How Settlements Make Strange Bedfellows: Or How the Federal Trade Commission has Managed to Unite the Entire Pharmaceutical Industry (but only in Opposition to the FTC's Position on Exclusion Payment Settlements)[1]

I. Introduction

It is a great pleasure to be here today. I want to thank GPHA – and Kathleen Jaeger – for inviting me.

But come to think of it, perhaps the pharmaceutical industry – both brand and generic – should be thanking us, the Federal Trade Commission. After all, GPHA and Pharma companies are almost always fighting with each other, yet we seem to have unified the entire industry. At least, that is, in your opposition to *our* position on exclusion payments. Indeed, whenever the phone rings in my office, I half expect it to be a call from the Nobel Committee telling me that the FTC has been nominated for a Peace Prize.

More seriously, today you – that is, the generic industry – have much to be proud of. Over the past 25 years, you have challenged weak patents, designed around narrow ones, brought legitimate competition to the market years before patent expiration, and saved consumers billions of dollars – in fact, billions of

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[1] This text is based on a speech given to the Generic Pharmaceutical Association's Annual Policy Conference on September 29, 2006, in Washington, D.C.

dollars alone on blockbusters like Prozac, Prilosec, and Paxil. Just as importantly, by being such tough competitors, you have spurred brand companies to develop more innovative new drugs themselves. Yours is truly a record that has fulfilled the promise of the Hatch-Waxman Act.

II. Discussion

To continue to fulfill that promise, though, you'll no doubt face more challenges on the road ahead. I'll comment on a few of them today. Maybe the simplest map for my talk is to start with some of the areas about which we agree, move on to those where we may need more study, and then conclude with a discussion about the one area where we're in stark disagreement. But don't worry, I read in the conference materials that the cocktail reception was "a big hit with last years attendees" so I won't go on for too long.

Let me also make clear that my remarks do not necessarily reflect the views of the Commission or of any other individual Commissioner.

A. Areas of Agreement

An area where we agree, for example, is in the need to reform the "Citizen's Petition" process – one susceptible to systemic abuse.

It is no coincidence that brand companies often file these petitions at the eleventh hour before generic entry and that the vast majority of citizen petitions

are denied. According to Mylan, since 2003 the FDA has denied 20 of the 21 petitions that it has ruled on.[2] Over a longer period, the statistics are much the same; the FDA recently testified that between 2001 and 2005, it issued 42 responses to citizen petition, denying 33 entirely, denying three in part, and granting six.[3]

To be honest, that's not surprising: the cost of filing a petition is low, but the benefit of delaying a generic even for a few months can mean hundreds of millions of dollars in additional profits to brand companies – and in additional costs to consumers.

The FTC has made proposals to the FDA on ways to minimize the harm from potential Citizen's Petition abuse. I support these reforms; however, they are mostly procedural ones designed to improve transparency. We probably need to look at some sort of congressional approach, for example, that would prohibit the FDA's consideration of citizen petitions after a certain date – unless there is good

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[2] Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm., 107th Cong. (Apr. 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) at 12, available at http://commerce.senate.gov/hearings/042302jaegar.pdf

[3] Statement of Gary Buehler, RPH, Director of the Office of Generic Drugs, before the Special Committee on Aging of the United States Senate (July 20, 2006), available at http://aging.senate.gov/public/_files/hr161gb.pdf.

cause for the delay – or that would allow the generic to go forward while the FDA is still reviewing the petition.

Another area of agreement is the need to fix the declaratory judgement problem – or "the DJ," as we fondly call it around the Commission. Recent court cases have created a Catch-22 for some generics once the first-filer has settled: the courts won't let subsequent generics bring a patent challenge, and the FDA won't let them go to market without first winning one.

Simply put, this makes no sense. The 180-day exclusivity should be a reward for generics bringing competition to the market, not a tool for companies to bottleneck competition.

The Commission proposed a solution to this problem in 2002. Senator Gordon Smith, Chairman the Aging Committee and of the Commerce Committee's FTC Subcommittee, said at a hearing in late July that he wants to solve this problem "post-haste." The Lott-Stabenow and Waxman bills take a slightly different approach from the Commission's proposal in 2002 but seeks a similar result. We look forward to working with you – and all interested parties – to solve this problem.

B. Areas that Need More Study

Now, let me talk about a few areas that need more study.

With respect to so-called authorized generics, I know that most of you want Congress to ban them.

I understand your concerns; to some extent I share them. Although there are likely to be short-term benefits to consumers from an authorized generic, the growth of the practice generally seems designed to send a signal (and a disturbing one) to your industry – something along the lines of, "If you thought you were going to make big profits like you used to, you should forget about it."

In the long-term this may result in fewer generic competitors, especially for non-blockbuster drugs – those with, say, $50 million to $250 million in annual sales.

As many of you know, along with Senators Rockfeller, Grassley and Leahy, I urged the Commission to conduct a study of authorized generics.

Commission staff is in the process of doing just that.

Quite rightly, the Commission will wait for the results of the study before developing a position or taking any action.

But I do appreciate GPHA's efforts, including your suggestion that the study focus on qualitative evidence – that is, what the PhRMA companies are

doing and thinking – in addition to quantitative evidence, or data. And we appreciate the way in which you, more than anyone else, brought this matter to the attention of policy makers.

Generic biologics present another important matter that needs to be examined. If we can do for generic biologics what Hatch-Waxman did for chemical compounds, then we will be achieving something truly important: bringing consumers more choices, lower prices and greater innovation.

One question is how often the science will support a methodology for approving a generic biologic.

But though there are complicated issues about patents and substitutability that need to be resolved, the science is clearly going to exist for many biologics. So as legislation moves forward my hope and expectation is that the Commission will play a major role in ensuring that any law maximizes competition, benefits consumers, and provides a legitimate (but fair) pathway to drug approval.

C. An Area of Disagreement

Now, let me talk briefly about exclusion payments – an area where we part company – that is, when a brand pays a generic, as a part of a patent settlement, to stay out of the market.

Why is the Commission so committed to eliminating these settlements? The Prozac case gives a good example. In the course of the patent litigation over generic Prozac, Barr reportedly offered to drop its challenge if Lilly would fund $75 million for Barr's research and development on an unrelated product and if the settlement protected Barr's 180-day exclusivity rights. Barr's CEO also publicly expressed a willingness to accept $200 million to drop its challenge.[4] Lilly refused, in part, because it believed such a settlement would violate the antitrust laws – at the time, of course, so did almost everyone else. Barr won the patent litigation, and consumers – including state and federal governments – saved over two billion dollars from early entry.[5]

Under the legal standard articulated in the *Schering* and *Tamoxifen* cases, though, that settlement would have been legal, generic entry would have occurred far later, and consumers would be left holding the bag – or, more appropriately, footing the bill.

That's why the FTC has taken such a resolute, bipartisan stand.

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[4] David J. Morrow, "Trial Is Getting Under Way Today in Prozac Patent Lawsuit" NY TIMES, January 25, 1999, available at http://query.nytimes.com/gst/fullpage.html?sec=health&res=9B02EEDD1439F936A15752C0A96F958260 (last visited November 26, 2006)

[5] Stephanie Kirchgaessner & Patti Waldmeir, "Drug patent payoffs bring a scrutiny of side-effects," FIN. TIMES UK, Apr. 25, 2006, 2006 WLNR 6910048.

In addition to the harm these settlements cause, there are a handful of disturbing myths used to attack the FTC's position. Let me try to dispel a few of them.

Myth #1: The FTC is Against All Settlements

One senior member of the branded industry, in commenting on the FTC's position on *Schering* recently, said, "I don't know how you don't allow two litigants to settle their case if they want to. I don't know how – that's unconstitutional."

Well, that comment is just plain wrong: the FTC does not want to stop all settlements. In fact, the agency enters into dozens of them every year. The FTC supports them almost all of the time in every industry, and we support them in yours: we just don't support them when we believe they violate the antitrust laws.

And, by the way, we certainly support the Constitution. As an independent agency, you get in lots of hot water with Congress if you don't!

Since 1993, there have been more than 50 final Hatch-Waxman settlements or interim agreements. The Commission has challenged only five of those agreements, all of which involved brands paying generics and generics agreeing to stay off the market. In each of these situations, the brand company was sharing its monopoly rents to eliminate the possibility of generic competition.

So the problem with Barr's proposed settlement in Prozac wasn't that it was a settlement. It was that the settlement would have paid Barr not to compete. The strength of the patent would not have determined the settlement terms, the cash payment would have.

Myth #2: Companies Cannot Settle Patent Litigation Without Exclusion Payments

The evidence simply does not support the claim.

Between 1993 and 2004, there were literally dozens of settlements in which the generic did not receive a payment for staying off the market. The settlements simply reflected the strength of each party's case.

In other words, companies found ways to settle without paying their rivals not to compete.[6]

Myth #3: Exclusion Payments are in the Long-Term Interest of the Generic Industry

The generic industry has consistently defended these settlements – again, at least publicly – and fought any attempt to limit the ability of companies to enter

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[6] One article mistakenly suggests that the proportion of cases settled dropped substantially in response to antitrust enforcement actions challenging exclusion payments. Gregory Glass, "Why Settle?", Update, Sept-Oct. 2005, at 17-19. Nothing coulc be further from the truth. That study reports only five settlements for the entire 18-month period from January 2004 through June 2005, which is factually incorrect. Federal law requires drug companies to file their all settlements of paragraph IV litigation with the FTC. The Commission's data shows that for this period there were 22 settlements covering 18 products.

into them. Now, at one level I understand your position. These settlements will always be extraordinarily profitable for both sides. What company wouldn't want to make more money for its shareholders? In fact, you're obligated to do so.

But I want to ask you to think about where this road will lead you.

If exclusion payments become clearly legal, things will change. Generic entry prior to patent expiration will become rare or disappear entirely. From a policy perspective, this result makes little sense.[7] Instead of racing to file ANDAs to compete, you will be racing to file ANDAs to be the first to settle – the first to be paid not to compete. I doubt any industry – except maybe the trial lawyers – can long survive when a primary profit center is in settlements, not in selling products.

Your industry is aggressively lobbying Congress for reform of citizens petitions, a ban on authorized generics, and a solution to the 180-day bottleneck –

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[7] Indeed, this is especially true because the evidence suggests that a good many pharmaceutical patents are weak. Between 1992 and 2000, the generic company prevailed in 73 percent of the litigated cases. Generic Drug Entry Prior to Patent Expiration: A Federal Trade Commission Sudy at 20 (July 2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (visited November 26, 2006). Another recent analysis of patent infringement cases found consistent results: patent-holders in the pharmaceutical industry were successful on the merits (validity, infringement, or enforceability) only in 30 percent of Federal Circuit decisions from 2002 through 2004. Paul Janicke & Lilan Ren, "Who Wins Patent Infringement Cases?" 34 AIPLA Quart. J.1, 20 (2006). Glass reports a much higher winning percentage for branded pharmaceutical companies in patent litigation, but he counts procedural victories as well as victories on the merits. Glass, *supra* n.5, at 18.

as you should be. I can imagine enlightened lawmakers adopting some of these proposals. But without eliminating exclusion payments, those reforms would not do a whole lot for the people that Congress represents. They would merely up the ante of how much a brand has to pay you to keep its monopoly years longer.

Why should Congress adopt those reforms without stopping exclusion payments – or solving the *Schering* problem? To ask the question is to answer it: They won't.

As I said earlier, you have a record to be proud of. And a reputation to be proud of as well – one historically based on forging alliances with patients and consumers; one based on wearing the white hat. To my mind that, more than anything else, is what has gotten you so much good will with the American public and a surprising amount of traction with Congress. Why would you want to risk that reputation, which could easily be the case, if you continue to support these deals?

On the other hand, however, nothing would enhance your credibility more as the industry that promotes low-cost, high quality health care – as an industry that holds the high moral ground – than saying, "Yes, these settlements are profitable, but they still should be illegal."

As you seek these other reforms, I hope you will also support an end to these problematic settlements.

You have to make that decision yourselves, of course, but I do think its in your best interest.

And I do think it is going to happen anyway.

Again, thank you. I'm happy to take questions.