

EIP

UPC denies provisional injunction on insulin pump

Insulet Corporation v. EOFLOW Co., Ltd. (UPC_CFI_380/2024 relating to EP4201327)

Order of 22 November 2024 (ORD 56716/2024 [1])

This Decision from the Court of First Instance of the Unified Patent Court Central Division in Milan relates to EP4201327, which is registered as a Unitary Patent. The Applicant, Insulet Corporation ("Insulet"), requested an ex parte provisional injunction against EOFLOW Co., Ltd. ("EOFLOW") on 3 July 2024.

Insulet requested an order to stop EOFLOW from selling, possessing and distributing the allegedly infringing insulin pump, EOPatch, in the territories of the UPC Member States covered by the Unitary Patent, and provide Insulet's counsel with documentation related to the origin and distribution channels of the allegedly infringing devices.

The Court denied the requested provisional injunction because of doubts regarding the validity of the patent in question and did not allow Insulet to amend the patent in the proceedings for provisional measures.

Application for ex parte injunction

In February 2023, Insulet obtained a separate provisional injunction against the main German distributor of EOPatch, BERLIN-CHEMIE AG, based on the German part of EP1874390B1. BERLIN-CHEMIE AG is part of the Menarini Group, with MENARINI Diagnostics s.r.l. ("Menarini") being the main distributor of EOPatch in Europe.

The initial outcome of a separate preliminary injunction in the USA, later overturned on appeal, led to an announcement from Menarini in November 2023 informing its customers of its intention to stop selling EOPatch.

Following a press release from Menarini dated 24 May 2024 announcing the resumption of distribution of EOPatch, and the grant of Insulet's patent EP4201327 on 19 June 2024, Insulet filed a request for a provisional injunction against EOFLOW on the basis that EOFLOW's EOPatch insulin pump fell entirely within the scope of EP4201327.

Insulet argued the need of urgent preliminary measures following the imminent resumption of distribution of EOPatch in UPC Member States including Belgium, Luxembourg, Sweden and the Netherlands. Insulet requested provisional measures to be ordered without hearing the other party (Rule 206.3 RoP), claiming that the distribution of EOPatch would have negated 20 years of work and investment, causing a damage that could scarcely be remedied by the outcome of the infringement proceedings.

Upon consideration of the potential harm for either of the parties (Rule 62 UPCA), and in accordance with Rule 209.1 RoP, which is to be applied even when the application is made pursuant to Rule 206.3 RoP, the Court declined to decide the case *ex parte* and invited EOFLOW to lodge an objection to the application for provisional measures.

EOFLOW filed an objection, arguing that:

- there was no need for a provisional injunction, as no invasion of the market could occur within one year, the expected timeframe for issuing a Decision on the merits, given EOFLOW's low market share of 0.25% and the fact that its products were prized comparably to Insulet's;
- EP4201327 should be considered invalid in light of prior art references US2009/0124994 and WO2010/055504A1.

Parallel cases

Insulet filed a separate application for a provisional injunction against Menarini before the Milan Local Division [2] on 8 July 2024, with similar requests and arguments.

EOFLOW subsequently filed a request for a Connection Joinder (Rule 340 RoP) between the two cases on 26 August 2024, which was rejected by the Court by order of 4 September 2024. A subsequent application for review of this order (RoP 333) was also rejected [3].

Following the Court's Decision, Menarini filed an application to intervene in proceedings against EOFLOW on 16 September 2024, arguing that the Decision of the case would have

affected Menarini's interests based on its contractual relationship with EOFLOW and the customers. The Court did not grant Menarini's request, considering that Menarini could sufficiently achieve its objectives in the parallel proceedings and should be given no double possibility to represent the case in front of two different Courts. Insulet was awarded costs against Menarini for this unsuccessful attempt [4].

Amendments

Following the objections from EOFLOW based on these prior-art documents that were not considered in EPO prosecution, Insulet submitted auxiliary requests for the amendment of the claims in its submission of 27 August 2024 and then in its submission of 16 September 2024.

The Court considered whether the amendments submitted by Insulet would qualify as amendments to the patent claims (Rule 30 RoP) or amendments to the pleadings in the provisional injunction (Rule 263 RoP). The Court dismissed Insulet's argument that the proposed amendments were modifications to the pleadings, and decided that Rule 30 RoP should be applicable, as the amendments fell under the scope of patent amendments.

The Court ruled that the nature of provisional measures is time-sensitive, and therefore unsuitable for accommodating patent amendments. Moreover, allowing Insulet to modify the patent during provisional injunction proceedings, where there is no risk of patent revocation, would have given Insulet an unreasonable procedural advantage in the form of reframing the claims to specifically address the infringement without a risk of a ruling on patent invalidity.

Validity examined before infringement

As a requirement for granting provisional measures, an applicant must provide evidence to satisfy the Court with a sufficient degree of certainty of:

- its entitlement to initiate proceedings under Art. 47 UPCA;
- validity of the patent;
- existence of the alleged infringement, or imminence of such infringement (Rule 211.2 RoP).

The Court decided to examine the validity of EP4201327 before assessing infringement, based on:

- procedural efficiency, following the superfluous nature of an infringement assessment in the presence of strong evidence suggesting invalidity of a patent;

- the requirement for a swift Decision for a provisional injunction superseding the need for an in-depth inquiry;
- the fact that the patent seemed to be subject to amendments, suggesting that the prior art presented by EOFLOW was relevant to patentability.

The Court stated that the validity of EP4201327 was uncertain for the purpose of RoP 211.1 in view of US2009/0124994, as all features claimed in EP4201327 seemed to have been disclosed.

Insulet's counterargument emphasized the differences between EP4201327 and US2009/0124994, and raised concerns over some of the features of US2009/0124994 that allegedly made the device unworkable.

The Court rejected Insulet's counterargument and decided that the subject matter of claim 1 of EP4201327 was unlikely to be considered novel in light of US2009/0124994.

Decision

The Court rejected the application for a provisional injunction. Insulet was required to bear the costs of the proceedings pursuant to Art. 69 UPCA and Rule 118.5. RoP. The value in dispute was set at € 2,500,000.00 and the ceiling for the reimbursable representation costs was set at € 400,000.00.

The Court reached a similar Decision on the request for a provisional injunction against Menarini before the Milan Local Division [2] on 22 November 2024, dismissing the application for provisional measures, ordering Insulet to pay an amount of € 117,465.00 as an interim award of costs and setting the value in dispute at € 2,500,000.

[1] <https://www.unified-patent-court.org/en/node/1270>

[2] <https://www.unified-patent-court.org/en/node/1266>

[3] <https://www.unified-patent-court.org/en/node/1133>

[4] <https://www.unified-patent-court.org/en/node/1363>