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Hatch-Waxman Success: Start the Invention Story at the Beginning

One key to a successful outcome against generic challengers in a Hatch-Waxman case is a compelling and factual invention story based on evidence that was created in real time—during the drug development and regulatory process, according to Fish & Richardson's Chad Shear and Geoff Biegler.

By **Chad Shear and Geoff Biegler** | August 21, 2020

Fish & Richardson principals Chad Shear and Geoff Biegler (Photo: Courtesy Photo)

Twenty years or more can pass between a drug's development and a Hatch-Waxman trial related to that drug. One key to a successful outcome against generic challengers in a Hatch-Waxman case is a compelling and factual

invention story based on evidence that was created in real time—during the drug development and regulatory process.

Timing of Hatch-Waxman Litigation

The drug development process, by any standard, is very long. Although the exact timing varies considerably, clinical trials alone typically take six to seven years and that does not account for the drug discovery and preclinical testing work that must be done before clinical trials begin. From there, it can take several more years to go through the FDA review process before the drug can enter the market.

The Hatch-Waxman Act was a compromise that balanced the interests of pioneer pharmaceutical companies and the generic drug industry. For pioneer companies, the Act provides various types of regulatory exclusivities after New Drug Application (NDA) approval, during which time the FDA will not approve a generic application. The Act also allows the holder of an NDA to file a complaint for patent infringement against a company that files an Abbreviated New Drug Application and seeks to market a generic version of the NDA holder's drug prior to the expiration of patents associated with the drug. Given the exclusivities provided by the Act, a trial in a Hatch-Waxman case might occur seven or more years after a drug is approved by the FDA.

The Importance of Stories

Every Hatch-Waxman trial is different and understanding what a Hatch-Waxman trial might look like is the first step to effective preparation during drug development.

In most Hatch-Waxman cases, the defendants will assert that the NDA holder's patents are invalid. The validity or invalidity of a patent often turns on highly

complex science. To communicate these complexities effectively, it is helpful for litigants to use storytelling to present their case.

The story is often told through a variety of witnesses. In a typical Hatch-Waxman trial, those witnesses often include the public-facing clinician employee, the drug's inventors and one or more commercial witnesses. Importantly, the testimony of these witnesses will be more credible and, perhaps, more reliable when supported by documents created long before trial.

Develop an Invention Story

The invention story can be a key to success in Hatch-Waxman trials. By the time of trial, however, the inventors' memories may have faded. Surprisingly, in some cases, the inventors may remember facts that are in fact not accurate.

Accordingly, it is important to document the invention story from early in the drug development and patent prosecution process. To create a story, talk to inventors to understand and document the critical benchmarks of the invention. Some questions to ask include:

- What was the problem the inventors were trying to solve?
- How did the inventors uniquely appreciate the problem?
- What were the "eureka" moments?
- What failures and hurdles did the inventors face along the way?
- What is the benefit of the invention compared to previous treatments?

It is just as important to understand and document the failures the inventors encountered along the way along with their successes. These failures can later help show why the invention was not obvious.

It is also key to thoroughly document the entire drug development process so that the inventors can rely on documents to support their memory of the invention story. Documents that are often relied on by inventors in a Hatch-Waxman case include:

1. The patent
2. The prosecution history
3. Lab notebooks
4. Team meeting minutes
5. Reports to management

Without proper planning, lab notebooks, team meeting minutes and reports to management can be more difficult to locate. Lab notebooks may often contain the most direct and contemporaneous evidence of the events and timing that led to the invention. However, lab notebooks also often contain scientific jargon and drawings that may not jump off the page. Meeting minutes tend to use more basic language and may provide more context for particular work or experiments, while management reports are specifically intended to communicate scientific information to non-scientist executives and often lay out the invention from a big-picture perspective. As such, each of these documents are ideal to explain complex scientific stories to judges.

You need not wait until a Hatch-Waxman trial to tell the invention story. It can be beneficial to highlight the problem, hurdles and benefits of the invention consistent with the inventors' story in the patent specification itself. The specification can then support the inventor's testimony at trial. The patent claims should also be consistent with the invention story by focusing on the key features of the invention and by being commensurate in scope with what the inventors say they invented.

The Clinical and Commercial Chapters

The story in a Hatch-Waxman trial should also include information on the drug's clinical benefits and commercial impact. To develop clinical and commercial stories, a company's IP team must coordinate with its clinical, commercial and regulatory teams from development through marketing to ensure consistent messaging.

Judges are commonly interested in how a drug helps patients. Help facilitate that understanding in the clinical story by clearly showing the problem the drug is solving and why it is better than the prior standard of care. Ensure that regulatory filings are consistent with these themes, as well as the patents and the invention story, particularly those concerning the state of the art and the standard of care.

Like any great story, a pharmaceutical patent's starts at the beginning. The documentation being created now could be a key to protecting the patent decades from now.

Geoffrey D. Biegler *is a principal in Fish & Richardson's Southern California office. His IP litigation practice focuses on pharmaceutical and life sciences. He can be reached at* ***biegler@fr.com***

Chad Shear *is a principal in Fish & Richardson's Southern California office and a leader in the firm's life sciences and pharmaceutical litigation group. He can be reached at* ***shear@fr.com***