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Drug Pricing

A Bridge Too Far? Hillary Clinton's Proposed Plan to Limit Prescription Costs Would Stifle Innovation

By Gerard P. Norton

and Michael S. Montgomery

In response to public outrage over increasing prescription drug prices—stoked by Turing Pharmaceuticals raising the price of Daraprim from $13.50 to $750 per pill—Democratic presidential candidate Hillary Clinton has unveiled a number of proposed reforms to the prescription drug market. Announced on Sept. 22, these proposed reforms include limiting how much patients would have to spend out of pocket for prescriptions to $250 per month or $3,000 per year, as well as allowing the government to negotiate Medicare prices. Clinton also proposed several reforms to pharmaceutical and biotechnology patent protection and regulatory exclusivity that we believe are well intentioned but ill advised.

Chair of Fox Rothschild's Intellectual Property Litigation Practice Group, Gerard P. Norton, Ph.D., has extensive experience litigating complex matters pertaining to patents, trademarks, copyrights, trade secrets and breach of contract. He can be reached at gnorton@foxrothschild.com.

Michael S. Montgomery is an associate with the firm practicing in the Intellectual Property Group. He can be reached at mmontgomery@foxrothschild.com.

Clinton's proposed reforms include:[1]

- cutting the proposed regulatory exclusivity period for novel biologics from 12 to seven years, which is closer to the five-year regulatory exclusivity period for new pharmaceutical compounds; and
- eliminating ''pay-to-delay'' or ''reverse payment settlements,'' which are effectively settlement agreements in a patent infringement suit where name-brand pharmaceutical manufacturers pay generic competitors to settle an infringement suit rather than face a non-infringement or invalidity challenge to their patents. Presidential candidate Sen. Bernie Sanders (I-Vt.) has suggested a similar approach on his campaign website.[2]

Biologics Regulatory Exclusivity

The regulatory exclusivity period for novel biologics was set at 12 years in the Biologics Price Competition and Innovation Act of 2009 (BPCIA), a relatively small but significant part of the much greater Patient Protection and Affordable Care Act (ACA). The BPCIA was enacted into law on March 23, 2010. The 12-year regulatory exclusivity period was selected after careful consideration of the time and expenses involved in researching, formulating and gaining regulatory approval for a novel biologic compound.

For example, the time required to develop a novel biologic compound is estimated at between 10 to 15 years.[3] With the U.S. having joined the rest of the world in the adoption of a ''first-inventor-to-file'' patent re-

[1] http://www.bloomberg.com/politics/articles/2015-09-22/hillary-clinton-drug-plan-would-cap-consumer-costs-mandate-r-d-spending.

[2] http://www.sanders.senate.gov/newsroom/recent-business/stop-skyrocketing-drug-prices-sanders-says_---.

[3] http://www.phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf.

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gime in 2013, as part of the America Invents Act (AIA)—another very consequential piece of legislation enacted by the Obama administration—a premium has been placed on applicants to ''rush'' to the U.S. Patent and Trademark Office (USPTO) to secure a filing date for patent applications. Furthermore, under the current patent regime (June 1995-present), patent terms run for 20 years from the earliest (non-provisional) filing in the patent family. This combination puts significant new pressures on applicants. Previously, an applicant could conceive of the invention, begin reducing it to practice and then proceed to wait a reasonable time period before filing with the USPTO in order to ensure both an adequately broad and enabling disclosure as well as to maximize patent term. If an applicant was faced with a rejection over prior art, the applicant was able to ''swear behind'' certain references with prior inventions. Not so any longer.

With such a long time required to develop novel biologic compounds, and with a premium being placed on being the absolute ''first to file,'' pharmaceutical and biotechnology developers find themselves in a position where they are by necessity filing patent applications on relatively nascent technology—often within the first few years of the typical 10-to-15-year development period—and then refining it through subsequent applications, drawing priority to previous filed applications, all while watching the proverbial sand fall through the 20-year hourglass. This places a significant premium on the 12-year regulatory exclusivity period granted by the FDA, as the issued patents, all too often, have only a few precious years of term left for the name brand entity to recoup its significant investment, which is up to a cost of about $1.2 billion per new biologic.[4]

Indeed, many experts have already cast their opinion that, for biologics, the regulatory exclusivity period will prove to be more valuable and critical to the success of this rapidly growing and emergent field than patent protection will, as patent protection is subject to collateral attack by generic (and other) competitors, and is limited to the claim scope of the patents, which are carefully narrowed during patent prosecution to secure patentability. Regulatory exclusivity is much broader and represents the government's recognition of the investment and contribution the developer has made to society in bringing a safe and effective novel biologic to market approval.

'Reverse Payment' Settlements

Clinton's proposal to eliminate ''reverse payment'' settlements is an equally flawed proposition. As an initial matter, ''reverse payment'' settlements were held as not presumptively unlawful restraints on trade by the U.S. Supreme Court in *FTC v. Actavis, Inc.* (2013 BL 158126, 133 S. Ct. 2223, 6/17/13), and are subject to a ''rule of reason'' analysis, like any standard licensing or settlement agreement. The Supreme Court recognized that there ''may be justifications for reverse payment that are not the result of having sought or brought about ''anticompetitive consequences'' and noted that such ''payment may reflect compensation for other services the generic promised to perform—such as manufacturing or distributing the patented item, or helping to develop a market for that item.''

[4] *Id.*

Legal argument aside, Clinton's rhetoric unfairly suggests that pharmaceutical patent holders are engaging in unscrupulous conduct, seeking to box out competition. But one need only look to the unique nature of ''reverse payment'' settlements to realize that it is the patent holders who are the truly disadvantaged party. The fact that the patent holders feel the need to effectively pay ransom to generic manufacturers makes clear two distinct points. The first is that the patent must provide immense value to the patent holder in the right to exclude the generic competition for the lawful term of the patent, and the second is that it is relatively costless for the generic manufacturer to seek non-infringement or invalidation of the patent. For the generic manufacturer, it is a win-win scenario. If they win a patent infringement suit, they get to market that much faster. If they settle, they still rake in a payout. The investment costs for a generic pharmaceutical ($1 million to $5 million) or biosimilar (estimated $100 million to $200 million) are tiny in comparison to the costs for a new name brand pharmaceutical or biologic, thus making the calculus for bringing suit rather straightforward for generics.

In fact, the Hatch-Waxman Act—the much more established (1984) counterpart to the BPCIA (2009) that relates to laws regulating generic pharmaceuticals—incentivizes generic manufacturers to seek claims of invalidity or non-infringement of brand pharmaceutical patents through what is known in the industry as a ''paragraph IV certification.'' The FDA will grant a 180-day period of regulatory exclusivity to the first generic company to submit an application with the FDA that is coupled with a ''paragraph IV certification'' that ''affirms'' that the patents which cover the name brand product are either invalid or not-infringed.

While it is true that willful infringement of a patent will provide the basis for triple damages, ''good faith'' reliance on an opinion of non-infringement or invalidity by outside counsel will prevent a finding of ''willful infringement,'' which has basically had the practical effect of creating a market for these opinions. As such, generic manufacturers find themselves in an already advantageous position, and do not need the likes of a reduced exclusivity period, or the elimination of ''reverse payment'' settlements.

Conclusion

At the end of the day, the numbers don't lie. Generic pharmaceuticals represented 84 percent of prescriptions filled in 2012 in the U.S., up from just 49 percent in 2000.[5] Generic pharmaceuticals represented 39 percent of global pharmaceutical sales in 2015, up from 20 percent in 2005.[6] What the future holds for biosimilars, which are ''generic'' biologics, remains to be seen. On March 6, 2015, the FDA approved its first ever biosimilar, Sandoz's Zarxio, which was deemed ''similar'' to, but not ''interchangeable'' with, Amgen's Neupogen.[7] This is a significant distinction, as regulatory exclusivity for biosimilars relies on interchangeability, while

[5] *Id.*

[6] https://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/Documents/The_Global_Use_of_Medicines_Report.pdf.

[7] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.htm.

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regulatory approval relies only on similarity. For now, the U.S. remains the world's largest market for prescription drugs and biologics in particular. Post-recession, the biotechnology sector has been one of brightest spots for growth, as biologics and biotechnology represent the new frontier for modern medicine. Oncology therapy spending in particular has reached $75 billion to $80 billion per year as of 2015.[8]

[8] *Id.*

As a strong candidate to be the next U.S. president, Clinton should resist catering to popular opinion on these issues, and instead should send a message of supporting, not stifling, technological innovation. In order to compete internationally, the U.S. must maintain a strong patent and regulatory system that attracts talent and the investments that follow. Nowhere is this exclusivity more important to recovering significant research and development costs than in the pharmaceutical/biotechnology landscape.