

July 24, 2002

STATEMENT ON S. 812, THE GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT OF 2001

In a letter issued today, Attorney General Eliot Spitzer has written in support of the Greater Access to Affordable Pharmaceuticals Act of 2001 (“GAAP”), introduced by Senators McCain and Schumer to amend the Hatch-Waxman Act of 1984 (the “HWA”). This statement explains in greater detail the arguments set forth in that letter, and the problems with the HWA that led to its submission.

Protecting consumers' access to quality health care at affordable prices is one way in which the State Attorneys General serve the American public. To that end, State Attorneys General have, in recent years, brought five antitrust actions arising, in whole or in part, out of efforts by brand-name drug manufacturers to manipulate the HWA's procedures to keep cheaper generic drugs off the market, and to maintain monopoly pricing long after the brand-name drug's patent expiration date. These are:

- ? *State of Ohio, et al. v. Bristol-Myers Squibb, Co.*, concerning the anti-cancer drug Taxol® (the “Taxol litigation”);
- ? *State of Alabama, et al. v. Bristol-Myers Squibb Co., et al.*, concerning the anti-anxiety drug Buspar® (the “Buspar litigation”);
- ? *State of New York, et al. v. Aventis, S.A., et al.*, concerning the anti-hypertension drug Cardizem CD® (the “Cardizem litigation”);
- ? *State of Florida, et al. v. Abbott Laboratories, Inc.*, concerning the anti-hypertension drug Hytrin® (the “Hytrin litigation”); and
- ? *Commonwealth of Pennsylvania v. Schering-Plough Corp. et al.*, concerning the potassium supplement K-Dur 20 (“the K-Dur 20 litigation”).

As described in more detail below, these cases starkly illustrate the weaknesses of the HWA.

The New York Attorney General has reviewed the terms of GAAP against the backdrop of this experience, and believes that this bill represents a substantial step towards correcting the HWA's flaws, and restoring the appropriate balance that Congress initially intended between protecting innovation and ensuring affordable drug prices. Indeed, much of the misconduct challenged in these cases would not have been possible had GAAP been in force.

By this statement and in his letter, the Attorney General highlights the need for reform. After a brief summary of the present law, the statement describes state enforcement actions in greater detail, and show how GAAP effectively closes loopholes that allowed for the misconduct addressed by these actions.

By passing GAAP, Congress can protect consumers, lower drug prices, and avoid the need for time-consuming and expensive litigation. For those reasons, the New York Attorney General has strongly urged that Congress enact GAAP into law.

I. Generic Drugs and the Hatch-Waxman Act

Generic drugs are bioequivalents of brand-name drugs in dosage, form, safety, strength, route of administration, quality, performance characteristics and intended use. They tend, however, to be priced significantly below their brand-name equivalents. An increase in the use of generic drugs would be an important step in controlling the rising costs of pharmaceuticals, and of health care in general.

In 1984, Congress passed the HWA, which streamlined the regulatory approval process for generic drugs. In particular, the Act permits the manufacturer of a new generic drug to submit an Abbreviated New Drug Application (“ANDA”), which may rely on the safety assessments of the New Drug Application (“NDA”) filed by the “pioneer” – i.e., brand-name – drug’s manufacturer. An ANDA entails far less expense than an NDA, and can be approved by the FDA far more expeditiously.

Although it is not necessary for purposes of this statement to delve into all the intricacies of the HWA, two elements – the 30 month stay and the 180-day exclusivity period – play an important role in allowing pharmaceutical companies to delay generic entry and deny consumers the benefits of competition, despite the good intentions of the HWA’s drafters. These elements are addressed below.

II. The HWA’s Loopholes

A. The 30 Month Stay

The Food and Drug Administration (“FDA”) maintains a list of pharmaceutical patents commonly known as the “Orange Book.” Upon receiving FDA approval for a brand-name drug, the manufacturer must inform the FDA, in substance, of all patents that would be infringed by the non-licensed sale of a generic equivalent for that drug. The FDA then includes those patents on its Orange Book list. Before marketing a generic drug, an ANDA filer must certify that the listed patents will not prevent sale of the generic version, for any of several reasons, and notify the brand-name manufacturer of its certification. One such certification – the so-called “paragraph IV certification” – attests that the pioneer drug patent “is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” Once an ANDA applicant – the generic manufacturer – submits a paragraph IV certification, the brand-name manufacturer has 45 days within which to bring a patent infringement action against the applicant. If the brand-name manufacturer initiates such a suit, the FDA’s approval of the ANDA is automatically delayed for 30 months.

The 30 month period is referred to as a “stay.” More accurately, it is an injunction that takes effect immediately on the brand-name manufacturer’s filing of its case, regardless of the strength or weakness of its patent infringement claims, and without any judicial oversight whatsoever. The statutorily-created injunction relieves the brand-name manufacturer of the responsibility of satisfying a court that it is entitled to a preliminary injunction against generic entry -- a threshold that the brand-name manufacturer would have to meet in the absence of the HWA. The FDA itself lacks the expertise or the resources to evaluate the validity of patents identified for listing in the Orange Book and, in consequence, lists patents solely in reliance on the brand-name manufacturer’s listing request.

Given the minimal standard for placement in the Orange Book, and the financial rewards of such a listing – a 30-month roadblock to generic entry – it is no surprise that drug manufacturers go to extraordinary lengths to insure that the FDA list any unexpired patent covering a profitable brand-name drug. Often, as the initial patent for a drug’s active ingredient nears expiration, the brand-name

manufacturer will seek “secondary patents” on specific aspects of the drug, such as mode of delivery – the validity of which may be dubious, at best – and which the manufacturer claims apply to previously approved uses of the drug. Armed with such new patents, manufacturers have been able to suppress generic alternatives, which would otherwise be available to consumers.

The cases brought by the States illustrate the potential for misuse inherent in the 30 month stay provision:

- ? The *Buspar* litigation concerns, in part, an effort by Bristol-Myers Squibb (“BMS”) to extend its patent monopoly for the profitable buspirone anti-anxiety medication. As BMS’s patent for buspirone was about to expire, it received a patent for a metabolite that the body naturally produces – BMS claimed – as the result of introducing buspirone into the body. BMS then had the FDA list the patent in the Orange Book eleven hours before the first generic ANDA was to be approved. Although BMS explicitly stated to the United States Patent Office that its new patent did *not* cover buspirone, its Orange Book entry made precisely the opposite claim. As a result, generic makers of buspirone were barred from the market, and consumers paid hundreds of millions of dollars more than they would have paid, had a generic alternative been available.

A federal district judge found that BMS’s conduct before the FDA was improper and ordered the patent delisted, thereby permitting the sale of generic alternatives.¹ On appeal, the Federal Circuit held that, as a matter of procedure, generic entrants could not sue to obtain delisting from the Orange Book, and vacated the order without evaluating BMS’s behavior before the FDA.² This past February, yet another federal district judge found BMS’s Orange Book filing to be “objectively baseless,” and an effort to “justify taking property that belongs to the public.”³

- ? The *Taxol* litigation addresses efforts by BMS to preserve its monopoly on Taxol, an important treatment for breast cancer and other tumors that the federal government itself initially developed and then licensed to BMS for five years. In their complaint, the States allege that BMS fraudulently obtained patents for Taxol, listed them in the Orange Book, and then filed litigation for the sole purpose of delaying generic entry into the market via the HWA’s stay provision. It took nearly three years before a court rejected BMS’s claims, during which cancer patients were deprived of access to less expensive generic alternatives.

In a particularly egregious manipulation of the HWA, BMS entered into an arrangement with generic manufacturer American Bioscience, Inc., by which BMS *consented* to be

¹*Mylan Pharms., Inc. v. Thompson*, 139 F. Supp.2d 1 (D.D.C.), *rev’d*, 268 F.3d 1323 (Fed. Cir. 2001).

²*Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001).

³*In re Buspirone Patent Litig.*, 185 F. Supp.2d 363, 376 (S.D.N.Y. 2002). BMS is trying to secure appellate review of this ruling as well.

subject to a court-ordered temporary restraining order, issued upon ABI filing a lawsuit demanding that BMS list one of ABI's Taxol patents in the Orange Book. Based on the order, BMS had the FDA list ABI's patent in the Orange Book – in an apparent effort to clothe the fraudulent listing with the seeming legitimacy of a court decree. After generic manufacturers and the Federal Trade Commission filed papers challenging the collusively obtained order, the Court ruled that ABI was not entitled to sue BMS to obtain an Orange Book listing, and dismissed the case.

GAAP takes important steps towards resolving the problems addressed by these cases, in two ways. *First*, GAAP limits drug manufacturers to a single 30 month stay per drug. As initially drafted, GAAP eliminated the 30 month stay altogether. While the original might better encourage pharmaceutical competition, the compromise version passed by the Senate Health, Education, Labor and Pensions Committee represents a substantial improvement over the present legal regime.

In the *Buspar* case, BMS was able to obtain a 30 month stay for *the third* patent it claimed barred generic versions of buspirone, after the initial patent had expired and without the need to obtain a court ruling on infringement. GAAP instead requires drug manufacturers that obtain such follow-on patents to protect their intellectual property in the same manner as other patent holders – by going to court, proving that their case has a likelihood of success, and securing an injunction against the alleged infringer. That option provides recourse for genuinely aggrieved patent holders, while prohibiting brand-name manufacturers from gaining an advantage, to the detriment of consumers, solely on the basis of their own assertion of a valid patent and their willingness to file suit.

Second, GAAP would allow generic competitors to seek declaratory relief on the validity of an Orange Book listing at the time an NDA is approved -- when, under GAAP, the brand-name manufacturer would still be entitled to a thirty month stay. As the Federal Circuit's *Buspar* ruling demonstrates, the FDA's decision to list a patent in the Orange Book may not be subject to any judicial review under existing law, and frivolous or fraudulent listings can become impassable roadblocks to generic entry. Although a previous version of the bill would have afforded even greater opportunity for challenging Orange Book listings, this aspect of GAAP would still provide potential entrants with the means to challenge such roadblocks in court, in those cases where the thirty-month stay would still apply.

B. The 180-Day Exclusivity Period

HWA gives the first ANDA filer with a paragraph IV certification a 180-day exclusivity period following a court ruling permitting entry, during which no other manufacturer of a generic version of the same drug could enter. This provision provides an incentive for generic manufacturers to challenge brand-name patents. But as currently structured, the HWA provides a means for brand-name and generic manufacturers acting in collusion to bar new generic competitors for significantly longer periods. In effect, the brand-name manufacturer simply "buys" the first ANDA filer's agreement neither to enter the market nor to transfer its exclusivity rights, thereby creating a perpetual bar against other generic competitors. This can have a profound impact on drug prices, because generic drugs are typically not priced at their full discount until the exclusivity period has expired and additional generic competitors are able to enter the market.

Cases brought by the Attorneys General illustrate this abuse of the HWA:

- ? The *Cardizem* litigation arises from an agreement between brand-name manufacturer Hoechst Marion Roussel, Inc. (“HMRI”) and generic drug manufacturer Andrx Corporation (“Andrx”), under which HMRI paid Andrx nearly \$90 million in exchange for Andrx’s agreement to keep its cheaper alternative to HMRI’s Cardizem CD heart medication off the market. As part of the agreement, Andrx agreed to stay off the market while still prosecuting its ANDA – so as to maintain its right to the 180-day exclusivity period granted the first-filer under the HWA – and pledged not to transfer or sell its exclusivity rights. Thus, the agreement effectively barred any further generic entry. Only after private suits challenged this arrangement and the FTC opened an investigation, did Andrx enter the market, thereby removing the block against additional generic competitors. A federal district court has since held the HMRI/Andrx agreement to constitute a *per se* violation of the antitrust laws.⁴ (That ruling is now on appeal.) In yet another case, the Court of Appeals for the District of Columbia Circuit reinstated a generic manufacturer’s claim challenging the HMRI/Andrx agreement.⁵
- ? The *Hytrin* litigation challenges an arrangement under which Abbott Laboratories (“Abbott”) paid generic manufacturer Geneva Pharmaceuticals, Inc. (“Geneva”) over \$60 million, in exchange for Geneva’s agreement not to market a generic version of Abbott’s hypertension medication, Hytrin. In that agreement – as in *Cardizem* – Geneva promised not to give up the 180-day exclusivity period as the first ANDA filer. No other generic manufacturers were able to enter the market, and Geneva and Abbott shared the profits from the resulting exclusion of competition. The district court held this arrangement *per se* unlawful.⁶ (That ruling, too, is on appeal.)

Under GAAP, the first ANDA filer loses its right to exclusivity if it does not come to market within 60 days of the date on which it is declared eligible to do so by the FDA. Further, the 180-day exclusivity period runs from either the date of a final court decision on the patent infringement action, *or* the date on which a settlement order or consent decree is signed by the court, whichever is earlier. These provisions should severely limit the ability of the brand-name manufacturer and first generic entrant to act collusively to bar other generic alternatives from reaching consumers.

III. Conclusion

In the examples above, antitrust suits seeking full recompense for injured consumers helped cause the wrongdoers to cease their misconduct, and may aid in deterring further abuses. But antitrust

⁴*In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 682 (E.D. Mich. 2001).

⁵*Andrx Pharmaceuticals, Inc. v. Biovail Corp., Int’l*, 256 F.3d 799 (D.C. Cir. 2001).

⁶*In re Terazosin Hydrochloride Antitrust Litigation*, 164 F. Supp.2d 1340 (S.D. Fla. 2001).

enforcement on a case-by-case basis will not solve the problems underlying the lawsuits, which are inherent in the HWA itself. As enacted, the HWA affords unscrupulous manufacturers with both means and incentive to extend brand-name monopolies beyond the patent exclusivity period set by Congress.

Not all such misconduct comes to the attention of law enforcers or private plaintiffs; antitrust litigation is time-consuming, expensive and risky; and pharmaceutical companies are learning from previous legal setbacks, and are adopting ways to exploit the present law that may be less vulnerable to antitrust challenges – yet still deleterious to the goal of harnessing competition to provide affordable health care. Amending the HWA so as to remove available avenues for anticompetitive and anticonsumer actions, rather than relying on individual lawsuits for costly after-the-fact remedies, is a far more effective means to protect consumers.