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Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck!

(The Role of the Commission, Congress, and the Courts)

I. Introduction

Let me start with the usual disclaimer that this speech does not necessarily reflect the generics. Last November, we sued to unwind an agreement under which Warner Chilco

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II. FTC Challenges to Pharmaceutical Patent Settlements

Hatch-Waxman, of course, has largely been a success for consumers. To be sure, it is not invulnerable to chicanery – companies on both sides of the industry take opportunities to game the statute. For example, starting in the late 1990s, the Commission began to see pharmaceutical patent settlements in which brand firms paid generics to stay off the market. This conduct stopped, though, after we challenged several such agreements.

Having said that, recent appellate decisions that sanction this type of conduct are threatening the core of Hatch-Waxman. If the Supreme Court – or Congress – doesn't reverse this trend, the result could be a substantial increase in drug costs – and substantial harm to the consumers who pay for these drugs.

A. The Success of Hatch-Waxman

When Hatch-Waxman was enacted it had a few simple goals: "to make available more low cost generic drugs by establishing a generic drug approval procedure . . .",[5] while providing additional protections for innovator firms. The results of this law far exceeded what was envisioned back in 1984. More than twenty years after enactment, we still have a thriving pioneer drug industry – an industry that is the envy of the rest of the world, introducing new and innovative products year after year, allowing people to live longer, healthier and more productive lives. We also have a vibrant generic drug industry, one that had been virtually non-existent before Hatch-Waxman.

Let me give you a few examples of the benefits of early generic entry prior to patent expiration: generic entry on Prozac in 2001, approximately three years before the patent expired, resulted in consumer savings of about $2.5 billion; generic entry on the heartburn drug Prilosec in 2002, more than fifteen years before the last of AstraZeneca's patents expired, saved consumers approximately $360 million per year; and finally, generic entry on Paxil in 2003, three years before the last patent would have expired, saved consumers about $2 billion during that period. It's clear then, that the incentives fostered by Hatch-Waxman haven't hurt industry, but have delivered substantial benefits.

B. The Current Threat

The unquestioned vitality of that statute, though, is being threatened by the *Schering* and *Tamoxifen* decisions. In 2003, the Commission found that Schering's payments to settle patent suits in exchange for deferred generic entry violated the FTC Act as illegal restraints of trade

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there were sixteen settlements between brands and generics. *Three* had payments to the generic accompanied by an agreement to defer entry. This is not a surprising development – the Eleventh Circuit opinion in *Schering* came out in March 2005, midway through the fiscal year.

The most recent evidence – though not complete for fiscal yea226 complent evidenctlementscs.m0 a

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consumer savings. And since we are still early in 2006, assuming Apotex could have launched in the next year or so – consumers potentially lost the opportunity to benefit from these savings over

We also have seen another novel strategy to bottleneck subsequent entrants. The Federal Circuit decision in *Teva v. Pfizer* held that ANDA filers who are not sued by the brand – or lack a "reasonable fear" of a lawsuit – cannot obtain a declaratory judgment about whether their product infringes or the patent is valid.[17] Read in combination with *Schering* and *Tamoxifen* – and taken to its logical extent – this could mean that a brand firm, having settled with the first-filer can block *all* subsequent generic entrants simply by declining to sue. We seem to be seeing a growing trend employing this strategy[18] – one that could deny consumers access to cheaper drugs until patent expiration – in other words, it's as if Hatch-Waxman never existed in the first place.[19]

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empowered by the courts to pay the generic more than it would have made by competing – these rivals will have *carte blanche* to avoid competition and share resulting profits, and we will see minimal competition before patent expiration. Such results fly in the face of Congress's efforts in 1984 to create incentives for early generic entry, and in 2003 to ensure review of these settlements that troubled them.

The practical consequences are also disturbing. Just last year, eleven generic companies were in patent litigation against brands for drugs with nearly $25 billion in annual sales.[20] Early entry means billions in consumer savings; delayed entry following settlement with an exclusion payment means consumers save substantially less – and are left holding the bag.

C. What is to be Done?

We are optimistic that if the Supreme Court takes the *Schering* case, it will understand the implications of the Eleventh Circuit ruling – and decide in favor of the Commission, competition, and consumers. But it is not certain it will even grant *cert*. On the one hand, the Court has sought the Solicitor General's views on this case. That's a good sign. On the other hand, it's not at all clear that the Solicitor General will encourage the Court to accept our petition. That's often the death knell for *cert*.

But talk about divided government – in an unprecedented twist, should that occur, we would actually get a reply brief to our own Solicitor General. In any event, we'll likely learn what happens in the next month or two, by the time the Supreme Court term ends.

If *cert* is rejected, the Commission will decide collectively whether (and how) to respond – we are the epitome of a consensus driven agency. However, we should think about a two-pronged approach: first, look for appropriate enforcement cases which may create a clearer split in the circuits; second, encourage Congress to act, as it has in the past.

We could bring a case in the Sixth Circuit, which has somewhat more favorable case law; in the Ninth Circuit, which is generally more receptive to antitrust claims; or perhaps in the D.C. Circuit, which has significant experience in antitrust and with enforcement agencies.[21] As for a legislative fix, the 2003 Medicare Amendments attempted to address t -1 0 12 487.3sBT/c4</MCID 13 lit

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that are intended to keep lower-cost drugs off the market."22 So Congress has recognized this problem in the past; it might be willing to step in again to solve it in the future. You could write a law in a variety of ways. For example, you could banMpayments above a de minimis amount or simply repudiate the Schering/Tamoxifen holdings. Determining the best statutory approach won't be easy, bBBowe'll have some time to think aboBBothis – if we have to. III. Conclusion Many years ago, Will Rogers said "legislation is like sausage, it comes oBBofine, bBBoyou don't want to know how it's made." This analogy fits Hatch-WaxmanM– an oddity of a statute to be sure, and the only one I know that <</ually encourages litigation – bBB a law that has led to great benefits for consumers. Given those benefits, for many years it was appropriate for us to stay oBBoof the way and let the market function – so long as the gaming was minimal and the statute remained largely in alignment. BBBowhen a law gets oBBoof whackM– as we may be seeing with the resurrection of exclusionaryMpayments – we still have aMvital role to play owhether by studying the issue or by enforcing the law. Again, I appreciate the opportunity to share my thoughts with you. You should feel free to disagree with what I've said; you should feel free to do so passionately. I'm happy to hear your comments and to