

# NOVARTIS/ PHARMATHEN DECISION CONFIRMED ON APPEAL

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By judgment of 26 March 2024 in preliminary injunction ('PI') proceedings brought by Novartis AG, the Court of Appeal of Amsterdam confirmed that Pharmathen must pay €7,500,000 in penalties forfeited for breach of an injunction imposed for patent infringement. This judgment of the Court of Appeal upholds the first instance PI decision of 12 December 2022.<sup>1</sup>

Novartis was the proprietor of EP 2 337 519 B1 ('EP 519') for a long-acting release product with octreotide ('the LAR product'), which expired on 18 November 2023. A Greek subsidiary of Pharmathen Global BV ('Pharmathen') also made a LAR product. In proceedings in 2019, the Greek court ruled that the Greek subsidiary did not infringe EP 519. Novartis then went to the Dutch court in The Hague and sued Pharmathen for facilitating the infringement of the Greek subsidiary and independently infringing EP 519.

On 19 July 2022, the District Court of The Hague had ruled that there is the threat that Pharmathen would induce its Greek subsidiary Pharmathen SA to infringe EP 519 and, by doing this, commit an unlawful act *vis-à-vis* Novartis. The court ordered Pharmathen to cease and desist from (i) inducing the

infringement of EP 519 by its Greek subsidiary, and (ii) infringing EP 519, subject to an incremental penalty payment of €100,000 per day.

On appeal, the Court of Appeal in The Hague ruled on 15 November 2022 that Pharmathen had in fact itself infringed EP 519 by exercising control over the infringing acts committed by the Greek subsidiary, and it confirmed the order to cease and desist from infringing EP 519. Currently, this decision is up for review by the Supreme Court of the Netherlands and is expected on 27 September 2024. In addition, the case on the merits in first instance was set for 1 May 2024.

After the PI decision at first instance, Novartis found that Pharmathen had breached the injunction, by (i) sending infringing products to Guatemala and (ii) not removing the LAR-product in the Global Products Catalogue 2021 on the CPHI website. Novartis notified Pharmathen on 12 August 2022 that €7,500,000 in penalties had been forfeited as a result of the breach. This incited the second round of PI proceedings, this time before the District Court of Amsterdam. On 12 December 2022, the PI court in first instance confirmed that Pharmathen must pay the €7,500,000 for breach of the preliminary injunction.

Pharmathen lodged an appeal at the Court of Appeal of Amsterdam, which confirmed the first instance decision on 26 March 2024. The Court of Appeal first considered that 'offering' has to be interpreted broadly. In line with the first instance decision, it concluded that the fact that the 2021 Catalogue with the LAR product could still be found on the CPHI website was considered an act of 'offering' and therefore infringement. The Court of Appeal rejected Pharmathen's argument that a new Global Products Catalogue 2022 had been published without the LAR product and that buyers would interpret this publication as a withdrawal of the 2021 Catalogue.

1) ECLI:NL:GHDHA:2022:2327.

The Court of Appeal was also unconvinced by the explanation of Pharmathen that the LAR products had been sold by Pharmathen's Greek subsidiary to Costa Rica prior to the PI decision, and subsequently by a third party from Costa Rica to Guatemala, as proof of this was not provided and Pharmathen had not provided a reasonable explanation why Greece, instead of Costa Rica, was specified as the country of origin in the Guatemalan public records.

This case shows again how important it is, when a patent infringement injunction is issued, to exercise great care to ensure that everything which may be considered an infringing act is completely discontinued. This includes searching for any remaining promotional or informative material regarding the infringing products which can be found on third-party websites or via the Wayback Machine.