

essential action

Access to Medicines Project

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Ensuring Effective Biogenerics Legislation: Timely Patent Dispute Resolution and Patent Disclosure

Providing timely access to affordable, safe and effective products should be the central purpose of U.S. legislation that introduces a regulatory pathway for the approval of generic substitutes for biologic pharmaceuticals (also known as “biotech drugs”). Provisions that extend the monopoly protection period of brand-name companies, making it unreasonably difficult to sell affordable biogenerics to patients as soon as possible after patent expiration, would defeat the purpose of the new rules.

To meet these objectives, U.S. biogenerics legislation should include provisions that encourage rapid resolution of patent disputes. Requiring brand-name companies to disclose all relevant patents is one key element to ensure potential generic competitors have sufficient information to make an informed assessment of the potential barriers to competition. Several of the biogenerics proposals under consideration by Congress do not require such disclosure as part of the proposed patent dispute resolution system, or do not contain any provisions governing patent dispute resolution related to biogenerics. Essential Action recommends that biogenerics legislation should incorporate the four principles outlined below.

1. Patent Disclosure Should Be Mandatory

The patent system is premised on public disclosure. Not only is the basic fact of a patent claim supposed to be public knowledge, but the very provision of a patent is supposed to embody a trade-off whereby the means to make the underlying invention is publicized in exchange for grant of the patent monopoly. Moreover, to perform their property-delineating function effectively, patents must provide effective notice to the public and potential industry competitors.

Given the essential public component and notice functions of the patent system, there is no legitimate public policy rationale in patent claims on medicines being treated as proprietary or subjected to industry gamesmanship.

Routine patent disclosure should therefore be the norm for medicines. For conventional drugs registered under the Food, Drug and Cosmetic Act, this routine disclosure is achieved through Orange Book listings. This is a problematic approach because of the patent linkage system associated with the Orange Book, but it does at least achieve the disclosure objective. We believe a sound public policy approach would require disclosure of claimed patents as a condition of enforcement, and believe this regime should be adopted for biologics registered under the Public Health Service Act.

Thus, initial registrants should be required at the time of application to indicate any granted or filed patents that they believe apply to the biologic for which they seek marketing approval. This should include both patents granted to the registrant or which have been licensed to them. They should be required to update this list for any new patent filings, within a statutorily defined period, perhaps 30 days. Failure to disclose should forfeit the right to enforce.

2. The Patent Resolution Process Should Be Available at Any Point After Initial Registration

Given the centrality of patents to pharmaceutical manufacture, and the considerable up-front costs of undertaking tests to determine generic substitutability (or comparability, or therapeutic equivalence, or similarity), it is often impractical for generic manufacturers to introduce a product onto the market without ascertaining that they can do so without infringing the patents held or licensed by the registrant of the reference product. For biologics, the expected greater cost of achieving and demonstrating substitutability, comparability, equivalence, or similarity will likely deter in many cases pre-marketing investments unless there is certainty about the patent landscape. It is thus vital that there be a system for pre-marketing resolution of the validity and applicability of reference product patents to a subsequent generic or similar product.

The objective of such a system should be to clear patent claims so that a) invalid patents do not delay investment in, or introduction of, generic or similar products; b) non-applicable patents do not delay investment in, or introduction of, generic or similar products; and c) all potential patent claims are resolved in advance of any applicable marketing exclusivities.

The originators have a legitimate interest in protecting and enforcing their patents. They do not have a legitimate interest in enforcing invalid patents, however, or delaying second entrant entry by brandishing patents that do not apply to the second entrant's product.

Delays in starting the process of pre-marketing patent resolution serve only to enable invalid or non-applicable patents to delay second entrant investment or marketing. If a pre-marketing patent resolution process leads to a finding that a patent is valid and/or applicable to a second entrant, then the originator will be able to obtain full protection for that patent, no matter when the process is originated.

We thus believe that potential second entrants should be free to initiate patent resolution processes at any point following approval of an originator product.

With such a system, there may be cases in which a second entrant initiating a patent resolution process does so before developing its process to make its version of the reference product. In such a case, it might not be able to obtain clarity on process patents. This would be a risk borne by the second entrant. It would retain the right to initiate a patent resolution process for potentially applicable process patents at a later date.

3. The Second Entrant Should Not Be Required to Share Confidential Information During the Administrative Process

Some legislative proposals for early patent resolution require the second entrant to share confidential information with the maker of the reference product. Statutory promises of protection notwithstanding, it is hard to imagine such information remaining confidential and not being shared with scientists employed by the originator company. Such a requirement to share confidential information is notably discordant with the confidentiality protections afforded to originators.

Second entrants should not be required to share confidential information with reference product makers, at least until a court proceeding is underway.

This problem can be avoided by placing responsibility for initiating a patent resolution process on to the second entrant. If the second entrant identifies claimed patents that it believes to be invalid or not

to cover its product, then those disputes can be litigated or resolved through an appropriate process, without any pre-screening of second entrant confidential information by the originator.

The originator company would reserve the right to enforce at a later date any patent not addressed through the pre-marketing patent resolution process.

4. Second Entrants Should Have the Right to Opt Out of the Early Patent Resolution System

Second entrants should reserve the right to bypass the early patent resolution system. It is especially important to preserve this right if the early patent resolution system requires the second entrant to share confidential information.

There is no diminution of the patent holders' rights if a second entrant chooses to bypass a pre-marketing patent resolution process.

Because there are significant business risks in doing so, it is unlikely that most second entrants would exercise this option. But it should remain open. It may be the preferred choice for second entrants in particular cases, or because the pre-marketing patent resolution process evolves in such a fashion as to constitute a barrier to investment and marketing.

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