The Metropolitan
Corporate Counsel®

www.metrocorpcounsel.com

November 2013 Volume 21, No. 11

Roche's Chief Patent Counsel Joins Gibbons P.C.

In October, ***George W. Johnston,*** *former Chief Patent Counsel for Hoffmann-La Roche Inc., joined the Intellectual Property Department at Gibbons P.C. in Newark, NJ. "The firm's approach to servicing its clients is what I expected when I was a client and what I want to achieve with my new clients – personal attention, professionalism, knowledge of the business, creativity, and budget sensitivity," notes Mr. Johnston. Below, he discusses his broad familiarity with issues faced by in-house patent counsel, and how his background perfectly positions him to contribute to the Gibbons IP team's already exceptional efforts.*

Editor: Why did you choose Gibbons over other firms you had the opportunity to join?

Johnston: My reasons for joining Gibbons are the same reasons I was a Gibbons client. Throughout more than 35 years at Roche, I found Gibbons attorneys to possess the singular ability to "think like a client." The Intellectual Property Department has long focused its recruiting efforts on attorneys with hands-on in-house experience, particularly in the pharmaceutical industry. A significant percentage of the Gibbons attorneys with whom I have worked, and continue to work, are former chief patent, IP, or licensing counsel at businesses similar to Roche, running intellectual property operations at international companies that develop some of the most advanced, exciting products on the market. Many other Gibbons IP attorneys have advanced degrees in life sciences and technology and have worked in various research and development, engineering and other scientific capacities. So I have long thought that Gibbons attorneys are uniquely able to strategically address intellectual property issues from a genuine in-house, industry perspective – to understand, then tackle, the specific challenges and opportunities in-house patent counsel face. Gibbons is a perfect fit for me and for any former in-house counsel looking to join a team with a familiar viewpoint, approach, and recognition of innovative, effective solutions.

George W. Johnston

Editor: You mentioned challenges and opportunities specific to in-house patent counsel. What are some of those issues?

Johnston: Meaningful intellectual property protection remains critical to the business strategies of innovative companies. IP-intensive industries account for about a third of the gross domestic product and generate 40 million jobs – more than a quarter of the jobs in the U.S. To remain competitive, we must continue to invest in research and development, invent new products that people want and need, and file for patents to protect our research assets in a global environment.

Many chief patent counsel would agree that global competition is fierce in all business sectors, so the granting of high-quality patents is critical to thwart a rise of global infringing activity and to spur investment in high-risk areas, such as healthcare. The America Invents Act – the most significant U.S. patent reform in our lifetime – was intended to reduce the time to obtain a patent and improve the quality of patents issued. But, understandably, it has taken time for the Patent and Trademark Office to fully implement this very different patenting system and for counsel to appreciate its nuances and ramifications. IP counsel must be at the top of our game to understand the new law and recognize its impact on our businesses and competitors.

While the AIA attempts to improve consistency in obtaining patents, many recent U.S. Supreme Court patent decisions seem to erode the predictability of resulting patent litigation. Being a "constitutional law court" that often balances individual rights against state or federal actions, the Supreme Court has made broad patent policy proclamations combined with broad requirements to balance multiple competing factors. The federal appellate and trial courts are then left to figure out the details and apply the law to the given facts. By establishing these broad balancing tests, the Supreme Court has abolished many of the "bright line" tests previously favored by the Federal Circuit – which generally had taken a more business-oriented, pragmatic approach to interpreting patent rights – and made it more challenging for counsel to advise management of the risks and chances of success when enforcing patents.

Controlling costs will always remain a concern to in-house patent counsel. In one recent poll of corporate counsel, the majority of respondents reported using alternative fee arrangements including caps, flat fees for specific activities, and volume discounts as cost-controlling measures. In-house counsel must also constantly monitor the size of the attorney teams with which their outside counsel staff their litigations, one of the few ways we have found effective to rein in patent litigation costs.

All in all, it's an exciting time to be a patent counsel and particularly rewarding to practice in New Jersey, still a hotbed for extraordinary R&D innovation and associated patenting.

Editor: New Jersey is where you worked for your entire career. Are there intellec-

Please email the interviewee at gjohnston@gibbonslaw.com with questions about this interview.

tual property issues specific to the state that in-house pharma counsel face?

Johnston: While there have been significant changes in New Jersey's pharma landscape, including mergers, layoffs and closing of facilities, many successful New Jersey-based biotechnology companies with promising portfolios have emerged, and the remaining pharma companies have become more globally competitive. New Jersey is still home to America's finest pharmaceutical research and development laboratories, whose existence is vital to our local economy.

Due to New Jersey's pharmaceutical prominence, its federal district court system remains a popular destination to bring pharmaceutical suits, commonly called Hatch-Waxman Paragraph IV litigations, which continue to increase as generic companies challenge the patents of blockbuster drugs and much smaller drugs. Many recent U.S. Supreme Court decisions dealing with FDA use claims, subject matter patentability, research tools and safe harbor directly impact our Paragraph IV litigation approaches. Moreover, as a result of other Supreme Court cases, biotech inside counsel need to rethink claim-drafting strategies for diagnostic method claims involved with personalized healthcare and to explore the implications of the Court's decisions on their pending and issued patents covering isolated proteins.

In addition, the AIA Patent Office procedures for challenging issued patents are now in force. Previously, brand companies had at least four years from FDA drug approval before a generic could challenge the brand's patents. Smaller generic companies now are taking advantage of these relatively low-cost AIA procedures by attacking the patents even earlier than before. As a result, brand in-house counsel need to review the strength of their patent portfolios and develop strategies well before FDA approval in anticipation of early AIA patent attacks.

Before joining Gibbons, I was approached by a well-funded investment consortium wanting me to help them analyze, purchase, and then assert patents against the brand pharmaceutical industry in order to obtain big-money payoffs by licensing the pharma industry. These "shakedown" approaches from non-practicing entities (NPEs) – often called trolls – are common in the high-tech and software industries, where the cost of dragged-out litigation often outweighs the price for taking a license. Apparently, the approach is gaining interest in the pharmaceutical arena, and in-house patent pharma counsel may find themselves assessing the threat of many new patent troll litigations. It is worth noting that Gibbons has devised a clever means to address the threat of these troll litigations in a very cost-effective manner and thus prevent clients from having to capitulate because of anticipated litigation costs.

Editor: How has your in-house experience equipped you to help your new clients address these patent issues, those specific to New Jersey and otherwise?

Johnston: For over three and a half decades, I was privileged to be a member of the patent group of a highly respected, major global healthcare company with headquarters located outside the U.S. For a Jersey boy, it was an enlightening experience to have the pleasure of working with a diverse group of talented, multicultural individuals, while quickly recognizing that there is more than one way to achieve a common goal. This global perspective and depth of understanding gained from my various roles and assignments have contributed to my view that intellectual property plays a critical role as a key driver for innovation and human progress.

Over time, I moved from an entry position of patent attorney – when I was affectionately called "the Kid" – up through the ranks to vice president and chief patent counsel, at which point I was affectionately (I hope!) called "Boss." Our projects were diverse, as was the technology. Our patent management welcomed us taking the initiative to be creative and achieve more than just ordinary results – for example, to be the first to structure a successful co-promotion arrangement; to file for one of the original patent term extensions under the Hatch-Waxman Act; or to be one of the first companies to obtain an additional six months exclusivity under pediatric exclusivity rights. With these approaches, we were able to generate bottom-line value for the corporation.

From my experience, I learned how to successfully navigate the sometimes choppy waters of a multicultural organization. Many of these strategies and approaches could be equally valuable to other organizations. For example, I have learned that experienced patent attorneys, both in-house and outside counsel, possess the ability to see and understand the broader global technology picture and the skills to sort through and understand the layers of ever-increasing business, political, legal, and regulatory risk. We need to create the right global structures and support networks to foster innovation via effective communication, collaboration, and teamwork between local and international legal, R&D, and business personnel for prompt review and decision making. Moreover, it is just as important to foster a positive, creative environment where smart patent practitioners are free to make enormous contributions. My experience could be helpful to organizations – small or large – in establishing this environment.

Editor: You have been active in preeminent professional organizations, including the Gibbons Institute of Law, Science & Technology. What value do they provide?

Johnston: Encouraged by my prior company, I served as the first chair of the Patent Law Committee for what is now the Biotechnology Industry Organization (BIO) and on the Pharmaceutical Manufacturers Association's (PhRMA) Patent Committee and the board of directors of the Intellectual Property Owners Association (IPO). While on PhRMA's Patent Committee, I helped negotiate and lobby Congress to pass the Hatch-Waxman Act and assisted in the passage of pediatric exclusivity rights, both of which significantly benefited my former company. At BIO, we sought to strengthen our right to assert process patents against foreign importation, culminating in the Process Patent Amendments Act. This work provided an opportunity to see consensus emerge on timely policy issues impacting intellectual property.

By recognizing the existence of diverse interests within the patent community, we learned how best to advise policymakers on important patent issues. For example, this year the Gibbons Institute filed two amicus briefs to assist the courts in tackling some controversial issues important to the pro-patent bar, providing the courts needed insight on the potential impact their decisions may have on industry – something about which they might not otherwise have been aware. I look forward to continuing on the Gibbons Institute Board of Advisors.