The Fentanyl Decision – Lessons to be learned for Claim Construction and Novelty

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By final judgment of November 18, 2010 (Xa ZR 149/07, published in Mitt. 2011, 66 (in German only)), the German Federal Court of Justice (FCJ) decided on two interesting issues in nullity appeal proceedings regarding the German patent DE 101 41 650 pertaining to a patch containing the opioid fentanyl, a strong analgesic drug.
Firstly, novelty: The Court held that novelty of a substance (or composition) cannot be established if a material was available at the priority date that contained all claimed features of the later invention, even if the state of the art offers no scientific explanation as to why this combination of features provides the effect claimed in the patent.

Secondly, claim construction: The Court held that supposed contradiction within the features of the preamble and the characterising portion of a claim should not be resolved by simply disregarding the preamble, especially if and when the literal meaning of the claim as a whole also permits a consistent interpretation and when this consistent interpretation is supported by the working examples of the description.

To put it in a simplified form, the facts were as follows: Claim 1 of the granted patent in dispute was directed at "*a transdermal therapeutic system (TTS) consisting of (a) a drug-impermeable backing layer, (b) at least one matrix layer based on polyacrylate and comprising fentanyl, and (c) a protective film to be removed before use, characterized in that [...] the drug-containing layers contain at least 80 wt-% of the drug to be incorporated in dissolved form*".

In the first instance proceedings before the Federal Patent Court, the Patentee defended the patent in amended form with the following (again slightly simplified) claim 1 as a main request: "*a transdermal therapeutic system (TTS) consisting of (a) a drug-impermeable backing layer, (b) a matrix layer based on polyacrylate and comprising fentanyl, and (c) a protective film to be removed before use, characterized in that [...] the fentanyl-containing matrix layer contains at least 5 wt-% fentanyl, of which 80% are in dissolved form*".

The interesting question which the Federal Court of Justice had to address was whether the feature "the active compound-containing layers" in the characterising portion represented a limitation of claim 1 as granted by requiring that more than one such layer be present. If so, patentee's claim 1 as defended would constitute an inadmissible extension of the scope of the patent as granted, because it would then also allow just one fentanyl-containing "matrix layer" to be present. In the first instance, the Federal Patent Court had indeed revoked the patent because it thought that the plural "layers" in the characterizing portion of the claim overrides the singular/plural of "at least one layer" in the preamble of the claim. Furthermore, the Federal Patent Court found the patent, even after amendment, to lack inventive step (GRUR 2009, 145 – Fentanyl-Pflaster).

On appeal, the Federal Court of Justice disagreed with the Federal Patent Court on claim construction, but dismissed the appeal for other reasons. The FCJ held that claim 1 as granted only required the presence of "at least one" matrix layer, which might as well be just one layer. This would be in line with the description of the patent and particularly the examples which only provided for one such layer. The court further held that there is no general preference of the features of the characterizing portion of the claim over the preamble. In paragraph [29] of its decision the FCJ stated this:

"*According to the established case law of the Federal Court of Justice, the interpretation of a claim is determined by that technical meaning which the claimed features have in their individuality as well as in their entirety, when viewed by a skilled person (citations omitted). To accomplish this, an analysis of the individual features is required. However, this must not result in their consideration and interpretation independent of the overall context.*"

Hence, the Court held that in this case the claimed TTS can optionally contain one or more matrix layer(s), as provided in the preamble, whereas the further definition in the characterising portion only refers to the composition of these layers. The plural "drug-containing layers" in the characterizing part of claim 1 was therefore understood to mean "all drug-containing layers present in the system", which might include just one or several layers.

Turning now to novelty, there were two issues. The most critical issue was whether a certain prior art reference implicitly disclosed the feature that at least 80 wt-% of the drug to be incorporated are in dissolved form. There was agreement that the prior art document did not explicitly specify how much of the fentanyl that it disclosed were in dissolved form, but the reference did disclose a fentanyl content of 12 wt-%. Nullity plaintiff argued that this value would inherently be obtained when using such a drug content, since the saturation solubility of fentanyl is above 9.6 wt-%. Hence, at least 9.6 wt-%/12 wt-% = 80% of the fentanyl must be in solution. The patentee denied that the saturation solubility is as high as 9.6. wt-% and argued that the saturation solubility depends on many factors. To support this, he pointed to a source from which a saturation solubility of only 6.157 wt-% could be calculated. The court expert testified that this "calculation" is only an estimate and that the actual value could also be in the order of 10 wt-%.
In the end, the Federal Court of Justice left this question undecided and argued that a skilled person would in any case select the fentanyl concentration near or just above the solubility limit, so as to keep the crystalline portion of the drug as low as possible. Thus, the court found it obvious to have more than 80 wt-% of the fentanyl in the dissolved state.

The second issue turned around the properties of the specific adhesive DUROTAK 87-4098 that was used in this prior art reference. The claim required that the polyacrylate of the matrix layer is free from carboxylic acid groups and is only prepared starting from monomeric esters of certain alcohols and acrylic acid and/or methacrylic acid without free functional groups. It further required that fentanyl must have a saturation solubility between 4 and 12 wt-% in this polyacrylate. On the composition of the polyacrylate matrix, the only evidence was manufacturer's information designated as "confidential".

As to public availability, another catalogue confirmed that the DUROTAK material was on the market at the priority date, even though it did not reveal any specifics on its composition or properties. But this was irrelevant for the court. It held:

"According to the case law of this court, it is irrelevant whether the skilled person was aware of these properties and whether he was able to identify them by appropriate analyses. For a novelty-destroying disclosure it is sufficient if a material is identified that exhibits all claimed features. A scientific reasoning as to why the use of such a material allows the success according to the patent to be obtained is not required."