THE NON-DISCRIMINATORY NATURE OF INDIA’S NATIONAL PHARMACEUTICAL PRICING POLICY

Clarification in Response to the Testimony of Ms. Linda Dempsey, House Energy and Commerce Committee Hearing on India’s Industrial Policy

On June 27, 2013, Ms. Linda Menghetti Dempsey (Vice President of International Economic Affairs, National Association of Manufacturers) said the following with regard to the Indian government’s new National Pharmaceutical Pricing Policy 2012:

“India imposes price caps on hundreds of medications. However, those caps do not apply to drugs Indian researchers develop.”

Patented drugs, including those exported from the U.S., are not subject to the price ceilings. India’s price ceilings will primarily impact local manufacturers of generic medicines.

The new pharmaceutical pricing policy, which replaces the Drugs (Price Control) Order 1995, establishes a price ceiling formula to be applied to generic drugs included in the National List of Essential Medicines, regardless of where they were developed (although the vast majority are locally manufactured). Other generic medicines are not subject to the price ceiling formula, but are limited to price increases of 10% per year (§4(xiv)).

The policy categorically excludes patented medicines from these price caps. Patented medicines exported from the U.S. to India are not subject to price ceilings imposed by the new policy. It is possible that patented medicines may, in the future, be subject to a system of reference pricing in accordance with the recommendations of the Committee on Price Negotiation for Patented Drugs (§4(xv)), which were recently open for public comments.1 Because the Committee’s report was issued six years after the Committee was formed, commentators remain quite uncertain whether the Indian government will adopt the Committee’s recommendations.

The new policy also states that Indian drug manufacturers may request a five-year exemption from price controls for newly approved drugs developed with Indian investments and produced only in India (§4(xvi)). Notably, BIO explicitly supported an exemption for medicines developed and exclusively introduced in India from the pricing policy in its public comment submission to the Committee’s report.2

A comprehensive consideration of India’s rules affecting pharmaceuticals should acknowledge that India’s new pricing policy primarily impacts generic medicines, as it explicitly excludes patented medicines from its pre-determined price controls.

For more information on India’s IP policies, please see Public Citizen’s submission to the hearing.

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1 Section 4(xv) Patented Drugs: There is a separate Committee constituted by the Government order dated 1st February, 2007 for finalizing the pricing of Patented Drugs, and decisions on pricing of patented drugs would be taken based on the recommendations of the Committee.

2 “For medicines developed and introduced in India first (p. 32), BIO recommends that no price negotiation or controls be placed on these medicines by the Indian government whatsoever. This is to encourage, not discourage, the discovery of medicines primarily for the benefit of the Indian people. As noted before, placing limits on the returns of Indian biopharmaceutical companies will undoubtedly dissuade some investigators from pursuing promising discoveries” (pp.5-6).