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## An Example of Why it is Not the Best Idea to Initiate Infringement Litigation Without a Lawyer

The Federal Circuit described the case as a "quintessential example" of a "peddled product that conspicuously capitalizes on another's intellectual property."

Edge Systems had patent rights that covered hydradermabrasion products to improve skin health. It also owned common law trademarks, including DERMABUILDER.

Aguila sold over the web similar products under Edge System's trademarks. Edge sued Aguila.

The Federal Circuit found that the district court properly sanctioned Aguila for using fraudulent invoices to establish prior use of its trademarks. The district court also properly struck Aguila's defense of prior use.

Aguila also complained that the district court failed to strike the expert report of Edge which was filed late. The Federal Circuit replied that the district court had the discretion to allow the late report.

And, Aguila sought to take ten depositions during the last week of discovery. The district court only allowed five. The Federal Circuit again found that the lower court properly exercised its discretion.

The Federal Circuit also turned away Aguila's argument that summary judgment of patent infringement was improper. This was due to Aguila failing to present evidence of non-infringement and instead just conclusory arguments.

### COMMENTS:

Once there was a finding of "manufactured" documents by Aguila, it was probably all downhill from there in trying to convince the court of the merits of other issues.

## Amgen Settles Patent Infringement Suit Over AbbVie's Humira

In September 2016, Amgen received FDA approval of its Amjevita, a biosimilar to AbbVie's blockbuster Humira. In March 2017, Amgen received European Commission approval for the biosimilar.

However, patent litigation between the parties has prevented Amgen from getting its drug to market.

The parties have now settled with Amgen receiving a license to the patents which begins in 2018 for Europe and 2023 for the US.

### COMMENTS:

It seems that the delayed start of the license will give AbbVie significant time to build more market share.

## Dexcom Files ITC Complaint to Stop Importation by AgaMatrix

The US International Trade Commission (ITC) has the authority to investigate potential patent infringement of devices (not just medical) being imported into the US. If infringement is found, imports into the US can be excluded.

Dexcom, in California, owns patents for continuous glucose monitoring systems. The patented technology improves the processing of the monitored data.

Under the WaveSense brand, AgaMatrix, in New Hampshire, competes with Dexcom. AgaMatrix imports their products from China and Korea.

The complaint describes some background. AgaMatrix previously filed a patent infringement suit against Dexcom in Oregon. Dexcom sought inter partes review in the US patent office to have AgaMatrix's patents declared invalid. Dexcom also filed patent infringement suits in California and Delaware against AgaMatrix.

### COMMENTS:

Perhaps the next move is AgaMatrix filing another infringement action. We can only wait and see how things develop.

## Allergan Transfers Restasis Patents to Avoid Invalidity Determination

An alleged infringer has the ability to initiate in the patent office an *inter partes* review (IPR) of a patent to have the patent declared invalid.

However, entities who are entitled to sovereign immunity cannot be forced to remain as a patent owner party to an IPR.

Universities have successfully used their sovereign immunity to stay out of IPRs.

Allergan owns patents to its dry-eye drug Restasis. To take advantage of sovereign immunity and prevent IPR challenges to its patents, Allergan has transferred those patents to the Saint Regis Mohawk Tribe.

The transfer included an upfront payment of \$13.75M and yearly royalty payments of \$15M to the Tribe.

### COMMENTS:

The Federal Circuit will likely need to sort out this strategy.

## 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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