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The relevance of court-appointed examiners on patent cases in Brazil

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Judges deciding patent matters in Brazil usually have none to limited technical background. In view of the complexity of patent cases, it is often that we see judges appointing a court examiner, as defined by law: "the judge will be assisted by a court expert whenever the proof of the fact depends on technical or scientific knowledge" (Section 156 of the Code of Civil Procedure).

Although the Code of Civil Procedure allows judges to weigh the court expert report and "indicate in the trial judgment the reasons that led them to consider or disregard" it is very common that the judge follows the technical report issued by the court examiner when deciding patent cases.

Two cases pending appeals before the Federal Court of Appeals for the 2nd Circuit are great examples of how the court expert's report dictates – or, at least, heavily influences – the judges' conclusions in judgments over the validity of patents.

Wyeth LLC v. BRPTO. Wyeth filed a lawsuit seeking to reverse the patent office's decision that rejected a patent application for the use of one or more estrogens and a compound of formulae I or II in the preparation of pharmaceutical composition for the treatment or prevention, in mammals, of bone loss, syndromes associated with estrogen deficiency, cardiovascular diseases and diseases resulting from the proliferation or abnormal development of endometrial tissue.

The lawsuit seeks to overcome the denial by the BRPTO due to non-compliance with Section 32 of the Brazilian IP Statute, which establishes that changes may be made to the patent application until the request for examination, "as long as those are limited to the matter initially disclosed in the application". The BRPTO supported a position in the lawsuit arguing that, in filing a divisional that replaced a dosage regimen claim for a Swiss-type claim, Wyeth unduly altered and broadened the intended scope of protection to add matter that was not claimed in the set of claims of the parent application.

In view of the complexity of the technical aspects of the case, the judge appointed Dr. Kappel Jordão, an industrial pharmacy graduate with a MSc and PhD in Organic Chemistry as the court examiner. Upon analyzing the case, the expert concluded that there was no impediment to the change of scope promoted by Wyeth, as "it is evident that claims in Swiss-type format are narrower" and "the adjustment of the format of the claim is legitimate". The expert report concluded that the change was allowed, as the claimed matter remained limited to the initial disclosure of the application, noting that Section 32 of the IP Statute established the disclosed

matter as a limiting parameter, not the matter claimed in the previous set of claims. The same conclusion was reached in regard to the compliance with Section 26 (which regulates divisionals), where Dr. Kappel Jordão stated that "the patent application may be divided, as long as it does not exceed the matter initially disclosed" and that "it is evident that the use of the described compounds its provided for in the parent application, which confirms that the 'use' claims, present in the divisional, are limited to the matter disclosed in the [parent] application". When rendering the trial judgment, the judge highlighted that, despite the BRPTO's challenge to the expert's conclusions, the report addressed all of its arguments and concluded that "in this clash of technical opinions, one must adopt those of the unbiased court expert when duly grounded, which is the case in these records", as is the case law of the Federal Court of Appeals for the 2nd Circuit. This decision shows the importance of the court-appointed report when deciding patent cases in Brazil.

Hebron Farmacêutica Ltda. v. BRPTO. Hebron, a Brazilian pharmaceutical company, filed a lawsuit challenging the denial of a patent application by the patent office. The lawsuit involves, in addition to the main discussion of alleged violation of Section 32 of the Brazilian IP statute in its claim of use of misoprostol in the preparation of pharmaceutical compositions applied vaginally to induce labor in pregnant women with unripe cervix, other issues such as novelty, non-obviousness, enablement. The BRPTO answered to the complaint reaffirming that amending a dosage regimen claim to a Swiss-type claim would represent an undue alteration and broadening of the scope of protection, adding matter that had not been claimed when of the request for examination.

The court expert appointed to this case was Mr. Rodrigo Oliveira, a pharmacy graduate with a MSc in pharmaceutical sciences related to depression and the central nervous system and a former examiner of the BRPTO. In his analysis, the expert concluded that, despite being novel, the application was obvious and lacked enablement, in addition to having violated Section 32 of the Brazilian IP Statute. According to the expert's report, Hebron's removal of the *dosage regimen* claim in favor of the *Swiss-type* claim still during prosecution, would represent a change in the category of the claims that substantially alters the scope of protection beyond what had been previously claimed (regardless of what had been disclosed in the application as filed), and was rightly rejected by the BRPTO.

Hebron challenged the conclusions of the expert report and requested a new unbiased expert to be appointed for a second examination, but the judge denied the request and accepted all conclusions reached by the court expert in the trial judgment, keeping the denial of the patent application.

Conclusion

Both cases have appeals pending before the Federal Court of Appeals for the 2nd Circuit, and, despite the differences in some of the underlying discussion and conclusions, it will be interesting to see how the court of appeals is going approach the evidence produced in these lawsuits.

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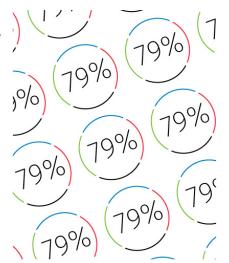
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This entry was posted on Tuesday, September 19th, 2023 at 5:32 pm and is filed under Brazil, evidence, Litigation

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