Barr Pharmaceuticals, Inc.

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September 30, 2008

Federal Trade Commission
Office of the Secretary
Room H-135 (Annex F)
600 Pennsylvania Ave., NW
Washington, DC 20580

Re: "Emerging Health Care Competition and Consumer Issues – Comment, Project No. P083901"

Dear Sir/Madam:

On behalf of Barr Pharmaceuticals, Inc., as well as the millions of American consumers we serve each year, we thank the Federal Trade Commission for its interest in legislation to establish an effective and workable generic biologic approval pathway. Given the considerable importance of such legislation to all Americans, Barr takes this opportunity to respond to the questions that the Commission presented on or about August 27, 2008.

After reviewing Barr's responses, should you have any questions or require any additional information, please do not hesitate to ask. Barr looks forward to continuing to work with the Commission and Congress on this critical issue.

Sincerely,

Bruce L. Downey
Chairman and CEO, Barr Pharmaceuticals, Inc.

Enclosure

"Emerging Health Care Competition and Consumer Issues – Comment, Project No. P083901"
Written Responses From Barr Pharmaceuticals, Inc.

Barr Pharmaceuticals, Inc. submits the following written responses to the questions propounded by the Federal Trade Commission ("FTC") on or about August 27, 2008 with respect to follow-on biologic drugs, also referred to as generic biologics:

Regulatory Exclusivities and Follow-On Biologic Drugs

1. *What is the likely competitive effect of the market entry of a follow-on biologic competitor? Are there empirical models that predict the nature of this competition based on existing biologic drug product competition? How has competition developed between referenced and follow-on products in European markets? Would referenced product manufacturers lower their prices, offer discounts, and/or engage in enhanced marketing activities?*

Response: The competition that will result from the introduction of generic biologics, pursuant to an effective approval pathway, will benefit consumers in at least two material respects. First, Hatch-Waxman has demonstrated that a considerable financial benefit will flow from the introduction of "biosimilar"/"comparable" generic biologics, with consumers and taxpayers achieving the most significant savings with the introduction of interchangeable generic products. To be sure, the cost savings that will follow from increased competition brought by generic biologics will be substantial. While we have not undertaken an independent analysis of the cost savings that would flow from an effective and workable generic biologics approval pathway, others have done so. For example, Citizens Against Government Waste in May 2007 released a report entitled "Biogenerics: What They Are, Why They Are Important, and Their Economic Value to Taxpayers and Consumers." The report estimates that if Congress enacts an appropriate statutory framework to approve generic biologics, these drugs could save taxpayers and consumers *$43.2 billion between 2011 and 2020.* (*See* Biogenerics: What They Are, Why They Are Important, and Their Economic Value to Taxpayers and Consumers, by Everett Ehrlich, Ph.D., Elizabeth L. Wright (May 2, 2007)). Express Scripts also conducted a study. According to that study, an effective approval pathway would result in *$71 billion* in savings during the first 10 years. (*See* Potential Savings of Biogenerics in the United States (February 2007)). While BIO has quibbled with the Express Scripts figure, at the end of the day, not even BIO disputes that an effective pathway will save consumers and taxpayers billions of dollars each year.

Second, as discussed in greater detail in response to question #4 below, the competition that will flow from the introduction of generic biologics will spur new innovation from brand companies. New research and development efforts – efforts that brand companies have little financial incentive to pursue absent generic competition – inevitably will lead to the development of new biologic drug products. These new drug products will benefit patients.

With respect to competition between brand biologics and biosimilars in the EU, we are not aware of any models reporting on how competition has developed in the EU.

Finally, how brand companies will respond to the introduction of generic biologics is a question best answered by the brand industry. With respect to small molecule drug products approved under Hatch-Waxman, however, brand companies historically have not lowered their prices or engaged in enhanced marketing activities upon introduction of a generic equivalent.

2. *What is the likely impact of a follow-on biologic product being designated "interchangeable" (i.e., receiving an approval that would permit pharmacists, without physician authorization, to fill a prescription for the referenced product with the follow-on product)? What are the prospects for the use of "authorized follow-on biologics" in these circumstances? Do the answers to these questions differ based on the type of biologic product involved?*

Response: In terms of the economic impact of interchangeable generic biologics, as discussed above, studies analyzing cost savings to consumers and taxpayers agree that the cost savings would be significant. For example, according to one source, the estimated savings would be *$43.2 billion* between 2011 and 2020 (Biogenerics: What They Are, Why They Are Important, and Their Economic Value to Taxpayers and Consumers, by Everett Ehrlich, Ph.D., Elizabeth L. Wright (May 2, 2007)); another source estimates *$71 billion* in savings during the first 10 years (Potential Savings of Biogenerics in the United States (February 2007)).

To the extent that this question also is addressing possible safety implications of interchangeable generic biologics, any potential safety risk from interchangeability would be a different clinical effect and an increased risk of immunogenicity. This, however, would be assessed by FDA prior to deeming the brand and generic products interchangeable, just as FDA currently does when assessing whether two small molecule drug products should be deemed interchangeable. Thus, if FDA deems one biologic interchangeable for another, then there should be no impact on patient safety, and health care providers and patients should feel comfortable with substitution by the pharmacist.

With respect to the prospects for "authorized follow-on biologics," this also is a question best answered by the brand industry. Based upon our experience with small molecule drugs, however, it seems reasonable to believe that brand companies will continue to engage in any tactic that enhances their revenues, even when such tactics severely harm the generic industry, and in the process create a disincentive for generic companies to invest in new, lower-priced products.

Finally, at present, we have no basis for believing that these responses will differ based upon the type of biologic product involved.

3. *What competitive concerns are raised by joint research and development, supply, licensing, marketing, and distribution agreements between referenced biologic*

manufacturers and their follow-on biologic competitors? What would be the likely impact of a requirement that agreements between referenced drug product manufacturers and follow-on biologic applicants be filed with the FTC and the Department of Justice Antitrust Division?

Response: We do not believe that joint research and development, supply, licensing, marketing, and distribution agreements between brand and generic companies present any competitive concerns *per se*. In other words, the mere fact that a generic and brand company enter into an agreement does not raise competitive concerns. Indeed, joint R&D agreements, supply agreements, and the like are commonplace in the pharmaceutical industry, just as they are in other industries. That said, it seems unlikely that the generic industry would oppose an effort by Congress to extend to generic biologics the MMA's agreement reporting requirements, which currently apply only to agreements involving applications submitted under Hatch-Waxman (*see* 21 U.S.C. § 355, Notes).[1]

4. *How would the prospect of competition from follow-on biologic drugs influence research and development for new biologic drugs, improvements to existing biologic drugs, and the timing and rollout of new and/or improved biologic drugs? Does the market experience with non-biologic generic pharmaceutical drug products provide insights into these issues?*

Response: With respect to developing new and improved biologic drugs, competition in the biologics arena not only would enhance America's competitiveness, but would spur new innovation. This is, of course, precisely what happened when Congress enacted Hatch-Waxman in 1984 – it created a significant incentive for brand companies to create new products, rather than simply sit back and enjoy a never-ending stream of monopoly profits on old products.

Without competition, brand companies have little, if any, incentive to develop the new, truly innovative products that benefit patients. Rather than invest significantly in entirely new products and product lines, they can simply rely on the generous revenue stream that their ongoing monopolies on older products generate. But competition from generic products pressures brand companies to develop new products to maintain profit margins. Indeed, the biologic drug industry may owe itself in part to generic competition. After Congress passed Hatch-Waxman in 1984, brand companies knew that they would face increased competition for sales of traditional small molecule drugs. Many began investing their resources in what was then a fledgling industry, developing biologic drug products. These investments brought about numerous new life-saving drugs, as well as significant advances in the technology needed to produce and characterize these drugs. Hundreds of additional products currently are in the pipeline. While these investments might eventually have been made, the competitive pressures

[1] The "MMA" refers to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

from generic drugs provided the incentive for this research and development to be done sooner rather than later. Thus, as noted above, the market dynamic created by generics benefits the U.S. (including U.S. consumers) in two important ways. First, generics provide the public with quality, lower-priced alternatives to brand name drugs, saving consumers and taxpayers billions of dollars a year while increasing access to those with restricted income. Second, generics provide the urgency for innovation, forcing brand companies to constantly strive for new and revolutionary treatments. And as brand companies develop new biologic products, they will obtain patents to protect them, which will further the U.S.'s leadership in intellectual property matters.

To the extent Congress ultimately decides to provide some type of regulatory exclusivity period for branded biologics, it is important that Congress look to Hatch-Waxman, which provides important lessons in several respects. For example, consumers receive the most benefit from truly innovative new products, rather than minor tweaks made to existing products – tweaks which brand companies most often do for patent protection reasons, rather than for true scientific advancement. Congress recognized this fact when designing Hatch-Waxman by providing a greater period of exclusivity for new chemical entities (5 years) than for "improvements" to existing products (3 years for certain improvements). Similarly, it is critical that as with Hatch-Waxman, any exclusivity awarded for new indications for biologic products extend solely to the new indication, and not act as a complete barrier to generic approvals, even for older indications.

5. *How does the method used by Medicare for reimbursement of biologic drug products affect pricing and competition of referenced biologic products? What factors are important for this effect and why? How would the Medicare reimbursement system likely affect prices for both the referenced and follow-on biologic products? For example, does Medicare reimburse Part B drugs, including biological drugs, based on the Average Sales Price of all the biological drugs whose National Drug Codes (NDCs) reference the same Biologic License Application (BLA)? If so, how would a follow-on biologic drug that does not reference the BLA of the referenced drug affect the Medicare reimbursed price for referenced drug product? How will these and other Medicare reimbursement methodologies likely affect models of price competition after follow-on biologic drug entry?*

Response: As we understand it, the Medicare reimbursement of biologic drug products, as currently established in the 2003 MMA, will need to be modified to ensure that generic biologics face a competitive environment similar to that enjoyed by traditional small molecule generic drug products, which in turn, would ensure that taxpayers enjoy significant savings from generic biologics – just as they do from the introduction of generic small molecule drugs. More specifically, the current statutory scheme does not give providers the same incentive to use generic biologics as it does to use generic small molecule drugs. Thus, as we see it, at least some modifications to the Medicare reimbursement rules for biologics will be necessary for taxpayers to benefit from the savings that flow from generic market entry.

6. *How are the patent portfolios claiming biologic drugs similar or dissimilar to the patent portfolios that claim small molecule (nonbiologic) drugs approved under the federal Food, Drug, and Cosmetic Act (FDCA)?*

Response: As discussed *infra*, how traditional and biological drug products are claimed might be different, but brand companies are able to obtain patents to protect their biologic products from competition, just as they can to protect traditional small molecule drugs. Thus, any claim by the brand industry that patents do not offer sufficient protection (thus allegedly justifying their request for lengthy regulatory exclusivity) simply is not credible. Indeed, PhRMA and BIO were extremely vocal during Congress' patent reform discussions because, they said, biologic patents are so valuable and important to their members. And of course, the protection afforded by brand biologic patents can be readily seen by looking at the number of times that such patents have been successfully asserted against other biologics makers in the brand vs. brand disputes that have been, and continue to be, litigated in the courts.

7. *Are the regulatory exclusivities currently provided to pharmaceutical drug products in the FDCA appropriate for new biologic drugs and/or significant improvements to existing biologic products? Are they appropriate for specific types of biologics? Why or why not?*

Response: As an initial matter, it must be understood that the law currently provides branded biologics manufacturers with a multitude of financial incentives to develop new products, including for example:

Current Incentives Available To Brand Biologics Companies	
Hatch-Waxman Patent Term Restoration	Compensates drug manufacturers for a maximum of 5 years of patent time lost while testing a product and awaiting government approval. *See* 35 U.S.C. § 156.
Hatch-Waxman PTO Patent Restoration	If a patent's approval is delayed due to the fault of the PTO, gives drug manufacturers one day for every day over three years for review of patent. *See* 35 U.S.C. § 154(b)(1)(B).
Orphan Drug Exclusivity	Gives drug manufacturers 7 years of market exclusivity for drugs intended to treat rare diseases (affecting less than 200,000 people or where the cost of development cannot reasonably be recouped by U.S. sales). *See* 21 U.S.C. § 360cc.
Orphan Drug Tax Credits	Allows drug manufacturers to claim a tax credit equal to 50% of the cost of human clinical trials for drugs intended to treat rare diseases. *See* 26 U.S.C. § 45C.

Current Incentives Available To Brand Biologics Companies	
Puerto Rico Activity Tax Credit	Allows U.S. corporations to exempt 40% of their income from business operations they own in Puerto Rico, the Virgin Islands, or other U.S. Territories. *See* 26 U.S.C. § 936.
Foreign Tax Credit	Allows U.S. corporations paying taxes to foreign governments to claim a limited tax credit for those payments. *See* 26 U.S.C. § 901
Uruguay Rounds Agreement Act Patent Term Restoration	Gives drug companies a 20 year patent from the date that the patent was filed (rather than 17 years from patent issuance). *See* 35 U.S.C. § 154(a)(2).

To the extent that brand companies believe additional incentives are necessary, they should come forward with actual evidence supporting this request. While members of Congress have requested the submission of such evidence, brand companies so far have supported their demands for additional exclusivity solely with self-serving speculation.

If Congress nevertheless considers providing additional exclusivity incentives, the past 20-plus years have demonstrated that Hatch-Waxman struck the right balance between innovation and increased generic access. The exclusivity awarded under Hatch-Waxman is considerable, and the objective facts demonstrate that it has provided ample incentives for the development of new drug products. At the same time, Hatch-Waxman allows consumers to obtain faster access to a wider range of affordable generic products, which saves literally billions of dollars each year. Consequently, Hatch-Waxman establishes the maximum number and length of the regulatory exclusivities that should be awarded to branded drug companies – whether traditional or biologic. Indeed, if anything, biologics companies likely need fewer incentives because they will not experience the same extent of generic competition that traditional drug makers face. For example, unlike companies under Hatch-Waxman, biologics makers will have fewer generic competitors, particularly at the time Congress enacts generic biologics legislation. (*See, e.g.*, October 22, 2007 *Investor's Business Daily* ("Pfizer also has figured out that biologics can be more profitable than pills . . . . A drug firm might get 10 years of patent protection on conventional, chemical-based drugs. Biologics, which are made from human or animal-based proteins, can keep a hold on their markets longer because production is too complicated and expensive for most generic manufacturers.")).

8. *What are the appropriate factors to consider when determining the optimal length of regulatory exclusivity periods for biologic drug products? Do these factors change based on the type of referenced product involved, the extent of competition facing the referenced product, or patent portfolios claiming the referenced product, and if so, how?*

Response: As previously discussed, Congress already has made a thoughtful determination as to the factors that should be considered when deciding on the length of regulatory exclusivity periods for branded drugs. When enacting Hatch-Waxman, Congress correctly concluded that new, truly innovative products should receive a regulatory exclusivity period. Congress also correctly concluded that improvements to previously-approved drug products were not entitled to the same amount of exclusivity as new drug products. Indeed, Congress correctly concluded that only certain improvements to previously-approved drugs would receive any exclusivity at all. While brand biologics makers naturally want far more exclusivity than awarded traditional drugs under Hatch-Waxman, Hatch-Waxman nevertheless establishes the maximum number and length of the regulatory exclusivities that should be awarded to branded drug companies. Again, the exclusivity awarded by Hatch-Waxman has provided ample incentives for the brand industry to both develop new drugs and make "improvements" to older molecules.

Moreover, as noted in response to question #7, it is important to remember that brand biologics makers already get the benefit of Hatch-Waxman's patent term extension provisions. Indeed, brand biologics makers have been reaping the significant benefits that flow from these patent extensions since 1984, and have done so without facing generic competition like their traditional drug counterparts.

Finally, at present, we do not see why the factors Congress considers should change based upon the specific brand product involved, the competition that a particular branded product might face, or how successful the brand company has been at obtaining patent protection for a particular brand product.

9. *How does the European Medicines Agency's approach to regulatory exclusivities in its abbreviated regulatory approval pathway for follow-on biologics inform the U.S. approach?*

Response: While the brand industry repeatedly points to the EU exclusivity periods when demanding even lengthier periods here in the United States, the actual facts show that the EU exclusivity system is not a legitimate model for the United States. The current EU model is suitable for the EU, as it provides a pathway for biosimilars to be approved and for EU patients to have access to life-saving biosimilar products at a reduced cost. But the EU model is neither portable nor transposable; it cannot be simply copied and implemented in a country like the U.S. The fact is that longer exclusivity periods in the EU might be justified given the price controls that the EU imposes on branded drug products. But of course, the United States does not impose any price controls on brand drug products, which explains why U.S. consumers and taxpayers pay far more than their EU counterparts for the same drug products. Yet another reason why Congress should not be guided by the EU exclusivity periods is the fact that EU and U.S. patent laws differ. The U.S. patent law, as we understand it, allows companies to obtain broader protection than the EU patent law, and U.S. patents have a longer life than provided by some countries in the EU. Thus, comparing the EU incentive system to the

U.S. system is a pointless apples-to-oranges comparison that does not meaningfully advance the dialogue on this important issue.

10. *Is a marketing exclusivity period necessary to encourage companies to develop follow-on biologics and to seek their approval by the FDA? If so, why, and how should such an exclusivity period be structured?*

Response: Market exclusivity is necessary to encourage companies to develop generic biologics. Indeed, long ago Congress recognized that generic companies need an incentive to undertake costly and time-consuming patent disputes – disputes needed for pre-patent expiration generic market entry. Thus, the first generic company to challenge the patents protecting the brand-name drug by submitting a paragraph IV ANDA is entitled to a period of marketing exclusivity. The importance of the generic exclusivity period cannot be overstated. For example, the revenues from this incentive allow generic companies to recoup their investments, and significantly, provides the capital necessary to develop additional products and undertake future patent challenges. And given the patent portfolios that brand companies (including biologics makers) now pursue, a generic exclusivity incentive is more important today than it was when Congress created it in 1984.

In terms of how market exclusivity for generic biologics should work, Congress should support a structure like that found in H.R. 1038. That bill provides exclusivity for the first interchangeable generic biologic, but such exclusivity does not prevent the immediate approval of a non-interchangeable, but comparable, generic biologic product. It also provides exclusivity to the first interchangeable product to be approved by FDA, rather than to the company that filed the first application seeking approval of such a product, as happens under Hatch-Waxman.

Patent Dispute Resolution Issues

1. *Would it be important to have the litigation of any patent disputes proceed concurrently with the abbreviated FDA approval process for follow-on biologics? Why or why not? What has been learned from the experience under Hatch-Waxman about the incentives necessary to encourage early resolution of patent issues?*

Response: An efficient patent dispute resolution mechanism will be an essential component to any effective generic biologics legislation. By way of background, generic companies, by definition, sell their products for less – most often far less – than the corresponding branded drug product. As a result, generic companies must have patent certainty prior to marketing. Without it, an at-risk product launch could subject the company to massive damages that threaten its very existence. The required certainty for some patents, but by no means all patents, will come through litigation. Thus, the most efficient and effective generic biologics legislation will contain a patent component that allows the generic company to decide which, if any, patents should be litigated *before* product launch.

This is not to say that a patent holder (whether the brand itself or a third party) should be foreclosed from bringing suit on any patent that it in good faith believes is infringed. Rather, it is a question of timing: Only certain patents should be litigated during the FDA review process before the generic biologic product is launched. Specifically, the only patents that should be litigated immediately, during the FDA review process, are those patents that would prevent the generic company from launching until questions of validity, enforceability or infringement are resolved. Litigation on all remaining patents would take place *after* the generic product actually enters the market. There are many reasons for this, not the least of which is the fact that the more patents involved in the litigation, the longer the litigation will take, and as a result, the longer the public will have to wait for the introduction of affordable generic biologics. This is a lesson that has been learned from Hatch-Waxman, which allows the brand to automatically delay generic market entry for up to 30 months even when the patents at issue are of questionable scope, validity or enforceability.

Equally as important, if a brand company refuses to participate in the patent process, as we have seen under Hatch-Waxman, the generic company must be allowed to enter the market without risking potentially massive infringement damages. H.R. 1038 accomplishes this by limiting the remedies available to patent holders that refuse to participate in the patent process. In other words, these provisions simply ensure compliance with clear-cut statutory obligations. The generic industry's experience with Hatch-Waxman has shown that some brand companies do not always comply with express and unambiguous statutory requirements when failing to do so provides a commercial benefit without penalty. Hatch-Waxman, for example, does not provide a penalty for failing to comply with the Orange Book listing requirements. Several brand companies routinely abuse the FDA Orange Book patent listing process in order to delay ANDA approvals. FDA refused to enforce Hatch-Waxman's express patent listing requirements, and the courts refused to allow private companies to enforce those requirements. Consequently, when crafting effective generic biologics legislation, provisions ensuring compliance with the patent resolution mechanism are crucial.

2. *How long might the approval process for a follow-on biologic application take? What factors might influence this timing?*

Response: As with approvals of generic drugs under Hatch-Waxman, two of the most important factors in terms of the timing of approvals likely will be the ability to have timely consultations with FDA and the availability of the funds necessary for FDA to promptly review such applications. Some of the pending generic biologics bills envision that companies would pay user fees (as brand companies currently pay under PDUFA) when seeking approval of a generic biologic product. Particularly under a statutory scheme involving the payment of fees and the establishment of agency performance goals similar to PDUFA, generic companies anticipate prompt and timely approval of their applications.

3. *How might differences between patent portfolios for small molecule drugs and biologics affect patent litigation involving follow-on biologics? How long might patent litigation involving a follow-on biologic product take?*

Response: As discussed above, how traditional and biological drug products are claimed might be different, but branded biologics companies (just like traditional drug makers) get patents effectively covering, among other things, the compound itself; manufacturing processes; individual steps in the manufacturing processes; various delivery devices; dosing regimens; and methods of use. Thus, we presently are not aware of any differences between patent portfolios for small molecule drugs and biologics that might affect patent litigation involving generic biologics.

With respect to how long brand/generic biologics patent litigation might take, that likely will in large part be the function of the patent resolution process contained in a final generic biologics bill. If, as discussed above, generic companies are allowed to litigate the patents that truly could create a barrier to market entry prior to launch (and any other patents after launch), pre-generic launch patent litigation could be resolved at least as expeditiously as Hatch-Waxman litigation. If, however, the brand companies have their way, and are allowed to litigate any and all patents that they choose pre-generic launch, litigation will take years and years to complete. Indeed, brand companies would be able to use patents of questionable validity, enforceability or scope to deprive the public of access to affordable biologics for years longer than can reasonably be justified. It is, therefore, critical that Congress adopt a workable patent resolution process.

4. *When is it in the interest of a referenced biologic drug manufacturer to resolve patent issues prior to marketing by a follow-on applicant? When is it in the interest of a follow-on biologic applicant to resolve patent issues prior to marketing its follow-on biologic? When is it in the interest of either party to resolve patent issues following commercial marketing of the follow-on product?*

Response: With respect to generic companies, as discussed above, it is in the generic's interest to immediately litigate only those patents that would prevent the generic company from launching until questions of validity, enforceability or infringement are resolved. Litigation on all remaining patents would take place after the generic product actually enters the market. This way, generic biologics can be introduced as quickly as possible. From the brand perspective, they want generic marketing to be delayed as long as possible. Thus, as discussed above, if brand companies are allowed to assert any and all patents of their choosing pre-generic launch, then it nearly always will be in the brand's financial interest to assert all of its patents prior to generic marketing. The more patents litigated during the FDA review process, the more likely it is to delay generic launch.

5. *What are the legal impediments facing a follow-on biologic applicant that has not been sued for infringement to obtaining a declaratory judgment on patent infringement or invalidity issues prior to commercial marketing of its follow-on product?*

Response: Since the U.S. Supreme Court's decision in *MedImmune*, which cut down the Federal Circuit's so-called "reasonable apprehension" test for determining whether a declaratory judgment patent action can be maintained in court, the legal impediments facing a generic biologics applicant seeking to assert a declaratory judgment claim should be minimal, if any exist at all. Nevertheless, Congress should consider enacting declaratory judgment provisions for generic biologics applicants along the lines of those enacted in 2003 as part of the MMA.

6. *Are regulatory exclusivities needed to encourage follow-on biologic applicants to challenge patents? Why or why not?*

Response: Exclusivity for generic biologics is critical in terms of achieving the goal of expediting consumer access to affordable versions of biological medicines. As discussed above, when enacting Hatch-Waxman, Congress recognized that generic companies need an incentive to undertake costly and time-consuming patent disputes, and as a result, Congress created the 180-day generic exclusivity period for the first generic company to challenge the patents protecting the brand-name drug. Again, the importance of the generic exclusivity period cannot be overstated. The revenues from this incentive provide the capital needed for generic companies to develop additional products and undertake future patent challenges. The public needs generic companies to have such an incentive because without it, brand companies can use their extensive patent portfolios to keep affordable medicines off the market for years, even using weak or suspect patents. In terms of structure, Congress should support a structure like that found in H.R. 1038, which provides exclusivity for the first approved interchangeable generic biologic, but such exclusivity does not prevent the immediate approval of a non-interchangeable, but comparable, generic biologic product.

7. *What opportunities will biologic drug manufacturers and follow-on applicants have to manipulate proposed new regulatory obligations (e.g., application notification obligations, declarations of patents claiming biologic drugs, etc.) and exclusivity periods surrounding a concurrent patent resolution process? What are the prospects for the improper use of citizen petitions to delay approval of follow-on biologic applications?*

Response: This question asks for speculation on a statutory scheme that does not yet exist. Nevertheless, some provisions found in a few of the pending generic biologics bills do contain provisions that could be abused by brand companies to unduly delay generic market entry. For instance, some pending bills, such as the BIO-backed H.R. 5629, H.R. 1956 and S. 1505, contain mandatory guidance or rule-making processes, which easily could be abused to delay generic market entry. More specifically, these bills require FDA to undertake and complete a guidance process allowing for public comment and participation prior to approval (if not prior to submission) of a generic biologics application. Brands have long used the FDA guidance and rule-making process to delay generic approvals under Hatch-Waxman. The same likely will be true for generic biologics. Similarly, the patent dispute resolution mechanisms found in H.R. 5629 and S. 1505 also are cause for significant concern. Both

mechanisms are wholly unworkable in terms of providing an efficient system for resolving patent disputes in a timely way. Each, in fact, contains numerous provisions which easily could be abused in order to delay generic marketing. These are just a few examples of the types of provisions contained in some pending bills which could be used to prevent generic companies from timely marketing safe and affordable biologic drugs.

With respect to citizen petitions specifically, brand companies already are using the citizen petition process to delay generic biologic approvals. For example, BIO and several brand companies filed citizen petitions seeking to prevent FDA from issuing generic biologic guidance documents, and in fact, FDA never did issue the anticipated guidances. Similarly, brand companies have filed citizen petitions seeking to delay or prevent approval of biologics approved under the FFDCA, including petitions relating to Omnitrope® and Lovenox®. Consequently, absent Congressional action, we do not see such abuses of the citizen petition process changing. Congress, however, easily could include provisions that would minimize, if not eliminate, the approval delays for generic biologics. Bills such as H.R. 1038 in fact include such provisions.

8. *How might referenced biologic product manufacturers and follow-on biologic applicants structure patent settlement agreements given the competitive dynamics arising from the marketing of follow-on biologic drugs? What incentives might exist for these companies to enter anticompetitive settlements? Should patent settlement agreements be filed with the antitrust agencies? What would be the likely effect of the filing requirement on settlements?*

Response: The FTC's position with respect to brand/generic settlements of Hatch-Waxman patent litigation is well-known: FTC actively seeks legislation banning any such settlement where the generic company receives "consideration" from the brand other than pre-patent expiration market entry, no matter what pro-consumer provisions the settlement might otherwise contain. This question suggests that the FTC will view any settlement of brand/generic biologics patent litigation in the same manner, again no matter how pro-consumer the results of such a settlement. Respectfully, this is unfortunate since consumers have benefited significantly from settlements of Hatch-Waxman patent cases.[2] That said, as noted above, it seems unlikely that the generic industry would oppose an effort by Congress to extend to generic biologics the MMA's settlement agreement reporting requirements. Such a case-by-case approach would allow the actual facts and circumstances of each specific case to be carefully evaluated.

[2] This is not to say that brand or generic companies have plans to settle any specific patent litigation involving generic biologics. They plainly do not. The simple fact is, however, that many patent cases settle, including brand vs. brand patent cases involving biologics patents. It thus seems reasonable to believe that assuming Congress enacts a generic biologic approval pathway, there will be brand/generic litigation and some of that litigation will be resolved by settlement.