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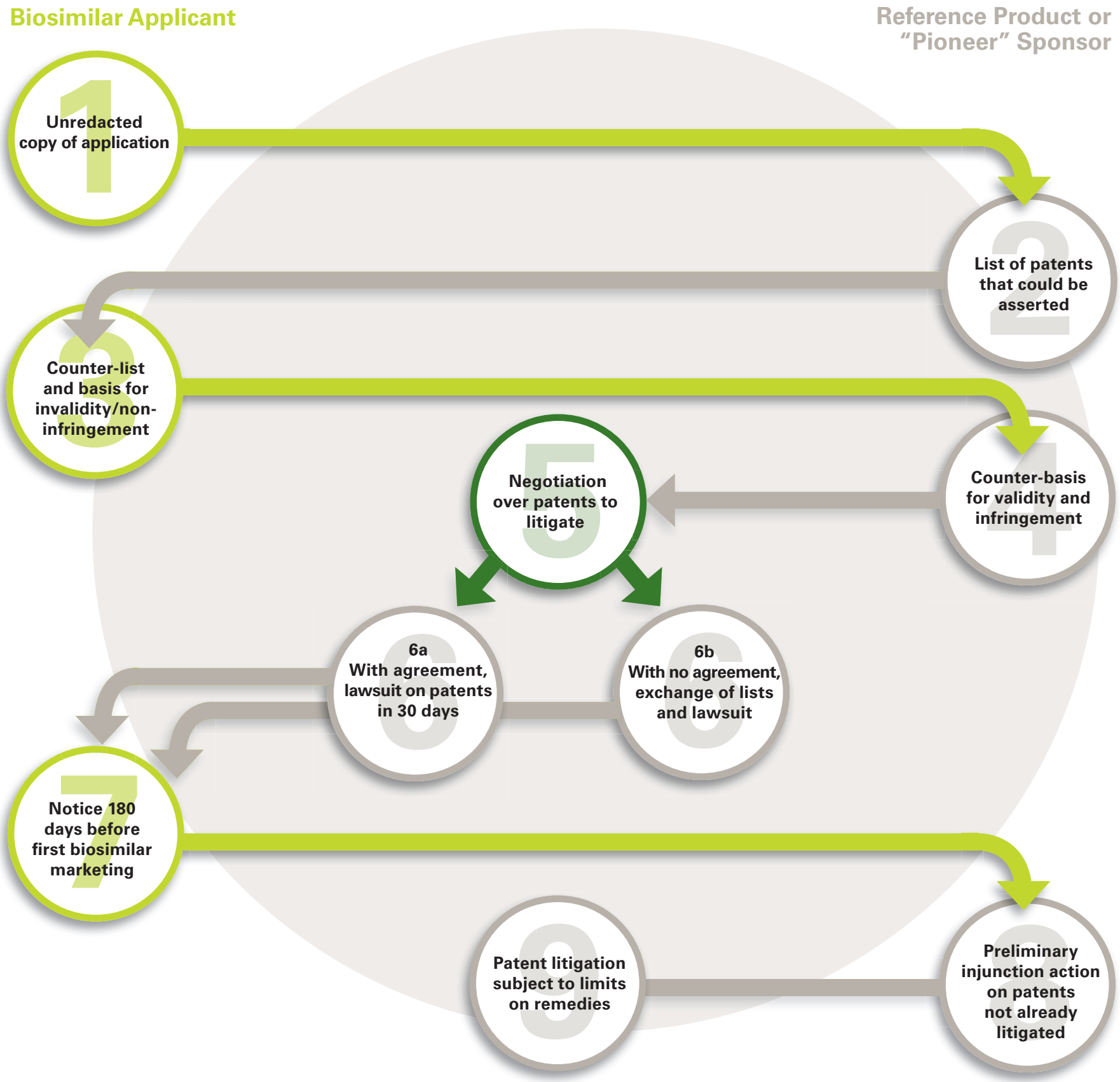
Patent Exchange and Litigation Provisions

The following graphic and explanatory notes summarize the patent exchange and litigation provisions of the Biologics Price Competition and Innovation Act, enacted on March 23, 2010 as Subtitle A, Title VII, of the Patient Protection and Affordable Care Act, Pub. L No. 111-148. The relevant provisions of the Act are to be incorporated in 42 U.S.C. § 262 and 35 U.S.C. § 271.



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1 Within 20 days of FDA filing the biosimilar application, the Biosimilar Applicant must provide the Reference Product Sponsor or "Pioneer" with an unredacted copy of the application and a description of the processes used to manufacture the product; the Biosimilar Applicant may provide other information, including that requested by the Pioneer. 42 U.S.C § 262(l)(2)

2 Within 60 days of its receipt of the application, the Pioneer must provide the Biosimilar Applicant with a list of all patents the Pioneer believes could reasonably be asserted against the Biosimilar Applicant (by the Pioneer or a patent owner who has exclusively licensed the patent). The Pioneer must also identify those patents that it would be willing to license to the Biosimilar Applicant. 42 U.S.C. § 262 (l)(3)(A)

3 Within 60 days of receipt of the Pioneer's list, the Biosimilar Applicant may provide its own list of potentially infringed patents that could be asserted by the Pioneer and shall provide for each patent either (a) a detailed, claim-by-claim statement of the factual and legal basis for its belief that the patent is invalid, not infringed, or unenforceable, or (b) a statement that it is not challenging the patent. The Biosimilar Applicant must also respond to the Pioneer's license offer. 42 U.S.C. §262 (l)(3)(B)

4 Within 60 days of its receipt of the Biosimilar Applicant's statement, the Pioneer must provide the Biosimilar Applicant with a counter detailed, claim-by-claim counter statement of the factual and legal basis for validity, enforceability, and infringement. 42 U.S.C. § 262 (l)(3)(C)

5 For up to 15 days, the parties shall negotiate in good faith to develop a list of patents to be litigated immediately based on the set or sets of patents identified in [2] and [3] above. 42 U.S.C. §262 (l)(4)(A)

6 **6a.** If the parties agree on a list, the Pioneer shall bring an infringement suit on each patent on the negotiated list within 30 days. 42 U.S.C. §262 (l)(6)(A)

6b.1 If the parties fail to agree on a list, the Biosimilar Applicant shall provide the Pioneer with the number of patents that it will provide to the Pioneer, per the process outlined below. 42 U.S.C. §262 (l)(4)(B), (5)(A)

6b.2 Within five days, both parties shall simultaneously exchange lists of patents that they believe should be litigated immediately; the Pioneer cannot exceed the number of patents provided by the Biosimilar Applicant. If the Biosimilar Applicant provided zero as the number of patents to be litigated, the Pioneer may list one patent. 42 U.S.C. §262 (l)(5)(B)

6b.3 The Pioneer shall bring an infringement suit on each patent on both lists (i.e., up to twice the number provided by the Biosimilar Applicant) within 30 days. (42 U.S.C. §262 (l)(6)(B))

7 No later than 180 days before the first commercial marketing of the Biosimilar Applicant's product, the Biosimilar Applicant shall provide the Pioneer with notice. (42 U.S.C. §262 (l)(8)(A))

8 After the 180-day notice but before any marketing, the Pioneer may initiate preliminary injunction proceedings on any patent identified in the lists described in [2] or [3] above, but not [5] or [6B.2] (i.e., not those which have been litigated earlier). 42 U.S.C. §262 (l)(8)(B)

9 The Pioneer or patent owner may seek injunctive relief against infringement (not against FDA approval) until expiration of a patent. Damages are available if there has been actual (not only artificial) infringement of the patent. A permanent injunction is available after a court of appeals decision. If the patent is on the negotiated [5] or exchanged lists [6B.2], and a suit is brought after 30 days or is not litigated to judgment, then only a reasonable royalty is available. If a patent is not timely on the initial list [2], then there is no cause of action until after FDA approval of the product. 35 U.S.C. § 271(e)(2), (4), and (6)

Confidentiality Provisions (42 U.S.C. § 262 (l)(1))
Recipients of the biosimilar application shall include:

- One or more outside counsel and one inside counsel; no one can be involved formally or informally in patent prosecution related to the reference product.
- One representative of an "exclusively licensed" patent owner, if the representative agrees to maintain confidentiality.

The application and other information may be used for the sole purpose of determining whether a claim of infringement may be asserted. No disclosure is allowed to anyone else without prior written consent of the Applicant, which shall not be not unreasonably withheld. This information also may not be included in public pleadings. Confidentiality shall remain in effect until a protective order is put in place and, if no lawsuit is filed, the information must be returned and destroyed.

Patent List Supplements (42 U.S.C. § 262 (l)(7))
If a new patent is issued or exclusively licensed to the Sponsor after provision of the initial list [2], and the Sponsor reasonably believes that a claim of infringement could be asserted (by it), the Sponsor may supplement the list within 30 days of issuance or license. The Applicant must provide the Sponsor with an updated factual and legal basis statement [3] within 30 days of receiving such a supplement.

Limits on Declaratory Judgment (DJ) Actions (42 U.S.C. § 262 (l)(9))
If the Applicant provides its application [1], there may be no DJs by either the Applicant or Sponsor until after the 180-day notice [7] on any patent that was on the initial lists [2] or [3], but not on [5] or [6B.2]. If the Applicant fails to provide its application, the Sponsor may bring a DJ on any patent that claims the product or a use of the product. If the Applicant fails to provide the factual and legal basis statement [3], the number of patents [6B.1], the exchanged list [6B.2, or the 180-day notice [7], or fails to notify FDA of any complaint, the Sponsor may bring a DJ on any patent on the initial list [2].

Limits on Remedies (35 U.S.C. § 271(e)(2), (4), and (6))
The law provides for injunctive relief against infringement (not against FDA approval) until expiration of a patent. Damages are only available if there has been actual (not only artificial) infringement of the patent. A permanent injunction is available only after a court of appeals decision. If the patent is on the negotiated [5] or exchanged lists [6B.2], and a suit is brought after 30 days or is not litigated to judgment, then only a reasonable royalty is available. If a patent is not timely on the initial list [2], then there is no cause of action until after FDA approval of the product.

For more information, please contact one of the following Hogan Lovells lawyers:

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