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Antitrust in Life Sciences

Panel 2

Generics Exclusion: What Conduct Crosses the Lines?

What Conduct Crosses the Lines? Product Hoping, Patent Settlement, Class Certification.

Webinar, 1 July 2020

*Interview with Elinor R. Hoffmann (NY Attorney General, Antitrust Bureau) by Jeffrey Bank (Wilson Sonsini)**

Elinor R. Hoffmann *(Deputy Chief, New York Attorney General, Antitrust Bureau), has been interviewed by* ***Jeffrey Bank*** *(Partner, Wilson Sonsini) in anticipation of the* ***Antitrust in Life Sciences*** *webinar, to be held on 1 July 2020. This webinar was originally a conference that would take place on 23 March 2020. However, due to the COVID-19 outbreak, it has been transformed into a webinar.*

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Jeffrey Bank: **The life sciences industry has long been a focus for many state attorney general offices (including New York), federal enforcers, and private plaintiffs. What factors have made the industry ripe for antitrust enforcement from your perspective, and do you see that trend continuing?**

Elinor R. Hoffmann: The pricing and availability of pharmaceuticals, including life-saving pharmaceuticals, continue to threaten the health and well-being of consumers throughout the United States. The Kaiser Family Foundation and JAMA published data last fall that indicated that over the past 20 years, US drug spending has increased by 330% compared with a 208% increase in total US health expenditures. And three in ten people surveyed reported they have not taken medications as prescribed in the past year because of the cost.

Although these issues have bi-partisan attention, and there are some legislative proposals that have been adopted on the state and federal levels, we have long been concerned about potentially illegal conduct being at the root of at least some of the problems we see in the market. So we've brought cases like the litigation alleging generic drug pricefixing, pay for delay (like the Tricor case and the amicus brief we authored in FTC v. Actavis), and monopoly maintenance (like NY v. Actavis and Suboxone.) We recognize the importance of innovation, and the high cost of developing innovative drugs and bringing them to market. Nevertheless, competition is the best way to promote innovation while protecting consumers and other payors from artificially high pricing.

We intend to continue to be vigilant and we are not afraid of bringing cutting edge cases in this sector, as we did in NY v. Actavis. The stakes are high.

Over the last twenty years, some pharmaceutical manufacturers have routinely engaged in conduct that courts have found, in certain circumstances, to be anticompetitive. This includes so-called reverse payments, product hopping, restricted distribution systems, sham petitions and litigation, exclusive dealing, and more. Do you think these issues should be addressed through legislation rather than enforcement or private litigation, and why do you think state legislatures and Congress have generally been slow to pass such legislation?

It seems pretty clear that both legislation and enforcement should have a role. For example, in 1984 Congress enacted the Hatch Waxman Act creating a quicker approval path for lower cost generic drugs. And at the same time, it extended the patent life for patents relating to innovator pharmaceuticals. The Hatch Waxman Act benefited consumers because in fact, it facilitated the launch of many lower cost generic drugs. But over time, we saw firms engaging in conduct that undermined the objectives of that law, gaming with pay for delay schemes, product hopping and sometimes blatant price-fixing. So while thoughtful and enforceable legislation is critical, so is active enforcement to prevent and punish anticompetitive conduct and anticompetitive mergers.

Scholars and antitrust practitioners have written extensively about how some of the same conduct undertaken to exclude or delay generic pharmaceuticals could be used to exclude or delay biosimilar products. Given that biosimilar competition has progressed

slower than anticipated in the U.S., why do you think there has not been the same pace of enforcement actions and private litigation brought in the biologic-biosimilar context as there has been in the small molecule-generic context?

The reasons for the slow development of biosimilar competition are unclear. Right now, biologics, or drugs made from living organisms, comprise close to 40% of prescription drug spend, but we are talking about a far smaller universe in volume than traditional chemically synthesized pharmaceuticals—biosimilars are about 2% of total prescription volume. So the dollars are clearly huge. On the other hand, it apparently costs far more to develop and launch a biosimilar than a traditional generic I don't know how accurate the numbers are, but there does appear to be a significant difference.

And there are regulatory issues that affect biologics differently than traditional drugs. For example, the Hatch Waxman Act does not generally apply to biologics, and state substitution laws are more restrictive with regard to biologics than with regard to traditional drugs, in the sense that there is less opportunity for automatic substitution. Regardless, according to the FTC and FDA, biosimilars marketed in the United States typically launched with initial list prices 15 to 35 percent lower than the list prices of the reference products, so there is reason to try to insure that biosimilars are not facing anticompetitive impediments.

Just recently, the FDA and FTC issued a joint statement promoting competition in markets for biologics, referring to the 2010 Biologics Price Competition and Innovation Act and noting that it was intended to foster competition for biologics, including biosimilars. The BPCI Act created an abbreviated pathway for biological products demonstrated to be biosimilar to or interchangeable with an FDA-licensed reference product, similar to what the HWA did with regard to traditional brand drugs and generics.

The FDA/FTC statement indicates that these agencies are watching the biologics area carefully. And certainly the states, too, are watching this space and will take appropriate action if we have reason to believe a firm is engaging in anticompetitive conduct.

** The views and opinions expressed in this document do not necessarily represent those of the speakers' institution or clients.*