Hatch Waxman - Business Strategies

Ms. Patricia Lecca

European and French Patent Attorney of Lecca & Associates Ltd

The Hatch-Waxman Medicare Act of 2003 allows a New Drug Application (NDA) holder to list their patents covering the marketed drug, in the "the Orange Book." The Orange Book is something that the Food and Drug Administration maintains. Once those patents are listed in the Orange Book, a generic company that would like to market the same drug must assert that those patents in the Orange Book are somehow invalid or not infringed by what the ANDA (Abreviated NDA) filer plans to do. Once the ANDA holder makes that assertion, the patent holder or NDA filer has forty-five days to file suit. Upon filing suit, there is an automatic thirty-month stay of FDA approval of the ANDA, until there is a court decision in the ANDA filer's favor. The Hatch-Waxman Act granted 180-day marketing exclusivity to the first filed ANDA containing a paragraph IV certification. If the first filed paragraph IV applicant was sued and won in court, they would get 180 days of exclusive marketing of the generic.

Although this forms the basic essence of this act, since its introduction numerous business strategies have evolved around this. Generic companies knew that the first approved generic product would attract relatively high prices and take the majority of the generic market share, and those who entered later would reap lower margins. Innovator also started exploring novel means to keep the generics from reaping benefits. Majorly competition amongst the generic companies increased so tremendously that each generic company started tailoring their own strategy to carve their own niche. Innovators in turn introduced the concepts of "pay for delay settlements" and "authorized generic" to make life difficult for generic pharma.

Amongst the myriad tools that are available for experimentation by companies in a Hatch Waxman scenario, the recently introduced patent office post-grant review procedures created by the AIA, particularly the post-grant review (PGR) and the inter partes review (IPR) have left many in the pharmaceutical industry—particularly those who frequently participate in Hatch- Waxman litigation—wondering whether these new mechanisms will alter the litigation landscape. Existing post-grant review procedures, such as ex parte reexaminations, are not commonly utilized by generic pharmaceutical companies to challenge the validity of Orange Book-listed patents. Many feel that the existing procedures take far too long to be worthwhile; others are hesitant of submitting their defenses at the patent office which may not applied in a court case later. Aspects of some of the new post-grant review procedures created by the AIA, particularly the post-grant review (PGR) and the inter partes review (IPR) procedures, may address these concerns. Companies could integrate the practice of these new procedures into their Paragraph IV Business strategies to leverage on novel mechanism s to tackle the innovator's patent and bring a generic drug sooner into the US market.