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## THE PARAGRAPH FOUR REPORT®

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### WELCOME

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### THE PIV IMPACT OF HEARTLAND

WHAT DOES VENUE HAVE TO DO WITH THIS?

Over recent editions of the *Quarterly Note*, I have mentioned the U.S. Supreme Court decision *Heartland v. Kraft Foods*, No. 16-341, which may have an impact on PIV cases and the PIV Market. The case was decided last May, and I think we can start to see a few trends develop.

The case is really one of procedure, and as the subtitle to this *Note* jokingly suggests, hinges on a purely legal interpretation of a couple of venue statutes and answers the question of *where* the defendant in a patent case can be sued. As most of my readers are not lawyers, do not be concerned. *The Quarterly Note* should never be mistaken for a legal treatise, and I will keep the legal interpretations and machinations of the court opinion to their minimum.

As the name implies, *Heartland v. Kraft Foods* was not a PIV case, not even remotely. It had something to do with flavored drink mixes and the fact that Kraft Foods thought Heartland was infringing its patents. So, Kraft Foods sued for patent infringement in Delaware.

Because Heartland was an Indiana corporation and had its headquarters there, it argued that it could not be sued in Delaware and asked to have the case moved to Indiana. Its only meaningful contact with Delaware was the fact that it sold some of the alleged infringing product in the state.

The District Court disagreed, finding that the case could proceed in Delaware and the Court of Appeals, in effect, agreed as well. The case then went to the U.S. Supreme Court.

In a unanimous 8-0 decision, the Supreme Court reversed, finding that the patent infringement case was not properly in Delaware as it was not the proper *venue*. The Court concluded that over the centuries, the evolution of where a defendant in a patent infringement case may be sued is slightly different than a general civil dispute brought in a federal court.



In interpreting and following the venue statute for a patent infringement case, the Court concluded that the place where a defendant can be sued is the place “where the defendant *resides*, or where the defendant has committed acts of infringement and has a regular and established place of business.”<sup>1</sup>

While it seems rather straightforward, there is a general venue statute and prior cases regarding the issue of where a defendant “resides” which open up competing legal arguments. Where a corporation resides could lead to several possibilities, but the Supreme Court concluded that for patent infringement cases, a corporation resides in the State of incorporation.

This conclusion is a slight departure from prior cases and how some courts have interpreted venue in patent infringement cases. *Heartland* narrows the number of places where such a defendant can be sued in a patent case. In general federal court cases, the venue statute is broader and the venue rules typically allow for a variety of places where a defendant can be sued.

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<sup>1</sup> The patent infringement venue statute is 28 USC §1400(b). Emphasis added. Note also that *Heartland* only considered domestic (or U.S.) corporations.

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For example, applying the same facts to *Heartland*, say Kraft Foods had sued over a contract matter instead, the case would likely properly proceed in Delaware. Without getting into the details of a legal treatise, jurisdiction and venue would likely be proper there.

These broader rules have been applied to PIV defendants over the years as well, but now it appears that the PIV market has responded to *Heartland v. Kraft Foods* which has two implications. The first implication is that more cases will get filed in Delaware and New Jersey -- a trend that has already taken place.

Delaware has created a favorable environment for corporations. Companies incorporate in Delaware even though they are located elsewhere. Like many industries, the pharmaceutical industry is no exception -- many ANDA filers are incorporated in Delaware even though their headquarters and facilities may be elsewhere.

In addition, many, but certainly not all, ANDA filers have a heavy corporate and business presence in New Jersey. After *Heartland*, there has been an increase in cases filed in either Delaware or New Jersey. Over the past six months, 90% of PIV cases have been filed in either Delaware or New Jersey, an increase from the 84% filed in the same six-month time period last year (before *Heartland*).

The fact that more cases will be filed in Delaware or New Jersey is not necessarily a bad thing. The judges there have tried many PIV cases in the past and are well-versed on the PIV process, laws, and technical aspects of pharmaceutical patents and processes. Cases will likely run with more efficiency when compared to courts that do not normally hear PIV cases.

However, currently there is a bit of a down-side. Delaware typically maintains 4 full-time federal judges. One of the judges (Judge Robinson) retired last July, leaving the jurisdiction temporarily working at lower capacity. While it can borrow a judge from another jurisdiction on occasion, we can expect Delaware cases to take longer to process until the court returns to full-strength.

The second implication is that brand companies will be left with fewer choices of where to bring their PIV cases.

For a vast majority, this will likely be something they can work with in due course. However, it may change litigation strategy for others such as Eli Lilly and Company.

While I have been reading every PIV case filed for more than a decade, even a casual PIV follower would observe that Eli Lilly often filed its PIV cases in the Southern District of Indiana located in its hometown of Indianapolis. Typically, the ANDA defendant was located and incorporated elsewhere (like New Jersey and Delaware) and had only minimal contacts with Indiana.

Perhaps Eli Lilly believed its local venue to be an advantage, or, if nothing else, easier in terms of conducting its cases without having to leave the comfort and convenience of its headquarters. *Heartland* may prevent Eli Lilly from choosing Indiana as a place to file its PIV cases. It, like others, likely will have fewer options.

## ABOUT THE EDITOR



Gregory Glass is the Editor of The Paragraph Four Report.

Mr. Glass earned an MBA from the Fuqua School of Business at Duke University. For fifteen plus years, he has worked in the pharmaceutical industry in a variety of capacities including market research, legal, managed care sales, and product strategy and has authored many papers.

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