

---

# Healthcare statute signals major change for biosimilar products

The comprehensive healthcare bill recently passed by the US Congress includes an approval pathway for biosimilar biological products. The regime for biosimilar products in the United States is therefore set to change

---

By **Christopher Hughes** and **Michael P Dougherty**, Cadwalader, Wickersham & Taft LLP, New York

For several years the US Congress has been considering whether to establish an abbreviated approval pathway for biosimilar biological products (often called “follow-on biologics”). Essentially, such a pathway would do for biological products what the 1984 Hatch-Waxman Act did for small molecule drugs: allow the approval and sale of biological products that mimic the structure and properties of previously approved biological products without the exhaustive safety and efficacy testing required for new drugs. It is hoped that such a pathway would allow follow-on biologics to be sold at lower prices than the previously approved innovator products they are intended to copy.

On 21<sup>st</sup> March 2010, an abbreviated approval pathway for biosimilars became a reality when Congress passed the Biologics Price Competition and Innovation Act of 2009, which constitutes one part of a much larger, comprehensive healthcare bill.

Prior to its passage by Congress, there had been extensive reporting on the proposed biosimilars legislation, but virtually all of it focused on one issue: the market exclusivity period awarded to the sponsor of the original innovator product (the “reference product”). This is the time period after approval of the reference product during which biosimilar versions of that product may not be approved, regardless of whether any patent covering the

reference product has expired. The new biosimilars statute provides for 12 years of market exclusivity, which can be extended by six months if the sponsor completes paediatric studies involving the product. This has been controversial because the US Federal Trade Commission and patient advocacy groups have argued that no exclusivity period is necessary. In their view, the reference product sponsor should have to rely solely on patents to forestall the sale of biosimilar versions of the product. The Obama administration has taken an intermediate position, advocating a market exclusivity period of seven years.

Amid all the controversy over exclusivity periods, the patent-related provisions of the biosimilars pathway have received comparatively little attention. This is surprising because the patent provisions will have a significant effect on how and when biosimilar products are approved, and because the patent-related procedures of the new biosimilars law differ significantly from those of the earlier Hatch-Waxman Act. The new law contains detailed procedures for identifying patents that can be asserted against a party that files an application seeking approval to market a biosimilar version of an existing biological product. The new law also provides rules regarding how and when such patents can be asserted in infringement suits. In general, the new law’s patent-related provisions are more favourable to the party seeking approval to market the biosimilar product than to the maker of the reference product. For example, the new law allows the applicant to limit litigation to only one patent until shortly before the biosimilar product is ready for its commercial launch, regardless of how many patents the reference product sponsor may wish to assert.

### Big changes from Hatch-Waxman

Lawyers and business executives accustomed to the patent-related procedures of the Hatch-Waxman Act will find two aspects of the new biosimilars law especially significant. First, it does not provide for an “Orange Book” type listing of patents that cover a given biological product or a method of its use. Second, it does not provide for an automatic stay of approval for an application to market a biosimilar product if an infringement suit is brought.

Instead of an Orange Book listing of patents relevant to a given reference product, the new biosimilars law requires the applicant and the reference product sponsor to go through a process of exchanging information to identify the relevant patents and to determine which of these will be litigated. Shortly after an application for approval to market a biosimilar product is filed with the US Food and Drug Administration (FDA), the applicant must provide a copy of the application to the reference product sponsor, along with a description of the process by which the biosimilar product is manufactured. The reference product sponsor then decides which, if any, patents it owns or has exclusive rights under that it wishes to assert against the applicant. The applicant must then make a certification with respect to each patent identified by the reference product sponsor. The certification must state that the applicant either will not launch the biosimilar product commercially before the patent expires or believes that the patent is invalid, unenforceable or will not be infringed. If the applicant makes the latter type of certification, it must provide a detailed, claim-by-claim statement of the legal and factual basis for its contentions. Thereafter, the reference product sponsor can file an infringement suit.

Unlike the procedure under the Hatch-Waxman Act, however, the filing of such a suit does not stay the FDA’s approval of the application. On the contrary, there is no provision in the new biosimilars law by which a reference product sponsor can obtain a stay of the application’s approval. Rather, the most that the reference product sponsor can do is to obtain an injunction against the biosimilar applicant’s infringement. To obtain such injunctive relief, the reference product sponsor

#### Christopher Hughes

Partner

christopher.hughes@cwt.com

Christopher Hughes heads Cadwalader’s IP practice group and has over 30 years of experience in complex patent, trade secret and trademark trials and litigation, as well as licensing and IP counselling in the United States and abroad. He has represented major corporations in computer, telecommunications, medical devices and business method/financial services patent litigations in US district courts and International Trade Commission and World Intellectual Property Organisation arbitrations, and has directed corresponding European and other foreign proceedings.

#### Michael Dougherty

Special counsel

michael.dougherty@cwt.com

Michael Dougherty has more than 24 years of experience litigating pharmaceutical and biotechnology patent cases in the US district courts, the US Court of Appeals for the Federal Circuit and the US International Trade Commission. He has particular expertise in litigation between brand and generic pharmaceutical companies under the Hatch-Waxman Act, and in the new field of biosimilar biological products.

must obtain a judgment of infringement from a district court. Moreover, the injunction against the applicant’s infringement does not go into effect until the judgment has become final, which the statute defines as meaning that no appeal other than a petition for *certiorari* to the US Supreme Court has been or can be taken.

### Confusing inconsistencies between identification and infringement provisions

The scope of the patents that can be identified and asserted against a biosimilar application is broader than under the comparable provisions of the Hatch-Waxman Act. While the act allows only patents claiming the drug or a method of using the drug to be listed in the Orange Book and asserted against abbreviated new drug

application (ANDA) filers, the new biosimilars law allows the reference product sponsor to identify any patent that could reasonably be asserted against the unlicensed manufacture, use, sale, offer for sale or import of the biosimilar product. This embraces patents claiming methods used to manufacture the biosimilar product. As noted above, the applicant must make a certification with respect to every patent that the reference product sponsor identifies, either stating that it will not launch the biosimilar product before the patent expires or providing a detailed statement supporting a contention that the patent is invalid, unenforceable or will not be infringed.

To provide a jurisdictional basis for an infringement suit asserting these patents, the new biosimilars law amends the patent infringement statute (35 USC §271) to create a new act of infringement based on filing an application to market the biosimilar product. This is similar to provisions in the Hatch-Waxman Act that make it an infringing act to file an ANDA if the purpose of the application is to obtain approval to market the generic drug before the expiration of a patent claiming the drug or a method of its use. However, the language used by the biosimilars law to create this new act of infringement is inconsistent with the patent identification and certification procedures set forth elsewhere in the new statute.

Tracking the language of the Hatch-Waxman Act, the new biosimilars law makes the filing of an application to market a biosimilar biological product an act of infringement of any patent identified by the reference product sponsor “if the purpose of such submission is to obtain approval...to engage in the commercial manufacture, use, or

sale of a...biological product *claimed in a patent or the use of which is claimed in a patent* before the expiration of such patent”.

The new statute therefore provides that an act of infringement occurs only if the applicant is seeking approval commercially to make, use or sell the biological product before the expiration of a patent claiming the biological product or a method of its use. However, as noted previously, the scope of the patents that the reference product sponsor can identify and for which the applicant must provide a certification is significantly broader, embracing methods used in the manufacture of the biological product. In other words, the scope of the patents that can be infringed under the new biosimilars law is narrower than the scope of the patents that are subject to the law’s patent identification and certification provisions.

There is no immediately apparent explanation for this discrepancy. Limiting infringement claims to patents claiming the drug or a method of using the drug is logical in the context of the Hatch-Waxman Act because it is only patents claiming the drug or methods of using the drug that must be listed in the Orange Book and for which ANDA filers must provide certifications of non-infringement, invalidity or unenforceability. However, such a limitation on the types of patent that can be infringed is difficult to justify in the context of the new biosimilars law, which lacks an equivalent to the Orange Book and has identification and certification provisions that embrace a significantly broader class of patents.

### **Resolving the discrepancy**

The simplest way to resolve the discrepancy between the patent certification and patent infringement provisions of the new biosimilars

---

law would have been to amend them prior to final passage to make those provisions consistent with each other – for example, by changing the language to be added to 35 USC §271 to provide that infringement occurs if the applicant intends commercially to make, use or sell the biosimilar product before the expiration of any of the patents that the reference product sponsor has identified pursuant to the law’s patent identification provisions. One of the authors of this chapter proposed such a correction in letters to the bill’s sponsors in Congress.

In the absence of a subsequent amendment to the legislation, it will be up to the courts to resolve this discrepancy. A literal reading of the language in its current form would allow infringement suits based on patents claiming the process of making the biosimilar product only if the reference product sponsor owned another patent that claimed the biological product itself or a method of using the product. Such a construction would be consistent with the letter of the statutory text, but it is doubtful that this is the result that Congress intended. Congress was aware that process patents are of special importance in the biotechnology field – more so than in the context of small molecule drugs – and most probably intended that they could be asserted in their own right, regardless of whether the reference product sponsor happened to own a different patent claiming the biological product itself or a method of using it.

### Conclusion

Regardless of how the discrepancy between the patent certification and the patent infringement provisions of the new biosimilars law is resolved, the biotechnology industry will soon have to adjust to a new regulatory framework that differs fundamentally from that governing generic versions of small molecule drugs. The lack of an official listing of patents comparable to the Orange Book and the lack of an automatic stay of the biosimilar application’s approval upon the filing of an infringement suit are just some of the more significant differences. **iam**

*The views expressed are those of the authors and do not necessarily reflect the views of Cadwalader, Wickersham & Taft or its clients.*

## CADWALADER

**Cadwalader, Wickersham & Taft LLP**  
One World Financial Center  
New York, NY 10281  
United States

T +1 212 993 2902  
F +1 212 504 6666  
E [cwinfo@cwt.com](mailto:cwinfo@cwt.com)  
[www.cadwalader.com](http://www.cadwalader.com)