

“Abbreviated” Biologics Applications: The Reality of Providing Biosimilar Products

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Introduction

Biologic drug products (“biologics”) are drugs created by living organisms and biological processes. Biologics can include vaccines, allergenics, proteins or other products used to prevent, treat, or manage diseases like rheumatoid arthritis and cancer, and/or their associated conditions and symptoms. Biologics are typically large molecules with complex, unstable structures produced by complicated methods. Changing just one element in the manufacturing process or environment, such as the temperature of one particular reaction or operation, has the potential to completely change the function of the molecule.

For these and other reasons, an abbreviated pathway for biosimilar drugs that makes use of safety, efficacy, and other information for an earlier developed biologic has not been available. That is, until now. On March 23, 2010, President Obama signed “The Biologics Price Competition and Innovation Act of 2009” (“the Biologics Act”) into law. The Biologics Act amends section 351 of the Public Health Services Act, and creates a regulatory process for follow-on biologics to be licensed (approved) by the U.S. Food and Drug Administration (FDA). The compelling public interest for doing so is the goal of fostering competition to help make biologics more affordable once the first developer, or reference product sponsor, has had an opportunity to achieve some level of cost recovery and profit. This is similar to what the Drug Price Competition and Patent Term Restoration Act of 1984 (codified as amended at 21 U.S.C. § 355) (the “Hatch-Waxman Act”) and related subsequent legislation sought to do for small molecule pharmaceutical compounds.

Few of the provisions of the Biologics Act are comparable to the Hatch-Waxman Act, however, in part due to the substantial technical differences between small molecule pharmaceuticals and biologics. Some of the differences stem from the fact that approved active pharmaceutical ingredients are identical under the Hatch-Waxman Act, while under the Biologics Act, the licensed drugs cannot be identical, but only “biosimilar” as discussed below. The Biologics Act also sets out more detailed pre-litigation procedures than the Hatch-Waxman Act, and appears to rely far more heavily on private party interaction between the biologic marketer and the biosimilar applicant rather than having the FDA administer a public listing (namely, the Orange Book) of the patent rights alleged to cover the branded pharmaceutical. Through the comparison below of the Biologics Act to the Hatch-Waxman Act, one can begin to understand the new Biologics Act and the gaps that will need to be filled through further FDA regulation, possible additional legislation, and judicial decisions to help interpret the Biologics Act.

Biosimilarity vs. Interchangeability

Biosimilarity

There are two classes of drugs that may be licensed under the Biologics Act. The first class is a “biosimilar” drug. A “biosimilar” drug is a biologic that is highly similar to the reference product (*i.e.*, the brand name product), notwithstanding minor differences in clinically inactive ingredients.³ There must be

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³ 42 U.S.C. § 262(i)(2)(A).

no clinically meaningful differences between the biosimilar product and the reference product in terms of safety, purity, and potency.⁴ Analytical, animal, and clinical studies must be submitted to show safety and efficacy of the biosimilar or follow-on product.⁵ The exact meaning of these terms remains to be seen, and will likely be developed in the near-term through the FDA's rulemaking process and issuance of public guidance documents.

Moreover, the biosimilar application to the FDA must show that the biological product and reference product use the same mechanism or mechanisms of action for the condition(s) of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product.⁶ The biosimilar applicant must also show that the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.⁷ This has been problematic even for various brand and generic pharmaceutical manufacturing operations, and will likely be a more substantial problem for biologic manufacturers given the greater unpredictability of biologics manufacturing. Lastly, the biosimilar applicant must submit publicly available information regarding the FDA's previous determination that the reference product is safe, pure, and potent.⁸

Like the Hatch-Waxman Act, the biosimilar applicant must also show that the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product.⁹ The route of administration, the dosage form, and the strength of the biological product must be the same as those of the reference product.¹⁰ This is one of several areas that is ripe for a more detailed regulatory framework to better define these terms, and to provide guidance on best practices to design and carry out testing to streamline compliance in meeting these requirements.

Unlike generic pharmaceuticals, biosimilar drugs are considered an alternate therapy with a different active ingredient than the reference product. This is because of the unpredictability and variation between biologics. Pharmacies and hospitals will not substitute a biosimilar product for the reference drug unless the doctor expressly prescribes the biosimilar product. Thus, in addition to manufacturing, clinical studies, and production costs, successful biosimilar applicants will need to spend substantially more on marketing and advertising to inform doctors familiar with the reference product of the biosimilar product. Because of these expenses, the difference in price between the innovator and biosimilar drug is expected to be much smaller than the pricing discrepancy typical between brand name and generic drugs.

Interchangeability

The other class of drug that may be licensed under the Biologics Act is an interchangeable drug, which will be considered to have the same active ingredient and may be substituted for the reference product.¹¹ For an interchangeable drug to be licensed, the biosimilar applicant must show that it is sufficiently biosimilar to the reference product.¹² In addition, the biosimilar product must be expected to produce the

⁴ 42 U.S.C. § 262(i)(2)(B).

⁵ 42 U.S.C. § 262(k)(2)(A)(i)(I).

⁶ 42 U.S.C. § 262(k)(2)(A)(i)(II).

⁷ 42 U.S.C. § 262(k)(2)(A)(i)(V).

⁸ 42 U.S.C. § 262(k)(2)(A)(iii)(I).

⁹ 42 U.S.C. § 262(k)(2)(A)(i)(III).

¹⁰ 42 U.S.C. § 262(k)(2)(A)(i)(IV).

¹¹ 42 U.S.C. § 262(i)(3).

¹² 42 U.S.C. § 262(k)(4)(A)(i).

same clinical result as the reference product in any given patient.¹³ For a biological product that is administered more than once to an individual, it must be shown that the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than without the alternation or switch.¹⁴

Interchangeability will thus likely be difficult to demonstrate. The FDA is likely to set high standards for licensure, such that few products are expected to be approved.

The reward for the first licensed interchangeable product is exclusivity as to other interchangeable biological products for at least one year.¹⁵ Specifically, the second or subsequent interchangeable biological product cannot be approved for any condition of use until the earliest of the following occurrences:

1. One year after the first commercial marketing of the first interchangeable product;¹⁶
2. 18 months after a final court decision in favor of the applicant with respect to all patents in suit or a dismissal of the complaint with or without prejudice;¹⁷
3. 42 months after approval of the first interchangeable product if litigation is ongoing;¹⁸ or
4. 18 months after approval of the first interchangeable product if the first interchangeable applicant has not been sued.¹⁹

This exclusivity does not, however, bar the approval of another “biosimilar,” *i.e.*, not interchangeable, product.

In comparison, the Hatch-Waxman Act grants a 180-day exclusivity to the first successful abbreviated new drug applicant who seeks approval with a Paragraph IV certification that one or more of the brand patents is not infringed or is invalid. During this roughly six-month period, the successful first paragraph IV generic applicant is the only generic company on the market.

Reference Product Exclusivity

Many have argued that patent protection is insufficient to protect the interests of biotechnology companies researching and developing new biologics. First, because some biologics are naturally occurring substances, product claims are stated to be difficult to obtain. Any product claims that survive prosecution are argued to be narrow in scope. Product claims are preferred because they tend to be easier to detect and allege infringement. Typically, however, the patent applicant settles for method and process claims, which tend to be easier to design around than product claims and harder for a patentee

¹³ 42 U.S.C. § 262(k)(4)(A)(ii).

¹⁴ 42 U.S.C. § 262(k)(4)(B).

¹⁵ 42 U.S.C. § 262(k)(6).

¹⁶ 42 U.S.C. § 262(k)(6)(A).

¹⁷ 42 U.S.C. § 262(k)(6)(B).

¹⁸ 42 U.S.C. § 262(k)(6)(C)(i).

¹⁹ 42 U.S.C. § 262(k)(6)(C)(ii).

to detect infringement. Under this framework, a follow-on biologic may be similar enough to a pioneer biologic for regulatory approval purposes, but different enough to avoid the relevant patents.

The Biologics Act offers substantial incentives to innovate by giving marketing and data exclusivity to the initial biologic developer for a significant length of time. Biological applications cannot be approved for marketing until 12 years after the date the reference product was first licensed.²⁰ This is more than twice the length of new drug exclusivity granted for pharmaceutical molecules under the Hatch-Waxman Act. Moreover, an application for a biological product may not even be submitted to the FDA until 4 years after the license date of the reference product.²¹ To compare, the Hatch-Waxman Act provides only 5 years of market exclusivity for a new chemical entity, or 3 years for changes to existing molecules. A generic applicant that files a Paragraph IV certification can, however, submit an ANDA at the 4-year date. In both the Biologics Act and the Hatch-Waxman Act, an additional 6 months of exclusivity may be granted for the completion of pediatric studies requested by the FDA to help ensure efficacy and/or safety in pediatric populations.²²

The 12-year exclusivity period in the Biologics Act does not apply to: (1) new indications, routes of administration, dosing schedules, dosage forms, delivery systems, delivery devices, or strength of the reference biologic; or to (2) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.²³ In contrast, the Hatch-Waxman Act allows a 3-year exclusivity period for additional clinical studies and supplemental information in developing a drug product that contains an active moiety that has been previously approved. For example, changes in formulations, salts, indications, dosing regimens, or patient population may be granted exclusivity.

Pre-Litigation Patent-Related Procedures

The Biologics Act attempts to streamline dispute resolution by placing specific procedures in place to guide the biosimilar applicant and reference product sponsor through the pre-litigation process. It remains to be seen how effective the Act will be in streamlining the expected litigation over biosimilar products.

Patent Resolution

A biological applicant must provide a copy of its biosimilar application to the reference product sponsor within 20 days of the FDA's acceptance of the application.²⁴ Within 60 days, the reference product sponsor must provide a list of patents that it believes covers the biological product, including patents for which it is an exclusive licensee.²⁵ In contrast to the Hatch-Waxman Act, which excludes process and method patents from the Orange Book and therefore from litigation over the ANDA itself, the Biologics Act permits the list to include all related patent rights including processes and methods. The sponsor must also identify which patents on the list it would be willing to license to the applicant, if any.²⁶ Within 60 days of receipt of the reference product sponsor's patent list, the biosimilar applicant may provide its own list of patents that it believes can be reasonably asserted against it in view of the biosimilar application and proposed biosimilar.²⁷ In addition to the list, the biosimilar applicant must also provide a detailed factual and legal basis as to why the patents are invalid, unenforceable, or not

²⁰ 42 U.S.C. § 262(k)(7)(A).

²¹ 42 U.S.C. § 262(k)(7)(B).

²² 42 U.S.C. § 262(m)(2).

²³ 42 U.S.C. § 262(k)(7)(C)(ii).

²⁴ 42 U.S.C. § 262(l)(2).

²⁵ 42 U.S.C. § 262(l)(3)(A)(i).

²⁶ 42 U.S.C. § 262(l)(3)(A)(ii).

²⁷ 42 U.S.C. § 262(l)(3)(B)(i).

infringed, or a statement that it does not intend to market the drug until the patents expire.²⁸ The statement is similar to a Paragraph IV notice letter an ANDA applicant would send to the NDA holder and patentee, or a Paragraph III certification in the event of an election to market after patent expiration.

Separately, it should be noted that the reference product sponsor may supplement its patent list with a different, secondary clock that starts ticking for newly issued or licensed patents.²⁹ The supplementary list must be provided within 30 days of the issuance or in-licensing of any such patent to be added.³⁰ Within 30 days, the biosimilar applicant must then provide a detailed statement with the factual and legal basis for the belief that the supplemented patent rights are invalid, unenforceable, or not infringed, or that it will not begin commercial marketing until the supplemental patent(s) expire.³¹

Returning to the primary timing regime noted above, within 60 days of receipt of the biosimilar applicant's explanations of its basis to proceed, the reference product sponsor must provide a detailed counter-statement setting forth for each patent, on a claim-by-claim basis, why the patents will be infringed by the proposed biosimilar product, and/or why the patents are valid and enforceable.³² After the exchange of statements, the sponsor and applicant decide which of the patents on the list should be litigated.³³ The parties then have 15 days to reach an agreement.³⁴

If the parties agree on which patents should be litigated, the reference product sponsor must bring an action for patent infringement with respect to the agreed-upon patents within 30 days of the agreement.³⁵ Failure to do so results in fairly significant and dire ramifications for the patent holder. If the reference product sponsor brings an action after the 30 days have expired, or brings suit then dismisses it without prejudice, the sole remedy in any subsequent action for infringement of that patent will be a reasonable royalty, *i.e.*, no injunctive relief is then available.³⁶ If the reference product sponsor or the patentee fails to disclose a relevant patent in response to a request for patent information by an applicant, an action for patent infringement under "this section" may not be brought with respect to the proposed biosimilar product.³⁷ This language is likely to refer to all of 35 U.S.C. § 271, although a reference product sponsor may attempt to argue that it instead refers only to 35 U.S.C. § 271(e) relating to technical acts of infringement by filing a biosimilar application with the FDA. Section 271 includes other instances of the language "this section," most of which fairly clearly refer to all of 35 U.S.C. § 271. Additionally, the failure to list a relevant patent was likely intended to result in a more severe penalty than failure to bring suit on time or for dismissing a suit without prejudice. Those actions are penalized by eliminating injunctive relief, and Congress thus apparently intended "this section" to refer to all of 35 U.S.C. § 271 to more severely punish the greater offense of omitting an item from the list of relevant patents. The practical implication likely means that a patent not included on the list of relevant patents for a given biologic product can **never** be enforced, although a contrary argument may exist.

For the group of patents included on the list of relevant patents, but not selected for litigation by the sponsor and biosimilar applicant, suit may be brought on this group of patents only during the 180-day

²⁸ 42 U.S.C. § 262(l)(3)(B)(ii).

²⁹ 42 U.S.C. § 262(l)(7).

³⁰ 42 U.S.C. § 262(l)(7)(B).

³¹ *Id.*

³² 42 U.S.C. § 262(l)(3)(C).

³³ 42 U.S.C. § 262(l)(4)(A).

³⁴ 42 U.S.C. § 262(l)(4)(B).

³⁵ 42 U.S.C. § 262(l)(6)(A).

³⁶ 35 U.S.C. § 271(e)(6)(B).

³⁷ 35 U.S.C. § 271(e)(6)(C).

pre-marketing period once the biosimilar application provides notice of its intention to market. This is another requirement on the biosimilar applicant, which must provide to the reference product sponsor a notice of intention to market roughly 6 months before launching its proposed biosimilar product. On the other hand, there are no provisions in the legislation prohibiting settlement. The FTC may, however, eventually view such settlements in a similar light to the strongly disfavored settlements between brand and generic companies under the Hatch-Waxman Act.

If the parties do not reach an agreement on which patents to litigate, the parties exchange additional lists in an attempt to reach agreement. The biosimilar applicant first informs the reference product sponsor how many patents it believes should be litigated.³⁸ The sponsor may not designate a greater number of patents than the applicant submits unless the applicant designates none, in which case the sponsor can designate one.³⁹ The total number of patents can be up to double that designated by the biosimilar applicant because the patents chosen by the sponsor may not be the same patents chosen by the applicant. This is because the parties agree on the number of patents and then on which patents, and if the patents are all different, the number can be doubled.

The designated patent lists at this last step must be exchanged simultaneously so that neither party can manipulate its own list to include more or less patents.⁴⁰ Unfortunately, there is no suggested mechanism for such a simultaneous exchange, but perhaps third party vendors will offer such services in the future. After the proposed litigation patent lists of each party are exchanged, the sponsor must bring an infringement action with respect to all the patents on the two lists if no agreement is reached.⁴¹ In contrast to the Hatch-Waxman Act, there is no automatic regulatory stay of approval of the biological application during the course of the litigation, so reference product sponsors will need to be proactive in justifying preliminary injunctive relief.

Confidential Access to Biological Application

The biosimilar applicant is required to turn over the application to the reference product sponsor within 20 days after the FDA's notification that the application has been accepted for review.⁴² To minimize the risk that the sponsor does not misappropriate the biosimilar applicant's confidential information regarding the biosimilar product, the Biologics Act limits the permitted recipients of such information.⁴³ Outside counsel designated by the reference product sponsor may review the application, provided that such counsel does not engage in patent prosecution relevant to the sponsor's product.⁴⁴ The reference product sponsor may also designate one in-house attorney to receive and review the information, provided that the attorney also does not engage in patent prosecution relevant to its product.⁴⁵ If the reference product sponsor has exclusively in-licensed any patents, one representative of the patent owner may also view the application.⁴⁶ Each of these permitted recipients is restricted from disclosing the biosimilar applicant's confidential information to any other person without the consent of the biosimilar applicant, which must not be unreasonably withheld.⁴⁷

³⁸ 42 U.S.C. § 262(l)(5)(A).

³⁹ 42 U.S.C. § 262(l)(5)(B)(ii).

⁴⁰ 42 U.S.C. § 262(l)(5)(B)(i).

⁴¹ 42 U.S.C. § 262(l)(6)(B).

⁴² 42 U.S.C. § 262(l)(2)(A).

⁴³ 42 U.S.C. § 262(l)(1)(B)(ii).

⁴⁴ 42 U.S.C. § 262(l)(1)(B)(ii)(I).

⁴⁵ 42 U.S.C. § 262(l)(1)(B)(ii)(II).

⁴⁶ 42 U.S.C. § 262(l)(1)(B)(iii).

⁴⁷ 42 U.S.C. § 262(l)(1)(C).

Use of the confidential information in the biosimilar application is also limited. The permitted recipients can only use the confidential biosimilar information for the purpose of determining whether a claim of patent infringement can be reasonably asserted against the biosimilar applicant.⁴⁸ Ownership of the information remains with the biological applicant.⁴⁹ Thus, the reasonableness of whether consent is granted to share will likely be balanced against the need for additional permitted recipients to assist the reference product sponsor in its evaluation of infringement.

If the reference product sponsor files a patent infringement action, no confidential information shared under these provisions may be included in any publicly-available complaint or other pleading.⁵⁰ If no infringement suit is brought within the 30-day period, the reference product sponsor must return or destroy (and certify destruction of) all information received from the biosimilar applicant.⁵¹

The Biologics Act tips the scale on relief for violations of confidentiality obligations by a reference product sponsor in favor of the biosimilar applicant. Any disclosure in violation of the confidentiality terms is deemed to cause irreparable harm to the biosimilar applicant, and a court must consider immediate injunctive relief to be appropriate and necessary.⁵² This may be in recognition of the substantial independent development and clinical trials required of a biosimilar applicant to achieve FDA approval of a follow-on biologic application.

Preliminary Injunctions

In addition to patent list exchanges, the biosimilar applicant must give 180 days notice in advance of its first commercial marketing of its proposed biological product.⁵³ After receiving notice, the reference product sponsor may seek a preliminary injunction against the commercial manufacture or sale of the product based on alleged infringement of any patent that was not the subject of the initial litigation phase, but was initially listed by either party as potentially applicable to the proposed product.⁵⁴

Declaratory Judgment Actions

The Biologics Act also strictly limits declaratory judgment actions that may be brought by either party. Where the biosimilar applicant provides the reference product sponsor with its biosimilar application and other manufacturing process information for the biological product, no declaratory judgment actions may be brought on any patent from the originally-exchanged lists that is not included on the list of patents to be litigated until the notice of commercial marketing occurs.⁵⁵ Where the biosimilar applicant provides its biosimilar application in confidence but fails to comply with subsequent obligations, the reference product sponsor (but not the applicant) may bring a declaratory judgment action on any patents initially listed by the sponsor or on any newly issued or licensed patents.⁵⁶ In the unlikely event the biosimilar applicant fails to supply even its biosimilar application to the sponsor, the sponsor (but not the applicant) may bring a declaratory judgment action on any patent that covers the biological product.⁵⁷

Uncertainty in FDA Guidelines

⁴⁸ 42 U.S.C. § 262(l)(1)(D).

⁴⁹ 42 U.S.C. § 262(l)(1)(E).

⁵⁰ 42 U.S.C. § 262(l)(1)(F).

⁵¹ *Id.*

⁵² 42 U.S.C. § 262(l)(1)(H).

⁵³ 42 U.S.C. § 262(l)(8)(A).

⁵⁴ 42 U.S.C. § 262(l)(8)(B).

⁵⁵ 42 U.S.C. § 262(l)(9)(A).

⁵⁶ 42 U.S.C. § 262(l)(9)(B).

⁵⁷ 42 U.S.C. § 262(l)(9)(C).

The main concern for the FDA in approving and licensing biological products is expected to be patient safety. Because of the unpredictability and complexity of biological molecules, it is imperative to put appropriate guidelines in place for required testing, both for the original reference product sponsor's products as well as the biosimilar applicant's biosimilar product. One thing is certain—applicants will not be able to rely on the reference product sponsor's clinical data to show safety and efficacy. This is something that generic companies can do under the Hatch-Waxman Act, which efficiently avoids the need for different manufacturers to repeat expensive studies already conducted by the brand company. Instead, biosimilar applicants will be required to submit their own clinical data to prove biosimilarity or interchangeability. Unfortunately, this will mean little in the way of a discount to the drug-consuming public who purchases a biosimilar product and raises ethical concerns if patients receive a placebo in clinical trials despite existing marketed drugs having been proven to be safe and effective.

The million dollar question is just how much testing the FDA will require. This will likely depend on a number of factors including the ability to characterize the drug product, effectiveness of analytical methods, consistency of manufacturing processes, and regulatory and clinical experience to date. The FDA will most likely also require post-market safety evaluations because of immunogenicity issues.

Immunogenicity, which is an immune response to a drug, is a unique problem of biopharmaceuticals. It can happen when switching between two follow-on biologics or between a reference biologic product and a follow-on product. Most therapeutic proteins will induce antibodies in patients upon repeated treatment. These anti-drug antibodies can lead to serious problems because they can interfere with the efficacy of the drug. For example, these antibodies can neutralize the activity of the drug, induce allergic or anaphylactic reactions, or cross-react with the body's own counterpart to the drug. In a worst case scenario, the antibodies can attack and disable the patient's own naturally occurring protein. On the other hand, it may be that periodic switching between a reference product and a biosimilar product, or using smaller doses of each concurrently, might minimize the adverse effects of the antibodies each generates. Substantial studies will be required to prove the specific effects of any given biologic product, whether a reference product or a biosimilar product.

The Biologics Act allows the FDA flexibility to develop guidelines and license applications. The Biologics Act does not require that the FDA issue guidance documents for the FDA to review or consider a biosimilar application.⁵⁸ The FDA may, however, issue specific guidance for product classes.⁵⁹ Guidance documents may even state that the FDA will not currently license a product or product class (not including any recombinant protein) because the current science and experience does not support the licensure of a biosimilar in that product category.⁶⁰ The FDA may then, however, issue subsequent guidance to modify or reverse the guidance document that states that the current science does not support approval.⁶¹ The public will be able to comment on the FDA's proposed guidelines before final guidance is issued.⁶²

With time, the FDA can adapt to advances in science and technology and determine the specific requirements for licensure on a case-by-case basis. As analytical tools for biologics advance, eventually less clinical data may be required by the FDA. The challenge for the FDA will be ensuring adequate demonstration of safety and potency, while keeping the application process reasonably short so as to avoid unduly impeding progress with biologic product therapies.

⁵⁸ 42 U.S.C. § 262(k)(8)(C).

⁵⁹ 42 U.S.C. § 262(k)(8)(D).

⁶⁰ 42 U.S.C. § 262(k)(8)(E)(i).

⁶¹ 42 U.S.C. § 262(k)(8)(E)(ii).

⁶² 42 U.S.C. § 262(k)(8)(B).

Conclusion

The passage of The Biologics Price Competition and Innovation Act is a step, albeit a small one, in the right direction on the path of providing lower cost biologics. Given the substantially lengthy 12-year (possibly 12-1/2-year) data exclusivity period, the substantial cost to conduct the studies to show biosimilarity or interchangeability, and the limited price decrease expected even when a biosimilar product hits the market, many companies may be reluctant to use the Biologics Act pathway. Indeed, one of the major generic pharmaceutical companies in a position to manufacture biosimilar products, Teva Pharmaceuticals, has already stated that it intends to use the existing Biologic Licensing Act (“BLA”) framework given that the Biologics Act “falls short.”⁶³

Even for companies who elect to forge ahead as biosimilar applicants, it will take some time before a sizeable number of biosimilar applications are licensed. In many cases, once the expertise to make a biosimilar is achieved, it may be that the applicant has discovered a superior product and will pursue this as a new reference product. For companies using the Biologics Act, the FDA will play a key role in developing the regulations and policies that are critical to ensuring safe and efficacious biosimilar drugs.

⁶³ See http://money.cnn.com/news/newsfeeds/articles/reuters/MTFH02128_2010-06-23_18-17-28_N23196913.htm, (June 23, 2010).