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What is the Meaning of a "Pharmaceutical" in a Patent?

The Patent Trial and Appeal Board decided that AbbVie's patent covering their HUMIRA drug for rheumatoid arthritis was invalid because it was obvious in view of the prior art.

On the way to finding the patent invalid, the Board addressed the interpretation of the patent claim terms "pharmaceutical" and "pharmaceutical composition".

The patent claim at issue did not recite the production of antibodies on a commercial or industrial scale. Nor did it recite that the drug was suitable for FDA approval or commercialization.

AbbVie nevertheless argued that "pharmaceutical" must be interpreted in view of FDA regulations and that "pharmaceutical" is limited to a commercial product produced on an industrial scale.

The Board found that the patent specification did not define "pharmaceutical". Therefore, the Board looked to the "plain meaning" of the term as it would be understood by one skilled in the art.

By looking at a dictionary meaning, the Board concluded that "pharmaceutical" means a "medicinal drug" and does not have an added meaning of industrial-scale production or FDA-approvability.

COMMENT:

AbbVie may have overreached in its claim interpretation. That may have negatively affected the Board's receptivity of AbbVie's prior art arguments.

Patent Is Invalid if the Invention Was Publicly Sold More Than One Year Before Filing

The patent laws provide that if the patented invention was "on sale" more than a year before filing the patent application, the patent is barred or invalid.

Helsinn owned patents for reducing nausea and vomiting due to chemotherapy.

More than one year before applying for the patents, Helsinn entered into with MGI a License Agreement and a Supply and Purchase Agreement, both of which related to the inventions under the patents.

Several years after filing the patent applications, Teva filed an ANDA and sought FDA approval for a generic of the products covered by Helsinn's patents. Helsinn sued for infringement.

The Federal Circuit pointed out that MGI disclosed in an SEC filing the details of the Supply and Purchase Agreement, except for price and dosage levels of the patented drug.

Helsinn argued that since the dosage was not disclosed, the invention was not disclosed, and thus the on-sale bar did not apply.

The Federal Circuit disagreed and held that the on-sale applies even if there is no delivery of the patented product or even if the public cannot "ascertain" the invention. The bar applies when the "existence of the sale is public" and thus the invention is put "in the hands of the public."

COMMENT:

The decision may be a disadvantage to patent owners who need to exercise more caution when trying to "secretly" sell an invention.

J&J Claims Trade Secret Theft By Ex-Employee, Moving to Baxter

The medical device sector may not be any different than the tech sector (like Uber and Google) when it comes to trade secret issues.

Laura Angelini worked in marketing for various J&J companies for more than 20 years. In her most recent position, she signed a non-compete agreement that prevented her from working with a competitor for 18 months.

She received confidential emails relating to and then attended a three day workshop where J&J businesses made presentations.

J&J's obtained a preliminary injunction preventing Angelini from starting employment at Baxter. She appealed.

On appeal, Angelini argued that prior to the workshop she did not have confidential information because she did not pre-read workshop materials and the emails. J&J argued that Angelini was continuously exposed to confidential information and participated at the workshop.

The Eleventh Circuit sent the case back to the lower court for an evidentiary hearing.

COMMENT:

The Eleventh Circuit did not decide who was right or wrong. It only decided that the lower court needed to consider conflicting evidence before issuing an injunction.

NuVasive Prevails Over Medtronic on Claim Construction of "Lateral" Path

NuVasive obtained a patent for a surgical method of inserting a spinal implant along a "lateral, trans-psoas path" to the spine while using nerve monitoring. Medtronic initiated an inter partes review to invalidate the patent.

NuVasive argued that the prior art did not disclose a "lateral, trans-psoas path" because the prior art path "traversed only the psoas muscle's 'most anterior fibers,' which do not contain the sensitive nerves that NuVasive's patent was designed to avoid."

The Patent Board found that a "lateral trans-psoas path" includes a lateral path which "passes through any portion of the psoas muscle." And "lateral", according to the Board, meant lateral to any degree.

The Federal Circuit disagreed. It found that the patent specification distinguished between "lateral" and "postero-lateral", with the former being at the 3 o'clock and 9 o'clock positions. It also pointed out that the claim feature was NOT a "trans-psoas approach" or a "postero-lateral, trans-psoas approach." Rather, it was a "lateral" approach.

Therefore, according to the Federal Circuit, the Board's interpretation of "lateral trans-psoas path" was unreasonably broad.

COMMENT:

It seems that the specification distinction (not definition) between "lateral" and "postero-lateral" allowed the Federal Circuit to find in favor of NuVasive. This suggests that a claim term need not be directly defined in the specification but can be indirectly defined when contrasted with other claim terms.

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