Ms. Sandra Gallina
Director General for Health and Food Safety
European Commission
Rue Breydel 4, 1000 Bruxelles

Mrs. Kerstin Jorna
Director General for Internal Market,
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European Commission
Avenue d'Auderghem 45, 1040 Bruxelles

Mr. Olivier Guersent
Director General for Competition
European Commission
Place Madou 1, 1210 Saint-Josse-ten-Noode

13 April 2022

Dear Director General Gallina,
Dear Director General Jorna,
Dear Director General Guersent,

Object: Divisional patents and patent linkage: the case of Gilenya® (fingolimod) - Potentially Anti-Competitive Conduct

In regard to the previously discussed issues concerning abuses and misuses of divisional patent procedures as well as patent linkage in several Member States, as urged by several of our members we wish to bring to your attention a number of matters relating to potentially anticompetitive conduct in the European Union being undertaken with regard to Gilenya® (fingolimod).

The conduct stems firstly from what many of our members believe is an abuse/misuse of the patent system in Europe, and secondly from the consequent interference in pricing and reimbursement mechanisms for pharmaceutical products in Europe. Whilst it is recognized that not necessarily all use of the divisional patent procedure is problematic, the conduct detailed in this letter is having a negative impact on the launches of generic pharmaceutical products, which will in turn affect the healthcare budgets of Member States.

In this letter we wish to set out the facts of the matter as seen from the perspective of several of our member companies. We urge the European Commission to consult with the EPO and to take appropriate action, including with respect to policy initiatives by the EPO to limit the potential for abuses of the patent

system and to ban patent linkage in EU legislation, which contribute to delaying generic and biosimilar medicines market launches.

Gilenya® (fingolimod)

Novartis currently markets Gilenya®, a pharmaceutical product which is indicated as a single disease modifying therapy in highly active relapsing remitting multiple sclerosis. The active ingredient in Gilenya® is fingolimod. According to Novartis, the global sales of Gilenya® in the financial year 2021 were approximately 2.8 bn USD.

Gilenya® is available as capsules (0.25 mg and 0.5 mg). The recommended dose for adults is one 0.5 mg capsule taken once a day by mouth, the recommended dose for children depends on body weight.

In Europe, Gilenya® was first authorized in Europe by the EMA on 17 March 2011. The market exclusivity for Gilenya® expired on 22 March 2022, meaning that the data exclusivity for Gilenya® expired in March 2019, and that the earliest the marketing of any generic fingolimod products could commence was **23 March 2022**.

Due to the expiry of the market exclusivity for Gilenya®, many of the member companies of Medicines for Europe had been preparing to launch their generic fingolimod products from 23 March 2022 onwards. Such launches are now being delayed by the improper activities described below.

The Actions of Novartis on Gilenya® (fingolimod)

We wish to highlight two aspects of Novartis' conduct which we believe are worthy of bringing to the attention of the European Commission.

3.1 Abuse/misuse of Divisional Patent System

Many of Medicines for Europe members have communicated that they believe that Novartis has abused/misused the divisional patent system in Europe in relation to Gilenya® / fingolimod. They consider that this abuse/misuse is now having a direct impact on the launch of generic fingolimod products in the European market.

The details of this conduct are set out in **Part A** to this letter.

3.2 Unlawful Patent Linkage

There is also a concern that, across the Members States of the European Union (as well as Great Britain), Novartis has knowingly and deliberately intervened in the pricing, reimbursement and market access mechanisms for generic fingolimod products. In some cases, it appears to be a coordinated attempt to engineer "unlawful"[1] patent linkage across Europe, independent of any enforcement before the courts, and thus prevent and/or delay generic entry of fingolimod products, without any judicial scrutiny.

[1] Term used by the European Commission in the Final Report of the Sector Inquiry of 2009, p. 315.

The details of this conduct are set out in **Part B** to this letter.

Many of our Members assert strongly that the conduct explained in **Part B** (unlawful patent linkage) is directly linked to the conduct explained in **Part A** and part of an overarching strategy (abuse/misuse of divisional patent system).

Generic Entry of Fingolimod Products is Being Impacted

Many of our member companies had been expecting to launch generic fingolimod products from 23 March 2022 onwards. Indeed, many national health services of Members States of the European Union had been expecting the launch of generic fingolimod products from 23 March 2022 onwards and had been budgeting accordingly.

However, generic entry of fingolimod products is currently being deliberately delayed or prevented in a number of European countries. This will have a direct impact upon the healthcare budgets of Member States as well as on the actual access to the generic treatment for patients.

Conclusion

We trust that the matters raised in this letter are of significant interest to the European Commission, and indeed other authorities of Members States across the European Union.

We strongly urge the European Commission to take urgent action in consultation with the EPO, including with respect to policy initiatives to limit deliberate and calculated abuses of the patent system and to ban patent linkage in EU legislation, which contribute to delaying generic and biosimilar medicines market launches. Timely launch of generic and biosimilar medicines is a stated priority of the current pharmaceutical and IP reform.

Medicines for Europe, and its constituent member companies, stands ready to support the European Commission and provide any further clarification on the matters raised in this letter.

Yours faithfully

Adrian van den Hoven

Director General
Medicines for Europe

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PART A

A1 Abuse of the Divisional Patent System in Europe

We believe that the divisional patent system is currently being abused/misused in Europe.

Our members have observed that some patent applicants are using the patent system to strategically **file**, **withdraw**, and **re-file** divisional patent applications with the sole intention of prolonging the length of time that it takes to prosecute patent applications. Whilst it is recognized that in some specific cases divisionals may be filed and later withdrawn for legitimate and justified reasons (in line with our policy recommendations), in other cases such strategies are deliberately used to both frustrate the inherent checks and balances in the patent system that weed out invalid rights and to create significant uncertainty for third parties. Further, timing is often planned to avoid any decision from the European Patent Office ("EPO") or national courts prior to planned launch dates of pharmaceutical products.

These patents or patent applications may then be the subject of **aggressive enforcement** by the patent holders in the courts of member states across the European Union in an attempt to prevent the launch of generic pharmaceutical products. Such delays to generic entry can then have a direct impact upon the healthcare budgets of member states.

This abuse/misuse is nothing new. It was previously highlighted in the European Commission's Pharmaceutical Sector Enquiry in 2008.

For example, in its Final Report of the Sector Enquiry, the European Commission stated at paragraph (523):

> *2.1.4. Intended Effects of Patent Clusters and Divisionals*
>
> *The intended effects of both patenting strategies as analysed above are identical: in some case both patent clusters and divisionals seemingly serve to prevent or delay generic entry. While this, during the period of exclusivity, is generally in line with the underlying objectives of patent systems, it may in certain cases only be aimed at excluding competition and not at safeguarding a viable commercial development of own innovation covered by the clusters.*

Further, at paragraph (538):

> *1.1.4.2. Procedural Enforcement of Patent Rights*
>
> …
>
> *The preceding subsection showed that the use of patent clusters and divisionals by some companies may deter or delay generic entry merely by their existence. In other cases, companies may proceed with the development of generic versions with a view to enter the market at risk. In such cases, patent clusters and also divisionals are an indispensable asset*

for originator companies' implementation of their procedural enforcement strategies. These strategies will typically lead to patent litigation, but can also result in settlements, as discussed in subsequent chapters. Such patent positions may also be an argument originator companies raise in their interventions vis-à-vis the marketing authorisation, pricing and reimbursement bodies etc.

The European Commission is not alone in recognizing that the divisional patent system has been abused, and the EPO has also recognized that the patent system has been abused. For example, in Decision of the Administrative Council of the EPO on 15 January 2009 (EPO paper CA/145/08 Rev. 1, subject: Divisional applications, Munich, 15.01.2009), the EPO stated:

> ***There is a trend for applicants to abuse these procedural possibilities by using the divisional application procedure to achieve a "duplication" of the proceedings.*** *For example, the applicant files a*(n identical) *divisional application the day before the oral proceedings, i.e. before any refusal might occur and thus while the earlier parent application is still pending. If refusal ensues in the oral proceedings, instead of appealing against the negative decision of the examining division, the applicant simply pursues the divisional. Moreover, even if an appeal is filed and the refusal is confirmed by the board of appeal, this procedure allows him to have the same technical content discussed again. The applicant can repeat this tactic over and over again. This is detrimental both to legal certainty for third parties and to patent office workloads.*

Following the Preliminary Report of the Sector Enquiry in 2008, the European Patent Office took steps to restrict the ability of patentees to abuse the divisional patent system in Europe, a step that was acknowledged by the European Commission its Final Report of the Sector Enquiry, adopted on 8 July 2009. (See Final Report, para 1579, page 525).

However, the European Patent Office subsequently changed its rules on divisional patent applications in 2014, which re-opened the door to the abuse.

A2 Medicines for Europe Communications on Divisional Patent Abuse

We have previously written to you about the abuse of the divisional patent system in Europe. See for examples our letters of **23.3.2021** and **24.2.2022**. We have previously written also to President von der Leyen on **6.5.2021**.

We have also appreciated the opportunity to speak to you about this continuing abuse, such as in our meetings with DG Competition on **15.5.2021**, and our meetings with DG Grow on **19.5.2021**, **11.2.2022** and **23.2.2022**. Nevertheless, this case shows that the abuse continues.

Therefore, Medicines for Europe will continue to put before you specific examples where our members believe that the system has been abused, as has been requested by the Commission, aiming to achieve a rapid resolution of this policy issue

Accordingly, we now wish to highlight a particular example of the abuse, in relation to the Novartis product Gilenya® (fingolimod) and some of our members' difficulties to enter the market timely.

A3 Novartis' Divisional Patent Strategy for the 0.5 mg Dosage of Fingolimod

At the heart of this matter is the prosecution of patent applications that relate to the 0.5mg dosage of fingolimod by Novartis AG. In particular, the concern is the conduct in relation the Novartis patent application EP 2 959 894 ("EP 894"), the family of divisional application of which it is a member, and the series of other patent applications which came beforehand.

The strategy employed by Novartis appears to have been designed to deliberately extend the period of patent prosecution before the EPO, with the apparent aim of maintaining the application pending as long as feasible and of obtaining a granted patent as close as possible to the expiry of the market exclusivity for Gilenya®. It has employed the following steps in combination as part of an overarching strategy:

(i) The filing of a number of families of divisional patent applications, with each application with a later filing date, to create **cascades of divisional patent applications**;

(ii) The **strategic withdrawal** of earlier patent applications in the cascades that have almost identical subject matter to later patent applications in the cascades;

(iii) The **aggressive enforcement** of the latest of the patent applications before the courts, even before such patent application has been granted.

Ultimately, this strategy started from an initial patent application being filed by Novartis in **2006** leading to the now expected grant of a patent, **16 years later**, in **2022.** This patent application EP 894 is now being used by Novartis in the courts across Europe as a tool to prevent the launch of generic fingolimod products, even *prior* to the patent being granted.

Further details of the steps taken by Novartis to execute this strategy, which has led to the expected grant of EP 894, are provided below.

A3.1 History of Patent Families for Fingolimod 0.5mg Dosage

The EP 894 patent application is just one of several patent applications which makes reference to a 0.5 mg oral daily dose of fingolimod. Any of these applications could have been used to pursue subject matter as now claimed in EP 894. These patent applications have been filed and prosecuted at the EPO. All of these EP patent applications originate from two international (PCT) applications which were published with the numbers WO2006058316A1 and WO2008000419A1 respectively.

A3.2 "Family A"

The first family of cases relating to WO2006058316A1 includes the following European (EP) patent family members:

- #A1 = EP1819326
- #A2 = EP2359821
- #A3 = EP2384749

Notably, patent application #A3 from this family (EP2384749) claimed the following subject matter:

> "*Claim 1: A compound which is* [fingolimod] *in free form or in a pharmaceutically acceptable salt form, for use in a method of treating an automimmune disease in a patient in need thereof, whereby said method comprises administering a daily maintenance therapy of 0.5mg*".

Note that multiple sclerosis is an autoimmune disease. Accordingly, this claim encompassed fingolimod, in a dosage of 0.5mg, for the treatment of multiple sclerosis.

This patent application was **withdrawn** by Novartis on 4 February 2015.

A3.3 "Family B"

The EP '894 patent application was derived from the second PCT application, i.e., WO2008000419A1. This patent family includes the following EP members:

- #B1 = EP2037906
- #B2 = EP2698154
- #B3 = EP2959894
- #B4 = EP3797765

Notably, patent application #B3 from this family (EP2959894) claims the following subject matter:

> "*Claim 1: A* [compound] *for use in the treatment of relapsing-remitting multiple sclerosis, at a daily dosage of 0.5 mg p.o.* [per oral] *wherein said* [compound] *is* [fingolimod]".

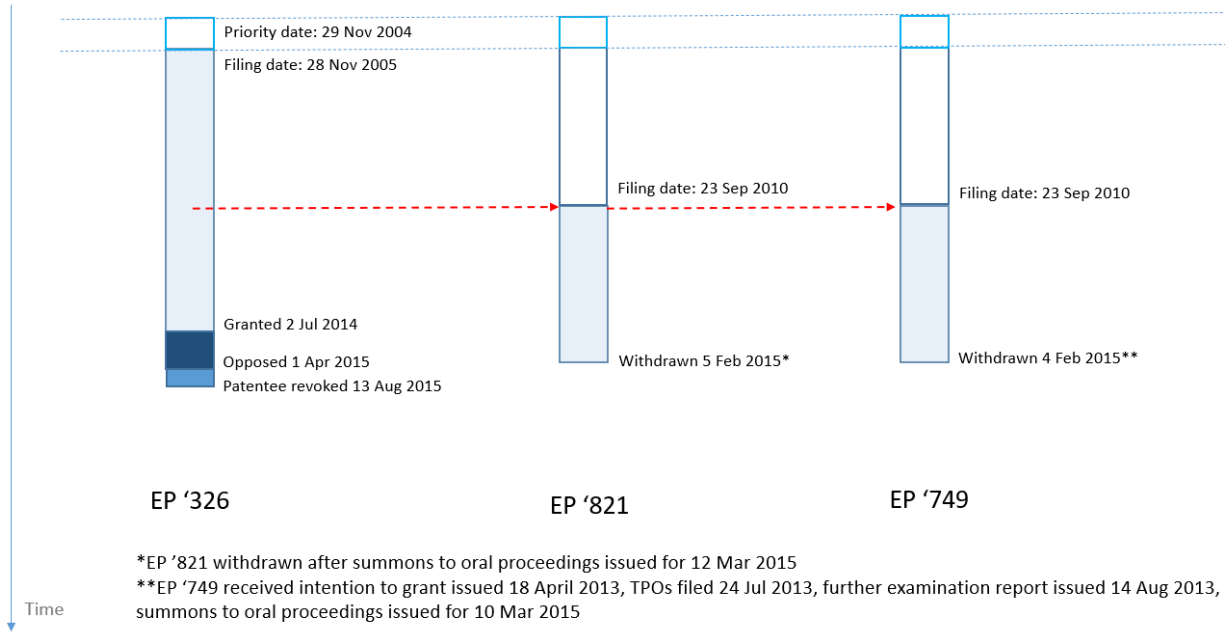
This patent application has not yet granted. The patent application was originally rejected by the Examination Division of the EPO on 19 November 2020. However, Novartis appealed, and on 8 February 2022 the Technical Board of Appeal allowed the appeal and instructed the Examination Division to proceed to the grant.

As of the date of this letter, EP 894 has not actually proceeded to grant. Nevertheless, Novartis is using this patent application to both: (i) commence litigation against generic companies before the courts; and (ii) intervene in the pricing and reimbursement mechanisms in member states across Europe to prevent or delay generic entry.

A3.4 Illustrative Timelines

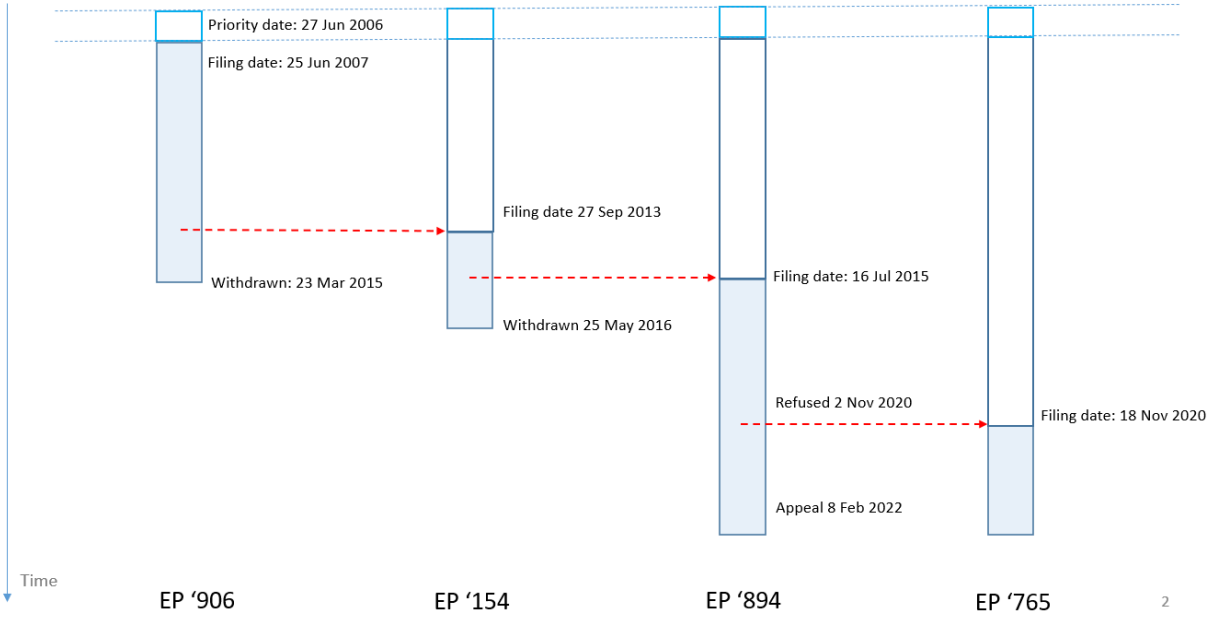
Illustrative timelines for cascades of divisional patents contained in each family, and the dates of sequential withdrawal of certain members of each family, are provided below.

Fingolimod Dosage Regime Divisional Patent Family A (WO2006058316)



*EP '821 withdrawn after summons to oral proceedings issued for 12 Mar 2015
**EP '749 received intention to grant issued 18 April 2013, TPOs filed 24 Jul 2013, further examination report issued 14 Aug 2013, summons to oral proceedings issued for 10 Mar 2015

Fingolimod Dosage Regime Divisional Patent Family B (WO2008000419)



A3.5 A Strategy of Delay

In addition to the fact that Novartis knowingly sought and then selectively withdrawn patent protection for essentially the same subject matter (ie. the 0.5mg dosage of fingolimod) in two separate patent families as explained above, the prosecution of the second patent family contains a series of deliberate delays by Novartis.

- Novartis obtained European regulatory approval for the 0.5 mg dose from the EMA in March 2011. At least by then, Novartis knew the dosage for which it desired protection.

- Novartis could thereafter have amended the then-pending patent application #B1 (EP2037906) to claim the 0.5mg dosage. However, despite filing amended claims in April 2012, it did not do so. Instead, Novartis withdrew patent application #B1 on 23 March 2015.

- On 27 April 2013 Novartis filed parent application #B2 (EP2698154), again without the 0.5 mg dose claim. On 19 August 2014 Novartis filed amended claims for parent application #B2, but again failed to claim a 0.5 mg dose. It withdrew the parent on 25 May 2016.

- In respect of the EP '894 application, patent application #B3, Novartis elected of its own accord to adjourn the video conference hearing of its appeal before the TBA on 29 May 2020.

Thus on at least four occasions since March 2011, Novartis itself has been responsible for deliberately delaying the grant of a patent covering a 0.5mg dose of fingolimod.

Novartis has thereby engineered a situation where the grant of a patent for the 0.5mg dosage form of fingolimod would occur (or be expected to occur) close to the expiry of the market exclusivity for Gilenya® (*ie*. 23 March 2022).

A4 Novartis' Litigation Strategy to Frustrate Launches of Fingolimod Products

Even though EP 894 has not, at this stage, actually been granted as a patent by the EPO, Novartis has decided to enforce such patent application before the national courts of various Member States.

For example, our members have informed us that Novartis has, as of the date of this letter, commenced the following enforcement actions:

(i) Netherlands

On 1 March 2022, Novartis commenced an action for unfair competition against Viatris before the courts in the Netherlands, seeking a preliminary injunction. In this action, Novartis alleged that, as EP 894 had been allowed to proceed to grant by the Technical Board of Appeal of the EPO, but even though EP 894 had not actually granted as a patent, the act of marketing a generic fingolimod product in the Netherlands before the expiry of EP 894 in 2027 amounted to unfair competition and should be restrained.

In a decision dated 22 March 2022 the court rejected this action. However, Novartis has sought and obtained permission to appeal this decision, and the appeal will be heard in the Hague on 14 April 2022. A further first instance preliminary injunction hearing to discuss the invalidity issues in relation to the patent application EP 894 has been scheduled for 17 May 2022.

(ii) Belgium

On 25 February 2022, Novartis commenced an action for unfair competition against Viatris before the courts in Belgium, seeking a preliminary injunction.

A hearing has been scheduled for 26 April 2022.

(iii) Greece

On10 March 2022, Novartis commenced an action for patent infringement and unfair competition against Viatris before the courts in Greece, seeking a preliminary injunction.

An *ex parte* preliminary injunction was refused by the court on 16 March 2022. An *inter partes* PI hearing has been scheduled for 16 May 2022.

(iv) Italy

On 9 March 2022, Novartis commenced an action for patent infringement based on EP 894 before the courts in Italy, seeking a preliminary injunction against Viatris.

At an *inter partes* hearing on 23 March 2022, upon the request of Novartis, the Court in Milan requested that Viatris did not enter the market for fingolimod products in Italy until 1 July 2022, on the basis that a further *inter partes* preliminary injunction hearing would be arranged for 24 May 2022.

(v) Finland

On 10 March 2022, Novartis commenced an action for unfair competition and patent infringement based on EP 894 before the courts in Finland, seeking a preliminary injunction. An *ex parte* preliminary injunction was awarded by the Finnish court on 11 March 2022.

Inter partes preliminary injunction proceedings are now pending.

(vi) Spain

On 3 March 2022, Novartis commenced an action for unfair competition and patent infringement based on EP 894 before the courts in Spain, seeking a preliminary injunction against Viatris and Teva, and later against Dr Reddy. An *ex parte* preliminary injunction was awarded by the Spanish court in Barcelona on 7 March 2022. This preliminary injunction will remain in force until at least 1 July 2022.

Inter partes preliminary injunction proceedings are now pending, and an *inter partes* hearing is expected at some point in May 2022.

(vii) Germany

On 31 March 2022 Novartis has filed request in Preliminary Injunction against Zentiva in front of Hamburg Regional Court for unfair competition based on not yet granted EP 894. The proceedings are currently pending.

Novartis has made a serious threat to commence an action against Viatris for unfair competition based on EP 894 before the courts in Germany, seeking a preliminary injunction.

(viii) Denmark

On March 30 2022 Novartis has filed a request in Preliminary Injunction for infringement of not yet granted EP 894 at Commercial and Maritime High Court of Copenhagen.

(ix) UK (Although no longer part of the EU, the activities in the UK may be illustrative further as to Novartis' behavior)

On March 3 2022, Novartis initiated a lawsuit at the U.K. High Court of Justice seeking an interim injunction, pending a decision on the merits, based on EP 894 application to prevent the launch by Dr. Reddy's, Glenmark, Teva, Tillomed, and Zentiva. The proceedings are currently pending.

A5 What Novartis Has Done

Through the strategy of:

(i) filing for a number of cascades of divisional patent families with almost identical subject matter; and

(ii) selectively withdrawing members of these families without detailed justification; and

(iii) engineering deliberate delays in the prosecution of patents in such families,

Novartis has cynically and strategically prolonged the prosecution timelines for patent protection for the 0.5mg dosage form of fingolimod.

The much-delayed grant of such divisional patent protection, which could have been sought many years earlier (which indeed was sought many years earlier, but which was withdrawn by Novartis), has now been the subject of immediate aggressive enforcement by Novartis before the courts of various Members States of the European Union, even before the grant of the patent. This suggests, crucially, that the steps taken are part of an intentional strategy to create delay and uncertainty rather than legitimate enforcement of valid and blocking IP.

Intentional delays to the grant of IP deprive generic companies of the ability to challenge the validity of such patent protection, whether before the EPO or before national courts. If made part of a deliberate strategy to avoid negative validity decisions that would significantly impair, and ultimately prevent, the originator's ability to extend exclusivity, such behavior raises serious concern.

The delays to the grant of patent protection to Novartis, which appear to have been engineered by Novartis, have shielded weak patent protection from judicial due process and extended the period of enforceability by many years.

PART B

We believe that, across the Member States of the European Union, Novartis has knowingly and deliberately intervened in the pricing, reimbursement and market access mechanisms for generic fingolimod products. In some cases, it appears to have done so in an underhand manner. This coordinated campaign of intervention is an attempt to engineer "unlawful" patent linkage across Europe, independent of any enforcement before the courts, and thus prevent and/or delay generic entry of fingolimod products

B1 Context

As explained above, our members have reported to us how Novartis has commenced litigation campaign across Europe on the basis of EP 894, seeking preliminary injunctions to prevent the launch of generic fingolimod products. Such litigation is based on either unfair competition laws, or on the alleged patent infringement of the patent application.

However, this enforcement before the courts is only half of the story.

In addition to the litigation campaign, Novartis has also intervened in the pricing and reimbursement mechanisms for generic fingolimod products, thus preventing generic entry without judicial scrutiny.

B2 Patent Linkage is Unlawful

The European Commission has strongly addressed the practice of patent linkage previously by defining it as an "unlawful" practice.

As stated by the European Commission in its Final Report of the Pharmaceutical Sector Inquiry (DG Competition), "*Patent linkage refers to the practice of linking the granting of MA, the pricing and reimbursement status or any regulatory approval for a generic medicinal product to the status of a patent (application) for the originator reference product. Under EU law, it is not allowed*".

There are several major forms of patent linkage:

- one that makes a marketing authorisation (MA), or a MA application, a potential act of patent infringement;
- one that makes a Pricing & Reimbursement (P&R) decision or P&R application for a generic medicine a potential act of patent infringement;
- one that prevents a generic medicine from entering into prescription databases;
- one that prevents generic medicines from being procured if any patent (incl. irrelevant secondary patents) exists.

Despite the fact that the European Commission considers patent linkage unlawful under EU law, as described below, patent linkage practices or legislations still exist in several EU Member States.

B3 Patent Linkage Under EU Law

The European Commission has stressed that "[u]*nder EU law, patent protection is not a criterion to be considered by the authorities when approving prices or granting reimbursement status*" since it is contrary to Directive 2001/83/EC and Regulation 726/2004, maintaining that "*[s]uspending the price approval procedure for any other reason than the ones indicated in the Transparency Directive is considered as a breach of the Directive*" and that "*Member States should disregard third party submissions raising patent, bioequivalence or safety issues*".

Linking MA grant and P&R decisions to the status of patents has indeed resulted in significantly delaying market entry of generic medicines, with a huge impact on healthcare costs and patient access to medicines. The European Commission has already addressed patent linkage issues due to their anticompetitive effects and has previously stated that it will "*strictly enforce the applicable rules* [and] *act against patent linkage*". The European Commission has also stated that it "*may launch infringement proceedings against any Member State which infringes the Directive*".

As the Competition Law Sector Inquiry from 2008 notes, originator companies have threatened to sue national authorities for damages if any regulatory/P&R decision is made during the term of an existing patent. However, for good reasons European Law requires national regulatory or P&R authorities to disregard the status of patents.

Since only a national court or patent office, can ultimately decide whether a particular patent is infringed or not, regulatory agencies are technically and legally not competent to determine the relevance and validity of patents. Patent linkage therefore erroneously places the burden of determining whether a generic product is permitted to enter a market or not on the regulatory agency.

B4 Novartis Press Statement of 15 February 2022

On 15 February 2022 Novartis issued the following press statement:

> *"Novartis announces European Patent Office orders grant of the European Gilenya® (fingolimod) 0.5mg daily dose patent*
>
> *"Novartis welcomes the decision by the European Patent Office on February 8th recognizing our innovation by ordering the European Gilenya 0.5mg daily dose patent (expiry 2027) to be granted. This decision means the European patent in its designated countries will cover all generics with European marketing approvals for fingolimod 0.5mg."*

Notwithstanding putting out this press statement, it appears that Novartis has gone a step further by carrying out a coordinated campaign of intervention with regulatory authorities.

B5 Specific Examples

Our member companies have informed us that Novartis is using the EP 894 patent application, in its communication campaign before national regulatory authorities and national pricing authorities across the EU, to frustrate the process by which generic products get reimbursement and/or market access, thereby impeding generic entry.

We have been informed by our members of (at least) the following activities taken by Novartis:

(i) Finland

As explained above, Novartis used EP 894 to obtain an *ex parte* preliminary injunction against Viatris to prevent the launch of its generic fingolimod product in Finland on 11 March 2022.

We understand that, shortly after the injunction was granted, Novartis' lawyers made a communication to the Finnish pricing authority informing them about the grant of the injunction and urging them not to grant a price for the period starting from 1 April 2022. This then led the Finnish pricing authority to contact Viatris to request that Viatris withdraw its then pending application for pricing and reimbursement of its generic fingolimod product.

It is important to recognize that the *ex parte* preliminary injunction granted by the court against Viatris did not order the withdrawal of Viatris' pricing and reimbursement for its generic fingolimod product.

(ii) Ireland

We understand that, in Ireland, the GMS codes for generic fingolimod products were expected to be issues on 1 March 2022, in advance of generic entry from 23 March 2022 onwards. We understand that at least one of the member companies sought clarification from the Irish Health Service Executive ("HSE") about why such codes were not granted.

The HSE explained to one of our member companies that:

"While PCRS does not track or monitor Drug Patents, we were legally notified of the patent protection for Fingolimod and therefore did not proceed to assign new codes."

It is our view that the HSE must have arrived at this position following a communication from Novartis.

Furthermore, one of our member companies followed up with the HSE about why such codes were not granted and was informed as follows:

"A High Tech code won't be assigned until whatever patent challenge is ongoing as notified directly to the HSE is over."

The absence of GMS codes for generic fingolimod products essentially means that generic entry cannot proceed.

It is our understanding that, as of the date of this letter, there are no "*patent challenges*" ongoing before the Irish courts in relation to fingolimod products.

(iii) France

We understand that, in late February 2022, Novartis communicated with the French pricing authority, CEPS. We understand that Novartis had stated to CEPS that Novartis had contacted CEPS to inform them that "*there had been a change in the IP situation*". This has led to a situation so that, as of the date of this letter, there has been no pricing approval of any generic fingolimod products in France.

(iv) Czech Republic

We understand that in the Czech Republic the pricing approval of generic fingolimod products is contingent on an exclusive supply arrangement that Novartis has with the Czech government regarding Gilenya® / fingolimod. We understand that, as of the date of this letter, all applications for pricing and reimbursement of generic fingolimod products have been refused by the Czech government.

(v) Slovakia

We understand that in Slovakia there is an exclusive supply arrangement that Novartis has with the government regarding Gilenya® / fingolimod. We understand that, as of the date of this letter, no generic entry of any fingolimod products will be possible until after 1 September 2022 at the earliest.

(vi) Latvia

We understand that Novartis has sent communications to the national health service in Latvia about the patent situation for fingolimod. We understand that, as a result of this communication, the Latvian national health service believes that generic entry of fingolimod products is not possible. We understand that the situation is further complicated by the fact that there is a complicated "claw-back" agreement in place between Novartis and the Latvian national health service concerning fingolimod and a number of other medicinal products.

(vii) Lithuania

We understand that the situation in Lithuania is similar to that in Latvia.

We understand that in or around the end of February 2022, Novartis sent a communication to the National Health Insurance Fund of the Republic of Lithuania about the patent situation for fingolimod. We understand that, as a direct result of this communication, the Lithuanian national health service rejected all applications for generic fingolimod products to enter the reimbursement list for H2 2022.

(viii) Greece

It is our understanding that Novartis has made communications to (at least) the regulatory agencies in Greece responsible for the approval of promotional material for generic pharmaceutical products. The approval of such promotional material is an important prerequisite step before the launch of any generic pharmaceutical product.

We understand that the review the promotional material for one of our member companies was refused in March 2022, directly as a result of the regulatory authority being of the view that Novartis had obtained a patent extension for fingolimod.

Indeed, the particular communication from the regulatory authority to one of our members stated as follows:

"Given (a) the patent extension of original fingolimod product (Gilenya) until 2027 and (b) not receiving an answer / clarification regarding the launch date of your product in the Greek market, following these recent developments we inform you that we are lifting the requested priority status regarding the evaluation of your … filing. Following the above we inform you that your filing will be reevaluated following the order of its submission."

(ix) Portugal

It is our understanding that Novartis has made communication to request PT Health Authorities not to list Generics fingolimod products in SPMS catalog (necessary to establish pricing) at expiration of Market Exclusivity expiring on March 22, 2022 because of future grant of EP 894 expiring in 2027. Novartis then has filed an urgent administrative proceeding to request SPMMS to suspend listing of Zentiva, Accord, Generis, Logista, Mylan and Teva, due notably to future grant of EP894, and also other patents – establishing a de-facto patent linkage if the request is successful.

In parallel Novartis has also sent letters to Hospitals, mentioning that ordering Generics fingolimod products at ME expiration would constitute an infringement of EP 894 and/or unfair competition.

(x) Germany

We understand that Novartis has sent threatening letters to Wholesalers mentioning that purchasing and storing Generics products even before grant of EP 894 could be considered as unfair competition. Accordingly, many wholesalers and customers are intimidated by Novartis and have refused to purchase generic fingolimod products, even prior to Novartis initiating any litigation. Thus, generic competition has been effectively blocked in Germany despite there being no judicial review and without a court order or injunction legally stopping generic products from being sold and administered.

The circumstances described above confirm the **urgent** need to explicitly ban patent linkage in EU law in the context of the ongoing pharmaceutical legislation reform.