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THE DISMAL HISTORY OF COMPULSORY LICENCES IN INDIA

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On 1st April 2016 the National Human Right Commission (NHRC) called on the Indian government to submit reports on the allegations that the Indian government had given private assurances to the US that India would adopt a stringent approach when granting compulsory licences over patented drugs.

While the Ministry of Commerce & Industry in a press report in March had denied such allegations, shortly after the NHRC Press Release Lee Pharma and BDR Pharma (the only two companies to file for compulsory licences after Natco) announced that they would not be pursuing appeals against the rejection of their compulsory licence applications by the Indian Patent Office. The Indian generic drug companies cite the government's proclivity against the granting of compulsory licences as the reason behind their decision.

While the Indian government's alleged promise to the US has definitely stirred up a hornet's nest among public health activists in the country, it is worth exploring whether the Indian government is as apathetic to the granting of compulsory licences as it appears to be.

Ever since its inception in the Patents Act in 1970 the compulsory licensing provision has remained an under-utilized provision. In the first four decades since the introduction of the Patents Act 1970, no compulsory licence application was filed in India and it was only in 2011 that Natco successfully filed a compulsory licence application over Bayer's anti-cancer drug, Nexavar.

Intellectual Property has always formed a top priority in the trade and policy discussions between India and the US, with the latter pushing for stronger IP protection in India. The Nexavar licence, which was the world's first market-initiated compulsory licence, was met with severe backlash by the United States which argued that compulsory licences can only be issued in times of public health emergencies and are restricted to certain diseases only. In 2012, the US Commerce Secretary, John Bryson, in a visit to India raised concerns over the Nexavar licence calling it a "dilution of the international patent regime".

The Nexavar licence had led to apprehensions worldwide that India would be quick to grant compulsory licences, however, the history of compulsory licensing has been fairly insipid in India, with only two applications under section 84 (market-initiated compulsory licences) filed after Nexavar. The first application pertained to Bristol-Myers Squibb's cancer drug, Dastanib, which was filed by Indian generic drug manufacturer, BDR Pharma. BDR's application was rejected at

the threshold because BDR had not made a sincere effort to procure a voluntary licence from Bristol-Myers prior to making an application under section 84 (a relevant factor for granting compulsory licence applications).

The second application was initiated by Lee Pharma Ltd. for compulsory licence over AstraZeneca's patented diabetes drug, Saxagliptin. The Saxagliptin application was rejected on the basis that the applicant had failed to provide evidence regarding any of the grounds under section 84: non-availability, non-affordability, non-working of the patented drug in India.

The number of compulsory licence applications filed in India after Nexavar has not been encouraging and it forces one to reconsider whether India has in fact been playing to the gallery as far as the US is concerned. In both the Dastanib and the Saxagliptin case, the Indian Patent Office rejected the applications due to procedural shortcomings on the part of the applicants.

In the absence of an order reflecting the ideology of the Indian Patent Office when granting (or rejecting) compulsory licence applications, it is too early in the day to conclude that such a secret arrangement between India and the United States has in fact been made.

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