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Oxycodone – An Unfinished Battle and an Undisclosed Question

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Litigation and EPO Oppositions/Appeals surrounding a controlled-release dosage form of the drug oxycodone, a morphine-like opioid analgesic developed in 1918, has kept Europe's Pharma IP Lawyers busy for a couple of years. One of the key EP patents in this battle has been EP 722 730, and almost everything about this patent is out of the ordinary. The patent is owned by no less than 13 separate companies from the Purdue Pharma/Napp/Mundipharma group. It is the first divisional application of EP 576 643 and itself forms the parent application of no less than 13 further divisionals and grand-divisionals, according to epoline. It is distinguished from its parent application by a disclaimer which was introduced in claim 1 and in the description from the very beginning. Whether this disclaimer is allowable under Art. 76 EPC / Art. 123(2) EPC or constitutes "added matter" was the subject of fierce debate all over Europe.

The EP patent was opposed in 2003 by two companies who were later joined by four intervenors. Infringement proceedings were ongoing in at least the UK (up to the Supreme Court), the Netherlands, Germany, Norway and Finland. The EPO opposition proceedings took almost five years in the first instance and ended with maintenance of the patent in the form of the proprietor's ninth auxiliary request, whereas the patent as granted and the claims of several auxiliary requests that the proprietors were trying to enforce in litigation were found not to comply with the requirements of the EPC. In particular, it was held that the disclaimer introduced in claim 1 added matter which was not clearly and unambiguously disclosed in the parent application.

Unsurprisingly, the Proprietors appealed. So did most of the opponents.

While EPO appeal proceedings were ongoing, the proprietors had a number of quite spectacular successes, particularly in the UK, where they were able to persuade the UK courts (Floyd J. in the High Court and Jacob LJ., Neuberger LJ. and Collins in the Court of Appeal) that the 730 patent is valid in its entirety, despite the decision of the Opposition Division. It seems that the UK courts, in accordance with their established practice, thought it neither necessary nor appropriate to stay their cases pending the final outcome of the EPO appeal. Instead, Floyd J. wrote that he had given the decision of the Opposition Division *its appropriate consideration* but was *in the end not persuaded by its reasoning*, so he decided against it. The proprietors also succeeded in the Netherlands and did not fail to let the Technical Board of Appeal know about all favorable decisions in more than one way, urging it to come to the same conclusion.

Before this background, it will come as no surprise that the result of the EPO Appeal Proceedings,

in which accelerated proceedings were requested, was eagerly expected. Yet also this appeal case proved to be unusual in more than one respect. On the whole, it took the Board of Appeal 3.3.2 more than 3.5 years and no less than three oral proceedings to reach a final conclusion, despite continued requests by the opponents (who were partly enjoined on the basis of the patent by national infringement courts) to deal with this case as fast as possible. The first hearing in October 2009 ended after two days on 19:40 – and came to no formal decision on the patent. Yet the Board at least orally expressed the opinion, that Patentee's main request and auxiliary requests I – Vb were not allowable under Art. 76 EPC. Consequently, the debate on these requests was declared closed and the proceedings were continued in writing with respect to the further auxiliary requests.

The parties were again summoned for oral proceedings on 19 October 2010. This second hearing took a quite surprising course for all parties involved: The Board opened the proceedings with a brief remark that it considered that neither the disclaimer contained in the main request (and some of the still pending auxiliary requests), nor the subject-matter disclaimed thereby is clearly and unambiguously disclosed in the parent application as filed. After a short skirmish between the parties in which the Proprietor strongly took issue with the Board's view, the Board got entangled in internal deliberations for hours, before finally announcing that the Board intended to refer questions to the Enlarged Board of Appeal. These questions were to concern, said the Board, *inter alia* the allowability of a disclaimer in a claim wherein the subject-matter is delimited by both structural and functional features. However, the Board failed to present a precise question for discussion with the parties, and no party really understood what the Board's problem(s) was/were or might have been. The proceedings were then again continued in writing, much to the frustration of the opponents/appellants, who had hoped to finally succeed or at least have legal certainty, but now saw themselves confronted with an increasing number of infringement decisions against them and with the fear that the patent (filed in November 1992) was about to expire before they were able to obtain any return on their investment. The proprietors, conversely, cheered and emphatically supported the Board's intention to refer a question of law to the EBA, even though – according to their representatives' own statements – they too did not understand which question the Board intended to refer. It was a valuable gain of time for them anyway.

One might therefore have expected the Board of Appeal to swiftly act in accordance with its intentions as expressed to the parties, both orally and in the minutes, and to now finally draw up the ominous “undisclosed” referral question. Yet months went by, and nothing happened. Instead, in May 2011, the Board again summoned the parties to attend oral proceedings, this time for three days in November 2011 (!) and before a new (enlarged) composition to five members. By that time at the very latest, it was to be assumed, almost with certainty, that the Board had re-considered its position of referring a question of law to the Enlarged Board, since it would not have been normal, let alone appropriate to schedule a hearing for three days and before a different composition of the Board, if the only subject of the proceedings was to discuss a referral question with the parties. Furthermore, it had already transpired around that time that decision G2/10 might come out earlier than expected, as oral proceedings were scheduled in that case in August 2011. G 2/10 then actually issued shortly afterwards, i.e. on 30 August 2011. Even though it was never explicitly expressed in a written communication by the Board, the TBA's change of mind appeared so clear indeed that a representative of one of the opponents even publicly betted the proprietor's representative a crate of wine, in a hearing before the opposition division in one of the divisional applications, that the Board of Appeal would no longer refer the '730 case to the Enlarged Board.

G2/10 confirmed that an amendment to a claim by the introduction of a disclaimer disclaiming from it subject-matter disclosed in the application as filed infringes Article 123(2) EPC (or Article

76(1) EPC when only introduced upon filing a divisional application) if the subject-matter remaining in the claim after the introduction of the disclaimer is not, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person using common general knowledge, in the application as filed. Determining whether or not that is the case requires a technical assessment of the overall technical circumstances of the individual case under consideration, taking into account the nature and extent of the disclosure in the application as filed, the nature and extent of the disclaimed subject-matter and its relationship with the subject-matter remaining in the claim after the amendment. In the oxycodone case, the proprietors argued that the disclaimer was just excluding one embodiment (an acrylic resin matrix) which was claimed in the parent patent, whereas any other controlled release dosage form would still be clearly and unambiguously disclosed in the parent application. The opponents argued, in turn, that the parent application did in fact **not** disclose an acrylic resin matrix in combination with the other features of claim 1, so that it was also not possible to exclude this undisclosed embodiment by way of a disclaimer, nor was “the rest” clearly and unambiguously disclosed in the parent application.

The Technical Board of Appeal informed the parties with a communication dated 25.10.2011 in preparation of the oral proceedings of 14-16 November that the Board envisages to re-open the debate for all requests on file in view of the enlargement of the Board to a five members board in accordance with Art. 21(4) b) EPC and in view of G2/10. The proprietors reacted on the very same day with urging the TBA to postpone the oral proceedings if the Board indeed dared to issue a decision on the merits in that three-day-hearing, arguing (or pretending – whichever way you look at it) that they were completely surprised by the TBA’s change of mind and needed more time for an adequate preparation of a hearing of the substantive aspects of this case. The Board immediately complied with this request, without even notifying, let alone hearing the Opponents beforehand. The Opponents’ vigorous protests against this further delay of the appeal proceedings, which they considered as being both unjustified and to massively go to their economic detriment, were not commented by the Board.

Shortly afterwards, also the last remaining the opponent-appellant settled with the proprietor and withdrew its appeal. This did not dispose of the proprietor’s appeal, though, because this was still resisted by one opponent who had not himself filed an appeal. The Board summoned the parties for a three-day hearing from 7-9 March 2012. In the written procedure running up to the hearing, the proprietor pleased the Board with several submissions requesting, inter alia, a new preliminary opinion on the issues to be discussed in the hearing (which the Board refused), a number of legal opinions from respected experts cautioning the Board not to take any surprise decision and to let the parties know what the “undisclosed question” was, as well as 117 auxiliary requests, filed only one month before the hearing. A few days before the hearing, even a letter by the Comptroller General of the UKIPO to the President of the European Patent Office was submitted, wherein the Comptroller voiced various of the proprietor’s concerns, in particular the concern that there was, in the proprietor’s opinion, no indication of the specific issues to be discussed in the third oral proceedings and the inability to have an opportunity to address those issues. The proprietor even alleged, and the Comptroller of the UKIPO took up this issue, that his human rights had been violated by the Board’s conduct of the proceedings. At the latest when this letter (and a similar one by the Dutch Patent Office) was filed, it must have been clear to everybody that this case was played with highest stakes, even on the political level.

This hearing, again an exhausting, if not even grueling one for both the Board and the parties, just ended last Friday, at about 20:25 in the evening. The result was that the proprietor’s appeal was dismissed, despite all attempts by the proprietor to avoid or at least further delay such an outcome.

The only substantive issue discussed in the oral proceedings was Art. 76 EPC, including the disclaimer question. As was to be expected, no question of law was referred to the Enlarged Board of Appeal.

In view of the above, the decision in writing may be expected with considerable interest and so will be the proprietor's announced petition for review to the Enlarged Board of Appeal under Art. 112a EPC. In any case, the oxycodone battle is not (completely) over yet, but whatever the outcome will be, we will probably never get to know what the "undisclosed question" was that TBA 3.3.2. once had in its mind for a referral to the Enlarged Board. Do we have to know the solution to this conundrum at all? Or, to put it in other words, do the parties have a right to know a question of law that a Technical Board once considered for referral but later dropped and found no longer of relevance to the case, particularly in a case like this where new legal guidance appeared in the meantime by way of G2/10? Stay tuned and wait for one of the Enlarged Board's next R decisions.

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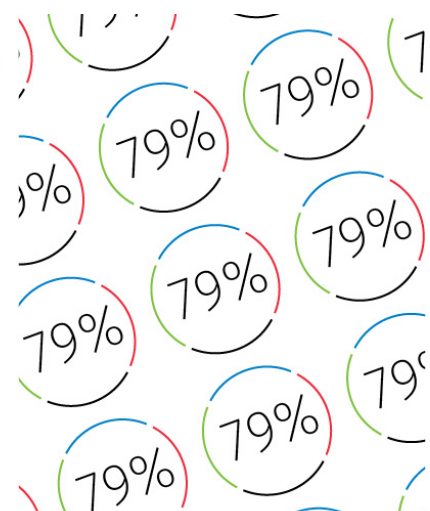
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