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NEWSALERT

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ABUSE OF DOMINANT POSITION: INQUIRY ORDERED AGAINST ROCHE

1. INTRODUCTION

The Competition Commission of India (the "**CCI**"), in the matter of Biocon Limited ("**Biocon**"), Mylan Pharmaceuticals ("**Mylan**"), F. Hoffman La-Roche AG, Genetech Inc and Roche Products (India) Private Limited (collectively the "**Roche Group**") (the "**CCI Order**")[1] has held the Roche Group to be *prima facie* in contravention of section 4(2)(c) of the Competition Act, 2002 (the "**Act**").

2. BACKGROUND

2.1. The Roche Group had developed an antibody called Trastuzumab for treating breast cancer caused due to human epidermal growth factor receptor 2 (HER-2) protein, for which it had registered a patent in 2007. This patent was challenged in a post-grant opposition and subsequently lapsed in 2013 before a decision could be reached in the matter. In the Indian market, Trastuzumab was introduced by the Roche Group under the brand name, HERCEPTIN, which was then withdrawn and replaced by two low cost versions of the same drug under the brand names, BICELTIS and HERCLON (collectively the "**Roche Drugs**").

2.2. In the year 2008, Biocon and Mylan together initiated the development of bio-similar drugs for Trastuzumab in joint collaboration. A manufacturing license was granted for this purpose by the Drugs Control Department at Karnataka in 2013 and the launch of the bio-similar Trastuzumab was announced in 2014 under the brand names CANMAb and HERTRAZ (collectively the "**Biosimilar Drugs**"). The Biosimilar Drugs were available at prices significantly lower than Trastuzumab drugs manufactured by the Roche Group.

2.3. Subsequently, the Roche Group filed a civil suit[2] against Biocon and Mylan asking for an injunction restraining Mylan and Biocon from launching and selling their respective drugs in the Indian market by ascribing biosimilarity with and relying on any data relating to the Roche Drugs. A single judge of the Delhi High Court passed an interim order on April 25, 2016 allowing Mylan and Biocon to manufacture, market and advertise the Biosimilar Drugs. However, Biocon and Mylan were restrained from claiming or ascribing biosimilarity with the Roche Drugs (the "**Impugned Order**"). On an appeal by Biocon and Mylan, a division bench of the Delhi High Court passed an order on April 28, 2016 staying the Impugned Order till the next hearing (the "**Division Bench Order**").

2.4. Since 2013, the Roche Group had written letters to various authorities including the Drugs Controller General of India, the National Pharmaceutical Pricing Authority, the State Drugs Controller and the Ministry of Health and Family Welfare raising concerns regarding the clinical trials undertaken by Biocon and Mylan on the Biosimilar Drugs and trying to create a perception that the usage of the Biosimilar Drugs may pose potential harms to patients. After the Division Bench order,

[1] Case no. 68 of 2016

[2] C.S. (O.S) No. 355 of 2014

the Roche Group communicated the Impugned Order to various doctors and authorities *without* disclosing the Division Bench Order, thereby creating an impression that the use of the Biosimilar Drugs may be prohibited.

2.5 Biocon and Mylan approached the CCI alleging abuse of dominant position against the Roche Group on the following grounds: (i) the prevention of penetration of biosimilars in the relevant market by misinforming doctors and hospitals about the pending civil suit and denigrating the Biosimilar Drugs by citing health and safety concerns; (ii) writing letters to various hospitals, government agencies and other regulatory authorities which resulted in the denial of market access to Biocon and Mylan and also in influencing tender conditions in favour of the Roche Group; and (iii) resorting to vexatious litigation against Biocon, Mylan and other competitors with the intention of preventing the launch or market penetration of the approved biosimilars of Trastuzumab.

3. KEY HIGHLIGHTS OF THE CCI ORDER

3.1 The CCI observed that Roche was a dominant player in the relevant market for '*biological drugs based on Trastuzumab, including its biosimilars in India*', owing to not only the market share held by the Roche Group in the relevant market, but also the size of the resources of the Roche Group, the dependence of consumers on the Roche Drugs due to the first mover advantage available to it, the absence of countervailing buying power and high entry barriers in the relevant market.

In this context, the CCI paid close attention to the conduct of the Roche Group in sending letters to various doctors, hospitals and authorities, wherein the Roche Group disclosed only the Impugned Order to persons who constitute relevant distribution channels for the drugs, raising doubts regarding the safety of the Biosimilar Drugs in their minds.
Based on such analysis, the CCI, in its *prima facie* opinion, held that the Roche Group was in contravention of section 4(2)(c) of the Act and directed the Director General to carry out a detailed investigation into the matter and to submit a report to the CCI within 60 (sixty) days.

3.2 The CCI also laid down important principals while analyzing the abuse of dominant position by the Roche Group, which we summarize below.

(a) Relevant Market

The CCI held that while the Act provides the definition of '*relevant market*', delineation of the relevant market cannot be done without looking into the peculiarities of the particular sector under consideration. It was observed that in the pharmaceutical sector, the ultimate consumer (the patient) is dependent upon the doctor for a prescription and the consumption of medicine.

Hence, price sensitivity is limited in this sector. Therefore, the *intended use* of a drug gains more relevance, which, for the purposes of substitutability in this sector, is governed by its 'quality', 'safety' and 'efficacy'. On the basis of this test, the CCI delineated *drugs based on Trastuzumab and its biosimilars in India* as the relevant market in the current case.

(b) Parameters for establishing Abuse of Dominance

In the pharmaceutical sector, apart from pricing strategies, the CCI observed that firms also participate in non-price strategies to unlawfully raise their rivals' costs or exclude them from the market. Some of these practices which have gained a reasonable degree of acceptance by other competition authorities as being abusive when adopted by dominant entities are as follows:

(i) Rendering rivals' products incompatible without adding any technical improvement to the replaced product;

(ii) Indulging in vexatious litigation purely aimed at harassing rivals;

(iii) Influencing government or regulatory procedures; and

(iv) Impeding entry of generics/biosimilars by denigrating or disparaging rivals' products.

(c) Vexatious Litigation

The CCI observed that the right to bring civil litigation and other claims to assert or defend key interests is a legal right and the mere fact that litigation was unsuccessful does not render it vexatious. It laid down that in exceptional cases, vexatious litigation may be used as a tactic by a dominant player for preventing entry of other players in the relevant market and though there cannot be any straightjacket formula for identifying such cases, the following two guiding principles may be relied upon to examine the case:

(i) It must be established that the impugned legal action, on an objective view is baseless and appears to be an instrument to harass the defendant or respondent; and

(ii) The legal action appears to be conceived with an anti-competitive intent or a plan to eliminate competition.

(d) Denial of market access

The CCI held that the denial of market access within the meaning of section 4(2)(c) of the Act, need not be complete and absolute in nature. Even a partial denial of market access that takes away the freedom of a substitute to compete effectively and on merits in the relevant market, may amount to a contravention under section 4(2)(c) of the Act.

Further, the CCI placed importance on the sensitivity of the pharmaceutical sector wherein safety of the patient takes paramount importance. The CCI emphasized that any act of a party that creates a doubt in the mind of a doctor can adversely affect the market for biosimilars in an irreparable manner. Such disparagement may also have ripple effects within the medical community. Such denigration by a dominant player can oust such players from the market which do not have strong marketing channels amongst the doctors.

(e) Responsibility of the Dominant Player

The CCI observed that a dominant player is endowed with a special responsibility not to allow its conduct to impair undistorted competition in the relevant market. It further observed that the Act places special responsibility on such dominant enterprise to not conduct business in a manner which is prohibited under section 4(2) of the Act. It went on to hold that the Roche Group had *prima facie* shirked such responsibility.

IndusLaw View:

The CCI Order seems to be borne out of exceptional circumstances wherein, the act of misleading the relevant market participants (doctors, hospitals and authorities) was viewed strictly under the lens of abuse of dominant position by the CCI. This approach of the CCI can be linked to public health concerns and the sensitivity of the relevant market to disparagement of competitors by a dominant player.

Further, the CCI has also emphasized the responsibility of the dominant player to not impair competition in the market. It will be interesting to see the decisional practice that develops in cases of similar highly sensitive markets and the 'elder brother' approach that may be expected out of dominant enterprises in this regard.

Authors: Avimukt Dar, Shreya Suri, Devya Sharma

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