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NTUI Statement

Compulsory licensing: redefining a legal space for generic drug manufacturers

The NTUI welcomes the landmark judgment by India's patent office that on 12 March 2012 granted the first compulsory license since the creation of the provision in the Patent Act in 2005. The NTUI sees this judgment as an important step in the struggle for a sustainable public health system, to which the Indian generic drug industry contributes significantly by cheapening drug prices. This judgment is a step towards strengthening and rejuvenating a weakened industry and the public health system.

The Controller of Patents granted the license to generic drug manufacturer NATCO Pharma Limited in response to an application filed under Section 84 of the Indian Patents Act, 1970. The decision means that NATCO has the right to produce and market life extending cancer medicine *sorafenib tosylate* without the consent of Bayer at nearly 3% of the price that Bayer was charging - Rs 8,800 per month instead of Rs 2.8 lakh per month - against paying Bayer a royalty of 6% on net sales. The progressive interpretation of Section 84 implicitly recognises the importance of public interest over private right over knowledge and its use for profit maximization. However, *sorafenib tosylate* still remains unaffordable for the large majority of the working class, and therefore the NTUI considers this judgment as opening the space for public policy measures on medicine pricing. This of course requires the political will for a system of universal access to affordable healthcare that includes reasonably priced medicines.

The generic drug industry is meant to contribute to reducing prices of medicines and widening their accessibility, which is necessary for a sustainable public health system and the realisation of universal access to health. Cheaper generic medicines are also necessary as a response to predatory price setting measures adopted by monopoly companies. However, the generic drug industry is facing a crisis following the legal changes required as a consequence of India 's signing of the World Trade Organisation (WTO) agreement on Trade-related aspects of intellectual property rights (TRIPS). The introduction of product patents legally rendered out of reach earlier spaces of production, including the production of New Chemical Entities (NCE). This posed additional risks to the profits of generic drug manufacturers since their activity might be deemed illegal. An expression of the crisis faced by Indian generic drug manufacturers is the new phenomenon of Indian manufacturers selling to multinational pharmaceutical companies. Rejuvenation of the generic drug industry will depend on the industry's capacity to regain a legitimate space and options for profitable ventures involving lower risks. By ruling that a generic drug manufacturer has the legitimate right to produce a generic version of a patented medicine, the judgment by the Indian Patent Office recognises that, within the Indian law, the production of generic medicines is legal and defines the framework that justifies this legality. The NTUI believes this process will contribute to reinvigorating the national generic drug industry, and welcomes this prospect.

The NTUI demands that the Government of India use the powers available to it under Section 100 of the Patent Act, to issue notifications calling for application by generic drug manufacturers for the grant of compulsory licenses by the Patent Controller on specific drugs. The NTUI believes that the development of the generic drug industry under the leadership of public sector enterprises has to contribute to a sustainable public health system. It is about time government addresses industrial policy for the pharmaceutical industry that is integrated with public health policy. Workers in the industry will play a key role in ensuring the contribution of the industry to the public health system and the integration of industrial policy and public health policy.

Ashim Roy
General Secretary

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