

Hatch-Waxman: The Interplay Between Innovation And Lowering Pharmaceutical Costs

The Editor interviews **Donald Rhoads**, Litigation Partner in the Intellectual Property Group, and **Jonathan Caplan**, Litigation Partner in the area of Patent Litigation, Counseling and Prosecution at *Kramer Levin Nafalis & Frankel LLP*.

Editor: Would you each tell our readers something about your backgrounds and professional experience?

Rhoads: As an undergraduate, I was a biology major and then I went to graduate school in pharmacology. However, I dropped the graduate work before receiving my Ph.D. as I was simultaneously attending law school. Upon graduation from the University of Michigan, with my pharmaceutical background and my law degree in hand, I joined a patent boutique, Fish & Neave. Subsequently, I joined Kramer Levin where I have been since 1998. I do primarily "pharma" work and Hatch-Waxman work, but I also do patent litigation for high-tech clients, both mechanical and electrical. Most of my work is litigation, but I also do counseling and prosecution.

Caplan: I have an undergraduate degree in electrical engineering. After college, I joined the Air Force and then went to law school in Philadelphia at Temple. I started practicing law in New York in the early '90s at Kenyon & Kenyon, doing a lot of prosecution in a variety of arts. In the late '90s, I moved to Kramer Levin, and my current practice is mostly litigation work. I also do a fair amount of counseling and prosecution. My original focus has been the electronics and communication areas, but over the last few years I've become more involved with "pharma" cases, including Hatch-Waxman actions. Like many lawyers in our department, we tend to work across technologies.

Editor: Would you give our readers a brief overview of the Hatch-Waxman Act?

Rhoads: When the Hatch-Waxman Act was passed a little over 25 years ago, it created the generic drug industry as we know it today. The formal title of the Act is the "Drug Price Competition and Patent Term Restoration Act," so the title itself shows you that it was a compromise bill between two concerned groups. On one side were the patentees/branded drug companies (the brandeds) who developed drugs, and on the other side were the generic companies (the generics) who wanted to produce generic versions of the drugs. Before Hatch-Waxman, it was very difficult for generics to produce the drugs because of the patents protecting them and because the generics had to run extensive clinical trials. However, the Act created an avenue where the generics have an opportunity to attempt to challenge patents and simply show bioequivalence in limited clinical trials and thereby produce lower cost generic drugs much earlier. Hence, people have asserted that the Act lowered health care costs in some ways.

Editor: Would you tell us about the intersection between intellectual prop-



Donald Rhoads



Jonathan Caplan

erty law and antitrust law in the pharmaceutical industry?

Rhoads: If you look at the history of patents, there always has been a tension between intellectual property (IP), and patents in particular, and antitrust law. Since patents are important in the pharmaceutical industry, the tension exists there also. A good example is if the new administration, through the FTC or otherwise, steps up scrutiny and/or enforcement of reverse payment agreements.

Editor: Jonathan, for those of our readers who may not be familiar with the concept of reverse payments, could you explain it in a couple of sentences?

Caplan: In its very simplest form, if a generic plans to sell a drug currently protected by a patent, the Hatch-Waxman Act provides a mechanism that once the abbreviated new drug application (ANDA) is filed by the generic, the generic provides notice to the branded regarding the patents covering the drug, following which the branded will initiate patent infringement litigation to attempt to stop the generic launch. Sometimes, both parties decide it is in their mutual best interests to settle via a significant payment from the patent owner/branded to the generic to keep the generic drug off the market for awhile for various reasons. Under this arrangement, the generic may make more money than by rushing to market the drug. The branded may also make more money by paying the generic to defer marketing the drug for a certain period of time. In other words, a reverse payment, with certain of the risks and the uncertainties of litigation accounted for. The question is whether there is an anti-competitive effect by keeping lower priced drugs off the market for a longer period. However, the branded company needs to recoup its investment, or R&D for new drugs will dry up. These agreements can be very pro-competitive and pro-consumer. You just can't dismiss them as anti-competitive.

Editor: Given the current focus on reducing health care costs, do you foresee Hatch-Waxman being amended in the near future? If so, in what ways?

Caplan: Obviously, lowering the price of drugs would lower health care costs, and one camp advocates providing generics with a fast-track ability to sell generic drugs. Conversely, there is a lot of discussion about the need for our economy to be an innovation-based economy. The pharmaceutical industry, and in particular, the branded pharmaceutical industry, is a major source of innovation.

The current system provides incentives for brandeds to invest in research to develop drugs, to test them, and to get them to market. You have to balance allowing brandeds to maintain their exclusivity long enough to fund R&D and give their investors a satisfactory return on their investment (ROI). Too early introduction of generic drugs would hurt the R&D pipeline that is so essential to the overall industry. Conversely, you have to give the generics a chance to challenge the amount of time of the exclusivity so that they can get a lower, less expensive form of the drug to the market.

Rhoads: Currently, there are a number of proposals in the House and Senate to tweak Hatch-Waxman further, but the tension remains between innovation and the cheaper drugs. The fear is that unless the brandeds get a satisfactory ROI, the brandeds will stop innovating. Every year, bills are introduced in Congress on patents, in general and for pharma specifically, and most of these proposed bills never get out of committee. Our view is that you'll see things continue essentially as they currently are, for the near future anyway.

Editor: What trends have you seen in the regulation of pharmaceuticals? How has it affected your practices?

Caplan: From a litigation perspective, Hatch-Waxman litigation has been very robust and shows no sign of abating. We're still in the midst of a cycle where there are a lot of big-selling, patented drugs approaching the end of their patent term. Consequently, a lot of litigation is being initiated.

We also see a lot of growth in the biologics area, and there is a real debate regarding whether there should be a Hatch-Waxman-comparable structure for them. It presents some different issues because biologics, by their nature, aren't quite as predictable as extant drugs. So you're going to see a continuing evolution of this current structure with two competing interests. Because the pharmaceutical industry is a major industry for this country, I don't foresee future regulations putting a strangle hold on pharmaceuticals, including biologics.

Rhoads: When you work for and with an industry, you have to monitor lots of proposed changes, many of which never take place. For example, there has been some recent tweaking of the FDA rules that apply to generics, but no major changes in how the Act works. With the U.S. Patent and Trademark Office (USPTO), the challenge continues to be the same thing year after year: the timely review and granting of patents (assuming that they are granted). The USPTO tried to introduce new rules on how patents would be procured, but they were recently struck down in court. Unfortunately, the USPTO is very behind in reviewing patent applications and handling appeals. They are trying to solve that problem, but getting patents out of the USPTO is a very big problem for our clients.

In the courts, there also have been some changes in the law applied to patents. The appeals courts have been making some significant changes in the law on matters such as inequitable conduct defenses, willfulness, injunctions and damages, the written description requirement, and the obviousness defense. Regarding the obviousness defense, a patent claim is invalid as obvious if a hypothetical person of ordinary skill in the art would have come up with the same solution. The U.S. Supreme Court recently decided an important case on obviousness, *KSR v. Teleflex*, that can be argued to make patents easier to invalidate and harder to obtain.

Editor: Given your knowledge of your clients' industries, what other services can you, as litigators, provide to your clients?

Rhoads: I think one of the things we always have tried to do is to fit our litigation advice into our client's business. So it's not just litigation advice we give; it's how our advice fits into their business and how it will make business sense for them. We don't like to look at litigation problems in a vacuum. Because we understand how the client's business works, our advice can be practical and make sense for them.

Caplan: Our business perspective extends to the services we provide our clients - our practice is not button-holed into solely IP and we handle a variety of different types of litigation, not just patent litigations. We do antitrust, false advertising and breach of contract litigation to name a few. We also often handle arbitrations and mediations when they arise for our clients. Importantly, and I say this as a litigator, is that we do not litigate unless the matter definitely needs to be litigated. We also have the benefit of working in a general practice firm that has a real team approach to its clients. If there is a business problem, we can bring in our tax people, our corporate people, and our bankruptcy people. It's a big advantage.

Editor: What features in the health care bill would the pharmaceutical industry like to see? What do you think would be beneficial to both the industry and to consumers?

Caplan: I think health care reform largely was trying not only to reduce overall costs, but also to bring uninsured people into the system. If you bring millions of new people into the system, both the brandeds and the generics would benefit by having more people with plans helping them get prescribed drugs. The open issue is who's going to negotiate the drug prices. I think the administration was trying to get some concessions, especially from the brandeds, as to what they were going to charge for drugs that were to be dispensed to all these new people. While there is support for reform to bring more people into the system, the fly in the ointment is going to be who is negotiating and what the ultimate prices will be, so that industry overall achieves an acceptable return on investment.

Please email the interviewees at drhoads@kramerlevin.com or jcaplan@kramerlevin.com with questions about this interview.