



# **Federal Trade Commission**

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## **THE FEDERAL TRADE COMMISSION'S PERSPECTIVE ON BIOSIMILARS:**

### **CURRENT INITIATIVES AND LONG-TERM GOALS**

**Remarks of  
Commissioner Pamela Jones Harbour**

**Biosimilars 2008  
Washington, DC  
September 23, 2008**

## **I. INTRODUCTION**

Good morning. It is my pleasure to join you all today.

My comments will reflect my own views, not necessarily those of the Federal Trade Commission or any of my fellow Commissioners. But having said that, I am pleased to report that the Commission as a whole has become increasingly involved in the biosimilars debate. I welcome this opportunity to tell you about some of our recent initiatives.

Before I begin, let me make a note about my choice of terminology. I realize that the nomenclature itself may be an issue for some, and that the terms “biosimilar,” “follow-on biologic,” and “generic biologic” are not necessarily interchangeable. But for purposes of this presentation, my intent is to use neutral language, so please forgive any imprecision.

## **II. MY INVOLVEMENT WITH BIOSIMILARS**

I first spoke publicly about biosimilars in June 2007,<sup>1</sup> and I believe I was the first person from the FTC to do so. My audience for that talk was a group of lawyers who specialize in issues at the intersection of antitrust and intellectual property. Back then, I predicted that follow-on biologics would become a “hot topic” – and I announced that I wanted to see the Commission get more involved in the debate. I was up-front about my agenda.

First, I wanted to ensure that the dialogue on generic biologics would include a principled and rigorous analysis of competition dynamics – especially from the perspective of consumers, whose interests I am sworn to protect.

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<sup>1</sup> Pamela Jones Harbour, Commissioner, Fed. Trade Comm’n, *The Competitive Implications of Generic Biologics*, Remarks at the Intellectual Property Antitrust Conference of the Sections of Antitrust and Intellectual Property Law, American Bar Association (June 14, 2007), available at <http://www.ftc.gov/speeches/harbour/070614genbio.pdf>.

Second, I wanted to ensure that the FTC would be an integral part of the dialogue on generic biologics. For years, the Commission has been intimately involved in shaping competition law and policy relating to generic drugs, and has pursued enforcement actions when firms exploit the Hatch-Waxman process in ways that injure competition.<sup>2</sup> The Commission also has engaged in empirical research regarding the effects of certain elements of Hatch-Waxman,<sup>3</sup> and this research has formed the basis for important Hatch-Waxman reforms.<sup>4</sup> The FTC's expertise is unique and valuable. I knew it would make sense to tap that expertise further – especially given the Commission's long history of working closely and cooperatively with the FDA, whose scientific expertise complements our competition expertise. I also hoped to take advantage of our excellent relationship with legislators who focus on issues relating to drug costs.

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<sup>2</sup> See, e.g., *FTC v. Cephalon, Inc.*, Civil Action No. 08-CV-2141-RBS (E.D. Pa.) (complaint filed in D.D.C. Feb. 13, 2003; transfer order entered Apr. 28, 2008), available at <http://www.ftc.gov/os/caselist/0610182/index.shtm>; In the Matter of Schering-Plough Corp. *et al.*, FTC Dkt. No. 9297, available at <http://www.ftc.gov/os/adjpro/d9297/index.shtm> (administrative proceedings) and <http://www.ftc.gov/os/caselist/0023387/index.shtm> (federal court proceedings); *FTC v. Warner Chilcott Corporation and Barr Pharmaceuticals*, Civil Action No. 1:05-CV-2179-CKK (D.D.C.) (complaint filed Nov. 7, 2005; amended complaint filed Dec. 2, 2005; final order against Warner Chilcott issued Oct. 24, 2006; final order against Barr issued Nov. 27, 2007), available at <http://www.ftc.gov/os/caselist/0410034/0410034.htm>; *Perrigo Company and Alpharma Inc.*, Civil Action No. 1:04-CV-01397-RMC (D.D.C.), (complaint filed August 17, 2004; final orders issued August 25, 2004), available at <http://www.ftc.gov/os/caselist/0210197/0210197.shtm>.

<sup>3</sup> See, e.g., Fed. Trade Comm'n, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>; David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, Fed. Trade Comm'n Bureau of Econ. Working Paper No. 248 (Feb. 2002), available at <http://www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf>.

<sup>4</sup> See, e.g., Comment of the Fed. Trade Comm'n to the Food & Drug Admin., U.S. Dep't of Health & Human Servs., *Applications for FDA Approval to Market a New Drug; Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed* (Dec. 23, 2002), available at <http://www.ftc.gov/be/v030002.pdf>.

The Commission has made major progress toward both of my original goals, and will be hosting a workshop on follow-on biologics later this fall. But before I go into details, I'd like to provide a little bit of background regarding the Commission's perspective on the biosimilars debate.

### **III. THE ROLE OF COMPETITION**

Biologics are a huge and growing market. These drugs drastically reduce disabling symptoms, help to manage chronic diseases, and sometimes even save lives. But they come at an extremely high price to consumers. As a result, consumers cannot always afford the best-available treatments for their conditions.

Biologics are expensive, in part, because they cost so much to develop and manufacture. I certainly do not mean to understate the huge investments required by drug companies to develop effective and safe treatments. These companies need to recoup their investments and turn a profit – whether it's a small startup courting potential buyers or seeking to attract venture capital, or a large firm that wants to re-invest profits in R&D projects to develop the next generation of miracle drugs. The need for profitability is a basic economic fact of the drug industry, and must be taken into account if we hope to preserve long-term incentives to innovate.

But there is another major reason for the high price of biologics. You are probably familiar with the saying, "When you're a hammer, everything looks like a nail." Well, when you are steeped in antitrust law and competition policy, as we are at the FTC – and when you see extremely expensive drug products whose prices continue to rise – you immediately start asking, "Is there enough competition in these markets?" And it's the right question to ask. As we know, with very rare exceptions, there are no generic versions of biologics available in U.S. markets.

That is why we are all here today. Conferences like this one allow us to explore ways to create an abbreviated regulatory pathway to facilitate market entry of safe and effective follow-on

biologics, in situations where the science supports it. And that’s an important caveat. The scientific and patient safety questions are paramount, and they are beyond the Commission’s expertise. The FDA is the expert agency on the scientific front. As I have done before,<sup>5</sup> I urge the FDA to take the lead, to objectively determine the circumstances under which safe and effective follow-on biologics are possible. But based on the current state of scientific knowledge, it seems as though, over the last year or so, the discussion has shifted from “whether” to “when” an abbreviated approval process will exist. It seems likely that a law will emerge from Congress at some point.<sup>6</sup> It still remains unclear, however, what form that law will take, and what compromises will be reached along the way.

#### **IV. LETTER TO HOUSE COMMITTEE ON ENERGY AND COMMERCE**

As most of you know, in April 2008, the Chairman and Ranking Member of the Subcommittee on Health, House Committee on Energy and Commerce, sent a letter and multiple pages of questions to 35 organizations, to solicit their views on biosimilars and to inform the development of legislation.<sup>7</sup> I was excited – and gratified – that the FTC was included on the list of stakeholders. This outreach from the Hill provided an excellent mechanism for the Commission to share some of its expertise. Thanks to our talented staff, who had been tracking these issues for quite awhile, the Commission was poised to provide some preliminary thoughts.

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<sup>5</sup> Harbour, *supra* note 1.

<sup>6</sup> See, e.g., Pathway for Biosimilars Act, H.R. 5629, 110<sup>th</sup> Cong. (2008); Biologics Price Competition and Innovation Act of 2007, S. 1695, 110<sup>th</sup> Cong. (2007); Affordable Biologics for Consumers Act, S. 1505, 110<sup>th</sup> Cong. (2007); Patient Protection and Innovative Biologic Medicines Act of 2007, H.R. 1956, 110<sup>th</sup> Cong. (2007); Access to Life-Saving Medicine Act, H.R.1038 and S. 623, 110<sup>th</sup> Cong. (2007).

<sup>7</sup> Letter from Frank Pallone, Jr., Chairman, & Nathan Deal, Ranking Member, Subcomm. on Health, Comm. on Energy & Commerce, U.S. House of Reps., to 35 groups (including Fed. Trade Comm’n) (Apr. 3, 2008), *available at* [http://energycommerce.house.gov/Press\\_110/110-ltr.040308.list.Biologic%20ltr.pdf](http://energycommerce.house.gov/Press_110/110-ltr.040308.list.Biologic%20ltr.pdf).

The Commission submitted a ten-page letter<sup>8</sup> focused primarily on one specific question posed by the Subcommittee: “What lessons can we learn from the Hatch-Waxman Act, and apply towards Congress’s discussion about [follow-on biologics]?” Our letter endorsed the concept that an abbreviated approval process for follow-on biologics, with less stringent requirements than those for a new drug approval, would enhance competition, lead to lower prices, and accelerate the pace of innovation. We also noted that, from a competition perspective, an ideal abbreviated approval pathway would create incentives for multiple entrants, and provide a mechanism for automatic substitution, to maximize the benefits of competition.

The basic message of our letter was this: Congress should take care to avoid “unintended consequences” that might severely limit or eliminate the benefits of biosimilars legislation. We highlighted several situations where companies have attempted to “game” the generic drug approval system, securing greater profits for themselves without providing a corresponding benefit to consumers.

We identified three types of unintended consequences that Congress should seek to avoid in legislation governing the approval of generic biologics.

**A. Risk of Exclusion Payments**

First and foremost, the Commission’s letter warned that generic biologics legislation presents a substantial risk of creating a new arena for so-called “exclusion payment” patent settlements, which have become prevalent under Hatch-Waxman.

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<sup>8</sup> Letter from C. Landis Plummer, Acting Secretary, by direction of the Fed. Trade Comm’n, to Frank Pallone, Jr., Chairman, Subcomm. on Health, Comm. on Energy & Commerce, U.S. House of Reps. (May 2, 2008), *available at* [http://energycommerce.house.gov/Press\\_110/110-ltr.050208.respto040308.FTC.pdf](http://energycommerce.house.gov/Press_110/110-ltr.050208.respto040308.FTC.pdf).

One of the ways that Hatch-Waxman promotes rapid generic entry is to establish special procedures to enable generic firms to challenge invalid or narrow patents on branded drugs, even before the generic product has been marketed. These procedures facilitate earlier resolution of patent litigation, and allow consumers to receive the benefits of generic drug entry prior to patent expiration.

But when the generic firm's expected profits from competing are less than the profit the brand-name firm stands to lose from competition, it may be more profitable for both parties if they strike a deal and split the difference. Exclusion payment settlements occur when, under the guise of settling patent litigation, the brand-name firm pays its potential generic competitor to abandon the patent challenge and delay entering the market. The branded drug maintains its monopoly, and the branded firm and the first filer split the monopoly profits. Meanwhile, the pace of innovation slows down, because the monopolist does not face a credible threat of near-term competition.

The Commission has been outspoken in explaining that these agreements are made at the expense of consumers. Consumers' access to lower-priced generic alternatives is delayed, sometimes for many years. Consumers lose additional benefits of competition when new and improved products emerge more slowly – for example, drugs with fewer side effects or more convenient dosing schedules. Through advocacy as well as aggressive enforcement, the Commission has fought to avoid these anticompetitive effects by maintaining competition in markets for generic drugs. FTC officials and staff have been particularly active in supporting

legislation to end anticompetitive exclusion payments from branded firms to generics under Hatch-Waxman.<sup>9</sup>

In the generic biologics realm, just as with traditional small-molecule drugs, patent challenges are likely to be important for promoting generic entry. As the Commission's letter pointed out, a pre-marketing patent litigation process can, in theory, speed up generic entry. But the potential consumer benefits will not be realized if the parties can collude to avoid competition and share the resulting profits. For this reason, the Commission recommended provisions that would prevent generic biologics legislation from fostering exclusion payment settlements. The Commission also recommended a reporting requirement, similar to the one that now exists under Hatch-Waxman,<sup>10</sup> so that the agencies and Congress can monitor the nature of patent settlements involving generic biologic products.

## **B. Potential Dangers of Marketing Exclusivity**

Second, the Commission's letter urged caution in creating a marketing exclusivity period for follow-on biologic drug applicants.

An exclusivity period is supposed to promote generic entry, by providing an extra incentive to the first generic firm to challenge a branded firm's patents. But as suggested by our experience under Hatch-Waxman, exclusivity may be abused in ways that harm consumers. The exclusivity

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<sup>9</sup> See especially Fed. Trade Comm'n, *Protecting Consumer Access to Generic Drugs: The Benefits of a Legislative Solution to Anticompetitive Patent Settlements in the Pharmaceutical Industry*, Prepared Statement before the Subcomm. on Commerce, Trade, and Consumer Protection, Comm. on Energy & Commerce, U.S. House of Reps. (May 2, 2007), available at [http://www.ftc.gov/os/testimony/P859910%20Protecting\\_Consume\\_%20Access\\_testimony.pdf](http://www.ftc.gov/os/testimony/P859910%20Protecting_Consume_%20Access_testimony.pdf).

<sup>10</sup> See FTC News Release, *Medicare Prescription Drug and Improvement Act Requires Drug Companies to File Certain Agreements with the Federal Trade Commission and U.S. Department of Justice* (Jan. 2004), available at <http://www.ftc.gov/os/2004/01/040106pharmrules.pdf>.



period for the first generic filer can create a “cork in the bottle” that blocks entry by any generic firm, as long as the first filer refrains from entering the market. This creates an incentive for the branded firm to encourage the first filer to delay entry. For this reason, the Commission’s letter suggested that if Congress creates any exclusivity period for follow-on biologics, the approval scheme should ensure that branded companies cannot use the exclusivity as a way to prevent generic entry.

But the letter makes a further point. The letter asks Congress to consider whether an exclusivity period for generic biologics is really necessary at all. Under Hatch-Waxman, one of the main rationales for 180-day exclusivity is to provide an incentive for the first generic filer to bear the cost of patent litigation to challenge potentially invalid or narrow patents, knowing that other generic applicants will be able to “free-ride” on the work done by the first generic company. But the economics of entry may be different in the realm of follow-on biologics.

For example, it is unclear how “abbreviated” any abbreviated approval process will be, and how much the costs and time of approval will be reduced for follow-on biologics filers. The rewards that the market provides may be incentive enough for firms to seek approval to market generic biologics products, even without the additional incentive of an exclusivity period for the first filer.

Furthermore, the degree of interchangeability affects the amount of competition between a first generic applicant and subsequent generic applicants, which, in turn, affects the need for exclusivity to create entry incentives. Under Hatch-Waxman, all generics that are AB-rated to the same branded drug are fully interchangeable. Therefore, a high level of generic competition is expected, and exclusivity may be necessary to incentivize the first filer to bear the up-front costs of a patent challenge. If generic biologics legislation does not permit the same degree of interchangeability among different generic products, the first follow-on applicant may have less to lose via subsequent entry, so an exclusivity period may not be necessary.

### C. “Gaming” of the System

Third, the Commission’s letter points out several ways that parties have found to “game” the Hatch-Waxman system to lengthen exclusivity periods and thwart generic entry. For example, until the 2003 reforms to Hatch-Waxman, branded manufacturers could obtain “stacked” 30-month stays delaying FDA approval of generic alternatives by listing additional patents, even if those patents were narrow or weak, or covered only minor aspects of the branded drug. Another strategy branded firms have pursued is to make minor, non-clinically significant changes to a branded product, then “switch” the market to the new version to limit generic competition and obtain multiple exclusivity periods. Branded firms also have used the FDA “citizen petition” process to delay generic drug approval. The Commission’s letter urged Congress to ensure that these strategies cannot be replicated with respect to generic biologics.

Experience has taught us that the potential for gaming is particularly pronounced when FDA approval of a generic entrant is tied to events in the patent litigation between the generic firm and the branded company, because the timing and scope of the litigation are largely under the control of the litigants themselves. The Commission’s letter asked legislators to consider whether they should link the patent litigation process with FDA approval of generic biologics, as is the case under Hatch-Waxman. De-linking the two might remove incentives to skew the conduct of patent litigation to extend exclusivity periods beyond the length determined by Congress.

Finally, the letter warned that generic biologics legislation should not create any new avenues for regulatory delays or abuse of regulatory process. Of course, it is necessary to safeguard patient safety, which will impose numerous procedural hurdles to obtain approval of a follow-on product. But to the extent possible, consistent with safety, Congress should minimize the potential for strategic delays through citizen petitions or lengthy notice-and-comment periods.

## V. FEDERAL REGISTER NOTICE

After we submitted our letter to the Subcommittee on Health, we decided to take the next step to get more involved in the generic biologics debate. An important part of the FTC's mission is our research and scholarship function. We frequently hold workshops and hearings to help inform the Commission, and the public, about emerging legal and economic issues that affect competition and consumer protection. We invest these resources not only to maintain our own expertise, but also so that we may continue to provide leadership and education on important policy issues.

And so, a few weeks ago, the Commission published a Federal Register notice to announce a forthcoming public workshop on competition issues involving follow-on biologics.<sup>11</sup> I believe the notice has been included in the conference materials. It is also available on the FTC website.

As a precursor to the workshop, the Commission published a list of questions and invited public comment. The Commission is particularly interested in promoting an abbreviated regulatory approval pathway that strikes the right balance between exclusivity periods and competition, in order to spur innovation of new and improved biologics, as well as to increase competition among biologics so as to reduce prices. Therefore, the Commission has posed a series of questions that explore whether, or to what extent, the incentives provided by regulatory exclusivity periods are necessary for the approval of follow-on biologics, or whether sufficient incentives exist without additional regulatory exclusivity periods. The workshop sessions should help us examine how competition will evolve upon entry of follow-on biologic competitors, and to predict how this

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<sup>11</sup> FTC News Release, *FTC Announces Workshop and Roundtable on Emerging Health Care Competition and Consumer Protection Issues* (Aug. 27, 2008), available at <http://www.ftc.gov/opa/2008/08/hcissues.shtm>; see also Fed. Trade Comm'n, *Public Workshops and Roundtables: Emerging Health Care Competition and Consumer Issues*, Notice of Public Workshops and Roundtables and Opportunity for Comment, 73 Fed. Reg. 51479 (Sept. 3, 2008).

competition will affect incentives to innovate; how these markets would be affected by varying degrees of interchangeability; and how Medicare reimbursement mechanisms affect competition.

The Commission also put forth a series of questions relating to patent dispute resolution. The Commission is interested in exploring what we have learned under Hatch-Waxman, which encourages Paragraph IV certifications and early patent litigation, but appears to have led to various abuses of the regulatory structure in ways that restrain competition, as I discussed a few minutes ago. These questions will help us understand how biologics markets may differ from small-molecule drug markets, and how the incentives to challenge patents may be different in the biologics context.

The public comment period closes next Tuesday, September 30<sup>th</sup>. Soon thereafter, the Commission will publish an agenda for the workshop, which is scheduled for Friday, November 21<sup>st</sup>, here in Washington.<sup>12</sup> I encourage all of you to review the Federal Register notice and, if you are so inclined, to submit comments – either now, or for up to a month after the workshop. And I hope that many of you will find the time to attend the workshop itself. The Commission expects to issue a report next spring that summarizes the workshop findings and further analyzes the potential implications of various policy choices.

## **VI. CONCLUSION**

To conclude, the Commission supports the development of an abbreviated approval pathway for follow-on biologics, balanced by an appropriate recognition of consumer safety and incentives to innovate. The availability of generic biologics is likely to lower prices, expand the benefits of these treatments to a greater number of consumers, and accelerate the pace of innovation. But as

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<sup>12</sup> When posted, information will be available on the Commission’s website as a link from the “Conferences and Workshops” page at <http://www.ftc.gov/ftc/workshops.shtm>.

I have warned before, policymakers should tread carefully, to ensure they fully understand the likely competitive implications and long-term consequences of their decisions.

I am excited that the FTC will continue to play an important role in this policy debate. I hope you will all pay attention to our upcoming workshop and our subsequent report, and as always, we welcome your input.

Thank you.