

Biocon Limited and Mylan Pharmaceuticals Private Limited (Informants) And F. Hoffmann-La Roche AG & Others (Opposite Parties)

Through this quarterly publication, CUTS International intends to undertake independent examination of relevant competition cases in India (on-going as well as decided). The objective is to provide a brief factual background of the facts of relevant cases, followed by an analysis of the predominant issues, therein. This publication will expectantly help readers to better comprehend the evolving jurisprudence of competition law in India.

The issues have been dealt in a simplistic manner and important principles of competition law have been elucidated in box stories, keeping in mind the broad range of viewership cutting across sectors and domains. The purpose of this publication is to put forward a well-informed and unbiased perspective for the benefit consumers as well as other relevant stakeholders. Additionally, it seeks to encourage further discourse on the underlying pertinent competition issues in India.

Executive Summary

It is often agreed that laws on Intellectual Property Rights (IPR) in general and patent laws specifically act as the most important policy pillars, which promote innovation. The patent system holds special significance for companies in the pharmaceutical sector, which enjoy exclusive protection for innovating drugs and such monopoly inducing protection is purportedly required to maintain the incentives to innovate.

The patent system also acts as an indemnifier for big pharmaceuticals and shoulders their high costs of Research and Development (R&D).¹ However, once the monopoly hold expires, the system allows for more competition by allowing the production of generics and biosimilars of the same drugs.

The introduction of generics and biosimilars provides the necessary constraint on the market power of an innovator and increases competition in the market. Understandably, it is in the monopoly holder's interests to somehow stop this from happening and to maintain the *status-quo*. In order to do so, there are several tactics, such as pay for delay agreements and ever greening, which originators adopt. Another relevant practice, which is the subject matter of competition law scrutiny in the present case is 'restriction of market access' through disparaging or maligning the image of competitors producing biosimilars, thereby causing competitive disadvantages to them.

The present order discusses this business strategy in detail wherein a big pharma company (The Rouche Group) is accused of abusing its dominant position by its competitors who have already entered the market with a biosimilar drug which cures cancer.

The Competition Commission of India (CCI) discusses several allegedly anti-competitive tactics like vexatious litigation, misrepresentation in front of regulatory authorities and negative advertisement and draws attention of the reader towards international case law in this regard. The chief focus on conducts, such as communications with government and unfair utilisation of legal processes makes this a unique and intriguing case law in Indian competition jurisprudence.

CCI's *Prima Facie* Opinion

Background

The present information was filed by two companies, which are chiefly engaged in the business of developing and selling of pharmaceutical products (Mylan Pharmaceuticals Private Limited) and manufacturing generic active pharmaceutical ingredients (APIs) in India (Biocon Limited). The informants primarily alleged abuse of dominance on the part of F. Hoffmann-La Roche (and its subsidiaries Genentech, Inc. and Roche Products (India) Pvt. Ltd.), which is stated to be the second largest pharmaceutical company in the world.² The facts of the case are mentioned below.

La Roche and its subsidiaries had developed an antibody, namely Trastuzumab, the basic function of which was to attack cancer cells and check their growth. It introduced the same in the Indian market under the form of a drug named Herceptin.³ However, in 2012, in order to prevent the development of its biosimilar version by other competitors and to avoid the imposition of a compulsory licence, the company withdrew Herceptin from the Indian market and introduced a lower-cost version called Trastuzumab.⁴ Concurrently, the informants collaborated to develop its cheaper biosimilar version and started to manufacture the same after receiving a licence in 2013 from the Drugs Control Department, Government of Karnataka.⁵

After the informants launched the biosimilar version in the market, it was alleged that the Roche Group (opposite parties), with the intention of preventing the entry of new players in the market of 'Trastuzumab', started to indulge in frivolous litigations against the Informants.⁶ Moreover, it was contended that the opposite parties engaged in frivolous communications with various authorities with the intention of impeding entry of its competitors.⁷

It was further claimed that Roche Group being a dominant player in the Trastuzumab market, indulged in a series of abusive practices to evade entry of the competitors' products, which hampered their growth.⁸ As a consequence, these acts were alleged to be in contravention of the provisions of Section 4 of the Competition Act of India.

Relevant Market

As the first step of the analysis under Section 4, the CCI sought to determine the relevant market and interestingly the informants proposed two alternative sets of relevant markets. The first, which was broader in nature, was that for “biological drugs-based on Trastuzumab (including biosimilar Trastuzumab) in India” while the alternative narrow market proposed was interestingly divided into three distinct sub-markets:

- market for sale of biological drugs (including biosimilars) used in the targeted therapy of HER-2 positive metastatic breast cancer within the territory of India;
- market for sale of biological drugs (including biosimilars) used in the targeted therapy of HER-2 positive early breast cancer within the territory of India; and
- market for sale of biological drugs (including biosimilars) used in the targeted therapy of HER-2 positive metastatic gastric cancer within the territory of India⁹

On the other hand, the Roche Group contended that biosimilars were not identical to reference biological drugs, just as generics were to chemical drugs.¹⁰

Box 1. What are Biosimilars?

Biological products are any virus, therapeutic serum, toxin, antitoxin, vaccine, blood component or derivative, allergenic product, protein (except any chemically synthesised polypeptide) or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man.¹¹ Biopharmaceuticals are drugs produced from living cells through the biological process, and mimic natural biological substances, such as hormones.¹² Indian guidelines define a *similar biologic product* as that which is similar in terms of quality, safety and efficacy to an approved Reference Biological product-based on comparability.¹³

While delineating the relevant product market, the Commission interpreted Section 2(t) of the Act, and stated that the relevant product market need not necessarily comprise products, which exhibit ‘identical’ properties – it may also include products which are ‘similar’ in terms of their intended use.¹⁴

Therefore, the Commission recognised that despite not being identical to the reference biological product, a biosimilar is highly analogous to an already approved

biological product and may not have any meaningful differences from the reference product.¹⁵

Hence, it was *prima facie* held that despite nominal differences, biological drugs as well as its biosimilars formed part of the same relevant product market i.e. 'market for biological drugs-based on Trastuzumab, including its biosimilars'.¹⁶

With regard to the relevant geographic market, the Commission found that the conditions of competition, being homogenous across India for pharmaceutical products, the relevant geographic market in the present case would be 'India'. Therefore, the relevant market in the present case was demarcated as "biological drugs based on Trastuzumab, including its biosimilars in India".¹⁷

Abuse of Dominance

It was further contended that the opposite parties held a dominant position in the broader as well as narrow markets because it held 100 percent market share in both.¹⁸ In response, the Roche Group contended that after the introduction of Informants' biosimilars, its market share fell down drastically and it was further decreasing with the passage of time.¹⁹ This was acknowledged by the Commission which also observed that the market share of the Roche Group went down in the relevant market during 2014 and 2015.²⁰

However, as the allegations levied in the present case pertained to abuse of dominance from 2013 onwards, the Commission noted that until 2014 the Roche Group enjoyed 100 percent market share.²¹

Moreover, despite its falling market share after Trastuzumabs biosimilar was introduced in the market, it still enjoyed a considerable market share and *prima facie* remained the dominant player (in terms of both value and volume of sales) in the relevant market.²² As market share is not the only criteria, which determines dominance, the Commission also analysed other factors as mentioned under Section 19(4) of the Competition Act.

The analysis concluded that size of the Roche Group and its first-mover advantage added to its market power and consumers already taking their drugs seemed to be locked in, countervailing buyer power (ability of patients already taking Roche's drugs to switch to its biosimilars) remained low and entry barriers remained high

(owing to significant costs involved in producing biosimilar and presence of significant regulatory approvals), which effectively made the Roche Group *prima facie* dominant in the relevant market.

Vis-à-vis abuse, the informants highlighted a series of allegations against Roche Group. It was alleged that Roche Group attempted to distort the competition in the market for biosimilars by indulging in vexatious litigations, influencing the regulatory authorities, making misrepresentations to tender authorities, disparaging the reputation of biosimilars, etc. thereby, foreclosing the market for its competitors in terms of Section 4(2)(c) of the Act.²³ The Commission rightly recognised the unique nature of the pharmaceutical industry; wherein to exclude market players, apart from devising pricing strategies, firms also indulge in non-pricing strategies and try to unlawfully raise their competitors' costs.²⁴

Against this backdrop and the possibility of non-pricing anti-competitive behaviour, the Commission analysed the allegations in an in-depth manner. Firstly, the Commission tested the allegation of vexatious litigation. It essentially looked at whether the legal action taken by the Roche Group (pending civil suit filed in the Delhi High Court) was baseless and whether the intent was to harass the defendant.

Additionally, the Commission analysed whether the legal action was conceived with an anticompetitive plan to eliminate competition. The answer to both these questions was answered by the Commission in the negative and the allegation of vexatious litigation was held to be *prima facie* without merit.

Secondly, the Commission looked at whether the Roche Group wrongly influenced regulatory authorities and denied market access to the informants. Through letters to the regulatory authorities, it was alleged that the Roche Group tried to create a perception that biosimilar versions of the informant's drug might pose unknown risks to consumers.²⁵ Moreover, it was pointed out that the Roche Group also indulged in negative advertisements which were aimed at denigrating competing products.²⁶

The Commission analysed the evidence and arguments put forth by all parties and stated that it *prima facie* appeared that the Roche Group had entered into various practices aimed at adversely affecting the penetration of biosimilars in the market. This included practices to influence regulatory authorities and the medical fraternity including doctors, hospitals, tender authorities, institutes, etc. 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 court.²⁷ Due to the inherent nature of pharma industry, such actions might create doubts about the efficacy and safety of biosimilars, which might have adverse effects on the market of biosimilars.

Analysis by CUTS

Non-Economic Measures Distort Competition

The fundamental goal of the Competition Commission of India is to enforce the provisions of the competition law and prevent parties from adversely affecting competition in the market to the detriment of consumers. The most common anti-competitive practices, which entities usually indulge in, include exclusionary as well as exploitative pricing strategies and other questionable economic behaviour.

However, one of the most effective ways for entities to acquire or abuse market power is through influencing and abusing government processes.²⁸ This is because the party engaging in such conduct bears minimal costs, but the anti-competitive effects of such actions are severe.²⁹ Therefore, competition enforcement agencies should remain vigilant about non-economic practices and behaviour, such as abuse of government processes which might go undetected.

The alleged non-economic practices in the present case included the letters/communications sent by the Roche Group to hospitals, authorities like The Drug Controller General of India (DCGI), the National Pharmaceutical Pricing Authority (NPPA) and representations made before doctors regarding safety issues in case of biosimilars in general, and of the Informants' drugs in particular.

Bearing in mind that the overarching intention behind these communications and representations was to denigrate the efficacy and safety of competing products, it was rightly recognised to be *prima facie* anti-competitive. Although it could be argued that in businesses, it is common practice to belittle one's competitors, but in extremely fragile and socially relevant industries, such as pharmaceuticals, maligning a drug through misrepresentations can practically lend a huge competitive disadvantage to competitors.

Moreover, in the case where the efficacy and safety of a particular biosimilar is questioned without any strong evidence to back it up, patients and doctors in the

long-run can grow a sense aversion towards biosimilar varieties of essential medicines. As acknowledged in the order, this can adversely affect penetration of biosimilars in the market and can foreclose the market to new entrants.

This can have a cascading impact on choice and price of essential drugs as well as constrain market access to competitors. Collectively, these factors encouraged the Commission to dig deeper into the alleged practices and the Commission rightly ordered the Director General to conduct a detailed investigation into the matter.

The Noerr Pennington Doctrine and Sham Litigation

However, while assessing and challenging the presence of non-economic anti-competitive conduct, such as communications with governmental or other official bodies, competition authorities have to be very careful so as to not infringe upon the rights of the parties to approach the said institutions.

To assess the scope of antitrust scrutiny over communications of parties with the government, the US Supreme Court in the case of *Eastern Railroad Presidents' Conference v. Noerr Motor Freight, Inc.*³⁰ held: (1) antitrust law (enshrined in the Sherman Act) does not prohibit efforts to influence the passage and enforcement of laws; and (2) insofar as criticism to customers and the public was alleged to be part of a strategy to influence legislation and law enforcement, such disparagement was 'incidental' to petitioning and therefore protected as well.³¹

This exception to antitrust scrutiny, called the *Noerr Pennington doctrine* basically means that claims of anti-competitive conduct cannot solely rely on the contention that entities indulged in concerted efforts to secure government-imposed restraints on competition.

However, this exception to competition law scrutiny is not absolute and is subject to conditions. This was also discussed in the Commission's order, which deliberated the case of *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*³² wherein the US Supreme Court held:

"Although those who petition government for redress are generally immune from antitrust liability (Noerr Pennington doctrine), such immunity is withheld when petitioning activity 'ostensibly directed toward influencing governmental action, is a **mere sham** to cover an attempt to interfere directly' with a competitor's business relationships...to be a **sham, litigation must meet a**

two part definition. First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. Only if challenged litigation is objectively meritless may a court examine the litigant’s subjective motivation.

Under the second part of the definition, a court should focus on whether the baseless suit conceals ‘an attempt to interfere directly’ with a competitor’s business relationships, through the “use of the governmental process-as opposed to the outcome of that process – as an anti-competitive weapon”.

However, it is important to recognise that the sham exception to the *Noerr-Pennington* doctrine can also have a chilling effect on those who seek redress in the courts. Thus, the CCI rightly held that there are certain guiding factors, which might help in objectively examining a case. These have been reiterated below:

“First, it needs to be established that the impugned legal action, on an objective view, is baseless and appears to be an instrument to harass the defendant/respondent; and, second, the legal action appears to be conceived with an anti-competitive intent/plan to eliminate competition”.³³

The Commission rightly applied these legal principles and stated that such determination ought to come sparingly and in exceptional circumstances. In the present facts and looking closely at the evidence – the Commission was not convinced that any such circumstance had arisen.³⁴ Nevertheless, keeping in mind Roche Group’s other practices related to misrepresentations and negative advertisements, the CCI ordered the Director General to conduct a detailed investigation.

Conclusion

Abuse of dominance is commonly seen from the perspective of economic distortions, such as unfair and discriminatory pricing, limiting of production and denial of market access. However, there might be cases wherein non-economic measures can also impede access to markets for new or prospective entrants.

One such measure which can be adopted by dominant entities is to influence regulatory and government decisions through misrepresentations and sham litigation. Although the presence of **sham** litigation and price discrimination were not

prima facie apparent in the present case, other actions of the Roche Group were seen an adversely impacting competition and restrictive to market access, which is a contravention of Section 4(2)(c) of the Competition Act.

Interestingly, even though the informants also alleged price related distortions to competition including unfair pricing and leveraging dominance to enter into other markets, the Commission solely found merit in the allegations, which put forth non-economic abuse.

The Commission rightly recognised that there is a special responsibility of a dominant entity i.e. not to allow its conduct to impair undistorted competition in the relevant market and not to conduct its business *in any manner*, which is prohibited under Section 4(2) of the Act. The focus on non-economic factors and conduct related to governmental and legal processes makes this a unique and intriguing case study in competition law.

Endnotes

- 1 Erin Fox, How Pharma Companies Game the System to Keep Drugs Expensive, Harvard Business Review (2017), available at <https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive>
- 2 Biocon Limited and Mylan Pharmaceutical Private Ltd. (Informants) and F. Hoffmann-La Roche AG & Others (Opposite Parties) at p.3, available at http://www.cci.gov.in/sites/default/files/68%20of%202016_0.pdf
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- 4 Ibid.
- 5 Ibid.
- 6 Ibid. at p.6
- 7 Ibid.
- 8 Ibid.
- 9 Supra 2, at p.7
- 10 Ibid. at p.21
- 11 Guest Post: The New India Guidelines on Similar Biologics, available at <https://spicyip.com/2012/10/guest-post-new-india-guidelines-on.html>
- 12 Rajiv Kumar and Jagjit Singh, *Biosimilar drugs: Current status*, Int J Appl Basic Med Res. 2014 Jul-Dec; 4(2): 63–66
- 13 Government of India, *Guidelines on Similar Biologics Regulatory Requirements for Marketing Authorization in India*, available at <http://www.ableindia.in/images/resources/1471597420-Guidelines%20on%20Similar%20Biologics%20wef%2015%20Aug%202016.pdf>
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- 27 Ibid. at p.33
- 28 Federal Trade Commission, *Enforcement Perspectives on the Noerr-Pennington Doctrine*, 3 (2006), available at <https://www.ftc.gov/sites/default/files/documents/reports/ftc-staff-report-concerning-enforcement-perspectives-noerr-pennington-doctrine/p013518enfperspectnoerr-penningtondoctrine.pdf>
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- 32 508 U.S. 49 (1993)
- 33 Supra 2, at p.26
- 34 Supra 2, at p.28

This edition was prepared by Parveer Singh Ghuman, Senior Research Associate (psg@cuts.org), CUTS International.

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