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FINGOLIMOD – DANISH COURT GRANTS PI, ALBEIT DISSENTING OPINION FINDS PATENT INVALID DUE TO LACK OF INVENTIVE STEP

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On 28 February 2023, the majority of the Danish Maritime and Commercial High Court did not find sufficient grounds for rebutting the presumption of the validity of the Danish patent DK/EP 2 959 894 (the "Contested Patent"), held by Novartis, and thus decided to grant a preliminary injunction against Zentiva. Notably, though, the opposing judge held the Contested Patent to be invalid, as it was devoid of inventive step. The Contested Patent was a pharmaceutical patent used for the treatment of multiple sclerosis.

The dispute of the case – and the decision by the Court – was whether the presumption of validity of the Contested Patent had been undermined to an extent that rendered the grounds for issuing a preliminary injunction uncertain. The Contested Patent, with priority as of 27 June 2006 derived from a British patent, was issued 22 October 2022, following reviews by both EPOs Examining Division and Technical Boards of Appeal. Consequently, a presumption of validity applied to the Contested Patent. This presumption was contested by Zentiva with respect to the requirements for i) a sufficient description of the invention and ii) inventive step.

Pursuant to section 8(2) of the Danish Patent Act (and article 83 of the European Patent Convention), the patent document must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. With reference to the examinations and conclusions reached by the EPO, a unanimous Court found the criteria to be satisfied.

Although the patent application did not include any test results pertaining to the experiments described in the application, the Court found that the experiments were not to be regarded as merely prophetic, as they were substantiated by an inside report by Novartis dated 12 May 2009 concerning experiments performed in the years of 2000 and 2005. Thus, external information was used to substantiate the requirement for a sufficient description.

Next, in considering whether a person skilled in the art would be able to carry out the invention on the basis of the patent application, the Court noted that the relevant parts of the disclosure were vaguely described, and thus open to interpretation. Presented with conflicting interpretations, the Court relied on the assessment reached by the EPO, according to which calculations based on the applicable factor for dosage conversion from rats to humans was considered as general knowledge for a person skilled in the art. Consequently, the description in the patent document was found to sufficiently disclose the invention.

Turning to the issue of inventive step, the Court disagreed in its stance. Pursuant to the Danish Patent Act section 2(1) (and article 52(1) of the European Patent Convention), in order for an industrial invention to be patentable, it must satisfy the substantive requirements for novelty and inventive step. An invention is deemed new, if it does not form part of the state of the art, whereas an inventive step is present, if, having regard to the state of the art, the invention is not obvious to a person skilled in the art, cf. articles 54 and 56 of the European Patent Convention.

The parties – and the judges – disputed on the determination of the state of the art – in specific, whether this comprised Novartis' presentation of the invention dated 21 June 2005 or their press release of 6 April 2006 – and the involvement of an inventive step.

Two out of three of the judges held, in line with EPO, that the press release was to be regarded as the state of the art and that the invention, with respect to this, was not obvious to a person skilled in the art. It was held by Zentiva that the presentation, which had not been included in the examination by the EPO, constituted an older, untried and more detailed prior art-disclosure. Albeit granting that the presentation did contain relevant – and even additional – information about the invention, the majority stated, at the same time, that the presentation was unclear as to the testable doses, and that the press release referred to updated information.

As the presentation did not provide any further, novelty-defeating descriptions of the invention, the press release was considered the closest prior art, to which the invention was to be compared. With reference to the statements given by experts before the EPO, with three arguing that the effect of a dose of 0,5 mg fingolimod was not obviously deducible from the press release and one of the opposite opinion, the majority found both interpretations plausible. Ultimately, it did not find sufficient grounds for setting aside the decision by EPO.

By contrast, the dissenting judge found the Contested Patent to be devoid of inventive step and thus invalid. The dissenting opinion considered the presentation of 21 June 2005 to be the closest prior art, as it contained sufficient and detailed information about the Contested Patent, among this an intention to perform tests with lower doses, including 0,5 mg fingolimod.

By comparing the different information in the presentation, a person skilled in the art would be able to deduce that the dose of 0,5 mg was intended for a daily intake. As mentioned, this was dismissed by the majority, which found that the uncertainty concerning the dosage regimen could not be completely disproved by comparing information in the different parts of the presentation.

This requirement of absolute certainty represents a strict interpretation of the presentation, which, to the utmost, could narrow the state of the art and, as a result, lower the requirements for patentability. In addition, this interpretation does not seem to have been made from the perspective of a person skilled in the art, as otherwise done in the dissenting opinion. Taking into account the general knowledge of a person skilled in the art and the information about the Contested Patent provided in the presentation, the dissenting judge argued that a person skilled in the art would find it probable that a dose of 0,5 mg fingolimod a day could have a therapeutic effect in the treatment of multiple sclerosis. Accordingly, as the presentation was considered a part of the state of art, the dissenting opinion concluded that the Contested Patent did not involve an inventive step and was hence invalid.

Reported by Rikke Wehrmann

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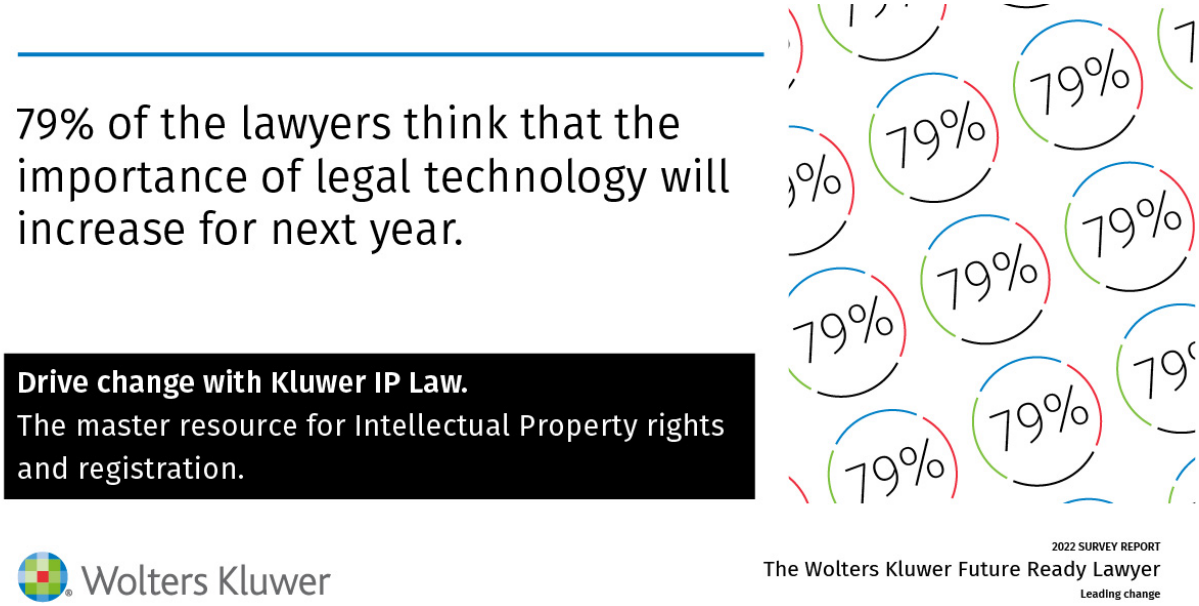

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