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ITC Institutes Investigation of Fuji Breast Imaging Devices

The US International Trade Commission (ITC) has the authority to investigate potential patent infringement of devices (not just medical) being imported into the US.

The ITC can decide to initiate an investigation upon the filing of a complaint by a US company against a foreign importer. The decision to investigate does not mean the ITC has found infringement. They have only decided to investigate whether infringement has occurred.

Hologic owns several patents that relate to x-ray breast imaging devices. They market a product under the name Selenia Dimensions. Hologic describes their product as the "fastest breast tomosynthesis scan available".

Fuji imports a product under the name Aspire Cristalle. Fuji describes their product as having "image capture technology and intelligent image processing, optimizing contrast and dose based on breast density".

COMMENT:

As is common with ITC investigations, Hologic also sued Fuji in US district court. The court can award monetary damages, whereas the ITC can only halt the importation.

Does Your Patent Adequately Describe Your Invention? Purdue Pharma Does Not

The patent laws require that a patent contain a description of the invention in a way that "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date."

In other words, the patent must describe the invention "understandable to that skilled artisan and show that the inventor actually invented the invention claimed."

Purdue Pharma's patent application related to controlled-release oral formulations of hydrocodone, a pain killer. The application explained that an "object of the invention" was to provide controlled-release formulations that "provide a substantially increased duration of effect as compared to immediate release" formulations.

The patent claims, however, included both controlled release (CR) multi-particulates and immediate release (IR) multi-particulates. The patent specification said "an effective amount of the hydrocodone in immediate release form may be coated onto the substrates of the present invention."

Recro filed a patent application for oral formulations of hydrocodone. An interference proceeding was initiated in the USPTO to determine priority of invention.

The Federal Circuit found that the Purdue application did not disclose a formulation with only IR multi-particulates - i.e., inert beads coated directly with an IR layer. Instead, the application described IR as a granulate or as a coating on a capsule that contained the CR formulation.

According to the Federal Circuit, even though the patent specification described IR and CR beads, it did not describe IR and CR beads combined in a single dosage form. Therefore, the patent specification did not support the patent claims and thus the patent claims were not patentable.

COMMENT:

This is a reminder of the benefit of having a word-for-word correspondence between the patent claims and the patent specification.

Enzo's Jury Verdict of \$60M for Patent Infringement by Applera is Overturned

Patent infringement can be established literally or by equivalence.

Infringement by equivalence can be established if every limitation of a patent claim is found in the accused product/process and where there is only an insubstantial difference between the equivalent and the claim limitation.

Whether there is an equivalent can be determined by whether a component in the accused product performs substantially the same function as the claimed limitation in substantially the same way to achieve substantially the same result.

Enzo sued Applera for infringement of several patents that covered a technology for detecting the presence of a strand of DNA or RNA in a sample.

Enzo argued that it was not asserting equivalents of all direct detection labeling, just a subset. The Federal Circuit disagreed and characterized the patent claims as covering "indirect" detection, as distinguished from "direct" detection.

Therefore, the Federal Circuit affirmed the lower court finding of non-infringement following the jury verdict in favor of Enzo.

COMMENT:

The Federal Circuit relied on its patent characterization of "indirect" by referring to the patent specification which criticized the prior use of radioactive materials for detection - which was interpreted as "direct" detection. This can be a warning against including in the patent a specific description of how the invention differs from the prior art.

Philips Nets \$7M from Zoll in Ongoing Patent Disputes

Philips sued Zoll in 2010 for infringement of patents relating to heart defibrillator technology. The defibrillators are portable and to be used by non-medical professionals.

In 2012, Philips sued Zoll again and added more patents to the lawsuit.

Zoll responded in 2013 by asking the USPTO to review the validity of Philips' patents that were the subject of the lawsuits.

Next, the Federal Circuit said the USPTO did not have to review the validity of the patents.

Now, a Boston jury awarded Zoll \$3M for patent infringement by Philips. Interestingly, Philips agreed with that amount.

At the same time, the jury awarded Philips \$10M for patent infringement by Zoll. Philips asked the jury to award it \$217M.

COMMENT:

This is an example of how protracted patent infringement disputes can be. Here, the parties will likely appeal to the Federal Circuit - so the saga will continue.

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