Biocon Limited and Anr. v. F. Hoffmann-La Roche AG and others (Case No 68 of 2016)

Decision date: 21.04.2017

Keywords: *abuse of dominant position; patents; biological drugs*

Issue: Whether Roche Group is a dominant player in the Trastuzumab market and has indulged in a series of abusive practices?

Rule: Sec. 4 of the Competition Act, 2002

The case involves the alleged abuse of dominance by Roche Group. In 1990, Roche Group developed a monoclonal antibody, which is used in the targeted therapy to treat breast cancer that over expresses the HER-2 (human epidermal growth factor receptor 2) protein. The International Non-Proprietary Name for this monoclonal antibody is Trastuzumab. This drug was exclusively sold by a subsidiary of Roche Group under the brand name HERCEPTIN, outside the USA. HERCEPTIN was introduced in India in 2002. Roche Group also obtained registration of its trademark HERCEPTIN on 23rd April, 2005 (valid up to 09th

October, 2018) and patent for its API 'Trastuzumab' on 05th April, 2007, in India. Its patent was, however, challenged by Glenmark Pharmaceuticals Limited in a post-grant opposition on 12th December, 2008. Before a decision could be reached on this opposition, the Roche Group stopped paying annuities in May, 2013 and consequently, the patent lapsed.

The informant launched biosimilar Trastuzumab under the brand names, CANMAb and HERTRAZ, respectively. The price of the 440 mg vial of Trastuzumab manufactured by the Informants is claimed to be 25% lower than HERCLON and BICELTIS and 50% lower than HERCEPTIN. It is alleged by the Informants that Roche Group, with the intention of preventing the entry of new players in its market of 'Trastuzumab', started indulging into

frivolous litigations against the Informants and writing frivolous communications to various authorities thereby attempting to impede the entry of the Informants. The Informants have claimed that Roche Group is a dominant player in the Trastuzumab market and has indulged in a series of abusive practices to evade entry of the Informants' products and/or to hamper their growth.

The Commission considered the relevant market to be the market for a biological drug and its bio-similars. Hence, in the present case, the relevant market was held as the "*market for biological drugs based on Trastuzumab, including its biosimilars in India*."

With regards to dominance, the Commission decided that Roche Group enjoyed a market share of 70.9% in terms of value and 61% in terms of volume of sales, which didn't reduce substantially despite the introduction of cheaper bio-similar products; and a first-mover advantage in the industry. This shows a dependence of consumers on the product and an absence of countervailing market power. Further, the market was characterised by high entry barriers. All these factors led the Commission to conclude *prima facie* that Roche Group enjoyed a dominant position in the relevant market.

The Commission then observed that Roche Group left no stone unturned to evade their entry and/or penetration in the relevant market. Various strategies were adopted by Roche Group to influence regulatory and other authorities in its favour. When they were not successful in evading entry, Roche Group approached doctors, hospitals, tender authorities, *etc.,* to influence their perception about the efficacy and safety of the Informants' products. Thus,

the practices adopted by Roche Group to create an impression about the propriety of the approvals granted, the safety and efficacy of biosimilars, the risk associated and the outcome of the on-going court proceedings in the medical fraternity, including doctors, hospitals, tender authorities, institutes *etc.*, when seen collectively, *prima facie* appear to be aimed at adversely affecting the penetration of biosimilars in the market.

Based on the foregoing analysis, the Commission was of the considered view that *prima facie,* the contravention with regard to Section 4(2)(c) of the Act was made out against Roche Group, which warranted detailed investigation into the matter. It thus directed the DG to carry out a detailed investigation into the matter, in terms of Section 26(1) of the Act, and submit a report to the Commission.