



On June 1, 2023, the new European Unified Patent Court (UPC) opened its doors, and enforcement of European patents in (currently) 17 contract member states is now possible with one action. This series of articles – directed at U.S. practitioners trying to familiarize themselves with the basic features of the UPC – aims to provide a high level view of the key aspects of the UPC system, compare them to patent litigation in the U.S., and consider their implications on U.S.-European parallel patent litigation.

To read other articles in this series, see here.

This part of the series discusses the procedural options for challenging the validity of a patent in the UPC. One focus of the discussion is the procedural scenario many alleged infringers aim for: a stay of the infringement case until their challenge of the asserted patent's validity is decided.

There are three procedural ways to challenge the validity of a patent in the UPC: by way of a counterclaim for revocation in response to an infringement claim, by way of a revocation action, or by way of an opposition (if still available) in the European Patent Office.

### **COUNTERCLAIM FOR REVOCATION**

In a U.S. infringement action, the defendant routinely raises the affirmative defense of invalidity and, in many cases, a counterclaim for a declaration of invalidity. Comparably, the defendant in a UPC infringement action, which is brought in one of the UPC's local or regional divisions,<sup>1</sup> may bring a counterclaim for revocation of the patent in suit.

<sup>&</sup>lt;sup>1</sup> See UPC Agreement, Article 33(1).

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The requirements of a counterclaim for revocation in the UPC are much stricter than those of a counterclaim of invalidity in the U.S. In the U.S., the assertions of invalidity in a declaratory judgment counterclaim must meet the plausibility standard of the Supreme Court's Twombly/Iqbal decisions ("sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face"2), and in some U.S. district courts, an affirmative defense of invalidity need not even reach the Twombly/Igbal standard.3 The party challenging validity in a U.S. court typically will not be required to disclose its detailed invalidity contentions until later during the fact and expert discovery phases of the litigation. In the UPC, in contrast, the counterclaim for revocation must, among other requirements, contain the grounds for revocation, including legal arguments and claim construction positions, an indication of the facts and evidence relied on or expected to be offered, as well as witness statements.4 And, the defendant must pay the same fee as the plaintiff paid for the infringement action, though capped at €20,000.5

Responding to the counterclaim of revocation, the plaintiff files a defense to the counterclaim for revocation within two months, with substantive requirements comparable to the counterclaim.<sup>6</sup> If the plaintiff is not the owner of the patent,<sup>7</sup> the counterclaim for revocation is served on the owner, who then becomes a party to the revocation proceedings.<sup>8</sup> The defendant's reply, within two months, and the plaintiff/proprietor's rejoinder, within one month, follow.<sup>9</sup>

In a U.S. infringement action, the patent owner cannot amend its claims; that option is only available in proceedings at the Patent and Trademark Office (see below). In the UPC, in contrast, the patent owner, in its defense against the counterclaim, may also include an application to amend the patent.<sup>10</sup> The patent may not be amended in such a way as to include new subject

<sup>2</sup> See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 556, 570 (2007)).

matter, or to extend the scope of patent protection.<sup>11</sup> The application must contain the proposed amendments to the claims and may include one or more alternative sets of claims ("auxiliary requests"); additionally, the applicant must explain why the amendments are allowable, and why the amended claims are valid and, if applicable, infringed.<sup>12</sup> If only conditional, the proposed amendments must be reasonable in number.<sup>13</sup>

Within two months, the defendant files a defense to the application to amend. Apart from arguing that the proposed amendments are not allowable and/or that the patent cannot be maintained as requested – and supporting such arguments, again, with grounds for revocation, legal arguments, claim construction positions, indications of the facts and evidence relied on or expected to be offered, as well as witness statements – the defendant may make alternative non-infringement arguments with respect to the proposed amendments. The proprietor may then file a reply within one month, and the defendant a rejoinder within another month, closing the written procedure.

In the U.S., both the infringement and invalidity issues proceed in the district court. However, many defendants aim for a stay of the district court action by petitioning an *inter partes* review (IPR) in the Patent and Trademark Office (discussed below in more detail) and then moving the district court to stay the litigation. Many courts are receptive to such a motion, expecting that the PTO's decision on validity will simplify, or even moot, the district court case. The chances of a motion to stay are even higher if the *inter partes* review has already been instituted by the PTO – making a PTO decision a certainty rather than a mere possibility – and if the district court action has not yet advanced significantly.

In the UPC, after all of the mentioned briefing is done and the written procedure is closed, the panel of the respective local/regional division (not only the judge-rapporteur) decides how to proceed with the case. In doing so, it has the discretion to steer the proceedings in significantly different directions, and it can be expected that parties will argue for their preferred option vigorously.

<sup>&</sup>lt;sup>3</sup> U.S. courts are divided regarding whether the *Twombly/Iqbal* plausibility standard applies to affirmative defenses.

<sup>&</sup>lt;sup>4</sup> See UPC Rules of Procedure (RoP), Rule 25.

<sup>&</sup>lt;sup>5</sup> See RoP, Rule 26; UPC Administrative Committee, Table of Court Fees (8 July 2022), Section III.

<sup>&</sup>lt;sup>6</sup> See RoP, Rules 29(a) and 29A.

<sup>&</sup>lt;sup>7</sup> See UPC Agreement, Articles 47(2) (unless provided otherwise in the license agreement, an exclusive licensee is entitled to bring actions) and 47(3) (a non-exclusive licensee may bring actions in so far as expressly permitted by the license agreement).

<sup>&</sup>lt;sup>8</sup> *See* RoP, Rule 25.2.

<sup>&</sup>lt;sup>9</sup> See RoP, Rules 29(d) and (e).

<sup>&</sup>lt;sup>10</sup> See RoP, Rule 30.

<sup>&</sup>lt;sup>11</sup> See RoP, Rule 30.1(b); Articles 123(2) and (3), European Patent Convention.

<sup>&</sup>lt;sup>12</sup> See RoP, Rule 30.1(a) and (b).

<sup>&</sup>lt;sup>13</sup> See RoP, Rule 30.1(c).

<sup>&</sup>lt;sup>14</sup> See RoP, Rule 32.1 and .2.

<sup>&</sup>lt;sup>15</sup> See RoP, Rule 32.3.

<sup>&</sup>lt;sup>16</sup> See UPC RoP, Rule 37.1.

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**First**, the local/regional division can proceed with both the infringement and revocation claims<sup>17</sup> – structurally comparable to a U.S. district court action proceeding without staying any part of the case. While the U.S. case often proceeds in front of a judge who is not technically trained and a jury that consists of laypeople, in the UPC, a technically qualified judge with qualifications and experience in the field of the concerned technology is added to the panel, unless one was already added before; the panel then consists of three legally qualified judges and one technically qualified judge.<sup>18</sup>

**Second**, the local/regional division can refer the revocation counterclaim to the central division<sup>19</sup> (a U.S. district court has no comparable way of referring the invalidity issues to another forum). Unless a technically qualified judge is requested by one of the parties or the panel itself, the panel of the local/regional division then consists of three legally qualified judges.<sup>20</sup> The panel of the central division consists of two legally qualified judges and one technically qualified judge.<sup>21</sup>

If the revocation counterclaim is referred to the central division, the local/regional division may either proceed with the infringement action, or suspend (or "stay") it pending a final decision in the revocation proceedings.<sup>22</sup> The local/regional panel "shall" stay the infringement proceedings "where there is a high likelihood that the relevant claims of the patent will be held to be invalid on any ground by the final decision in the revocation proceedings."<sup>23</sup> Neither the UPC Agreement nor the Rules of Procedure give any further guidance on what factors the court should consider in deciding whether to stay the infringement case or not. In the context of a potential stay in light of parallel opposition proceedings in the European Patent Office (EPO) (see below), the Central Division (Munich) recently explained that "in exercising its discretionary power the UPC must observe the principles of proportionality, flexibility, fairness and equity."24

In the U.S., "[d]istrict courts typically analyze stays under a three-factor test: (i) whether a stay would un-

to the non-moving party; (ii) whether a stay will simplify the issues in question and trial of the case; and (iii) whether discovery is complete and whether a trial date has been set."<sup>25</sup> Broadly speaking, these factors – prejudice to the plaintiff, simplification of the issues, and timing considerations – seem equally applicable in the UPC context, and it can be expected that parties in the UPC will develop and present respective arguments to the court.

duly prejudice or present a clear tactical disadvantage

In U.S.-UPC parallel litigation, it will be interesting whether courts in either jurisdiction will consider the status of a challenge of the corresponding patent in the other jurisdiction. For example, if the European member of a patent family is subject to a UPC revocation counterclaim that will be decided fairly soon, and the U.S. member of the same patent family is in suit in a U.S. district court action, will the U.S. court give the impending UPC decision any weight in deciding whether to stay the case?

A revocation claim that was referred to the central division is, depending on the classification of the challenged patent (or the common classification of the majority of the challenged patents), assigned to one of the three sections of the central division<sup>26</sup> – Paris (e.g., for patents with International Patent Classification H – Electricity), Munich (e.g., class F – Mechanical Engineering), or Milan (A – Human Necessities).<sup>27</sup> The central division's "judge rapporteur" for the matter may direct further conduct of the written procedure (i.e., presumably to request further briefing) or request translations of (all or only parts of the) written pleadings into the language of the challenged patent<sup>28</sup> – a potentially costly proposition, considering the substantial extent of briefing during the written procedure in the local/regional division. If the infringement action in the local/regional division was not stayed, the central division accelerates its revocation proceedings and "shall endeavor" to hold its oral hearing prior to the oral hearing in the infringement action.29 The UPC thereby tries to avoid a gap between the grant of remedies in the infringement action, in particular an injunction, and a decision on the validity of the asserted patent (often referred to as the "injunction gap" in patent practice under the bifurcated German system).

<sup>&</sup>lt;sup>17</sup> See UPC Agreement, Article 33(3)(a).

<sup>&</sup>lt;sup>18</sup> See UPC Agreement, Article 8(2)-(5).

<sup>&</sup>lt;sup>19</sup> See UPC Agreement, Article 33(3)(b).

<sup>&</sup>lt;sup>20</sup> See UPC Agreement, Article 8(2)-(5).

<sup>&</sup>lt;sup>21</sup> See UPC Agreement, Article 8(6).

<sup>&</sup>lt;sup>22</sup> See UPC Agreement, Article 33(3)(b); UPC Rules of Procedure (RoP), Rule 37.4.

<sup>&</sup>lt;sup>23</sup> See UPC RoP, Rule 37.4.

<sup>&</sup>lt;sup>24</sup> See UPC\_CFI\_80/2023, <u>ORD\_579547/2023</u> (Central Division Munich, November 20, 2023), pp. 4-5.

<sup>&</sup>lt;sup>25</sup> Murata Mach. USA v. Daifuku Co., 830 F.3d 1357, 1361 (Fed. Cir. 2016).

<sup>&</sup>lt;sup>26</sup> See RoP 38(a) and 17.3.

Decision of the Administrative Committee under Article 87(2) UPCA amending the Agreement (26 June 2023).

<sup>&</sup>lt;sup>28</sup> See RoP 38(c) and 39.

<sup>&</sup>lt;sup>29</sup> See RoP 40.

**Third**, with the agreement of both parties, the local/regional division can refer the entire case to the central division.<sup>30</sup> It seems, however, unlikely that parties will often so agree; usually, either one of the parties will perceive an advantage in having the infringement claim decided in the local/regional division, unless it wants to avoid a stay of the infringement action. The composition of the central division's panel, in case of referral of the entire case, is the same as when only validity is in front of it: two legally qualified judges and one technically qualified judge.<sup>31</sup>

Over time, it can be expected that different local/regional divisions will develop different preferences between proceeding with the entire case or referring the revocation counterclaim to the central division, and in the latter case, between suspending or proceeding with the infringement action. Much like plaintiffs in the U.S. pay close attention to a district court's practice with respect to, for example, the court's willingness to stay cases due to inter partes review proceedings,32 prospective plaintiffs in the UPC will closely monitor these emerging preferences and factor them into their venue selection strategy: a local/regional division that has a history of proceeding with the entire case will presumably be more popular with plaintiffs than one that has a history of referring the revocation counterclaim to the central division and suspending the infringement action. That expected calculation by future plaintiffs, in turn, may provide an incentive for local/ regional divisions that would like to attract new cases, at least in the beginning phases of the UPC system, to choose the option of proceeding with the entire case.

## **REVOCATION ACTION**

Comparable to a U.S. action for declaratory judgment of invalidity of a patent, a party can also file an independent revocation action in the UPC.<sup>33</sup> Such an action can be filed by any natural or legal person "who is concerned by a patent"<sup>34</sup> – a requirement that is unlikely to be interpreted as a high hurdle, although it remains to be seen whether challenges by "strawmen" will be allowed. In contrast, the standing required to bring a declaratory judgment action in the U.S. is a significant

<sup>30</sup> See UPC Agreement, Article 33(3)(c).

barrier; courts require that "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."<sup>35</sup>

Generally, a UPC revocation action is to be filed in the central division.<sup>36</sup> However, if an infringement action between the same parties relating to the same patent is already pending in the local/regional division, a revocation action must be brought there.<sup>37</sup> In a recent case, a parent corporation was the defendant in an infringement action pending in the Munich local division, and had brought a revocation counterclaim there. Its wholly-owned subsidiary then filed a separate revocation action against the same patent in the central division. The central division held that parent and subsidiary were not to be considered the "same party" and the subsidiary's revocation action could therefore proceed in the central division.<sup>38</sup> It therefore seems that parties have room for procedural maneuvers to avoid the bundling of infringement and invalidity claims at the local division.

In turn, if a revocation action is already pending before the central division, an infringement action between the same parties relating to the same patent may be brought before a local/regional division or the central division; if brought before a local/regional division, that division has the discretion to proceed in one of the three ways described above for a revocation counterclaim.<sup>39</sup> In case the infringement action proceeds in the local/regional division and the revocation action in the central division, the local/regional division may render its decision on the merits of the infringement claim under the condition that the patent is not held to be wholly or partially invalid in the revocation proceedings.<sup>40</sup>

A revocation action is started by the claimant's "Statement of revocation." Similar to a counterclaim for revocation, it must contain, among other things, the grounds for revocation, including legal arguments and claim construction positions, an indication of the facts and evidence relied on or expected to be offered, as

<sup>&</sup>lt;sup>31</sup> See UPC Agreement, Article 8(6).

<sup>&</sup>lt;sup>32</sup> As an example, the popular Waco-division of the Western District of Texas is notoriously reluctant to stay cases because of *inter partes* review proceedings.

<sup>33</sup> See UPC Agreement, Article 32(1)(d).

<sup>&</sup>lt;sup>34</sup> See UPC Agreement, Article 47(6).

<sup>&</sup>lt;sup>35</sup> MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007).

<sup>&</sup>lt;sup>36</sup> See UPC Agreement, Article 33(4).

<sup>&</sup>lt;sup>37</sup> See UPC Agreement, Article 33(4).

<sup>&</sup>lt;sup>38</sup> See UPC\_CFI\_255/2023, <u>ORD\_578356/2023</u> (Central Division Paris, November 13, 2023).

<sup>&</sup>lt;sup>39</sup> See UPC Agreement, Article 33(5).

<sup>&</sup>lt;sup>40</sup> RoP, Rule 118.2(a).

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well as witness statements.<sup>41</sup> The fee for bringing a revocation action is fixed at €20,000.<sup>42</sup> Within two months, the defendant files a defense to revocation, with substantive requirements comparable to the counterclaim.<sup>43</sup> The claimant's reply, within two months, and the defendant's rejoinder, within one month, follow.<sup>44</sup>

As in the case of a counterclaim for revocation, the defendant, in its defense to revocation, may include an application to amend the patent. The requirements discussed above for such an application and the challenger's defense to such an application in the context of a counterclaim for revocation equally apply in the context of a revocation action.

In its defense to revocation, the defendant may also include a counterclaim for infringement; it must include the same substantive requirements as a claim in an infringement action (including instances of the alleged infringement, the identification of the asserted claims, legal arguments and claim construction positions, an indication of the evidence relied on or expected to be offered, as well as witness statements), as well as pay the applicable fee. Within two months, the claimant files a defense to the counterclaim for infringement, with comparable substantive requirements as the counterclaim; the parties may then file reply and rejoinder, respectively. 46

# OPPOSITION IN THE EUROPEAN PATENT OFFICE

In parallel to a district court action, accused infringers in the U.S. often challenge the validity of the asserted patent in the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office. If within 9 months of grant, the challenge can be raised in postgrant review (PGR) proceedings; thereafter (and statistically much more often), in *inter partes* review (IPR) proceedings. Among other advantages over seeking invalidity in the district court, IPR proceedings are usually cheaper than litigating validity in a district court, are decided by a panel of three technically trained

judges specialized in patent law, and are subject to a lower standard of proof on the challenger (preponderance of the evidence) than in court (clear and convincing evidence). And, as discussed above, they are often the basis for the procedural posture many defendants aim for: the suspension of the infringement case in the district court until the IPR proceedings are decided.

On the other hand, while the patent owner cannot amend their claims in district court, they can do so in IPR proceedings. Moreover, if the PTAB concludes in an IPR that a patent claim is patentable, the petitioner (along with any other "real party in interest" and those in privity) will be estopped from challenging the validity of the claim in a district court, the ITC, or any other patent office proceeding, such as another IPR or an *ex parte* reexamination, based on any prior art that reasonably could have been raised during the IPR.

A UPC-defendant can also challenge the patent in the patent office that granted it – but only if the short time window for doing so has not closed yet: If still within 9 months of the publication of grant, the patent may be challenged by an opposition in the European Patent Office (EPO) – instead or in parallel to a revocation action or counterclaim in the UPC. Compared to the fees in the UPC (see above), the EPO's fees for opposition proceedings are significantly lower; furthermore, while costs are awarded to the winning party in the UPC, each party in EPO opposition proceedings generally bears its own costs, which reduces the financial risk of the patent challenger.<sup>47</sup> And, the patent challenger is not estopped from bringing the same arguments in each forum.<sup>48</sup>

A party must inform the UPC of any pending EPO opposition proceedings.<sup>49</sup> The court can then take the pending EPO opposition proceedings into account in various ways. For example, the court may stay its proceedings "when a rapid decision may be expected" from the EPO.<sup>50</sup> The Central Division recently stated that "what is to be considered 'rapid' has to be determined based on the facts and circumstances of every case," but explained that generally, "there should be a concrete expectation (i.e. a known date in time) for

<sup>&</sup>lt;sup>41</sup> See RoP, Rule 44.

<sup>&</sup>lt;sup>42</sup> See RoP, Rule 46; UPC Administrative Committee, Table of Court Fees (8 July 2022), Section III.

<sup>43</sup> See RoP, Rules 49 and 50.

<sup>44</sup> See RoP, Rules 51 and 52.

<sup>&</sup>lt;sup>45</sup> See RoP, Rules 50 and 13, and Rule 53. For a detailed discussion of fees, see Part 2 of this series of articles.

<sup>46</sup> See RoP, Rule 56.

<sup>&</sup>lt;sup>47</sup> See The Sedona Conference, Framework for Analysis for Resolution of Disputes before European Unified Patent Court, 24 SEDONA CONF. J. 219, 313-14 (2023).

<sup>&</sup>lt;sup>48</sup> See Schweighart/Stratmann/Vocke in Hoffman Eitle, The Unified Patent Court and Unitary Patent: A Practitioner's Handbook (2nd ed.) 250.

<sup>&</sup>lt;sup>49</sup> See UPC Agreement, Article 33(10).

<sup>&</sup>lt;sup>50</sup> See UPC Agreement, Article 33(10); RoP, Rules 118.2(b) and 295(a).

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a decision which date should be in the near future such that it is clearly expected to be delivered before an expected decision by the UPC."<sup>51</sup> The decision that is expected need not be final, the court explained, although "[t]he circumstance that a first instance EPO decision is likely to be appealed and that such an appeal is likely to take considerable time is nevertheless a factor that may be taken into account by the Court."<sup>52</sup>

In that case, Astellas was developing a certain cell product and initiated a revocation action to obtain clarity as to its freedom to operate as far as possible in advance of the launch of its product. In rejecting the patent owner Healios's request to stay the proceedings, the court concluded that Astellas's interests in proceeding with the revocation action outweighed patent owner's interests, at least at the time of the decision. It explained that Astellas had credibly established its interests in obtaining commercial certainty and that "[i]n general, and in particular where a product is being developed that requires significant and increasing investments over time, such as (undisputed) the Product in the present case, there is an interest to obtain such commercial certainty as early as possible."53 However, the court did indicate that it would revisit the issue of a potential stay at the interim conference in March 2024, when the EPO's decision would be available.54

As in the case of parallel revocation proceedings (see above), the local/regional division in infringement proceedings may also render its decision on the merits of the infringement claim under the condition that the patent is not held to be wholly or partially invalid by the EPO.<sup>55</sup> And, it may – at the request of a party or even of its own motion – request that the EPO opposition proceedings be accelerated in accordance with EPO rules, and stay the case pending the outcome of the request itself and any subsequent accelerated proceedings.<sup>56</sup>

#### CONCLUSION

Compared to a U.S. district court action, the front-loaded approach of the UPC's written procedure and the ability of the patent owner to amend claims are some of the most significant differences a party has to consider when challenging the validity of a patent in the UPC. As in the U.S., the UPC has considerable discretion to stay infringement-related proceedings in light of a validity challenge, and it can be expected that the different UPC-divisions' emerging approaches to staying cases will be a significant factor in a plaintiff's venue selection.

Georg Reitboeck and Mark Chapman are IP litigation partners at Haug Partners LLP in New York City.

 <sup>&</sup>lt;sup>51</sup> See UPC\_CFI\_80/2023, <u>ORD\_579547/2023</u> (Central Division Munich, November 20, 2023), p. 4.
<sup>52</sup> Id.

<sup>&</sup>lt;sup>53</sup> *Id.* at 5.

<sup>&</sup>lt;sup>54</sup> See id. at 6. Remarkably from a U.S. standpoint, the court further elaborated that it would contact the EPO "to explore if it would be feasible" for the EPO to render its written decision "well in advance" of the oral hearing in the UPC. See id.

<sup>&</sup>lt;sup>55</sup> See RoP, Rule 118.2(a).

<sup>&</sup>lt;sup>56</sup> See RoP, Rule 298.