COMPETITION COMMISSION OF INDIA

Case No. 68 of 2016

In Re:

Biocon Limited
20thKM Hosur Road, Electronic City,
Bangalore, Karnataka - 560100 **Informant No. 1**

Mylan Pharmaceuticals Private Limited
Plot No. 1-A/2, MIDC Industrial Area, Taloja,
Panvel, Raigad (Dist),
Maharashtra - 410208 **Informant No. 2**

And

F. Hoffmann-La Roche AG
Konzern-Hauptsitz, Grenzacherstrasse 124,
CH-4070 Basel, Switzerland **Opposite Party No. 1**

Genentech Inc.
1 DNA Way, South San Francisco,
CA - 94080 **Opposite Party No. 2**

Roche Products (India) Private Limited
1503, 15thFloor, 'the Capital',
Plot No. C-70, Behind ICICI Bank,
BKC, Bandra (E),
Mumbai - 400051 **Opposite Party No.3**

CORAM

Mr. Devender Kumar Sikri
Chairperson

Mr. S.L. Bunker
Member

Mr. Sudhir Mital
Member

Mr. Augustine Peter
Member

Mr. U.C. Nahta
Member

Justice G.P. Mittal
Member

Presence

For IP 1 & 2:	Mr. Amit Sibal, Senior Advocate Mr. G.R. Bhatia, Advocate Mr. A. Hussain, Advocate Ms. Modhulika Bose, Advocate Mr. Rohan Alva, Advocate Mr. Tamir Siddiqi, Advocate Ms. Kanika Chaudhary Nayar, Advocate Ms. Rishika Taneja, Advocate Ms. Deeksha Manchanda, Advocate Mr. Akhilesh Nand, General Counsel, IP-1 Mr. Bhaskar Sharma, Assistant Manager, IP-1 Mr. Sandeep Rathore, Vice President, IP-2 Ms. Sofiyah Sulaiman, Assistant General Manager, IP-2
For OP-1, 2 & 3:	Mr. Ramji Srinivasan, Senior Advocate Mr. Samir Gandhi, Advocate Mr. Rahul Rai, Advocate Mr. N. Mahabir, Advocate Mr. Vishal Gehrana, Advocate Ms. Shivanghi Sukumar, Advocate Ms. Rhea Srivastava, Advocate Mr. Rahul Vartak, Director Patents, OP-3 Mr. Simpson, Director Market Access, OP-3 Mr. Tushar Bhardwaj, Advocate, OP-3

Order under Section 26(1) of the Competition Act, 2002

1. Biocon Limited (hereinafter the '**Informant No. 1'/'IP-1**') and Mylan Pharmaceuticals Private Limited (hereinafter the '**Informant No. 2'/'IP-2**') have filed the present information, under Section 19(1)(a) of the Competition Act, 2002, (hereinafter the '**Act**') against F. Hoffmann- La Roche AG

(hereinafter the '**Opposite Party No. 1'/'OP-1**'), Genentech, Inc. (hereinafter the '**Opposite Party No. 2'/'OP-2**') and Roche Products (India) Pvt. Ltd. (hereinafter the '**Opposite Party No. 3'/'OP-3**') alleging contravention of the provisions of Section 4 of the Act.

Facts, as stated in the information, in brief

2. IP-1, a company incorporated under the Companies Act, 1956, is engaged in the business of manufacturing generic active pharmaceutical ingredients (APIs). IP-2, also a company incorporated under the Companies Act, 1956, is engaged in the business of development and sale of pharmaceutical products in India. It is stated that IP-2 is a subsidiary of Mylan Inc., a global and specialty pharmaceutical company, incorporated in the State of Pennsylvania, USA. IP-1 and IP-2 are hereinafter collectively referred to as the **'Informants**'.

3. OP-1, a joint stock company incorporated under the laws of Switzerland, is stated to be the second largest pharmaceutical company worldwide, having 240 associate companies and subsidiaries in 92 countries. OP-2, a company incorporated in the State of Delaware, USA, is a wholly owned subsidiary of OP-1. It is stated to be a leading biotechnology company that develops, manufactures and commercialises medicines for treating patients with serious medical conditions. OP-3, a company incorporated under the erstwhile Companies Act, 1956, is also a wholly owned subsidiary of OP-1, having its registered office at Mumbai, Maharashtra. OP-1, OP-2 and OP-3 are hereinafter collectively referred to as '**Roche'** or '**Roche Group**', being part of the same group in terms of Explanation (b) to Section 5 of the Act.

4. In 1990, OP-2 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 (hereinafter **'INN'**) for this monoclonal antibody is Trastuzumab. The function

of Trastuzumab is to block the effects of HER-2 protein, which sends growth signals to cancer cells. Trastuzumab targets a specific form of breast cancer *i.e.* HER-2 – positive breast cancer. This drug is included in the National List of Essential Medicines, prepared by the Ministry of Health and Family Welfare, Government of India.

5. OP-2 signed an agreement with OP-1 in July, 1998, whereby OP-1 was given the exclusive marketing rights to sell Trastuzumab, under the brand name HERCEPTIN, outside the USA. HERCEPTIN was introduced in India in 2002 by OP-1. The drug was imported and marketed in India initially through a distributor, Taksal Pharmaceuticals, under a marketing arrangement. This arrangement was subsequently terminated, and the marketing was thereafter done by OP-3.

6. The Drug Controller General of India (hereinafter '**DCGI**'), the authority empowered to grant or revoke licenses for, *inter alia*, import, manufacture, distribution and sale of drugs in India, granted its approval to OP-3 on 11th October, 2002, for the import of HERCEPTIN in India for treatment of patients suffering from 'metastatic breast cancer'. DCGI's approval was granted for importing HERCEPTIN in 440 mg vials in India, which was priced at around Rs. 1,20,000 per vial. On 25th January, 2008, OP-3 also received DCGI's approval to import and market HERCEPTIN in 150 mg vials. However, the same was never introduced by the Roche Group in India. HERCEPTIN also received DCGI's approvals for HER-2 positive early breast cancer (adjuvant and neo adjuvant) and HER-2 positive metastatic gastric cancer on 07th August, 2006 and 03rd April, 2010, respectively.

7. In addition to the regulatory approvals obtained by OP-3, OP-2 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.

8. In September, 2012, OP-1 withdrew HERCEPTIN from the Indian market and rather introduced a lower cost version of Trastuzumab, known as BICELTIS, which was distributed and marketed by Emcure Pharmaceuticals as per an agreement entered into between it and OP-1. The Informants have claimed that BICELTIS, which was priced at USD 1270 (Rs.75,000) per 440 mg vial, was primarily introduced in India due to the threat of compulsory licensing and development of biosimilar Trastuzumab. The Roche Group also launched another low cost version of Trastuzumab under the brand name HERCLON in India at a price of USD 1270 (Rs. 75,000) per 440 mg vial.

9. IP-1 initiated the development of a biosimilar drug for Trastuzumab, in joint collaboration with IP-2, in the year 2008. Manufacturing license for the same was granted to IP-1 by the Drugs Control Department, Government of Karnataka, on 13th December, 2013. Thereafter, on 18th January, 2014, the launch of biosimilar Trastuzumab was announced by IP-1 and IP-2, under the brand names, CANMAb and HERTRAZ, respectively. It has been stated that the drug was proposed to be launched in vials of 150 mg priced at Rs. 19,500/-per vial and 440 mg priced at Rs. 57,500/- per vial. 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.

10. After the launch of its drug for HER-2 positive metastatic breast cancer, IP-1 approached DCGI seeking extrapolation to two other indications for Trastuzumab, for which the reference biologic drug was already approved: HER-2 positive early breast cancer and HER-2 positive metastatic gastric cancer. DCGI, based on the recommendation of the Subject Expert Committee,

granted its no objection to IP-1 for extrapolation to the other indications *vide* letter dated 17th March, 2015.

11. 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.

12. 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. Such conduct of Roche Group has been alleged to be in contravention of the provisions of Section 4 of the Act.

13. The Informants have proposed two alternative sets of relevant markets in which Roche Group is alleged to be dominant. The first relevant market defined is the broader relevant market, *i.e*, the '*market for biological drugs based on Trastuzumab (including biosimilar Trastuzumab) in India*'. The alternative narrow relevant markets proposed by the Informants are divided into three distinct sub-markets, based on the kind/stage of cancer:

a) '*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';*
b) '*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';*
c) '*market for sale of biological drugs (including biosimilars) used in the targeted therapy of HER-2 positive metastatic gastric cancer within the territory of India';*

14. It has been alleged that Roche Group holds a dominant position in both the broader market as well as the narrower sub-markets based on various factors enshrined under Section 19(4) of the Act. It has been contended that, till February, 2014, Roche Group had a 100% market share in the broader as well as the narrower relevant markets. Even after the introduction of biosimilars by the Informants, *i.e.* in February, 2014, Roche Group continued to maintain a 100% market share, in terms of volume and value of sales, in two of the narrower relevant markets, *i.e.* the '*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 the '*market for sale of biological drugs (including biosimilars) used in the targeted therapy of HER-2 positive metastatic gastric cancer within the territory of India*'. In the broader relevant market and in the narrower relevant market, *i.e.*, the '*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*', it is stated that Roche Group has a market share of 70% in terms of value of sales. It is further stated that Roche Group's size and resources in India and worldwide, contribute towards its position of dominance. Further, it has a comparative advantage over its competitors on account of being the innovator of the biological drug, Trastuzumab, in a market which has high entry barriers. Further, consumers' dependence on Roche's products is also stated to be one of the factors contributing to Roche Group's dominant position.

15. It is alleged that Roche Group, having a dominant position, has implemented or attempted to implement a series of actions to impede the entry and/or growth of biosimilar Trastuzumab in India, and thus, adversely affected competition in the relevant market. The series of events/practices of Roche Group alleged to be abusive, are briefly highlighted in the following paragraphs.

16. The Informants have alleged that the Roche Group started targeting the Informants' biosimilar drug right from its inception. In 2013, when the Informants approached DCGI for seeking approvals for their respective biosimilar drugs, Roche Group made a representation to DCGI, *vide* letter dated 11th October, 2013, alleging serious concerns on the regulatory approval pathway for biosimilar Trastuzumab. In its letter, Roche Group stated that the Informants have not conducted clinical trials as per the Department of Biotechnology (DBT) - Central Drugs Standard Control Organization (CDSCO) guidelines and trials conducted need to be stringently reviewed by experts who understand Equivalence trials, as recommended by the said guidelines. However, despite this representation by Roche Group, DCGI granted its approval to IP-1 to manufacture Trastuzumab Bulk and Trastuzumab Injection on 23rd October, 2013.

17. Thereafter, when IP-1 sought approval for its carton, label and package insert for additional indications, OP-1 sent a notice/letter dated 10th June, 2015, to DCGI and the State Drug Controller, Karnataka, cautioning them that "*any package insert, packaging or any other material presently submitted to the DCGI by Biocon Limited purporting to rely on the published data of the Plaintiffs' Drug and any approval issued thereupon…will be in violation of the terms of the orders"* passed by the Hon'ble Delhi High Court. However, despite Roche's efforts, approval for the carton, labels and package insert for the additional indications was also granted to IP-1, *vide* letter dated 28th July, 2015. The Informants have also referred to the letters dated 18th March, 2016 and 28th April, 2016, written by Roche to the National Pharmaceutical Pricing Authority (hereinafter '**NPPA**') for exclusion of the Informants' biosimilars for calculating the ceiling price of Trastuzumab.

18. The Informants have further alleged that, apart from influencing regulatory authorities, Roche Group has also resorted to vexatious litigation against the

Informants and other competitors/potential entrants in the relevant markets, with the sole intention of preventing launch and/or market penetration of approved biosimilars of Trastuzumab. In support of this allegation, the Informants have highlighted the following series of litigations that have taken place since 2014.

19. On 04th February, 2014, OP-1 filed a civil suit before the Hon'ble Delhi High Court, being C.S. (O.S) No. 355 of 2014 (hereinafter '**Civil Suit**') against DCGI, IP-1, IP-2 and Mylan Inc., along with an application for interim injunction being I.A. No. 2371 of 2014. In the Civil Suit, OP-1 claimed that IP-1 and IP-2 are misrepresenting their drug as 'Trastuzumab', 'biosimilar Trastuzumab' and biosimilar version of HERCEPTIN. OP-1 hence, sought an injunction restraining IP-1 and IP-2 from launching and selling their respective drugs in the Indian market by ascribing biosimilarity with Roche's products and/or by relying on any data relating to HERCEPTIN, HERCLON or BICELTIS.

20. On 05th February, 2014, the Hon'ble Delhi High Court passed an ex parte ad-interim injunction order whereby IP-1 and IP-2 were restrained from relying upon or otherwise referring to HERCEPTIN, HERCLON or BICELTIS or any other data relating to Trastuzumab marketed as HERCEPTIN, HERCLON or BICELTIS, including data relating to its manufacturing process, safety, efficacy and sales, in any press releases, public announcements, promotional or other material, for IP-1 and IP-2's drugs and from claiming any similarity with HERCEPTIN, HERCLON or BICELTIS.

21. The aforesaid order was challenged by IP-1 and IP-2 by filing Appeals before the Division Bench (F.A.O (OS) 91 and 92/2014), which were disposed of with the direction that the same be considered as applications under Rule 4 of Order XXXIX of the CPC and the matter be listed before the Single Judge again. Subsequently, the Learned Single Judge, *vide* order dated 14th February, 2014, modified its earlier order dated 05th February, 2014 and it was held that if IP-1 has already obtained the approval for package inserts from the competent

authority, then it is entitled to use the same till the next date of hearing. Thereafter, between 14th February, 2014, and 25th April, 2016, various applications were filed in the Civil Suit by the Informants as well as by Roche Group, which are not mentioned here for the sake of brevity.

22. On 25th April, 2016, the Learned Single Judge of Hon'ble Delhi High Court passed an interim order granting the following reliefs to Roche Group:

i) IP-1 and IP-2 were permitted to manufacture, market and advertise their drugs under the brand name CANMAb or HERTRAZ. However, they were restrained from claiming or ascribing biosimilarity with HERCEPTIN/BICELTIS/HERCLON;

ii) While IP-1 and IP-2 were permitted to use the INN Trastuzumab to describe their products, they were prohibited from using the INN standalone on their cartons or package inserts as a brand name. Further, IP-1 and IP-2 were permitted to use the INN as Biocon's Trastuzumab or Mylan's Trastuzumab, wherever applicable, to describe the composition of the molecule on the product as well as in its insert, but the same would not be done in a prominent manner. These expressions were to be used at the bottom of the carton in small size letters;

iii) IP-1 and IP-2 were restrained from using the data relating to the manufacturing, safety, efficacy and tests conducted for the safety of their drugs, as complained of by Roche Group till the time the final decision on the issue of biosimilarity is made in the present suit.

23. The Hon'ble Delhi High Court, *vide* the said order, also directed that if IP-1 and IP-2 intended to claim biosimilarity as a description of their products or in their promotional campaigns, IP-1 would reapply for the license with the relevant authorities including DCGI, which would be obliged to decide the application in

accordance with the relevant Rules and the Guidelines on Similar Biologics: Regulatory Requirement for Marketing Authorization in India, 2012 and observations made by the Court in this order.

24. Aggrieved by the aforesaid order, IP-1 and IP-2 filed appeals being F.A.O. (OS) 132 of 2016 and F.A.O (OS) 133 of 2016 respectively before the Division Bench of the Hon'ble Delhi High Court. The Division Bench, *vide* order dated 28th April, 2016, directed that the position as on 24th April, 2016, (*i.e.*, prior to the issuance of the impugned order dated 25th April, 2016) would continue to operate till the next date of hearing. In response, OP-1 also filed an appeal dated 22nd July, 2016, before the Division Bench of the Hon'ble Delhi High Court.

25. The Informants have alleged that a similar strategy has been adopted by OP-1 against Reliance which had developed a biosimilar version of Trastuzumab under the brand name, TrastuRel. It has been stated that, despite obtaining approvals for manufacturing and marketing authorisation in June, 2015, Reliance's drug could only be launched in May, 2016 due to a suit filed by OP-1 (being C.S. (OS) 3284 of 2015) before the Hon'ble Delhi High Court. Another pharmaceutical company, Cadila Healthcare also developed a biosimilar drug under the brand name, Vivitra. However, prior to the launch of Cadila Healthcare's biosimilar in the market in January, 2016, it approached the Hon'ble Bombay High Court through a pre-emptive suit on 30th October, 2015 seeking an injunction to restrain OP-1 from preventing the launch of Cadila Healthcare's biosimilar Trastuzumab.

26. In addition to the aforesaid acts/practices, the Informants have also alleged that Roche Group has misled various authorities by endorsing the Delhi High Court's Single Judge Order dated 25th April, 2016, without informing them about the Division Bench Order dated 28th April, 2016. It has been alleged that Roche Group has also tried to prevent the penetration of biosimilars in the market by

misinforming doctors and hospitals about the pending Civil Suit and warning them of severe consequences as a result of prescribing HERTRAZ while the suit is pending. It has been further alleged that Roche Group wrote letters to various government agencies and hospitals to influence tender conditions in its favour.

27. The Informants have highlighted that because of Roche's persistent efforts, Odisha State Medical Corporation Limited ('**OSMCL**') changed the eligibility criteria for procurement of Trastuzumab from 2 years to 3 years. A representation made by Emcure, on Roche's behalf, to Sher-I-Kashmir Institute of Medical Sciences ('**SKIMS'**) on 01st December, 2014, was also highlighted. *Vide* this representation, it is stated that Emcure and Roche were the only two companies with approvals for all three indications. The Informants also pointed to another tender floated by Madhya Pradesh Public Health Services Corporation Limited ('**MPPHSCL'**), wherein IP-1 participated for five products including Trastuzumab, 150 mg and 440 mg. *Vide* letter dated 17th May, 2016, IP-1 was informed that both the products were dropped from the tender which, as per the Informants, was done on account of Roche's interference. The Informants further highlighted a letter dated 25th May, 2016, written by Roche Group to Store Officer, AIIMS, requesting it to abide by the eligibility condition of three years' manufacturing experience in Trastuzumab.

28. Based on the aforesaid, the Informants have prayed to the Commission to direct the Director General ('**DG'**) under Section 26(1) of the Act to investigate into the alleged anti-competitive practices and abusive conduct adopted by the Roche Group, its affiliates, group entities, distributors (including Emcure) and agents. Besides, through a separate interim relief application dated 28th July, 2016, the Informants have, *inter-alia*, prayed that the Roche Group should be restrained from approaching doctors, regulatory authorities, officials of State and private tender committees and making any representation on the medicinal reputation of CANMAb and HERTRAZ produced and marketed by the Informants.

Observations and findings

29. The Commission considered the information in its ordinary meeting held on 21st September, 2016 and decided to call the Informants as well as the Roche Group for a preliminary conference. On 10th November, 2016, both the parties presented their oral submissions before the Commission, through their respective learned counsel. Thereafter, they filed their respective brief written submissions on 11th November, 2016.

30. During the preliminary conference, Mr. Amit Sibal, the learned senior counsel representing the Informants, reiterated the facts and allegations, as elucidated in the information. After providing brief background facts of the case, Mr. Sibal highlighted the various practices adopted by Roche Group to oust competition from the market. He submitted that Roche, being a dominant player, has a special responsibility not to distort free and fair competition in the market. However, in complete disregard of this special responsibility, Roche Group has made misleading statements and misrepresentations before hospitals, doctors and tender authorities, which has led to confusion and apprehension on the efficacy and safety of the Informants' biosimilar drugs. It was argued that these drugs have no meaningful differences from that of the reference biological product. Mr. Sibal further argued that the Informants' drugs are prescribed for a highly sensitive health condition and any negative publicity of the same has huge ramifications and hamper their growth. Mr. Sibal also highlighted various communications made by Roche Group to hospitals and other procurers, whereby Hon'ble Delhi High Court's Single Judge's order dated 25th April, 2016 has been endorsed, without disclosing the order dated 28th April, 2016, passed by the Division Bench of the Hon'ble Delhi High Court on appeal. Roche Group was also alleged to be influencing tender conditions in its favour by writing to tender authorities. On being queried as to whether these misrepresentations and alleged anti-competitive acts by the Roche Group has led to any harm, Mr. Sibal

submitted that OSMCL's tender condition relating to the pre-qualification criteria of having marketing/manufacturing experience of 2 years was changed to 3 years only at the instance of Roche Group and also, IP-1 lost the tender floated by MPPHSCL because of interference by the Roche Group. Mr. Sibal also pointed towards the global presentation made by Roche to highlight the differences between reference biological drugs and their biosimilars, which has been alleged to have been made, with an intention to adversely influence the market for biosimilars. Based on these submissions, Mr. Sibal prayed that an investigation be ordered in the present case against the Roche Group.

31. On the other hand, Mr. Ramji Srinivasan, the learned senior counsel appearing for Roche Group refuted all the allegations regarding anti-competitive conduct by Roche Group. At the outset, he argued that all the issues elucidated in the information are squarely due for adjudication before the Hon'ble Delhi High Court in the Civil Suit pending before it. He claimed that when the Informants had already chosen to raise these issues before the Hon'ble Delhi High Court, raising the same before the Commission should not be permitted. Thereafter, Mr. Srinivasan, without denying the letters/communication/evidence relied upon by the Informants, provided justifications for them. He submitted that the Act is aimed at protecting competition and not individual competitors. He averred that development of an innovative drug requires heavy investments in terms of time and resources. Only after rigorous clinical trials and other regulatory processes, is approval granted by regulatory authorities. Thus, it is imperative for an innovator to ensure that its research is not blemished by non-efficacious biosimilars. He contended that biosimilars are not generics and may differ in their efficacy, quality and safety. Thus, if these biosimilars are allowed to rely on reference biological drug's name and data, it will not only amount to compromising patients' safety but will also take away the incentive of the originator to innovate.

32. In its written submissions dated 11th November, 2016, the Roche Group has submitted that the Informants have misinterpreted the Division Bench Order of the Hon'ble Delhi High Court dated 28th April, 2016. It is submitted that the Division Bench Order was passed solely on account of practical considerations, as IPs' products were already available in the market in large numbers and despite repeated submissions by the Informants to stay the interim order dated 25th April, 2016, the Division Bench refused to "stay" the same. It is further alleged that the Division Bench Order only alters the direction given by the Learned Single Judge, which required the Informants to "qualify the INN name Trastuzumab but not to use the said name stand alone on the carton or package insert as a brand name". The remainder of the decision continues to operate.

33. With regard to the alleged dominance of the Roche Group, Mr. Ramji Srinivasan submitted that the first mover advantage of an innovator company exists only until new competitors enter the market. The fact that the market share of the Informants continues to grow in the last two years shows that Roche Group is not dominant.

34. The next submission of the Roche Group was with regard to various representations made by it to various public authorities. *In re* letter dated 11th October, 2013, written by Roche to DCGI, it was submitted that the letter is merely a statement of opinion and cannot conceivably be viewed as being a misrepresentation by it. With respect to the letter dated 10th June, 2015, written by Roche to DCGI and the State Drug Controller, Karnataka, it is submitted that the letter is a statement informing DCGI about the Hon'ble Delhi High Court's interim orders dated 5th February, 2014, 14th February, 2014 and 28th February, 2014 and cannot be viewed as being a misrepresentation made by it. *In re* letter dated 22nd September, 2015, written by Roche to the Ministry of Health and Family Welfare, requesting modification of the eligibility criteria to 3 years instead of 2 years, it has been submitted that the letter communicates Roche's

opinion in the matter and was aimed at promoting patient safety. With regard to Roche's letters dated 18th March, 2016 and 28th April, 2016, to NPPA, for exclusion of the biosimilars for calculation of the ceiling price of Trastuzumab, Roche has submitted that such request for exclusion of biosimilars was based on the pending Civil Suit before the Hon'ble Delhi High Court, primarily on the ground of incorrect approval of DCGI. *In re* letter dated 20th September, 2016, written to the Additional Director, Central Government Health Scheme, Pune, which contained the Learned Single Judge Order dated 25thApril, 2016, Roche has submitted that it was purely an expression of its opinion.

35. Further, Roche has provided justifications on the Informants' allegations regarding letters written by Roche to private entities for modification of the eligibility criterion in the tender conditions. Roche has submitted that the letter dated *nil* written to OSMCL was merely a request to abide by its tender conditions and that the same cannot be considered as anti-competitive. With regard to the representations made to SKIMS by Emcure, Roche has submitted that the said representation is factually correct as Emcure and Roche were the only two companies with approvals for all three indications as on that date. Biocon and Mylan received approvals for the additional indications only in February, 2015. *In re* tender floated by MPPHSCL, Roche has claimed that it has also received an almost identical letter, stating that Trastuzumab 440 mg was dropped from the tender and accordingly, MPPHSCL, took a decision not to procure Trastuzumab at all.

36. With regard to the letter dated 25th May, 2016 written by Roche to the Store Officer, AIIMS, requesting it to abide by the eligibility condition of three years' manufacturing experience, Roche has submitted that the letter was merely a request to AIIMS to abide by its tender conditions. Such a request cannot be considered to be anti-competitive. Further, the Informants have pointed towards another letter dated 3rd June, 2016, written to the Store Officer, AIIMS, wherein

AIIMS was informed of the interim decision dated 25th April, 2016 of the Learned Single Judge of the Hon'ble Delhi High Court without revealing the order of the Division Bench dated 28th April, 2016. The Informants have claimed that these letters are misrepresentative in nature and were aimed at ousting the Informants from the market. In this regard, Roche has submitted that the letter was stated to be purely informational in nature, containing only statement of facts.

37. The Commission has examined the material available on record, including the written submissions filed by all the parties, and heard the oral submissions made by their respective learned senior counsel on 10th November, 2016. The Informants are primarily aggrieved by the Roche Group's conduct whereby, it has allegedly denied market access to its competitors in contravention of Section 4(2)(c) of the Act. Besides, the Informants have also alleged violation of Section 4(2)(a)(ii) for imposition of unfair prices, Section 4(2)(a)(i) for imposition of unfair conditions, Section 4(2)(e) of the Act for leveraging and Section 4(2)(b)(i) for limiting or restricting the market.

38. Before analysing the aforesaid allegations within the realm of the Act, it is pertinent to deal with the preliminary objection raised by the Roche Group on maintainability of the present case. During the hearing, Roche Group has argued that the issues raised in the present information are squarely covered by the Civil Suit pending before the Hon'ble Delhi High Court and thus, the Informants should not be permitted to raise similar issues before the Commission. In response, the Informants have stated that the reliefs available from both the forums, *i.e.* the Hon'ble Delhi High Court and the Competition Commission of India, are distinct. While the issues before the Hon'ble Delhi High Court pertain to the validity of approvals granted by DCGI to IP-1, the primary issue before the Commission is whether the Roche Group's conduct in the market is abusive or not.

39. The Commission finds merit in the submissions made by the Informant. It is true that the Informants and Roche Group are parties to the Civil Suit before the Hon'ble Delhi High Court as well and that some of the facts stated in the information have also been alleged before the Hon'ble Delhi High Court. However, the same is not conclusively sufficient to exclude the Commission's jurisdiction to look into the OPs' anti-competitive behaviour.

40. Similar objections relating to Commission's jurisdiction were raised by Telefonaktiebolaget LM Ericsson before the Hon'ble Delhi High Court in *Telefonaktiebolaget LM Ericsson (Publ) vs. Competition Commission of India and Anr.* (hereinafter **'*Ericsson case*'**), wherein it was argued that the Commission would have no jurisdiction to determine those issues which are pending before civil courts. *Vide* order dated 30th March, 2016, the Hon'ble Delhi High Court dismissed the said argument. The observations and findings of the Hon'ble Delhi High Court, though made in the context of the alleged overlaps between the Patents Act, 1970 and the Competition Act, 2002, would be of relevance while dealing with the Roche's objections to the Commission's jurisdiction in the present case. The relevant excerpt from the aforesaid order of the Delhi High Court is reproduced in verbatim below:

> *162. It is clear from the above that the remedies as provided under Section 27 of the Competition Act for abuse of dominant position are materially different from the remedy as available under Section 84 of the Patents Act. It is also apparent that the remedies under the two enactments are not mutually exclusive; in other words grant of one is not destructive of the other. Thus, it may be open for a prospective licensee to approach the Controller of Patents for grant of compulsory licence in certain cases. The same is not inconsistent with the CCI passing an appropriate order under Section 27 of the Competition Act.*

41. The Commission notes that the Civil Suit before the Hon'ble Delhi High Court has been filed by the Roche Group, where the Informants are merely

Respondents in the said suit. Thus, the defence taken by Informants, which is only a response to the Civil Suit filed by Roche, cannot take away their right to approach the Commission for a remedy enshrined under Section 27 of the Act. The main issues before the Hon'ble Delhi High Court relate to the propriety of the approvals granted by the DCGI to the Informants' products and alleged passing off by the Informants of their products as Roche's products. The Informants have, *inter alia*, highlighted before the Hon'ble Delhi High Court that Roche Group has filed the Civil Suit in order to maintain its monopoly and restrict the entry of the Informants' drugs. The Commission observes that even if various issues have been highlighted by the Informants in their defence in the Civil Suit, the Hon'ble Delhi High Court will only adjudicate upon the issues which are pending before it. Whether Roche Group is dominant and has abused its dominant position or not, is a question that is covered under the provisions of the Act, and falls under exclusive jurisdiction of the Commission and the Competition Appellate Tribunal under Section 61 of the Act. The allegations relating to abuse of dominant position are not the subject matter of the Civil Suit pending before the Hon'ble Delhi High Court. In view of the above, it is clear that the pending Civil Suit in the Hon'ble Delhi High Court does not impede the Commission's jurisdiction to look into the present matter. Thus, the Commission finds no infirmity with proceeding in the present case relating to abuse of dominant position by the Roche Group.

42. Having decided the preliminary question of maintainability in affirmative, the Commission finds it appropriate to examine whether there exists a *prima facie* case under Section 26(1) or the case needs to be closed under Section 26(2) of the Act. Since the allegations pertain to Section 4 of the Act, delineation of relevant market is essential for ascertaining dominance and analysing the alleged abusive conduct of the Roche group.

43. A relevant market, as defined under Section 2(r) of the Act, means a market comprising of a relevant product market or relevant geographic market or both. A relevant product market, as defined under Section 2(t) of the Act, means a market comprising all those products or services which are regarded as interchangeable or substitutable by the consumer, by reason of characteristics of the products or services, their prices and intended use. Although the definition provided under the Act plays a vital role in guiding the delineation of the relevant market, the same cannot be done by overlooking the peculiarities of the sector under consideration. The pharmaceutical sector is characterised by a structure where the ultimate consumer, *i.e.* patient, is not the decision maker. The treatment of a particular disease is determined by the doctor, thus, making the demand for drugs/medicines/therapy prescription induced. The words of the doctor are generally considered as sacrosanct by the patients. Price sensitivity is, therefore, limited in this sector. Since the health of a patient is of paramount importance, the intended use of a drug gains more relevance which, for the purposes of substitutability, is governed by its 'quality', 'safety' and 'efficacy'.

44. As stated in the information, there are various treatments for HER-2 positive breast cancer *viz*, surgery, radiotherapy, chemotherapy, hormone therapy and targeted therapy, which differ from each other and are prescribed based on the stage and type of breast cancer. None of these treatments appear to be substitutable with each other; rather, they are used either in conjunction with or as a follow up of one another. Further, targeted therapy is more effective than other therapies, as it targets a particular group of cancer cells and has fewer side effects. Hence, all kinds of therapies/treatments cannot be included in the same relevant product market.

45. Even within targeted therapy, the Informants have highlighted 4 types of monoclonal antibody therapies (targeted therapies) which are used for the treatment of HER-2 positive breast cancer, namely, Trastuzumab, Pertuzumab,

Ado-Trastuzumab emtansine (Kadcyla) and Lapatinib (Tykerb). As per the information, Pertuzumab is used in combination with Trastuzumab. Ado-Trastuzumab is used as a follow on drug to Trastuzumab and cannot be substituted with it. Lapatinib is used with other drugs to treat patients with HER-2 positive breast cancer that has progressed after treatment with Trastuzumab. It may be inferred that all these monoclonal antibodies are either used in combination with Trastuzumab to treat HER-2 positive breast cancer or as a follow up to Trastuzumab. By virtue of their non-substitutability with each other, they cannot be included in the same relevant product market.

46. The above observations are in sync with the Commission's view in combination matters, in relation to the definition of the relevant product market in pharmaceutical cases. In the combination matters, C-2014/05/170 (*Sun Pharma/Ranbaxy*) and C-2015/10/324 (*Strides Shasun / Sun Pharma*), the Commission has defined the relevant product market at the molecular level in the case of chemical drugs, *i.e.*, medicines/formulations based on the same active pharmaceutical ingredient (API). At the molecular level, branded as well as generics based on the same API, were considered part of the same relevant product market.

47. As per the information, Trastuzumab falls at the fifth level of Anatomical Therapeutic Chemical (ATC) Classification System, which denotes chemical substances. In case of biological drugs, Trastuzumab appears to be equivalent to the molecular level. Thus, going by the analogy, drugs based on Trastuzumab, *i.e.*, the reference biological drug as well as its bio-similars, would be considered part of the same relevant product market.

48. Roche Group has contended that bio-similars are not identical to reference biological drugs, just as generics are to chemical drugs. The Commission is cognizant of the aforesaid assertion. A generic drug is an exact copy of a branded/chemical drug and by virtue of possessing identical characteristics,

generic drugs are considered to be bioequivalent to chemical drugs. While chemical drugs are manufactured using chemical compounds, biological drugs are developed from living organisms (plant or animal cells). Thus, because of this fact, biological drugs cannot be identical in nature. However, a relevant product market, within the meaning of Section 2(t) of the Act, need not comprise of products which exhibit 'identical' properties; it may also include products which are 'similar' in terms of their intended use. In this regard, the Commission finds force in the submission made by the Informants that a biosimilar drug obtains an approval from the regulatory authority only after proving itself to be similar to the reference biological drug in terms of 'safety' 'efficacy' and 'quality'. Despite not being identical to the reference biological product, a bio-similar is highly analogous to an already approved biological product and may not have any meaningful differences from the reference product. It also serves the same intended use as that of the reference biological drug and can be said to be posing a competitive constraint to it.

49. Hence, despite nominal differences, which might also exist in two different batches of the same branded biological drug, the Commission is of the considered opinion that biological drugs as well as its biosimilars form part of the same relevant product market. In the present case, the relevant product market, thus, would be the "*market for biological drugs based on Trastuzumab, including its biosimilars*".

50. With regard to the relevant geographic market, the Commission finds that the conditions of competition are homogenous across India for pharmaceutical products. Therefore, the relevant geographic market in the present case would be '*India*'.

51. Accordingly, the relevant market, in the present case, would be the "*market for biological drugs based on Trastuzumab, including its biosimilars in India*".

52. After delineation of the relevant market, the next issue to be examined is whether the Roche Group holds a dominant position within this relevant market or not. As per the information, Roche Group introduced Trastuzumab under the brand name HERCEPTIN in the year 2002. In the year 2012, it withdrew HERCEPTIN from Indian markets and introduced cheaper versions of Trastuzumab, *viz.*, BICELTIS and HERCLON. As highlighted by the Informants, till February 2014, there was no other player in the market producing a biosimilar Trastuzumab and, consequently, the market share of Roche Group was 100 % in the relevant market. Thereafter, in February 2014, IP-1 and IP-2 introduced biosimilar Trastuzumab by the names, CANMAb and HERTRAZ, respectively (approved by DCGI in October, 2013).

53. The Roche Group has argued that after the introduction of Informants' biosimilars, its market share fell down drastically and it is further decreasing with the passage of time. It is contended that the market share of IP-1 rose from 13.07% in 2014 to 24% in 2015 and that of IP-2 rose from 9.7% in 2014 to 14.6% in 2015, in terms of volume of sales, in India. On the other hand, the market share of the Roche Group had fallen to 77% in 2014 and 61% in 2015, in terms of volume of sales, in India.

54. The Commission observes that undoubtedly, after the introduction of biosimilars, the market share of Roche Group has gone down in the relevant market during 2014 and 2015. However, the allegations in the present case pertain to abusive conduct by Roche Group during the period starting from year 2013 till date. Till 2014, Roche Group had 100% market share. Although its market share fell in the year 2014; it still held a considerable market share in 2014 (83.9% in terms of value and 77% in terms of volume of sales) and 2015 (70.9% in terms of value and 61% in terms of volume of sales). Despite CANMAb and HERTRAZ being cheaper than, and allegedly as effective as, BICELTIS and HERCLON, the reduction in Roche Group's market share is not

very substantial. Moreover, market share is only one of the factors guiding determination of dominance under Section 19(4) of the Act. The Commission, thus, finds it appropriate to look into other factors enshrined under Section 19(4) of the Act, to analyse whether Roche Group holds a dominant position in the relevant market delineated above or not.

55. According to the Annual Report of OP-1 for the year 2015 (as provided in the information), it has around 91,147 employees in over 100 countries and supplies medicines and has conducted diagnostic tests in over 150 countries worldwide. It has approximately 25% of the global biological production capacity. It is also the second largest pharmaceutical company in the world by revenue. Its total revenue for the year 2015 was USD 49 billion and its net income for 2015 was USD 9.2 billion. On the contrary, IP-1 had USD 468.42 million as total revenue and USD 74.13 million as net income for the year 2015. IP-2 had USD 9.4 billion as total revenue and USD 847 million as net income for the same year. Further, the facts that Roche held the patent rights for Trastuzumab in India upto 2013, HERCEPTIN was the blockbuster drug in the market for breast cancer, Roche enjoyed the first-mover advantage in the relevant market *etc.*, add to its position of strength.

56. The dependence of consumers on an enterprise also strengthens its position. It may be noted that introduction of the biological drug, Trastuzumab, has given Roche, being its innovator, a significant edge over its competitors. Further, existing patients, who are already undergoing treatment based on the reference biological drug, would not switch to its substitutes, as the doctors may not prescribe an alternative medicine during ongoing treatment, especially considering the nature of the disease. Thus, there does not seem to be any countervailing buying power, as this is a prescription induced market where patients may not be able to pose any constraint on the dominant enterprise.

57. It is also noted that there are high entry barriers in the said market, which makes the position of Roche Group even stronger. There is significant cost, time and expertise involved in the development of biosimilar Trastuzumab. Further, there are significant regulatory approvals which are required to be obtained for the development, manufacturing/import and marketing of a drug. Thus, it *prima facie* appears that this market is characterised by high entry barriers.

58. On the basis of the aforesaid factors, *i.e.*, market share, size and resources of Roche Group, dependence of the consumers, absence of countervailing buying power and high entry barriers, it *prima facie* appears that Roche Group is dominant in the relevant market and can operate independently of the market forces.

59. The Informants have highlighted a series of allegations against Roche Group. It is alleged that Roche Group has 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.

60. The Commission observes that in the pharmaceutical industry, apart from pricing strategies, firms also indulge 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:

(a) Rendering rivals' products incompatible without adding any technical improvement to the replaced product;
(b) Indulging in vexatious litigation purely aimed at harassing rivals;
(c) Influencing government or regulatory procedures; and

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

61. However, the aforesaid conduct needs to be analysed carefully, as every enterprise, including a dominant enterprise, as a matter of right, is entitled to petition public/regulatory bodies and courts to gain an advantage that may be legitimately available to it under any legal and regulatory architecture. Further, competitive strategy adopted by an entity aimed at strengthening its own position is permissible under the Act. The Commission has, thus, analysed each allegation with regard to the alleged abusive practices adopted by Roche Group, in the subsequent paragraphs.

62. The first allegation is with regard to the Civil Suit filed by Roche Group before the Hon'ble Delhi High Court on 04th February 2014, which, as per the Informants, amounts to vexatious litigation. The Commission observes that the right to bring civil litigation and other claims to assert or defend key interests is a legal right. Such right should not be interfered with, except when warranted by special circumstances. Mere fact that litigation was ultimately unsuccessful does not render it vexatious. However, in exceptional cases, the legal processes can be pursued by a dominant enterprise as a tactic to exhaust smaller rivals' resources and delay or prevent their entry in the relevant market. Where anticompetitive litigation of this kind by a dominant enterprise is identified, it amounts to an abuse within the meaning of the Act. Though there cannot be any straightjacket formula for identifying such exceptional circumstances, there can be certain guiding factors which may help in examining a case. *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.

63. In this regard, the Informants have relied upon certain decisions of other competition authorities. It was submitted that in *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc. [508 U.S. 49 (1993)*], the U.S. Supreme Court noted:

> *"although those who petition government for redress are generally immune from antitrust liability, (Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464) 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…[t]o 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 this 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, (Noerr, supra, 365 U.S., at 144, 81 S.Ct., at 533), through the "use [of] the governmental process-as opposed to the outcome of that process – as an anticompetitive weapon'" (Columbia v. Omni Outdoor Advertising, Inc., 499 U.S. 365, 380, 111 S.Ct. 1344, 1354, 113 L.Ed.2d 382). This two-tiered process requires a plaintiff to disprove the challenged lawsuit's legal viability before the court entertain evidence of the suit's economic viability."*

64. Further, the Informants have also relied upon the decision of the European Commission in *AstraZeneca* (*COMP/A.37.507/F3*) to argue that the civil suit filed by Roche Group amounts to vexatious litigation and therefore, an abuse of Roche's dominance. In the said decision, the European Commission has observed that the '*use of public procedures and regulations, including administrative and judicial processes, may also, in specific circumstances, constitute an abuse, as the concept of abuse is not limited to behavior in the*

market only and misuse of public procedures and regulations may result in serious anticompetitive effects on the market'.

65. Placing reliance on these case laws, the Informants have argued that Roche Group has attempted to affect the successful entry of almost all biosimilars by initiating legal proceedings against companies who sought requisite approvals to launch such biosimilars in the Indian market. The Commission notes that to render a litigation or legal recourse an abusive strategy, it needs to be first established that such legal recourse by the dominant entity has no objective basis and can only be explained as an instrument of harassment to the competitor. In this regard, it is noted that the Civil Suit filed by Roche Group against the Informants has been pending before the Hon'ble Delhi High Court for almost 3 years and has not reached any finality yet. There are interim orders *vide* which certain reliefs have been granted to Roche Group. *Vide* an order dated 25th April, 2016, the Single Judge granted certain interim relief to Roche Group. However, on an appeal filed by the Informants, the Division Bench, *vide* its order dated 28th April, 2016, *inter alia* directed that "*the position, as obtaining on 24th April, 2016 (i.e. prior to the issuance of the impugned judgment dated 25th April, 2016) shall continue to operate till the next date of hearing*". This order of the Division Bench is currently under challenge. Considering the long drawn legal battle between the parties before the Hon'ble Delhi High Court, the Commission is reluctant to hold that the litigations filed by Roche Group are baseless. Recourse to legal proceedings, being a right of every party, cannot be concluded to be tainted with ulterior motives as a general principle. Such determination has to come sparingly in exceptional circumstances and the Commission is not convinced that any such circumstance has arisen in this case. Thus, for the foregoing reasons, the allegations of the Informants with regard to vexatious litigation are, *prima facie*, found to be without merit.

66. The next allegation pertains to Roche Group influencing regulatory authorities, which has allegedly resulted in denial of market access to the Informants. In support of this allegation, the Informants have submitted various letters written by Roche Group to regulatory authorities, such as:

(i) Letter dated 11th October, 2013 to DCGI;
(ii) Letter dated 10th June, 2015 to DCGI and State Drugs Controller, Karnataka;
(iii) Letter dated 22nd September, 2015 written to the Ministry of Health and Family Welfare; and
(iv) Letters dated 18th March, 2016 and 28th April, 2016 to NPPA, *etc.*

67. The contents of these letters have already been stated in the preceding paragraphs, and the same are not discussed again for the sake of brevity. *Vide* these letters, Roche Group has raised concerns regarding the clinical trials undertaken by the Informants for biosimilars and has tried to influence DCGI and other authorities. It has also tried to create a perception that biosimilar versions of the Informants' drugs may, "*pose potential unknown risks to patients*".

68. In this regard, it may be relevant to take into account the decision of the General Court in *AstraZeneca v. Commission* (T-321/05) case, wherein it was held that the submission to public authorities of misleading information, which was liable to lead them into error, is not competition on the merits and is not keeping with the special responsibility of dominant firms. It was further confirmed that such practices would be considered as capable of restricting competition by their nature and therefore, proof of competition actually being affected as a consequence thereof would not be required. On appeal to the European Court of Justice (*AstraZeneca v. Commission*, C-457/10 P), it was held that such an approach '*is manifestly not consistent with competition on the merits and the*

specific responsibility on such an undertaking not to prejudice, by its conduct, effective and undistorted competition'.

69. The Informants have claimed that Roche Group has handed out copies of various orders in the Civil Suit, which were in its favour, to such authorities without providing the subsequent or preceding orders, which go against them, thereby creating misinformation about the Civil Suit and misleading doctors and through them, the patients. A letter dated 03rdJune, 2016, sent by Roche to the Stores Officer of AIIMS, conveyed only the Learned Single Judge's Order dated 25th April, 2016, without disclosing the subsequent order of the Division Bench dated 28th April, 2016. This would typically give a public or medical authority the impression that the use of biosimilars are prohibited pursuant to the Learned Single Judge's Order dated 25th April, 2016, which evidently is not the case, given the relief granted to the Informants by the order dated 28th April, 2016 by the Division Bench of the Hon'ble Delhi High Court.

70. It is also alleged that Roche Group has indulged in negative advertisements aimed at denigrating competing products, *i.e.* biosimilars, which amounts to anti-competitive conduct. The Informants have claimed that doctors have been informed by Roche or its representatives that biosimilars are unsafe, that IP-1 and IP-2 have not followed the required procedures under the Biosimilar Guidelines 2012, and that the number of patients used by IP-1 and IP-2 for clinical trials were too few to make a proper assessment of biosimilars' safety and efficacy. The Informants have further contended that doctors have been cautioned on the serious repercussions of prescribing CANMAb, if any adverse consequences are faced by a patient, which was further escalated when doctors were told that they may be held liable for prescribing the Informants' drugs, despite the pending Civil Suit. The Informants also apprehended that doctors have been warned that the Hon'ble Delhi High Court may at any point, injunct the supplies of CANMAb, in which case the supplies of CANMAb will stop

abruptly. The Informants have filed an Affidavit in support of these apprehensions.

71. The Commission has perused each and every letter/communication in light of the allegations made by the Informants and the justifications offered by the Roche Group. It is observed that Roche Group has not challenged the veracity of any of the letters/communications relied upon by the Informants. However, it has countered the allegations stating that such letters/communications can, at the best, be labelled as an expression of opinion or statement of facts or benign marketing strategy adopted by every player, which cannot be held to be anti-competitive.

72. The Commission observes that it is well-acclaimed and acknowledged that introduction of generics intervenes with the monopoly position of an innovator/originator drug and infuses competition in the market. This competition not only brings affordability because of reduced prices but also ensures accessibility. However, since competition intervenes with the monopoly position of the innovator drug, such innovator often resorts to strategies to delay or oust the entry of generics/bio-similars. While efforts aimed at meeting competition on merits, *e.g.* reducing prices, improving quality by introducing improved drugs that leave the generic/bio-similar entrants behind, are certainly legitimate under the Act, resorting to anti-competitive strategies to distort genuine competition go against the very aim that competition law seeks to achieve.

73. Roche Group has submitted that the objective of the Act is not to protect any individual competitor but to protect competition in the market. The Commission fully agrees that the Act is aimed at protecting and promoting competition in the market. However, Roche's conduct is inconsistent with the assertions made by it. Two of Roche's competitors, IP-1 and IP-2, have approached the Commission alleging anti-competitive conduct adopted by Roche Group. They have argued

that Roche Group has not left any stone unturned to evade their entry and/or penetration in the relevant market. They have highlighted various strategies adopted by Roche Group to influence regulatory and other authorities in its favour. When they were not successful in evading entry, Roche Group has approached doctors, hospitals, tender authorities, *etc.,* to influence their perception about the efficacy and safety of the Informants' products. The Commission is conscious that competitors, in normal business parlance, indulge in tactics to belittle competitors' products. However, there is difference between puffery aimed at promoting one's own product and adopting practices which disparage or malign the image of competitors, thereby causing competitive disadvantages to them. This is even more harmful in the pharmaceutical sector, where such disparagement is made to the doctors who are treating the patients of cancer. The line of difference between these two business strategies is very thin, however, when crossed by a dominant enterprise to its own illegal advantage, it warrants intervention by the competition authority.

74. It, thus, *prima facie* appears to the Commission that Roche Group has tried to influence regulatory authorities, especially with regard to intimating the Hon'ble Delhi High Court Single Judge's Order dated 25th April, 2016, fully knowing that there existed a Division Bench order of the same court, which reinstated the position prevailing prior to issuance of the Single Judge's order dated 25th April, 2016. The Commission is conscious that the Roche Group has challenged the regulatory approvals granted to the Informants by DCGI before the Hon'ble Delhi High Court in the Civil Suit. However, as things stand today, the Informants have valid approvals granted by DCGI, which have neither been revoked by DCGI nor have been held to be wrongly granted, by any court. 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.

75. The letters/communications sent to hospitals, authorities such as DCGI, NPPA or tender authorities or representations made before doctors regarding safety issues in case of biosimilars in general and of the Informants' drugs in particular, may not have individually affected the market for Informants' drugs. However, when seen collectively in the background of surrounding facts and circumstances, they only appear to be a part of the bigger plan/strategy of Roche Group to eliminate competition posed by biosimilars to Roche's products in the relevant market.

76. Each such letter/communication to the medical fraternity may have a cumulative effect of foreclosing the market for biosimilars. Further, Roche Group has admitted that biosimilars are different from generics, which are identical copies of the branded drugs. Being developed from plant/animal cells, biosimilars can never have identical characteristics even if they are equally efficacious and safe, as compared to a reference biological drug. In such a scenario, any denigration of a biosimilar drug may have far reaching ramifications.

77. During the hearing, Roche Group has also argued that the Informants' drugs have already been approved and their market shares are growing substantially. The Commission is cognizant that the Informants' drugs have received approvals from DCGI, despite the attempts made by Roche Group and they were able to enter the market. The same, however, does not rule out the possibility of Roche's actions amounting to denial of market access. 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 of Section 4(2)(c) of the Act. With regard

to the Informants' market shares, which Roche Group has claimed is substantial, the Commission observes that, at this stage, it is very difficult to ascertain the impact of Roche Group's strategies on the market shares of the Informants. It is a subject matter of investigation as to whether their market shares could have been higher absent the alleged anti-competitive strategies adopted by Roche Group.

78. We are dealing with a case which involves a highly sensitive sector, where the safety of the patient is of paramount importance. Thus, creating any iota of doubt in the minds of doctors can adversely affect the market for biosimilars, which is prescription induced, beyond repair. Such disparagement may also have ripple effects within the medical community. In this scenario, those biosimilar manufacturers who do not have strong marketing channels amongst doctors may be forced out of the market because of abusive denigration by a dominant player.

79. The Commission further notes that a dominant enterprise is endowed with a special responsibility not to allow its conduct to impair undistorted competition in the relevant market. The Act places special responsibility on such enterprise not to conduct its business in a manner which isprohibited under Section 4(2) of the Act. *Prima facie*, it appears to the Commission that Roche Group has shirked such responsibility and indulged in abusive conduct.

80. With regard to the Informants' allegation on unfair pricing under Section 4(2)(a)(ii) of the Act, the Commission is *prima facie* not convinced that a case is made out against the Roche Group. Being the innovator, it might have invested huge sums on research and development of Trastuzumab. Thus, initial high prices can be attributable to being the reward for innovation. Further, it subsequently introduced cheaper versions in the market *viz.* BICELTIS/HERCLON. The Informants have also alleged leveraging on the part of Roche Group. In this regard, the Commission notes that it has taken the *prima*

facie view that the relevant market in the instant case is '*market for biological drugs based on Trastuzumab, including its biosimilars in India*' and the impugned conduct of Roche Group therein amounts to contravention of Section 4(2)(c) of the Act. Thus, at this stage, the Commission does not find it relevant to deal with the alleged contravention of Section 4(2)(e) of the Act, which would arise only in case of delineation of narrower relevant markets as defined in the information *i.e.*'market of sale for biological drugs (including biosimilars) used in the targeted therapy of HER-2 positive metastatic breast cancer within the territory of India', 'market of sale for biological drugs (including biosimilars) used in the targeted therapy of HER-2 positive early breast cancer within the territory of India' and 'market of sale for biological drugs (including biosimilars) used in the targeted therapy of HER-2 positive metastatic gastric cancer within the territory of India'. However, the *prima facie* determination of the Commission in this order regarding the relevant market and abuse therein shall not preclude the DG from delineating narrower relevant markets on the basis of investigation into relevant facts and also examine whether the impugned conduct of Roche Group constitutes a contravention of Section 4(2)(e) of the Act. With regard to the Informants' allegation under Section 4(2)(a)(i) of the Act, Roche Group has claimed that it is its prudent business strategy not to import 150 mg vials of BICELTIS / HERCLON. The Commission agrees with the assertion made by Roche Group and hence, *prima facie*, does not find any imposition of unfair condition in that and accordingly, does not find any contravention under Section 4(2)(a)(i) of the Act.

81. Based on the foregoing analysis, the Commission is of the considered view that *prima facie*, the contravention with regard to Section 4(2)(c) of the Act is made out against Roche Group, which warrants detailed investigation into the matter. The DG is, thus, directed 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, within 60 days.

82. It is, however, made clear that nothing stated herein shall tantamount to an expression of final opinion on the merits of the case and the DG shall conduct the investigation without being influenced by any observations made herein.

83. The Secretary is directed to send a copy of this order, alongwith the information and the documents filed therewith, to the DG.

Sd/-

(Devender Kumar Sikri)
Chairperson

Sd/-
(S. L. Bunker)
Member

Sd/-

(Sudhir Mital)
Member

Sd/-

(Augustine Peter)
Member

Sd/-

(U. C. Nahta)
Member

Sd/-

(Justice G.P. Mittal)
Member

New Delhi
Dated: 21/04/2017