Hospira Healthcare Corporation v. Kennedy Trust for Rheumatology Research, 2020 FCA 30

January 30, 2020

The appellants, Hospira Healthcare Corporation, appealed the Federal Court's (FC) decision that the respondent's 630 Patent was valid and infringed by the appellants. The 630 Patent claims the combined use of methotrexate (MTX) and the anti-tumour necrosis factor-α (anti-TNF-α) antibody "infliximab" for the treatment of rheumatoid arthritis (RA) in patients that are incomplete responders (IRs) to treatment with MTX. The appellants sell Inflectra, which is a biosimilar product, and which the FC found to be infringing. The Federal Court of Appeal (FCA) was asked to determine whether the FC had erred with respect to, among other things, the FC's claim construction, and infringement, method of medical treatment, anticipation, obviousness, and double patenting analyses. The FCA's reasons on each of these issues is summarized below.

Claims Construction

The FCA decided that the FC made no error by purposively construing the claims. In doing so, the Federal Court made no palpable and overriding error in finding that the Swiss type claims were claims to a medicament rather than strictly "use" claims.

The FCA also decided that it was permissible for the judge to turn to the patent's disclosure to understand the scope of the claims in question. The FC did not err when it held that the claims' scope was not limited to use on an IR patient that was receiving **only** MTX. Instead, the claim was construed to include use on an IR patient who was receiving MTX whether or not the patient was also taking other anti-rheumatic drugs. There was no error by the FC in turning to the disclosure to arrive at this construction.

Infringement

There was no direct evidence of the appellants' product being used to treat MTX IRs, and this use was not specifically prescribed on Inflectra's product monograph. Despite this lack of evidence of direct acts of infringement, the FCA held that it was appropriate for the FC to infer that the appellants were infringing. This inference was open to the judge because: 1. Patients were only reimbursed for treatment with Inflectra if they

failed to achieve satisfactory results by combination treatment with MTX and other anti-rheumatic drugs (i.e. they were MTX IRs); and 2. The appellants achieved regulatory approval for Inflectra by testing it in MTX IRs. Therefore, the FCA was willing to uphold a finding of infringement without direct evidence infringement for the medical product claims. The same reasoning allowed for a finding of induced infringement of the use claims: the appellants induced patients to use Inflectra with MTX as the product monograph prescribed this use, despite no reference to MTX IRs being present.

Method of Medical Treatment

The FCA briefly reviewed the history of the method of medical treatment prohibition, noting that the origin was the *Tennessee Eastman* case, which relied on a section of the *Patent Act* that has since been repealed. The FCA noted that FC jurisprudence teaches that a claim to a vendible product, including a substance intended for the treatment of a medical condition, can be good subject matter for a patent claim, but not if the claim encompasses the skill of a medical professional such as a dosage range rather than a fixed dosage. Noting the unsatisfactory state of the law in this area, the FCA questioned this approach, indicating that a drug is no less a vendible product simply because its dosage or interval of administration is not fixed. Similarly, the FCA stated that a medical professional's skill and judgement would seem to be constrained whether the claims are to a fixed dosage or a range of dosages. The FCA concluded that this was not an appropriate case to tackle this issue straight on, as the majority of the claims were to a vendible product. The FC was found not to have erred in finding that the claims at issue were not methods of medical treatment.

Anticipation

The first issue regarding anticipation that the FCA dealt with was whether the 630 Patent could claim priority to a 1996 US application, when that 1996 U.S. application itself claimed priority to a 1992 application. The FCA stated that since the appellants did not meet their burden to prove that the contents of the 1992 application supported the subject matter of the 630 Patent, the FC did not err in deciding that the 630 Patent could claim priority to the 1996 U.S. application.

The second issue that the FCA dealt with was whether the FC erred in determining that the 630 Patent was not anticipated by two prior art references. The FC decided that since both prior art references were speculative (they proposed use of either infliximab or an anti-TNF-α antibody with MTX, but without having actually done any trials), and did not disclose the special advantages of the combined therapy, the 630 Patent was not anticipated.

The FCA stated that in order for any particular results from the claimed combination treatment to be a basis for distinguishing over the prior art, it would be necessary to conclude that such results constituted an essential element of the claim in question. Although an essential element of the claims was that the combination therapy used by MTX IRs reduces or eliminates the symptoms of RA, it was not clear whether this essential element was the same "special advantages" that the judge said distinguished the 630 Patent from the prior art. Furthermore, one of the prior art references seemed to indicate that the type of improvement from the combined therapy was the same as the essential element in the claim: improved long-term disease suppression. Therefore, the

FCA held that the FC erred in performing the anticipation analysis, and sent the case back to the FC to reconsider this matter.

Obviousness

The FCA first corrected the FC's interpretation of the law concerning the "state of the art". The FCA stated that it is an error to exclude from the "state of the art" prior art that was available to the public at the relevant date simply because it would not have been located in a reasonably diligent search by the person of ordinary skill in the art (POSITA). The FCA stated that whether or not prior art references would have been found by the POSITA can be a factor in step four of the obviousness analysis: whether differences between the state of the art and the inventive concept constitute steps which would have been obvious to the POSITA. However, judges should not exclude prior art from the obviousness analysis that has already disclosed the alleged invention simply because that prior art may have been difficult to find.

The FC was also found to have erred in its application of the "obvious to try" test. Instead of answering the question: "is it more or less self-evident to try to obtain the invention?" the FC was found to have made the "obvious to try" determination by answering the question: "is it more or less self-evident that what is being tried ought to work?" This second question is merely a factor to consider, not the ultimate question to be decided.

Regarding whether the invention was obvious to try, the FC found that the POSITA did not have the skills necessary to design and conduct the experiments described in the 630 Patent. However, this assumed that the results provided by those experiments were part of the claimed invention, which, according to the FCA, was an error, since the results of those experiments were not part of the essential elements of the claims.

Therefore, this issue was also sent back to the FC so that it could reconsider the obviousness and obvious to try analyses while implementing the FCA's guidance.

Double Patenting

The appellants argued that the 630 Patent was invalid for double patenting with respect to a prior Canadian patent, the 647 Patent. The FCA stated that it was the claims of the two patents that must be compared when assessing allegations of double patenting. Since the claims 647 Patent included an anti-CD4 antibody in combination with the anti-TNF-α antibody, and there was no mention of an anti-CD4 antibody in the 630 Patent, the claims were patentably distinct, and the FC made no error in its double patenting analysis.

Addition of New Parties

The Respondents added a member of their supply chain as an additional plaintiff after the trial on the infringement issues had been decided. The FCA held that the FC did not err in allowing this addition. The test is whether the person claiming under the patentee is a person who derives his or her rights to use the patented invention, at whatever degree, from the patentee. It was not necessary that the member of the supply chain be

a licensee of the patent, because its position as part of the supply chain was derived from the patentee. Therefore, the member of the respondent's supply chain was a person claiming under the patentee, and their addition as another plaintiff was appropriate.

Conclusion

In conclusion, the FCA decided that the errors made by the FC on the issues of anticipation and obviousness warranted remitting this matter to the FC for reconsideration.

Expertise

Intellectual Property, Patents, Copyright, Industrial Design, Licensing, Trademarks, Intellectual Property Litigation

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