

EIP



Provisional injunction denied for clay-based haemostatic agent

Teleflex Life Sciences II LLC v Speed Care Mineral GmbH (UPC_CFI_701/2024 relating to EP2007811)

Order of 21 February 2025 (ORD_ 68880/2024)[1]

Application for preliminary injunction refused.

The Applicant, Teleflex Life Sciences ("**Teleflex**"), provides an array of medical technologies and solutions across a broad range of medical specialities. One such range of products relates to emergency medical products, including haemostatic products to stimulate blood clotting and stem heavy bleeding. The Teleflex patent which was the subject of the application, EP 2 007 811 (the "**Patent**"), related to a clay-based haemostatic agent.

The Defendant, Speed Care Mineral ("**Speed Care**"), primarily provides expertise in the field of mineral processing and refinement for use in haemostatic medical products but also works on mineral based technologies in other industries.

The application for the preliminary injunction included a considerable body of expert and experimental evidence in relation to infringement, hitherto unusual in applications for provisional relief at the UPC.

The decision of the Court discusses the burden of proof that applicants seeking provisional measures are required to meet and focusses in large part on whether the evidence relied on by Teleflex, and Speed Care's response, allowed Teleflex to satisfy their burden to demonstrate infringement of the Patent.

Burden of proof

The bulk of the decision deals with the Teleflex's (failed) attempts to satisfy the Court as to the likelihood that their patent is infringed and Speed Care's evidence in response.

To obtain provisional relief at the UPC, an applicant must assure the Court to 'a sufficient degree of certainty'^[2] that their patent is infringed. This burden is only reversed once the applicant has provided reasonable indications that an infringement has occurred. The Court in this case commented that the burden of proof for summary proceedings must not be set too high, with regard to the necessarily limited nature of the evidence in these proceedings, nor too low such that defendants are harmed by provisional measures that are later revoked. The court goes on to state that the burden is 'to prove more likely than not' that there is infringement of the patent. A large portion of Teleflex's arguments, and Speed Care's response, focussed on one issue of infringement of the Patent related to the presence of a binder.

Proving Infringement: Experimental Evidence

In support of its application for a preliminary injunction, Teleflex submitted an expert report, including several experiments, to attempt to demonstrate the presence of a binder in the allegedly infringing product, as required by a feature of the Patent claim. Teleflex's evidence included the results of an infrared spectroscopy technique which, when interpreted by their expert, was alleged to demonstrate the presence of a particular binder (chitosan).

This evidence was met with several criticisms from the Defendant, who instructed their own experts to rebut Teleflex's expert evidence. Speed Care's criticisms of Teleflex's evidence were made on a number of bases, including that the IR spectrum comparison relied on by Teleflex was 'not completely overlapping' with the textbook spectrum for the binder (and in fact, by Teleflex's expert's own calculations there was only a 73.8% match). Another detailed line of criticism sought to undermine a 'central thesis' of Teleflex's argument based on academic literature, relied on by their experts, which claimed that a particular peak on the IR spectrum was associated with a type of cross-linking indicative of the presence of the binder. The opinion of the Court was that Speed Care 'convincingly' explained that Teleflex's thesis was wrong. Speed Care contended that the academic

research relied on by Teleflex was a secondary source and that when one looked to the primary research it could be seen that i) the peak which formed part of Teleflex's central thesis was not supported in the primary academic literature, and ii) the primary research suggested there was in fact another peak indicative of the type of cross-linking which Teleflex sought to prove, but this peak was not present in Teleflex's expert's analysis of Speed Care's product (i.e. on Speed Care's case, Teleflex's own analysis indicated the binder was not present).

Further infringement arguments

The Court's decision looked at a number of other lines of argument on infringement, none of which the court found to be convincing. These included an argument by Speed Care that the claims in the Patent should be limited to hydrated forms of clay, a limitation which the Court decided was not merited, particularly given the mention of a dehydrated clay in a preferred embodiment in the Patent.

Teleflex also attempted to infer details of the allegedly infringing product from some aspects of Speed Care's own patents, particularly the 'binder to adhere the clay to the gauze substrate' integer which was also the subject of the expert evidence discussed above. Again, these arguments were rejected as 'unconvincing' by the Court as not all the claims of the Speed Care patent required a binder, and in fact there were references in the Speed Care patent to embodiments which 'advantageously' did not require a binder in the sense claimed in the Patent.

In one final attempt to demonstrate infringement at the oral hearing, the Applicant presented photographs (taken with a microscope) which they claimed to show certain particles sticking together in the allegedly infringing product, as evidence of the presence of a binder. If a binder was not present, Teleflex alleged, then the particles would fall apart. The Court cast doubt on this evidence, not least as the particles which Teleflex claimed could be seen in their images were said by the Court to be some 4-5 orders of magnitudes smaller than the magnification of the presented images, and hence 'they could not be made visible using the selected magnification'.

Conclusions

The Court ruled that Teleflex had failed to establish infringement of their patent to the standard required to award a preliminary injunction. The Court therefore saw no need to consider the validity of the patent or any other requirements for awarding preliminary relief. Teleflex was also ordered to pay the costs of the proceedings.

Teleflex, and Speed Care in their response, presented unusually large volumes of

technical evidence in their attempts to argue for or against infringement in this application for provisional measures. There was no criticism in the decision of the type or volume of the evidence submitted for the application but the result of this, not inconsiderable amount of work, was that the Court did not accept any of the main infringement points argued by either party based on the expert evidence in the case.

Perhaps one point to reflect on is the opening comments in the decision stating the burden of proof in summary proceedings should reflect circumstances 'in which the opportunities for the parties to present facts and evidence are limited'. This case appears to be one in which parties were able to produce ample quantities of evidence and one might ask if lowering the burden of proof remains appropriate in circumstances such as these. It is likely too early to say whether technical evidence of the kind in this application will become more commonplace in applications for preliminary measures, but applicants should take note that more detailed evidence may in turn draw more detailed scrutiny of their case, something which Teleflex fell foul of in this instance.

[1] <https://www.unified-patent-court.org/en/node/75684>

[2] Art. 62 (4) UPCA in conjunction with R. 211.2 RoP