



8 October 2012

Compulsory Licensing of Patents Inquiry
Productivity Commission
Locked Bag 2, Collins St. East
MELBOURNE, VIC 8003

Re: *Comments on Issues Paper on the Compulsory Licensing of Patents*
Submitted via Electronic Mail to patent@pc.gov.au

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to submit comments and provide the views of its members with respect to the subject of compulsory licensing of patents. BIO believes that the Commission's invitation for comments represents a constructive effort on the part of the Australian Government to prepare a thoughtful and comprehensive report on the subject. We also appreciate the time and effort the Productivity Commission has committed to studying the intersection of compulsory licensing and public health.

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations globally. BIO's members are involved in the research and development of innovative health care and agricultural and environmental biotechnology products, thereby expanding the boundaries of science by providing better medicines, enhanced agriculture, and a cleaner and healthier environment.

BIO's member companies are committed to serving the Australian market and have a strong interest in the protection and enforcement of intellectual property rights. Robust intellectual property protection is critically important to fostering the development and commercialization of new biotechnologies. Compulsory licensing not only threatens valuable patent rights, but dampens the motivation to bring new and innovative technologies to the market to treat patients, aid farmers, and promote environmental sustainability. For these reasons, BIO believes that compulsory licensing laws must be carefully scrutinized and narrowly crafted so as to minimize the potentially negative effects on innovation.



BIO and its member companies recognize the merits of modern free trade agreements, like the Australia-United States Free Trade Agreement (AUSFTA), which build on the TRIPS Agreement by clarifying and updating intellectual property standards to reflect current commercial realities. BIO has long supported the AUSFTA, as well as other trade agreements, which provide an enhanced framework of commitments for protecting biotechnological innovations. Thus, BIO has a strong interest in ensuring that these trade agreements are properly implemented and enforced.

The Issues Paper on *Compulsory Licensing of Patents* recognizes Australia's obligations and commitments under the AUSFTA. In the section entitled *Impact of International Agreements on Australia*, the Productivity Commission accurately identifies a potential inconsistency between the AUSFTA and the reasonable requirements of the public interest test in Australia's Patent Act. The Commission further infers that the "AUSFTA could be interpreted as not including the public interest as a ground for compulsory licensing." (Page 19 of Issues Paper.)

BIO shares the concern expressed in the Issues Paper that the current compulsory licensing provisions in the Patents Act are not consistent with Australia's obligations under the AUSFTA. The AUSFTA provides narrowly defined grounds for when a party to the agreement may grant a compulsory license. Specifically, Section 17.9(7) of the agreement limits the use of a patented invention without the consent of the patentee to the following circumstances: (a) remedying a practice determined to be anti-competitive under either Party's law relating to the prevention of anti-competitive practices; or (b) in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency. Section 17.9(7)(b)(i) further requires that any use under 17.9(7)(b) must be limited to use by the government or third persons authorized by the government.

In contrast, the *Patents Act 1990* permits the granting of compulsory patent licenses upon satisfaction of a public interest test that is overly broad and inconsistent with Australia's obligations under the AUSFTA. Fulfillment of the public interest test set forth in Section 133(2)(a) of the *Patents Act 1990* is based on a showing that the reasonable requirements of the public with respect to the patented invention have not been satisfied. However, there is no corresponding requirement that the use of the patented technology under the compulsory license be limited to public non-commercial use. Nor is there a limitation to the existence of a national emergency or other circumstance of extreme urgency. Moreover, the *Patents Act 1990* does not contain language specifying that any use under the "public interest" umbrella be limited to use by or on behalf of the government. Without these important safeguards,



compulsory licenses may be granted in Australia on a broader basis than permitted by the AUSFTA. For these reasons, Australia's public interest test alone is not a sufficient basis for issuing a compulsory license under the AUSFTA.

It bears emphasis that the compulsory licensing provisions of the AUSFTA reflect a measured approach to the use of compulsory licensing so as to protect against overly broad licenses. Granting compulsory licenses for reasons that extend beyond the circumstances recited in Section 19.9(7) of the AUSFTA would have grave implications. Because compulsory licenses result in a curtailment of patent rights and unpredictably undermine innovators' investment-backed expectations, they jeopardize the research, development, and commercialization of new and innovative biotechnologies. Thus, BIO underscores the importance of complying with the narrowly defined set of circumstances for issuing compulsory patent licenses under the AUSFTA.

In conclusion, BIO respects and understands the rights of a country, under clearly defined circumstances, to issue compulsory licenses. Providing strong and effective intellectual protection for biotechnological innovation is a central focus for BIO and its members. The AUSFTA preserves the incentives for the development and commercialization of new biotechnological products. With this goal in mind, we encourage Australia to consider ways to address its health challenges, while maintaining the standards for intellectual property protection set forth in AUSFTA that promote investment, research, and innovation of new cures and treatments for patients suffering with unmet medical needs.

Respectfully submitted,

Joseph M. Damond
Senior Vice President, International Affairs