

'Compulsory licensing of innovative products generally isn't effective means for promoting affordable health'

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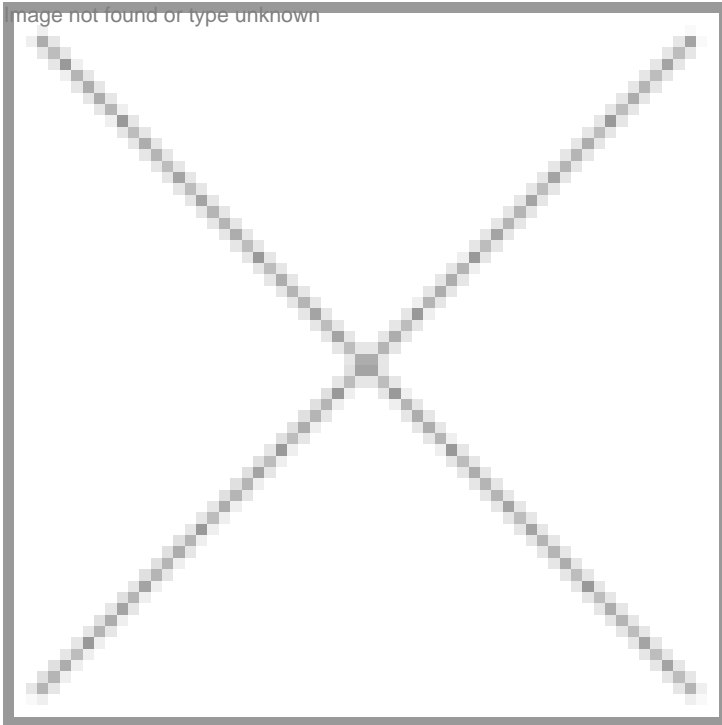


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James C Greenwood

president & CEO, Biotechnology Industry Organization (BIO),
USA

India, an emerging destination for outsourcing and contract manufacturing has been attracting big pharma firms in the last few years. Taking this opportunity, Biotechnology Industry Organization (BIO), the world's largest biotechnology trade association, headquartered in Washington, providing advocacy, business development, and communications services for more than 1,100 members worldwide offered a platform for global companies from North America, Europe and Asia to meet and explore business opportunities with India's emerging biotech sector since 2010. In an email interview with *BioSpectrum*, Greenwood, president and CEO, BIO, USA talks about how he views India's biotech industry.

Q What changes do you foresee in the Indian biotech industry with the release of the guidelines for Similar Biologics? Do you think such a policy document will have a major impact on the biotech industry in India?

Greenwood: BIO considers the issuance of India's guidelines on biosimilars as a step in the right direction. The guidelines recognize the scientific and regulatory complexities presented by the development and

manufacture of biologics medicines.

BIO hopes that these guidelines will be implemented in a manner that continues to protect patient safety, and that India will further include adequate protections for innovators to ensure continued research and development of new cures and treatments.

Q With a host of regulatory issues plaguing the Indian biotech industry, where do you think India stands, as compared to other countries in terms of progress in biotechnology?

Greenwood: In the Scientific American Worldview report, India was among the countries recently named as likely to have the strongest gains in developing next generation life-saving products in the coming decade. Due to the colossal increase in capital, a well-educated population, and India's established and existing biotech and pharmaceutical companies, research will move progressively towards India, especially as the demand for improved healthcare increases.

Q The compulsory licensing of Nexavar has been hailed by other South Asian countries as well as key policy makers around the world as a progressive step. However it has come under criticism from the US government. Your inputs? And what impact do you think such a move can have on big pharma?

Greenwood: BIO does not believe that the compulsory licensing of innovative products or technology generally is an effective means of promoting access or affordability of healthcare. Moreover, it undermines incentives for companies and individuals to innovate in India, since it creates uncertainty about receiving economic returns for their innovations. Indiscriminate use of compulsory licenses would thus jeopardize India's goal of developing a research oriented biotechnology industry, and is a unsound policy.

It is also important to remember that this move does not just impact big pharma. Compulsory licenses affect the entire innovative biotechnology ecosystem jeopardizing government and private investment funding for small and medium sized biotechnology companies everywhere.

Finally, the decision impacts patients around the world who need access to new treatments and cures that are yet to be developed. BIO believes there is much more than profit at stake.

What are the major objectives that you hope to achieve through BIO India 2012?

Q **Greenwood:** As a non-profit trade association that represents the biotech industry, BIO is pleased to bring the BIO India International Conference back to India in an effort to further create and drive business development and collaborations between the US and Indian industry in all areas relating to biotechnology.

To help facilitate this collaboration BIO looks at a variety of factors including research and development (R&D) potential, protections for biotechnology innovations and regulatory mechanisms. In terms of R&D potential, BIO along with the Association of Biotechnology Led Enterprises (ABLE), have co-hosted the BIO India International Partnering Conference. The conference, held in Mumbai brought together the global business and thought leaders in the area of biotech for partnering.

Q A large part of the Indian biotech industry comprises of small and medium sized emerging enterprises. What can they look forward to, from an event such as BIO?

Little: BIO India brings together biotech and pharmaceutical leaders from the US, Europe and Asia to explore potential partnerships and collaborations with India's life science companies. Event attendees will have the opportunity to connect with potential partners of their choice through BIO's one-on-one partnering system to hold 30-minute meetings in private rooms provided by BIO onsite at the conference.

BIO's industry-specific, web-based interactive software enables participants to prepare prior to the conference by using search criteria to identify potential partners, reviewing profiles of those attending companies and sending select companies personalized meeting requests. Over 1250 of these one-on-one partnering meetings have been held in the past at BIO India.

These small and medium-sized emerging companies may also opt to take center stage to present their programs and gain visibility by giving a company presentation to an audience of interested attendees.

What do you think will differentiate BIO India from other industry events?

Q **Little:** BIO India is a platform for various overseas companies to interact and tap business opportunities with India's emerging biotech sector. BIO brings to India more than 10 years of

experience and expertise in biotech and pharmaceutical partnering. It is renowned for its successful partnering meetings around the globe, including the biotech world's largest partnering event, the Business Forum, at the BIO International Convention.

The event offers high-level keynote speakers, educational India-focused panels, networking opportunities, company presentations, and the BIO one-on-one partnering system. Through this conference and ongoing advocacy efforts, BIO aims to help the industry flourish within India's borders and help patients and citizens benefit from the promise of biotech.

Manasi Vaidya