"ANTITRUST AND INNOVATION: REBALANCING THE SCALE" REMARKS OF COMMISSIONER JULIE BRILL INTERNATIONAL BAR ASSOCIATION SEPTEMBER 14, 2013

Thank you, Jan, for the kind introduction, and thanks to the IBA for inviting me to share with you my views on the role that antitrust agencies can play in protecting and promoting innovation.

Before I dive into substance,

We	have	more	recently	begun	to	pay	close	attention	to	so-called	patent	assertion	entities

generic drug entry, and thus generic drug competition, while at the same time increasing brand name incentives to innovative. In the words of the sponsor Representative Henry Waxman, this was Yet Representative Waxman noted for the Congressional record that the overarching goal of the legislation low-cost, generic drugs for gs to people who purchase drugs, including the taxpayer. Sponsor Representative Waxman graph of the legislation gs to people who purchase drugs including the taxpayer.

ith respect to generic competition, Hatch-Waxman reconfigured the existing generic drug approval process in order to speed up generic drug introduction to the market, while at the same time ensuring that generics were as safe and effective as their branded equivalent

drug industry in the United States stems in significant part from the Hatch-Waxman Act. And generic drug competition has become the primary means through which the U.S. health care system achieves savings in prescription drug spending which totaled over \$260 billion in 2011.¹⁹

The careful balance struck by the Hatch-Waxman Act has, however, been under significant threat in recent years from reverse payments, or pay-for-delay. Pay-for-delay refers to a practice whereby branded and generic drug companies agree to settle Hatch-Waxman litigation—through which the Act intended to create a pathway for generic drug competition—with a payment from the brand to its generic rival to ensure delayed generic entry. These payments can even exceed the amount the generic could have earned had it entered the market and competed. The threat is therefore that rather than competing with branded drug firms and thus lowering prescription drug prices for consumers, generic firms will instead join forces with brands by sharing in monopoly rents.

Of course, the branded drug firms do not lose out either. In fact, one CEO notoriously announced to analysts that a settlement which subsequently became the subject of an FTC challenge had bought the company

And that was just one drug. O4(e)4(.5ETBT/1h7(sc)024 474[(one)] TJETB estimated that pay-for-delay costs consumers on average \$3.5 billion each yearh7(sc)024 474[(one)] TJ5/F9 446

settlements in 2012 alone. ²⁶ The years between 2005 and 2012 were lonely ones for the FTC, as we continued to fight pay-for-delay deals, and were viewed by increasingly hostile opponents as the pay-for-delay Don Quixote tilting at windmills.²⁷ Thankfully, however, we did not give up the good fight on behalf of consumers, competition, and ultimately innovation.

Our dogged effort to balance the scales of innovation and competition continued with the Actavis case, which we filed in January 2009.²⁸ The case involved a pay-for-delay settlement over the product Androgel, a topical gel used to treat male testosterone deficiency. In finding against the FTC, the Eleventh Circuit

actor [] would take

In other words, the court erased competition from the congressional Hatch-Waxman equation balancing innovation and competition.

Fortunately, not all courts agreed with the Eleventh Circuit. Shortly after the Actavis decision, the Third Circuit found, in a case involving K-Dur, a drug used to treat low potassium levels, that antitrust did in fact apply to pay-for-delay agreements. In so doing, the Third Circuit attached considerable weight to the fundamental balance of the Hatch-Waxman Act. In words that were music to this FTC ears, the K-Dur court said that udicial policy preferences such as those expressed by the Eleventh Circuit should not displace which is

evident from the structure of the Hatch-Waxman Act and the statements in the legislative record. 30

clear split among the U.S. circuit courts with respect to pay-for-delay, thus clearing the path to the U.S. Supreme Court. The FTC was cautiously optimistic that the Supreme Court would find in our favor. After all, earlier in the year the Supreme Court had ruled in favor of the agency in the Phoebe Putney case (involving a hospital merger) in order to uphold the fundamental national values of free enterprise and economic competition that are embodied in the federal antitrust laws. 31

Actavis³² decision I believe that these national values went to the heart of the Supreme C in which the Court held that antitrust laws apply to pay-for-delay agreements. The Court rejected the scope of the patent test, finding that it automatic antitrust 33 on pay-for-delay settlements. Instead, the Court found that the legality of agreements not to compete between a patent holder and a would-be rival are to be assessed using

³⁰ In re K-Dur Antitrust Litig., 686 F. 3d 197, 217 (3d. Cir. 2012).

²⁶ FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003, at 1 (2013).

²⁷ Ed Silverman, Tilting at PTD Windmills, Contract Pharma, (Nov. 10, 2010), available at http://www.contractpharma.com/issues/2010-11/view_pharma-beat/tilting-at-ptd-windmills/.

²⁸ FTC v. Watson Pharm., Inc., 677 F. 3d 1298 (2012).

³¹ FTC v. Phoebe Putney Health Sys., Inc., No. 11-1160, 570 U.S. (2013), slip op, 7.

³² FTC v. Actavis, Inc. 133 S. Ct. 2223 (2013).

³³ Id. at 2237.

? You see - with all due respect to my European

counterparts -