

EIP

Injunction granted in 10x Genomics v NanoString

The UPC Local Division in Munich handed down a decision on 19 September 2023 following a hearing over two days on 5/6 September 2023, granting a provisional injunction against NanoString to restrain infringement of EP4108782 of which 10x Genomics is the licensee. This is by a wide margin the lengthiest judgment to have been issued by the UPC, running to over 100 pages, and is the first following a contested hearing held in public. For keen watchers of the UPC, it is interesting that the Decision appeared on the EPO's Unitary Patent Register^[1] in advance of the redacted version being published by the UPC on its website,^[2] so for Unitary Patents, the EPO Register seems to be the place to go for more up-to-date information.

The judgment has many interesting aspects.

First, the action was filed on 1 June 2023. This was before the formal grant date, being the date of publication of grant by the EPO in the Bulletin, namely 7 June 2023 (the earliest date on which a European Patent could grant and benefit from Unitary Effect). The decision on Unitary Effect was not taken until 12 June 2023, and published on the same day. The Court seems to have had no problem entertaining an action that was filed before the patent was granted, and indeed the Defendants do not seem to have challenged this.

Second, the UPC effectively conducted a mini trial of both validity and infringement. This is optional, but not mandatory, according to Rule 211(2) which provides "In taking its decision the Court **may** require the applicant to provide reasonable evidence to satisfy the Court with a sufficient degree of certainty that ... the patent in question is valid and that his right is being infringed..."

The defendants opposed the granting of a provisional injunction under many grounds.

These are considered in turn.

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Jurisdiction

The jurisdiction of the Munich local division was contested. This jurisdiction was established on the basis of the place of infringement pursuant to Article 32(1)(a) UPCA. The Court considered that relevant offers to supply did in fact take place, inter alia, in Germany, and therefore the chosen Division was indeed competent.

Admissibility

Many objections to the admissibility of the application for a provisional injunction were raised, but these were all dismissed by the Court. In one example, an allegation that the validity of the patent had not been substantiated according to Rule 206(2)(d), which in turn refers to Rule 211(2) quoted above, was considered an impermissible attempt to reverse the burden of proof onto the patent proprietor, whereas in fact the burden of proof on an allegation of invalidity of the patent would fall on the Defendants (according to Article 54 UPCA, which specifies that the burden of the proof of facts shall be on the party relying on those facts". More generally, the Court noted that an application for provisional measures cannot be dismissed as inadmissible because it is manifestly unfounded – in order to be admissible it needs only to formally satisfy the required content specified in Rule 206(2).

Entitlement of Applicants

The Defendants challenged the entitlement of both Applicants to bring the action. In relation to the second applicant, the patentee, allegations that certain contraventions under US law of the Bayh-Dole Act concerning ownership of inventions arising from government funded research (since the underlying research received NIH funding) were raised, but the Court was not convinced by these. In relation to the first Applicant, the licensee, the Court decided that it was not necessary to decide whether the licence was exclusive or non-exclusive, since either way a licensee was entitled to bring an action with the consent of the patentee, which had obviously been provided in this case.

Delay

The Defendants suggested that provisional measures should be refused on the grounds of delay, since the Applicants had requested delay of grant of the European application from which the patent derived, in order to be able to benefit from Unitary Effect. The Court considered that the clear advantages of a Unitary Patent justified this delay, and the action itself had been filed on the first possible day.

Substantive merits

The Court considered the validity of the patent under added matter, novelty and inventive step having regard to several prior art documents, and sufficiency, and was in the end convinced with the "sufficient certainty" required under Article 62(4) UPC and Rule 211(2), namely with a clear preponderance of probability, that the patent in suit is valid, noting that as a matter of principle the burden of proof in demonstrating invalidity of the patent lies with the Defendants. Similarly, the Court was convinced with sufficient certainty, namely with at least a high degree of probability, that the Defendants infringe the patent in suit both directly and indirectly. It seems that the Court has defined the standard of "**sufficient** degree of certainty" more concretely for validity than for infringement (by using "at least" in the latter case), in particular as it applies to the circumstances of the present case. However, the requirement to demonstrate validity or infringement with sufficient certainty may not apply in all cases, since Rule 211(2) says "**may** require". It could be envisaged that the Court may not require this, for example, where the relevant interests of the parties are balanced differently (see the analysis of Necessity in the next section).

It is unclear whether a detailed consideration of validity and infringement will be generally required to succeed in a provisional injunction application, or whether under some (and if so, which) circumstances the UPC may grant provisional measures without a detailed, if preliminary, consideration of the substantive validity and infringement issues.

Necessity of provisional measures

The Court was convinced of the necessity of provisional measures. The Court noted that the mere finding of a (threatened) infringement is not sufficient for ordering provisional measures – it is clear from Rule 211 that the possible damage that the applicant may suffer must also be taken into account (while the possible damage to the defendant must be taken into account when weighing up the interests).

The Court noted that the Defendants continue to offer the challenged product in the contracting states of the UPC Agreement and that the Applicants have filed an application for provisional measures at the earliest possible time. Furthermore, it considered that the marketing activities of the Defendants are likely to cause the applicants (whether as licensors or licensees of the patent in suit) considerable, in particular long-term, damage.

The Court further noted that, as confirmed by the advertising measures of the Defendants, the market for the patented products is very young and is in an initial phase in which it is decided to which suppliers customers of high-multiplex in-situ imaging

systems will commit themselves for the next decade. The parties were in agreement about this – the Applicants argued that, due to the acquisition of the infringing product customers would commit themselves to purchasing the detection reagents and decoder probes from the opposing parties for many years; similarly the Defendants submitted that the market would be closed for years by an injunction to their detriment, because customers would commit themselves for years by making a purchase. Thus, there was a mirror image risk resulting from long-term customer loyalty.

The Court considered that the interest of the right holder in not having their rights infringed outweighs the interest of the potential infringer in securing market share immediately through the continuation of the infringement, although this was against a backdrop in which the Court considered there was a high degree of certainty the patent was infringed and a clear probability that it was valid.

A further argument that an injunction should not be issued because the Defendants would be entitled to a licence either under US law (as a result of the NIH funding of the research) or under EU law (competition law) was not found convincing.

Additional points of interest

An additional point raised by the Defendants for the court to consider in balancing the parties' interests was that an injunction would be disproportionate because the patented process was part of a larger complex product. However, the Court rejected this, noting that there is no legal principle that third party rights can be infringed without the risk of an injunction if it is part of a complex product which had been developed at great expense.

The Defendants also argued that as one of the Applicants was a non-practicing entity ("NPE") there was no need for an injunction, but the Court thought this was of no significance, and that in any case financial damage can justify an injunction.

Consequence

For the above reasons, the Court granted a provisional injunction, based closely on the wording of the claims of the patent. No security was required from the Applicants. The Defendants were ordered to pay the costs of the proceedings. The sanction should the Defendants breach the injunction was set at €250,000 for each infringement. This decision can be appealed within two months.^[3]

[1] <https://register.epo.org/application?number=EP22170334&lng=en&tab=ueDoclist> although entitled with incorrect date of 15 September 2023 (body of the text correctly gives the decision date of 19 September 2023)

[2] Now published https://www.unified-patent-court.org/sites/default/files/upc_documents/2023-09-19-ld-munich-upc_cfi_2-2023-act_459746-2023-app_528389-2023-anonymized_part-1-of-2.pdf and https://www.unified-patent-court.org/sites/default/files/upc_documents/2023-09-19-ld-munich-upc_cfi_2-2023-act_459746-2023-app_528389-2023-anonymized_part-2-of-2.pdf (in German)

[3] According to the Decision itself; however it seems that this Decision is actually an Order appealable under Article 73(2)(a) and Rule 220(1)(c), so that the deadline to appeal under Rule 224(1)(b) is 15 days.