From: [redacted]@novartis.com>
Sent: 29 April 2022 16:05
To: [redacted] <[redacted]@nhs.scot>
Cc: [redacted] <[redacted]@novartis.com>; [redacted]
<[redacted]@nhs.scot>
Subject: RE: Gilenya (Fingolimod)

Hi [redacted]

In addition to the below communications, please see an update on the current status of fingolimod.

If you have any questions, please do let me know.

> We write further to our previous correspondence regarding Gilenya (fingolimod). As you will no doubt be aware, Novartis was unsuccessful in obtaining a preliminary injunction ("**PI**") restraining the generic fingolimod manufacturers from entering the UK market prior to the judgment following the trial of the proceedings that Novartis has instigated for alleged infringement of its patent for the Gilenya dosage regimen ("**the Infringement Proceedings**").
>
> Novartis is seeking to appeal the decision not to award a PI, and we will advise NHSS with further information in this regard once it becomes available.
>
> However, during the hearing of PI proceedings in March 2022, the Judge ordered the trial of the Infringement Proceedings to take place in early October 2022. Following the trial, the judgment of the Court could be expected before the end of the calendar year. Accordingly, it appears that there will be resolution on this matter towards the end of 2022, subject to any appeals that may ensue.

Kind Regards,

[redacted]

From: [redacted]
Sent: 22 February 2022 16:29
To: [redacted] <[redacted]@nhs.scot>
Cc: [redacted] <[redacted]@novartis.com>; [redacted]@nhs.scot
Subject: Gilenya (Fingolimod)

> Hi [redacted]
>
> I hope this email finds you well?
>
> Please find an update to the Gilenya® (fingolimod) patent.
>
> If you have any questions, please do let me know.

Further to our recent correspondence regarding our product Gilenya (fingolimod), you will be aware that Technical Board of Appeal ("**TBA**") of the European Patent Office ("**EPO**") decided to grant our patent application EP 2 959 894 ("**EP '894**") with the title "*S1P Receptor Modulators for Treating Multiple Sclerosis*". EP '894 protects the active ingredient fingolimod for use in the treatment of relapsing-remitting multiple sclerosis at a daily dosage of 0.5mg.

Whilst the marketing protection period for Gilenya expires on 22 March 2022, once formally granted (due approximately June/July 2022), the EP '894 patent will then expire on 25 June 2027 (unless revoked earlier in national proceedings or as a result of a successful opposition being filed before the EPO). Please note that Novartis initially filed its patent application covering the 0.5mg daily dose for Gilenya to treat relapsing remitting multiple sclerosis ("**RRMS**") in 2007, and the application has been transparent and open to the public for years. However, Novartis required the intervening time to navigate the patent examination process, and ultimately to work with the EPO to obtain this patent covering our innovation. The duration of a patent is 20 years from the original filing date; therefore, the 2027 expiry date of this patent is in accordance with the standard timeline.

Novartis is aware that several generic pharmaceutical companies have applied for and obtained marketing authorisations in the UK for fingolimod. The licensed indication for Gilenya is the treatment of highly active RRMS and the approved dosage in adults is 0.5mg of fingolimod per day. Consequently, while EP '894 is in force, it would be an infringement of the patent for generic 0.5mg fingolimod products to launch in the UK, including by offering for sale, selling, importing, manufacturing or keeping fingolimod products.

Novartis remains at NHSS's disposal, should any questions arise in connection with the above or should any additional documents be required.

Kind Regards

[redacted]

[redacted]

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