EIP

Abbott v. Sibio: a tale of two applications for provisional measures

The Hague Local Division of the Court of First Instance of the UPC has recently issued two decisions concerning provisional measures involving the same parties - the Patentee Applicant, Abbott Diabetes Care, Inc., and the Defendants, Sibio Technology Limited and Umedwings Netherlands BV.

The Court granted provisional measures in UPC_CFI_130/2024 relating to EP2713879 (EP'879), despite the Defendants unilaterally offering a cease-and-desist declaration and denied provisional measures in UPC_CFI_131/2024 relating to European Patent EP3831283 (EP'283) on the basis that the patent is more likely than not invalid due to added matter. The Court's exercise of competence in respect of Ireland in the former and its adoption of EPO's "gold standard" added matter test in the latter is causing some flutters!

Background

EP'879 and EP'283 both relate to Continuous Glucose Monitoring (CGM) devices used in the management of diabetes. These patents were initially opted-out of the UPC but the opt-outs were withdrawn on 14 March 2024 just prior to filing applications for provisional measures on 20 March 2024.

Patentee Applicant (Abbott) is the main supplier of CGM devices in Europe with its FreeStyle Libre product having a market share of approximately 80%. Defendant 1 (Sibio) also manufactures CGM systems and entered the European market with its CGM device, GS1, at the end of 2023. The other Defendant was named as an EU importer.

Orders

EP'879 is in force in UPC contracting states Germany, France, the Netherlands and Ireland. Ireland has, of course, not yet ratified the UPC Agreement.

A Protective Letter concerning the patent was filed on September 2023 by a company linked to the Defendants stating that it (or a member of the group) would not infringe the patent by providing the GS1 devices in Contracting Member States. Abbott was provided with this Protective Letter upon lodging its application for provisional measures on 20 March 2024 and decided not to withdraw its application.

The Defendants did not challenge the validity of the patent or the alleged infringement. They also did not challenge the urgency of the application (until quite literally the very last minute) or the competence of the Court. Instead, the Defendants provided a cease-and-desist declaration with certain undertakings concerning the withdrawal of the GS1 device from the market in Germany, France and The Netherlands and argued that the application for provisional measures had, therefore, become devoid of purpose.

Interestingly, Abbott's application set out that "The Patent is valid and in force in the Contracting Member States of Germany, France, The Netherlands and also Ireland. It is also in force in the UK." **The Court read this to mean that Abbott wished the order to also cover Ireland** (but not UK), even though Ireland has not yet ratified the UPC Agreement. In this case (unlike the parallel case discussed below), **Defendants did not challenge competence of the Court with respect to Ireland.** According to Art. 31 UPCA (which provides that the international competence of the court is established in accordance with Brussels Regulation 1215/2012 as amended by EU Regulation 542/2014, "BR"), and Art. 26, 35 and 71, 71a and 71b BR, the Court considered it was competent to hear the case. The Court also noted that Art. 24 BR does not apply as no invalidity defence had been raised.

The **Court decided there was sufficient interest in the case despite the unilateral cease-and-desist declaration because Abbott demonstrated that Defendants were not fully complying with their own unilateral declaration** - Abbott was able to place an order for a GS1 device in both Germany and the Netherlands after this declaration and even after Defendant had apparently "reorganized its sales activities", Abbott was still able to purchase another GS1 device through a website where the GS1 device was offered in Dutch to the Dutch public. Moreover, any penalty payment in case of breaches of such declaration would require Abbott to initiate new proceedings before the Court instead of simply executing the order sought. Furthermore, since the **Defendant had already agreed to leave the markets where the patent is in force**, the Court did not find any

legitimate interest on their part in opposing the preliminary injunction sought. Abbott's interests therefore outweighed the defendant's interest and all conditions set out in R. 211 RoP regarding a preliminary Injunction were considered met.

A preliminary injunction and delivery up were ordered in respect of the GS1 device at issue. A financial penalty for failure to comply with the order was also provided for but at a reduced level to that sought by Abbott. Abbott's request for further information was denied as the Court did see sufficient interest for that in the context of these provisional measure proceedings and in view of the declaration already provided by the Defendants.

EP'283 was in force in several UPC contracting states including Ireland. Here, provisional measures were denied because the Court held that, on the balance of probabilities, the patent in question is more likely than not to be invalid due to added matter.

While arguing for provisional measures, Abbott contended that the patent was valid and independent claim 1 as well as several dependent claims were infringed by the Defendants. Unlike the case discussed above, here the **Defendants argued that the Court is not competent for Ireland**, the patent is not infringed and that the patent is (likely) invalid due to concerns regarding added matter, lack of novelty and lack of inventive step.

On the issue of Ireland, **Abbott indicated that it did not mean to include Ireland so the Court did not need to decide the issue of competence.** Therefore, this issue remains ripe for clarification in another case where jurisdiction of the court over Ireland is clearly requested and properly challenged.

The Court went on to consider validity and referred to R. 211.2 RoP in conjunction with Art. 62 (4) UPCA which provide that the Court may ask the applicant for provisional measures to satisfy the Court to a sufficient degree of certainty that the patent is valid and infringed or that such infringement is imminent. **A sufficient degree of certainty is lacking if the court considers on the balance of probabilities to be more likely than not that the patent is not valid.**

The Court found that, on the balance of probabilities, it is more likely than not that claim 1 of the patent will be held to add matter. Interestingly, the Court applied the long standing **"gold standard" disclosure test** applied by the EPO in coming to this conclusion because **both parties had relied on EPO's test and case law and had not indicated whether, and in which way, the court should apply a different test.** The court has left open the possibility of a different approach (perhaps in more contested borderline cases) but noted that EPO's approach is also followed by various national courts. It is worth noting that EPO Boards of Appeal often take a stricter view on added matter issues than

many national courts.

Applying the test to the facts of this case, the Court held that the combination of features as set out in claim 1 of the patent likely added matter. More specifically, patentee was relying on specific figures and embodiments from the description as basis for claim 1 and the Court held that certain specific features in claim 1 had been taken out of the disclosed context (recess recited in claim 1 only disclosed in combination with elastomeric seal in the description while such seal is not recited in the claim) thereby resulting in an **impermissible intermediate generalization.** Patentee's reference to other embodiments was also rejected by the Court as disclosures relating to different embodiments (working in a reverse way) which would have to be combined with the embodiment providing basis for claim 1 without any pointer for such a combination in the application. Hence, the claims relied upon by patentee were held to be more likely than not to add matter and provisional measures were denied.

Conclusion

The Court's conclusions in these two cases, involving the same parties and relating to the same devices, may seem counter-intuitive at first glance. There also seems to be some contradiction in the Court's position on competence with respect to Ireland. However, upon review of the facts and reasoning, it becomes clear that each order is very much in the context of the strength of the patent at issue and the requests of the parties in each case.

The Court's exercise of competence with respect to Ireland was in the context of no objection from the Defendants to such competence or indeed to the validity of the patent in question. In the matter where the Defendant objected to such competence, the patentee withdrew its request for Ireland so the Court did not need to decide this issue.

It is also interesting to see EPO added matter test and case law applied by the UPC. However, both parties used this approach so it was not controversial and the UPC can still very much develop its own unique approach to assessment of added matter if needed in the appropriate scenario.

Appeals on both cases are possible but more likely for EP'283 where provisional measures were denied as Defendants had already provided cease and desist undertaking in respect of EP'879.