

EIP

Auxiliary claim requests inadmissible and indicative of likely invalidity in applications for provisional measures.

ONWARD Medical N.V. v. Niche Biomedical, Inc.,

UPC_CFI_693/2025 (Munich LD), decision of 17 October 2025[1]

- **Introduction**

In UPC_CFI_693/2025, the Munich Local Division of the Unified Patent Court refused a patentee's request for preliminary injunctive relief against an alleged infringer, due to serious doubts about the patent's validity. The case concerned European Patent EP 3 421 081 B1, titled "System zur Neuromodulierung" ("System for Neuromodulation"), which covers a medical device system delivering electrical stimulation to a patient's nervous system in pre-programmed spatial and temporal patterns. The decision – issued on 17 October 2025 by the Munich local division (Panel 1, Presiding Judge Dr. Matthias Zigann) – addresses whether a patent proprietor can obtain interim injunctive relief based on amended (narrowed) patent claims when the original granted claims face validity challenges. In summary, the patent owner's attempt to rely on auxiliary claim versions was rejected, and the application for an interim injunction was denied.

- **Facts of the Case**

The claimant, ONWARD Medical N.V., is the registered proprietor of European Patent EP 3 421 081 B1, filed in 2017 and granted in 2020. The patent covers a neuromodulation system delivering pre-programmed electrical stimulation patterns to a patient's nervous

system. The defendant, Niche Biomedical, Inc. (doing business as “Aneuvo”), a US-based medtech company, markets the “ExaStim” neurostimulation system in Germany and France.

On 30 July 2025, Onward applied for a preliminary injunction under Article 62 UPCA, alleging that the ExaStim system infringed claim 1 of its patent. The application sought urgent injunctive relief, including a cease-and-desist order, product seizure, and disclosure of distribution details. The accused product included the ExaStim Stimulator, programmer, ReCure electrode pad, and cable.

Niche had already filed a protective letter on 25 July 2025 and, in response to Onward’s application, contested the injunction, arguing that claim 1 lacked novelty over prior art, particularly US 2016/0263376 A1 (“Yoo”). Niche asserted that these disclosures already taught the core features of the claimed system, including spatial and temporal stimulation patterns and variable parameters.

To counter the validity challenge, Onward submitted eight auxiliary claim versions on 29 August 2025, requesting that the court consider these narrowed claims as alternative grounds for granting the injunction. Niche opposed this, arguing that such amendments were procedurally improper in interim proceedings and further demonstrated the weakness of the granted patent.

- **Court’s Reasoning and Decision**

The Munich Local Division denied the request for preliminary measures in its entirety. It found that Onward failed to meet the requirements for a UPC interim injunction, chiefly because the patent’s validity was not “sufficiently secure” in the court’s view. The auxiliary (alternative) claim requests were also refused as inadmissible and unjustified in this summary procedure.

1. Validity and Likelihood of Success

To grant a preliminary injunction, the UPC Agreement (Art. 62(4) UPCA) and the UPC’s Rules of Procedure require the court to “satisfy itself with a sufficient degree of certainty” that the patent is likely valid and infringed (in addition to considering urgency and balance of harm). The Court of Appeal has held that this standard means the judge must deem it “at least more likely than not” that the patent will withstand validity scrutiny (UPC_CoA_335/2023, order of 26 February 2024[2]). In this case, after a summary assessment, the Munich panel was not convinced that the patent-in-suit was more likely than not valid in its granted form.

- **Validity Doubts (Novelty over “Yoo”):** The decision underscores that there were “significant doubts”

as to the novelty of claim 1 of EP 3 421 081 B1 in light of the prior art Yoo publication, Art. 54 EPC. Upon comparing claim 1 to Yoo, the court concluded that all essential elements of the claimed neuromodulation system were already disclosed in Yoo's system. In particular, Yoo describes a neurostimulation device with a controller and memory storing stimulation protocols, an array of electrodes interfacing with the patient's body, and the ability to deliver spatial-temporal patterns of stimulation that vary over time according to a stored therapy program.

- Given that Yoo appeared to disclose each contested element of claim 1, the court was not persuaded of the patent's probable validity. On the contrary, it found it more likely that claim 1 as granted was anticipated (and thus not novel) over the prior art. This finding alone doomed the injunction request. The court emphasized that it had no need to evaluate the patent in any hypothetically amended form at this stage – its validity assessment focused strictly on the patent as granted.

Because the lack of likely validity was clear, the decision does not delve into a detailed infringement analysis or other PI factors. The failure to clear the validity hurdle was sufficient to reject the application.

2. Auxiliary Requests for Amended Claims

The most significant part of the decision addresses the patentee's auxiliary requests (the attempt to salvage the injunction by narrowing the patent claims during the PI proceeding). The Munich Local Division took a strict stance on this issue:

- **Admissibility in Principle:** The court acknowledged that procedural rule 263 RoP allows a party to amend its case or requests in the course of proceedings, and this rule applies in principle even to provisional (interim) proceedings. Indeed, the UPC Court of Appeal in a 2024 decision had confirmed that a claimant could modify or expand the relief sought at the interim stage (in that case, the addition of a request for provisional cost reimbursement was permitted) (see UPC_CoA_182/2024[3]). By analogy, filing auxiliary requests proposing an amended claim scope is not procedurally barred in a PI per se.
- **Substantive Treatment:** No PI if Patent "Needs" Amendment: However, the court drew a crucial distinction between what is procedurally admissible and what is substantively justified in a preliminary injunction context. It held that if a patent requires an amended claim to be (probably) valid, then by definition no injunction can be issued on that patent in its original form. In other words, the need for an auxiliary request signals a fatal weakness in the patent under the stringent standard for preliminary relief. The judges reasoned as follows:
 - They emphasized that the summary PI procedure is not intended to grant

measures on the basis of a patent that is evidently deficient in its granted claims. The patent to be enforced in a PI must be already robust, not one that might become valid after a notional fix. Granting an injunction on a corrected version of a claim would essentially amount to protecting a different patent than the one that was examined and granted. The only patent relevant in a PI is “the patent as it stands at the time of the application” (i.e. the granted patent or its current form). The court cited its earlier decision UPC_CFI_17/2023 (10 October 2023) which likewise made clear that the requisite confidence in the patent’s validity under Art. 62(4) UPCA and Rule 211(2) RoP refers to the patent as granted, not to any hypothetically amended version.

- **Rule 30 vs. Preliminary Relief:** The decision draws an analogy to revocation (nullity) proceedings, where Rule 30 RoP does allow a patent to be amended (claims narrowed) in response to validity attacks. That scenario is fundamentally different: in a nullity action or counterclaim, the question “can the patent be saved by amendment?” is squarely in issue. By contrast, in a preliminary injunction setting, such substantive claim amendments are not contemplated – Rule 30 does not apply to provisional measures under Art. 62 UPCA. The court flatly stated that alternative claim versions “are not objects of examination” in a PI proceeding. The patent either stands on its granted claims or the request for urgent relief fails.
- The Munich panel underscored that this approach is not unduly harsh on patentees, but rather a logical consequence of the patentee’s own responsibilities. It is chiefly the patent proprietor’s job to ensure the patent is granted in a form that is legally sound. If there were mistakes or over-broad claims in prosecution, remedies exist (e.g. post-grant amendments or limitations) at later stages – but the patentee cannot expect to enjoy “full” and immediate enforcement “at any time” from a patent that was granted with substantial defects. In a notable passage, the court stated that it is not an intolerable hardship for the patentee to withhold injunctive relief in such cases; the patentee “had it in their hands” to obtain a resilient patent, and if they failed to do so, they cannot demand urgent relief on a faulty claim.
- Consequently, Onward’s auxiliary requests 1–8 were all rejected. The court declined to consider the merits of those narrowed claims since, having found the original claim likely invalid, it would not switch to evaluating alternative patent scopes in this summary forum. The preliminary injunction was refused outright on the basis of the doubtful validity of the granted patent, and that outcome could not be cured by tweaking the claims.

Overall, UPC_CFI_693/2025 (Onward Medical v. Niche Biomedical) aligns with the principle that interim relief is an extraordinary measure – available only for patents that

appear both infringed and likely to withstand validity challenges. The ruling also provides valuable clarity that auxiliary claim requests are generally futile in such proceedings, thereby encouraging patent owners to ensure their granted claims are litigation-ready if they intend to seek rapid enforcement. The Munich court's approach in this case will likely serve as persuasive authority for other UPC divisions faced with similar attempts to introduce claim amendments at the PI stage, until the Court of Appeal weighs in definitively on this issue.

[1] <https://www.unifiedpatentcourt.org/en/node/159629>

[2] As reported on here:

[https://eip.com/global/latest/article/why did the court of appeal reverse the local division injunction](https://eip.com/global/latest/article/why-did-the-court-of-appeal-reverse-the-local-division-injunction)

[3] <https://www.unifiedpatentcourt.org/en/node/1248>