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India, EU resolve dispute on generic drugs

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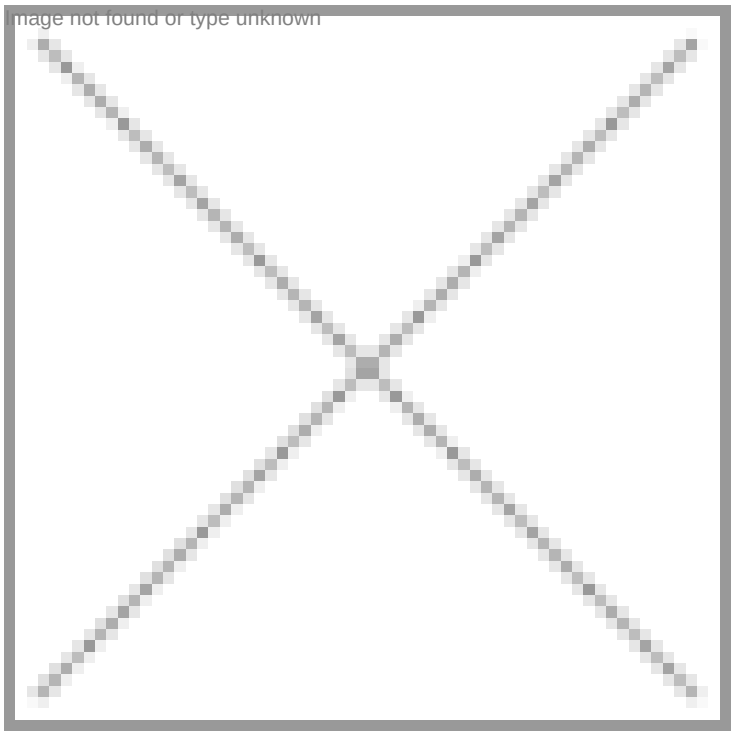

The dispute triggered by the repeated instances of seizure of Indian generic drugs that are destined for export to Latin American and other countries at European Union (EU) ports, has been resolved. According to a statement by Ministry of Commerce on July 28, 2011, India initiated dispute settlement consultations on May 11, 2010, at the World Trade Organization with the EU on the issue of detention of Indian generic medicines while in transit through the EU.

The custom authorities at EU ports had made detentions of the generic medicine consignments under the ECs Regulation 1383/2003, which contains customs procedures for taking action against goods suspected of infringing intellectual property rights. These detentions were in violation of the obligations of the EU and the Netherlands under Article V of GATT that enshrines freedom of transit of goods through the territory of each contracting party of GATT via the routes most convenient for international transit, said the statement, adding that they were also inconsistent with the EU and its member states obligations under Articles 41 and 42 of the TRIPS Agreement.

Brazil also filed a similar complaint against the EU before the Dispute Settlement Body of the WTO. India and Brazil jointly held two rounds of consultations with the EU in Geneva and EU acknowledged that some provisions of the EC Regulation 1383 were misinterpreted while detaining the Indian generic drugs. Thereafter, India engaged in extensive consultations with the EU with the assistance of legal experts. India and EU reached an understanding which, inter-alia, contains the principles to guide border enforcement of intellectual property in the EU.

Approval to market Nyloxin in India

Nutra Pharma, a biotechnology company developing treatments for multiple sclerosis (MS), human immunodeficiency virus (HIV), adrenomyeloneuropathy (AMN) and pain, has received approval in India for its Nyloxin line of pain relievers. Following the approval, Nutra Pharma accepted orders for the products through their distributor, Nutritional Alliance, for export to India-

based importers.

â€œThe India approval is our first regulatory authorization overseas and represents one of the more significant international market opportunities for Nyloxin,â€? said Mr Rik J Deitsch, chairman and CEO of Nutra Pharma Corporation. â€œWith the population of India exceeding a billion people and with limited patient access to opioid-based pain relievers throughout the country, India represents a potentially significant customer base for Nyloxin.â€?

â€œWe were honored that Nutra Pharma partnered with us on their distribution and growth of Nyloxin,â€? said Mr Jim Airaghi, founder and president of Nutritional Alliance. â€œWe have already been working diligently with domestic and international distributors. The registration in India represents the first step in our global marketing plan that we believe will make Nyloxin one of the most exciting healthcare products of 2011.â€?

Nyloxin is an over-the-counter pain reliever clinically proven to treat moderate to severe (stage II) chronic pain.

US FDA approval for Acarbose tablets

Strides Arcolab has received US FDA approval for Acarbose tablets (25 mg, 50 mg and 100 mg). Acarbose is a niche anti-diabetic drug used to treat type 2 diabetes mellitus. According to March 2011 IMS data, the total US market for Acarbose tablets approximated to $21 million with no Indian generic players in the market.

The pharma division has a total of 37 filings with the US FDA (21 under the PEPFAR program and 16 as generics). So far,22 approvals (17 under PEPFAR and five generics) have been given. This product will be marketed and sold by Perrigo under a profit sharing partnership. It is expected to be launched in Q3 2011.

Industry call to expedite BRAI bill

To request policy makers to expedite the process of turning the Biotechnology Regulatory Authority of India (BRAI) Bill into law, farmers, scientists and industry experts came together in support of the bill at an event in New Delhi. The event was organized by the Association of Biotechnology Led Enterprises (ABLE). The participants sought the establishment of a single-window regulatory authority in biotechnology. While stressing that the time was ripe for the government to act and streamline the regulatory process in India, the group demanded that Parliament clear the BRAI and Seeds Bill. They agreed that use of new technologies in agriculture was the only hope for farmers and a solution to address the challenges of food security. The group emphasized on expeditious approvals of biotech crop trials and commercialization under the existing system until the BRAI Bill was approved.