetitive conduct. The original patent for Pfizer's glaucoma drug Xalatan (EP 1 225 168) was set to expire in September 2009. Pfizer filed for, and obtained, a divisional patent (EP 0 364 417) 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. This cost the Italian Health service an additional €14 million. The Italian Council of State confirmed this decision on appeal in 2014.

*Boehringer (COPD)*

- 4.16.2 Also in 2011, the Commission closed an antitrust investigation into allegations that German pharmaceutical company Boehringer Ingelheim ("**Boehringer**") filed for unmeritorious patents regarding new treatments for chronic obstructive pulmonary disease (COPD). As part of its strategy in this case, Boehringer filed a number of divisional patents, which it did not assert (but could in theory have asserted at any future time). This allowed any patent dispute to be prolonged beyond the period of time it would take for a decision to be reached on the basic patent. Please see further details of this at paragraph 3.4.1 above.

- 4.17 Notwithstanding the above two cases, activities described above in relation to the misuse of the divisional patents system appear to have continued. One Medicines for Europe member noted that "*[o]ne of the biggest barriers is the uncertainty caused by the abuse of the divisional patent system where, post generic market formation,*

<sup>40</sup> European Commission, *Final Report: Pharmaceutical Sector Inquiry* (8 July 2009), para. 275

[[https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf)]

<sup>41</sup> *Ibid.*

<sup>42</sup> *Ibid.*, para. 511

<sup>43</sup> European Commission, *Report from the Commission to the Council and the European Parliament: Competition Enforcement in the Pharmaceutical Sector (2009-2017): European Competition Authorities Working Together for Affordable and Innovative Medicines* (2019)

[[https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/report\\_en.pdf](https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/report_en.pdf)]

*originators design tailored retrospective patent claims targeting generic formulations". Another stated "the abuse of the divisional patent system has indeed deteriorated over the past years and it increases the length of oppositions. Often, nowadays, the patentee lets the previous patent or patent application be deemed withdrawn and continues the examination procedure with a second or third generation divisional with identical or very similar claims."*

4.18 The impact of exploitation of the divisional patent system is exacerbated by the lengthy timelines for grant of patents before the EPO, for example:

4.18.1 In 2004, a parent patent application was filed for the use of propylene glycol in liraglutide formulations. This patent was not granted until 2017, was subsequently opposed and maintained in 2020, which decision is now under appeal.

4.19 A member of Medicines for Europe has explained "*[t]he abuse of the divisional patent system has increased over the last decade. The focus of abuse is on secondary patents, such as formulation patents, use patents or claims on particle size or crystalline forms being granted and leading to legal disputes that delay generic and biosimilar launch. This can also be seen in patents covering routine clinical studies, adverse effects or dose adjustments that cannot be carved-out from the SmPC. Recently, we have seen an increase in the number of parent patents being abandoned before an adverse decision is made in appeal proceedings, sometimes even at the oral hearing itself, in favour of divisionals that are at early stage of examination or recently granted. This prolongs the timelines for final decision and adds more uncertainty about the potential launch date, sometimes leading to generic companies delaying or abandoning launch*".

4.20 The practice of withdrawing patents just prior to a final decision on their validity, coupled with filing a divisional patent application that may be almost identical in scope of protection to the parent, can extend the period of uncertainty for generic and biosimilar competitors. In effect, this avoids a negative judgment while resuscitating the parent patent in an almost identical form in the divisional and starting the entire process again. For example:

4.20.1 A therapeutic use patent was opposed by three parties, with an oral hearing set for January 2020. The original patent was surrendered a few days prior to the scheduled hearing. Deriving from the original patent, mention of grant of a divisional patent was published in the patent bulletin in December 2019. For this patent, the opposition period expires in September 2020, extending the period of uncertainty for those seeking to bring competitor products to market.

4.20.2 In relation to a valuable oncology product, for which numerous divisional patent applications had been filed, claiming various indications for the product, a parent patent was withdrawn by the patentee just prior to the Board of Appeal providing its decision on the appeal of a decision by the Opposition Division to revoke the patent. The effect of this was that there was no written decision as to the patentability or otherwise of the subject matter of the parent patent, which may have been useful in opposition or other proceedings concerning the divisional patents.

4.20.3 A product for the treatment of cancer, for which the basic patent and SPC expired in 2018, had a composition patent which was opposed by 15 parties but withdrawn by the patentee in appeal shortly before oral proceedings. A divisional of the parent was refused in examination<sup>44</sup>. A further Patent Cooperation Treaty ("**PCT**") application has been filed, which is yet to enter

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<sup>44</sup> This decision is currently under appeal.

the European phase. This serves to extend the period of uncertainty for companies seeking to bring competitor products to market.

- 4.21 Another potential tactic is to seek a divisional with broad claims similar to those of the parent patent application as filed, where there may be a risk the parent patent will be narrowed or limited during examination or in opposition. This permits the wide scope of the original parent patent to be maintained for a longer period of time regardless of the outcome of any opposition or appeal, meaning any uncertainty the broader claims create will persist until conclusion of all of the relevant proceedings. For example:
- 4.21.1 In relation to a drug for the treatment of hyperparathyroidism, the basic patent has expired. However, a secondary formulation patent and a series of seven divisionals have been filed, some of which were filed almost 14 years after the filing of the parent. Following opposition proceedings, the Technical Board of Appeal upheld the parent patent in amended form, with narrower claims and an amended specification. However, the current divisional system has meant that the patentee was able to maintain the broad scope of the original parent application by filing for divisionals prior to conclusion of the proceedings of the parent patent. This means that generic and biosimilar companies continue to face uncertainty as to the scope of protection conferred by the patent family.
  - 4.21.2 In relation to a drug for multiple sclerosis, there are two patent families with sixteen divisional patents at varying stages of examination, opposition and appeal. In relation to one of these patent families, the parent patent relating to extended release formulations has been revoked in opposition proceedings with an appeal pending. However, a divisional patent application has been filed with a broader scope of protection covering not only prolonged release formulations but also enteric coated formulations. This divisional was granted by the EPO, although it has since been revoked in opposition with an appeal hearing scheduled in 2021. The applicant has filed a further series of divisional patent applications covering a similar broad scope. Three of these divisional patent applications have received an intention to grant communication several times (up to five times in one instance) and each time the divisional patent application was abandoned and the proceedings were subsequently resumed when further processing was requested. This has caused delay to the grant of the divisional applications, which in turn extends the uncertainty faced by companies seeking to launch competitor products. Due to the length of time taken for opposition and appeal proceedings at the EPO, it is very likely that opposition proceedings will not be concluded for all pending divisional patent applications before expiry of the 20-year patent term.
  - 4.21.3 A patent relating to a medication for chronic obstructive pulmonary disease was opposed and maintained in amended form at first instance. The decision was appealed by both parties and oral proceedings were cancelled because the patentee requested the revocation of the patent. The patentee had also filed a divisional patent that has been granted with similar scope of protection to the parent. The divisional has been opposed by 10 opponents, although a subsequent divisional has also been filed.
- 4.22 As illustrated by the examples listed below, the filing of multiple divisional applications is commonplace in the pharmaceutical sector. Where these divisional applications are filed on a sequential basis or remain pending for significant periods of time, uncertainty is generated for competitors, requiring investment of significant time and cost to navigate. The proliferation of patents can also result in the patent 'thicket' issues discussed at section 3 above. For example:
- 4.22.1 A pharmaceutical combination drug designed to treat very severe idiopathic restless leg syndrome is protected by fifty-five divisional patents across seven patent families.



- 4.22.2 An immunomodulating drug primarily used for treating multiple sclerosis is protected by nineteen divisional patents across six patent families. One of the families includes a patent application concerning use of the drug in the paediatric population. With regard to the parent patent and one divisional, we understand the applicant has withdrawn the pending patent applications after being summoned to an oral hearing or receiving communication from the Examining Division with strong objections against novelty and inventive step whilst continuing to file further divisional applications.
- 4.23 A member of Medicines for Europe raised the use of delaying tactics as a real issue, stating "*it appears that originators deliberately use tactics to delay patent examination at EPO leading to very late grant, often even close to its expiry date. Although it is possible to oppose patents or invalidate them at national level, these procedures are often extremely lengthy, costly and time consuming. The purpose of the tactic is to ensure that spurious patents cannot be challenged in advance of a launch and so create a risk to the generic entrant, hence potentially delaying their launch.* In some cases, uncertainty is perpetuated by retaining pending divisional patent applications for extended periods of time. Mechanisms may be deployed to seek to ensure that this happens; for example, by disapproving the text for grant of divisional patents<sup>45</sup>. In one case in relation to a controlled release pharmaceutical formulation, the patentee received five communications of intention to grant a divisional patent and to each responded disapproving the text intended to grant, including correction of minor typographical errors. For example, correcting "Invention" to "invention". This behaviour was repeated in relation to two further divisionals where two and five communications of intention to grant, respectively, were received. Such apparent misuse of systems for approving text intended to grant has strayed from the original intention of these procedures, which is primarily concerned with the patentee completing the final formalities of patent grant, such as filing the translation of the claims and paying the necessary fees.
- 4.24 In relation to divisional applications with clearly overlapping claims, the EPO Boards of Appeal has referred a question to the Enlarged Board of Appeal (G 4/19) in Case T 0318/14 in relation to the status of patents for the prevention and treatment of allergic diarrhoea<sup>46</sup>. The question under consideration is whether "*a European patent application [can] be refused under Article 97(2) EPC if it claims the same subject-matter as a European patent which was granted to the same applicant and does not form part of the state of the art pursuant to Article 54(2) and (3) EPC*" and what the acceptable conditions for such a refusal would be.<sup>47</sup> The outcome of this decision could have implications for the future of the strategy of granting divisional patents with largely overlapping claims.

## 5. PATENT LINKAGE

- 5.1 'Patent linkage' describes a practice whereby the standing of a generic or biosimilar product with regard to a marketing authorisation or other administrative approval or procedure required before market entry<sup>48</sup> is linked to the status of a patent (or patent application) pertaining to the reference medicinal product. These administrative processes should remain entirely independent from the status of any patent, given the rights afforded by a patent are very well protected under the current patent system. The artificial linkage of patent status to these processes is readily exploited as a tactic designed to hinder market entry for generic or biosimilar products. In practice, this tactic is effective and is particularly problematic where the patent being relied upon is ultimately found to be invalid.

<sup>45</sup> See footnote 7 of this whitepaper.

<sup>46</sup> European Patent Office, Case T 0318/14 (Double patenting) of 7.2.2019 (7 March 2019) [<https://www.epo.org/law-practice/case-law-appeals/recent/t140318ex1.html>]

<sup>47</sup> *Ibid.*

<sup>48</sup> For example, pricing approval, agreement to reimbursement status.



- 5.2 Patent linkage was described as "*unlawful*" by the 2009 Report and it is prohibited under European law<sup>49</sup>. In the 2017 Resolution, the European Parliament acknowledged that 'patent linkage' continues to be a problem across the EU<sup>50</sup>. It requested that the Commission focus on "*guaranteeing timely entry into the market for generic and biosimilar medicines*" and "*ending patent linkage according to the Commission's guidelines*"<sup>51</sup>.
- 5.3 Article 126 of Directive 2001/83/EC (relating to medicinal products for human use) (the "**Directive**") states that "[a]n authorization to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in the Directive". Patent protection covering a medicinal product is not listed under the exhaustive set of grounds in the Directive. Furthermore, in the context of Article 10 of the Directive, provision is made to exempt from patent infringement the conduct of such studies and trials as necessary pursuant to the abridged approval procedure<sup>52</sup>, the Bolar exemption. As described at 5.11.2 below, any attempt to practise patent linkage by Member States undermines the Bolar exemption, which was intended as a crucial tool to achieve the Commission's aim of bringing affordable medicines to the market promptly.
- 5.4 Although the law is clear in relation to the prohibition of patent linkage in obtaining marketing authorisation approval, some uncertainty remains in the context of pricing and reimbursement activities. Directive 89/105/EEC (the "**Transparency Directive**", which governs the transparency of pricing of medicinal products across Member States) does not contain an equivalent provision as that set out above in relation to marketing authorisation approval.
- 5.5 In a proposal to amend the Transparency Directive in 2012, the following express prohibition was proposed:

*"Article 14(2) - The protection of intellectual property rights shall not be a valid ground to refuse, suspend or revoke decisions relating to the price of a medicinal product or its inclusion within the public health insurance system."*

- 5.6 However, the proposal was not progressed due to political reasons. As recently as 2017 (in the 2017 Resolution) the European Parliament called upon the Commission to revise the Transparency Directive as a means to end patent linkage<sup>53</sup> and the Commission's view on patent linkage is also clear.
- 5.7 'Patent linkage' may occur in a number of ways:

### *Marketing authorisation linkage*

- 5.7.1 The grant of marketing authorisation to a generic product may be tied to the expiration of patent rights attaching to the reference medicinal product. Alternatively, an originator may exploit or misuse procedures for the granting of an MA for a competitor claiming that the application for an MA represents an infringement of its relevant patent(s). This often results in litigation proceedings being issued by an originator.
- 5.7.2 Portugal has historically had a strong practice of patent linkage. The 2008 Paper referred to the 70 cases brought against Portuguese regulatory authorities in 2007, and between 2011 and January 2019, Portugal operated

<sup>49</sup> European Commission, *Final Report: Pharmaceutical Sector Inquiry* (8 July 2009), para. 872

[[https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf)]

<sup>50</sup> European Parliament, *Resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI))* (2 March 2017), para. 57 [[https://www.europarl.europa.eu/doceo/document/TA-8-2017-0061\\_EN.pdf](https://www.europarl.europa.eu/doceo/document/TA-8-2017-0061_EN.pdf)]

<sup>51</sup> *Ibid.*

<sup>52</sup> Article 10(6) of Directive 2001/83/EC

<sup>53</sup> European Parliament, *Resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI))* [[https://www.europarl.europa.eu/doceo/document/TA-8-2017-0061\\_EN.html](https://www.europarl.europa.eu/doceo/document/TA-8-2017-0061_EN.html)]

a system of mandatory arbitration between patent holders and generics when a generic applied for an MA<sup>54</sup>.

- 5.7.3 Despite this system of mandatory arbitration having come to an end, an application for an MA continues to be considered to be grounds for patent infringement proceedings in Portugal, ensuring that linkage is still an issue for generics trying to enter its market. The law requires generics to file MA applications on the national medicines agency's website. Though not a linkage issue in itself, this is problematic in light of an originator's right to bring an infringement action before the Portuguese Intellectual Property Court, or using voluntary arbitration, within 30 days of a generic entering an MA application on the list<sup>55</sup>.
- 5.7.4 The 2008 Paper also cited that, at the time: (i) Slovakia was operating a system of MA-based linkage comparable to that of Portugal; and (ii) Hungary required applicants for an MA to sign an undertaking stating that they do not intend to infringe the relevant innovator patent if they wanted their product to be approved<sup>56</sup>.
- 5.7.5 Currently, in France, the Medicine Act provides that a generic should provide notice to a patentee of its application for a generic MA. Furthermore, the French Medicines Agency (ANSM) will inform innovators within one month of any relevant MAs granted to generics during the innovator's period of patent protection<sup>57</sup>. The same legislation contains an obligation for generics to refrain from marketing a product until after the expiry of the relevant intellectual property rights and to inform ANSM, prior to launch, of forms and dosages for which the rights have not yet expired<sup>58</sup>.

### *Pricing & reimbursement linkage*

- 5.7.6 In some Member States, the act of seeking pricing or reimbursement approval is considered to be an infringement of a patent and thus those bringing competitor products to market are required to wait until patent expiry to take these steps without risk. Some Member States do not allow pricing and reimbursement decisions to be taken during the term of a patent relating to the reference medicinal product, and there are examples of patentees going further and issuing court proceedings seeking to restrain the competent authority from carrying out pricing and reimbursement activities in relation to a competitor product during a patent term
- 5.7.7 In Italy, despite condemnation from both the Commission and Italy's national competition authority, generics may not list pricing and reimbursement schedules until originator patents expire (under the so called "Balduzzi Decree")<sup>59</sup>.
- 5.7.8 In Poland, generics need to confirm that their product is available on the market before they may apply for a reimbursement status. Given that first launch is considered to constitute patent infringement or is blocked by market exclusivity, the product is not available for patients until it is included in the reimbursement list, which is often some time after patent or market exclusivity expiry.

<sup>54</sup> European Generic Medicines Association, *Patent-related Barriers to Market Entry for Generic Medicines in the European Union*, May 2008, pp. 23 and 24

<sup>55</sup> *Ibid.*

<sup>56</sup> *Ibid.*

<sup>57</sup> *Public Health Code*, ss. L5121-10 and R5121-5

<sup>58</sup> *Public Health Code*, ss. L5121-10

<sup>59</sup> *Ibid.*, p. 7

- 5.7.9 In Germany, the *Informationsstelle für Arzneispezialitäten* ("IFA") holds a price list of products which, if listed, enables reimbursement from public health insurance funds<sup>60</sup>. IFA's current policy is not to list a generic product if a patent holder has filed an objection against its listing. More recently, the IFA has begun requesting information on the patent expiry of reference medicinal products where a generic company seeks to apply to have its generic product listed in the IFA database<sup>61</sup>.
- 5.7.10 In France, originators may inform the French pricing authority (CEPS) of any patents relevant to reference medicinal products. Unless the generic manufacturer provides a statement to the CEPS confirming that it will not infringe with its product<sup>62</sup>, it may not be listed as a 'reimbursed' product until six months prior to the expiry of the relevant patent<sup>63</sup>.

### *Procurement linkage*

- 5.7.11 An originator may exploit/misuse procedures for communication with competent authorities for procuring pharmaceuticals in Member States to perturb generics from entering these markets. Delaying access of a generic or biosimilar product under development to procurement procedures through asserting patent rights has the inevitable effect of delaying market entry.
- 5.7.12 In addition, differences between Member States as to what constitutes an act of infringement of a patent, particularly in relation to procurement, further complicates the issue of patent linkage. Listing in the Lauer-Taxe in Germany during the patent term is considered to be an infringing act, even where the product will be physically placed on the market after the expiry date of the patent (*Simvastatin*, 5 December 2006). Likewise, in the Netherlands, listing a generic product on the *G-Standaard* medicines database, a necessary step prior to the product being sold, is considered to be an act of patent infringement (*Glaxo v Pharmachemie*, 22 June 2012)<sup>64</sup>. Submitting bids for tender processes pre-patent expiry, where the product will be supplied after patent expiry are likewise often considered to be acts of patent infringement<sup>65</sup>  
<sup>66</sup>.

### *Prescription listing based linkage*

- 5.7.13 In order to be available for prescription by healthcare practitioners in some Member States, a drug must be listed in a prescription listing, or formulary. Patentees may assert that this listing is an act of patent infringement and, based upon the listing, seek judicial relief on the basis of granted patents. Subject to the precise mechanisms in each Member State, it may not necessarily be the case that simply listing a product within such a database means that the product is available for sale and thus such actions may not necessarily be considered to be an offer for sale, within national patent legislation<sup>67</sup>.

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<sup>60</sup> *Ibid*, p. 6

<sup>61</sup> Whilst there is as yet no evidence that the IFA are using this information to reject the listing of generic and biosimilar products in their database, there is the potential for such patent linkage to occur, thus creating a barrier to generic and biosimilar entry.

<sup>62</sup> This information is shared with the patentee.

<sup>63</sup> *Ibid*.

<sup>64</sup> *Ibid*, p. 7

<sup>65</sup> Cf. the situation in the UK, where an offer to supply a product post-expiry that was made prior to expiry of a patent may not be considered to amount to infringement (*Jacob J in Gerber Garment Technology Inc v Lectra Systems Ltd & Anor* [1995]). In France, the situation is less clear, which itself may create barriers to generic and biosimilar entry.

<sup>66</sup> Some jurisdictions have attempted to introduce measures to mitigate the consequences of this, for example, in Italy, where a biosimilar product enters the market, regional authorities must re-open any supply agreements within 60 days.

<sup>67</sup> What constitutes an act of patent infringement is defined by patent law in each national jurisdiction in some instances. This in itself can have a negative impact on generic and biosimilar market entry.

- 5.8 Notwithstanding the above-identified risks of patent linkage and the repeated indications from the Commission that patent linkage is not to be used within Member States, the practice continues unabated.
- 5.9 For example, the holder of various patents protecting Alimta (pemetrexed) sought injunctive relief against two generics in 2019. The Higher Regional Court in Munich dismissed the applications against the two generics and the patentee subsequently withdrew its applications against other generic manufacturers.
- 5.10 Notwithstanding this decision, in parallel proceedings, the patentee filed an action against the IFA objecting to the listing of generic pemetrexed and obtained an injunction prohibiting the IFA from listing the generic product. This application was based upon the same patent asserted directly against the generic manufacturers and has resulted in the prevention of a generic alternative to Alimta entering the German market.
- 5.11 Ultimately, 'patent linkage' activities hinder and delay access to the European pharmaceuticals market for generic and biosimilar medicines, to the ultimate detriment of patients and healthcare providers. Furthermore, 'patent linkage' brings about a number of specific disadvantages. For example:

### *Limited compensation for delay*

- 5.11.1 If patent linkage is enshrined in legislation and the competent authority is acting in accordance with the legislation, there is often limited, if any, compensation available to the manufacturer of the product who suffers delayed market access. The same is also true for the health services and patients deprived of competition and lower cost medicines. This is so notwithstanding the Commission's view that linkage is contrary to EU law.

### *Undermining of the 'Bolar provision'*

- 5.11.2 The purpose of the so-called 'Bolar provision' is to allow generics to conduct the necessary studies and clinical trials required to obtain marketing authorisation and to undertake those activities without risk of patent infringement proceedings being brought against them. Linkage of the regulatory approval processes to patent infringement directly undermines this provision and may result in generics undertaking those activities only upon patent expiry, thereby delaying access of those products to the market.

### *5.11.3 Cost of patent-based litigation to generics*

- 5.11.4 'Patent linkage' is conducive to a proliferation of patent-based litigation, which creates additional costs for generics seeking to enter the market. The 2009 Report found that the estimated total cost of patent litigations in the EU between 2000 and 2007 was in excess of €420 million<sup>68</sup>. The general perception is that the situation has not improved since 2009

### *5.12 Involvement of regulators in questions outside their competence*

- 5.12.1 Asking regulators of pharmaceutical safety and quality to become involved in assessing the validity of patents undermines the exclusive competence of the national courts to rule on these matters. Put simply, regulatory competent authorities are experts in matters other than patent infringement or validity and may be pushed to make assessments on those questions based upon incomplete information. This is particularly problematic, as recognised in the 2009 Report, where "actions are accompanied by a threat to sue the

<sup>68</sup> European Commission, *Final Report: Pharmaceutical Sector Inquiry* (8 July 2009), para. 660 [[https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf)]

*marketing authorisation body for damages if marketing authorisation is granted.*<sup>69</sup>

### 6. PRODUCT HOPPING

6.1 'Product hopping' refers to the introduction by pharmaceutical companies 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 period of time<sup>70</sup>.

6.2 The second generation product may be more expensive 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'). A successful switch will ensure the product market retains patent protection for a longer period of time, as the market for the first generation product has effectively been eliminated prior to generic entry. A generic entrant seeking to bring a generic version of the first generation product to market will find that all patients have already been established on the second generation product. Issues such as prescriber inertia inhibit switching back to the first generation product even though a generic version of equivalent therapeutic value may now be available at a lower cost. The second generation product will be established as the incumbent product of choice. The fact it also benefits from patent or regulatory exclusivities effectively neutralises all the potential benefits of generic competition.

6.3 The 2008 Paper included 'Fosamax' (an osteoporosis medicine) as an example of a product market being manipulated through the introduction of a secondary product combined with marketing efforts to shift the market:

*"The originator... used its marketing resources to shift the market from Fosamax® to Fosavance®, which is the same medicine as Fosamax® with the addition of a small amount of vitamin D. This 'new' medicine, with no substantial added therapeutic value, is even the subject of a patent application despite the fact that patients who were prescribed Fosamax® in the past were instructed to consume this medicine in combination with vitamin D"*<sup>71</sup>.

6.4 The 2009 Report noted that it was common practice for a variety of measures to be used in order to "maximise revenue streams from existing pharmaceutical products by delaying or damping the effect of generic entry"<sup>72</sup>. One such strategy was the introduction of follow-on products, often shortly before the primary product's patent protection expired, combined with targeted efforts to switch customers to the secondary product<sup>73</sup>.

<sup>69</sup> European Commission, *Final Report: Pharmaceutical Sector Inquiry* (8 July 2009), p.315 [[https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf)],

<sup>70</sup> Those marketing reference medicinal products may also seek to prevent the approval of generic competitor products by refusing to provide their product for the purposes of carrying out mandatory bioequivalence studies, necessary for the generic to obtain an MA.

<sup>71</sup> *Ibid*, p. 15

<sup>72</sup> European Commission, *Final Report: Pharmaceutical Sector Inquiry* (8 July 2009) para. 1050 [[https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf)],

<sup>73</sup> *Ibid*, chpt. 2.6, para. 989



- 6.5 A number of pharmaceutical companies commented in the 2009 Report on the importance of timing to the introduction of a secondary product in order to facilitate this switch. One generic company noted that (underlining for emphasis):

*"A pre-patent expiry entry of the second generation product enables the Innovator to switch patients in a pricing climate where the first generation product price is stable. The second generation product may be priced at or slightly below the first product, and positioned as being 'better and similarly cost effective'. If the prescriber is prepared to accept this Innovator argument and switch prescribing, he is unlikely to go back subsequently to the first generation product when a generic is available. If the second generation product appears after patent expiry of the original product, then the pricing climate will be different. The generic will have caused the market price to fall, and thus to switch to the newer product will likely incur a cost penalty to the physician budget, something he is likely to resist unless the second generation is a compellingly better product. This is seldom if ever the case."*<sup>74</sup>

Another pharmaceutical company noted that (underlining for emphasis):

*"The launch of [our second generation product] is a challenge, not experienced until now, as generics firms, [...] press onto the market with all force and as we have to fear the loss of our patent [...]. This means each patient that is not switched quickly enough to [our second generation product] is forever lost to the generics. Once the patient is switched to [our second generation product] the physician does not have to, cannot and will not switch him to a generic, and what is more important: the pharmacist cannot substitute!!"*<sup>75</sup>

- 6.6 The Report noted the use of certain strategies by the originator to facilitate switching prior to generic launch. These included: (i) decreases in marketing spend on the first generation product and increased spending in support of second generation products<sup>76</sup> and/or intervention with marketing authorisation bodies or pricing/reimbursement bodies<sup>77</sup> as the primary product patent came closer to expiry<sup>78</sup>; (ii) the withdrawal of the first generation product<sup>79</sup>; or (iii) actions with the equivalent effect to withdrawing the first generation product; for example, litigation<sup>80</sup>.
- 6.7 In relation to the final point, generic companies claimed that: *"such withdrawals before generic market entry leave doctors and patients with no other choice than to switch to the second generation product"*<sup>81</sup>. In the Commission's investigation, it found that in at least 30% of the cases where the launch of the secondary product was shortly before the loss of exclusivity of the first product, the primary product was withdrawn from the market<sup>82</sup>.
- 6.8 The 2009 Report cited generic companies complaining that switching patients to the next generation product before patent expiry may have an effect on their market entry:

*"In some cases we develop a product... but by the time we come to launch... the market has completely gone or switched to another molecule / form and our opportunity has diminished."*<sup>83</sup>

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<sup>74</sup> *Ibid*, para. 1026

<sup>75</sup> *Ibid*, para. 1028

<sup>76</sup> It is noted that this strategy is no longer effective following a revision of Directive 2001/83/EC.

<sup>77</sup> European Commission, *Final Report: Pharmaceutical Sector Inquiry* (8 July 2009), paras. 1042-1043 [[https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf)]

<sup>78</sup> *Ibid*, paras. 1037-1039.

<sup>79</sup> *Ibid*, para. 1045.

<sup>80</sup> *Ibid*, para. 1040.

<sup>81</sup> *Ibid*, para. 1045.

<sup>82</sup> *Ibid*, paras. 1031 and 1045.

<sup>83</sup> *Ibid*, para. 1047.

*"[T]he market situation was not favourable to generic versions due to the introduction of a new pharmaceutical form by the originator company, which would [make it] difficult for generics to achieve a reasonable market share."*<sup>84</sup>

- 6.9 The 2009 Report additionally quoted a national pricing and reimbursement authority which observed that:

*"There are a number of examples where the introduction of a second generation – patent protected-version of a product prior to such generic entry and at the same time withdrawal of the first (or previous) generation of that originator product from the market... caused a shift of budgets towards the second generation patent protected, therefore no generics"*.<sup>85</sup>

- 6.10 In its summary of life cycle strategies for follow-on products, the Commission found that<sup>86</sup>:

6.10.1 For 40% of the medicines in the sample selected for in depth investigation, which had lost exclusivity between 2000 and 2007, originator companies launched so called second generation/follow-on medicines.

6.10.2 On average, the launch took place one year and five months before loss of exclusivity of the first generation product. In some cases the first medicine was withdrawn from the market some months after the launch of the second generation medicine.

6.10.3 Nearly 60% of the patent related litigation cases between originator and generic companies examined in the context of the inquiry concern medicines that were subject to switch from first to second generation products.

- 6.11 The 2019 Report does not specifically refer to product hopping. However, in its section on the misuse of regulatory framework it does consider both the *AstraZeneca*<sup>87</sup> and *Reckitt Benckiser*<sup>88</sup> cases, which may be regarded as examples of product hopping as a strategy to delay generic entry.

- 6.12 *Previous developments*

- 6.13 The most well-known examples of this behaviour within the EU are the Commission's decision against AstraZeneca and the UK's Office of Fair Trading's ("**OFT**") decision against Reckitt Benckiser.

- 6.13.1 *AstraZeneca*:

In 2005 the Commission found that AstraZeneca had abused its dominant position through, amongst other things, the launch of a tablet form of Losec combined with the deregistration of the marketing authorisations for the capsule form of Losec in national markets where the patent or SPC was due to expire, and withdrawal of those capsules<sup>89</sup>. This finding was appealed and upheld by the European Courts.

Both the General Court and Court of Justice observed that (underlining for emphasis): *"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*

<sup>84</sup> *Ibid*, para. 1049.

<sup>85</sup> *Ibid*, para. 1048.

<sup>86</sup> *Ibid*, p.367.

<sup>87</sup> *AstraZeneca AB and AstraZeneca plc v Commission*, T321/05, *AstraZeneca AB and AstraZeneca plc v European Commission*, C-457/10 P.

<sup>88</sup> Office of Fair Trading, *Abuse of a dominant position by Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc*, Decision No. CA98/02/2011 (2011)

<sup>89</sup> COMP/A.37.507 – *AstraZeneca* (2005)

enable it to deal with competition from generic products is legitimate and is part of the normal competitive process, 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.<sup>90</sup>

In this instance, the Courts found that the deliberate deregistration of the MA was designed to hinder the introduction of generic products and parallel imports and therefore could not be considered competition on the merits<sup>91</sup>. Internal documents evidenced AstraZeneca's underlying intent and failed to demonstrate its arguments at trial that it had legitimate reasons for deregistration<sup>92</sup>.

While it was acknowledged that AstraZeneca had a right under law to request the withdrawal of its MA, this did not prevent such conduct also being an abuse of AstraZeneca's dominant market position, and it was noted that the majority of cases concerning the abuse of a dominant position consisted of behaviour that would otherwise be lawful under other branches of law<sup>93</sup>.

It should be noted that in this case, the abuse and commentary surrounding it primarily related to AstraZeneca's withdrawal of the marketing authorisation in certain jurisdictions for the capsule form of Losec. At the time, this prevented generic companies from relying on it for their own marketing authorisations. Such activity would no longer prevent a generic company from relying on it<sup>94</sup> and, therefore, this aspect of AstraZeneca's abusive behaviour would no longer impact generic competition.

### 6.13.2 *Reckitt Benckiser.*

The OFT's 2011 decision found that Reckitt Benckiser had abused its dominant position through the withdrawal and delisting of Gaviscon Original Liquid from the NHS prescription channel in 2005. This withdrawal was made after the expiry of the patent, but prior to the publication of a generic name. This meant that following withdrawal, most prescriptions were instead written for Gaviscon Advance Liquid, which was another version of the product still under patent protection<sup>95</sup>.

The OFT found strong evidence that Reckitt Benckiser's decision to withdraw Gaviscon Original was to restrict competition and encourage switching to Gaviscon Advance<sup>96</sup> and the timing of this withdrawal was deliberately intended to limit and deter generic competition<sup>97</sup>. Furthermore the OFT found evidence in Reckitt Benckiser's internal documents that the withdrawal was not economically viable (i.e. it expected to suffer material market share losses from implementing the strategy) and was likely to be loss-making in the first instance<sup>98</sup>. From this, the OFT concluded that there was no commercially rational reason to have employed the strategy and that other than seeking to exclude effective competition to its Gaviscon product line, there would have been no logical reason for it to have implemented the strategy<sup>99</sup>.

<sup>90</sup> *AstraZeneca AB and AstraZeneca plc v European Commission*, C-457/10 P, para. 129

<sup>91</sup> *Ibid*130

<sup>92</sup> *AstraZeneca*, OJ 2006 L332/24, para. 789 and *AstraZeneca AB and AstraZeneca plc v European Commission*, C-457/10 P, para. 136

<sup>93</sup> *AstraZeneca AB and AstraZeneca plc v European Commission*, C-457/10 P, para. 132.

<sup>94</sup> European Commission, *Final Report: Pharmaceutical Sector Inquiry* (8 July 2009), para. 1041

[[https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf)]

<sup>95</sup> Office of Fair Trading, *Abuse of a dominant position by Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc*, Decision No. CA98/02/2011 (2011)

<sup>96</sup> *Reckitt Benckiser*, paras. 6.8 and 6.9

<sup>97</sup> *Reckitt Benckiser*, paras. 6.14 and 6.23

<sup>98</sup> *Reckitt Benckiser*, paras. 6.30

<sup>99</sup> *Ibid.*

Reckitt Benckiser sought to argue that its withdrawal strategy could be objectively justified and had stressed to stakeholders the benefits of Gaviscon Advance Liquid over Gaviscon Original Liquid due to a lower sodium content. However, the OFT considered that "*any such safety advantage in terms of [Gaviscon Advance Liquid] would not justify the Withdrawal*" given in part that in the seven years both products had been available, the majority of GPs had continued to prescribe Gaviscon Liquid and Gaviscon Liquid was suitable for the majority of patients. Furthermore, these arguments were undermined by internal documents which indicated that Reckitt Benckiser was more concerned by its potential competitors than the safety issues and that Gaviscon Advance was equally unsuitable to some patients due to its high levels of potassium<sup>100</sup>.

It should also be noted that Reckitt Benckiser's internal documents suggested it had been considering actions which could delay or inhibit the publication of the generic name for Gaviscon Liquid<sup>101</sup> and the OFT also investigated whether actions taken between 1996 and 2006 to delay these regulatory processes were abusive<sup>102</sup>.

### 6.13.3 Servier

In an investigation into Servier's perindopril product, the Commission found in 2016 that Servier had a strategy of switching patients from its first generation perindopril product to its second generation perindopril product, which had obtained patent protection until 2023. Servier then withdrew the first generation product before generic companies could enter the market.

The Commission noted that "*[d]epending on the national regulatory regime, generic substitution was made impossible or limited. It is undisputed that the second generation product has no therapeutic advantages for patients over the first generation product.*"<sup>103</sup>

### 6.13.4 Essential Pharma

The CMA launched an investigation on 6 October 2020 by the CMA under Chapter II of the Competition Act 1998 into a potential 'abuse' of a dominant position by Essential Pharma. This relates to Essential Pharma's intention to discontinue the supply of Priadel, a lithium carbonate medication, for the treatment of bipolar disorder. The allegation appears to be that the withdrawal of Priadel would force customers to switch to Camcolit, a more expensive lithium carbonate treatment also sold by Essential Pharma. The suggestion is that Priadel 400mg is priced at £4.02 while Camcolit 400mg costs £48.18. Essential Pharma has agreed to continue to supply Priadel while the investigation is ongoing<sup>104</sup>.

- 6.14 The theory of harm in these cases is that the withdrawal of the original product or MA was designed to hinder generic competition and ensure patients and prescribers were switched to secondary or alternative products. In the case of AstraZeneca and Reckitt Benckiser, the finding of an abuse and the lack of an objective justification was demonstrated in contemporaneous internal documents that showed the true intentions behind such actions.

<sup>100</sup> Reckitt Benckiser, para. 6.93

<sup>101</sup> Reckitt Benckiser, para. 1.12

<sup>102</sup> Reckitt Benckiser, paras. 2.17

<sup>103</sup> AT.39612 – Perindopril (Servier), (2014) para. 8

<sup>104</sup> CMA, 'CMA to investigate the supply of bipolar drug' (Press Release 6 October 2020) [<https://www.gov.uk/government/news/cma-to-investigate-the-supply-of-bipolar-drug>], accessed 14 October 2020

6.15 There have also been a number of instances where allegations of product hopping in breach of the Sherman Act have been considered by different courts in the United States.

6.15.1 Abbott twice changed its product formulation (through marginally lowering the drug's strength and changing from capsule to tablet), stopped supplying the older versions and took active steps to change the code in the National Drug Data File for the older versions to obsolete, in effect preventing pharmacists from filling prescriptions with a generic versions of these older drugs<sup>105</sup>. A court found that by removing the old products from the market and changing the code in the National Drug Data File, consumer choice was removed, such conduct was considered "consumer coercion" and was "potentially anticompetitive"<sup>106</sup>. The claim was settled by the parties.

6.15.2 Reckitt Benckiser switched the market from opioid dependence-treating Suboxone tablets to sublingual film<sup>107</sup>. Reckitt's alleged actions included disparaging Suboxone tablets by warning about false safety concerns and publicly announced the removal of tablets for these fabricated safety reasons. A court considered that "the threatened removal of the tablets from the market in conjunction with the alleged fabricated safety concerns could plausibly coerce patients and doctors to switch from tablet to film".

The Federal Trade Commission ("**FTC**") brought an antitrust action against Reckitt Benckiser in 2019 also alleging that Reckitt "employed a 'product hopping' scheme where the company misrepresented that the film version of Suboxone was safer than Suboxone tablets because children are less likely to be accidentally exposed to the film product"<sup>108</sup>. In November 2019, Reckitt settled the case agreeing to pay \$50 million and provide the FTC with various commitments to disclose information about future product reformulations to the FTC, including a prohibition of withdrawing an original product for a certain period after the launch of the follow on product.

6.15.3 As Forest's Alzheimer's drug Namenda IR (twice daily dose) neared the end of its patent term, it introduced Namenda XR (once a day dose), with a patent expiring fourteen years later. Forest announced its intention to discontinue the IR product in August 2014.

A court found that "*when a monopolist combines product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits and to impede competition, its actions are anticompetitive under the Sherman Act*"<sup>109</sup>

6.16 We have come across alleged instances of product hopping occurring in different Member States within the EU including the use of a 'hard switch' where a product has been withdrawn from a market prior to patent expiry.

## 7. PREDATORY PRICING / ANTI-COMPETITIVE REBATES

7.1 Article 102 of the Treaty on the Functioning of the European Union ("**TFEU**") prohibits "*any abuse by one or more undertakings of a dominant position within the internal*

<sup>105</sup> *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc. (TriCor)* 432 F. Supp. 2d 408 (D. Del. 2006), Section IV A. This case was also cited in *Walgreen Co. vs AstraZeneca* 534 F.Supp. 2d 146 (D.D.C. 2008), where it was alleged that AstraZeneca had sought to engage in product hopping by withdrawing marketing support for its original product and aggressively marketing its newly reformulated product. This case was dismissed by the Court, as absent the withdrawal there was no loss in consumer choice and generics successfully gained 30% of the market.

<sup>106</sup> *Abbot Laboratories v Teva Pharmaceuticals USA*, Section IV A 4.

<sup>107</sup> *In re Suboxone Antitrust Litigation* 64 F. Supp. 3d 665 (E.D. Pa. 2014).

<sup>108</sup> *Federal Trade Commission v Reckitt Benckiser Group Plc, Case 1:19CV00028*

<sup>109</sup> *New York ex rel. Schneiderman v. Actavis PLC (Namenda)*, 787 F.3d 638 (2d Cir. 2015), p. 35



market or in a substantial part of it"<sup>110</sup>. This general prohibition is mirrored in the national law of European countries (for instance in Chapter II of the Competition Act 1998 in the United Kingdom).

- 7.2 Key to this prohibition is the principle that dominant undertakings have a "*special responsibility*" not to impair competition through conduct falling outside the scope of competition on the merits<sup>111</sup>. There have been numerous examples of where companies have been found to have breached this prohibition for different behaviours in different sectors.
- 7.3 A key area of abuse has been through the imposition of unfair pricing practices, such as predatory pricing or anti-competitive rebates, in an attempt to exclude competition from the market in the long term. These abuses are not unique to the pharmaceutical industry; however, they may form an additional tactic used by dominant pharmaceutical companies to restrict entry and/or discourage competition.
- 7.4 Predatory pricing is a deliberate strategy whereby a dominant company sets its prices at loss making levels in order to drive its competitors out of the market. The sale of a product below the average variable cost (i.e. the cost of goods) will automatically be presumed to be an abusive strategy by a dominant undertaking, while the pricing of goods above the average variable cost, but below the average total cost (i.e. the total cost of producing and selling the product), may still be abusive if evidence is found that demonstrates an exclusionary strategy.
- 7.5 A dominant undertaking is also prohibited from entering into exclusive agreements with its customers. Behaviour which in effect encourages exclusivity has also been scrutinised. One of the key areas where such behaviour is seen is through rebates that require and/or encourage a customer to purchase all of their requirements from the dominant undertaking. It is common practice for pharmaceutical companies to negotiate discounts and/or rebates<sup>112</sup> and these can be beneficial as they result in lower prices. However, competition law practice has also shown that rebates can be anti-competitive. For instance, a loyalty rebate conditional on customers purchasing more than 80% of their requirements from the dominant company may be anticompetitive if it excludes competitors from the market.
- 7.6 These behaviours are not unique to the pharmaceutical sector. However, the structure of the market, and the probable dominance of patent holders during market exclusivity, may incentivise patent holders to develop pricing strategies designed to limit the impact of generic and biosimilar entry.
- 7.7 Although neither predatory pricing nor anti-competitive rebates were featured in any of the previous reports mentioned elsewhere in this paper, there have been a number of examples where the pricing practices of pharmaceutical companies have been investigated by European competition authorities. For instance, the UK Competition and Markets Authority (the "**CMA**") has found instances of predatory pricing (*Napp Pharmaceuticals*<sup>113</sup>) and more recently investigated Merck for its discount scheme<sup>114</sup>, although it ultimately found it had no grounds for action. *Hoffman la Roche v Commission*<sup>115</sup> is one of the earliest instances in a body of the EU case law on abusive rebates and the French competition authority has found a number of abusive pricing practices by pharmaceutical companies, such as *GlaxoSmithKline*<sup>116</sup> and *Schering-*

<sup>110</sup> Article 102 TFEU

<sup>111</sup> See for instance, *AstraZeneca AB and AstraZeneca plc v Commission*, T321/05, para. 355

<sup>112</sup> See European Commission, *Final Report: Pharmaceutical Sector Inquiry* (8 July 2009), para. 358 [[https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf)]

<sup>113</sup> Case CA98/2/2001, *Napp Pharmaceutical Holdings Limited and Subsidiaries* (2001)

<sup>114</sup> Case 50236, *Remicade: No grounds for action decision* (2019)

<sup>115</sup> Case 85/76, *Hoffman La Roche v Commission* (1979)

<sup>116</sup> Decision No. 07-D-09 14, *relative à des pratiques mises en œuvre par le laboratoire GlaxoSmithKline France*, March 2017. However, this decision was later overturned on appeal as the Court considered that the French Competition Authority had not adequately demonstrated a link between GlaxoSmithKline's dominance on one market and its

*Plough*<sup>117</sup>. Furthermore, in the Netherlands, the Dutch Authority for Consumers and Markets (“ACM”), in its 2019 TNF-alfa inhibitors sector inquiry report, commented that the offering of conditional discounts by originators to hospitals may be restrictive of competition in certain circumstances<sup>118</sup>.

### 7.7.1 *Napp Pharmaceuticals*<sup>119</sup>

The OFT investigated Napp Pharmaceuticals following a complaint that its use of discounts of over 90% effectively prevented its competitors from gaining a foothold in the market for the supply of sustained release morphine to hospitals and to pharmacies in the community<sup>120</sup>. The OFT found that this strategy was complemented by excessive prices of the same products to community pharmacies and wholesalers where there were high barriers to entry and limited competition. Napp Pharmaceuticals prices to the community segments were in most cases over 1000% higher than the prices charged to hospitals<sup>121</sup>.

The OFT found that such behaviour was abusive, as Napp Pharmaceuticals was pricing below the average variable cost. Case law on predatory pricing has previously found that “a dominant undertaking has no interest in applying such prices except that of eliminating competitors”<sup>122</sup> and as such it can be assumed that such discounting is intentionally designed to eliminate competition. This decision was upheld by the Competition Appeal Tribunal<sup>123</sup>.

### 7.7.2 Competition and Markets Authority Case 50236: *Remicade*<sup>124</sup>

In December 2015 the CMA opened a formal investigation into whether Merck Sharp & Dohme Limited (“MSD”) had abused a dominant position by offering loyalty-inducing discounts for the sale of Remicade (infliximab) in the UK.

The CMA considered that MSD's discount scheme was designed to induce the NHS to be loyal to Remicade and, therefore, have an exclusionary effect. In particular, the discount scheme was intended to force biosimilars to sell at very low prices in order to compensate the NHS for the discount it would lose on purchases of Remicade if it switched, and the criteria of the scheme meant that most of the NHS's purchasing requirements for infliximab would need to be of Remicade in order to benefit from the discount. Furthermore the NHS had understood how the discount scheme would work and was concerned about the implications<sup>125</sup>.

However, the CMA eventually dropped the case as the discount scheme failed to limit competition. The CMA did find evidence of an anti-competitive intention; however, MSD's assumptions about the market and the effect of its discount scheme were wrong and failed to have the desired effect<sup>126</sup>.

However, the CMA cautioned companies that “if it had been successful, MSD's discount scheme could have delayed the NHS from benefitting from

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predatory pricing practices on another market (*Cour d'Appel de Paris, 1ère Chambre, Section H, GlaxoSmithKline, Case no. RG 2007/07008, 8 April 2008*)

<sup>117</sup> Decision No. 13-D-21, *relative à des pratiques mises en œuvre sur le marché français de la buprénorphine haut dosage commercialisée en ville*, 18 December 2013

<sup>118</sup> Authority for Consumers and Markets, Sector Inquiry: TNF-alfa Inhibitors (September 2019), p.5

<sup>119</sup> Office of Fair Trading Decision No. CA98/2/2001

<sup>120</sup> The OFT was one of the UK's competition authorities prior to 2013 along with the Competition Commission. The OFT and Competition Commission were replaced with the CMA in 2013.

<sup>121</sup> Office of Fair Trading Decision No. CA98/2/2001, paragraph 252

<sup>122</sup> Office of Fair Trading Decision No. CA98/2/2001, paragraph 188

<sup>123</sup> *Napp Pharmaceutical Holdings Limited and Subsidiaries v Director General of Fair Trading* [2002] CAT 1

<sup>124</sup> CMA, *No Grounds For Action Decision Competition Act 1998: Remicade 50236* (2019)

<sup>125</sup> CMA, *No Grounds For Action Decision Competition Act 1998: Remicade 50236* (2019), para. 1.15

<sup>126</sup> CMA, *No Grounds For Action Decision Competition Act 1998: Remicade 50236* (2019), para. 1.16

*increased competition and making significant savings" and "had MSD's scheme in practice been likely to prevent or limit competition from rivals, the company could have faced severe financial penalties"<sup>127</sup>.*

### 7.7.3 Schering-Plough<sup>128</sup>

Following a complaint, the French competition authority investigated Schering-Plough for abusing its dominant position and entering into an anti-competitive agreement with its supplier Reckitt Benckiser. Both of these findings related to a strategy by Schering-Plough to prevent the generic version of Subutex from successfully entering the market.

This strategy was implemented primarily through two different measures. Firstly, the disparagement of generic versions by disseminating an alarmist message to doctors and pharmacists on the risks of prescribing the generic and suggesting a change of treatment could cause psychiatric instability in patients. Secondly, pharmacists were given large financial incentives through rebates to purchase large quantities of Subutex with the intention of flooding the market and ensuring that the pharmacists did not have any space available to stock the generic version. The French competition authority found that there could be no objective justification for these rebates that also exceeded the maximum legal cap.

These strategies were found to be very successful and affected competition at two key stages of generic substitution. The campaign to disparage generics resulted in a significant increase in non-substitutable prescriptions and the discounted price levels incentivised pharmacists not to substitute Subutex when an open prescription was written. This meant that substitution was minimal and generic competition negated<sup>129</sup>.

This decision was confirmed by the Court of Cassation in 2017.

### 7.7.4 Abbvie (Humira) & the ACM's TNF-alfa inhibitors sector inquiry report

Between 2018 and 2019, the ACM investigated the state of competition in the Dutch TNF-alfa inhibitors market (TNF-alfa inhibitors are biological drugs used for rheumatism, psoriasis and Crohn's disease)<sup>130</sup>.

This coincided with an article in De Groene Amsterdammer in March 2019 alleging that AbbVie had used various tactics to keep lower-cost biosimilar versions of Humira (the brand name for adalimumab – a rheumatism medication) off the market<sup>131</sup>. The primary allegation was that AbbVie had offered discounts of up to 89% to hospitals (which are responsible for the purchase of the medicine in the Netherlands) on the condition that they purchase the branded product for all patients<sup>132</sup>. For example, an alliance of hospitals treating c.10 percent of Humira patients in the Netherlands, the Santeon group, had identified Amgen as a more attractively priced alternative drug for its rheumatism treatment needs. However, AbbVie subsequently approached each group hospital individually, outbidding Amgen with an 85%

<sup>127</sup> CMA, 'CMA warns business after ending Remicade investigation' (Press Release 14 March 2019), [<https://www.gov.uk/government/news/cma-warns-businesses-after-ending-remicade-investigation>], accessed 6 June 2020

<sup>128</sup> Decision No. 13-D-21, *relative à des pratiques mises en œuvre sur le marché français de la buprénorphine haut dosage commercialisée en ville*, 18 December 2013.

<sup>129</sup> Autorité de la concurrence *Medicinal Products* (Press Release 19 December 2013) [<https://www.autoritedelaconcurrence.fr/en/communiqués-de-presse/19-decembre-2013-medicinal-products>], accessed 6 June 2020

<sup>130</sup> Authority for Consumers and Markets, *Sector Inquiry: TNF-alfa Inhibitors* (September 2019), p.2

<sup>131</sup> Hordijk, L., 'Het patent gaat voor de patiënt', *De Groene Amsterdammer* (27 March 2019) [<https://www.groene.nl/artikel/het-patent-gaat-voor-de-patient>]

<sup>132</sup> *Ibid*

price reduction<sup>133</sup>. The article concluded that the scheme had been successful overall, with at least 70% of Dutch patients continuing to use the originator product at the time of publication, despite the availability of biosimilars with cheaper list prices<sup>134</sup>.

In its TNF-alfa inhibitors market inquiry report, the ACM noted that “*competition from biosimilars results in substantially lower net purchase prices of TNF-alfa inhibitors*”<sup>135</sup>. It added that a “*possible explanation for the limited entry of biosimilars is the conditional discounts applied by originators [because] if a hospital does want to switch to a biosimilar, it will pay a much higher price for the group of patients who are unwilling or unable to switch*”<sup>136</sup>. The ACM explained that the result of this can be that, even though a biosimilar manufacturer offers a lower list price than an originator, switching to it as an alternative can become “*financially unattractive*” for a hospital in the face of such conditional discounts from originators<sup>137</sup>.

Although the ACM has not taken enforcement action against Abbvie in respect of the allegations outlined above, it has condemned the use of conditional discounts by originators, concluding that “*the practice of offering conditional discounts by originators to hospitals may under certain circumstances be restrictive of competition*”<sup>138</sup>. It added that, “*where practices with a potential exclusionary effect are identified, it aims to take enforcement measures where appropriate*”<sup>139</sup>. The report also recommended best practices for health insurers and hospitals to encourage the increase in the take up of biosimilars, and legislative changes by the Government to adjust price regulation to avoid higher prices for residual patients<sup>140</sup>.

### 7.7.5 Roche Romania: Erlotinib

In January 2020, the Romanian Competition Authority fined Roche Romania c.€3.4 million for abusively implementing a strategy to prevent sales of cheaper alternatives to Erlotinib. It was found that Roche had been directing patients to their most expensive product and encouraging sales by covering the difference that patients paid between the expensive product and cheaper equivalents. This was found to have cost the National Health Insurance Fund an additional c. €410,000 in reimbursement costs compared to the cost if patients had chosen the cheaper equivalent drugs<sup>141</sup>.

7.8 The impact of generic and biosimilar entry on a market will normally have a significant impact on market shares and prices. Where this does not happen, this could point to outside factors which are inhibiting market entry, including the possibility of dominant companies seeking to exclude their competitors.

7.9 A finding of predatory pricing by a competition authority would rely on access to a company's cost of goods and internal documents in order to determine whether there was an exclusionary strategy. Absent this information, an exclusionary strategy may still be suspected, as was the case by Napp Pharmaceutical's competitors who complained to the competition authority, but would be challenging for any third party to prove.

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<sup>133</sup> *Ibid*

<sup>134</sup> *Ibid*

<sup>135</sup> Authority for Consumers and Markets, Sector Inquiry: TNF-alfa Inhibitors (September 2019), p.2

<sup>136</sup> *Ibid*, p.4

<sup>137</sup> *Ibid*

<sup>138</sup> *Ibid*, p.2

<sup>139</sup> *Ibid*, p.2

<sup>140</sup> *Ibid*, p.4 and p.5.

<sup>141</sup> Consiliul Concurenței România, *The Competition Council Sanctioned Roche Romania with Fines of 12.8 million Euro*, (January 2020) [[http://www.consiliulconcurenței.ro/wp-content/uploads/2020/04/amenda\\_roche\\_ian\\_2020\\_english.pdf](http://www.consiliulconcurenței.ro/wp-content/uploads/2020/04/amenda_roche_ian_2020_english.pdf)], accessed 9/10/20



### 8. DENIGRATION IN ORDER TO HARM COMPETITION

- 8.1 Denigration is the false or misleading criticism of a competitor's product in order to influence the purchasing patterns or habits of consumers. For instance, false or misleading criticism from the patent holder to prescribers about the equivalence or efficacy of a generic or biosimilar product may have the effect of limiting the impact of generic or biosimilar entry or excluding those generic and biosimilar potential competitors from the market.
- 8.2 In the pharmaceutical market, misleading information may have a particularly detrimental impact, as *"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"*<sup>142</sup>.
- 8.3 The 2019 Report notes that *"another type of practice affecting generic competition is the strategy used by some dominant companies to disparage (denigrate) the generic entrant to hinder the uptake of cheaper generics"*<sup>143</sup>. The report explores a number of decisions by the national competition authorities, in particular the French authority, which has been particularly active in its enforcement of this practice. Some of these cases are explored in more detail below.
- 8.4 The 2019 Report in particular notes that *"disparagement practices are often only part of a broader strategy aimed at hindering generic competition"*<sup>144</sup>. This is clearly the case and is demonstrated in some of the cases also considered in other sections. For instance the FTC's settlement with Reckitt Benckiser in relation to Suboxone noted a strategy of misrepresentation designed to facilitate the product hopping<sup>145</sup>. The 2013 decision by the French competition authority against Schering-Plough found that the strategy of anti-competitive rebates and disparagement was abusive<sup>146</sup>.
- 8.5 Finally, the 2019 Report also notes that other market participants may also unduly restrict generic competition to preserve their own financial interests. In March 2009 the Spanish competition authority<sup>147</sup> intervened because associations of pharmacists were making recommendations against Laboratories Davur's generic products and its members made the decision to collectively boycott these products. This was apparently motivated by reduced profits that pharmacists would obtain due to Laboratories Davur's cheaper products.<sup>148</sup>
- 8.6 Past decisions by national competition authorities have considered denigration under both the laws prohibiting anti-competitive agreements and abuse of dominance depending on the circumstances.

<sup>142</sup> Case C-179/16, *Hoffman la Roche and others v Autorità Garante della Concorrenza e del Mercato* (2018), paragraph 93

<sup>143</sup> European Commission, *Report from the Commission to the Council and the European Parliament: Competition Enforcement in the Pharmaceutical Sector (2009-2017): European Competition Authorities Working Together for Affordable and Innovative Medicines* (2019), p. 28  
[\[https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/report\\_en.pdf\]](https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/report_en.pdf)

<sup>144</sup> European Commission, *Report from the Commission to the Council and the European Parliament: Competition Enforcement in the Pharmaceutical Sector (2009-2017): European Competition Authorities Working Together for Affordable and Innovative Medicines* (2019), p. 29

<sup>145</sup> *Federal Trade Commission v Reckitt Benckiser Group Plc, Case 1:19CV00028*

<sup>146</sup> Decision No. 13-D-21, *relative à des pratiques mises en œuvre sur le marché français de la buprénorphine haut dosage commercialisée en ville*, 18 December 2013.

<sup>147</sup> European Commission, *Report from the Commission to the Council and the European Parliament: Competition Enforcement in the Pharmaceutical Sector (2009-2017): European Competition Authorities Working Together for Affordable and Innovative Medicines* (2019), p. 30; see also *Productos Farmacéuticos Genéricos* – Decision of the CNC of 24 March 2009 in Case 649/08.

<sup>148</sup> Note that this decision related to four different pharmaceutical associations. In 2014, the Spanish Supreme Court quashed the decision relating to one of these associations (the other three were not granted leave to appeal) and found that the communications circulated by the association were not aimed at harmonising its members' behaviour. (See *Productos Farmacéuticos Genéricos*- Judgment of the Tribunal Supremo of 24 October 2014 in Case 1220/2011).



- 8.7 The leading European case was an Article 267 TFEU reference by the Italian courts. In *Hoffman la Roche v AGCM*<sup>149</sup>, the CJEU was asked, among other things, whether "a concerted practice intended to emphasise that a medicinal product is less safe or less efficacious [should] be regarded as a restriction of competition by object"<sup>150</sup> when the claims could not be either proved or disproved by scientific evidence.
- 8.8 The Italian competition authority had previously found that Hoffman la Roche, which markets Avastin, and its licensee Novartis, which is licensed to market Lucentis, had sought to "create an artificial differentiation between those two medicinal products by manipulating the perception of the risk associated with the use of Avastin for the treatment of those diseases through the production and dissemination of opinions which, based on an 'alarmist' interpretation of available data, could give rise to public concerns regarding the safety of certain uses of Avastin and influence the therapeutic choice of doctors, and by downplaying any scientific knowledge to the contrary"<sup>151</sup>. This action was taken to dissuade doctors from prescribing Avastin, the cheaper product, off-label and the AGCM found that these actions had caused a shift in demand towards Lucentis, resulting in an increase in costs to the national health services of €45 million in 2012 alone<sup>152</sup>.
- 8.9 The CJEU noted that the requirements of pharmacovigilance might call for steps to be taken to inform "healthcare professionals and the general public of information relating to the risks associated with off-label use"<sup>153</sup>. However, these requirements are solely for the holder of the MA and, therefore, would not require the collusion of two undertakings marketing competing products.
- 8.10 In particular it was noted that "given the characteristics of the medicinal products market, it is likely that the dissemination of such [misleading] information will encourage doctors to refrain from prescribing that product"<sup>154</sup> and the provision of misleading information to regulatory bodies, healthcare professionals and the general public also constituted an infringement of the EU rules governing pharmaceutical matters that could also give rise to penalties. Given this, the CJEU held that an agreement to disseminate misleading information in the context of scientific uncertainty could constitute an infringement by object under EU competition law<sup>155</sup>. It is understood that the appeals are still ongoing in Italy.
- 8.11 In September 2020 the French Competition Authority also imposed a fine of €444 million on Novartis, Roche and Genentech for abusing their collective dominance by exaggerating the risks of using Avastin off-label and spreading an alarmist and sometimes misleading discourse to public authorities regarding the risks of Avastin to treat age-related macular degeneration. According to the French Competition Authority, this had the effect of maintain the price of Lucentis, which was 30 times more expensive (Lucentis was €1161 per injection; Aventis was €30/40 per injection), as well as artificially inflating the price of Eylea, a competing product<sup>156</sup>. It is understood that the parties are likely to appeal the decision.
- 8.12 The French competition authority has also issued a number of decisions where denigration was found to be an abuse of dominance:

### 8.12.1 Sanofi-Aventis<sup>157</sup>

<sup>149</sup> *Hoffman la Roche and others v Autorita Garante della Concorrenza e del Mercato* (2018) Case C-179/16

<sup>150</sup> *Ibid* para. 36

<sup>151</sup> *Ibid* para. 89

<sup>152</sup> *Ibid* para. 33

<sup>153</sup> *Hoffman la Roche and others v Autorita Garante della Concorrenza e del Mercato* (2018) Case C-179/16, para. 91

<sup>154</sup> *Ibid* para. 93

<sup>155</sup> *Ibid* para. 95

<sup>156</sup> Autorite de la concurrence, *Treatment for AMD: the Autorité fines 3 laboratories for abusive practices* (9 September 2020) [<https://www.autoritedelaconcurrence.fr/en/press-release/treatment-amd-autorite-fines-3-laboratoires-abusive-practices>], accessed 9 October 2020

<sup>157</sup> Décision 13-D-11 relative à des pratiques mises en œuvre dans le secteur pharmaceutique, (14 May 2013).

In May 2013 the French Competition Authority found that Sanofi-Aventis had implemented a strategy of denigrating the generic versions of its branded drug, Plavix, to pharmacists and doctors with the aim of limiting generic entry.

It was found that Sanofi-Aventis implemented a global and structured communication strategy "to emphasise the [...] patent related differences, however irrelevant, for generic substitution, to deter doctors and pharmacists from the generic substitution process" insinuating "that these difference could lead to the health professionals' liability should medical problems arise from the use of the competitors' generics"<sup>158</sup>. These alleged concerns were not followed up with regulatory action, such as alerting health officials to the claimed risk of safety or efficiency. The Commission's press release insinuates that presumably such steps would have been taken if Sanofi-Aventis' claims were genuine.

The French Competition Authority found that this behaviour fell outside competition on the merits and was therefore abusive. This decision was upheld on appeal<sup>159</sup>.

### 8.12.2 Johnson & Johnson<sup>160</sup>

In December 2017, the French Competition Authority found that Janssen-Cilag (and its parent company Johnson & Johnson) had abused its dominant position and consequently delayed the arrival of the generic version of Durogesic by:

- repeated approaches to the French agency for medical safety of health products (AFSSAPS) with the aim of convincing the agency to refuse to grant at national level the generic status to competing medicinal products, despite this status already having been obtained at EU level; and
- implementing a major campaign of falsely disparaging the generic version and using misleading language to create doubt in the minds of healthcare professionals about the effectiveness and safety of these generic products<sup>161</sup>.

Influenced by the alarmist messages from Janssen-Cilag the AFSSAPS initially refused to recognise the generic status of competitor products, and later granted generic status with a warning attached, recommending careful monitoring of certain patients in the event of changing between fentanyl-based medicinal products.

This strategy of denigration included various messages to hospitals, doctors and pharmacists that the generic was not equivalent, highlighting the warning it had procured from the AFSSAPS. This included the training of 300 medical sales representatives, extensive circulation of medical newsletters direct and to the specialist press, training and telephone calls.

<sup>158</sup>European Commission, *France: The Autorité de la Concurrence fines Sanofi-Aventis € 40 600 000 for denigrating Generic Versions of branded Drug Plavix* (Press Release)

[[https://ec.europa.eu/competition/ecn/brief/03\\_2013/fr\\_sanofi.pdf](https://ec.europa.eu/competition/ecn/brief/03_2013/fr_sanofi.pdf)], accessed 8 June 2020

<sup>159</sup> Arrêt du 18 octobre 2016 de la Cour de cassation : rejet

<sup>160</sup> Decision No. 17-D-25, *relative à des pratiques mises en œuvre dans le secteur des dispositifs transdermiques de fentanyl*, 20 December 2017

<sup>161</sup> Autorité de la concurrence, *20 December 2017: Medicinal products* (Press Release)

[<https://www.autoritedelaconcurrence.fr/en/communiqués-de-presse/20-decembre-2017-medicinal-products#:~:text=Following%20a%20referral%20by%20the,generic%20version%20of%20the%20Durogesic>] accessed 8 June 2020.

This combined strategy was effective. 128,000 pharmacies were found to have been influenced by this message (i.e. just over half of French pharmacies). As part of a study to consider the effects of its campaign, 83% of pharmacists asked had memorised "*the risks associated with changing between fentanyl-based medicinal products*". 12,000 GPs had the screensaver emphasising the warning from the AFSSAPS. All of this consequently meant that penetration levels of the generic product were low.

- 8.13 In a similar pattern of behaviour to denigration, allegations are occasionally made of patent holders abusing the system by making misleading statement to authorities<sup>162</sup> or even vexatious or sham litigation<sup>163</sup>. While the latter has previously been recognised as a potential abuse by the European Courts, because it provides an exception to the general human right principle of access to the courts, the bar to prove this is high and the test is strictly applied<sup>164</sup> <sup>165</sup>. However, this may be an easier test to meet if it can also be proved that during the course of litigation, the dominant company was providing misleading information to the authorities or courts.

## 9. CONCLUSION

### 9.1 Overview of state of affairs for generics

- 9.2 The previous reviews, the number of examples and feedback from members of Medicines for Europe suggest, at least anecdotally, that generic and biosimilar companies are finding it more difficult and expensive to navigate the large number of barriers to entry discussed above. The exploitation of these barriers also appears to have increased in sophistication. In some cases, a generic or biosimilar may still be able to secure market entry but this is only after expensive and complex litigation across many jurisdictions. The high costs inherent in this process inevitably need to be recouped. This may result in higher prices for healthcare providers, or the impact on margins for generic and biosimilar manufacturers may result in market exit for smaller manufacturers and ultimately a negative impact on competition in the generics and biosimilar space. There are also many cases where the barriers successfully prevent market entry leading to a significant delay in the introduction of generic competition to the detriment of patients. In some cases, although it is more difficult to quantify, it is also the case that the barriers alone exert a chilling effect and are sufficient to intimidate generics so that market entry is not even attempted because of the potential risk and cost.

### 9.3 Recommendations for reform

#### 9.4 Patent linkage - Amend the Transparency directive

- 9.5 As referred to in paragraph 5.6 above, from as early as 2012 there have been calls for an express prohibition on patent linkage to be included in the Transparency Directive. As the EU looks again at its strategy to improve and accelerate patients' access to safe and affordable medicines<sup>166</sup>, now is an opportune moment to end the uncertainty of patent linkage in the context of pricing and reimbursement activities. This paper calls upon the Commission to amend the Transparency Directive to include an express

<sup>162</sup> For instance, in *AstraZeneca AB and AstraZeneca plc v European Commission*, C 457/10 P, AstraZeneca was found to have made misleading statements to the Patent Office in order to obtain SPCs that extended its exclusivity in relation to Losac.

<sup>163</sup> When the Commission first launched its Inquiry in 2008, vexatious litigation was one of the abuses it was seeking to investigate ([https://ec.europa.eu/commission/presscorner/detail/en/IP\\_08\\_49](https://ec.europa.eu/commission/presscorner/detail/en/IP_08_49)), however this did not end up featuring in the 2009 Report.

<sup>164</sup> *ITT Promedia NV v Commission of the European Communities*, Case T-111/96 (1998), paragraphs 30 and 61.

<sup>165</sup> We have also come across allegations of vexatious litigation and legal action against regulatory authorities. While this point has not been explicitly considered by the courts, it seems likely that a similar test and similar high burden of proof would apply to allegations that sham litigation had been brought against an authority.

<sup>166</sup> European Commission, *Communication: Pharmaceuticals – safe and affordable medicines (new EU strategy)* (2 June 2020) [<https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12421-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines>]

prohibition on patent linkage in relation to pricing and reimbursement activities, which should be also not blocked during market exclusivity period.

9.6 Product hopping: legislation

9.7 In September 2019, a bill was introduced to the US House of Representatives, which sought to prohibit product hopping. The proposed bill establishes that a pharmaceutical manufacturer will have engaged in an "unfair method of competition" if the manufacturer engaged in either a "hard switch" by announcing withdrawal or destroyed inventory while marketing a follow on product or a "soft switch" if this "unfairly disadvantage[d] the listed drug or reference product relative to the follow-on product [...] in a manner that impedes competition from a generic drug [...] and has no clinically meaningful difference with respect to safety, purity and potency"<sup>167</sup>. Such switches can be justified if the pharmaceutical company can demonstrate it would have taken those actions regardless of generic competition for certain specific reasons such as safety concerns or manufacturing problems outside its control.

9.8 The bill was referred to the Subcommittee on Antitrust, Commercial and Administrative Law<sup>168</sup> and is still being considered. However, this indicates a political will in the United States to prevent this type of behaviour and an effective proposal for achieving this goal. The introduction of similar legislation in the EU would serve to limit the scope for 'product hopping' style abuses to be carried out by innovator companies in the EU and is, therefore, commended by this paper.

9.9 Product hopping – maintaining access to earlier generation products

9.10 As shown in the US examples at paragraph 6.15 above, product hopping allegations may require some level of balancing between competitive harm to the generic and biosimilars market and the consumer benefit delivered through modifications. One solution for balancing out these concerns recommended by this paper is for innovators to maintain access to first generation products on the market until patent expiry allows for generic and biosimilar entry. At this stage, the market can then determine whether the purported 'improvements' of the second generation product outweigh the significant cost benefits provided by generic versions of the first generation product.

9.11 Reform of divisional patent application filings

9.12 As outlined at section 4 above, the proliferation of divisional patents is a key factor in prolonging the uncertainty around originator products and delaying the entry of generic and biosimilar competitors. Such uncertainty arises both from the lengthy time periods taken to examine patent applications (including divisionals) at the EPO and the ability of applicants to apply for divisional applications at the EPO so long as an application is pending, creating the 'cascade' of divisionals described in section 4.

9.13 Placing time limits on when an applicant can file divisional applications, as has been seen in national patent systems, and providing mechanisms such as *Arrow* declarations under which generic and biosimilar companies can obtain commercial certainty in the face of a multitude of divisional applications, should be considered to overcome the barrier that the current practice has on generic and biosimilar entry. In particular, imposing time limits to restrict the filing of third, fourth and fifth (and so on) generation divisional patents many years following filing of the parent patent is strongly recommended.

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<sup>167</sup> H.R.4398 *To amend the Federal Trade Commission Act to prohibit anticompetitive behaviours by drug product manufacturers, and for other purposes* (<https://www.govinfo.gov/content/pkg/BILLS-116hr4398ih/pdf/BILLS-116hr4398ih.pdf>)

<sup>168</sup> US Congress, *Affordable Prescriptions for Patients Through Promoting Competition Act of 2019* (<https://www.congress.gov/bill/116th-congress/house-bill/5133/all-info>)



- 9.14 Given the lengthy time periods encountered, additional EPO resources are suggested in order to minimise the time period from filing to grant and to enable a closer examination of the proposed scope of protection of divisional patents to seek to limit proliferation and the harm that this causes.
- 9.15 Some members of Medicines for Europe suggest that concerns raised by the divisional patent system could be addressed through changes to the European Patent Convention, such as divisionals with similar claims being dealt with together with the parent patent in the same opposition or appeal proceeding. For example, one suggestion is that *"it should be possible to decide the validity of the whole family simultaneously and prevent the filing of new divisional members of the same family at a later date"*. Another suggestion is *"the divisional system should be reviewed to limit the number of divisionals and date when they can be filed. There need[s] to be legislative changes to prevent delaying strategies such as the withdrawal of patents, which is one way we are seeing originators avoid an adverse decision, especially when divisionals are pending"*.
- 9.16 *Ensure consistent EU-wide application of the IP Enforcement Directive*
- 9.17 Directive 2004/48/EC requires all Member States to apply effective, dissuasive and proportionate remedies and penalties against those infringing intellectual property rights. In addition, Article 9 of the IP Enforcement Directive provides that in Member States, competent judicial authorities may make provisional measures, such as preliminary injunctions, subject to the provision of adequate security or equivalent assurance to ensure compensation in the event the provisional measure is ultimately found to have been incorrectly granted. Furthermore, where it is ultimately found that there is no infringement or threat of the same, the judicial authority shall have the power to order the applicant to provide appropriate compensation for any injury caused by that provisional measure. In this way, any losses suffered by a generic as a result of a wrongly granted preliminary injunction should be compensated by the patentee.
- 9.18 The framework exists to enable compensation of losses suffered by a generic as a result of an incorrectly ordered preliminary injunction, but implementation of the provisions of, in particular Article 9 of the IP Enforcement Directive varies between Member States, a circumstance which if addressed could deal with the difficulties considered in paragraphs 2.17 and 2.18 above.
- 9.19 Similar provisions directed at losses suffered by national healthcare providers; insurance companies and other payers in similar circumstances would ensure that all those suffering loss where generic and biosimilar medicines are kept from the market by preliminary injunctions which are ultimately quashed, are compensated.
- 9.20 *More enforcement by competition authorities given investigative powers*
- 9.21 Anticompetitive strategies based on the misuse of divisional patents, reliance on patent linkage systems and use of product-hopping strategies have a significant detrimental impact on competition by delaying generic and biosimilar entry. In the absence of an objective justification, such behaviour by companies with a dominant market position should be considered abusive. Authorities already have the powers to tackle this anticompetitive behaviour and, given the importance of generic and biosimilar entry to reducing the price of pharmaceuticals (as acknowledged by the Commission - see paragraph 2.28 above) and increasing access to treatments for patients, they should devote greater resource to the prevention of this type of abuse. While such cases tend to be complex and require an in depth knowledge of the pharmaceutical sector, there is a significant multiplier effect in terms of the benefits. A successful case will have a significant deterrent effect within the pharmaceutical sector as confirmed by the Commission's investigation of reverse payment settlement agreements.



- 9.22 Another valuable feature is the precedent value of any successful case particularly as some of these cases are relatively innovative within the EU competition law context. Generic and biosimilar companies will be able to use these cases to call out analogous behaviour and inhibit some of the more egregious conduct in order to overcome these barriers to entry.
- 9.23 An additional solution is raised by the potential introduction of the Commission Competition Tool which is currently being consulted on<sup>169</sup>. If implemented, a number of the options currently being considered would potentially give the Commission a chance to reconsider the European pharmaceuticals market more holistically in order to identify and remedy structural competition problems that are difficult to address under the current EU competition rules. The Commission could potentially address some of the concerns identified in this paper through structural and behavioural remedies and even recommendations for legislative changes that would improve the functioning of the market.
- 9.24 *Private action by generic and biosimilar companies*
- 9.25 The high cost expenditure and complexity involved in bringing a private competition law action against an originator is a factor which deters many generics and biosimilar manufacturers from lodging claims against originators for some of the obstructive behaviours described in this whitepaper. The cost involved is exacerbated by the need for sufficient disclosure to access the internal strategy documents of the defendant, given the importance of internal documents to proving such a case. Furthermore, the asymmetry of resources between generics/biosimilar companies and originators deters generics and biosimilar companies from taking on such actions. One potential solution to this is for generic and biosimilar companies to consider collaborative actions, sharing cost and risk where this is possible.

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<sup>169</sup> For more information, see [<https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12416-New-competition-tool>]



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