* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

% *Judgment pronounced on : April 25, 2016*

\+ **I.A. Nos.2371/2014, 2988/2014, 2990/2014, 4649/2014, 4677/2014, 5956/2014, 14533/2014, 11224/2015, 12830/2015, 12862/2015, 16703/2015, 16704/2015 & CCP(O) No.69/2015 in CS(OS) No.355/2014**

ROCHE PRODUCTS (INDIA) PVT LTD & ORS ..... Plaintiffs

Through Mr.Rajiv Nayar and Mr.Sandeep Sethi, Senior Advocates with Ms.Niti Dixit, Mr.Darpan Wadhwa, Ms.Samiksha Godiyal, Mr.N. Mahavir, Ms.Roshni Namboodiry, Mr.Tanmay Singh, Mr.Anugrah Robin Frey, Advs.

versus

DRUGS CONTROLLER GENERAL OF INDIA AND ORS

..... Defendants

Through Mr.Sanjay Jain, ASG with Mr.Amit Mahaan, CGSC and Mr. Krishanu Barua, Adv. for D-1/UOI.

Mr.Harish Salve, Dr.Abhishek M. Singhvi and Mrs.Pratibha M. Singh, Senior Advocates with Mr.Vijay K. Sondhi, Mr.Mayank Grover, Ms.Cauveri Birbal, Mr.Anshul Sehgal, Mr.Arjun Sawhney, Ms.Pallavi Sharma & Ms. Suhasini Raina, Advs. for D-2.

Dr.C.S Vaidyanathan and Mr.Amit Sibal, Senior Advocates with

Mr.Nirupam Lodha, Ms.Gayatri Roy, Mr.Ayush Dhawan and Ms. Rhyea Malik, Advs. for D-3 & 4.
Ms. Rameshwari, Adv. for intervenors in I.A. No.3955/2015

CORAM:
HON'BLE MR.JUSTICE MANMOHAN SINGH

MANMOHAN SINGH, J.

1. The plaintiffs filed the present suit for injunction against four defendants. By this order, I propose to dispose of the abovementioned pending applications.

2. The plaintiff No.1, Roche Products (India) Private Limited, a company incorporated under the Companies Act, 1956, as amended (the "Companies Act"), is an affiliate of plaintiff No.2, and is the importer and marketer of innovator molecule Trastuzumab in India. Trastuzumab is stated to be a biological drug used primarily for the treatment of HER 2 positive breast cancer. In India, Trastuzumab is sold under the brand names HERCEPTIN®, HERCLON™ and BICELTIS®. It is stated that Trastuzumab has become the accepted biological treatment for HER 2 positive breast cancer on a worldwide basis and enjoys a global reputation.

Plaintiff No.2, F. Hoffmann-La Roche AG, a joint stock company incorporated under the laws of Switzerland is an affiliate of plaintiffs No.1 and 3, and the manufacturer of innovator molecule Trastuzumab. Plaintiff No.3, Genentech Inc., a corporation incorporated in the State

of Delaware, USA, is an affiliate of plaintiff No.2. Plaintiff No.3 is the innovator of the biological drug Trastuzumab and is the only entity worldwide entitled to claim the right to manufacture the biologic Trastuzumab. It is also the registered proprietor of the trademark HERCEPTIN® worldwide (including India). Plaintiff No.3 obtained registration of the trade mark HERCEPTIN® in India under Class 5 - Registration No. 358259 dated April 23, 2005 valid up to October 9, 2018.

Plaintiff No.3 was granted a secondary, formulation patent in relation to Trastuzumab from the Controller General of Patents, in India, which was effective from May 3, 1999 and it has been lapsed on May 3, 2013. All the three plaintiffs hereinafter collectively referred to as the "plaintiffs".

3. Defendant No.1, the Drug Controller General of India, Central Drugs Standard /Control Organization, Ministry of Health and Family Welfare, Government of India, is responsible for the approval of new drugs under the Drugs and Cosmetics Act, 1940, as amended (the "Drugs Act") and the rules framed thereunder. (hereinafter referred to either defendant No.1 or DCGI)

The defendant No.2, Biocon Limited, a company incorporated under the Companies Act, with its registered office at Bangalore, Kamataka - 561229, is a co-developer of a purported biosimilar version of Trastuzumab, along with defendant No.3, Mylan Inc., a corporation incorporated in the State of Pennsylvania, USA, with its principal office at Pennsylvania 15317, USA, who conducts business in India, through

Mylan Pharmaceuticals Private Limited (defendant No.4 herein), Mylan Laboratories Limited and Mylan Laboratories India Private Limited. Defendant No.2 after filing of the suit markets its purported biosimilar Trastuzumab in India under the brand name CANMAb.

4. Defendant No.4, Mylan Pharmaceuticals Private Limited, a company incorporated under the Companies Act, with its registered office at Mumbai, is a subsidiary of defendant No.3 and pursuant to the co-development agreement between defendant No.2 and defendant No.3, has now launched a purported biosimilar version of Trastuzumab in India under the brand name HERTRAZ. Defendants No.1, 2, 3 and 4 are hereinafter (referred to as the "defendants").

5. Originally the suit was filed on account of imminent threat of the introduction of purported biosimilar version of plaintiff No.3's biological drug Trastuzumab, which is claimed to have been jointly developed by defendants No.2 and 3, under the brand names CANMAb (150 mg/440 mg) by defendant No.2 and HERTRAZ (150 mg/440 mg) by defendant No.1. CANMAb and HERTRAZ are together referred as the defendants' drugs. It was the plaintiffs' contention at that time that the defendants' drugs are, inter alia, being misrepresented as "Trastuzumab", "biosimilar Trastuzumab" and a biosimilar version of HERCEPTIN® without following due process in accordance with the Guidelines on Similar Biologics for the purpose of obtaining appropriate approvals.

6. The pleadings in the interim applications and in the main suit are almost same. Thus, the facts are narrated from the pleadings of the main suit.

Brief facts as per unamended plaint

7. In 1990, plaintiff No.3 developed a biological drug containing the active ingredient Trastuzumab, a monoclonal antibody, which is used primarily in the treatment of HER 2 positive breast cancer. Biological drugs are synthesized by cells or living organisms as opposed to chemical drugs which are produced by chemical synthesis.

7.1 It is claimed that between 1992 and 1998, extensive clinical trials (Phase I, Phase II and Phase III) were carried out by plaintiff No.3 to test the safety and efficacy of Trastuzumab. Trastuzumab has received manufacturing and marketing approvals worldwide after rigorous tests to confirm its safety and efficacy.

7.2 Among other approvals, Trastuzumab was approved by the U.S. Food and Drug Administration in September 1998 and by the European Medicines Agency in August 2000. This biological drug has been sold by the plaintiffs worldwide since 1998, inter alia, under the well-known trademark HERCEPTIN®.

7.3 The medical community has become accustomed to associating Trastuzumab for treatment of HER 2 positive breast cancer with the plaintiff No.3's trademark HERCEPTIN®. As a result, the brand "HERCEPTIN®" has acquired extensive goodwill and a distinctive reputation. In India, the innovator molecule Trastuzumab has been

marketed under one of the brand names HERCEPTIN® for almost 12 years. HERCEPTIN® has been recognised as a targeted therapy for the treatment of HER 2 positive breast cancer.

Further, under a brand user agreement with plaintiff No.2, Emcure Pharamceuticals Limited distributes Trastuzumab in India under the brand name BICELTIS®. Plaintiff No.3 is the registered proprietor of BICELTIS® in India (under Class 5-Registration No. 945910 dated February 22, 2011 valid up to April 23, 2019).

7.4 The plaintiffs obtained approval for the import and marketing of innovator Trastuzumab in India in the year 2002. The said approval was granted by the defendant No.1 on October 11, 2002 under Rule 122A of the Drugs and Cosmetics Rules, 1945, as amended (for short "the Drugs Rules"). Trastuzumab is presently imported into India by plaintiff No.1 from the manufacturing facilities of plaintiffs No.2 and 3.

7.5 The plaintiffs were the first to introduce a targeted treatment for the patients of HER 2 positive breast cancer with the launch of HERCEPTIN® in 1998. HERCEPTIN® has a well-established and documented track record of quality, safety and efficacy; has become the accepted biological treatment for HER 2 positive breast cancer, a particularly aggressive form of the disease, on a worldwide basis and enjoys a global reputation. It is now the standard of care for women with HER 2 positive breast cancer.

7.6 As per averments, the plaintiff No.2's Annual Reports for the years 2011, 2012 and 2013, the global sales for HERCEPTIN® were as follows:

Year	Sales in US$
2011	5.7 billion
2012	6.4 billion
2013	6.75 billion

Case set up by the Plaintiffs against the Defendants

8. It is alleged in the plaint that defendants No.2 and 3 have stated in their press statements that they have entered into an exclusive strategic collaboration for the development, manufacturing, supply and commercialization of multiple, high value generic biologic compounds for the global marketplace. According to the terms of this collaborative arrangement available in the public domain, thus defendant No.3 has exclusive commercialization rights in respect-of the purported "biosimilar" drug in the USA, Canada, Australia, New Zealand including India; defendants No.2 and 3 enjoy co-exclusive commercialization rights with each other. As a part of the collaborative arrangement between them, defendants No.2 and 3 have purportedly jointly developed a drug which they claim is biosimilar to Trastuzumab. Based on press releases issued by defendants No.2 and 3. Defendant No.2's press release specifically states that CANMAb will become available in India in the first week of February 2014. Further, defendant No.3's press release refers to the imminent launch of HERTRAZ.

9. It is averred in the plaint that under the procedure for the approval of new drugs by defendant No.1 in India, after NDAC (NEW DRUGS ADVISORY COMMITTEE) has reviewed an application for a new drug and given its recommendation, on 18th October, 2013 it refers such application to a Technical Committee (the "TC"), along with its recommendation, for consideration. After the TC has endorsed the recommendation made by NDAC, it refers the application to the Apex Committee, and only after both TC and the Apex Committee have endorsed the recommendation of the NDAC, should defendant No.1 consider granting its approval to such application. This is usually a time consuming process and the consideration by the NDAC, the TC and the Apex Committee is unlikely to be completed in a short span of five days i.e. on 23rd October, 2013. The undue haste with which the approval was granted by defendant No.1 suggests that all factors relevant to the approval of a biosimilar drug under the Guidelines on Similar Biologies and under other internationally recognised standards were not taken into consideration at the time of granting such approval. It is also uncertain whether the TC and the Apex Committee were provided an opportunity to endorse the NDAC's recommendation before approval was granted by defendant No.1. In the European Union, while defendant No.3 started Phase III clinical trials for a purported biosimilar Trastuzumab on November 27, 2012, no approval for such purported biosimilar has been granted as yet. It is stated in the unamended plaint that the plaintiffs reserve their right to challenge the marketing authorisation granted by defendant No.1 to defendant No.2.

10. In the subsequent paras of the plaint, it is stated that the defendants No.2 to 4 have made many misrepresentations to the public about the approvals and making their product without any basis. The said approvals are contrary to guidelines of biosimilar and in breach of provisions. The proposed drug of the defendants is mis-branded drug.

Main defence as per written statement by defendant No.1

11. In its written statement, the defendant No.1 alleged that due procedure has been followed for Grant of approval to defendant No.2 to manufacture and / or import new drugs including vaccines and Recombinant DNA derived products are governed under the regulatory provisions as provided in the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. There is a specific provision in the Schedule under which the toxicological and clinical data requirements for grant of permission of new drugs or to undertake clinical trials, may be abbreviated, deferred or omitted, as deemed appropriate by the Licensing Authority. The defendant No.2's application for manufacture of its drug was in conformance with the statutory requirements as contained in the relevant rules read with schedule Y. Under the Drugs & Cosmetics Act & Rules, the term "Similar Biologics" has not been defined. However, the defendant No.1 along with the Department of Bio Technology has prepared "Guidelines on Similar Biologics: Regulatory Requirement for Marketing Authorization in India" in the

year 2012. These guidelines are not statutory under the Drugs and Cosmetics Act and the Rules made thereunder.

11.1 At the time of application made by the defendant No.2, neither the firm applied for permission to conduct Phase I and Phase II clinical trials nor these were necessary as per requirement specified in the Drug Act and Rules. However, the defendant No.1 is obliged to strictly act in terms of relevant provisions of the Drugs and Cosmetics Rules, in particular the provisions of Rules Rule-122 A, 122B & 122D. In terms thereof, no new drug shall be imported or manufactured except under, and in accordance with, the permission granted by the Licensing Authority as defined in clause (b) of Rule 21 (i.e. DCGI). Apart from the procedure and safeguards specified in the Drugs and Cosmetics Rules, in case of products produced by recombinant technology, prior approval of RCGM (Review Committee on Genetic Manipulation) under Department of Biotechnology is required before granting the clinical trial permission by the office of Drugs Controller General India.

It is submitted that the applications for approval for manufacture/import of new drugs are evaluated in consultation with New Drug Advisory Committees or Investigational New Drug Committees as the case may be. The Technical Committee and Apex Committee are involved only for the evaluation of proposals for conduct of clinical trial and not for evaluation of any proposal for approval of new drugs for manufacture and market in the country.

11.2 As far as **Trastuzumab,** being a monoclonal antibody, is concerned, it is produced by recombinant DNA technology. The drug is indicated for the treatment of patients with metastatic breast cancer. M/s Roche Switzerland is the innovator of the drug. The innovator's drug is being marketed globally in various countries under different brand names viz. "Herceptin", **"Herclon" or "Biceltis".** The drug Trastuzumab is already listed in United States Pharmacopeia which is a book of standard for drug followed in the USA and Martindale-the complete drug reference which provides details of various drugs. It is denied by the defendant No.1 that there was any deviation from the statutory requirements or that there was any undue haste in dealing with the defendant No.2's application for manufacture of its drug.

11.3 It is also pleaded in the written statement that under Rule 122 DC, “any person aggrieved by an order passed by the licensing authority under this part, may within 60 days from the date of such order, appeal to the Central government, and the Central government may after such enquiry into the matter as is considered necessary, may pass such order in relation thereto as it thinks fit". In terms of the provision, it is open for the plaintiffs to invoke the said provision and file an appeal with the Central government. Instead of doing so, the plaintiffs have approached the court without exhausting the statutory remedy.

11.4 The original plaint does not seek any relief against the defendant No.1 qua the permission to manufacture granted by it to the defendant No.2. A bare averment has been made that "the plaintiffs

reserve the right to challenge the marketing authorisation granted by defendant No.1 to defendant No.2." The pleas regarding alleged infirmities in the procedure adopted by the defendant No.1 for granting permission to manufacture to the defendant No.2. From the conduct of the plaintiffs, it is evident that the plaintiffs have sought monopoly and to interfere with the statutory prerogatives conferred on defendant No.1 to grant permission to manufacture for the drug in question, such actions on the part of the plaintiffs are contrary to public interest. The price of the plaintiffs' product is high and there is no justification for blocking other potential manufacturers in the guise of absurd interpretation/application of statutory provisions. These are the main defences raised by the defendant No.1 who has also dealt with each paras of the plaint in its written statement.

The defence of defendant No.2 as per written statement.

12. Several pleas raised by defendants No.2 to 4 are common as pleaded by the defendant No.1 by filing of separate written statements. For the sake of brevity, the same are not repeated. It is stated in the written statement filed by the defendant No.2 that it has been granted all the requisite approvals, as per law, for manufacturing and marketing its bio-similar drug CANMAb, by the defendant No.1/Approving Authority after the drug CANMAb has being evaluated under the stringent tests and procedures laid down under applicable laws. At the stage of the approval process, the Expert Committees having technical experts in multiple fields including in the field of Quality, Efficacy and Safety, have undertaken in-depth evaluation and recommended to the

appropriate licensing and regulatory authorities for approval of the defendant's drug. The approval process involved review by the independent IBSC expert member, Multidisciplinary experts in RCGM, DCGI, the Medical experts in Ethics Committee, the Oncology experts in NDAC and the State Licensing Authority. Further, NDAC (New Drug Advisory Committee) comprising of renowned oncologists from leading hospitals all over India have monitored and approved the results establishing similarity between Bmab-200/ CANMAb and plaintiffs' drug HERCEPTIN.

The entire basis of the approvals granted to Bmab-200/CANMAb was on the basis that the said drug successfully established bio-similarity to Herceptin in terms of safety, efficacy and quality. The defendant No.2 is entitled to refer to its drug Bmab-200/CANMAb by its International Non Proprietary Name (hereinafter referred to as the "INN") i.e. `Trastuzumab'. The defendant No.2 is entitled to claim as similar to the 'Reference Product i.e. Herceptin and bio-similar to Trastuzumab marketed as Herceptin.

12.1 The 2012 Guidelines on Similar Biologics (hereinafter referred to as the "2012 Guidelines") are not statutory. Notwithstanding the fact that the said guidelines merely consolidate the existing regime and procedure for approval of a similar biologic under the Drugs Act and Drugs Rules and are only for the purpose of providing guidance to the pharmaceutical industry. The process took over 5 (five) years for the defendant to undergo the entire procedure and to obtain the

manufacturing and marketing approval for its bio-similar drug Bmab-200/CANMAb. The entire procedure was regulated, supervised and approved by experts having scientific and technical knowhow. Therefore the plaintiffs cannot allege that the said authorizations *"could not have been"* in accordance with law.

12.2 It is admitted that during the course of obtaining approvals for conducting Phase III trials, the defendant No.1 vide letter dated May 03, 2011 sought a justification from the defendant No.2 for directly carrying out Phase III trial without any Phase I/II trial. After response by exercising its discretion under Sub-Rule 3 of Rule 1 of Schedule Y of the Drugs Rules, the defendant No.1 by its letter dated August 19, 2011 granted permission to the defendant No.2 to directly conduct the Phase III trial. Thus, there has been no omission in not conducting or registering Phase I and Phase II trials. In fact the defendant No.2 conducted a combined study of Phase I and Phase III trial after obtaining requisite permission from the defendant No.1. It was also denied that the marketing approval was granted in haste.

12.3 It is alleged that Reference Product i.e. Herceptin of plaintiffs by the defendant cannot be said to constitute an action of passing off. The instant case is not a case where any confusion is created as to the source and hence no action for passing off is made out. An action for passing off is not maintainable as the defendant No.2 nowhere represented or misrepresented its drug to be of the plaintiffs. The defendant has only made statements like *"CANMAb, jointly developed*

by Biocon and Mylan under a global partnership, is the world's first biosimilar version of Herceptin". Such statement was made with honest and bonafide practices to convey that there are two different drugs in the market which come from two independent sources and the defendant's drug CANMAb is a product which is 'like' plaintiffs' drug Herceptin.

12.4 The defendant No.2's drug is biosimilar to the plaintiffs' Herceptin as the defendant No.2 has established comparable safety, efficacy and quality with the Reference Product- Herceptin is justifiable after the grant of an approval to the defendant No.2 to manufacture and market the Bmab-200/ CANMAb by the defendant No.1, therefore the plaintiffs are not entitled to any relief. A reference to the reference biologic is necessary for the understanding of the prescribing oncologists, doctors, dispensing chemists as also the patients. Hence the defendant No.2's drugs cannot create confusion regarding the nature of the drug and cause patients and medical practitioners to use the drug incorrectly.

12.5 There is a bar to the jurisdiction of Civil Court for monitoring and governing the process and procedure for obtaining requisite approvals in relation to the drug in dispute once the remedy to challenge the approvals as granted is available with the plaintiffs. Rule 122 DC of the Drugs Rules provides for a remedy to any person aggrieved by an order of the Licensing Authority/ Approving Authority

to challenge the grant of approvals. The suit for injunction is not maintainable.

The plaintiffs in the present suit with the sole motive of stifling competition under the garb of public safety and health for an illegitimate and mischievous attempt to retain monopoly by the plaintiffs over sale of its drug(s) HERCEPTIN, HERCLON and BICELTIS.

12.6 The reason behind the present suit is that for many years the plaintiffs had been the only manufacturer for the drug used in the treatment of HER2 positive metastatic breast cancer and therefore enjoyed a monopoly over the pharmaceutical industry in this segment. But soon after the defendant No.2's announcement on a similar drug, the plaintiffs realized that they will no longer enjoy the monopoly and control over the treatment of HER2 metastatic breast cancer, therefore, in order to maintain the monopoly and restrict the entry of the defendant's drug, the plaintiffs filed the present suit under the garb of lack of approvals.

The defence as per written statement of defendants No.3 and 4

13. In addition to the written statement of defendants No.1 and 2, it is alleged that the entire suit is entirely speculative and nothing more than a fishing expedition, the plaintiffs do not have any *locus standi* to initiate and prosecute the present civil action before a court of law. It is submitted that the Drugs and Cosmetics Act, 1940 ("Drugs Act") does

not create any civil right of action in the plaintiffs. The present suit is barred by law.

13.1 Defendant No.3 is one of the world's leading generics and specialty pharmaceutical companies and defendant No.4 is its Indian subsidiary. The defendant No.2 is a company engaged in the business of manufacturing biotechnological products that cater to the healthcare segment. Defendant No.2, in collaboration with defendant No.3, has developed a biosimilar trastuzumab, the International Non-proprietary Name (as recognized by the World Health Organization) for a biological molecule used primarily for the treatment of HER-2 positive breast cancer.

13.2 The relief of passing off is not sustainable in the nature i.e. to restrain the defendants from "relying upon or otherwise referring to HERCEPTIN®.." or "relying upon or otherwise referring to data relating to Trastuzumab marketed as HERCEPTIle" or "claiming any similarity with HERCEPTIN®."

14. When the suit and applications were listed before Court on first date i.e. 5th February, 2014, after hearing, limited interim order was passed against the defendants No.2 to 4 and they were restrained from relying upon or otherwise referring to HERCEPTIN®, HERCLON™ or BICELTIS® or any 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 the

defendants' drugs, i.e. CANMAb and HERTRAZ and from claiming any similarity with HERCEPTIN®, HERCLON™ or BICELTIS®.

15. The order dated 5th February, 2014 was challenged by the defendants No.2 to 4 by filing two appeals under Order XLIII read with Section 151 CPC and Section 10 of Delhi High Court Act, 1966, being FAO (OS) 91/2014 and FAO (OS) 92/2014, which were listed before the Division Bench and disposed of on 14th February, 2015 by direction to hear the interim application and application filed by defendants No.2 to 4 which were ordered to be treated as applications under Order XXXIX Rule 4 CPC on behalf of the appellant and they be re-numbered as such. The matters be listed before the learned Single Judge today itself at 2:15 pm."

16. By order dated 14th February, 2014, the earlier order passed by the Court on 5th February, 2014 was modified to the extent that if defendant No.2 has already obtained the approval of Package Insert in question, the same can be used as the interim applications were under consideration, however, it was clarified that the remaining interim order already passed would continue. The order was modified for the reason as the statement was made on behalf of defendant No.2 that on 13th December, 2013 the defendant No.2 also obtained the approval from the Drugs Controller General of India with regard to the Carton, Labels and Package Insert.

17. During the completion of hearing of interim applications, large number of applications are filed by both parties in view of subsequent

events i.e. for discovery of documents, rejection of plaint, contempt petitions, amendment of plaint. The matter was heard from time to time wherein common submissions were advanced by the parties on all applications. It may be mentioned here that though common arguments were addressed by both parties, however, the defendants No.2 to 4 were stressing time and again that the issue of maintainability should be decided first. The arguments addressed in the amendment applications by the defendants No.2 to 4 were without prejudice. Even the day when the order was reserved after hearing, two fresh applications, being I.A. No.16703/2015 and I.A. No.16704/2015, were filed by the defendants No.2 and 3 to 4. The defendants No.3 and 4 also filed an application, being I.A. No.18578/2015, after the reserving the order for review of order dated 13th August, 2015. It was ordered that since all the relevant issues involved in the matter have been addressed by all the parties, no correction or modification of any nature is necessary.

18. Before pronouncing the orders in the above said application, draft of which was almost ready, another suit, being CS(OS) No.3284/2015, Genentech Inc and Ors. v. Drugs Controller General Of India and Others, was filed along with interim application against third party having the same common case. The said suit was listed before Court on 2nd November, 2015 and after hearing limited ad-interim order was passed not to launch the drug which was yet to be introduced. The said order was challenged by the defendant No.3 in appeal before the Division Bench, being FAO (OS) 625/2015. During the pendency

of the application, both sides completed the pleadings and concluded their arguments and the order was reserved on 13th January, 2016 in the application, being I.A. No.23041/2015 under Order XXXIX Rule 1 and 2 CPC. Subsequently, the appeal filed by the third party i.e. Reliance was disposed of mainly on the reasons that the order has been reserved. As facts and legal issues in both the cases are common, therefore, this Court was of the view that both orders should be pronounced together. Therefore, the delay has occurred in passing the orders.

19. The details of pending applications filed by the parties are given as under:

i) <u>I.A. No.2371/2014 (under Order XXXIX Rule 1 & 2 CPC by plaintiffs)</u>

The above mentioned application has been filed by the plaintiffs under Order XXXIX Rule 1 and 2 CPC seeking the interim orders against the defendants.

ii) <u>I.A. No.2988/2014 and I.A. No.2990/2014 (under Order XXXIX Rule 4 CPC by defendants No.2 to 4)</u>

The above mentioned two applications are treated as filed under Order XXXIX Rule 4 read with Section 151 CPC filed by defendants No.3 and 4 and defendant No.2 respectively for vacation of the interim orders passed on 5th February, 2014 in I.A. No.2371/2014. The same are numbered in view of orders passed in

appeals, being FAO (OS) 91/2014 and FAO (OS) 92/2014. The grounds taken in the said applications are similar to the pleas raised in the written statements filed by the defendants, therefore, the same are dealt with my order while disposing of interim applications.

iii) <u>I.A. No.4649/2014 dated 28th February, 2014 (under Order VI Rule 17 CPC by the plaintiffs)</u>

The above mentioned application has been filed under Order VI Rule 17 read with Section 151 CPC for amendment of the plaint by the plaintiffs. In the unamended plaint, admittedly the plaintiffs had expressly reserved their right to challenge the purported approvals granted in connection with the defendants' Drugs and modify the plaint and / or to enlarge the reliefs sought against the defendants. It is mentioned that after the filing of the plaint, the plaintiffs have been provided certain documents by defendant No.2, including copies of the purported approvals issued in connection with Bmab-200, Based on the documents provided by defendant No.2 to the plaintiffs, additional factual information has become available to the plaintiffs.

iv) <u>I.A. No.4677/2014 (under Order XXXIX Rule 2A CPC)</u>

The above mentioned application has been filed by the plaintiffs under Section 94(c) read with Order XXXIX Rule 2A read with Section 151 CPC for breach of interim order passed on 5th February, 2014.

v) <u>I.A. No.5956/2014 dated 28th March, 2014 filed by plaintiffs</u>

The above mentioned application is filed under Order XI Rule 12 and 14 read with Section 151 CPC by plaintiffs for discovery and production of documents by defendant No.2.

vi) <u>I.A. No.14533/2014, filed by plaintiff on 25th July, 2014</u>

The above referred application under Section 94(c) read with Order XXXIX Rule 2A and with Section 151 CPC has been filed by the plaintiffs for breach of orders passed on 5th February, 2014 and modified order dated 14th February, 2014 and order dated 28th February, 2014 alleging that despite knowing, the defendants have intentionally and wilfully disobeyed the directions issued by this Court in its order dated February 28, 2014 wherein it was observed that neither of the parties will, till further orders, go to the media on the safety or undesirability of the product of the other.

vii) <u>I.A. No.11224/2015 dated 21st May, 2015 by the plaintiffs</u>

The plaintiffs have filed the present amendment application to amend the suit to bring on record facts relating to the grant of approval to Bmab-200, based on the above referenced manufacturing and marketing authorisation dated October 23, 2013, for additional indications, namely ER2+ early breast cancer and HER2+ metastatic gastric cancer (the **"Additional Indications")** during the pendency of the present suit, and to seek appropriate reliefs in view of such facts. Such reliefs arise from the cause of action identified in the plaint.

viii) I.A. No.12830/2015 dated 30th June, 2015 by defendant No.2

The above said application is filed on behalf of the defendant No.2 under Order VII Rule 11(a) and (d) read with Section 151 CPC for rejection of plaint on the main ground that the plaint does not disclose a cause of action.

ix) I.A. No.16703/2015 dated 12th August, 2015 by defendant No.2 listed on 13th August, 2015

The above said application is filed on behalf of the defendant No.2 under Section 151 CPC for adjudication of the following:

i. Application bearing IA. No.2990 of 2014 filed by the defendant No.2 under Order XXXIX Rule 4 CPC ('Application for Vacation of Injunction');

ii. Application bearing IA. No.2371 of 2014 filed by the plaintiffs under Order XXXIX Rules 1 & 2 CPC ('First Application for Injunction');

iii. Issue of jurisdiction of the Court recorded by the Court vide its order dated 31.03.2014.

x) I.A. No.16704/2015 dated 12th August, 2015 by defendants No.3 and 4 listed on 13th August, 2015

The above mentioned application has been filed on behalf of the defendants No.3 and 4 under Section 151 CPC on the similar grounds as raised in I.A. No.16703/2015 filed by the defendant No.2.

xi) CCP(O) No.69/2015 dated 30th June, 2015 by defendant No.2

The above referred contempt petition has been filed by the defendant No.2 under Sections 11 and 12 read with Section 2(c) of the Contempt of Courts Act, 1971 for contempt of orders dated 5th February, 2014, 14th February, 2014, 28th February, 2014, 5th May, 2015 and 28th May, 2015 passed by this Court in view of letter dated 10th June, 2015 on behalf of the plaintiffs to the defendant No.1.

xii) I.A. No.12862/2015 dated 30th June, 2015 by defendants No.3 and 4

The above mentioned application has been filed under Order XXXIX Rule 1 and 2 CPC read with Section 151 CPC praying to restrain the plaintiffs from issuing letters, press releases, publication and/or material in any form or manner in relation to the present proceedings and also to withdraw the letter dated 10th June, 2015 or any other letter of such nature and demand issued to the DGCI.

xiii) I.A. No.3955/2015 (filed by third party i.e. stranger)

The above mentioned application has been filed by the third party i.e. for impleading as party in the present suit on various grounds.

20. On behalf of plaintiffs, the matter was argued by Mr.Rajiv Nayar and Mr.Sandeep Sethi, Senior Advocates, from time to time. Mr.Darpan Wadhwa has also made his submissions on 13th August, 2015 at the time of rejoinder arguments. Mr.Sanjay Jain, learned ASG,

made his submissions on behalf of defendant No.1. Mr.Harish Salve, Dr.A.M. Singhvi, Ms.Prathiba M. Singh, Senior Advocates made their submissions on behalf of the defendant No.2. Dr.C.S.Vaidyanathan and Mr.Amit Sibal, Senior Advocates, made their submissions on behalf of the defendants No.3 and 4 on various dates.

21. After analysing the pleadings of the parties along with the documents filed therewith and submissions advanced by the learned counsel for the parties at length on the applications, the points of contentions can be summarised. On the basis of unamended plaint the following questions are framed. The pleas which are not covered in the following questions are dealt with separately in the present order. For the sake of convenience, the following questions can be said to be sufficiently answering the contentions raised by the parties in the facts of the present matter:

i) Whether the plaintiffs have any right of action in the present case or not? If yes whether the suit is expressly or impliedly barred in law in view of the provisions of Drugs and Cosmetics Act 1945?

ii) If the suit is maintainable, whether this Court is within its powers to embark upon the approvals granted by the Drug controller in relation to the drugs in case it impinges the civil rights of the plaintiffs in order to protect the said civil rights or not?

iii) What is the impact of the Guidelines on Similar Biologics framed in the 2012 under the aegis of Drug Controller of India/ defendant No.1 and the government of India, Ministry of Bio technology and whether these guidelines would have any bearing in relation to the grant of the marketing and manufacturing approvals by the defendant No.1 especially granted after the framing of the said guidelines or not?

iv) Whether the approval granted by the defendant No.1 to the defendant No.2 by omitting the requirements of the clinical trials phase I and II would have any bearing upon the already granted approvals in the case of the similar biologics product or not and whether the defendant No.2 has conducted all the clinical trials of drug as required under the strict provisions of the Act and Rules and Bio-similar Guidelines of 2012?

v) Whether the common law remedy can be pursued by the plaintiffs for misrepresentation and false information allegedly made by the defendants No.2 to 4 in view of peculiar circumstances of the present case?

22. **Maintainability / Jurisdiction of Civil Court:**

Objections of all defendants

Submissions on behalf of defendant No.2

a) The first and foremost objection raised by all defendants is with regard to the jurisdiction of Civil Court on the grounds that the Drugs and Cosmetics Act, 1940 is a complete code itself. There exists a bar to the jurisdiction of Civil Courts (having original jurisdiction). The Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the '**Rules'**) specifically provide for a mechanism of filing an 'Appeal' for challenging the Approvals granted under the Act. It is stated that Rule 122 DC as amended (the Drug Rules) and Section 37 of the Act as amended provide for a remedy to any person aggrieved by an order of the Licensing Authority. As the Act expressly provides for a mechanism for challenging the orders of the Licensing Authority, plaintiffs cannot be allowed to continue with the present proceedings before Civil Court. If the plaintiffs wanted to challenge the approvals, they should have filed a writ petition, the other remedy which is available to them, but the suit is impliedly barred.

b) It is argued by all defendants that if a civil court would start to examine the grant of Approvals, it will undermine and / or usurp the powers of the defendant No.1 and its various constituents comprising of expert bodies and committees (Institutional Bio-safety Committee - IBSC, Review Committee on Genetic Manipulation- RCGM, New Drug Advisory Committee- NDAC

etc.) who have examined and approved the drug before grant of manufacturing and marketing license under the Drugs Act and Rules. The present suit is an attempt to take upon themselves the role of a Drug Regulator where a statute expressly/impliedly provides a provision for an alternate remedy. Unamended plaint does not challenge the approval for manufacturing and marketing authorisation dated 23rd October, 2013.

c) Mr.Sanjay Jain, learned ASG, appearing on behalf of the defendant No.1 referred the following decisions:

a) State of A.P. v. Manjeti Laxmi Kantha Rao (dead) by Lrs and Others (2000) 3 SCC 689

b) Raja Ram Kumar Bhargava (dead) by Lrs. v. UOI (1998) 1 SCC 681

> In these judgments, it has been laid down that the test adopted in examining such a question is (i) whether the legislative intent to exclude arises explicitly or by necessary implication, and (ii) whether the statute in question provides for adequate and satisfactory alternative remedy to a party aggrieved by an order made under it. and wherever a right, not pre-existing in common law, in created by a statute and that statute itself provided a machinery for the enforcement of the right, both the right and the remedy having been created uno flatu and a finality is intended to the result of the statutory proceedings, impliedly barred."

d) It is argued by defendant No.2 that the relief of injunction as claimed in the instant suit falls within the domain of the Specific Relief Act, 1963 and is discretionary relief which is circumscribed by the provisions of the Specific Relief Act, 1963 and is to be

available only when there is no alternative efficacious remedy available as the defendant No.2 has been granted all the requisite approvals, as are required under law, for manufacturing and marketing its bio-similar drug CANMAb, by the defendant No.1. The said approvals have been granted after following due procedure as prescribed under the Act by the defendant No.1 after the defendant No.2's drug CANMAb being evaluated under the stringent tests and procedures laid down under applicable laws.

e) The following decisions are referred by the defendants No.1 and 2 on this aspect:

i. **N.D. Jayal & Anr. v. Union of India & Ors. (2004) 9 SCC 362**

> **Para 20.** *"This Court cannot sit in judgment over the cutting edge of scientific analysis relating to the safety of any project. Experts in science may themselves differ in their opinions while taking decisions on matters related to safety and allied aspects. The opposing viewpoints of the experts will also have to be given due consideration after full application of mind. When the Government or the authorities concerned after due consideration of all viewpoints and full application of mind took a decision, then it is not appropriate for the court to interfere. Such matters must be left to the mature wisdom of the Government or the implementing agency. It is their forte. In such cases, if the situation demands, the courts should take only a detached decision based on the pattern of the well-settled principles of administrative law. If any such decision is based on irrelevant consideration or non-consideration of material or is thoroughly*

arbitrary, then the court will get in the way. Here the only point to consider is whether the decision-making agency took a well-informed decision or not. If the answer is "yes", then there is no need to interfere. The consideration in such cases is in the process of decision and not in its merits."

ii. Systopic Laboratories (Pvt.) Ltd v. Dr Prem Gupta 1994 Supp(1) SCC 160

Para 21: *"… As to whether clinical trials should have been conducted or not was primarily for the experts to decide and if the experts felt that in respect of the drugs in question such clinical trials were not necessary, it is not possible to hold that there has been no proper evaluation of the material that was submitted by the manufacturers before the Experts Committee…"*

f) In addition, it is argued on behalf of the defendant No.2 that the defendant No.2 has not skipped Phase I trial as the objective of a Phase I trial is to establish comparative pharmacokinetics (pK) and this pK data was generated by defendant No.2 as the initial part of the Phase III trial. Defendant No 2 did the Phase I and Phase II trials as part of the same sequential study since it was necessary to do the pK study in patients and not in healthy volunteers. The Phase II study as dose finding and POC studies are not required for follow-on products (biosimilars or generics). The said justification was accepted by the defendant No.1. The allegations of the plaintiffs that the approval was granted to the defendant No.2 without conducting Phase I, Phase II trials is

contrary to law. Even at the time of obtaining the ex-parte order Mr.Rohatgi conceded that if approval is granted, the same would be challenged by the plaintiffs as per law and in the present case the suit does not challenge the approval granted to the defendant No.2. Therefore, the plaint is liable to be rejected on account of lack of cause of action.

Submissions on behalf of defendant No.3 and 4

g) Mr.Amit Sibal, learned senior counsel on behalf of defendant no.3 and 4 by raising the similar objections as argued by the defendant No.2, in addition, he argued that the plaintiffs have failed to establish and even aver in the plaint about the breach of any statutory duty by the defendant No.1. He referred the case of **Rohtas Industries Staff Union and Ors. v. State of Bihar and Ors.**, reported in AIR 1963 Pat 170, the Patna High Court wherein while considering the question as to whether under the Industrial Disputes Act, 1947 employers had a legal right to claim damages from employees who had taken part in an illegal strike and after discussing the English case laws, came to the conclusion that the employers have no right of Civil action for damages against the employees participating in an illegal strike within the meaning of Section 24(1) of the Industrial Disputes Act." [emphasis supplied]

The said decision of the Patna High Court was upheld by a three Judge bench of the Supreme Court in **Rohtas Industries**

Ltd. and Anr. v. Rohtas Industries Staff Union and Ors., reported in (1976) 2 SCC 82.

h) Mr.Sibal has also referred the decision of the Supreme Court in the case of **Premier Automobiles Ltd. Vs Kamlekar Shantaram Wadke & Ors.**, reported in 1976 1 SCC 496, wherein the plaintiffs, who were individual workmen suing in a representative capacity, filed a civil suit seeking a declaration that a certain Settlement Agreement arrived at between Premier Automobiles Ltd. and the Association Union under Section 18(1) of the Industrial Disputes Act, 1947 was not binding upon them and further for a permanent injunction restraining Premier Automobiles from enforcing or implementing the terms of the impugned Settlement Agreement. The Supreme Court in this case observed as under, before giving its finding to the same effect at paragraph 23(3) of the judgment has held that the civil court will have no jurisdiction to try and adjudicate upon an industrial dispute if it concerned enforcement of certain right or liability created only under the Act. The civil court will have no jurisdiction even to grant a decree of injunction to prevent the threatened injury on account of the alleged breach of contract if the contract is one which is recognized by and enforceable under the Act alone be referring the quotation referred in **Doe v. Bridges** at page 859 are the famous and oft-quoted words of Lord Tenterden, C.J. saying "Where an Act creates an obligation and enforces performance in a specified manner, we take it to be

a general rule that performance cannot be enforced in any other manner."

i) Lastly he submits that the challenge to the grant of approval is available under Rule 122DC of the Drugs Rules. In the present case DCGI is the appropriate statutory authority to grant manufacturing and marketing approvals to new drugs under the Drugs Act. The plaintiffs have not availed of the remedy provided under Rule 122DC of the Drugs Rules to challenge the approvals granted to defendant No.2. The nature of the reliefs sought by the plaintiffs cannot be granted by the Civil Court though a writ petition under Article 226 may be maintainable against a remedy available under a statute but a civil suit is barred.

He has referred the following decisions:

i) In **State of Bihar v. Dhirendra Kumar**, reported in (1995) 4 SCC 229, it was held by the Supreme Court of India that:

> "...Thus, it could be seen that the Act is a complete code in itself and is meant to serve public purpose. We are, therefore, inclined to think, as presently advised, that by necessary implication the power of the civil court to take cognizance of the case under s.9 of CPC stands excluded, and a civil court has no jurisdiction to go into the question of the validity or legality of the notification under s.4 and declaration under s.6, except by the High Court in a proceeding under Article 226 of the Constitution. So, the civil suit itself was not maintainable. When such is the

situation, the finding of the trial court that there is a prima facie triable issue is unsustainable."

The said dicta was affirmed in **Commissioner, Bangalore Development Authority & Anr v. Briiesh Reddy & Anr.**, reported in (2013) 3 SCC 66, wherein the Supreme Court, in view of the assertions made by the authority (defendant) in their written statement on the process followed under the Land Acquisition Act held that the suit is not maintainable as the Act was a complete code and jurisdiction of the civil court is impliedly barred.

ii) The judgment of seven-Judge Bench of the Supreme Court of India in **Kamala Mills Ltd. v. State of Bombay**, reported in AIR 1965 SC 1942, is also referred by Mr.Sibal wherein the Supreme Court discussed the issue of exclusion of jurisdiction of a civil Court under a special statute. The Bench held in the context of Section 20 of Bombay Sales-Tax Act, 1946 that:

"It would thus be seen that the appropriate authorities have been given power in express terms to examine the returns submitted by the dealers and to deal with the questions as to, whether the transactions entered into by the dealers are liable to be assessed under the relevant provisions of the Act or not. In our opinion, it is plain that the very object of constituting appropriate authorities under the Act is to create a hierarchy of special tribunals to deal with the problem of levying assessment of sales tax as contemplated by the act. If we examine the relevant provisions which confer jurisdiction on the appropriate authorities to levy assessment on the dealers in

respect of transactions to which the charging section applies, it is impossible to escape the conclusion that all questions pertaining to the liability of the dealers to pay assessment in respect of their transactions are expressly left to be decided by the appropriate authorities under the Act as matters falling within their jurisdiction. Whether or not a return is correct; whether or not transactions which are not mentioned in the return, but about which the appropriate authority has knowledge fall within the mischief of the charging section; what is the true and real extent of the transactions which are assessable; all these and other allied questions have to be determined by the appropriate authorities themselves; and so, we find it impossible to accept Mr. Sastri's argument that the finding of the appropriate authority that a particular transaction is taxable under the provisions of the Act, is a finding on a collateral fact which gives the appropriate authority jurisdiction to take a further step and make the actual order of assessment. The whole activity of assessment beginning with the filing of the return and ending with an order of assessment, falls within the jurisdiction of the appropriate authority and no part of it can be said to constitute a collateral activity not specifically and expressly included in the jurisdiction of the appropriate authority as such. "

j) It is argued by Mr.Amit Sibal, learned Senior counsel, that the reasoning in the **Kamala Mills Case** (supra) applies with equal force in the instant case. The Drugs Act and Drugs Rules is a special statute that regulates the import, manufacture and distribution of drugs including biologic drugs. The said act contains an entire machinery for the determination of inter alia new drug approvals right upto the Central Government. The

present civil suit has been filed to make a civil court examine the approvals admitted in the plaint to have been granted by a regulatory authority (i.e. DCGI) pursuant to the Drugs Act and Drugs Rules The DCGI under the Drugs Act and Drugs Rules is vested with the jurisdiction to determine Bmab-200's biosimilarity/comparability to HERCEPTIN, and to subsequently grant manufacturing and marketing authorizations thereon to defendant No.2 in exercise of its powers under Rule 122B of the Drugs Rules. Additionally, the remedy of an appeal to the Central Government is provided to any "aggrieved person" under Rule 122DC of the Drugs Rules. In this background it cannot be gainsaid that the jurisdiction of a civil court to entertain the present dispute has been ousted even under the provision in Section 37 of the Drugs Act mandates that "No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done under this Act"

k) Mr.Sibal submits that if Section 37 of the Drugs Act with Rule 122DC of the Drugs Rules is read conjointly, the jurisdiction of a civil court is barred. He referred the decision of the Supreme Court in **Public Prosecutor, Madras v. R. Raju and Anr.**, reported in (1972) 2 SCC 410, in which the Supreme Court was also concerned with examining a section excluding the jurisdiction of the civil courts. He submits that the language of Section 40(2) of the Central Excises and Salt Act, 1944 is similar to section 37 of the Drugs Act.

> "Section 40(2): No suit, prosecution or other legal proceedings shall be instituted for anything done or ordered to be done under the Act after the expiration of six months from the accrual of the cause of action or from the date of the act or order complained of "

However, when pointed out the factual position, Mr.Sibal admits that the Supreme Court, while deliberating on the appellant's contention that sub-section (2) of Section 40 was confined only to the government officers.

23. Before dealing with the submissions on behalf of the defendants, it is necessary to refer the specific averments made in the plaint. It is alleged in the plaint, after approval granted to the defendant No.2 in October 2013, on 26th November, 2013 defendant No.2 issued a press release in relation to the marketing authorisation for the purported biosimilar Trastuzumab developed jointly with defendant No.3 for the treatment of HER 2 positive metastatic breast cancer. But the press release made no reference to a manufacturing licence received by defendant No.2 in this regard. The plaintiffs were awaiting a response to the above referenced letter dated October 11, 2013 at this stage. Thereafter, on January 18, 2014, defendant No.2 announced that CANMAb would be introduced in India for the treatment of HER 2 positive metastatic breast cancer in the first week of February, 2014. Defendant No.2's press release of January 18, 2014. Therefore, the present suit for quia timet action was filed. The issue in hand is being considered by this Court mainly on the reason that the defendants No.1 and 2 are alleging that upon approvals the defendant No.2 has

acquired legal rights to claim as similar to the reference product of the plaintiffs. They are entitled to use all references, data, INN i.e. Trastuzumab and to promote the same in hospitals, doctors and public at large that their drug is similar with the drug of the plaintiffs. If that is not the situation, then the position would have been different while dealing with this issue. The plaintiffs have made specific averments in the plaint, the details of which are given as under:

i) In the plaint it is mentioned that defendants No.2 to 4 have misrepresented the nature of the defendants' drugs as “biosimilar Trastuzumab”, a Trastuzumab” and a “biosimilar version of HERCEPTIN®. Such misrepresentations are likely to deceive the patients using Trastuzumab regarding the efficacy and safety of the defendants' drugs as "Biosimilars" are biological products that are similar to the innovator biopharmaceutical product can only be similar to the innovator biopharmaceutical product; it cannot be a generic equivalent of the innovator biopharmaceutical product. Although biosimilars are gaining popularity in Indian and international markets, biosimilars are not in the nature of generic drugs. Rather these are unique molecules for which only limited data is available at the time of approval, and as such, the concerns and risks associated with the long term safety, efficacy and immunogenicity of biosimilars are significantly higher compared to those associated with a generic drug.

ii) As these products are very complex molecules, in the interest of patient safety, factors such as robustness of the manufacturing process, structural similarity to the innovator molecule, level of understanding of the mechanism of action, quality of the pharmacodynamic procedures utilised, demonstrated comparability in pharmacokinetics and immunogenicity and quality and quantity of clinical data, need to be necessarily considered before marketing approval is granted to biosimilars.

iii) The defendant No.2's protocol and study for testing for Bmab-200 was filed with and approved by defendant No.1 prior to the Guidelines on Similar Biologies becoming effective, defendant No.2 was already conducting Phase III clinical trials in relation to Bmab-200 (which is the last stage of tests to be conducted on a new drug prior to grant of marketing authorisation). Therefore, the tests carried out by defendant No.2 to compare the efficacy, safety and immunogenicity of its drug and other studies including product characterisation and pre-clinical studies could not have been in accordance with the Guidelines on Similar Biologies, and Bmab-200 cannot be considered a "biosimilar" under the Guidelines on Similar Biologies. The marketing authorisation was granted by defendant No.1 after the Guidelines on Similar Biologies became effective and these guidelines were not complied with in granting the marketing authorisation. Since defendant No.3

claims to have co-developed the purported biosimilar Trastuzumab.

iv) The defendants' drugs have not been tested against the standards set forth in the Guidelines on Similar Biologies and the marketing authorisation for Bmab-200 is not issued under the Guidelines on Similar Biologies. Defendants No.2 to 4 have falsely and wrongly represented the defendants' drugs as the first biosimilar version of Trastuzumab and a biosimilar version of HERCEPTIN® in various press statements. Further, even the marketing and promotional material for the defendants' drugs by defendant No.2 represent such drugs as "Trastuzumab for Injection" and "biosimilar Trastuzumab".

v) By referring to the defendants' drugs as a "biosimilar" product, defendants No.2 to 4 have misrepresented the nature of the tests to which the drug was subjected for the purpose of testing its safety and efficacy and thus compromised the safety of prospective patients. Such misrepresentation is in the nature of passing off since they seek to pass of the defendants' drugs as being of the same quality and class as HERCEPTIN®.

vi) By referring to the defendants' drugs as a "Trastuzumab", defendants No.2 to 4 have misled the consumers into believing that the active ingredient of the defendants' drugs is Trastuzumab itself. This is false to the knowledge of

defendants No.2 to 4 since Trastuzumab is a biological product and there cannot be a generic equivalent of Trastuzumab. Another biological drug can at best contain an active ingredient similar to Trastuzumab.

vii) The defendants No.2 to 4, by misrepresenting the defendants' drugs as a "biosimilar version of HERCEPTIN®" and by linking and likening the defendants' drugs to Trastuzimiab and HERCEPTIN® in various public statements, have sought to create a false impression regarding the quality, safety and efficacy of its drug in the minds of the public. Defendants No.2 to 4 have misrepresented that the defendants' drugs are comparable in quality to HERCEPTIN® and equally effective, even though this claim has remained unverified under the Guidelines on Similar Biologies. Even by comparing the price, storage conditions and formulation of the defendants' drugs with HERCEPTIN®, defendants No.2 to 4 are seeking to promote the unverified advantages of their product. Misleading, unfair and deceptive advertisements, as in the present case, are not permissible and should be enjoined. The advertiser in this case does not have reasonable basis for the assertions made in the advertisement and it is not permissible to make an unsubstantiated, false and misleading claim that the advertiser's goods are similar to or better than a competitor's. Confusion in the case of medical products may be fatal or could have serious consequences on public health

and safety. As such, deception and misrepresentation in the case of medical products' is especially dangerous and a stricter approach is adopted while testing the possibility of confusion of one medical product for another by consumers.

viii) Each of the defendants' drugs is a misbranded drug under Section 17 of the Drugs Act since the labels for the products falsely and misleadingly describes it as 'Trastuzumab for Injection'. Further, the marketing material for CANMAb falsely and misleadingly describes it as the 'first Trastuzumab biosimilar'. The defendants' drugs are not Trastuzumab and the representation to the contrary in defendants No.2 and 3's advertisements and marketing material is false, misleading and a misrepresentation. Accordingly, under Section 18 of the Drugs Act the manufacture and sale of each of the defendants' drugs is presently prohibited.

ix) The claim is made by defendants No.2 to 4 that in the trade Bmab-200 is developed for the treatment of HER 2 positive metastic breast cancer, it competes directly with the plaintiffs' biological drug HERCEPTIN® which is used for the treatment of HER 2 positive breast cancer throughout the world. They are aware (a) of the reputation enjoyed by HERCEPTIN® in the relevant market; (b) of the popularity of HERCEPTIN® for the treatment of HER 2 positive breast cancer; (c) that HERCEPTIN® and Bmab-200 target the same restricted market. As such. Defendants No.2 to 4 stand to gain

significantly by relying on the reputation and goodwill of HERCEPTIN® while promoting their product and making misleading and false comparisons with the plaintiffs' product. In the present case, it is not necessary for defendants No.2 to 4 to indicate or imply any kind of connection between HERCEPTIN and the defendants' drugs or to refer to data relating to the nature and sales of HERCEPTIN® in order to market their product in a fair manner.

x) By linking the defendants' drugs to HERCEPTIN® and referring to data relating to HERCEPTIN® including data relating to its price and sales in the promotional material for the defendants' drugs, defendants No.2 to 4 have sought to take unfair advantage of the reputation and goodwill of the trademark HERCEPTIN®, which has been developed by the plaintiffs over several years in the Indian market and worldwide. This is evident from the fact that although the plaintiffs market Trastuzumab under two other brand names in India, being HERCLON™ and BICELTIS, defendants No.2 to 4 have sought to link the defendants' drugs only with the widely recognised and world renowned HERCEPTIN®. By relying on the fact that HERCEPTIN® is a well-recognised biological drug for the treatment of HER 2 positive breast cancer in India and making misleading references to and comparisons with HERCEPTIN®, defendants No.2 to 4 are seeking to gain an unfair advantage in the Indian

pharmaceutical market and obtain an unfair and unjust commercial benefit on the basis of the reputation and goodwill of the plaintiffs' brand HERCEPTIN®.

xi) As Bmab-200 has not been sufficiently and adequately tested to be termed as a biosimilar product, as claimed by defendants No.2 to 4, there are reasonable apprehensions regarding the safety and efficacy of this drug. Moreover, as defendants No.2 to 4 have unfairly and incorrectly linked the defendants' drugs with HERCEPTIN®, any deficiency discovered in their product is likely to be imputed to the plaintiffs' brand HERCEPTIN® leading to a dilution of their reputation and goodwill built over many years.

xii) Therefore, defendants No.2 to 4 should be restrained from introducing the defendants' drugs in the Indian market as a biosimilar product until appropriate tests and studies as prescribed under the Guidelines on Similar Biologies have been conducted and appropriate approvals have been obtained. Defendants No.2 to 4 ought to be further restrained from using the plaintiffs' trademark HERCEPTIN®, and the reputation and goodwill attached to it, for their commercial benefit.

24. It is also mentioned in the plaint that the averments made and the reliefs sought in the present suit are based on the records available with the plaintiffs and the information available in the public domain.

Based on such information, the plaintiffs have, inter alia, through the letter of October 11, 2013 written to defendant No.1 regarding the inadequacy of the clinical trial design for the purported biosimilar Trastuzvmiab. The plaintiffs were awaiting a response to such letter. The plaintiffs seek leave of this Court under Order II, Rule 2 of the Code of Civil Procedure, 1908, as amended, to modify the plaint and / or to enlarge the reliefs sought against the defendants. The defendant No.2 has refused to give the inspection or discover the documents on the basis of which the approvals were obtained.

25. The unamended plaint and pleadings of the plaintiffs disclosed that Bmab-200 has not been adequately and/or appropriately tested, inter alia, under the provisions of the Biosimilar Guidelines and that the approval granted to defendant No.2 is, therefore, invalid and cannot be acted upon. The cause of action disclosed even in the unamended plaint is, inter alia, the improper grant of the manufacturing and marketing authorisation to defendant No.2 in the absence of adequate testing and reliefs have been sought in the unamended plaint on the basis of this cause of action.

26. The plaintiffs alleged that they became aware of the details of the inadequacy in the approval process and copyright violation subsequent to filing the suit (i.e. when defendant No.2 filed additional documents and Bmab-200 was launched in the market). As such, these details could not have been included in the unamended plaint.

27. After the filing of written statement, reply and documents, the plaintiffs filed the first application for amendment on the basis of disclosure of few details, yet the defendant No.2 refused to share any information with the plaintiffs with regard to tests and approvals granted on the basis of the said documents.

28. The second application for amendment was filed on the basis of another approval sought by the defendant No.2. Even at that time also the plaintiffs were not aware about the actual position. The factual position came to the knowledge of the Court and the plaintiffs only during the last week of May, 2015 that the defendants have also obtained approval of further two indications.

Both the applications were filed on the basis of the subsequent events. Those were not decided in between the hearing of interim applications though submissions were made because as and when two pending two applications of the plaintiffs for amendment of the plaint, discovery of documents and three contempt petitions, are taken up by this Court, the defendants No.2 to 4 insisted for giving the decision of the interim applications by referring the orders passed by the Division Bench on 14th February, 2014 in FAO (OS) 91/2014 and FAO (OS) 92/2014 as well as the objections raised by them about the maintainability of the suit. Even replies to the amendment applications were filed by the defendants No.3 and 4 without prejudice.

Arguments addressed on behalf of plaintiffs

29. Mr.Rajiv Nayar and Mr.Sandeep Sethi, learned senior counsel appearing on behalf of the plaintiffs, *inter alia*, argued that since the approvals are contrary to the provisions of the Act, Rules and Guidelines of 2012 by Government and the defendants are making misrepresentations to the doctors, hospitals and patients in the absence of requisite tests, the plaintiffs have no other remedy but to file the suit. They submit that despite of expiry of patent rights in 2013, the plaintiffs are manufacturing and marketing the drug in question and they are still market leaders in the entire world and the drug is one of the best drugs for the purpose of cancer treatment although they are not claiming data exclusively for comparison purposes at the time of obtaining the approval or any right on the molecule which was the subject matter of patent after its expiry. But the defendants on the basis of said approvals are trying to destroy the business of the plaintiffs and are also cheating the public at large by making misrepresentation in order to earn easy amount on the basis of spreading false information to the hospitals, doctors and patients providing the similar data and tests admittedly not conducted by them. The said illegal activities of the defendants have compelled the plaintiffs to file the suit. They argued that the drug of the defendant No.2 is not bio-similar. If they otherwise manufacture and market the cancer drug in question without claiming bio-similarity, the defendants No.2 to 4 are free to do so. They also argued that all the defendants have admitted before the Court that the defendant No.1 is not empowered to hear the grievances of the plaintiffs as per rules, thus, the suit filed by the plaintiffs is maintainable.

It is also argued that once the defendants are guilty of violations of the rights of the plaintiffs and false information of biosimilar product in the public, the civil court has the jurisdiction to entertain the suit as the legal rights of the plaintiffs can only be decided by the civil court who has the jurisdiction to pass the interim orders for illegal activities of the defendants No.2 to 4 and the plaintiffs have become aggrieved parties as the defendants are insisting their product as reference product of the plaintiffs. They argued that none of the decisions referred by the defendants are applicable to the facts of the present case. The facts in the cases referred by the defendants are materially different.

30. Let me now first decide the issue of maintainability of the suit. The same is being decided on the basis of averments made in the unamended plaint and also on subsequent events. In the famous Wednesbury case, 1948 (1) KB 223, it is rightly held that the Court should not interfere with the administrator's decision unless it was illegal, contrary to law, failed to follow conditions in the statute, illogical or suffer from procedural impropriety or was shocking to the conscience of the Court or it is in defiance of moral standards whole deciding the objection raised by all defendants. These principles are to be kept in mind in the facts of the present case while deciding the issue in hand.

31. The plaintiffs in the unamended plaint sought the following reliefs:

(a) an injunction restraining Defendants No.2 to 4 from launching, introducing, selling, marketing and/or distributing the Defendants' Drugs, or any other biosimilar version of Trastuzumab, in the Indian market until appropriate tests and studies as prescribed under the 'Guidelines on Similar Biologies: Regulatory Requirements for Marketing Authorization, in India' issued jointly by the Department of Biotechnology, Ministry of Science and Technology, Government of India and the Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Government of India, which became effective from September 15, 2012 (the "Guidelines on Similar Biologies") have been conducted and appropriate approvals have been obtained;

(b) an injunction restraining Defendants No.2 to 4 from representing the Defendants' Drugs as 'biosimilar Trastuzumab' until appropriate tests and studies as prescribed under the Guidelines on Similar Biologies have been conducted and appropriate approvals have been obtained;

(c) an injunction restraining Defendants No.2 to 4 from representing the Defendants' Drugs as 'Trastuzumab' or 'Trastuzumab for Injection' in any press releases, public announcements, promotional or other material for the Defendants' Drugs; and

(d) an injunction restraining Defendants No.2 to 4 from relying upon or otherwise referring to the Plaintiffs' trademarks HERCEPTIN®, HERCLON™ or BICELTIS®, or any 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 the Defendants'

Drugs and from claiming any similarity with HERCEPTIN®, HERCLON™ or BICELTIS®.

32. In case the prayers made in the plaint are examined, it is evident that the plaintiffs were seeking an injunction for launching, introducing the drug by the defendants No.2 to 4, an injunction from representing as bio-similar products until appropriate tests and studies are conducted including guidelines on similar biologics and injunction from press releases and relying upon or referring to the plaintiffs trade mark claiming similarity of two drugs. The plaintiffs are not alleging that the defendants No.2 to 4 is infringing their trade mark or their rights in respect of expired patent in 2013. Their main concern is that without establishing the safety and efficacy as required under the Act, Rules and Guidelines 2012, they are not entitled to claim that it is a biosimilar drug of the innovator and would not be entitled to use the data of the plaintiffs and give references in its package insert, carton and publicity materials by making the false statement and misrepresentation. Otherwise, independently, they are entitled to market drug in question without any such references. If the clinical trials are not conducted, the Regulatory Authority is liable to take action under Rule 122 DB. But if the references of biosimilar are made by the defendants No.2 to 4 for promoting and selling the drug in question, the plaintiffs are entitled to file the suit.

33. It is settled law that Section 9 of the Code provides that civil court shall have jurisdiction to try all suits of a civil nature excepting the suits of which their cognizance is either expressly or impliedly barred. To put

it differently, as per Section 9 of the Code, in all types of civil disputes, civil courts have inherent jurisdiction unless a part of that jurisdiction is carved out from such jurisdiction, expressly or by necessary implication by any statutory provision and conferred on other Tribunal or Authority. Thus, the law confers on every person an inherent right to bring a suit of civil nature of one's choice, at one's peril, howsoever frivolous the claim may be, unless it is barred by a statute. Even as per the decision referred by defendant No.1 in the case of State of Andhra Pradesh (supra) it is held that the normal rule of law is that the civil courts have jurisdiction to try all suit and such exclusion is not readily inferred and the presumption to be drawn.

34. It is trite and debated time and again that the rule of pleadings postulate that a plaint must contain material facts. When the plaint read as a whole does not disclose material facts giving rise to a cause of action which can be entertained by a civil court, it may be rejected in terms of Order 7, Rule 11 of the Code. Similarly, a plea of bar to jurisdiction of a civil court has to be considered having regard to the contentions raised in the plaint if averments disclosing cause of action and the reliefs sought.

a) In **Smt. Ganga Bai v. Vijay Kumar & Ors.** (1974) 2 SCC 393, this Court had observed as under:

> "There is an inherent right in every person to bring suit of a civil nature and unless the suit is barred by statute one may, at ones peril, bring a suit of one's choice. It is no answer to a suit, howsoever frivolous

> the claim, that the law confers no such right to sue. A suit for its maintainability requires no authority of law and it is enough that no statute bars the suit."

b) In **Dhannalal v. Kalawatibai & Ors.** (2002) 6 SCC 16, relying on the afore-extracted observation in **Ganga Bai's** case (supra), this Court had held as follows:

> "Plaintiff is dominus litis, that is, master of, or having dominion over, the case. He is the person who has carriage and control of an action. In case of conflict of jurisdiction the choice ought to lie with (1974) 2 SCC 393 (2002) 6 SCC 16 the plaintiff to choose the forum best suited to him unless there be a rule of law excluding access to a forum of plaintiff's choice or permitting recourse to a forum will be opposed to public policy or will be an abuse of the process of law."

35. Originally the suit was filed as Quia Timet Action. It is settled law that such an action is maintainable. If a party fears or apprehends, then the injunction may be passed by the court on some threatened act being done in future, would cause him substantial damage where monetary relief would not be an adequate or sufficient remedy. In a quia timet action, the Court can pass an injunction as a preventive measure so as to prevent the future occurrence of the wrong on the basis that the reasonable apprehension of the injury to be occurred in future rather than waiting for the perfection of the wrong. In the case of **Kuldip Singh v. Subhash Chander Jain & Ors.**, AIR 2000 SC1410 in

para 7 it is held that "A quia timet action is a bill in equity. It is an action preventive in nature and a species of precautionary justice intended to prevent apprehended wrong or anticipated mischief and not to undo a wrong or mischief when it has already been done. In such an action the Court, if convinced, may interfere by appointment of receiver or by directing security to be furnished or by issuing an injunction or any other remedial process "

36. It has been stated in paras 16 to 18 of the plaint that from the press releases issued by defendants No.2 and 3, limited information available in the public domain about the clinical trials available with the plaintiffs, though as per notification No." F.No. 12-01/09-DC-(Pt-32) issued by defendant No.1 (effective from June 15, 2009), registration of all phases of a clinical trial with the Clinical Trials Registry - India (the "CTRI") is mandatory. There is no publicly available record of registration of Phase I and Phase II clinical trials by defendants No.2 or 3 for the purported biosimilar Trastuzumab and on the basis of such information, the quia timet action was filed. The plaintiffs reserved their right to amend the plaint after information disclosed.

37. Thus it appears that on the date of filing of a suit the plaintiffs were not fully aware and in view of the proposed launch of the product by the defendants. They wanted to exercise their right to approach the court by seeking an immediate injunctive relief. The plaintiffs have averred the procedural lapses in process of grant of the approval which are apparent on face of it. Thus, the said action premised on quia timet is permissible and reasonably justify the plaintiffs position that the

plaintiffs were not having all the facts in hand while exercising the remedy and the amendments are necessitated in view of the facts as they are divulged during the course of the litigation and does not prevent the plaintiffs from seeking an amendment in view of the subsequent events and also does not bar the suit in the present form.

38. It is not disputed that there is no specific bar of civil court jurisdiction in the Act and Rules. It is also admitted position that the main dispute is between the private parties i.e. plaintiffs and defendants No.2 to 4. It is not denied by the defendants that the suit is not filed against any government employees who were involved in the process of approvals. It is admitted by the defendant No.1 that as per Act and Rules there is no procedure for cross-notice or to hear the grievances of the plaintiffs that the authority has not considered the clinical trials properly or to send the copy of the approvals and backed up documents who claimed himself as an aggrieved party.

39. In view of the attendant circumstances discussed above, I have already observed as to how the plaintiffs have an enforceable right to seek an interdict the court and the court can exercise the jurisdiction not merely on the basis of private lis between the parties but by invoking the public interest doctrine which also guide the courts, still, I am discussing the provisions of Section 9 of the Code of civil procedure in order to discuss the plea raised by the defendant in relation to the ouster of the jurisdiction. Section 9 of the Code of Civil Procedure ("CPC") mandates that civil courts have the jurisdiction to determine all disputes of a civil nature, unless their jurisdiction is

barred under a statute, either expressly or by necessary implication. It is settled law that if the appropriate authority has acted in violation of the fundamental principles of judicial procedure that may tend to make the proceedings illegal and void, then Civil Court's jurisdiction may not be taken away which has under those circumstances have the jurisdiction to examine the non-compliance with such provisions of the statute. There is inherent right in every person to bring a suit of a civil nature unless the suit is barred expressly and impliedly. (See **Dhulabhai v. State of Madhya Pradesh and Anr.** (1968) 3 SCR 662, **Abdul Gafur and Anr. v. State of Uttarakhand and Ors.** (2008) 10 SCC 97, **Dwarka Prasad Agarwal v. Ramesh Chander Agarwal** (2003) 6 SCC 220, **Harbanslal Sahnia and Anr. v. Indian Oil Corporation and Ors.** (2003) 2 SCC 107, **State of Madhya Pradesh and Anr. v. Bhailal Bhai** (1964) 6 SCR 261, **State of Kerala v. Ramaswami Iyer and Sons** (1966) 3 SCR 582, **Secretary of State v. Mask and Company** (1940 40 LR 222).

40. It is also settled law that the exclusion of the jurisdiction of the civil courts is not to be readily inferred, but that such exclusion must either be explicitly expressed or clearly implied. Even if jurisdiction is so excluded, the civil courts still have jurisdiction to examine into cases where the provisions of the Act have not been complied with, or the statutory tribunal has not acted in conformity with the fundamental principles of judicial procedure. If consequence of the same is that, it affects the civil right of the party, then the civil suit is maintainable. In the case of **Mohammad Din and Ors. v. Imam Din and others**, AIR

1948 PC 33 it laid down the principle that where the tribunals do not act in conformity with the fundamental rules of judicial procedure or where the rules of the law are not followed, the civil court has jurisdiction and to this extent no ouster can be inferred)

41. The decision in the case of Mohammad Din (supra) has been followed by the courts in India from time to time including the High Courts of Punjab and Haryana in the case of and also by Allahabad High Court recently in 2010 in the case of **Shivdhesar Singh v. Union of India**, 2011 2 AWC 1202 wherein the learned judge while affirming the said principle observed thus:

> " In Mohammad Din and Ors. v. Imam Din and others, : AIR 1948 PC 33, it was clearly laid down that where the authorities/executive acts beyond its jurisdiction, civil court has power to entertain suits challenging such actions. It implies that the final order passed ultimately in the departmental remedies is always open to challenge by means of a civil suit for which at least there is no bar either express or implied" (Emphasis Supplied)

42. I have already observed that on scheme of Drugs Act, there is no express or implied bar which can be inferred for the suit of the present nature as the proposition in the present case is that the approvals have been granted by the defendant No.1 are without jurisdiction and consequently they affect the civil rights of the plaintiffs. It is the case of the plaintiffs in the plaint as well that the defendant No.1 acted in haste and overlooked the objections of the plaintiffs by granting the approval within three days time. Under such circumstances, it becomes a case

where the tribunal has not followed the fundamental judicial procedure and acted by overlooking its own guidelines. The said issue is raised in the plaint and thus requires determination.

43. Applying the dictum of **Mohammad Din** (supra) which still holds the field and followed by the courts, the present suit cannot be said to be barred in the present form. I find that the judgments cited by Mr.Sibal on the breach of the statutory duty are also distinguishable in the facts of the present case as it is not merely the case of the breach of any statutory duty but also the violation of the rules of the judicial procedure by not following the guidelines framed by the controller on his own and granting the approvals on the basis of different regime in an undue haste when the Supreme Court order also mandated the conducting of the clinical trial. All this have the bearing on the rights of the plaintiffs giving them right to enjoin the defendants till the time the defendants accomplish the onerous task of seeking approvals as per the bio similar regime framed in the form of the guidelines.

44. In the unamended plaint and prayers made therein, it is avered that the defendants have not conducted the requisite trials as per the drugs and cosmetics Act and the guidelines passed on similar Biologics so as to attribute their drug as bio similar to that of the plaintiffs drug HERCEPTIN and the defendants should be prevented from doing till the time all the requirements are complied to call it biologically similar products as it effects their reputation. The plaintiffs have alleged the cause of action on the basis of the passing off, act of unfair competition and thereby sought an injunction. After more

discussion, it is necessary to refer the important aspect of regime of bio-similar.

Regime of Bio-Similar

45. Let me now deal with the latest trend of regime of Bio-similar drug. Admitted position is that when the patent for the original molecule expires, other companies can launch follow-on versions of the same. If the molecule is chemically synthesized, the follow-on molecule is called a "generic" whereas when the molecule is a biological (like a monoclonal antibody), the follow-on molecule is called a biosimilar. 'Generics' and 'Biosimilars' are developed by comparing their properties to the original molecule, which is called a reference product. Any follow-on biological product that is approved based on evaluation of comparative data to the reference product is called a biosimilar.

46. In view of the development and growth of the market for biosimilars in India and the international standards for approval of such products, the Guidelines on Similar Biologies were issued in 2012. These guidelines lay down specific standards for development and evaluation of similar biologies; these are in addition to the general standards for evaluation of new drugs that exist under the Drugs Act and the Drugs Rules and seek to ensure comparability of safety, efficacy and quality between the innovator biologic and the biosimilar, prior to the approval of such biosimilar.

47. The Guidelines on Similar Biologics provide a detailed and structured process for comparison of the similar biologic with the reference biologic to test the safety, efficacy and immunogenicity of the similar biologic as against the reference biologic at each stage including the product characterisation, the pre-clinical studies and clinical trials. Under these guidelines demonstration of similarity of biologics is a sequential step-wise approach. This process is aimed at ensuring that the similar biologic is comparable inquality to the reference biologic and can be safely used in the treatment of specified disease or disorder.

48. After the issuance of the Guidelines on Similar Biologics on 15th September, 2012, all applications for manufacturing and marketing authorisation of similar biologies in India are required to be evaluated on the basis of the standards set forth in the Guidelines on Similar Biologies. The Guidelines on Similar Biologies ensure that adequate tests are conducted prior to the approval of biosimilars. These may not be statutory in nature but as per guidelines of the Government from time to time, it is essential that they are also followed at all stages in order to ensure the safety of patients. In the case of life saving drugs, no one can deny that at thorough consideration should be given to the scientific basis of the study design, objectives, study end-points, sample sizes and study duration of the applicant's product before approval is granted under the Guidelines on Similar Biologics and only products which have been approved under the Guidelines on Similar Biologics should be allowed to be represented as biosimilar products.

The said 2012 Guidelines provide that similar biologics are regulated as per the Drugs & Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 so that the approval of biosimilar products of parties must satisfy all the stringent regulatory requirements before manufacturing and marketing its product.

49. The 2012 Guidelines provide that similar biologics are regulated as per the Drugs & Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. In nutshell, the 2012 Guidelines stipulate that the approval of biosimilar products of a party must satisfy all the stringent regulatory requirements and having been duly approved is entitled to manufacture and market its product.

50. The Biosimilars have existed even prior to the 2012 Guidelines and then the application of the applicant was to be tested on a case-by-case evaluation governed under *"Notification Regarding Adoption Of The Recommendations Of The Task Force On R-Pharma Under The Chairmanship Of Dr R A Mashelkar, DG-CSIR With Effect From 1.4.2006"*. It is alleged by the defendant No.1 in the written statement that under the Drug and Cosmetics Act and Rules made the term "Similar Biologics" has not been defined. The defendants admit that the procedure laid down in the Act and Rules are to be applied stringently.

51. It is submitted on behalf of defendant No.2 that the protocol for tests provided by the Biosimilar Guidelines is similar to the standards laid down by the Mashelkar Committee Report (2006) ("Mashelkar

Committee Report"), which was followed by defendant No.2 for the approval of Bmab-200. Several biosimilars have been approved in India even before the Biosimilar Guidelines were issued (under the existing statutory regime and on the basis of the standards laid down in the Mashelkar Committee Report)'. It is stated by the defendants that not much importance is required to be given by the Court to the 2012 guidelines as basic Guidelines are already in place in 2006 which are being followed by the defendant No.1.

52. I have seen the Mashelkar Committee Report relied upon by the defendants and the said report appears to give some indication as to development of LMO (which is living modified organism) by way recombinant DNA technology. The report provides certain protocols for the development of indigenous product where end product is LMO which is starting point for someone who is attempting to development Living modified organism. To that extent, the defendant is right that the concept and mechanism to take approval of the biotechnology products and artificially engineered modified genetic sequences was available. But, by placing reliance on the said report to say that the biosimilar guidelines were already in place and the new guidelines have no role to play wherein an applicant/ defendant engineers his own biological compound and attempts to ascribe the same quality, efficacy, safety norms, dosage, potency of the compound with other characteristics same as the base compound which means that two persons are artificially engineering the genetic sequencing arriving at the same conclusion and also the same characteristics so as to call

their products as clones or biologically similar to each other was not specifically provided for in the Malshekar report and if so provided still the guidelines operate in the field which regulate the entire process of the study of the biosimilar products prior to the grant of the approval and fill the gaps in the entire regulatory procedure of the grant of the approval of bio similar by insistence of the clinical trials and other relevant steps which were not earlier not provided for by looking from greater degree of care and attention as is evident from that of the preface of the guidelines.

53. Thus, even if the starting point of the discussion in guidelines on similar Biologics of 2012 is Malshekar report, still, the defendant's plea that the system was already placed on the date of approval of drug of the defendant No.2 and the bio similar were already approved on the face of it a contradictory argument by defendant No.1 especially when the defendant No.1 is the head of the CDSCO (Central Drugs Standard Control Organisation) which is the central drug authority under the Act and has passed the guidelines with the close connection with Ministry of Science and Technology. The defendant No.1 by authoring the guidelines to say that the said biosimilars are to be treated distinctly with greater degree of care and circumstance as against the ordinary regime of bioequivalence cannot justify the contrary position by urging that the guidelines have no role to play or are not statutory in character and thus can be conveniently bypassed as non binding or there is nothing new about the approvals in biosimilar products as they were being granted earlier. All these stands are contradictory to the preface

of the guidelines to which the defendant No.1 is participant and thus cannot plead to contrary before this court.

54. As regard binding nature of the guidelines, it is well settled principle of law that the guidelines are in the nature of the directions issued by the government and till the time the said guidelines and directions are not in contradiction but are mere addition to the already existing rules and regulations, it cannot be said that the said guidelines are not having legal validity and are not required to be adhered to being non binding in character. The reference is invited to the case of **Bant Singh v. Man Singh**, AIR 1976 P&H 102, wherein the Division Bench of the High Court observed thus:

> "There are no rules which may regulate the supply of canal water for gardens and orchards. The rules which are in existence make a provision for regulating the supply of canal water to lands only, The Government in its wisdom thought of issuing some instructions for the purpose of regulating extra supply of canal water for gardens and orchards and those instructions with suitable amendments made off and on, bold the field till today. Obviously, these instructions were issued to supplement the rules in existence, which were silent on the question of supply of canal water to the gardens and orchards. By issuing these instructions, a complete and detailed procedure has been prescribed for the supply of canal water for the gardens and orchards. These instructions do in no way amend, supersede or alter the existing rules; rather the same have the effect of filling the gap and supplementing the existing rule." (Emphasis Supplied)

55. Likewise, it is also a settled law that the guidelines/ directions issued by the department though not statutory but are in contravention to the provision of the Act and rules framed thereunder cannot be said to be not to be complied with or non enforceable by the court of law. The Supreme Court in the case of **Virendra Hooda v. State of Haryana**, AIR 1999 SC 1701observed as under:

> "The view taken by the High Court that the administrative instructions cannot be enforced by the appellant and that vacancies became available after the initiation of the process of recruitment would be looking at the matter from a narrow and wrong angle. When a policy has been declared by the State as to the manner of filling up the post and that policy is declared in terms of rules and instructions issued to the Public Service Commission from time to time and so long as. These instructions are not contrary to the rules, the respondents ought to follow the same."(Emphasis Supplied)

56. The Constitution Bench of Supreme Court in the case of **Sant Ram Sharma v. State of Rajasthan** (1968) IILLJ 830 SC , has pointed out at p. 1914 SC that the Government cannot amend or supersede statutory Rules by administrative instructions, but if the rules are silent on any particular point Government can fill up the gaps and supplement the rules and issue instructions not inconsistent with the rules already framed.(Emphasis Supplied)

57. The aforesaid ruling of Sant Ram(supra) has been reiterated in paragraph 9 of the judgment by a three Judge Bench of Supreme

Court in the case of ***Union of India v. K.P. Joseph*** [1973] 2 SCR 752, as under:

> Generally speaking, an administrative Order confers no justiciable right, but this rule, like all other general rules, is subject to exceptions. This Court has held in SantRam Sharma v. State of Rajasthan and Anr. (1968)IILLJ830SC, that although Government cannot supersede statutory rules by administrative instructions, yet, if the rules framed under Article 309 of the Constitution are silent on any particular point, the Government can fill up gaps and supplement the rules and issue instructions not inconsistent with the rules already framed and these instructions will govern the conditions of service.(Emphasis Supplied)

58. From the reading of the aforementioned observations of Supreme Court in the case of the Sant Ram (Supra) and also K.P. Joseph (supra), it is clear that the administrative orders, directions or guidelines do not create any justiciable right is a rule not without exception and in the cases where the guidelines are framed with aim to fill the gaps in the legal framework or regulatory measures or are supplemental rules, the courts can proceed to enforce them in the form of legally justiciable right in such circumstances. The law laid down in the case of **Sant Ram** (supra) and **K.P. Joseph** (supra) has been further given imprimatur of Supreme Court in the case of **Dhananjay Malik v. State of Uttaranchal**, (2008) 4 SCC 171.

59. It is also trite law that the judicial interference is permissible in the cases the deviations from the guidelines so framed by the government are fundamental in nature and is totally contrary to the

object sought to be achieved by the said guidelines and directions issued and the public interest so required. In the case of **Narendra Kumar Maheshwari v. UOI**, AIR 1989 SC 2138, the Supreme Court observed thus:

> "The Court would be inclined to perhaps overlook or ignore such deviations, if the object of the statute or public interest warrant, justify or necessitate such deviations in a particular case. This is because guidelines, by their very nature, do not fall into the category of legislation, direct, subordinate or ancillary. They have only an advisory role to play and non-adherence to or deviation from them is necessarily and implicitly permissible if the circumstances of any particular fact or law situation warrants the same. Judicial control takes over only where the deviation either involves arbitrariness or discrimination or is so fundamental as to undermine a basic public purpose which the guidelines and the statute under which they are issued are intended to achieve." (Emphasis Supplied)

60. Applying the said principle of laws to the facts of the present case and testing the case of the parties upon touchstone of the law laid down by the courts with respect to the court's insistence of the adherence of the guidelines/ directions and their validity and enforceability, it can be said that the present qualifies all the tests which enable this court to interfere and insist on the due compliance of the guidelines as enforceable one as against permitting the deviations from the same.

It is important to mention that the defendant No.1 in the present case has specifically taken the stand that the guidelines are not

statutory in nature and it is not confirmed by defendant No.1 that they have been applied at the time of approval. It is contended by the defendant No.2 in the present case that those are not applicable but in second connected matter, being CS(OS) 3284/2015, defendant No.2 has argued that the approvals have been granted by defendant No.1 as per guidelines. However, the stand of defendant No.1 in connected suit remains the same.

61. After having considered the submissions and guidelines of 2012 and other material placed on record, I am of the opinion that the guidelines are to be considered at the time of approvals. My reasons for the same are enumerated as under:

- Firstly, as seen above, that the existing rules framed under the Drugs and Cosmetics Act do not provide the exhaustive mechanism for the dealing the dealing with the Bio Similar products as there are certain additional aspects which the guidelines insist to be taken into consideration in the process of the grant of the approval in the cases involving similar biologics. The said additional aspects include additional requirements for the clinical trial applications as per CDSCO guidelines which is evident from the reading of the guidelines, additional steps like product characterstization as per clause 6.3.2 of the guidelines, conducting of the quality comparability study as per 6.4 of the guidelines, insistence of the clinical studies and additional data requirements for the studies etc. All these aspects have been specifically provided for the in the guidelines with the preface that the similar biologics are required to be provided with the regulatory pathway keeping in mind the safety, efficacy and quality of a similar

biologic to an authorized reference biologic as against the previous pathway which was the abbreviated one. Thus, the existing rules were silent or were not adequate to provide for the pathway for regulating the regime of the control and approval of the bio similar/ similar biologic products in India for the reason of new and latest regime and the guidelines were therefore framed supplemental to the rules so that the requirements provided therein should be taken into consideration while approving the similar biologics based on the referenced products. Thus, the guidelines were supplemental to the rules framed under the Act and thus cannot be pleaded or stated to be irrelevant or non binding on the office of the defendant No.1 when the CDSCO is headed by the defendant No.1. The guidelines of 2012 thus qualify the test that the same are supplemental to the rules and are not aimed to replace or supplant the existing rules.

- Secondly, the guidelines of 2012 was aimed at providing the regulatory pathway for the similar biologics in India considering the safety, efficacy and quality of the similar biologic in consideration. Thus, the object sought to be achieved is to ensure the public health and safety so that the public should be provided with the medicines that are safe, efficacious and quality wise appropriate and at par with the innovator drugs which are based on artificially engineered micro-organism. Thus, considering the object which was sought to be achieved by the said guidelines which is in consonance with the objects and purposes of Drugs and Cosmetics Act, it cannot be said that the guidelines on similar biologics can be ignored and can be bypassed by defendant No.1. In the absence of the defendant's complying the same, the outweighing public

interests and the purpose sought to achieve by the said guidelines clearly allow this court to interdict in such matter as the deviation from the said guidelines in such a matter would be detrimental to the larger public interest and would be against the objects and reasons of the guidelines which are sought to be achieved at the time of the framing of the same.

- Thirdly, it is only the case of the defendant No.1 and other defendants that by mere fact that the guidelines are not statutory in nature but are issued by CDSCO, therefore the defendant No.1 despite being participant in framing the guidelines can ignore them (the argument which though I have already rejected separately). None of the defendants have argued or canvassed any submissions that the said guidelines are in contradiction with any rules and regulations framed under the Drugs and Cosmetics Act or ultra vires the Act. In absence any such successful plea of the said contradiction and considering that the guidelines are merely supplemental to the rules and do not aim to replace the rules but to apply them strictly along with the additional requirements considering the distinct nature of the regime of biosimilar products involved which require greater degree of regulatory measures, it cannot be assumed on a priori basis that the guidelines on similar biologics are empty formality or useless exercise and cannot be implemented by the defendant No.1. On this ground again, the inference to be drawn is towards the validity and enforceability of the guidelines as against non binding character.

62. Accordingly, I reject the argument of the defendants that the guidelines are of non binding character, not applicable being non-

statutory and are thus non enforceable and can be conveniently bypassed by the defendants while granting the approvals for manufacture of medicinal products based on similar biologic. Prima facie I am of the view that bio-similar guidelines of 2012 are applicable and the same are to be considered at the time of grant of approvals of bio-similar product.

Passing Off

63. As far as the common law principle of passing off is pretty clear on the subject for more than 200 years ago when the court of appeal in the case of **Frank Reddaway v. George. Barham** (1896) A.C. 1990 speaking through Lord Hersehell observed on page 209 that if the defendants were entitled to lead purchasers to believe that they were getting the plaintiffs' manufacture when they were not and thus to cheat the plaintiffs of some of their legitimate rights, it would be regretable to find that the law was powerless to enforce the most elementary principles of commercial morality….". The passing off as a principle originally had emerged on the basis of the general statement of law has been developed from time to time and in the modern form includes the use of the signs, trade names, domain names, logos, shape of the products or any indication which allows the consumers to attach the product of the competitor with that of the rival trader in order to deceive them.

64. The action of passing off is an action in deceit which has been recognised by the Supreme Court of India in case of ***Laxmikant V.***

Patel v. Chetanbhat Shah and Another, reported in (2002) 3 SCC 65, wherein the Supreme Court while considering a plea of passing off and grant of ad interim injunction held in no uncertain terms that a person may sell his goods or deliver his services under a trading name or style which, with the passage of time, may acquire a reputation or goodwill and may become a property to be protected by the Courts. It was held that a competitor initiating sale of goods or services in the same name or by imitating that name causes injury to the business of one who has the property in that name. It was held that honesty and fair play are and ought to be the basic policy in the world of business and when a person adopts or intends to adopt a name which already belongs to someone else, it results in confusion, has the propensity of diverting the customers and clients of someone else to himself and thereby resulting in injury.

65. The passing off is action in deceit. From the observations of Lord Hershell in the case of **Redway** (supra) at the time of the nascent stage of the evolution of law of passing off, it is clear that the law is not powerless to prevent the most elementary principles of commercial morality and the trading has to be fair and not unfair and in case there is an element of unfairness and deceit to the consumers, the court can always interdict in order to protect the consumer interests and prevent the deceit. Once the Court would notice that the party is trying to make misrepresentation or making a false statement on comparison of two drugs of the parties about the approvals of the product and it may affect the right of the suing party and if the said party alleged that the

rival party is trying to disparage the product, the action of passing off would lie. It is immaterial at the initial stage whether any strong case for passing off is made out or not.

66. Even in the case of ***N.P.Ponnuswami v. The Returning Officer, Namakkal Constituency, Namakkal, Salem Dist. And others,*** AIR 1952 SC 64, the Supreme Court held as under:-

> "12. It is now well-recognized that where a right or liability is created by a statute which gives a special remedy for enforcing it, the remedy provided by that statute only must be availed of. This rule was stated with great clarity by Willes J. in *Wolverhampton New Water Works Co. v. Hawkesford*, 6 C.B. (N.S.) 336, 356 in the following passage :-
>
> > "There are three classes of cases in which a liability may be established founded upon statute. One is where there was a liability existing at common law, and that liability is affirmed by a statute which gives a special and peculiar form of remedy different from the remedy which existed at common law; there, unless the statute contains words which expressly or by necessary implication exclude the common law remedy, the party suing has his election to pursue either that or the statutory remedy. The second class of cases is, where the statute gives the right to sue merely, but provides no particular form of remedy; there, the party can only proceed by action at common law. <u>But there is a third class viz., where a liability not existing at common law is created by a statute which at the same time gives a special and particular remedy for enforcing it</u>..... The remedy provided by the statute must be followed, and it is not competent to the party to pursue the course applicable to cases of the second class. The form

given by the statute must be adopted and adhered to."

The rule laid down in this passage was approved by the House of Lords in Neville v. London Express News Paper Limited (1919) A.C. 368 and has been reaffirmed by the Privy Council in Attorney-General of Trinidad and Tobago v. Gordons Grant & Co. (1935) A.C. 532 and Secretary of State v. Mask & Co (1940) 44 C.W.N. 709; and it has also been held to be equally applicable to enforcement of rights : see Hurdutrai v. Official Assignee of Calcutta (1948) 52 C.W.N. 343, 349. That being so, I think it will be a fair inference from the provisions of the Representation of the people Act to state that the Act provides for only one remedy, that remedy being by an election petition to be presented after the election is over, and there is no remedy provided at any intermediate stage."

Submission on Package Insert

67. Mr.Rajiv Nayar, learned Senior counsel appearing on behalf of the plaintiffs, submits that package insert used by the defendants No.2 to 4 makes misrepresentation as they are making the incorrect statement in order to create confusion and deception. Thus, the plaintiffs had no option but to approach the civil court with regard to misrepresentation, false information and violation of legal rights of the plaintiffs. He submits that it is evident from the package insert used by them that they have referred to data relating to the sales and price of HERCEPTIN in their distribution and marketing materials. They have reproduced data relating to the plaintiffs' Trastuzumab in the Summary of Product Characteristics (SmPC) for Bmab-200 and the package inserts for CANMAb and HERTRAZ. The plaintiff's case is that they

have made grave misrepresentations regarding the nature, quality, safety and efficacy of Bmab-200, in order to deceive doctors, hospitals and patients.

68. He has referred the comparison of two package inserts used by the parties and argued that without valid approvals from defendant No.1 the defendants No.2 to 4 cannot make misrepresentations and false information to the doctors, hospitals and patients. The details of the same are given as under:-

(i) SmPC for Bmab-200and the package inserts indicate that it may be used for treatment of (i) metastatic breast cancer,(ii) early breast cancer and (iii) metastatic gastric cancer. However, Bmab-200's approval is only for metastatic breast cancer. This misrepresentation could result in inappropriate switching of patients from the plaintiffs' Trastuzumab to Bmab-200 with grave consequences. Admittedly, the approval of early breast cancer and metastatic gastric cancer was never granted at the time of use of package insert of metastatic gastric cancer.

(ii) The package insert use the plaintiffs' clinical trial data regarding safety and efficacy and no comparative test results are included in the package inserts. It suggests that no independent tests have been done to establish safety and efficacy of Bmab-200. Further the data for the plaintiffs' Trastuzumab has not been segregated from data for Bmab-200, as it is done by the defendants No.2 to 4 with the intention to pass-off Bmab-200 as

having the same safety and efficacy as the plaintiffs' Trastuzumab. In fact, the package inserts do not use the name 'Bmab-200' or the term 'biosimilar' anywhere; the drug is referred to as 'Trastuzumab'.

(iii) Sample size is represented as being much larger than the actual sample size of 132 - "detected in 1 of 903 patients" and page 1001 - "data from studies 1 and 2 were obtained from 3206 patients" and "study 4 reflect exposure to Trastuzumab as part of adjuvant treatment regimen from 2124 patient". The package inserts cite results of pre-clinical studies conducted on cynomolgus monkeys but the tests conducted by defendant No.2 admittedly on Swiss albino mice and New Zealand white rabbits. As per record of defendant No.1 overall 135 patients were randomized in to THE study, out of total 67 in the Bmab-200 arm and 68 in Herceptin arm.

(iv) The package inserts state that the composition of the clinical trial population was: "84% of patients were White, 7% were Black, 4% were Hispanic, and 4% were Asian" but defendant No.2's clinical trial protocol shows that clinical studies were conducted over 23 sites in India. It is mentioned that the drug has been clinically tested "in combination with paclitaxel or an anthracycline" and also "in combination with anastrozole" but Bmab-200 was only tested in combination with docetaxel.

(v) Defendants claim that they used data from "Phase I, Phase II and pivotal Phase III studies" but defendant No.2's clinical trials only covered Phase III studies. Even the defendant No.1 in its written statement has made the specific statement that the test of phase I and phase II have not been registered with the defendant No.1.

(vi) In package inserts it was claimed that the median treatment duration in the defendants' clinical studies was 51 weeks but the clinical studies were actually conducted over a period of 24 weeks. Not only that, they have claimed part post marketing experience with Trastuzumab in their package inserts. Since defendants' drugs were launched only after the impugned order dated February 5, 2014, it could not have generated post marketing data as yet. It was also claimed in the package insert that they have conducted an open label study. Defendant No.2's letter dated August 9, 2011 to the DCGI mentions that their clinical trial protocol does not contain an open label study.

Therefore, it is submitted that since the defendants are comparing their drug with the drug of the innovator, the plaintiffs become aggrieved party who are entitled to know about the drug in question.

69. In view of above, I am of the view that prima facie the objection raised by the plaintiffs' counsel with regard to package insert during the course of hearing is a matter of civil nature and disputed question of

fact. I have been informed later on that the defendant No.2 has amended certain portion of the package insert. The Court has to see the conduct of the party on the date of filing of the suit.

70. These are the main reasons that I do not agree with the submission of Mr.Sibal, learned senior counsel for the defendants No.3 and 4 that the plaintiff would not have any civil right in the case in hand and the Drugs and cosmetics act would be exhaustive of all the remedies available to the plaintiff. I would rather say after analysing the scheme of the Drugs Act that remedies prescribed under the Drugs and Cosmetics Act would merely allow the plaintiffs to contest the grant or refusal of the approval granted by the defendant No.1 by way of the appeal (though the participation of the plaintiffs before the drug controller appears to be minimal which is only to the extent of the using the referenced product and nothing more). The civil right of the plaintiffs being the owner of the drug and only parting with the innovated product in a regulated regime so that the rival trader can merely make the biologically similar product for safety, efficacy and another reasons and should not pass off the defendants' products as those of the plaintiffs when they do not have such characteristics, can only be tested in the court of law and can be enforced therein and not before the drug controller. Thus, the judgments cited by Mr. Sibal in order to infer the ouster of civil court's jurisdiction for implicit bar or express bar are distinguishable.

71. The other circumstance is that the plaintiffs have filed the quia timet action as the time of the presentation of the suit, the plaintiffs

were not sure about the launch of product of the defendants No.2 to 4. The said product was in fact was launched on 5th February, 2014 after filing the suit. The plaintiffs admittedly reserved their right to amend the plaint. The application under Order II Rule 2 was filed.

72. The arguments addressed on behalf of the defendants are not sustainable in view of the decision of the Division Bench in the case of ***Ganga Ram Hospital Trust v. Municipal Corporation of Delhi***, 2001(60) DRJ 549. It was held as under:-

> "16. Section 169 provides for a remedy of appeal against levy or assessment of any tax under the Act while section 170 lays down conditions subject to which the right of appeal conferred by section 169 can be exercised. Neither of these two sections contain any provision barring a civil suit to challenge levy and assessment of tax under the Act. At best it may be argued that in view of the remedy of appeal provided under section 169 of the Act a party should have recourse to the said remedy. But a party filing a civil suit to challenge the levy and assessment of tax under the Act may like to urge that the levy and assessment of tax is not in accordance with the Act or is violative of the provisions of the Act. In other words it may be the case of a plaintiff that the authorities under the Act have not acted in accordance with the provisions of the Act while levying and assessing tax and, therefore, it is entitled to exercise its inherent right to challenge such a levy and assessment by way of a civil suit. Availability of an alternative remedy may be treated as a bar by the court while exercising its writ jurisdiction because writ jurisdiction under Article 226 of the Constitution of India is a matter of exercise of discretionary jurisdiction of the court but it is not the same case while entertaining a civil suit. Exercise of jurisdiction to entertain civil suit is not a discretionary matter before the civil court. A civil court may reject the plaint as per law or dismiss a

civil suit on merits. It cannot refuse to entertain the suit unless barred by law. The DMC Act does not contain any such bar to a civil suit in matters of levy and assessment of tax."

73. In the case of ***Norma (India) Ltd. v. Sameer Khandelwal and Ors.***, reported in 2007(93) DRJ 318, in para 14, it was held as under:-

"14. It is settled law that jurisdiction of the company law board under the Companies Act in relation to Section 397 of the said Act is a concurrent jurisdiction which may be exercised by civil courts where allegations pertaining to oppression and mismanagement partake the character of a civil dispute. Thus, it was the duty of the plaintiff to have made averments in the plaint or in the injunction application, giving material particulars of the dispute pending before the company law board. In particular, plaintiff ought to have disclosed about CA No. 39/2006 filed under signatures of Shri Gautam Khandelwal."

74. In the case of **K.G. Khosla Compressors Ltd. and Ors. v. Khosla Extraktions Ltd. and Ors.**, 1986 (6) PTC 211 (Del.), this Court in para 31 held as under:

"31. It is not disputed and may it could not be disputed that Civil Courts has jurisdiction in the suit. If any authority is needed reference may be made to decision of this Court in Bhandari Homeopathic Laboratories (supra). The Central Govt. has certainly no power to grant any injunction as prayed for in the present suit though a person disobeying the directions issued under sub-s. (1) of S. 22 of the Act might entail punishment. But, then in the present suit the plaintiff has also based its cause of action on passing off of the name of defendant No.1 as that of the plaintiff. I would rather say that the jurisdiction of the Central Government under Ss.20 and 22 of the Act and the jurisdiction of the Civil Court operate in two different fields. Further the

> Central Govt. has to act within the guidelines laid down under S. 20 of the Act, while there are no such limitations on the exercise of jurisdiction by the Civil Court."

75. With regard to other objection raised by the defendants about the exclusivity of civil jurisdiction impliedly bar under Rule 122DC. Rule 122DC does not cover appeals against approvals granted under Part XA - this rule is limited to appeals against orders passed by the DCGI under Part XA of the Rules. The terms "order" and "approval"/ "permission" have distinct meanings under Part XA of the Drugs Rules (refer to Rule 122DAB(3), Rule 122DAB(7), 122DAC(3), 122DAC(4), 122DB and Rule 122B(2A)*)*. In the present suit, the plaintiffs have not challenged any "order" passed by defendant No.1 under Part XA of the Drugs Rules. It does not confer a right on a third party to challenge an approval granted under Rule 122B – Rule 122DC applies to a person who is immediately and directly aggrieved by an order of the licensing authority, *inter alia*, refusing to grant licence to himself or to renew licence, and not to one who is consequently aggrieved, like the plaintiffs in the present case.

76. No doubt as Rule 122DC contains the appeal provision, the benefit of the appeal would be accrued only to a person who is before the regulator in the first instance and who would, therefore, have the knowledge of the order issued by the regulator. The said party is expected to file an appeal within 60 days from the date of the order, as contemplated under Rule 122DC. In the present case, approval for drug of defendant No.2 was not made available to the plaintiffs. Accordingly, this provision is not applicable to the plaintiffs in the

present case. The approvals of bio-similar in favour of defendant No.2 of innovator drugs are admittedly never notified of approvals granted or given any information available to manufacturers of innovator drugs.

77. The said Rule does not protect or enforce the right of the innovator drugs. Even Mr.Sanjay Jain, learned ASG appearing on behalf of the defendant No.1, has admitted that the procedure of granting approvals to manufacturers for biosimilar drugs does not involve a *lis* between the manufacturer of the innovator drug and the manufacturer of the biosimilar drug. Defendant No.1 does not determine the rights of such parties at the time of granting approvals to drug manufacturers. Therefore, the plaintiffs (*i.e.* the manufactures of the innovator drug in the present case) are entitled to file a civil suit to protect their rights in relation to the plaintiffs' Trastuzumab as efficacious remedy under this Rule is not available. (See **Ganga Ram Hospital v. Municipal Corporation of Delhi** (2001 (60) DRJ 549 at paragraph 20).

78. The next argument of the defendants is that a writ petition should have been filed to challenge an action under the Drugs Act and the Drugs Rule have also no force as an alternative remedy under a statute may be treated as a bar by the court while exercising its writ jurisdiction because writ jurisdiction under Article 226 of the Constitution of India is discretionary. Writ jurisdiction is not intended as an alternative remedy for reliefs which may be obtained in a suit. An infraction of the State's duty to act in public interest is amenable to

examination either in a civil suit or in writ jurisdiction (see **Dwarkadas Marfatia and Sons** ((1989) 3 SCC 293) at paragraph 21).

79. Even in the judgment of **Systopic Laboratories Pvt. Ltd. v. Dr. Prem Gupta & Ors.** ((1994) Supp (1) SCC 160) referred by the defendants, the writ petitions were not dismissed as non-maintainable on the ground that executive decisions of the expert committee could not be reviewed by courts – in fact, the Supreme Court reviewed the facts in detail to determine that the matter had been properly examined by the expert committee and did not require judicial interference.

80. It is settled law that Section 34 of the Specific Relief Act is not exhaustive in nature and does not circumscribe the jurisdiction of a court to grant declaratory reliefs in appropriate cases falling outside this provision (See **Vemareddi Ramaraghava Reddy v. Kondru Seshu Reddy** AIR 1967 SC 436 and **Supreme General Films Exchange Limited v. His Highness Sir Brijnath Singhji and Others** (1975) 2 SCC 530).

81. Therefore, the decisions in the matters of **Delhi Science Forum v. Union of India** ((1996) 2 SCC 405), **Jasbhai Motibhai Desai v. Roshan Kumar, Haji Bashir and Others** ((1976) 1 SCC 671), **N.D. Jayal v. Union of India** ((2004) 9 SCC 362), **NDMC v. Satish Chand** ((2003) 10 SCC 38), **Rajasthan State Road Transport Corporation v. Bal Mukund Bairwa** ((2009) 4 SCC 299) and **State of Andhra Pradesh v. M/s. Pioneer Builders** (AIR 2007 SC 113) do not support the defendants' arguments in relation to the maintainability of the

present suit. The facts appearing in the present case are entirely different.

82. It is also wrong to allege that the suit should be dismissed on the basis that the plaintiffs failed to provide the defendant No.1 two months notice prior to the filing of the suit, as required under Section 80 of the CPC as the plaintiffs' application for exemption under Section 80(2) of the CPC was allowed pursuant to the order dated February 5, 2014. Further, while notice on this application was issued to the defendant No.1 on February 5, 2014, no reply has been filed by the defendant No.1 as yet. The said non issuance of the notice is to be considered when the application shall be considered, in the absence of the reply, merely contending that the notice is the bar to the suit is untenable plea which shall be fully examined in the trial.

83. The argument of the defendants No.2 to 4 is totally baseless and misleading that at the time of obtaining the ex-parte ad-interim injunction, Mr.Mukul Rohatgi at the first date conceded that the unamended suit does not challenge the manufacturing and marketing authorisation granted to defendant No.2.

At the time of hearing, the counsel was not aware about the complete details and nature of approvals granted in favour of defendant No.2 including the approval of package insert. IT was a quia timet action. The plaintiffs were not aware about the requisite documents in their possession. He had argued at that time if the approval are validly granted, the defendant No.2 may continue to sell

the drug in the meanwhile after notice if it was found otherwise, the same would be challenged as per law. Even at the time of modification of order dated 14th February, 2014, no record from the office of defendant No.1 was produced. An impression was given to the Court that all the approvals were granted as per Act, Rules and Guidelines.

84. Even otherwise present dispute involves complicated questions of fact and evidence, the summary procedure in a purported appeal before the defendant No.1 or in writ proceedings is not the appropriate remedy. The defendants themselves are admitting that the present dispute is commercial dispute between the two set of parties. As the defendant No.1 has filed its written statement and has placed its stand before Court and produced the record of approvals of drug of defendant No.2. Further appearance in the matter is not necessary, hence the defendant No.1 is deleted from the array of the parties. The plaintiffs to file the amended memo of parties within four weeks from today. If so required they are entitled to summon the representative of defendant No.1 as one of the witnesses.

85. In the light of the above prima facie, it appears that the suit is not barred by law and this Court has also got the jurisdiction to decide the issue involved particularly when the serious allegations of misrepresentation about the approvals granted in favour of defendant No.2. The said information being provided by the defendants No.2 to 4 to the public at large and certain material is filed before Court. There is allegation that they are also providing the wrong information to the doctors, hospitals and patients. These issues are required to be

decided by the Civil Court that is competent to pass the interim order if the valid case is made out before Court.

86. When disputed questions of facts are involved, the same have to be determined in civil matter. Prima facie the objections of the defendants are not sustainable and the suit is not barred and the same is maintainable. Accordingly I.A. No.12830/2015, I.A. No.16703/2015 and I.A. No.16704/2015 are disposed of as the same have become infructuous in view of my detailed discussion in this order. Once the suit filed by the plaintiffs is held to be maintainable, there is no impediment to consider the pending applications in which the submissions were already made and the judgments were cited by both parties.

87. Now I shall deal with the other pending applications:

I.A. Nos.4649/2014 & 11224/2015 (u/o VI R.17 CPC, by plaintiffs)

The first application, being I.A. No.4649/2014, was filed by the plaintiffs on 1st October, 2014. Admittedly, in the plaint the plaintiffs had expressly reserved their right to challenge the purported approvals granted in connection with the defendants' drugs and modify the plaint and to enlarge the reliefs sought against the defendants. It is alleged in the application that after the filing of the suit, along with the copies of the purported approvals issued in connection with the impugned drug, the documents were also provided by defendant No.2 to the plaintiffs. In view of the additional information, the application was filed. The contention of the plaintiffs is that these are the subsequent

developments which have come to the knowledge of the plaintiffs after filing the suit. It is stated that the defendants No.2 to 4 have commercially launched the products after filing of the suit. The amendments were sought in various paras of the plaint, the details of which are given in para 3 of the application. It is submitted by the plaintiffs in the application that the said amendments are necessary for the purpose of deciding the real question of controversy between the parties and no prejudice would be caused if the same is allowed.

88. Reply to this application was been filed by the defendants. It was contended in the reply that the said amendments cannot be allowed, as one of the reliefs for declaration sought in the amendment application may give rise to alternative remedy prescribed under the Drug Rules, 1945. This Court has no jurisdiction to entertain the relief for declaration that the defendants' drugs have not been tested and/or approved as a bio-similar drug under the applicable law. The plaintiffs have an alternative remedy. The application was also opposed on the ground that the allegations of infringement of copyright are not sustainable on various reasons mentioned in para 7 of the reply. Besides, it is stated that the present amendment is not maintainable as the same is an abuse of the process of the law and the same deserves to be dismissed.

89. There is also no force in the argument of defendants No.2 to 4 that the unamended plaint does not contain any allegations against the DCGI and does not contain a categorical assertion that the DCGI has violated the legal rights of the plaintiffs and as per amended plaint

seeks a declaration that the manufacturing and marketing authorisation granted to defendant No.2 was invalid, the plaintiffs have not sought the consequential relief that such approval should be withdrawn. Accordingly, the declaratory relief sought by the plaintiffs cannot be granted under Section 34 of the Specific Relief Act, 1963, as amended.

90. The plaintiffs have, in addition to the declaration of invalidity of the manufacturing and marketing authorisation, sought an injunction against defendants No.2 to 4 from acting in furtherance of such authorisation.

91. In the second application for amendment filed by the plaintiffs being I.A. No.11224/2015, in para 4 thereof, it is stated that during the pendency of the suit, defendant No.2 has obtained approval for two additional indications, namely, HER2+ early breast cancer and HER2+ metastatic gastric cancer. Learned counsel for the plaintiffs in support of his submissions has referred the order dated 28th May, 2015.

92. The said fact has not been denied by the learned counsel for defendant No.2 that they have already obtained the approval from defendant No.1 with regard to the additional indications. They have also not denied the fact that their application for approval of specimen of the carton, labels and package insert is still pending for proposed additional indications. Learned counsel for defendant No.1 has admitted the said position. He has, in fact, on 28th May, 2015 as well as on 1st July, 2015 has informed that the application for such approval for specimen of the carton, labels and package insert will be

considered as per its own merits and as per the rules and regulations. He submits that the same will be considered after going through the pleadings of the parties and the orders passed by the Court from time to time.

93. The fact of the matter is that the approval of additional indications on drug was granted to defendant No.2. However, the approval of specimen of the carton, labels and package insert for the proposed additional indications is granted in July, 2015 by defendant No.1.

94. The case of the plaintiffs is that for the purpose of determining the real question of controversy between the parties, the amendment of the plaint in terms of the proposed amendments as set out in this application is necessary. It is submitted that the information given in the said applications is subsequent event which is not denied by the defendants, as the application for approval of additional indications on drug was filed in the month of August, 2014 when the matter was being heard on merits in the interim applications therefore no prejudice would be caused to the defendants if the subsequent events be brought on record by allowing the application, otherwise grave injustice, harm and loss would be caused to the plaintiffs.

95. Both these applications are opposed by defendants No.2 to 4 on the ground that the plaintiffs are seeking to challenge the very approval granted by defendant No.1 and if the same is allowed, that would change the nature of the case. It is stated that in the original plaint filed on 4th February, 2014, the plaintiffs chose not to challenge the

approvals granted by defendant No.1 and even, in the order dated 5th February, 2014 the Court did not grant ad-interim injunction with respect to the sale or marketing or distribution of the defendant No.2's drug in question. The only restraint on the said defendant is with respect to making use of the plaintiffs' trademarks and references as prayed for. There is also no restraint on the defendants from obtaining the approvals of additional indications as required under the law. It was also stated in the reply that the reading of both the applications for amendment would show that the plaintiffs are belatedly attempting to extend the scope of the plaint by changing the nature and character of the suit. Therefore, both the applications are liable to be dismissed. It is further stated in the reply that such relief of declaration would not be agitated before this Court in view of the alternative remedy prescribed under the Drug Rules, 1945 and it imposes bar on the jurisdiction of this Court. The present amendments would go beyond the scope of the original plaint, therefore, the same cannot be allowed. The defendants No.2 to 4 in their replies have also repeated the same objections as taken in the written statements and other applications filed from time to time.

96. It is also argued by the defendants that by virtue of the amendments sought in the first application, the plaintiffs are seeking relief of declaration by challenging the approval granted to defendant No.2 by defendant No.1. As far as the other amendments are concerned, which are subsequent events in nature, the same have occurred after filing of the suit about the application for additional

indications. The same have to be considered by the Court at the time of deciding the interim applications as during the course of the arguments, the defendant No.2 did not point out the said fact either to the Court or to the other side. As and when it has come to the notice of the plaintiffs, the fresh application has been filed.

97. The plaintiffs propose to make the amendments in the plaint to (i) Replace paragraph 1 of the plaint, (ii) Insert the following sub-paragraphs before paragraph 2(a) of the plaint, (iii) Since defendants 2 to 4 have already launched and introduced the defendants' drugs, delete the words *"launching, introducing,"* from the first sentence of paragraph 2(a) of the plaint, (iv) Insert the following sub-paragraphs after paragraph 2(d) of the plaint,(v) Delete the last sentence of paragraph I6(e) of the plaint, (vi) Insert the following new paragraphs after paragraph 17 of the plaint, (vii) Insert the following new paragraph after paragraph 29 of the plaint, (viii) Insert the following new paragraph after paragraph 30 of the plaint, (ix) Insert the following new paragraph after paragraph 34 of the plaint, (x) Replace paragraph 42 of the plaint, (xi) Replace paragraph 44 of the plaint, (xii) Insert the following new prayers before prayer (a) in the plaint,(xiii) Delete the words *"launching, introducing,"* from the first sentence of prayer (a) in the plaint and (xiv) Insert the following new prayers after prayer (d) in the plaint.

98. It is submitted that for the purpose of determining the real questions in controversy between the parties, the plaint should be amended in terms of the proposed amendments mentioned in this

application. No prejudice, harm or loss would be caused to the defendants if this application is allowed. On the contrary, grave injustice, harm and loss will be caused to the plaintiffs if this Application is not allowed, and the balance of convenience is in favour of the plaintiffs.

99. In the second application, being I.A. No.11224/2015, the plaintiffs propose to make the following amendments to the plaint, as amended pursuant to the First Amendment Application (the **"Amended Plaint")** i.e.(i) Insert the following sub-paragraphs before paragraph 2(a) of the plaint, (ii) Insert the following new paragraph after paragraph 10 of the Amended Plaint, (iii) Insert the following new paragraph after paragraph 13 of the Amended Plaint, (iv) Insert the following new paragraphs after paragraph 17C of the Amended Plaint, (v) Replace paragraph 29 of the Amended suit, Replace paragraph 29A of the Amended suit, (vii) Since defendants No.2 to 4 have started marketing and selling the defendants' drug in India after the filing of the present suit, replace paragraph 46 of the Amended Plaint and (viii) Insert the following new prayers before prayer (a) in the Amended Plaint.

100. It is submitted by the defendants that prior to filing of the present application, the plaintiffs had filed earlier application for amendment of plaint on 14th March, 2014 (I.A. No.4649 of 2014) which is yet to be adjudicated by this Court and currently the plaint that exists as on date is the original plaint filed by the plaintiffs at the time of instituting the present suit. Without any orders of this Court on the first application for amendment (I.A. No.4649 of 2014), the plaintiffs have

mischievously amended the plaint by incorporating paragraphs from the first application for amendment. A perusal of the proposed plaint which the plaintiffs now propose to introduce by way of IA. No.11224 of 2015 reveals that the plaintiffs have merged the paragraphs of the first application for amendment with the original plaint without any directions of this Court on the same. If amendment is allowed, it would amount to this Court allowing the I.A. No.4649 of 2014 without any adjudication of the same.

101. The prayer of second application is also opposed in the similar way as opposed in the first application. It is stated that in the original plaint filed on 4th February, 2014, the plaintiffs chose not to challenge the approvals granted by the defendant No.1 to the defendant No.2. Further, even in order dated 5th February, 2014,this Court did not grant any ad interim injunction with respect to the sale or marketing or distribution of the defendant No.2's drug CANMAb.

102. It is stated on behalf of the defendants that the restraint with respect to making use of the plaintiffs' trademark HERCEPTIN, HERCLON, BICELTIS in press release and public announcements which is also the basis of the plaintiffs' entire claim. It is submitted that there is no restrain against the defendant No.2 from obtaining requisite approvals on additional indications as required under law in relation to its drug CANMAb. The present Application for amendment of pleadings filed by the plaintiffs is an abuse of the process of law and is not maintainable. It is submitted that the proceedings are at the stage of rejoinder arguments on the applications under Order XXXIX Rules 1 &

2 CPC and Order XXXIX Rule 4 CPC wherein only the plaintiffs are left to address their rejoinder arguments. However, the plaintiffs are procrastinating their rejoinder arguments by filing one application after the other with no valid cause of action and thereby delaying an order of this Court on the injunction and vacation of injunction applications.

103. It is mentioned in the replies that the plaintiffs had wrongly reserved their right to challenge the purported approvals granted in connection with the defendants' drug and modify the plaint and/or to enlarge the reliefs against the defendants as the plaintiffs have, inter alia, through the letter of October 11, 2013 written to defendant No.1 regarding the inadequacy of the clinical trial design for the purported biosimilar Trastuzumab. The plaintiffs are awaiting a response to such letter. The plaintiffs were obtaining the leave under Order II, Rule 2 of the CPC wrongly even.

Thus, the amendment is not liable to be allowed. It would change the nature of the case and such amendment would also prejudice the defendants No.2 to 4. In the guise of the proposed amendments, the plaintiffs are now seeking to challenge the approvals granted by the defendant No.1 and if allowed, would positively change the nature of the case.

104. It is argued on behalf of the defendants No.2 to 4 that it is a settled law that when interim orders are obtained on particular pleadings, the confirmation / vacation of such an order must only be on the basis of such pleadings and consideration of an application for

amendment under Order VI Rule 17 CPC must await the determination of the applications under Order XXXIX Rule 1 & 2 and Order XXXIX Rule 4 CPC. Counsel for the plaintiffs referred **Revajeetu Builders and Developers v. Narayanswamy and Sons and Ors** - (2009) 10 SCC 84 and **Rajveer Food Marketing (I) Pvt. Ltd. v. Amrit Banaspati Company Ltd** - (2010)42 PTC147 (Del) (DB), as in the present case, the plaintiffs are attempting to disown the statement of their counsel recorded in the order of this Court dated February 5, 2014. The approvals ought to have been granted under applicable law and the Guidelines on Similar Biologies, 2012. In case the approvals had not been granted in this manner, the plaintiffs would take steps to challenge such approvals. His clients had expressly reserved their right to challenge such approvals under Order II Rule 2 of the CPC in paragraph 42 and paragraph 16(e) of the Plaint, which has been admitted it in paragraph 1 of the preliminary submissions of the reply. Counsel for the plaintiffs submits that it is wrong on the part of defendant No.2 to suggest that although the plaintiffs expressly reserved their right to modify the plaint, the plaintiffs' application should be rejected on the basis that "there was not even a whisper regarding any reservation of right to challenge the approvals granted in connection with the defendants' drug." The amendments sought in the plaintiffs' application and the first amendment application do not change the nature of the suit and necessary pleadings relating to the inadequacy of the tests conducted in relation to Bmab-200, the process of grant of approval for Bmab-200 and the basis of the additional reliefs sought pursuant to the plaintiffs' application and the

first amendment application are already included in the original plaint. The arguments were addressed on behalf of defendants No.2 to 4 without prejudice as they were pressing that once the suit was not maintainable, the question of amendment of plaint does not arise.

105. The necessary pleadings relating to the inadequacy of the tests conducted in relation to Bmab-200 and the process of grant of approval for Bmab-200 are already included in the original plaint. However, the facts sought to be included in the plaint pursuant to the plaintiffs' application arose subsequent to the filing of, and during the pendency of, the present suit. The plaintiffs could not have included these assertions in the original plaint and have taken prompt steps for amendment of the plaint to ensure a comprehensive determination of the real questions in controversy.

106. It is the admitted fact that the approval for Additional Indications granted after filing of the suit and during the course of hearing of injunction applications clearly establishes that defendant No.2 relied upon data relating to the plaintiffs' Trastuzumab, and claimed similarity with the plaintiffs' Trastuzumab in pursuing applications for approval of Bmab-200 for the Additional Indications, contrary to the directions and injunctions contained in the above referenced orders. Since Bmab-200 is claimed by the defendants to be biosimilar to the plaintiffs' Trastuzumab, no application for approval of Bmab-200 for the Additional Indications could have been made by defendants No.2 without reliance upon the data relating to the innovator drug in such application. Further, Bmab-200 has admittedly

been granted the Approval for Additional Indications solely on the basis of the data relating to the plaintiffs' Trastuzumab since admittedly no pre-clinical or clinical trials have been conducted on Bmab-200 for the Additional Indications by defendants No.2, as required under applicable law.

107. It is settled law that the parties to a suit are permitted to amend their pleadings at any stage of the proceedings for the purpose of determining the real question in controversy between them, if the amendments sought do not change the basic nature and character of the suit. It is equally settled law that the merits of the amendments are not to be gone into while deciding the amendment application. At this stage, it is not to be decided that the suit for infringement of copyright would not be maintainable if amendment is allowed. The said aspect has to be considered on merit. The plaintiffs might have weak case on that issue but at present it cannot be concluded that suit would not be maintainable as the Court is not examining the issue on merit.

108. The amendments proposed to be made are on the basis of information received by the plaintiffs after the filing of the suit which was either under the possession of defendant No.2 or under control of the defendant No.1. Even the defendant No.1 has granted fresh approvals for two additional indications without providing the information to the court uptil the end of May, 2015 or to the plaintiffs. Thus, the defendant No.2 on the other hand concealed the said factum and also obtained the approval concerning the package inserts contrary to the interim orders. All these necessitated a separate factual

foundation which the plaintiff is attempting to incorporate in the plaint as the further developments take place. The said facts were intended to be brought on record on the basis of subsequent events. Even first amendment application was pending. There is no harm if both applications for amendment of plaint can be decided together.

109. The plaintiffs seek to amend the original plaint to bring on record facts relating to the grant of approval to Bmab-200 for additional indications, namely HER2+ early breast cancer and HER2+ metastatic gastric cancer (the "Additional Indications"), which approval was sought and granted clandestinely during the pendency of the suit, and to seek appropriate reliefs m view of such facts. Pursuant to the plaintiffs' application, the plaintiffs are seeking to add and amend pleadings relating to the inadequacy of the approval granted to defendant No.2 for the Additional Indications (the "Approval for Additional Indications"). The Approval for Additional Indications was admittedly linked to the marketing and manufacturing authorisation granted for Bmab-200 on October 23, 2013 (the "Marketing Authorisation") and the invalidity of the Marketing Authorisation is indisputably the subject matter of the present suit.

110. The court's power to allow amendments is wide and can be exercised at any stage of the proceedings. The main purpose of allowing amendments is to minimise litigation and avoid multiplicity of proceedings, and it is for the court to consider whether the amendment sought is imperative for proper and effective adjudication of the disputes and whether disallowing the amendment would in fact lead to

injustice or multiple proceedings. If the necessary factual basis for the amendment is already contained in the unamended plaint, seeking additional reliefs on the basis of those facts will not change the nature of the suit.

111. A change in the nature of relief claimed will not be considered as a change in the nature of the suit and the power of amendment should be exercised in the larger interest of doing full and complete justice between the parties and the courts have to be liberal in allowing amendments if the application for amendment is filed prior to the commencement of the trial.

112. The application for the Additional Indications has been pursued by defendants No.2 and granted by defendant No.1, without information to this Court, during the pendency of the suit, pursuant to which the validity of the original approval of Bmab-200 for HER2+ metastatic breast cancer had been challenged before this Court and is subjudice. These actions of the defendants are in complete disregard of the terms of the above referenced orders and the directions issued by this Court.

113. If the necessary factual basis for the amendment is already contained in the unamended plaint seeking additional reliefs on the basis of those facts is permitted, in the interest of preventing multiplicity of proceedings, the prayer in the amendment application can be allowed. This Court has noticed that there was no delay in filing of applications for amendment of plaint. It is also not denied by

any of the defendants that these two applications were filed on the basis of subsequent events. The mere objection raised by the defendant was that once the original suit filed by the plaintiffs was not maintainable, the question of amendment in the subsequent stage does not arise. In the present case, I have already held that the suit filed by the plaintiffs is maintainable. The said objection has therefore no force.

114. Even otherwise, it is not in dispute in the present case that the relief sought by way of amendment by the plaintiffs could be claimed by way of a separate suit. It is held in the case of ***Abdul Rehman and another v. Mohd. Ruldu and others***, reported in (2012) 11 Supreme Court Cases 341,that an amendment seeking declaration of title shall not prejudice the case of the other side unless the reliefs claimed are not barred by limitation. It was observed in the case referred that no prejudice would be caused to the respondents if amendments were allowed. In order to avoid further litigation, the same should be allowed as all amendment which are necessary for the purpose of determining the real questions in controversy between the parties should be allowed if it does not change the basic nature of the suit. A change in the nature of relief claimed shall not be considered as a change in the nature of suit and the power of amendment should be exercised in the larger interests of doing full and complete justice between the parties.

115. The Supreme Court in the case of ***Rajesh Kumar Aggarwal and others v. K.K.Modi and others***, reported in (2006) 4 Supreme Court Cases 385 held in para 18 and 19 as under :

> "18. .....the real controversy test is the basic or cardinal test and it is the primary duty of the Court to decide whether such an amendment is necessary to decide the real dispute between the parties. If it is, the amendment will be allowed; if it is not, the amendment will be refused. In cases like this, the Court should also take notice of subsequent events in order to shorten the litigation, to preserve and safeguard rights of both parties and to sub-serve the ends of justice. It is settled by catena of decisions of this Court that the rule of amendment is essentially a rule of justice, equity and good conscience and the power of amendment should be exercised in the larger interest of doing full and complete justice to the parties before the Court.
>
> 19. While considering whether an application for amendment should or should not be allowed, the Court should not go into the correctness or falsity of the case in the amendment. Likewise, it should not record a finding on the merits of the amendment and the merits of the amendment sought to be incorporated by way of amendment are not to be adjudged at the stage of allowing the prayer for amendment. This cardinal principle has not been followed by the High Court in the instant case."

116. In any event, a change in the nature of relief claimed will not be considered as a change in the nature of the suit and the court may exercise its power to amend pleadings in the larger interest of doing full and complete justice between the parties as this Court has already that the suit filed by the plaintiffs is maintainable in view of facts and circumstances of the present case.

117. It is settled law that the application under Order VI, Rule 17 of the CPC can be decided before an earlier application under Order XXXIX, Rule 4of the CPC. Counsel for the plaintiffs referred to **Shivraj Gupta v. Rajendra Gupta**, (judgment of the Delhi High Court dated March 11, 2010) at paragraphs 9and 10 and **Mohun Bagan Athletic Club v. Deba Prasad Mukherjee** (AIR 2003 Cal 298 at paragraphs 30 to 33). Case of **Rajveer Food** (supra) does not apply to the present matter - the amendment application in that matter was not considered at the stage of considering the Order XXXIX applications since the plaintiffs had deliberately suppressed facts in the unamended plaint. The court held that allowing the amendment application at the Order XXXIX stage in those facts would enable a party to rush to court post haste without making a full disclosure of all the facts within its knowledge and subsequently seek incorporation of the said facts by way of an amendment while in the meantime continuing to enjoy the ex parte order obtained fraudulently and dishonestly. Such is not the case here where the plaintiffs have deliberately concealed something in order to gain advantage over the defendants and are malafidely sustaining the same. On the contrary, it is a case where the plaintiffs have discovered certain facts during the progression of the case which they want to incorporate or elaborate in the plaint.

118. As I have already observed that the un-amended plaint contained sufficient averments as to challenge the approval which the plaintiffs could have made at the relevant time. The plaintiffs are merely elaborating the said challenge more in the relevant paragraphs

sought to be amended in the plaint. Rather, the plaintiffs' endeavour to seek amendment to the plaint is in consonance with the statement made by plaintiffs' counsel that the approval would be challenged in accordance with the law before this court. If on account of the advise, if the plaintiffs are guided to seek amendment in the plaint to elaborate their challenge and seek a declaratory relief, then there is no reason as to why the said amendment is not in consonance with the challenge which was contemplated by the plaintiffs earlier to the drug approval.

119. **The defendants by raising such a plea that the amendment is impermissible because of hearing of the injunction application has commenced along side the hearing of the application seeking vacation of the injunction which is not the straight jacket law but is based on case to case basis (where malafide is to be inferred on facts) and simultaneously stating in the hearing of the injunction application that the un-amended plaint does not contain such a challenge cannot be allowed take advantage of the situation by continuing to delay the proceedings and manufacture the drugs in the meantime without adjudication of the claim of the parties, when otherwise the claim of the plaintiffs is maintainable and the amendments are permissible in law and plaintiffs have justifiable reasons for seeking the amendment**. Doing this would be abuse of the process of the law as the plaintiffs would be left in legal impediments of bringing amendments after amendments as the developments take place.

120. I am clear in my mind that in order to decide the real controversy between the parties, no harm or loss will be caused to the defendants if the amendment application is allowed since the proceedings are still at a preliminary stage and trial has not yet commenced - pre-trial amendments are liberally allowed.

121. The other argument of the learned counsel for defendants is that the plaintiffs were aware of Defendant No.2's application before the DCGI since 2011 and objected to such application in October 2013. The plaintiffs were aware of the contents of defendant Nos. 2 to 4'spackaging material and product insert before filing the present suit as the packaging material for CANMab has been reproduced in plaint. Therefore, these are not subsequent facts and the application for amendment of the plaint to include these facts should be rejected. Even if that submission is to be considered at the highest as correct, still, the question to be asked is as to whether the plaintiffs are not entitled to amend the pleadings by suitably elaborate the challenge even if it was known to them at the time of filing of the suit and whether the said amendment is not essential to decide the issue between the parties. In my view, the plaintiffs cannot be allowed to amend the pleadings as the suit is at the initial stage and the pending applications are being decided on the basis of original plaint and subsequent admitted events, some of which are brought to the notice of the Court and plaintiffs by the defendants themselves.

122. There is no much delay in filing the application. In fact, the defendants did not care to disclose the material facts about the

approvals to the Court as well as plaintiffs after filing of the suit. The amendments sought in both applications are in fact in the nature of subsequent events as well as elaboration of facts already stated in the unamended plaint and additional prayers made in the proposed amended plaint. The defendants were not ready at any point of time to share any information about the bio-similar products of the plaintiffs. Even otherwise small delay i.e. three months does not mean that the amendment application which has a merit should be dismissed. The delay in the present matter is wholly attributed to the defendant No.2 who has obtained the approvals of second set of approvals of additional indications in hidden manner.

123. Thus, under these facts, the prayers in both applications are allowed. The defendants are granted four weeks time to file the written statements to the amended plaint. However, it is clarified that since the defendants No.2 to 4 are yet to file the written statements to the amended plaint, the pending applications are being decided on the basis of unamended plaint and subsequent events happened during the course of hearing.

124. **I.A. No.5956/2014 dated 28th March, 2014 filed by plaintiffs under Order 11 CPC**

Now I shall take the above referred application for discovery of documents.

i) It is mentioned in the application that on February 10, 2014 and February 25, 2014, defendant No.2 provided certain documents to the

plaintiffs (the **"Defendant's Documents")** in support of their contention that the defendants' drugs have received manufacturing and marketing approval from defendant No.1 and that such approval is in accordance with the applicable law. However, the defendant's documents do not contain the entire correspondence exchanged by defendant No.2 with defendant No.1, the Review Committee on Genetic Manipulation (the "RCGM"), and the Office of the Drugs Controller, State of Karnataka (the **"Karnataka Drugs Controller").** Further, the defendant's documents do not contain, *inter alia,* all the Form filings, results of the product characterisation, pre-clinical and clinical studies and other enclosures. Defendant No.2 has deliberately sought to suppress and distort material facts in connection with the approvals obtained for the defendants' drugs.

ii) The defendant No.2 has selectively filed certain correspondence between defendant No.2 and other appropriate regulatory authorities, including defendant No.1 in relation to the approval of the defendants' drugs; it has deliberately failed to file the enclosures to such letters (including the various application forms and the results of the tests purportedly conducted on the defendants' drugs at each stage) before this Court. The plaintiffs are, therefore, entitled to the discovery and/or inspection of the entire correspondence (including form filings, test results and other enclosures) between defendant No.2 and defendant No.1 and the other appropriate regulatory authorities relating to the development, testing and approval of the defendants' drugs.

iii) The plaintiffs sought discovery and production of further documents, the discovery and production of the following documents in particular is prayed for:

> i) All the enclosures (including Form C3, draft study plans, etc.) to Defendant No.2's letter dated May 6, 2009, to the RCGM seeking permission to conduct preclinical studies;
>
> ii) All the enclosures (including Form C5, etc.) to Defendant No. 2's letter dated January 4, 2011 bearing No. RA/BLlRCGM/ll/004, to the RCGM, seeking approval of their pre-clinical studies data in relation to Bmab-200;
>
> iii) Summary report on the pre-clinical study data that would have been submitted by Defendant No.2 to Defendant No.1, pursuant to the RCGM's letter dated February 25,2011;
>
> iv) All the enclosures to Defendant No. 2's letter dated March 9, 2011, to DefendantNo.1 seeking permission to conduct the clinical trials;
>
> v) Defendant No.1's letter dated June 15,2011 bearing No. 4-90IBIOCON/11-BDto Defendant No.2;
>
> vi) The expert letter enclosed with Defendant No. 2's letter dated August 9, 2011bearing No. RA/BL/DCGI/11/114 to Defendant No.1;
>
> vii) All the enclosures to Defendant No. 2's letter dated July 16, 2012 bearing No.RA/BL/DCGI/12/078 to Defendant No.1; and
>
> viii) All the enclosures to Defendant No. 2's letter dated October 10,2013 bearing No.RA/BL/DCGI/13/205 to Defendant No.1.

It is stated in the application that if the prayer sought in this application is not granted, the plaintiffs will suffer prejudice as Defendant Nos. 2 to 4 will continue to market, sell and distribute the

Defendants' Drugs by relying on the purported approvals obtained by Defendant No.2 in relation to the Defendants' Drugs.

125. Reply on behalf of the defendant No.2 has been filed to the application filed under Order XI Rule 12 and 14 read with Section 151 CPC by the plaintiffs for discovery and production of documents by defendant No.2. It is mentioned in the reply that the present Application was filed by the plaintiffs in March 2014. However, the plaintiffs chose to press this application only on 8th April, 2015. The request for seeking sensitive information and trade secrets submitted by the defendant No.2 to the Licensing Authority under the Act during the process for seeking approval of its drug is barred in law.

The present application filed by the plaintiffs is aimed at seeking to examine further documents relating to the approvals granted to the Defendant No.2's drug. The plaintiffs can neither be given access to the record which is lying in a sealed cover before the Court nor can they seek the same documents from the Defendant No.2 because such documents are confidential in nature and contain sensitive and proprietary information belonging to the Defendant No.2 and its business, it would be potentially damaging to the Defendant No.2 if such information/documents containing sensitive, confidential and proprietary information come in the hands of a competitor such as the plaintiffs who would commercially exploit and utilize the said information/ documents to the detriment of the Defendant No.2.

126. It is strongly opposed and submitted that the plaintiffs have no locus to seek discovery of the documents as admittedly the documents sought are directly relating to the approval of Defendant's duly approved drug CANMAb and plaintiffs cannot be permitted to assume the role of the Licensing Authority and usurp the role of independently constituted, statutory or otherwise technical / expert bodies who have evaluated the Defendant's application for grant of approval of CANMAb. Such information is confidential in nature and is shared with the Defendant No.1 under its fiduciary relationship. Such information filed with the Defendant No.1 is subject to the restrictions envisaged under the Drugs Act as also the RTI Act, 2005 in addition to the protection available under common law for trade secrets.

127. The defendant No.2 in the present case has not only refused to discover or produce the documents but also opposed the request to inspect the file submitted by the defendant No.1. The defendants have assigned various reasons not to discover and produce the said documents. The defendant No.2 has admitted that the plaintiffs' documents pertaining to all approvals are already in public domain and in fact that the defendant No.2 has relied upon the data at the time of approvals.

128. It is a matter of fact that all the approvals of three indications on the basis of material produced before the appropriate authorities have been granted. The defendant No.2 has also relied upon the data and documents of the innovator. However, the defendant No.2 all the times refused to produce the documents sought

in the application. When particular documents are known, a party cannot ignore the said provision, subject to the condition that the documents sought to be discovered and produced are relevant and are in the possession and power and discovery and production of the said documents is necessary.

129. The basis of judgment of the Supreme Court in the case of ***M.L.Sethi v. R.P.Kapoor***, AIR 1972 SC 2379, wherein the entire procedure has been discussed, has been considered by the Courts from time to time in many judgments including in the case of ***Sasanandgouda v. Amarkhed***, AIR 1992 SC 1163 and ***Rajesh Bhatia v. G.Parimala***, 2006 (3) ALD 415. The relevant paras 30 and 31 of ***M.L.Sethi*** (supra) read as under:-

> "30. In ***M.L. Sethis's*** case (Supra) the Supreme Court held that:
>
> "Generally speaking, a party is entitled to inspection of all documents which do not themselves constitute exclusively the other party's evidence of his case or title. If a party wants inspection of documents in the possession of the opposition party, he cannot inspect them unless the other party produces them, The party wanting inspection must, therefore, call upon the opposite party to produce the document. And how can a party do this unless he knows what documents are in the possession or power of the opposite party? In other words, unless the party seeking discovery knows what are the documents in the possession or custody of the opposite party which would throw light upon the question in controversy, how is it possible for him to ask for discovery of specific documents?..."
>
> The Court, speaking about Order 11 Rule 12 CPC, held that:

"When the Court makes an order for discovery under the rule, the opposite party is bound to make an affidavit of documents and if he fails to do so, he will be subject to the penalties specified in Rule 21 of Order 11. An affidavit of documents shall set forth all the documents, which are, or have been in his possession or power relating to the matter in question in the proceedings. And as to the documents which are not, but have been in his possession or power, he must state what has become of them and in whose possession they are, in order that the opposite party may be enabled to get production from the persons who have possession of them (see Form No.5 in Appendix C of the Civil Procedure Code). After he has disclosed the documents by the affidavit, he may be required to produce for inspection such of the documents as he is in possession of and as are relevant".

"31. The Court also held that the documents sought to be discovered and not be admissible in evidence in the enquiry of the proceedings and it is sufficient that the documents would be relevant for the purpose of throwing light on the matter in controversy. In a subsequent decision, dealing with an election dispute, ***Sasanagouda V. S.B. Amarkhed*** AIR 1992 SC 1163, the position vis-a-vis production of documents on discovery and inspection was explained, in the following terms:

> "The court, therefore, is clearly empowered and it shall be lawful for it to order the production, by any party to the suit, such documents in his possession or power relate to any matter in question in the suit provided the Court shall think right that the production of the documents are necessary to decide the matter in question. The Court also has been given power to deal with the documents when produced in such manner as shall appear just. Therefore, the power to order production of documents is coupled with discretion to examine the expediency, justness and the relevancy of the documents to the matter in

question. These are relevant considerations, which the Court shall have to advert to and weigh before deciding to summoning the documents in possession of the party to the election petition."

130. The defendant No.2 in the present case has not only refused to discover or produce the documents but also opposed the request to inspect the file submitted by the defendant No.1. The approvals which have been granted to defendant No.2 are on the basis of certain documents produced before the Regulatory Authority who may or may not rightly or wrongly granted the approvals. The defendant No.2 now cannot claim the confidentiality in nature on the grounds that the access to the said documents would damage the case of the defendant No.1 particularly in view of the fact that the approvals of bio-similar product were obtained on the basis of the plaintiffs' product and their data has been used.

131. Mr.Sandeep Sethi, learned Senior counsel, appearing on behalf of the plaintiffs, has argued that some of the documents are most crucial tests, which the defendant No.2 is not inclined to share with the plaintiffs, is about characterisation stage and the production process of the similar biologic in order to demonstrate that its drug is consistent and the testing of the similar biologic must be sufficient to ensure that the product meets acceptable levels, safety, efficacy and quality. It is submitted that the defendant No.2 is deliberately wants to hide the said tests from the plaintiffs and at the same time the defendant No.2 wants to claim that its product is bio-similar and

informed the entire world in this regard in order to take the advantage. He says in fact the defendant No.2 does not want that the plaintiffs to address their submissions on this issue. Therefore, the defendant No.2 is avoiding inspection of most crucial documents. The case of the defendant No.2 is that they have conducted all trials as per rules. However, they are not ready to give the inspection to the plaintiffs who have time and again mentioned that all the trials and tests required for the purpose of approvals have not been conducted. The only explanation is that the defendant No.1 has already examined the documents.

It is wrongly stated by the defendant No.2 that the plaintiffs are nobody to inspect the same. As far as the Court is concerned, the record has been submitted, the Court may verify the same. They have informed to the Court that these documents are confidential in nature and the same can only be produced for satisfaction of the Court and they are sensitive documents from the business point of view containing the secret information and the plaintiffs may misuse the same, therefore, these documents cannot be revealed. At the same time, it is not denied by the defendant No.2 that it had obtained the entire published data of the plaintiffs and relied upon before defendant No.1 and on the basis of such data, the approval was obtained.

132. It is a matter of fact that he defendant No.2 is claiming that the approvals have been granted as per Act and approval and all the requisite clinical trials have been conducted. It is also stressed by the defendant No.2 that after approvals they are entitled to refer its drug as

biosimilar to the drug of the plaintiffs and they can declare to all hospitals, doctors and the entire world that their product is biosimilar and can compare both drugs. In view of such circumstances, the party has a right to know that under what circumstances the approvals were granted to the defendant No.2 of their bio-similar product or not. The plaintiffs are the aggrieved party. One fails to understand that once the approval is granted why now the data used by defendant No.2 before defendant No.1 cannot be examined by the plaintiffs. Though record has been submitted by the defendant No.1, this Court is not an expert for comparing characterisation of two drugs of the parties. Further the aggrieved party is entitled to know the nature of the clinical trials conducted by the party who intends to use the biosimilar drug of the innovator.

133. I have gone through the submissions made by the defendants while resisting the application for discovery of documents filed by the plaintiffs. It appears that the plaintiffs are seeking discovery of the documents so as to prove their case clinically and to provide the infirmities in the defendant's approval process of the drug. The defendant's position while resisting the injunction application has always been that the drug of the plaintiffs is already approved in India and thus data of the plaintiffs and its approval process can come in aid of the defendant while seeking its approval of the drug BMAB 200 based on referenced biologic.

134. If this position taken by the defendant No.2 qua the data and approval of the plaintiffs' drug by calling it a publically available

documents, it is beyond comprehension as to how the defendant No.2 after submitting the documents with defendant No.1 can call their documents as confidential in nature. The defendants' stand is surprising when they go on state that the plaintiffs cannot also inspect the documents from the office of the defendant No.1 as it is hotly contested matter. Off course, there is an attempt to withhold the documents from the plaintiffs who are the aggrieved parties whose product is referenced against by the defendant No.2 who cannot withheld the documents which would only reveal whether the requisite and crucial trials have been conducted by the defendant No.2 or not. There is no force in the submission of the defendant No.2 that since the original record is submitted by the defendant No.1, the Court may examine the same. As a matter of fact, the plaintiffs' assistance on this issue is required in order to find out the truth.

135. Under such circumstances, I do not find any impediment in allowing the application seeking discovery of the documents in as much as the moment the approval has been allowed, the document submitted before the defendant No.1 can be examined by the plaintiffs being aggrieved party. However, in order to strike the balance between the parties and concerns raised by the learned counsel for the defendant No.2 about confidentiality of the document, it would be proper that let the documents as mentioned in the application be filed in sealed cover within two weeks from today. The same be kept in safe custody of Registrar General. Two lawyers and an expert from the plaintiffs side would inspect the said documents in the presence of

two Advocates from the side of defendant No.2. They (members of club) would be bound by confidentiality and shall not make copies or disclose the contents of the said aforesaid documents to anyone, oral and written communications to the press, blog publications etc. in order to maintain the confidentiality except in the present proceedings. The inspection can only be done through the confidentiality club members and no copies will be made of such confidential documents. After the inspection, the aforesaid confidential documents, the same be resealed and again deposited with the Registrar General of this Court. After inspection, the plaintiffs would be at liberty to amend their pleadings if so required.

136. The application is accordingly allowed in terms as mentioned above.

I.A. No.4677/2014 (under Order XXXIX Rule 2A CPC filed on 11th March, 2014)
I.A. No.14533/2014 (under Order XXXIX Rule 2A CPC), filed by plaintiff on 25th July, 2014

137. The above said applications have been filed by the plaintiffs on respective dates. The averments made in the said applications are mentioned as per the application. First I shall refer the application, being I.A. No.4677/2014.

The said application has been filed by the plaintiffs under Section 94(c) read with Order XXXIX Rule 2A read with Section 151

CPC for breach of order dated 5th February, 2014 and modified order dated 15th February, 2014.

138. It is submitted in the application that defendants No.2 to 4 started selling CANMAb and HERTRAZ, with package inserts containing the Applicants' data, only after the February 5 order which prohibited the use of the Applicants' data, *inter cilia,* in the package inserts. Respondents No.1 to 3 have taken no action to discontinue the use of the Applicants' data in the package inserts for CANMAb and HERTRAZ after date of service of the February 5 order. As such, defendants No.2 to 4 have breached the terms of the February 5 Order and the injunctions contained therein. It is also stated in the application that at the hearing on February 14, 2014, the counsels for defendants No.2 to 4 made a categorical statement that the package insert being used by them, which was shown to the Court, could be used by them as they had received a specific approval for such package insert. It is in this background that the February 14 Order was passed.

139. Despite the claims made by defendants No.2 to 4 at the hearing on February 14, 2014, that they had approval for their labels, cartons and package inserts, no such specific approval has been placed on record in the above mentioned suit. It is submitted that defendants No.2 to 4 have not obtained the approvals for the package inserts that are being used for their respective products even though such a statement was made to this Court. Condition 8 of the marketing authorisation granted for Bmab-200 on October 23,

2013 states that "Specimen of carton, labels, package insert that will be adopted for marketing the drug in the country shall be got approved from the Licensing Authority before the drugs is marketed and the defendant No.2 has failed to produce any approval relating to package insert for Bmab-200."

140. On February 26, 2014, the plaintiffs purchased a sample of CANMAb from the market. The accompanying package insert is not in compliance with the orders since it extensively refers to and relies on the data relating to Trastuzumab marketed, *inter alia,* as HERCLON™ by the Applicants. A copy of the package insert for HERCLON™ is attached as Annexure B.

The package insert for CANMAb, *inter alia,* states as follows:

> "The following clinical efficacy results have been observed in various patient populations under the treatment with trastuzumab based on published information."
>
> *"The following undesirable effects and their frequencies have been observed under treatment with trastuzumab based on published information."*

141. The published information referred to in the package insert is the data for Trastuzumab which is marketed by the Applicants as HERCEPTIN®, HERCLON™ and BICELTIS®. By referring to and relying on such data in the package insert for CANMAb, after the February 5 Order, defendant No.2 has knowingly, intentionally and wilfully disobeyed and disregarded the Orders.

Copies of the invoice dated February 26, 2014 for the purchase of CANMAb together with the package insert for CANMAb as purchased on this date are annexed as Annexure C (Colly.).

142. The press releases on the websites of defendants No.2 to 4 continue to make references to HERCEPTIN and rely on the sales data for the plaintiffs' Trastuzumab despite the orders. The press releases dated November 26, 2013 and January 18, 2014 which are presently available on the website of defendant No.2, *inter alia,* state that: *"The global sales for trastuzumab stood at US$ 6.4 bn in 2012, while in India it recorded sales of US$21 Mn."* Therefore, defendant No.1 is continuing to rely on the sales figures of the plaintiffs' Trastuzumab despite the directions issued pursuant to the orders. Copies of the press releases dated November 26, 2013 and January 18, 2014 are presently available on the website of defendant No.2.

The allegations are made against the defendants No.2 to 4 that they have not taken any steps to remove such press releases from their websites, and have therefore, knowingly, intentionally and wilfully breached the Orders.

143. In the second contempt petition, being I.A. No.14533/2014, it is stated that the plaintiffs have become aware that defendants defendant No.2's annual report for financial year 2013-2014 (the **"Annual Report"),** as made available on the website of defendant No.1 at http://www.biocon.com/docs/Biocon Annual Report 2014.pdf, *inter alia,* states:

On page 54: *"CANMAb TM is being offered to HER2-positive metastatic breast cancer patients in India at [Rs` I 57,500 per 440 mg presentation, which is about 25% lower than the prevailing price of the reference product. It would be important to indicate that the reference product price was significantly reduced to current levels by the innovator in anticipation of competition and is now around a third of that in Europe and the US. This means CANM_Ab's price in India is a small fraction of global trastuzumab prices."* (emphasis supplied)

On page 100: "CANM_Ab (INN: trastuzumab) has the distinction of being the world's lowest priced antibody for treatment of HER2 positive metastatic breast cancer. Launched in Q4 FY14, CANMAb has been made available in 2 formats: 440 mg and 150 mg. Our drug can be stored for 1 month in both of these presentations and hence will ensure that there is no under-dosing or wastage of drug by Indian patients, which is quite common today." (emphasis supplied)

It is also averred in the application that these statements are false and misleading, they in fact are also in contravention of the terms of the February 28 Order and the directions. By making such statements, defendant No.2 in suit has knowingly, intentionally and wilfully disobeyed and disregarded the February 28 order. A copy of the Annual Report is filed as **Annexure C.**

144. It is submitted that the press release dated January 18, 2014, which is presently available on the website of despondent No.2 at http://www.biocon.com/biocon press release details.asp? subLink=news &Fileid=509, *inter alia,* state that:

"Biocon intends to make a significant difference in the treatment paradigm for HER2-positive breast cancer in India by enhancing access to more affordable treatment with CANMAb^{T}" (trastuzumab), which offers the same level of safety and efficacy as the reference product." (emphasis supplied)

"Unlike the product currently available in the market, both 150 and 440 mg formulations of CANM_Ab^{nt} can be stored for 1 month which is an important offering for patients in India, as it will ensure that there is no under dosing or wastage of drug which is quite common today." (emphasis supplied)

"CA_NMAb^{Tm} will be available at about 25% discount to the current list price of the reference product in India, which is already significantly lower than its price in developed markets. In addition, CANMAb's 150 mg formulation, priced at Rs 19,500/vial will allow extra savings to patients as they can buy smaller quantities as per their requirement."

Therefore, it is alleged that the defendant No.2 is continuing to state that the plaintiffs' Trastuzumab is undesirable as it is expensive and results in under-dosage and/or wastage, in their press releases. The defendant No.2 has not taken any steps to remove such press releases from its website, and has therefore, knowingly, intentionally and wilfully disobeyed the orders and the plaintiffs had also filed earlier application under Section 94(c) read with Order XXXIX Rule 2A and Section 151 of the CPC, i.e., I.A. No. 4677 of 2014, which is pending consideration by this Court. The plaintiffs are constrained to file this present application in view of the defendants' continuing disregard of the orders dated February 5, 2014 and February 14, 2014 and the subsequent disobedience of the February

28, 2014 order. The defendants conduct indicates the habitual disregard with which the defendants treat this Court's orders. The defendants are wilful disobedient of the directions issued by this Court.

145. The averments made in both applications have been examined along with documents filed. Prima facie, the case to issue show cause notice against the defendants is made out in view of material available on record. Thus, show cause notice is issued to the respondents in the applications as to why the contempt proceedings should not be taken against them for 2nd June, 2016 before the roster Bench. Replies to the same be filed within four weeks from the date of service. Rejoinders thereto be filed by the next date.

146. **I.A. No.3955/2015 (filed by third party under Order 1 Rule 10 CPC for impleadment)**

The above mentioned application has been filed by a third party. Both the parties admit that it is a commercial dispute between the two private parties. They are contesting their disputes strongly before this Court. Thus, it is not necessary to implead the party as prayed. The application is dismissed. As and when the presence of the said party would be required by the Court, the above application would be revived. At this interim stage, no arguments are necessary to be addressed by the third party as the similar issues are being argued by the defendants.

CCP(O) No.69/2015 dated 30th June, 2015 and I.A. No.12862/2015 dated 30th June, 2015 by defendants No.3 and 4

147. The above mentioned application has been filed under Order XXXIX Rule 1 and 2 CPC read with Section 151 CPC praying to restrain the plaintiffs from issuing letters, press releases, publication and/or material in any form or manner in relation to the present proceedings and also to withdraw the letter dated 10th June, 2015 or any other letter of such nature and demand issued to the DGCI. They have also filed a contempt petition for taking action for writing these letters.

148. In the present suit due to the gross contemptuous acts of plaintiffs in a letter dated 10th June, 2015 to the Drugs Controller Karnataka through their legal counsel directing the Authorities under threat of contempt proceedings, to take no action with regard to the approval vis-a-vis cartons, labels, package insert, packaging or any other material being submitted by the defendant No.2 to the Authorities.

149. The above mentioned application was taken up for hearing in Court on 1st July, 2015. The contention of the learned counsel for defendant No.2 was that despite of the order dated 28th May, 2015 passed by the Court, the plaintiffs have communicated with defendant No.1 i.e. the Drugs Controller General of India, by misleading it and asked the defendant No.1 not to grant the approval of the carton, labels and package insert. On the other hand, learned Senior counsel appearing on behalf of the plaintiffs submits that the plaintiffs have merely informed the defendant No.1 about the interim order passed

against defendant No.2. The plaintiffs have no intention to mislead the defendant No.1 in any manner. The plaintiffs have no objection if the application made by the defendant No.1 for approval of the carton, labels and package insert for additional indications be decided on merits after considering the orders passed by the Court from time to time and if the same is granted, the plaintiffs would challenge the same in accordance with law. Defendant No.2 is satisfied with the statement of the plaintiffs. There is a force in the submission of the learned counsel for the plaintiffs. The defendant No.1 also agreed to consider the application for approval of carton, labels and package insert after going through the interim orders dated 5th February, 2014 and 14th February, 2014 and the same would be decided on the basis of rules and regulations. During the course of hearing, I was informed that such approvals have been granted. Thus, no further order is required to be passed. The application is disposed of accordingly.

I.A. No.12830/2015 (under Order VII Rule 11(a) and (d) of CPC dated 30th June, 2015 by the defendant No.2

150. It is submitted in the application that in an attempt to overcome the deficiencies in the plaint, the plaintiffs have filed various misconceived Applications in the present proceedings. The plaint does not disclose any cause of action.

As all pleas raised in the application have been decided in earlier part of my order wherein it is held that at this stage the suit of plaintiffs is maintainable. Therefore, no further orders are required to

be passed as the prayer has become infructuous. The application is disposed of accordingly.

I.A. No.16703/2015 dated 12th August, 2015 and I.A. No.16704/2015 dated 5th August, 2015 by defendant No.3 listed before Court on 13th August, 2015

151. It is stated in the applications that the Defendant No.2 has been constrained to file the present application as the parties have argued at length on the Application for Vacation of Injunction (IA No.2990 of 2014), Application for Injunction (IA No.2371 of 2014) and jurisdiction of this Court. However, the plaintiffs are preventing the Court by derailing the present proceedings in vacation of injunction and to decide the issue of maintainability of the suit.

152. The above said applications have become infructuous in view of reasons given in my order while deciding the issue of maintainability of the suit and jurisdiction of this Court. The averment and the issue raised in the present applications as well as large number of applications filed by the defendants No.2 to 4 are of repetitive in nature. No further orders are required to be passed under these circumstances and the same are dismissed.

I.A. No.2371/2014 (under Order XXXIX Rule 1 & 2 CPC by plaintiffs) and I.A. No.2988/2014 and I.A. No.2990/2014 (under Order XXXIX Rule 4 CPC by defendants No.2 to 4)

153. Now I shall deal with the rival submissions of the parties in relation to main issue involved in the matter i.e. approvals of drug metastatic breast cancer, International Non-proprietary Name (in short

INN) Trastuzumab, concept of biosimilar drug and approvals and package insert, extrapolation which are granted by the authorities under the provisions of the Drug Act and Rules.

154. It is a well-settled salutary principle that if a statute provides for a thing to be done in a particular manner, then it has to be done in that manner and in no other manner. (See **Nazir Ahmad v. King Emperor**, AIR 1936 PC 253(2); **Rao Shiv Bahadur Singh v. State of Vindhya Pradesh**, AIR 1954 Supreme Court 322; **State of Uttar Pradesh v. Singara**, AIR 1964 SC 358). When the State lays down the Rules, the same are imperative to be followed.

155. **Before dealing with the submissions, it is necessary to mention that it is admitted in the written statements that in the Act and Rules the term "Similar Biologics" has not been defined. The defendant No.2 neither applied for permission to conduct Phase I and Phase II clinical trials nor those were registered with the defendant No.1.**

<u>Biologic and Generic Drugs</u>

156. It is undisputed fact that biological drugs are synthesised by cells of living organisms, as opposed to chemical drugs which are produced by chemical synthesis. 'Biosimilars' are biological drugs that are similar to the innovator biological drug. Due to Owing to the complexity in the molecular arrangement and manufacturing process of a biological drug, it is not possible to replicate the structure and steps involved in the manufacture of the innovator biological drug and to

produce an identical follow-on biological drug. Biosimilars, therefore, cannot be generic equivalents of the innovator biological drug. The generic drugs are characterised by their chemical and therapeutic equivalence to the original, low molecular weight chemical drugs. These are identical to the original product and are sold under the same chemical name.

157. The plaintiffs in their Annual Reports have acknowledged the existence of biosimilars if the same may be safe and efficacious alternatives to the innovator drug. They have also stated that the WHO Guidelines on SBP's should be followed by all countries for the development of their regulatory framework for biosimilars in order to ensure safety and efficacy of a biosimilar product. The relevant extracts from the plaintiff's Annual Reports have supported the development for the approval of biosimilar products it is granted as per law applicable to the regulatory authorities by following the WHO guidelines on evaluation of similar biotherapeutic products.

158. All the defendants admit that the procedure laid down in the Act and Rules are to be applied stringently. Even this Court is of the view that all the protocol of biosimilars must be adhered to the compliances by demonstrating to the regulatory authorities a high degree of structural and functional similarity between their products and the approved original product.

The party, who applies for any approval, must satisfy the authorities that biosimilar manufacturing and marketing process is well

understood as biosimilar is a biological product that is almost and highly similar except minor meaningful differences from the approved biological drug in terms of safety, priority and potency otherwise it would lose its meaning.

159. In order to avoid any confusion, it is mentioned (as admitted by the parties also) that the approval process for generic drugs is not the same as the approval process for biosimilars. Biological drugs are synthesised by cells of living organisms, as opposed to chemical drugs which are produced by chemical synthesis. The 'Biosimilars' are biological drugs that are similar to the innovator biological drug. It is admitted by all parties that it is not possible to replicate the structure and steps involved in the manufacture of the innovator biological drug and to produce an identical follow-on biological drug. Thus, biosimilars cannot be generic equivalents of the innovator biological drug.

The generic drugs are characterised by their chemical and therapeutic equivalence to the original, low molecular weight chemical drugs. These are identical to the original product and are sold under the same chemical name.

Distinction between bio-similar and generic drugs

160. The Generic drugs are approved by testing procedures as two drugs i.e. the applicant and innovator are identical of chemical compound which cannot be applied to biosimilars. As it is associated with the long term safety, efficacy and immunogenicity of biosimilars

are significantly higher when compared to those associated with a generic drug.

161. The procedure for approval to manufacture a generic drug for sale and distribution under the Drugs and Cosmetics Act, 1940, as amended (the "**Drugs Act**") and the Drugs and Cosmetics Rules, 1945, as amended (the "**Drugs Rules**") is given as under:

> a) Under Explanation (ii) of Rule 122E of the Drugs Rules, generic drugs would fall under two categories – (I) generics of chemical drugs which have been in the market for more than 4 years and are therefore not 'new drugs' under Rule 122E of the Drugs Rules; and (II) generics of chemical drugs which have been in the market for less than 4 years and are therefore 'new drugs' under Rule 122E of the Drugs Rules.
>
> b) In case of generics of chemical drugs which have been in the market for more than 4 years, the procedure for approval to manufacture the generic drug for sale and distribution is under Part VII of the Drugs Rules which is as follows:
>
> > (i) The application for licence to manufacture is required to be made under Rule 69 of the Drugs Rules to the State FDA under Form 24.
> >
> > (ii) The licence for such manufacture is subsequently granted by the State FDA in Form 25 under Rules 70 and 71 of the Drugs Rules.
> >
> > (iii) This procedure is similar to the procedure for obtaining manufacturing licence for r-DNA drugs from the State FDA under Rules 75 and 76 of the Drugs Rules in Form 28D.
> >
> > (iv) However, unlike in the case of approval for 'new drugs' under Part XA, no approval from

Defendant No.1 is required under Part VII of the Drugs Rules prior to obtaining the State FDA licence.

162. The generics of chemical drugs which have not been in the market for more than 4 years are considered ‘new drugs’ under Explanation (ii) of Rule 122E of the Drugs Rules. The procedure for approval to manufacture such generic drugs for sale and distribution is under Part XA of the Drugs Rules. In case of generics of chemical drugs which have been in the market for less than 4 years, the generic ‘new drugs’ can either be generic versions of chemical drugs already approved in India or otherwise.

163. For approval of generic versions of chemical drugs not approved in India, the application for manufacturing authorisation has to be made under Rule 122B of the Drugs Rules in Form 44 and has to be accompanied by data in Appendix I to Schedule Y of the Drugs Rules, whereas, for approval of generic versions of chemical drugs already approved in India, an application under Rule 122B of the Drugs Rules in Form 44 has to be accompanied by data in Appendix IA to Schedule Y of the Drugs Rules. Appendix IA is applicable only to generics and not biosimilars as it requires the submission of bioavailability/ bioequivalence data to defendant No.1.

164. The defendants' drug is a Recombinant DNA (r-DNA) derived drug. Under Rule 122E of the Drugs Rules, all r-DNA derived drugs are treated as "new drugs" as being biosimilar, hence the defendants' drug, which is a "new drug" under Rule 122E. The

defendants No.1 and 2 have admitted that drug of defendant No.2 developed indigenously and tests were not conducted by the defendant No.2 globally which has also not been approved in any country outside India. The approval granted on 23rd October, 2013 is the first time approval of manufacturing and marketing in favour of the defendant No.2.

165. Biosimilar drugs are 'new drugs' under Explanation (i) of Rule 122E of the Drugs Rules, and therefore, the entire pre-clinical and clinical data is required to be submitted for their approval. Under Rule 122B(1)(b) and 122B(2) of the Drugs Rules, the application for such approval has to be made to defendant No.1 in Form 44 of the Drugs Rules along with the data in Appendix I. The issue in hand does not pertain to bioequivalence. It is in relation to bio-similarity of the drug of innovator.

166. Under paragraph 3(5) of Schedule Y of the Drugs Rules, bioequivalence and bioavailability studies are to be conducted in accordance with the Guidelines for Bioavailability and Bioequivalence Studies (March 2005) (the "**Bioequivalence Guidelines**"), which reflect that such studies are applicable only to generic drugs, and not biosimilars, for the purpose of their comparison with the reference chemical entity. The Bioequivalence Guidelines state that:

- Bioequivalence studies are conducted for comparison of two medicinal products containing the ***same*** active ingredient.

- The two drugs should be therapeutically equivalent (containing the ***same*** active substance and clinically showing the ***same*** efficacy and safety) in order to be considered interchangeable.

- The Bioequivalence Guidelines deal with studies for a generic drug.

167. A biosimilar drug is not considered the same as the approved reference product and the procedure applied for the approval of *"new drugs <u>already</u> approved"* in India or abroad, which is applied in the case of generics (i.e., chemical drugs), cannot be applied to biosimilars.

168. This Court in **Bayer Corporation and another v. Union of India and Others**, (2010 (43) PTC 12 (Del) (DB)), has rightly held that Appendix IA to Schedule Y of the Drugs Rules applies to generic versions of a patented drug. The manufacturer of a generic version of a patented drug is only required to satisfy defendant No.1 that its drug is bioavailable and bioequivalent to the patented drug (as required under Appendix IA). Even phase III clinical trials are not required for generics under Appendix IA.

Defendant No.2 in the present case has fairly admitted that its drug is not generic version and bio-equivalent who has admittedly filed the application in Form 44 accompanied with data in Appendix I to Schedule Y of the Drugs Rules and not under Appendix IA.

169. The definition of "new drug" has been specified in Rule 122E of Drugs & Cosmetics Rules while the requirements and guidelines for permission to Import and / or Manufacture of new drugs for sale or to undertake clinical trials are specified in Rules 122A, 122B, 122D and Schedule-Y of the Rules. Rule 122E of the Rules reads as under:

> "**Rule 122E-** Definition of new drugs
>
> (a) A drug, as defined in the Act including bulk drug substance which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labeling thereof and has not been recognized as effective and safe by the licensing authority mentioned under rule 21 for the proposed claims:
>
> Provided that the limited use, if any, has been with the permission of the licensing authority.
>
> (b) A drug already approved by the Licensing Authority mentioned in Rule 21 for certain claims, which is now proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form (including sustained release dosage form) and route of administration.
>
> **(c) A fixed** dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, viz indications, dosage, dosage form (including sustained release dosage form) and route of administration. (See items (b) and (c) of 3[Appendix VI] to Schedule Y.)
>
> Explanation- For the purpose of this rule—

(i) all vaccines and recombinant DNA (r-DNA) derived drugs shall be new drugs unless certified otherwise by the Licensing Authority under Rule 21;

(ii) a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval."

170. As far as the nature and quality of studies and clinical trials are concerned, it is a matter of fact that the same are examined by expert committees and approvals thereon are concerned, at this interim stage, the Court does not wish to express any opinion or to make comments thereon as this Court is aware that the scope of judicial review would remain limited and interference is only permissible if the approvals are granted contrary to law, procedural impropriety and without any logic which is shocking to the conscience of the Court. It is admitted position that the defendant No.2 in the present matter had refused to give the inspection of said relevant record to the plaintiffs under Order 11 CPC who claimed confidentiality of the those documents. In fact, in view of reluctant attitude adopted by the defendants No.2 to 4 during the hearing, it compelled the Court to go through the record itself without any assistance of plaintiffs side.

171. In view of rival submissions addressed by both sides and the nature of disputes and the allegation made in the unamended plaint, it is merely necessary to consider as to (i) whether the procedure as per rules has been followed or not at the time of grant of approvals of the bio-similar drug to defendant No.2; (ii) whether the clinical trials of Phase I and Phase II are necessary for the purpose of

granting the approval of drug to a biosimilar drug; (iii) whether any Phase can be exempted or any phase can be combined with subsequent Phase if biological drugs/ bio-similar product is involved; (iv) whether the Guidelines of 2012 are to be followed by the Authority; (v) whether the defendant No.1 has followed the due procedure prescribed under the Drug and Cosmetics Act, 1940 (as amended) at the time of granting approvals in favour of defendant No.2; (vi) If granted whether the same are granted by lapse in the procedure and due process, what are the consequences of inadequacy of details.

172. It is admitted by the learned ASG that the clinical trials of Phase I and Phase II of the drug in question are not registered with the defendant No.1, however, the approvals are granted after the justifications are given by the defendant No.2. Learned ASG submits that since the requisite approvals have been granted, thus the plaintiffs are not entitled for an injunction. Even otherwise the suit filed by them is barred by law and is not maintainable and this Court has no jurisdiction to examine the process of approvals which were granted after examining the Rules. The plaintiffs are trying to harass the defendants No.2 to 4 despite of valid approvals granted. The only remedy which was available with the plaintiffs is to file an appeal under Rule 122 BD before the Central Government against the grant of approvals being aggrieved party. The suit filed by them is an abuse of the process of law. It is the clear stand of the defendant No.1 that the guidelines are not statutory in nature and it is pertinent to mention that

the written-statement filed by the defendant No.1 does not contain any averment that the guidelines of 2012 have been followed.

173. The main case of the plaintiffs is that the defendant No.2 has not conducted various tests required under applicable law for the approval of the drug. Phase I and Phase II trials have also not been registered with the defendant No.1. The defendant No.2 has also not independently generated requisite data in order to demonstrate similarity between the drug and the plaintiffs' Trastuzumab, both in terms of the stages and the sample size of the tests conducted by defendant No.2.

174. It is stated by the defendant No.2 that though the clinical trials of Phase I and Phase II have not been registered with the defendant No.1 but it did not skip Phase I trial as the main the objective of a Phase I trial is to establish comparative pharmacokinetics (pK) and this pK data was generated by defendant No.2 as the initial part of the Phase III trial. Defendant No.2 did the Phase I and Phase II trials as part of the same sequential study since it was necessary to do the pK study in patients and not in healthy volunteers. The phase III studies were also registered with the Clinical Trial Registry-India **('CTRI**'). In fact, the 2012 Guidelines also contemplate that PD study can also be a part of Phase III clinical trials. Defendant No.2 tried to give its justification for not doing the Phase II study as dose finding and POC studies are not required for follow-on products (biosimilars or generics).

175. Defendant No.2 has argued that as per Indian law and certain other jurisdictions provide for purportedly abbreviated pathways for follow-on biologics, pursuant to which the requirement to conduct all stages of tests and studies for the approval of biosimilar drugs is waived simply by virtue of the innovator drug having conducted all such studies and tests (including all phases of clinical trials), as applicable.

176. Defendant No.2 has relied upon the first proviso to Rule 122B (3) of the Drugs Rules to contend that local clinical trials for the drug were exempted on the basis of data available from other countries. Defendant No.2 also seeks to rely upon the second proviso to Rule 122B (3) under which reduction of trial data may be permitted for "new drugs approved and marketed for several years in other countries". Admittedly, the drug has not been approved and marketed in any country outside India.

177. The defendant No.1 in its written statement has admitted that the clinical trials of Phase I and II are not registered with the authority. The trial of Phase III has been registered with the defendant No.1. The stand of the defendant No.2 is that the clinical trial of Phase I is combined with Phase III and Phase II trial was skipped as many formalities are required for the same which are not of serious nature.

178. It is also argued on behalf of the defendant No.1 stating that from a conjoint reading of the relevant Rules and Schedule 'Y', it emerges that Trastuzumab is a drug which has already been approved

in India as the plaintiffs themselves were granted permission under Rule 122 A of the Drugs and Cosmetics Rules to import and market the product Trastuzumab powder for Injection on 11th October, 2002.In view of the above, the second proviso to Rule 122A (1) (b) is applicable to the defendant No.2's application to manufacture the drug in question. In terms thereof, any application of defendant No.2 is to be accompanied by requisite fee and such information and data as required by appendix I or appendix IA of schedule Y which does not make it mandatory for conducting Phase I and Pphase II clinical trials for drugs which have already been approved in India and even for drugs approved outside India. Instead, appendix IA specifies the "Data required to be submitted by an application for grant of permission to import and/or manufacture a new drug already approved in the country". Further, schedule Y also prescribes that "for new drugs approved outside India, phase III studies need to be carried out primarily to generate evidence of efficacy and safety of the drug in Indian patience when used as recommended in the prescribing information". Schedule Y does not specify number of the subjects to be enrolled in different phases of clinical trials.

Data required to be submitted by an applicant for grant of permission to import and / or manufacture a new drug already approved in the country, as specified in appendix IA of Schedule Y to Drugs & Cosmetics Rules, includes chemical & pharmaceuticals information including structure physical, chemical properties, dosage form its

composition, test specification method of manufacture etc., stability data, sub-acute animal toxicity data for I.V. Infusion and injectables.

179. Defendant No.1 has explained that it applied Rule 122A (relating to permission to import new drugs) and Rule 122D (relating to permission to import or manufacture fixed dose combination) of the Drugs Rules, which are irrelevant in case of the defendants' drug.

180. It is submitted by Mr.Sanjay Jain, learned ASG on behalf of defendant No.1, that even alternatively paragraph 1(3) of Schedule Y of the Drugs Rules relates to abbreviated toxicological and clinical data requirement for drugs indicated for serious and life threatening diseases and is applicable to the approval of Bmab-200. As the drug already approved in India, the DCGI reviewed the application filed by defendant No.2 under Appendix I to Appendix lA to Schedule Y of the Rules. There is no infirmity in the approval granted to Bmab-200 can be inferred on this basis. He submits that it is standard practice treat applications relating to drugs already approved in India under Appendix l-A. The defendant No.2 supported the submissions of Mr.Jain on this aspect is same who stated that the defendant No.1 has exercised its discretion under sub-rule 3 of Schedule Y of the Drug Rules.

181. Mr.Jain, learned ASG, argued that there is no harm if the defendant No.1 suo motu treated an application filed under Appendix I as an application under Appendix I-A. It is also not necessary to communicate to the defendant No.2 that its application was being

considered under Appendix IA instead of Appendix I. He admits that Appendix I-A does not require submission of clinical trial data as required in Appendix I.

182. Let me now examine the said submissions of defendants No.1 and 2 in this regard. It is admitted by the defendant No.1 that the defendant No.2 on 15th October, 2013 applied to defendant No.1 in Form-44 for approval to manufacture and market the under Appendix I-A of Schedule Y of Rules. There is nothing on record produced before Court by the defendant No.1 which would show that it has exercised its discretion in writing to abbreviate the clinical trials of Phase I and Phase II or any other clinical trial(s) under sub-rule 3 of Rule 1 of the Schedule Y of the Drug Rules or to convert the application.

183. The Form-44 along with Appendix I was considered when the plaintiffs protest by letter dated 11th October, 2013 was already pending and the meeting was yet to be conducted on 18th October, 2013. In Appendix I-A, there is no requirement of clinical test of Phase I and Phase II, the said requirement is however there in Appendix I.

184. The chart which contains the details of regulatory regime under the Drugs and Cosmetics Rules, 1945 (the "Drugs Rules") for approval of various categories of drugs, is as under:

Category of drug	Relevant part of the Drugs Rules	Applicable provision of the Drugs Rules for approval for import/manufacture	Relevant forms for application and approval	Relevant Schedule of the Drugs Rules, if any	Whether Appendix I or IA of Schedule Y is applicable
Biologic (r-DNA) drug	Part XA	Import – Rule 122A Manufacture – Rule 122B	Application for Import – Form 44 Approval for Import – Form 45/ Form 45A Application for Manufacture – Form 44 Approval for Manufacture – Form 46 / Form 46A	Schedule Y	Appendix I
Biosimilar (r-DNA) drug	Part XA	Import – Rule 122A Manufacture – Rule 122B	Application for Import – Form 44 Approval for Import – Form 45/ Form 45A Application for Manufacture – Form 44 Approval for Manufacture – Form 46 / Form 46A	Schedule Y	Appendix I
Chemical innovator drug	Part XA	Import – Rule 122A Manufacture – Rule 122B	Application for Import – Form 44 Approval for Import – Form 45/ Form 45A Application for Manufacture – Form 44 Approval for Manufacture – Form 46 / Form 46A	Schedule Y	Appendix I
Chemical generic – innovator approved for less than 4 years + innovator not approved in India (but in other countries)	Part XA	Import – Rule 122A Manufacture – Rule 122B	Application for Import – Form 44 Approval for Import – Form 45/ Form 45A Application for Manufacture – Form 44 Approval for Manufacture – Form 46 / Form 46A	Schedule Y	Appendix I
Chemical generic – innovator approved for less than 4 years + innovator approved in India	Part XA	Import – Rule 122A Manufacture – Rule 122B	Application for Import – Form 44 Approval for Import – Form 45/ Form 45A Application for Manufacture – Form 44 Approval for Manufacture – Form 46 / Form 46A	Schedule Y	Appendix IA
Chemical generic – innovator approved for more than 4 years	Part VII	Application to manufacture – Rule 69 Licence to manufacture – Rules 70 and 71	Application to manufacture – Form 24 Licence to manufacture – Form 25	Schedule M	Not applicable

185. The specimen of requirement under Appendix I of the Drugs and Cosmetics Rules, 1945 by defendant No.2 are reproduced as under:

Provision and requirement under Appendix I of the Drugs and Cosmetics Rules, 1945
1. Introduction
A brief description of the drug and the therapeutic class to which it belongs.
2. Chemical and pharmaceutical information
2.1. Information on active ingredients Drug information (Generic Name, Chemical Name or INN)
2.2. Physicochemical Data (a) Chemical name and Structure Empirical formula Molecular weight (b) Physical properties Description Solubility Rotation Partition coefficient Dissociation constant
2.3. Analytical Data Elemental analysis Mass spectrum NMR spectra IR spectra UV spectra Polymorphic identification
2.4. Complete monograph specification including Identification Identity/quantification of impurities Enantiomeric purity Assay
2.5. Validations Assay method Impurity estimation method Residual solvent/other volatile impurities (OVI) estimation method

2.6.	Stability Studies (for details refer Appendix IX) Final release specification Reference standard characterization Material safety data sheet
2.7.	Data on Formulation Dosage form Composition Master manufacturing formula Details of the formulation (including inactive ingredients) In process quality control check Finished product specification Excipient compatibility study Validation of the analytical method Comparative evaluation with international brand(s) approved Indian brands, if applicable Pack presentation Dissolution Assay Impurities Content uniformity pH Force degradation study Stability evaluation in market intended pack at proposed storage conditions Packing specifications Process validation When the application is for clinical trials only, the international non-proprietary name (INN) or generic name, drug category, dosage form and data supporting stability in the intended container-closure system for the duration of the clinical trial (information covered in item nos. 2.1, 2.3,2.6,2.7) are required.
3.	**Animal Pharmacology (for details refer Appendix IV)**
	3.1. Summary 3.2. Specific pharmacological actions 3.3. General pharmacological actions 3.4. Follow-up and Supplemental Safety Pharmacology Studies 3.5. Pharmacokinetics: absorption, distribution; metabolism; excretion
4.	**Animal Toxicology (for details refer Appendix III)**
	4.1. General Aspects 4.2. Systemic Toxicity Studies 4.3. Male Fertility Study 4.4. Female Reproduction and Developmental Toxicity Studies 4.5. Local toxicity 4.6. Allergenicity/Hypersensitivity 4.7. Genotoxicity

4.8. Carcinogenicity
5. Human/ Clinical pharmacology (Phase I)
5.1. Summary 5.2. Specific Pharmacological effects 5.3. General Pharmacological effects 5.4. Pharmacokinetics, absorption, distribution, metabolism, excretion 5.5. Pharmacodynamics/ early measurement of drug activity
6. Therapeutic exploratory trials (Phase II)
6.1. Summary 6.2. Study report(s) as given in Appendix II
7. Therapeutic confirmatory trials (Phase III)
7.1. Summary 7.2. Individual study reports with listing of sites and Investigators.
8. Special studies
8.1. Summary 8.2. Bio-availability / Bio-equivalence. 8.3. Other studies e.g. geriatrics, paediatrics, pregnant or nursing women
9. Regulatory status in other countries
9.1. Countries where the drug is a. Marketed b. Approved c. Approved as IND d. Withdrawn, if any, with reasons 9.2. Restrictions on use, if any, in countries where marketed approved 9.3. Free sale certificate or certificate of analysis, as appropriate.
10. Prescribing information
10.1. Proposed full prescribing information
11. Samples and Testing Protocol/s
11.1. Samples of pure drug substance and finished product (an equivalent of 50 clinical doses, or more number of clinical doses if prescribed by the Licensing Authority), with testing protocols, full impurity profile and release specifications.

186. Data required to be submitted by an applicant for grant of permission to import and/or manufacture a new drug already approved in the country as per **Appendix I-A** is as under:

1. *Introduction*

   A brief description of the drug and the therapeutic class

2. *Chemical and pharmaceutical information*

2.1 Chemical name, code name or number, if any; non-proprietary or generic name, if any, structure; physico-chemical properties

2.2 Dosage form and its composition

2.3 Test specifications

(*a*) active ingredients

(*b*) inactive ingredients

2.4 Tests for identification of the active ingredients and method of its assay

2.5 Outline of the method of manufacture of active ingredients

2.6 Stability data

3. *Marketing information*

3.1 Proposed package insert/promotional literature

3.2 Draft specimen of the label and carton

4. *Special studies conducted with approval of Licensing Authority*

4.1 Bioavailability/Bioequivalence and comparative dissolution studies for oral dosage forms

4.2 Sub-acute animal toxicity studies for intravenous infusions and injectables."

187. The explanation given by the learned ASG about the converting of application from Appendix I to Appendix I-A of Schedule Y given by the defendant No.2 is not acceptable as it appears to the Court that the defendant No.1 was not clear regarding the legal regime applicable to approval of biosimilars in India, that the defendant No.2 filed its application under Appendix I being new drug. It is drug which was never earlier approved in India or abroad. Admittedly, as per procedure the DCGI sought justification from defendant No.2 for directly carrying out Phase III clinical trials. If defendant No.2's application was being considered under Appendix I-A as argued by defendant No.1, the regulator would not have asked the defendant No.2 to conduct the clinical trials of Phase I and Phase II. There is also no material available to show that the defendant No.1 in writing has allowed he defendant No.2 to skip Phase I and Phase II.

188. Here, it is necessary to examine Rule 122B as well as para1(I)(iv)(b) of Schedule Y wherein an application is to be filed for permission to import manufacture new drugs for sale or to understand clinical trials. The said application has to be made in Form-44 accompanying with data in accordance with Appendixes. Para 1(1)(iv)(a) and (b) of Schedule Y reads as under:

> "**Para 1(1) (iv) of Schedule Y** - human Clinical Pharmacology Data as prescribed in Items 5, 6 and 7 of Appendix I and as stated below:—
>
> (*a*) for new drug substances discovered in India, clinical trials are required to be carried out in India right from Phase I and data should be submitted as required under Items 1,

2, 3, 4, 5 (data, if any, from other countries) and 9 of Appendix I;

(b) for new drug substances discovered in countries other than India, Phase I data as required under Items 1, 2, 3, 4, 5 (data from other countries) and 9 of Appendix I should be submitted along with the application. After submission of Phase I data generated outside India to the Licensing Authority, permission may be granted to repeat Phase I trials and/or to conduct Phase II trials and subsequently Phase III trials concurrently with other global trials for that drug. Phase III trials are required to be conducted in India before permission to market the drug in India is granted;"

189. Rule 122B of Rules is reproduced as under:

Rule 122B Application for approval to manufacture new drug -

"(1)(a) No new drug shall be manufactured for sale unless it is approved by the Licensing Authority as defined in clause (b) of rule 21

(b) An application for the grant of approval to manufacture the new drug and its formulations shall be made in Form 44 to the Licensing Authority as defined in clause (b) of Rule 21 and shall be accompanied by a fee of fifty thousand rupees:

Provided that where the application is for permission to import a new drug (bulk drug substance) and grant of approval to manufacture its formulation/s, the fee to accompany such application shall be fifty thousand rupees only.

Provided further that where a subsequent application by the same applicant for that drug, whether in modified dosage form or with the new claims, is

made, the fee to accompany such subsequent application shall be fifteen thousand rupees:

Provided also that any application received after one year of the grant of approval for the manufacture for sale of the new drug, shall be accompanied by a fee of fifteen thousand rupees and such information and data as required by Appendix 1 or Appendix 1-A of Schedule Y, as the case may be.

(2) The manufacturer of a new drug under sub-rule (I) when applying for approval to the Licensing Authority mentioned in the said sub-rule, shall submit data as given in Appendix 1 to Schedule Y including the results of clinical trials carried out in the country in accordance with the guideline specified in Schedule Y and submit the report of such clinical trials in the same format given in Appendix II to the said Schedule.

(2A) The Licensing authority as defined in clause (b) of rule 21 after being satisfied that the drug if approved to be manufactured as raw material (bulk drug substance) or as finished formulation shall be effective and safe for use in the country, shall issue approval in Form 46 and/or Form 46A, as the case may be, subject to the conditions stated therein:

Provided that the Licensing Authority shall, where the data provided or generated on the drug is inadequate, intimate the applicant in writing, and the conditions, which shall be satisfied before permission could be considered

(3) When applying for approval to manufacture a new drug under sub-rule (I) or its preparations, to the State Licensing Authority, an applicant shall produce along with his application, evidence that the drug for the manufacture of which application is made has already been approved by the Licensing Authority mentioned in Rule 21:

Provided that the requirement of submitting the results of local clinical trials may not be necessary if the drug is of such nature that the Licensing Authority may, in public interest, decide to grant such permission on the basis of data available from other countries:

Provided further that the submission of requirements relating to Animal Toxicology, Reproduction studies, Teratogenicity studies, Perinatal studies, Mutagenicity and Carcinogenicity may be modified or relaxed in case of new drugs approved and marketed for several years in other countries if he is satisfied that there is adequate published evidence regarding the safety of the drug, subject to the other provisions of these rules."

190. Rule 122B provides the procedure for obtaining the approval for manufacturing and/or sale of the new drug. Rule 122A pertains to the application for permission to import new drug. The language and requirements of both rules are almost similar except for purposes. The Rule 122B provides the procedure in two circumstances:

a) In the first circumstances, the party seeks permission for manufacturing of new drugs and its formulations;

b) In the second circumstances, the party seeks permission to import new drugs (bulk drug substance) and further seeks for the approval to manufacture using the bulk drug substance.

The procedure to be applied for first circumstance:

To get the approval for manufacturing the new drug (i.e. bulk drug) and its formulation, the applicant is required to make an application on Form 44 to the licensing authority. The term "Licensing Authority" is defined in Rule 21B, which reads as:

> "Rule 21(B): "licensing authority" means the authority appointed by the Central Government to perform the duties of the licensing authority under these Rules and includes any person to whom the powers of a licensing authority may be delegated under Rule 22."

191. In India the licensing authority for new drugs is "Drug Control Authority of India". The prescribed fee that needs to accompany Form 44 is INR 50,000. While applying for the approval on Form 44, the applicant is required to submit data as given in Appendix I to Schedule Y. This Appendix I to Schedule Y is attached to this opinion.

192. The said exemptions from conducting local clinical trials and abbreviation of tests provided under Rule 122B(3) of the Drugs Rules are applicable only when the same drug sought to be manufactured in India by an applicant has already been approved and marketed in other countries for several years by the same applicant and based on data generated in global clinical trials by the same applicant. The exemption if any under Rule 122B(3) can only be available to the party who has already got the approval and marketed in other countries for the same drug. The plaintiffs are entitled to rely on their global trial data for approvals in India. (The defendant No.2 has never said before approval authority or before this Court that it has

already obtained any previous approval in India or any other country of the world).

193. In addition to this data the applicant is required to include the results of clinical trials carried out in India in accordance with the guidelines specified in Schedule Y, along with the report of the clinical trials, which should be given in the format as shown in Appendix II.

194. On receiving the application accompanied by the (a) data; (b) results of clinical trials and (c) the clinical trial reports, the drug controller (Licensing Authority) must satisfy himself that the drug to be manufactured (bulk drug substance) or in the form of a finished formulation is effective, and safe for use in India. If the drug controller is satisfied, he will issue an approval on Form 46. If the drug controller is not satisfied, for instance, if the data provided or generated on the drug is not adequate, he must intimate the applicant in writing and also give conditions, which if fulfilled will satisfy him for the grant of the approval.

195. <u>The procedure to be followed for second circumstance</u>:

In second circumstance the drug is already approved outside India, but has not been approved in India and the applicant seeks to obtain the grant of approval to manufacture formulations, such an application also needs to be made on the same Form 44 and the application procedure is the same as in first circumstance, excepting that the information and data is required to be submitted as per Appendix Form 1A of Schedule Y.

In the case of second circumstance, no clinical trial or report is necessary but if the party wants to import a new drug, the applicant needs to perform:

1) Bioavailability/ Bioequivalence and comparative Dissolution Studies, for oral dosage form.

2) Sub-acute animal toxicity studies for intravenous infusions and injectables.

These studies need to be conducted with the pre-approval of the licensing authority. Other conditions of first circumstance apply. Once, the licensing authority is satisfied, he will issue the approval on Form 46A. There is also a further approval envisaged in Rule 122B and that is if the same party who has obtained an approval of a new drug wants an approval to market the drug either: (i) in modified dosage form or (ii) with new claims.

196. In the present matter, after conducting the clinical trials of Phase III admittedly the defendant No.2 filed fresh application which is received by defendant No.1 on 15th October, 2013 in Form-44 of Appendix I (which is treated by defendant No.1 as Appendix I-A) for manufacturing and marketing authorisation for the defendants' drug filed on October 15, 2013 submitted data under "Permission to market a new drug" and not under "Subsequent approval / permission for manufacture of already approved new drug". As the drug of the defendant No.2 is biosimilar and is not identical drug to the innovator drug, it has to be called as "new drug" discovered by the defendant

No.2 who itself submitted that it has conducted various clinical trials independently.

197. Being the defendants' drug a new drug manufactured in India for the first time by defendant No.2, paragraph 1(1)(iv)(a) of Schedule Y, which mandates that all phases of the clinical trials must be conducted in India, is applicable to the defendants' drug, therefore, defendant No.1 had no legal basis for exempting defendant No.2 from conducting Phase I and Phase II of the clinical trials in the present case without assigning any valid reason. It is pertinent to mention that pursuant to the letter dated February 25, 2011, the Review Committee on Genetic Manipulation (the **"RCGM")** directed defendant No.2 to approach defendant No.1 for obtaining approval for conducting all phases of clinical trials (Phase I to Phase IV) in relation to the defendants' drug.

198. If there had been no requirement under the Drugs Act and the Drugs Rules to conduct Phase I and Phase II clinical trials, defendant No.1 would not have sought such an explanation from defendant No.2. In any event, in the letter dated May 27, 2011, while explaining why defendant No.2 was directly conducting Phase III clinical trials in relation to the defendants' drug, defendant No.2 did not seek an exemption on the basis that the defendants' drug was a new drug already approved.

199. The Appendix IA to Schedule Y of the Drugs Rules is not applicable to the approval of biosimilars if the drug is new and it is not

approved in its favour in earlier point of time in India or abroad. Admittedly the application for approval of the drug included data in Appendix I which requires a complete set of trials to be conducted for a 'new drug' as bio-similar Appendix IA is applicable to the generic drug/chemical compound drug which are identical in all respects or where the drug approved in the name of the same already applicant. Only under these circumstances, an exemption may be granted by the Regulatory Authority. It is also discretion and not mandatory.

200. Paragraph 2(8)(iii) of Schedule Y of the Drugs Rules relates to a drug approved outside India, which admittedly the impugned drug is not. When defendant No.2 had applied to defendant No.1 for permission to directly conduct Phase III clinical trial, defendant No.1 wrote to defendant No.2 seeking an explanation from defendant No.2 regarding the omission of Phase I and Phase II clinical trials. If there had been no requirement under the Drugs Act and the Drugs Rules to conduct Phase I and Phase II clinical trials for drugs, defendant No.1 would not have sought such an explanation from defendant No.2. Any reference to Paragraph 2(8)(iii) of Schedule Y of the Drugs Rules does not help the case of the defendant No.2 as it is the plaintiffs' drug which was approved outside India. The exemption if any can only be granted to the plaintiffs under Rule 122A and 122B. The unexplained exemptions in the data requirements granted to defendant No.2 during the process of approval of the drug are contrary to the Schedule Y.

Paragraph 1(1)(iv)(b) of Schedule Y of the Drugs Rules relates to new drug substances discovered in countries other than India and any abbreviation of clinical trials contemplated in this provision is therefore not applicable to drug which was admittedly developed in India, it would be applicable to the plaintiffs' Trastuzumab which was admittedly discovered outside India.

201. The claim of defendant No.2's that the impugned drug not being a "new drug discovered in India" is not correct as the drug is admittedly an indigenously-developed drug. Rule 122DA read with paragraphs 1(1)(iv)(a), 1(1)(iv)(c) and 2(6) to 2(8) of Schedule Y of the Drugs Rules require that **all three phases,** *i.e.* phases I, II and III of human clinical trials be conducted for a 'new drug' in a **sequential manner**, i.e., the data generated in phase I clinical trials should form the basis of phase II clinical trials and the data generated in phase I and phase II of the clinical trials should form the basis of phase III clinical trials.

202. Defendant No.1 has incorrectly stated that Appendix 1A of Schedule Y of the Drugs Rules is applicable in relation to the defendants' drug. Appendix 1A relates to data required to be submitted by an applicant for grant of permission to import and/or manufacture a new drug already approved in the country and the defendants' drug (Bmab-200) is not a new drug already approved in the country on the date of filing of application. I do not agree with the argument of defendants No.1 and 2 and I am of the view that the data required to be submitted for the approval of the defendants' drug is

set out in Appendix 1 of Schedule Y of the Drugs Rules. In fact, defendant No.2's application for permission to conduct clinical trials (filed with defendant No.1 on March 9, 2011) and for grant of manufacturing and marketing authorisation (filed with defendant No.1 on October 15, 2013) purportedly included information in Appendix I. As such, any reference to Appendix IA is evidently an afterthought and defendant No.1 is only trying to justify the unexplained exemptions in the data requirements granted to defendant No.2 during the process of approval of the defendants' drug.

203. Defendant No.1's assertions that (a) Phase I and Phase II clinical trials are not mandatory under Schedule Y of the Drugs Rules for drugs already approved in India or outside India; and (b) Schedule Y prescribes that for new drugs approved outside India, Phase III studies need to be carried out primarily to generate evidence of efficacy and safety of the drug in Indian patients; are without any basis and not relevant in the present case since the defendants' Drug was neither previously approved in India nor outside India.

204. The applications filed by defendant No.2 for approval of Bmab — 200 contradict the contents of the written statement filed by defendant No.1. Form 44 filed along with defendant No.2's application for manufacturing and marketing authorisation on October 15, 2013 was filed specifically under Rule 122B of the Drugs Rules, which relates to approval for manufacture of new drugs. Moreover, the manufacturing and marketing approval for the defendants' drug was granted by defendant No.1 in Forms 46 and 46A under Rule 122B of

the Drugs Rules. The entire Rule 122B along with provisos is to be read together with Rules and requirements of Schedule Y. The proviso of Rule 122B cannot be read in isolation. The defendant No.2 itself on 9th March, 2011 had made the application in the prescribed form of Rule 122DA in Form-44, Appendix I of Schedule Y whereby clinical trials of all phases are necessary. How could the defendant No.1 deal with the application of the defendant No.2 into Appendix I-A. It is cannot be called a technical mistake by the defendant No.2 as there is huge different in submitting the data between the two applications made under Appendix I and Appendix I-A. The said fact ought to have been brought to the notice to the NDAC committee in advance at least at the time of recommendation and approvals.

205. When these circumstances were pointed out to the defendant No.2, it was submitted that it was entitled to follow an abbreviated process for approval since its application related to subsequent approval for an already approved new drug. The same is contrary to defendant No.2's documents filed before this Court as the defendant No.2 has applied in the prescribed Form 44 application with Appendix I and not Appendix I-A which states that "Subsequent approval/permission for manufacture of already approved new drug not applicable" (emphasis supplied).

206. It is now submitted by defendant No.2 that there is the system of abbreviated pathways in certain jurisdictions particularly on the European model i.e. Argentina, Australia, Brazil, Canada, Japan, Malaysia, Mexico, South Africa, South Korea, Taiwan and Turkey

which allows regulatory authorities the discretion to consider whether certain phases of clinical trial are necessary for the application process for the follow-on biological drug or, alternatively, may be waived if similarity has sufficiently been established at the stage of pre-clinical studies. No doubt, it is true that the said practice is being followed in many countries. It is permissible subject to the condition if the regulatory authorities are **satisfied** that such waiver is (a) **permissible** in accordance with the rigorous standards of interchangeability and similarity with the innovator drug under applicable laws; (ii) **scientifically justified** pursuant to *complete* characterisation and pre-clinical studies having been concluded to establish comparability of the follow-on biologic drug with the innovator drug in terms of quality, safety and efficacy. Only after the fulfilment of these conditions by the follow-on drug manufacturer that the extent of possible reduction of pre-clinical and clinical trial data is determined by the regulatory authority, strictly on a case-by-case basis but never automatically.

In the present case, the defendant No.1 apparently impliedly abbreviated many clinical tests but without any reason as appeared from the record submitted that whenever and whatever explanations given by the defendant No.2, the same are taken on record by the defendant No.1 and proceeded further in the matter of the approvals sought by the defendant No.2.

207. As per Paragraphs 5, 6(a), 7 and 8 of the WHO Guidelines on Evaluation of Similar Biotherapeutic Products, 2009 (the "**WHO Guidelines**") relied on by defendant No.2, the entire set of

characterisation and comparability studies under applicable law are to be carried out in a step-wise manner to establish similarity of the follow-on drug to the innovator drug in terms of quality. The conduct of such studies is a prerequisite for *possible* reduction of non-clinical and clinical data, if permitted by the drug authority. In the present case, admittedly the defendant No.2 has not conducted studies in step-wise manner.

208. As mentioned above, it is the specific case of the plaintiffs that defendant No.2 has not conducted (a) comparative product characterisation studies; (b) comparative animal pharmacology studies; (c) comparative immune response studies; or (d) comparative animal toxicology studies. Even if in many countries an abbreviated pathway is allowed for biosimilar drugs and existed in India but the drug authorities cannot permit the waiver of phases I and II of human clinical trials for the drug on account of the inadequate characterisation studies and pre-clinical tests undertaken by defendant No.2 for its drug. The party who is intentionally and deliberately even not ready to given the inspection of documents of clinical trials by making so many excuses by claiming confidentiality by filing of application. The plaintiffs got opportunity to address their submissions on this aspect. The counsel for the defendant No.2 has tried to convince the Court by given two examples of third parties for the same drug by stating that they were exempted by the Regulatory Authority for Phase I and Phase II trials as evidenced in the international regime and contrary to the submissions of defendant No.2, Celltrion has separately conducted

Phase I and Phase II clinical trials in South Korea and the EU and Pfizer has separately conducted Phase I and Phase II clinical trials in the U.S.A. Thus, the submissions of the defendant No.2 on this aspect are also wrong and misleading.

209. Let me now also evaluate the contention of the defendant No.2 which relates to exemption to the clinical data requirement for the drugs relating to life threatening diseases. Sub-Rule 3 of Rule 1 of the Schedule Y 'Requirements and Guidelines for Permission to Import and/ or Manufacture of New Drugs for Sale or to undertake Clinical Trials' provides as follows:

"Paragraph 1(3) of Schedule Y -

For drugs indicated in life threatening / serious diseases or diseases of special relevance to the Indian health scenario, the toxicological and clinical data requirements may be abbreviated, deferred or omitted, as deemed appropriate by the Licensing Authority."

The above rule of the Drugs Rules indicates that only in life threatening diseases, toxicology and clinical data requirements can be abbreviated, deferred or omitted, as deemed appropriate by the Approving Authority.

210. The defendant No.2 submits that it is for the defendant No.1 to decide as to whether all phases of clinical trials are required to be conducted in a particular case. Once a new drug is approved in other countries, there is no requirement to conduct all phases of

clinical trials for a biosimilar drug (especially Phase I and II which are carried out on healthy volunteers). It is argued that in India, Professor Ranjit Roy Choudhary Committee has recommended that in case of drugs already in the market and well regulated, only Phase IV clinical trials should be conducted.

It is argued by the defendant No.2 that abbreviated pathway for approval of drug needs to be followed for approval of a follow on / biosimilar drug in view of various Guidelines and also the Drugs & Cosmetics Rules, 1945 which vest in the authorities, the discretion to abbreviate the pathway for approval of drugs (Refer Rule 122B read with Schedule Y: 1 (1) (iv) (b) and (c), Rule 1 (3)). Hence, there is no requirement to conduct the clinical trials for approval of a follow on drug.

211. It is stated by the defendants No.1 and 2 that the objective of a Phase I trial is to establish comparative pharmacokinetics (pK) and this pK data was generated by defendant No.2 as the initial part of the Phase III trial. Defendant No 2 did the Phase I and Phase II trials as part of the same sequential study, since it was necessary to do the pK study in patients and not in healthy volunteers. The defendant No.2 submits that it has not conducted Phase II study as dose finding and POC studies are not required for follow-on products (biosimilars or generics).

212. I do not agree with the submissions of defendants in this regard. Paragraph 1(3) of Schedule Y of the Drugs Rules is only

available for serious emergency situations such as an epidemic of an unknown disease and will not be applicable to a drug targeting a disease for which treatments are already available in the market (*refer to paragraph 7.20 of the Parliamentary Committee Report on the Functioning of the CDSCO*). In any event, defendant No.2 has not relied upon this provision in its reply to the plaintiff's application under Order XXXIX of the Code of Civil Procedure, 1908, as amended (the "**CPC**").

The defendant No.2's reliance on paragraphs 1(1)(iv)(b), 1(3) and 2(8)(iii) of Schedule Y of the Drugs Rules would not help the case of defendant No.2. Even there is nothing on record to indicate that exemptions under these provisions were sought by, or granted to, defendant No.2 while conducting clinical trials for the drug. Therefore, the reference to such exemptions is just an afterthought defence on the part of defendants. There is no specific order or valid reasons available on record about exemptions passed for Phase I and Phase II trials. The defendant No.1 has merely proceeded further with process of approval after the explanation given by the defendant No.2 for not conducting all the clinical trials of Phase I and Phase 2 in registration thereof with defendant No.1.

213. Even as per paragraph 8 of the Guidelines on Similar Biologics, 2012 (the "**Biosimilar Guidelines**") mandates that all phases of *comparative* human clinical trials including pharmacokinetic, pharmacodynamics, confirmatory safety, efficacy and immunogenicity studies must be carried out for a biosimilar drug. Defendant No.2 has

tried to justify the deficiencies in the tests conducted for drug on the basis of paragraph 6 of the Biosimilar Guidelines which states that the extent of testing of the similar biologic is "*likely to be less*" than that required for the reference biologic. The said provision envisages possible reduction in pre-clinical and clinical data with the condition that the testing of the similar biologic must be "*sufficient to ensure that the product meets* ***acceptable levels*** *of safety, efficacy and quality*". Accordingly, such reduction may be permitted only if comparability with the innovator drug has been *demonstrated* at the characterisation stage and the production process of the similar biologic is consistent. The extensive pre-clinical and clinical evaluation is necessary for the similar biologic if significant differences in safety, efficacy and quality studies emerge. Paragraph 1(1) (i) to (iii) of Schedule Y relates to chemical and pharmaceutical information and animal pharmacology and toxicology data.

214. It is required under paragraph A.3 of the Guidelines for Generating Pre-Clinical and Clinical Data for RDNA Vaccines, Diagnostics and other Biologicals, 1999 (the "1999 Guidelines"), paragraph 6.3.2 of the Biosimilar Guidelines and paragraph 8.2 of the WHO Guidelines on Evaluation of Similar Biotherapeutic Products, 2009 (the "WHO Guidelines").

215. The defendant No.2 in the present case even not ready to give the inspection of the documents which are used at characterisation stage, pre-clinical and clinical evaluation in order to allow the plaintiffs to make their submissions on merit but at the same

time, the defendant No.2 wishes to rely upon the entire data of the plaintiffs drug for the purpose of approval as well as at the time of marketing their product.

216. The explanation given by the defendant No.2 by placing the reliance of para l(l)(iv)(b) of Schedule Y is not possible as the defendants' drug is a new drug discovered in India. Para 1(1) (iv)(a) of Schedule Y is applicable which mandates that all phases of the clinical trials be conducted in India. No such justification was given by defendant No.2 in its letter to the DCGI dated May 27, 2011 which is acceptable under the Act, Rules as well as the Guidelines of Bio-similar, 2012.

217. Paragraph 7.3 of the Biosimilar Guidelines provides that the RCGM recommends the required phases of clinical trials based on an assessment of the pre-clinical test results as per paragraph 10 of the Office Order issued by the Department of Biotechnology bearing No.BT/BS/17/175/2005-PID and dated January 2, 2006. However, in the present case as mentioned by defendant No.2 in its application under Order XXXIX Rule 4 CPC the RCGM recommended that all four phases of clinical trials should be undertaking by defendant No.2. The DCGI does not have expertise to analyse the pre-clinical (animal study) reports and draw conclusions.

218. The defendant No.1 has incorrectly relied on Rule 122A i.e. Application for permission to import new drugs and Rule 122D (Permission to import or manufacture fixed dose combination), while

the only applicable provision is Rule 122B (Application for approval to manufacture new drug) wherein the defendant No.2 itself has filed the application on 15th October, 2013 in Form-44, Appendix I. Under the heading "subsequent approval/permission for manufacture of already approved new drug", in the form filed in the prescribed manner, it was mentioned "not applicable". The defendant No.1 has treated the application of defendant No.2 in Form 44-Appendix I as Appendix I-A in which clinical trials of all phases are not necessary. Even no written order was passed assigning any reason for abbreviation of Phase I and II and converting the Appendix I to Appendix II. Merely saying that part of clinical which are conducted have been combined with the Phase III neither here nor there, it would be contrary to the scheme of the Act because these are to be registered with the Regulatory Authority under the provision of Act and Rules.

219. It cannot be said that the said enquiry and procedure of the grant of the approval shall be as simplistic as contended by the defendants wherein the defendant No.2 makes an application for the conducting the clinical trial for phase 3 on presumptuous basis that the defendant No.1 will allow the same with bare minimum justification of the underlying purpose of the other two phases of the trials and giving a response that the clinical trials are conducted in a combined manner when there is no evidence of the registration of the separate trials. Surely, the process of the similar biologic require as a matter of rule to conduct the clinical trials with exceptions apart to reduce the requirement of the data submission depending upon the establishment

of the similarity on the various aspects, product characterisation, quality comparability studies and other matters discussed above.

220. Merely saying by the defendants is not enough that sufficient safeguards have been followed in granting the approval to the defendant No.2 in relation to the bio similar medicines. After all, it is a matter of the safety, efficacy and quality of the medicine which is meant for treatment of cancer and involve complex compound requiring differential treatment prescribed by the defendant No.1 itself and relevant department of the government.

221. The reliance of defendant No.2 is that the clinical trials of phase I and phase II have been combined by the defendant No.2 while seeking an approval from the defendant No.1 and in this respect, the defendant No.2 relied upon its reply dated 27th May, 2011 addressed to the defendant No.1 in response to letter dated 3rd May, 2011 when the defendant No.1 asked for the justification for not conducting the clinical trial. A mere reply for non conducting of the phase 1 and phase 2 trials provides an evasive answer to state that both the trials have been combined with the phase 3 trial as end points. Merely alleging that these have been combined is not enough because as per the scheme of Act and Rules, the same are to be registered or otherwise abbreviations have to be sought specially in writing under the Guidelines 2012 and the authority is supposed to give reasons for exemption. The defendant No.1 thereafter did not pass any speaking order ruling on the reasoning accorded by the defendant No.2 but instead raise no objection by way of letter dated 19th August, 2011 and

implicitly allow the defendant No.2 to conduct phase 3 trials directly and produce the same for the analysis. There is no provision in India or internationally in relation to an 'abbreviated pathway' in the form stated by defendant No.2 for the approval of biosimilar drugs.

222. The combining/skipping various phases of clinical trials is not justified as it would render redundant the underlying logic of sequential testing vis-a-vis primary end-points, target population and sample size. Paragraph 7.3 of the Biosimilar Guidelines clearly provides that the RCGM recommends the required phases of clinical trials based on an assessment of the pre-clinical test results, paragraph 10 of the Office Order issued by the Department of Biotechnology bearing No. BT/BS/17/175/2005-PID and dated January 2, 2006 wherein the RCGM recommended that all four phases of clinical trials should be undertaken.

223. In the present case all responses coming from Drug controller are contrary from the guidelines on similar biologics headed over by drug controller himself stating that the regime of the bio similar products are required to be regulated more strictly than the ordinary drug approvals in the case of bio equivalence and therefore strict rules and norms are required to be followed for the approval of bio similar products. It goes on to show that prima facie the response of the defendant No.1 if it is to be taken on the basis of the submissions advanced by the defendant No.1 in terms of regime relating to bio equivalence before this court. **This is due to the reason that in the event the drug is already marketed in India, the process for**

obtaining the approval in the regime of bio equivalence is simplifiedwherein the applicant has to only show that the medicine is bioequivalent to the medicine already marketed and on that basis, the clinical trials requirements can be relaxed.

224. However, in the present matter, **the defendant No. 1 as a Drug Controller was dealing with new drug of defendant No.2 who was seeking approval on the basis of claim of similarity of biological structure, composition and other characterstics and on the date of the granting the approval was already the participant in the guidelines requiring the stricter approach to be adopted in the case of the Bio Similar drugs.Thus, the question was not really before the defendant No.1 that the drug was already marketed in India as stated by the defendant No.1 in its written statement which normally eases the process of approval in the case of normal drugs, this has been admitted by the drug controller being party to the guidelines starting point of the guidelines commences from the departure to the approach of bioequivalence. If that is the level of contradiction in the stand of the defendant No.1 in the written statement, submissions advanced before this court vis a vis the guidelines framed on the similar biologics, then prima facie on the face of it, the approval granted by the defendant No.1 appears to be on the basis of the regime of the bio-equivalence on the premise that the drug is already marketed in India would lead all others to derive the benefit of the seeking the approval on the said basis when the**

scheme of bio similar is a complete departure thus rendering the approval contrary to its own guidelines.

225. In order to verify the exact position and objections raised by the plaintiffs in the original plaint and refusal of giving the inspection by the defendant No.2, with consent original relevant record has been deposited by the defendant No.1.

226. The defendant No.2 on 17th April, 2008 filed an application to the authority for permission to import Cell lines as part of the development of the product. On 8th July, 2008 permission to import from RCGM was granted. On 14th February, 2009 the defendant No.2 sought 'No Objection Certificate' to manufacture inter alia Bmab-200 formulations for the purpose of examining test or analysis.

227. The relevant details available from the record are given below:

(i) On 1st September, 2009 NOC was issued by defendant No.1 in favour of defendant No. 2 under Rule 89 of the Drugs and Cosmetics Rules, 1945 for obtaining license on Form 29 for the purpose of examination, test or analysis. On 13th July, 2009 Review Committee on Genetic Manipulation [RCGM] granted permission to conduct preclinical toxicological studies to defendant No.2. On 2nd December, 2009 license was issued by 'Drug Controller and Licensing Authority, Govt. of Karnataka on Form 29 for the purpose of examination, test or analysis.

(ii) On 18th March, 2011 defendant No.2 submitted application on Form- 44 for conduct of Phase- III clinical trial under Rule 122- DA of the Drugs And Cosmetics Rules. The Defendant No.2 along with their application had enclosed chemistry manufacturing control data, non-clinical data including animal toxicity data, protocol containing details like inclusion, exclusion criteria, primary and secondary end points with regard to safety and efficacy assessment, the names of the trial site, number of patients (sample size), the names of the Investigator etc as per the Drugs and Cosmetics Rules, 1945 for the proposed phase III clinical trial. The trial was titled as "Comparative PK, efficacy, safety and immunogenicity evaluation of Bmab-200 versus Herceptin, both in combination with docetaxel in patients with Her2+ metastatic breast cancer: A double blind, randomized, active control, parallel assignment, comparative, phase III clinical trial.

(iii) On February 25, 2011, the RCGM directed defendant No.2 to approach defendant No.1 for obtaining permission to conduct all phases (i.e. Phases I to IV) of the human clinical trials in relation to Bmab-200. However, defendant No.2's letter to defendant No.1 dated March 9, 2011, enclosing the application in Form 44 for permission to conduct clinical trials in relation to

Bmab-200, is restricted only to Phase III clinical trials (and does not cover Phase I or Phase II trials).

(iv) The defendant No.1 vide letter dated 3rd May, 2011 asked the defendant No.2 to provide justification for carrying out Phase III study directly and to provide comparability study to justify that Bmab 200 is similar to Herceptin.

In response to the said query, the defendant No.2 vide letter dated 27th May, 2011 informed the defendant No.1 that it has designed a clinical trial protocol that combines the endpoints for Phase I and Phase III into a single study.

Phase II is not required as the defendant No.2 will follow the dosing schedule of reference product and it is incorrect to assume that the optimal dosing schedules of both Bmab-200 and the plaintiffs' Trastuzumab would be the same or that the same dosing schedule can be followed. Defendant No.2 has also stated that their clinical trial protocol combines the end points for Phase I and Phase III into a single study.

(v) On 9th August, 2011 the defendant No.1 issued a letter to Dr.T.S. Sagar, Chairman and Prof., Department of Medical Oncology, Cancer Institute Adyar, Chennai, informing that the defendant No.2 sought the permission for conducting Phase III clinical trial and the defendant No.2 would

combine the end points for Phase I and Phase III into a single study.

(vi) Defendant No.2 was granted permission to conduct Phase III trials by DCGI vide its letter dated 19th August, 2011 and its amendment dated 16th March, 2012.

(vii) On 18th September, 2012 the defendant No.2 communicated to defendant No.1 informing that it has completed the Phase III clinical trial of Transtuzumab (Bmab-200) entitled "Comparative PK, efficacy, safety and immunogenicity evaluation of Bmab-200 versus Herceptin, both in combination with docetaxel in patients with Her2+ metastatic breast cancer: A double blind, randomized, active control, parallel assignment, comparative, phase III clinical trial. Protocol No.:BM200-CT3-001-11 Version 2.02 dated:04.07.2012 Supersedes 2.01 dated 10.01.12" in India. The defendant No.2 also convened a meeting of NDAC for the said purpose. However, no clinical trial report was submitted.

(viii) On 27th September, 2013 the defendant No.1 had forwarded the results of the Phase-III clinical trials to the NDAC by the defendant No.1 requesting for expert opinion as to whether defendant No.2 can be considered for granting marketing authorization. Simultaneously, the defendant No.1 also sought a clarification from the

defendant No.2 regarding administrative data, chemical manufacturing control (CMC) and other safety data. On 18th October, 2013 New Drug Advisory Committee (hereinafter referred to NDAC) on Oncology and Hematology [which is an expert body constituted vide order dated 31.3.2011 to advise defendant No.1 in matters relating to approval of new drugs] to advise the defendant No.1, examined the proposal of defendant No.2. The NDAC comprised of eminent experts and considered the data and information famished by defendant No.2 as also the results of the Phase-III clinical trials.

(ix) Prior to NDAC meeting, the plaintiffs on 11th October, 2013 raised serious concerns relating to the clinical trial including inadequacy of end point of drug and insisted for compliance of Guidelines on similar Biologics. It was inter alia alleged by the plaintiffs that defendant No.2 has not conducted animal pharmacology tests in relation to drug as part of its pre-clinical studies who has also not conducted any comparative pre-clinical studies between Bmab-200 and the reference product. Defendant No.2 has also not conducted a study of immune responses in animals in relation to Bmab-200 prior to using Bmab-200 in human clinical trials. No clinical trials of Phases I and II have been registered with defendant No.1 or any other authority.

(x) Defendant No.2 submitted the said application to DCGI along with Phase III Clinical Trial report as Module 5 along with Module 1, Module 2, Module 3 and Module 4 as per CDSCO Guidance for Industry. As per requirements contained in Schedule Y contained in the Rules, defendant No.2 also submitted copy of draft Summary of Product Characteristic (SmPC), label, carton and prescribing information.

(xi) As per record available the defendant No.1 received on 15th October, 2013 a fresh application whereby the defendant No.2 again applied to defendant No.1 on Form 44 under Rule 122B for approval to manufacture and market Trastuzumab. The said application was accompanied by data as contemplated under Appendix I of Schedule Y of the Drugs and Cosmetic Rules, although on the said date, all the studies and clinical trials were already circulated to NDAC.

(xii) Defendant No.2 was called to make a presentation before the New Drug Advisory Committee (Oncology and Hematology) (NDAC) on 18th October, 2013.

(xiii) The defendant No.2 was granted permission in Form 46 and Form 46A to manufacture Trastuzumab injection 150 mg/vial and 440 mg/vial and Trastuzumab drug substance

respectively by the DCGI vide letter dated 23rd October, 2013.

On 18th October, 2013 the NDAC recommended to allow the manufacturing authorization with condition to submit the PSUR and proposed Risk management plan duly after seeking approval of the NDAC. The firm also submits CMC and other related clarifications advised as per previous query letter issued by office of DCGI. The drug shall be prescribed by registered Oncologist only. On 23rd October, 2013 subject to the said conditions approval was granted.

228. The corrigendum was done in the NDAC meeting held on 27th November, 2013 wherein the meeting of 18th October, 2013 was corrected to read as "The Committee recommended to allow the approval with conditions as imposed in the meeting held on 18th October, 2013."

The minutes were signed on 29th November, 2013 and on the same day it was recorded that the defendant No.2 has submitted the Risk Management Plan of the Bmab-200 based on NDAC recommendations. Corrigendum in this regard was signed on 10th December, 2013.

229. It is admitted by the defendant No.1 on 27th September, 2013 that it has only sent the result of Phase III to NDAC for expert opinion as to whether defendant No.2 can be considered for granting marketing authorisation and as per admitted case of all the defendants that the fresh application under Rule 122B was filed on 15th October,

2013 along with clinical trial. The recommendation of approval was granted on 18th October. 2013 and approval letter was issued on 23rd October, 2013. Clinical study report is itself dated 3rd October, 2013.

230. The entire approval process was completed within three days. The approvals were recommended by the Committee on 18th October, 2013. The approval process and clinical trials and implied examination have not been examined by the Technical Committee and Apex Committee nor the Guidelines of 2012 appear to be followed as per record available. However, the defendant No.1 has granted manufacturing approval to the defendants' drug Forms 46 and 46A under Rule 122B i.e. Approval for Manufacture of a new drug formulation.

231. It is evident from the record that the approval was recommended in a very short time between the submission of Form 44 and defendant No.2's presentation dated 15th October, 2013 before the NDAC who could not have had sufficient opportunity to study the application before recommending the approval on October 18, 2013. Further, defendant No.2's application could not have been reviewed by the Technical Committee and the Apex Committee. As per earlier Guidelines referred by defendants themselves at least 90 days period is required to study the clinical trials. However, in the present case, the approval was granted within three days even by ignoring the objection raised by the plaintiffs.

232. It is necessary to mention here that the Mashelkar Committee Report (which the defendants have relied upon extensively) itself provides that the examination of clinical trial data and response by the DCGI should take 90 days approximately. In the present case, the clinical trial data for Bmab-200 was submitted to the DCGI on October 15, 2013 and the marketing authorization was granted to defendant No.2 on October 23, 2013 (within 8 days). It appears from the minutes that no speaking order was passed as per record available. Merely the recommendation was issued on the office report prepared on 21st October, 2013. Office note does not reveal any exemption of Phase I and Phase II or following the Guidelines of 2012.

233. With regard to Choudhary Committee Report (2013) relied upon by defendant No.2 is not applicable to the present dispute since the defendants' drugs were not on the market in well-regulated countries before being introduced in India in the year 2011. Rather said report goes against the defendants. The report recommends that Phases I to IV clinical trials of all new entities developed in India to be marketed in India will need to be carried out in India as per paragraph 16 on page 4 of the Report which also contemplates that only applications concerning national emergencies or drugs/biologicals for tropical diseases will receive priority for expedited review.

Approvals were not referred to the Technical and Apex Committees

234. Admittedly, the defendant No.1 and NDAC have not referred the approval process through the Apex and the Technical

Committees. The said Technical Committee and the Apex Committee were constituted in compliance to the submissions as made by the Union of India and its acceptance by the Supreme Court in its 3rd January, 2013, in the matter of **Swasthya Adkikar Manch v. Union of India and Ors.**, WP(C) No.33/2012. It was submitted before the Supreme Court that clinical trials of New Chemical Entity shall be conducted strictly in accordance with the procedure prescribed in Schedule Y of Drugs & Cosmetics Act, 1940 under the direct supervision of the Secretary, Ministry of Health & Family Welfare, Government of India. It was pointed out that as per notification dated 31 March 2011 of the Government of India the NDAC was constituted to advise defendant No.1 after evaluation of pre-clinical trial data and the protocols. As per Supreme Court order dated 21st October 2013, NDAC is required to evaluate prior to grant of approval of clinical trials. The Government has agreed to review the new drug discovery applications.

235. In the said case **Swasthya Adkikar Manch** (supra), the Supreme Court directed that clinical trials should be re-evaluated in accordance with the three-tier process (NDAC, Technical Committee and Apex Committee) because of the reason that on the date of the order of the Supreme Court, letter by way of objection on behalf of the plaintiffs as well as Guidelines of Bio-similars were already available with NDAC Committee.

236. An affidavit filed by the Ministry of Health and Family Welfare before the Supreme Court itself states "clinical trials are necessary for the development of new drugs in the country."

237. It is argued by defendants No.1 and 2 that approval process has gone through every step of the prevalent Regulatory Regime and is in compliance of the procedure prescribed under law. The procedure for obtaining biosimilar approvals began in the year 2008 and was duly completed in 2013 when the manufacturing and marketing authorization were granted to defendant No.2. Therefore, the Supreme Court orders in the clinical trials matter of bio-similar drug are not applicable to the present case as the Apex Committee and the Technical Committee were formed after defendant No.2 had started its clinical trials. It is canvassed that the Technical Committee and the Apex Committee were formed to examine applications for new chemical entities and thus there was complete application of mind by the DCGI in granting the manufacturing and marketing authorisation for Bmab-200 who has been satisfied to grant a licence to defendant No.2.

238. Admittedly the Technical Committee and Apex Committee have not reviewed Bmab-200's clinical trial application (as required pursuant to Supreme Court orders and Notification No.12-01/12-DC (Pt-133)/DFQC dated February 6, 2013 even though Bmab-200's clinical trial was approved on August 19, 2011 during the relevant period. On October 21, 2013, the Supreme Court directed that clinical trials which had been approved before the order dated January 3, 2013 should have been re-evaluated in accordance with the three-tier

process (NDAC, Technical Committee and Apex Committee). The distinction drawn between biological and clinical/chemical drugs in relation to clinical trials, in the above referenced notification relating to the Technical Committee and the Apex Committee is incorrect as the Drugs Rules (Schedule Y deals with new drugs and not new chemical entities/new clinical entities). The minutes of the Technical Committee meeting available on the website of the CDSCO indicate that the Technical Committee routinely provides recommendations for clinical trials of biological drugs in pursuant to the Supreme Court order dated January 3, 2013.

239. There is no force in the submissions of defendants No.1 and 2 that the Technical Committee and Apex Committee are only involved for the evaluation of proposals for conducting the trial and not for evaluation of any proposal for approval of new drugs for manufacturing and marketing in the country. Whether it is new chemical entity or biosimilar? One has to read the order of the Supreme Court in context and intention of the mandate of the order. It is a matter of fact that on the date of recommendation and approvals, all the orders and material and circumstances were already available which are apparently not brought to the notice of NDAC at the time of recommendation as per record available.

240. The main approval process was started when an application was received by defendant No.1 on 15th October, 2013 for manufacturing and marketing. The hearing on the said matter, being WP (C) No.22/2012, was being conducted in Supreme Court. The

Government also placed its stand before the Supreme Court by filing of affidavit(s) as well as by making the statement in the Supreme Court. The defendant No.1 presumably was aware about the orders at least on the date of approval i.e. 23rd October, 2013.

241. There is no force in the submission of the defendant No.2 that since the approval process of drug in question has taken five years, thus, it is presumed that all the protocols have been complied with. The said argument is wholly misleading as it is the admitted case of defendant No.1 itself that the result of Phase III was submitted by the defendant No.2 on 27th September, 2013. As per case of the defendant No.1, the defendant No.2 filed the fresh application on 15th October, 2013 for approval to manufacture and market Trastuzumab. The drug was recommended by NDAC on 18th October, 2013. Even while issuing the recommendation NDAC did not refer the matter to Technical and Apex Committee to consider the Clinical Trials. After recommendation on 18th October, 2013, the approval was issued on 23rd October, 2013.

242. Pre-clinical trials comprising (a) animal toxicology; and (b) animal pharmacology studies are required to be conducted under Rule 122B read with paragraphs 1(1)(ii) and (iii) of Schedule Y and Appendices I, III and IV, Schedule Y of the Drugs Rules. The mandatory animal pharmacology studies were not conducted by defendant No.2. It is required even as per Guidelines 2012, paragraph B.1 of the 1999 Guidelines and Section C of the CDSCO Guidance.

243. The defendant No.1 did not recommend skipping or combining any phase of clinical trials as per record available. Rather the defendant No.1 sought justification from defendant No.2 as to why Phase I and Phase II trials were being skipped. The explanation given by the defendant No.2 is self-serving service and contrary to the biosimilar Guidelines or Drugs Act and Rules.

244. Paragraph 8 of biosimilar Guidelines 2012 mandates that all phases of comparative human clinical trials including pharmacokinetic, pharmacodynamics, confirmatory safety, efficacy and immunogenicity studies must be carried out for a biosimilar drug. As per plaintiffs, comparative safety and immunogenicity studies were not conducted by defendant No.2. The defendants No.1 and 2 have admitted that the defendant No.2 has not performed a pharmacodynamics (PD) study for drug in question neither as a separate study nor as a part of the phase III. It is a matter of fact and as per record no exemptions from conducting any phase of clinical trial were available to defendant No.2.

Two Additional Indications

245. The defendant No.2 during the pendency of hearing has obtained the approval of two additional indications of the biosimilar drug. It was not brought to the notice of the Court at the first instant.

246. In fact after granting the approval of metastic breast cancer as per original application was filed, the defendant No.2 applied to the Drugs Controller and Licensing Department, Government of Karnataka

for permission to manufacture two additional indications under the license given under Form 28D i.e. for metastic early breast cancer and metastic gastric cancer.

247. This request was made to the State Licencing Authority on 24.10.2013for grant of additional product approval in Form-28D for Trastuzumab Bmab and its formulations along with (revised) Specimen Label, product general information (SmPC) & PI**.** CDSCO sub-zone - Bangalore, and State Licensing Authority carried out joint inspection of the manufacturing premises of defendant No.2 on 20th November, 2013 and submitted their report to office of CDSCO, New Delhi and State Licensing Authority.

248. The plaintiffs during hearing rightly apprehended and pointed out to the Court that the defendant No.2 was trying to obtain the approval of other two indications without conducting any trials. The plaintiffs filed two fresh applications including the application for fresh interim injunction. On the date of filing of such applications, the plaintiffs were not aware about the exact position. When query was raised, the defendant No.1 informed to the Court that the approval sought by defendant No.2 on 10th November, 2014 for two additional indications was granted on 17th March, 2015. Cop of the same was furnished by the defendant No.1 subsequently.

249. It is alleged by defendant No.2 that the additional indications as sought to be approved by the defendant No.2 are not beyond the already approved indications for which the plaintiffs'

drug/reference drug has already been approved. The said practice is also internationally accepted. It is further submitted that by letter dated 10th October, 2013 issued to the defendant No.1 had along with submitting the Phase-III clinical trial reports claimed for all the three indications i.e. MBC, EBC and MGC and an approval was granted on 23rd October, 2013 for MBC to the defendant No.2 after establishing Biosimilarity to the drug of the plaintiffs. The extrapolation of indications is thus simply a case of administrative confirmation by the defendant No.1 whereby the defendant No.2 is permitted to manufacture and sell its biosimilar Trastuzumab for EBC and MGC indication.

250. The defendant No.2 has admittedly not conducted any studies or tests in relation to two additional indications. The defendant No.2 has sought to extrapolate the data generated and relied on first indication i.e. metastic breast cancer for additional indications.

251. The defendant No.2 has tried to give justification for extrapolation of safety and efficacy data from one indication of trastuzumab to the additional indications. It is submitted that as per the Biosimilars Guidelines 2012, **Clause 8.5**, 'Extrapolation of Efficacy and Safety Data to Other Indications' Extrapolation of Efficacy and Safety Data of a Particular Clinical Indication (for which clinical studies has been done) for a similar biologic to other clinical indications may be possible if following conditions are met:

1. Similarity with respect to quality has been proven to reference biologic;
2. Similarity with respect to pre-clinical assessment has been proven to reference biologic;
3. Clinical safety and efficacy is proven in one indication;
4. Mechanism of action is same for other clinical indications;
5. Involved receptor(s) are same for other clinical indications;

252. It is submitted by the defendant No.2 that in all approved clinical indication the involved receptor are the same and shows its efficacy in approved clinical indication by interacting with HER2 protein and causing cell apoptosis and interfering with downstream signals. As all these conditions were met for the additional indications, therefore the approval was rightly granted by DCGI on merit. The objections of the plaintiffs are without any force.

253. As per Rule 122E(b) of the Drugs Rules, a drug already approved by the DCGI which is proposed to be marketed for a new indication, is a “new drug” for the purposes of the Drugs Rules. There is no provision under the Drugs Act and the Drugs Rules permitting exemption from conducting such tests for approval of a biosimilar drug for new indications. As per Clause D of Form 44 of the Drugs Rules, which form is required to be filed, inter alia, along with applications for approval for manufacture of new drugs, the applicant should provide therapeutic justification for the new claim and the data generated on safety or quality parameters.

254. It is evident that the extrapolation of the clinical data relating to one therapeutic indication to another different indication is not automatic or unqualified and **must be therapeutically justified** with safety and quality data.

255. It cannot be disputed that the appropriate clinical trial end points for a drug targeting HER2+ early breast cancer is disease free survival, which measures the length of time after primary treatment for a cancer ends that the patient survives without any signs or symptoms of that cancer.

256. It is the admitted position in the present case that the metastatic breast cancer cannot be cured, it can only be treated to prolong the patient's life and would be targeting metastatic breast cancer aim to control the growth of the cancer and/or to relieve symptoms caused by it. On the other hand, early breast cancer can be cured in some cases and metastic gastric cancer is not distinct from breast cancer and early breast cancer. Thus, prima facie, it cannot be said that all the three types of cancer are meant for the disease for the same purpose and it might be having distinct properties.

257. It is informed by the learned Senior counsel for the plaintiffs that the approval of the plaintiffs' Trastuzumab, which is the innovator drug in the present case, for HER2+ early breast cancer and HER2+ metastatic gastric cancer in India took almost 4 years and years respectively from the initial approval for HER2+ metastatic breast

cancer and was based on global clinical trials conducted by the plaintiffs.

258. It is submitted by the plaintiffs that the defendant No.2 has not conducted any clinical trial test model which could detect potential differences between the drug of the defendant No.2 and the plaintiff's Trastuzumab. HER 2+ metastatic breast cancer is not a sensitive clinical trial test model to detect potential differences in safety, efficacy and immunogenicity. The pharmacokinetics would be affected because of the patient's health status and tumor burden and the international practices do not permit immunogenicity data in immunosuppressed subjects to be extrapolated to an indication in healthy subjects or patients with autoimmune diseases, and therefore, data from HER 2+ metastatic breast cancer relating to tests conducted with immunosuppressed subjects cannot be extrapolated to HER2+ early breast cancer.

259. It is also submitted that the clinical trials for HER2+ early breast cancer would be conducted on a homogenous patient population, which would be a sensitive clinical trial test model to show the potential differences with the innovator biological drug and the identification of data from a treatment-free follow-up phase which is crucial for the comprehensive characterisation of the immune response.

260. Admittedly the recommendation is not based on the clinical trials purportedly conducted by defendant No.2 in relation to two

additional indications. Whatever studies and trials conducted by the defendant No.2 on patients are only in relation to with HER2+ metastatic breast cancer for which the original application was filed for clinical test was made for metastic breast cancer. Approval of two additional indications was granted by without passing the speaking orders and discussion. When the approval of first indication itself is not granted strictly as per rules and guidelines.

261. A party is entitled to the benefit of approval of extrapolation of clinical trial relating to one therapeutic indication to different if the due compliance and protocol are satisfied. The Drug Authority is supposed to examine the application for the same very carefully because it is to be granted without clinical trials. The approval cannot be granted in mechanical manner or on demand. The authority has to assign reasons.

TRASTUZUMAB

262. The defendant No.2 has been granted the approval of the name Trastuzumab which is one of the International Non-proprietary Names (INN). The defendants No.2 to 4 are using the said name in their carton(s) and package insert and data for the purposes of promoting their products. The materials are shown to doctors, hospitals and patients in order to claim biosimilar drug.

263. It is the case of the defendant No.2 that as per the 'World Health Organization Guidelines on the use of International Non-proprietary Names (INNs) for Pharmaceutical Substances', an INN

identifies a pharmaceutical substance by a unique name that is globally recognized and is a public property.

264. It is argued that the aim of the INN system has been to provide health professionals with a unique and universally available designated name to identify each pharmaceutical substance unlike the brand name of a particular company, the INN name is the name of the bulk medicine itself and has to be printed on every product containing the said drug as the generic and biosimilars of known substances are identified with the same INN name. In the present case, the plaintiffs cannot claim monopoly or ownership over the same as it is a public property. It is submitted that as the defendant No.2 has obtained all approvals for manufacturing and marketing Trastuzumab (marketed as CANMAb) and therefore it is essential for the defendant No.2 to refer to the INN name Trastuzumab for the convenience of the doctors and patients across the globe.

265. The case of the plaintiffs is that the INN "Trastuzumab" has been assigned by the WHO to the plaintiffs' innovator biologic drug. "Trastuzumab" is a biologic drug which is a recombinant DNA-derived humanized monoclonal antibody. INN Trastuzumab cannot be used by any party unless comparative tests establishing biosimilarity have been conducted.

266. Extracts from the WHO policy which are referred by learned senior counsel on behalf of the defendant No.2 are set out below:

> "The INN Programme's purpose is to assign nonproprietary names to medicinal substances so that each would be recognized globally by a unique name. INNs facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. In fact, unlike trade names, INNs do not give proprietary rights and can be freely used since they are in the public domain. The INNs form an essential part of the regulatory process in many countries where a nonproprietary name is required for licensing…" (emphasis supplied)

267. It is argued on behalf of defendants that the plaintiffs may have goodwill in the brand name HERCEPTIN and not in "Trastuzumab". "Trastuzumab" is an INN, it represents a drug of the plaintiffs for the last many years which has an intrinsic goodwill attached to such drug. The patent right in the drug in question has expired in 2013. Originally the said name may have been exclusively associated with the innovator drug but it cannot be called as brand name. It is a non-proprietary name. The new concept of biosimilar drug was based on and in relation to innovator product. Therefore, the defendant No.2 is entitled to use the said INN name.

268. It is admitted position that the regime of biosimilar is new one. It is still to be evolved in this country. Very few approvals have been granted by the Regulatory Authority in new regime. The process of approvals cannot be considered as same in the process of approvals of generic product in chemical form wherein the chemical drug is same, whereby and therefore risk is minimum, however, biosimilar/biological drug is not identical, risk involved is much higher

than generic drug. Therefore, the said issue has to be handled in careful manner.

269. The degree of similarity of the biosimilar drug has to be maximum to the near of innovator's drug otherwise it cannot be called as biosimilar. The clinical data has to be generated for the purpose of new drug. Thus, heavy burden is upon the Regulatory Authority to examine the clinical trials of biosimilar drug.

270. From the said discussion and overall facts and circumstances, I am clear in my mind that if all the clinical trials have been conducted by the party of biosimilar drugand all protocols are fulfilled under the Act and Rules and bio-similar guidelines 2012. Under those circumstances, the party/applicant would be entitled to use identical name of INN. Otherwise in failure to do so, the party has to use the said name with certain level of distinction in order to avoid confusion and deception. However, the said name cannot be used or displayed to patients, doctors, hospitals as a brand name. It is to be used to describe its drug only. Any party under the garb of INN name is not entitled to make the misrepresentation or to take any undue advantage, if he does so, he is not entitled to harm the innovator party due to reason that previously INN name was associated with the innovator.

Package Insert

271. The defendant No.2 has claimed that the approvals of package insert have been issued in December, 2013. The case of the

plaintiffs is that no such approvals are granted. The same is being used by defendants No.2 to 4 contrary to the interim orders dated 5th February, 2014 and modified order dated 14th February, 2014.

272. It is submitted by the senior counsel appearing on behalf of the defendant No.2 that the data relating to the clinical efficacy results of patients under the treatment of Trastuzumab / Herceptin is in public domain. In the present case, the literature of the defendant No.2's product is in fact a compilation of published data available in the public domain and the results of the clinical trials conducted by the plaintiffs which are not individually capable of being protected under Copyright Law and thus the alleged claim for copyright infringement contended by the plaintiff is untenable. Further, there is no law permitting data exclusivity in India which may prohibit the defendant No.2 to make use of data available in public domain, relating to Trastuzumab. Even other biosimilar drugs rely upon the data and/or information of the reference product in the package insert/ prescribing information of the biosimilar drug. For example, Reditux manufactured by Dr. Reddy's is biosimilar to Mabthera manufactured by the plaintiffs. It is also submitted that the original plaint does not claim any rights for infringement of copyright.

273. It is also submitted by the defendants No.2 to 4 that WHO Guidelines state that "The prescribing information for the biosimilar should as similar as possible to that of the reference product except for product-specific aspects, such as different excipient(s). This is

particularly important for posology and safety-related information, including contraindications, warnings and adverse events.

It is submitted that the using originator data as the basis for Package Inserts is the normal practice for biosimilars in India and in Europe, and is supported by WHO guidelines. WHO guidelines recommend that the drug substance of the Reference Product and the Similar Biologic must be shown to be similar, furthermore the prescribing information of the Similar Biologic should be as similar as possible to the Reference Biologic and biosimilars in India have followed this model by also including information from prescribing information/Package Insert of the reference product. The defendants No.2 to 4 have used the innovator's data from published sources including the European PI and American PI so as to contain all available information relating to safety, contraindications, efficacy, any special conditions, side effects, nature and other properties of the drug etc. to assist the prescriber of the drug.

274. This Court is aware that the WHO Guidelines on Evaluation of Similar Biotherapeutic Products, 2009 (the "WHO Guidelines") require the prescribing information for a biosimilar product to be similar to the prescribing information and package insert for the, reference product, and not a verbatim (slavish copy). The WHO Guidelines state that if the biosimilar product has been approved for fewer indications compared to the reference product, the information relating to indications for which the biosimilar product has not been approved should typically be omitted. If it is necessary to include the information

relating to other indications, it should clearly stated in the prescribing information that the SBP is not indicated for use in the specific indication(s) and the reasons why. In the present case for example paragraphs 2.1 to 2.7 (excluding paragraph 2.6.1.1) of HERCLON's package insert have been copied of CANMAb's package insert and of CANMAb's SmPC, the only change being substitution of the word 'HERCLON' with 'CANMAb' or 'Trastuzumab'.

275. The requirement that the package insert of the biosimilar product should be "as similar as possible" to the package insert of the innovator product as referred in paragraph 12 of the WHO guidelines does not imply that the biosimilar manufacturer can copy the innovator's package insert in mechanical way and by claiming the false claim. It also does not imply that the test data in relation to the biosimilar should not be included in the package insert. This is also supported by the Swissmedic FAQs dated February 17, 2014".

276. The WHO Guidelines specifically state that the prescribing information for the biosimilar product should be as similar as possible to the reference biologic except for product-specific aspects, such as different expedients and the manufacturer of a biosimilar product may choose to mention the biosimilar nature of the product and the studies that have been performed with the biosimilar product.

277. It is stated by the plaintiffs that the defendants No.2 to 4 have not identified that the data in their package insert is the plaintiffs' data for Trastuzumab. They have only mentioned that "following results

have been observed in various patient populations under the treatment with Trastuzumab based on published information". They have not specified whose published information is referred to thereby. The defendants have also failed to prove that independent/comparative test data is included in the package inserts and the defendants' drugs are not even referred to as a 'biosimilar' product in the package insert.

278. It is submitted by the plaintiffs that the data relating to indications that Bmab-200 is not approved for Metastatic gastric cancer and Early-breast-cancer in the package insert of CANMAb approvals of which were not granted at the time of introducing in the market yet the defendants No.2 to 4 still included. It is argued by the plaintiffs that as a matter of fact the defendants No.2 to 4 have included references to indications for which Bmab-200 is not approved to misrepresent and mislead patients and doctors and give an impression that the defendants' drugs are the same as HERCEPTIN. In support counsel for the plaintiffs has pointed out certain portion from the package insert filed before start of hearing. The details of the same are already mentioned in earlier part of my order. However, later on counsel for the defendant No.2 had informed that it was modified. The defendant No.2 has also been granted approval of package insert of other two indications by the defendant No.1 without informing the Court as it was informed to the Court when the query in this regard was made during the hearing.

279. It was earlier argued that no approval of package insert is required. There is no force in the argument that there is no

requirement to get a separate approval for package inserts once the manufacturing and marketing authorization for the drug is obtained. The said arguments of the defendants are self defeating arguments which have no merit since admittedly the package insert proposed to be used by defendants No.2 to 4 for the additional indications was separately approved pursuant to letter dated July 28, 2015. Approval of the package insert is specifically required at paragraph 8 of Form 46 and paragraph 1 (i)(vi) of Schedule Y of the Drugs and Cosmetics Rules, 1945, as amended (the "Drugs Rules").

280. The defendant No.2 submitted the package insert to the State FDA. The State FDA is not the appropriate authority to approve the contents of the package insert. The manufacturing approval granted by the State FDA on December 13, 2013 (Form 28D) cannot be considered as the approval for the package insert. In fact, the Form 28D itself requires defendant No.2 to comply with all conditions of the marketing authorization dated October 23, 2013 (which includes the requirement to obtain a separate approval for the package insert). Mere DCGI's counter-signature on Form 28D and the subsequent submission of the package insert to the DCGI on December 13, 2013 "for information and record purposes" cannot be considered compliance of paragraph 8 of Form 46. Contrary to paragraph l(l)(vi) of Schedule Y of the Drugs Rules, defendant No.2 made changes to the package insert submitted to the DCGI on October 15, 2013 (along with their Form 44 application) without obtaining DCGI's approval for such changes. There is no communication on record either from FDA or

defendant No.1 to show that written letter/order has been issued to defendant No.2 in this regard.

281. The package inserts of Bmab-200 available at pages Nos. 950, 993, 996, 1001, 1003 and 1005 would indicate that the drug used for treatment of (i) metastatic breast cancer (ii) early breast cancer and (iii) metastatic gastric cancer. However, Bmab-200's approval available at page No. 935 is only for metastatic breast cancer. This approval of additional indications were granted later on at page No.993- "*detected in 1 of 903 patients*" and on page No.1001- " *data from studies 1 and 2 were obtained from 3206 patients"* and "*study 4 reflect exposure of Trastuzumab as part of adjuvant treatment regimen from 2124 patient*." The said package inserts cite results of pre-clinical studies conducted on cynomolgus monkeys at page No.997, but the tests conducted by defendant No.2 were on Swiss albino mice and New Zealand white rabbits. The said inserts state that the composition of the clinical trial population was "*84% of patients were White, 7% were Black, 4% were Hipanics and 4% were Asian*" at page No.1001, but defendant No.2's clinical trial protocol shows that the clinical studies were conducted over 23 site in India as mentioned at page No.914. Further in the said inserts it is stated that the drug has been clinically tested "in combination with paclitaxel or an anthracyclie" and also "in combination with anastrozle" as mentioned at page No.992 but Bamb-200 was only tested in combination with docetaxel as is disclosed at page No.913. The package inserts state that the median treatment duration in the defendants 'clinical studies was 51 weeks as mentioned

at page No.999, but infact conducted over a period of 24 weeks as per the details available at page No.918. to all justifications given by the defendant Nos.2-4 is that they have post marketing experience with Trastuzumab in their package inserts at page No.1006. As defendants' drugs were launched only after the filing of suit and after the impugned order dated 5th February, 2014, it could not have generated post marketing data as yet.

282. Prima facie, it appears that the defendant No.2 has made contradictory averments in relation to the approval of its package insert. On one hand, defendant No.2 has stated that no separate approval for the package insert is required and on the other hand, it is contended that its package insert was in fact separately approved by the DCGI. Prima facie, it appears to the Court that the defendants have made misrepresentation in disclosing in data from Phase I, Phase II and pivotal Phase III studies at Page No.993, however, in fact as per the admission made by the defendant No.1, the defendant No.2 has conducted the trials only of Phase III studies and clinical trials of Phase I and Phase II are not registered.

283. The package insert which was originally submitted would show that certain part of it was reproduction. The WHO guidelines never recommend that if Phase I and Phase II trials are not conducted and approval of two additional indications i.e. early breast cancer and metastatic gastric cancer was yet to be granted, still a party is entitled to claim the approvals in the package insert. The party is not entitled to claim and cannot be allowed by the Court and Regulatory Authority

when the claims were that the pre-clinical studies are conducted on cynomolgus monkey but in fact the tests are conducted by defendant No.2 on white rabbit. It is correct that this Court is deciding the application on the basis of original plaint where no relief for infringement of copyright sought but it cannot be denied by the defendants that there are many averments in the plaint about the misrepresentation and false claim made by the defendant No.2 in the package insert.

284. No law in India or WHO Guidelines or other Guidelines of entire world can allow any party, who proposes to market biosimilar drug, to make its claim, which is false and misleading statement, in its package insert. Even the defendant No.1 failed to notice these misleading statements when approval of package insert was granted. It is the duty of the defendant No.1 to examine each and every part of data produced before granting approvals of label and package insert because the drug involved is meant for serious disease, otherwise, the purpose of the scheme of the Act, Rules and Guidelines would be frustrated and shall see that not even a single false statement is made.

285. The defendant No.2 is only entitled to rely on the plaintiffs' data relating to Trastuzumab for the purpose of seeking approval for Bmab-200 for comparison purposes for which the plaintiffs themselves are not claiming any rights. However, the defendants No.2 to 4 have no right to use identical package inserts on the basis of false claim. If any false and misleading statement is made in the package insert,

even the data of the innovator product in order to show biosimilarity cannot be used.

286. It is correct that when the innovator's data is also required to be used in prescribing label and information - the WHO Guidelines require that the prescribing information for biosimilars should be "as similar as possible" to the prescribing information of the innovator drug but subject to condition that all the information mentioned in the package insert is correct about their clinical trials and in case of untrue claims within the knowledge of a party, then the question of using any information or reference of any kind in order to show biosimilarity for comparison purposes does not arise.

287. The package insert should contain the correct details of a party who propose to manufacture and market bio-similar product as well as the clinical trials conducted. The data of innovator can be used in the package insert for comparison purposes subject to the conditions that the insert contains the correct details of clinical tests which should not make any misrepresentation and misleading statements.

288. In view of aforesaid reasons, I am of the view that if all the clinical trials have been conducted and protocol are complied by a party strictly as per Act and Rules of local laws and as per Guidelines, the data package insert may be similar as possible with the original innovator. But it shall not reproduction from the package approval of innovators and there should not be any incorrect and misleading

statement by a party. The defendant No.1 should not compromise any lapse or discrepancy if found at the time of granting the approval of package insert.

Data Exclusivity

289. India has not provided for data exclusivity as a matter of policy which would prohibit defendant No.2 from making use of data available in public domain, relating to Trastuzumab. The approval of defendant No 2's CANMAb which is a biosimilar is granted on the basis of comparative data generated with respect to that of the innovator drug.

290. In fact, the WHO Guidelines on SBP's clearly stipulate that the prescribing information should be as similar as possible to that of the reference biologic. The relevant extracts from the WHO guidelines are set out herein below:

> "**12 Prescribing information and label**
>
> The SBP should be clearly identifiable by a unique brand name. Where an INN is defined, this should also be stated. WHO policy on INNs should be followed (http://www.who.int/ medicines/services/inn/ innquidance/ en/ index.html) Provision of the lot number is essential as this is an important part of production information and is critical for traceability in cases where problems with a product are encountered.
>
> The prescribing information for the SBP should be as similar as possible to that of the RBP except for product-

specific aspects, such as different excipient(s). This is particularly important for posology and safety-related information, including contraindications, warnings and adverse events. However, if the SBP has fewer indications than the RBP, the related text in various sections may be omitted unless it is considered important to inform doctors and patients about certain risks; e.g. because of potential off-label use. In such cases it should be clearly stated in the prescribing information that the SBP is not indicated for use in the specific indication(s) and the reasons why. The NRA may choose to mention the SBP nature of the product and the studies that have been performed with the SBP including the specific RBP in the product information and/or to include instructions for the prescribing physician on how to use SBP products..."

291. It is argued on behalf of the defendant No.2 that the plaintiffs in their pleadings have unequivocally admitted that they do not claim data exclusivity or data protection or have any issue with regard to the use of their publicly available data for the purposes of seeking approval of defendant No.2's biosimilar product CANMAb. Herceptin is a publically available drug and its data relating to test results, dosage, formulations, dosage etc is in public domain. defendant No.2's approvals were granted after establishing similarity to Herceptin.

292. Defendant No.2 has relied upon the Satwant Reddy Report for the interpretation of Rule 122B of the Drugs Rules. Defendant No.2 has also argued that it is entitled to rely upon and appropriate the plaintiffs' published data entirely without conducting necessary tests to generate data which is to be used in comparison with the plaintiffs' data for establishing biosimilarity with the plaintiffs' Trastuzumab.

Counsel for the defendant No.2 has also referred The Pesticides Management Bill, 2008 and the Intellectual Property Rights Chapter of the TPP Treaty which are irrelevant to the present matter.

293. Counsel for the defendant No.2 has also informed that in many countries of the world have followed the procedure of biosimilar pathways and data and/or marketing exclusivity for innovator biologics and as details available in public domain and as pathway in place as of today. It is submitted that biosimilar abbreviated pathways would/can be adopted in India in which there is condition available as of today pertaining to Data Exclusivity for a reference product. The details supplied would show that data exclusivity has been granted for a reference biological product in many countries given as under:

S. No.	Country	Biosimilar (Abbreviated) Pathway in Place	Data/Marketing Exclusivity for a Reference Biological Product
5	Australia	Yes	Yes - 5 years
13	Canada	Yes	Yes - up to 8 years
14	Chile	Yes	Yes - up to 5 years
15	China	No	Yes - The "new drug monitoring period" of up to 5 years only applies to locally manufactured innovative biologics. No marketing exclusivity is available for biological products developed outside of China.

17	Costa Rica	Yes	Yes - 5 years
21	Europe	Yes	Yes - 8 years of data exclusivity and up to 2 years of market
30	Japan	Yes	Yes - A biosimilar applicant cannot be approved until the innovative product on which application relies has completed an eight-year re-examination or post-marketing surveillance period.
39	Malaysia	Yes	Yes - up to 5 years
46	New Zealand	Yes	Yes - 5 years
52	Peru	Yes	Yes - up to 5 years
56	Saudi Arabia	No	Yes - 5 years
57	Singapore	Yes	Yes- up to 5 years
60	Switzerland	Yes	Yes - 10 years
62	Taiwan	Yes	Yes- up to 5 years
66	Turkey	Yes	Yes - up to 6 years
68	Ukraine	Yes	5 years plus 1 year
70	United States	Yes	Yes - 12 years
74	Vietnam	Yes	Yes- up to 5 years

294. The said details provided on behalf of the defendant No.2 would also show that in many countries data exclusivity has not been granted as per Government policy of respective countries of the world. Similarly the details of bio-similar pathway in place in many countries

are given but at the same time the said abbreviation is not possible in few countries of the world. From the said situation in the entire world the respective governments have taken the policy decision. In India, as informed by both sides that as far as data exclusivity is concerned, so far there is no government policy framed as to whether data exclusivity can be granted to the party whose patent of innovator drug has expired. Similar is the position of pathway/abbreviation of biosimilar products very few approvals have been granted. With the help of so many authorities and intellect involved, while involving Government of India, the biosimilar guidelines of 2012 w.e.f. 15th September, 2012 are placed for the purpose of granting the approvals. However, in the present case, all the defendants addressed their respective arguments by stating that the guidelines are not applicable. As per Rules, the exemption of clinical trials and data of biosimilar product can be granted under sub rule 3 of Rule 1 of the Schedule Y only in life threatening and emergency condition in public interest or where the applicant who had already got the approval of the same drug of manufacturing and marketing for several years in India or other countries in case the process of approvals of biosimilar drug is involved. Certain exemptions are permissible in bio-similar products as per Guidelines, 2012. Nothing on record is available to show that such exemptions were sought under Guidelines, 2012 either from the side of defendant No.2 nor it appears that the approvals were granted by following the said guidelines, rather the stand of defendant No.1 is very strange.

295. The allegations of the plaintiffs against the defendant No.2 are that they conducted a very limited clinical trial and cannot be permitted to use the data and information for the plaintiffs' Trastuzumab which is publicly available without independently conducting the tests required under applicable law and without complying with the Drugs Act, the Rules or the Biosimilar Guidelines. They cannot rely upon plaintiffs' data in order to misrepresent TrastuRel as biosimilar to the plaintiffs' Trastuzumab.

296. It is the admitted position that the plaintiffs are not claiming data protection for the purpose of comparison of data already in public domain with the data of the applicant at the time of approval. It is stated on behalf of plaintiffs that the approvals have been obtained on the basis of all clinical trials as prescribed, the plaintiffs have no objection if the correct data available in public domain is used in package insert. However, it is argued that the defendant No.2 ought to have generated its own data at the time of comparison with the drugs of the parties face to face.

297. The patent not being for the molecule *per se* in its unmodified form was not a primary patent. The patent in simple terms was for a mixture of the unmodified molecule. Accordingly, drug manufacturers may manufacture biosimilar versions of the plaintiffs' Trastuzumab as a consequence of the lapse of the plaintiffs' patent, which drugs should be similar and never identical to the formulation as admitted by the defendants. Patent linkage is not relevant to the issues involved in the present matter since plaintiff No.1's patent in the

plaintiffs' Trastuzumab in India has lapsed. There is no separate legislation to protect the undisclosed test data.

298. In paragraph 1.10 of the Satwant Reddy Report expressly states that "…there are a large number of drugs which are mainly biotech drugs e.g. the monoclonal antibodies (MAB) which are clones of a single parent cell and which target sites in the body responsible for diseases – like cancer, tetanus and a host of other indications. It is difficult to make generics of such drugs. Although some of Indian companies have succeeded in doing so, yet there is lot more to be done in this area. In case data protection is provided, such categories of drugs may become available early in India as the innovator companies would have greater confidence in entering the Indian market." (emphasis supplied)

299. The report of Satwant Reddy was issued in 2007 when r-DNA products were not included in the definition of 'new drugs' (the definition was amended only in 2011). If it is examined carefully, the interpretation of Part XA of the Drugs Rules in the Satwant Reddy Report is applicable only to new chemical drugs and not biological drugs. As per the Report of the Satwant Reddy Committee, 2007 (the "**Satwant Reddy Report**"), India does not provide data exclusivity to pharmaceuticals and agrochemicals. There is no separate legislation to protect the undisclosed test data which is submitted to regulatory authorities in case of pharmaceuticals, and proprietary information is protected unless Government of India would take the Policy decision in this regard as in many countries of the world, they took the policy

decision respectively i.e. pathways and data and/or marketing exclusivity for innovator biologics.

300. No doubt, defendant No.2 is entitled to rely upon the plaintiffs' published data relating to the plaintiffs' Trastuzumab which can be used by defendant No.2 for conducting comparative tests and thereby establishing biosimilarity but such use cannot be extended to defendant No.2's test dossiers and/or marketing material in the absence of all clinical trials required.

301. In the present case, the defendant No.2 is claiming confidentiality of data relating to the development, testing and approval of drug which is not supported in international practice. In fact, all holders of marketing authorisations for all medicines for human use in the European Union and the European Economic Area are required to electronically submit information on such authorised medicines to the European Medicines Agency and keep such information up-to-date on the online database of the European Medicines Agency in the public domain. Pursuant to the mandate under Regulation (EU) No. 1235 of 2010 of the European Parliament and the Council dated December 15, 2010 amending Regulation (EC) No. 726 of 2014, the marketing authorisation holder's responsibilities in this regard "*include providing all available information, including the results of clinical trials or other studies*." The defendant No.2 time and again refused to give the inspection of the documents as sought by the plaintiffs about the main clinical and pre-clinical tests mainly on the grounds of claiming the confidentiality.

302. The reliance of decision under The Pesticides Management Bill, 2008 would not help the case of the defendant No.2 in view of the nature of drug involved in the present case is for cancer. The said principles cannot be applied in the present matter.

303. After having considered the arguments of the parties, I am of the opinion that unless Government of India frames policy to declare as to whether after expiry of patent, the data in public domain can be used as pathways or not, the regulatory authority can neither disclose nor rely upon the first applicant's data at the time of granting marketing approval to the subsequent applicants. It is for the Government to decide that such protection for certain fixed period to the innovator should be granted or not.

Have Guidelines 2012 been followed in the present case?

304. Now, I shall advert to the facts of the present case and evaluate the contention as to whether guidelines can be said to be inapplicable merely due to the reason that the defendant No.2 had already commenced the clinical trials by the time guidelines of 2012 was passed and will it give any leverage to the defendant No.1 or the committees framed under the rules to bypass the guidelines on that basis and proceed to grant the approvals on the premise that the guidelines are non est.

305. Defendant No.1 in its Written Statement has contended that the Biosimilar Guidelines are not applicable to the defendants' drug since the clinical trial protocol in relation to the defendants' drug

had been approved prior to the publication of the Biosimilar Guidelines. The justification is without any substance, *inter alia, on* the reasons that the Biosimilar Guidelines were implemented from September 15, 2012 and at such time the clinical trial in relation to the defendants' drug was still ongoing. Further subsequent to receiving defendant No.1's approval for the clinical trial protocol in relation to the defendants' drug, defendant No.2 had been required to make amendments to such protocol, based on recommendations received from defendant No.1 on August 9, 2011, January 20, 2012 and July 16, 2012. The effective process of approval was started in the second week of October, 2013. The Guidelines were operative with effect from 15th September, 2012 which one year earlier to the start of process.

As a matter of fact defendant No.1 should have insisted that the protocol for the clinical trial for the defendants' Drug be modified to be in compliance with the Biosimilar Guidelines, especially since the Guidelines explicitly state that *"comparative clinical trials are critical to demonstrate the similarity in safety and efficacy profiles between the similar biologic and reference biologic with few exceptions (e.g. recombinant human soluble insulin products for which only comparative clinical safety study is required). The design of the studies and the clinical comparability margins of the primary efficacy endpoints are important and should be given careful consideration*

306. No doubt the defendant No.2 was still conducting clinical trials of its product Bmab-200 when the Biosimilar Guidelines were

issued in the year 2012, However, the alteration in the regulatory framework by passing of the guidelines during the pendency of the application of the grant of the approval for manufacture does not allow the defendant No.1/ DCGI to overlook the guidelines which already came into force by 15th September, 2012. This is due to the reason that the defendant No.1 was still in sesin of the application for the grant of the approval and being a functionary under the Act and the rules framed thereunder considering the object which was sought to be achieved by the guidelines which was to ensure the safety, efficacy of the medicines in relation to complex compounds involving biologics, the defendant No.1 was obligated to take into consideration those guidelines passed by CDSCO of which the defendant No.1 was part at least, it was the duty of defendant No.1 to bring to the notice of the Committee about the guidelines.

307. Even nothing is available on record submitted by the defendant No.1 to suggest that the guidelines have been followed or if the same are ignored or some speaking orders are passed. Rather record discloses that when the request of all the clinical trials of Phase III was submitted the guidelines of 2012 were already in place, nor it was confirmed by the defendant No.1 during the course of hearing that those have been considered. The recommendation of approvals was granted on 18th October, 2013. The approval was granted on 23rd October, 2013 by ignoring the strict adherence to the rules in relation to the clinical trial processes and granting the approval as if it is case

of the bioequivalence which the defendant No.1 itself acknowledges is a regime that is a departure from that of biosimilar one.

308. Even the Mashelkar report, which the defendants rely heavily to contend that the system of approval was already in place and there was no deviation done by the defendant No.1 while granting the approval, also provide for the conducting of the clinical trials in phases and mandate for 90 days period for analysis of the clinical trial data and response thereon by the defendant No.1 and the committees formed under the rules. Thus, the defendant No.1/ NDAC immediately on receipt of the clinical trial data of the defendant No.2 on 18th October, 2013 (without having clinical trial results of phase I and phase II) could not have abbreviated the said phases without giving any reason. The process of recommendation on 18th October, 2013 and approval thereof on 23rd October, 2013 was done with undue haste while analysing the said data whatever was available on that date which was submitted and completed by the defendant No.2, three days ago even when there are four attendant circumstances which are staring on the face of the defendant No.1 that being; first is the time period provided by the expert report Mashelkar report providing the period of 90 days time to analyse the said data relating to clinical trial; second is the notification of the guidelines on similar biologics on 15th September, 2012 providing for the additional requirements keeping into mind the safety and efficacy of the medicines and also insisting on the conducting of the clinical trials and third is that the defendant No.1 was made aware by the time about the scheme of bio similar products while

being a participant to CDSCO guidelines that the regime of bioequivalence is totally distinct from that of the bio similar and thus the approval for the manufacturing of the drug based on similar biologic cannot be granted by merely demonstrating the similarity between the two compounds as done in bio equivalent but it requires demonstration of similarity in other terms as indicated in the guidelines.

309. In this backdrop, when the defendant No.1 was already made aware of these circumstances, in the absence of any special reasons to be given by the defendant No.1 to be recorded in the writing in relation to the exemption of the requirements of the guidelines or the requirements to conduct the clinical trials in three phases, the defendant No.1's grant of the approval to the defendant No.2 overlooking the plaintiff's objection letter dated 11th October, 2013.

310. Under Clause 6.3.2 of the Biosimilar Guidelines complete characterisation studies for similar biologies, including physico chemical characterisation studies, biological activity, immunological properties, functional assays, purity, contamination, strength and content is required. The explanation given by the defendant No.2 is that Biosimilar Guidelines are not applicable is hence not acceptable. The stand of defendant No.1 that those are not statutory is contrary to the scheme of the Act and Rules as well as the spirit of guidelines of 2012 framed by the Government.

311. Though learned ASG has informed during the course of arguments that the defendant No.2 may have combined the Phase I

and Phase II with the clinical trials of Phase III but it is a matter of fact which is admitted that the clinical trials of Phase I and Phase II are not registered with the defendant No.1 even as per record.

312. It is also submitted by defendant No.1 that the defendant No.2 may have conducted the physico chemical characterisation for Bmab-200 but without obtaining requisite manufacturing approvals for the purpose of examination, test and analysis as admittedly clinical trials of Phase I and Phase II have not been registered.

313. It is a matter of surprise, on one hand the defendants are arguing that the clinical trials of Phase I and Phase II are not required and guidelines of 2012 are not applicable, and on the other hand, they are canvassing that most of clinical trials applicable to Phase I and Phase II have been combined with Phase III. If these are combined with Phase III trial, why those Phase I and Phase II trials are not registered by the defendant No.1 as admitted.

314. The perusal of the guidelines of 2012 would show that no doubt that there exists a provision for the reduction in the requirement of the clinical data in the approval process of the bio similar product on the basis of the reference biologic. However, to counterbalance the same, the similarity with the referenced biologic has to be establish not merely in the manner of bioequivalence regime but also on other facets and requirement under bio-similar as well. There are provisions for the product characterization provided in detail for the purposes of the studies wherein similarities and characteristics of similar biologic has to

be seen and examined on various facets including structural and physicochemical properties, biological activities, purities and impurities etc. Likewise, for the clinical trial application, there are additional requirements which have been provided which are mentioned in para 6.2 of the guidelines.

315. From the reading of the guidelines holistically, it can be said that besides establishing the similarity on the several counts, the guidelines also lays great stress on the quality comparability studies, process parameters, comparability of manufactured product at clinical scale. Further, the comparative clinical trials are essential in order to ensure safety and efficacy of the similar biologics. The said clinical trial/ study analysis should spent sufficient amount of time so as to see the effects of the same on substantial number of patients in order analyse the similarity and difference between the similar biological product vis a vis the referenced product as per the paragraphs of the guidelines. Some of the excerpts of the guidelines are reproduced below:

> **Comparative clinical trials are critical to demonstrate the similarity in safety and efficacy profiles between the similar biologic and reference biologic with few exceptions (e.g. recombinant human soluble insulin products for which only comparative clinical safety study is required). The design of the studies and the clinical comparability margins of the primary efficacy endpoints are important and should be given careful consideration and should be justified on clinical grounds**. In line with the principle of similarity, equivalence trials with equivalence designs (requiring lower and upper

comparability margins) are preferred. If non-inferiority trials are required they must be clearly justified and applicants are advised to consult with CDSCO prior to study initiation. Sample sizes should have statistical rationale and comparability limits should be defined and justified prior to conducting the study.

The nature, severity and frequency of adverse events should be compared between the similar biologic and reference biologic and should be based on safety data from a sufficient number of patients treated for an acceptable period of time. **Efforts should be made to ensure that comparative clinical studies have a sufficient number of patients treated for acceptable period of time in order to allow detection of significant differences in safety between similar biologic and reference biologic**. (Emphasis Supplied)

316. If there are number of aspects which have been highlighted as a matter of studies to be done prior to the grant of the approval including the product characterization, comparability on the clinical trials, quality comparability studies and there are additional requirements for conducting the clinical trials with the importance of the same being underscored, the question to be asked is can we really say that the said process be compromised/ overlooked by proceeding to totally exempt the clinical trial route and solely on the ground that the drug has already been approved in India in favour of the plaintiffs which is the substratum of the argument of the defendants, I think that the defendant No.1 and defendant No.2 are proceeding on the misconception of the factual and legal position as that can never be the import of the guidelines nor can be intent of the framers of the same. These are the reasons why the guidelines are to be read in conjunction

with the Drugs and Cosmetics Rules and the aim of the guidelines are to achieve the safety, quality and efficacy of the similar biologic drug so that public get the safe medicine.

317. But in the present case, the stand of defendant No.1 and 2 is otherwise, as they are alleging that the guidelines of 2012 are not statutory and not to be applied as per defendant No.2 in his written submissions also. Further, the defendant No.2 is not ready to give the inspection the documents pertaining to comparative clinical trials and studies to the plaintiffs wherein the arguments in relation to similarities and characteristics of similar biologic are yet to be addressed.

318. The explanation of the defendant No.2 is that all the trials have been considered by the defendant No.1 and various committees. Therefore, the plaintiffs are not entitled to inspect the said documents and the defendant No.2 is claiming confidentiality of those documents. The said stand by the defendant No.2 cannot be accepted because of reason that on one hand, the defendants No.2 to 4 claim to be entitled as a matter of law to use the data, references and name of the plaintiffs in order to claim biosimilar drug based on the referenced drug, on the other hand, they do not want to give inspection of documents of characterization and comparability on the clinical trials so as to ascertain true and factual position between the parties. Learned senior counsel on behalf of the plaintiffs have rightly pointed out as to why defendants No.2 to 4 are hiding the detailed information of the crucial clinical trials from the plaintiffs whose bio-similar drug they intend to use after the approvals are already granted.

319. The said description of the processes by the defendant No.2 in an elaborative form is no answer to the fundamental complaint of the plaintiffs which is that the approval process of the defendant No.2's drug before the defendant No.1 ought to have satisfied the requirements of the guidelines on similar biologics framed in the year 2012 and followed the said pathway.

320. Therefore, assuming that the defendant No.2 might have undergone the onerous processes of the seeking many approvals, but that by itself does not ipso facto allow the defendant No.2 to contend that the norms and requirements framed under 2012 guidelines are fulfilled already.

321. The defendant No.1 and the authorities/ committees framed therein ought to have taken into consideration the guidelines when they were having time to analyse the clinical data as per the existing rules and could have also recorded the reasons for granting the specific exemptions as contended by the defendant No.2 before this court if so claimed by the said defendant and could not have straightaway proceeded to grant the approval to manufacture biosimilar products by completely overlooking the guidelines and the requirements to conduct the clinical trials which were aimed to ensure the safety, efficacy and quality of the medicines based on similar biologics.

322. In my analysis, given the distinct nature of the guidelines framed and object sought to be achieved by them, the argument of the

defendant No.1 and defendant No.2 that the Appendix IA is applicable in the case of the defendant No.2's drug and that is the reason for the abbreviated information being provided and prompt approval is granted suffers from fundamental flaw/ infirmity which no reasonable person who is made aware of the guidelines of 2012 already would undertake unless there is total non application of mind or other extraneous consideration.

323. It is not sure under these circumstances as to whether the defendant No.1 has or has not ignored the significance of the primary end-point of different phases of clinical trials. There is no overlap of primary end points of the four phases of clinical trials and, as stated in paragraph 8.3 of the Biosimilar Guidelines, "primary efficacy endpoints are important and should be given careful consideration and should be justified on clinical grounds."

324. At this prima facie stage, I find that the combining/ skipping various phases of clinical trials is not justified as the exemption is not specifically granted. The exemption is neither automatic nor implied as it would be otherwise rendered redundant the underlying logic of sequential testing vis-a-vis primary end-points, target population and sample size. Paragraph 7.3 of the Biosimilar Guidelines clearly provides that the RCGM recommends the required phases of clinical trials based on an assessment of the pre-clinical test results, paragraph 10 of the Office Order issued by the Department of Biotechnology bearing No. BT/BS/17/175/2005-PID and dated January 2, 2006 wherein the RCGM recommended that all four phases of

clinical trials should be undertaken. The defendant No.1 does not have expertise to analyse the pre-clinical (animal study) reports and draw conclusions. RCGM is the appropriate authority for this purpose.

325. I do not agree with the submissions of the defendants that since Biosimilar Guidelines of 2012 are prospective and not retrospective therefore defendant No.1 was not obliged to apply the same guidelines when the approvals granted as the defendant No.2. The relevant date for application of guidelines is of 2012, the date of approvals is the cut off date. In the present case, the date of approval was granted on 23rd October, 2013 when the Bio-similar Guidelines of 2012 were in place. There is no reason as to why as on the said date, the defendant No.1 being participant to the said guidelines would not take into consideration the same when they are in the nature of the administrative guidelines which are considered to be binding in law.

326. I also do not agree with the defendant No.2 that the said Guidelines do not state explicitly that the Guidelines or specific requirements under the Guidelines are applicable for ongoing clinical trials because of the reasons that most of the meetings relating to the approval of defendants case held after the guidelines were at the place. The safety and efficacy cannot be put at risk because there may be chances of lack of rigorous trials on crucial safety and efficacy parameters before a life saving drug is launched in India. It is mandatory that process of approval of bio-similar should be more stringent and rigorous than for other non-schedule drugs.

327. Therefore, it is the obligation of defendant No.1 to consider the Guidelines of Biosimilar on the date of approval as it is a matter of life and death of a patient(s) in case the approval is granted contrary to rules and guidelines even those may not be mandatory in nature. There is no force that defendant No.2 was not required to enhance the scope of the trials which was initiated in 2011 to comply with Guidelines.

328. As per the Drugs Act and the Biosimilar Guidelines envisage that all phases of clinical trials are required to be conducted by a drug manufacturer unless a particular phase is exempted in accordance with applicable law. As such, neither the RCGM nor the DCGI can permit the defendant No.2 to abbreviate the clinical trials' procedure outside the purview of this legal regime.

329. The defendant No.1 is admittedly serving a public purpose under the Drugs Act and is responsible for public safety, it is imperative for the defendant No.1 to ensure that drugs approved by it have been adequately tested before such drugs are introduced in the market. In the present case, surprisingly it is mentioned in the written statement that the price of the plaintiffs drug is extremely high and there is no justification for blocking other manufacturers and Guidelines on bio-similar are not statutory in nature and Schedule Y does not make mandatory for conducting Phase I and Phase II Clinical Trials for the drugs which have already been approved in India or outside India. Even it is alleged in the written statement that action of the plaintiffs is against the public interest. This defence apparently is unnecessary as

the defendant No.1 must be aware that after the grant of approvals of bio-similar to a party, certain rights are acquired whereby a party can declare in the entire world that its drug is bio-similar to the innovator drug who can also rely upon the data and compare with its product.

330. Prima facie, there is no objective satisfaction recorded by the defendant No. 1 which provide for any reason for dispensing with the requirement of conducting of the clinical trials of Phase I and phase II and even if as on the date of the grant of the permission to conduct phase III trial directly, the guidelines of 2012 were very much in force when on 27th September, 2013 the defendant No.1 had forwarded the results of the Phase-III clinical trials to the NDAC, the said bodies including defendant No.1 ought to have clarified for the requirements of conducting the clinical trials of all the phases or in the alternative asked for the reasons and justifications for not doing so once the contrary position is emerging from the guidelines on biosimilar products of 2012 and they were already in place and in effect, if so desired, the authorities should have passed the orders on the requirement of the reduction of the data submission in the appropriate case or should have insisted for the requirements or material in terms of the guidelines, none of the said recourses have been indicated or adopted by the defendant No.1 or expert bodies who were all aware of evolution in this field of science and developments in the policies in the form of guidelines on biosimilar products.

331. Obviously, when such circumstances were existing, the defendant No.1 had to deal with the situation with the extreme level of

sensitivity and care so that the due process is followed while granting the approval which has been on the face of it flouted and bypassed in the present case. Therefore, I also do not agree with the submission of the reasonableness as canvassed by Mr. Jain, learned ASG appearing on behalf of the defendant No.1. In the present case, the process followed is flawed and suffers from the vice of the non application of mind and non adherence of the statutory provisions of the Act and Rules as well as Biosimilar Guidelines by the defendant No.1 which itself rendered it amenable to the judicial interference not merely in the private interest but also in public interest.

332. Considering the overall facts and circumstances, I am of the considered prima facie opinion that the defendant No.2 has not obtained the approvals as per existing protocol of biosimilar drug. The same are contrary to the Rules, Guidelines of Biosimilar 2012 as well as directions issued by the Supreme Court. As per the case of defendant No.1 that guidelines are not in statutory and remaining defendants have canvassed that those are not applicable, the said arguments are wholly baseless and rejected, thus, the approvals which are in the hands of defendant No.2 granted about the drug manufactured and marketed by the defendants No.2 to 4 are not in accordance with the protocol of biosimilar drug and guidelines, so far the defendant No.2 has not been able to satisfy before the Regulatory Authority as to whether the drug manufactured and marketed by the defendants No.2 to 4 is biosimilar. It appears that the procedure adopted and applied in the present case by the defendant No.1 and

other authorities and committees is akin to the procedure of granted the approval of bio-equivalent drug which is quite distinct from the scheme of granting the approval of biosimilar drug, the same is not correctly examined by the Regulatory Authority as to whether tests in the present case are conducted were adequate or inadequate in compliance with applicable law. No doubt as per guidelines under various provisions, the regulatory authority's committees are empowered to apply pathway of abbreviation for bio-similar drug ban the unfortunate part of the matter is that guidelines have not been considered at all. The power to take action to suspend or cancel the permission/approval under Rule 122 DB is with the Licensing Authority.

333. In view of discussion held and prima facie findings arrived by me, the question now arises as to whether the plaintiff is entitled to any interim relief in the form of injunction as prayed for in the application. The plaintiffs have number of grievances with respect to the market approval granted to the defendant No.2. The said grievances include that the defendants product claiming to be biosimilar as that of the plaintiffs' drug bearing the trademarks HERCEPTIN, HERCLON or BICELTIS and use of the data of the plaintiffs drug, use the INN name and use the bio similar drug as a word to attract the customers in the course of the trade. I have already arrived at certain prima facie findings wherein it has been observed that the defendant No.2 products have been granted approval without adherence to the guidelines of 2012 and also on the premise that the scheme of the bioequivalence is akin to bio similar when it is infact not so. In this backdrop, it is to be really looked into as to whether it would

be befitting to altogether prevent the defendants to continue to manufacture and market the medicine involved in the present case and if not then to what extent the interim protection can be moulded so that pending the final decision on the validity of approval before this court (which the defendant No.2 already possesses) on the adherence of the guidelines, the interests of both the parties are not affected and simultaneously the public interest is equally upheld.

334. I am of the view that the approvals granted to CANMAb and Hertraz (used by Mylan) product are not on the basis of the adherence of the Guidelines of 2012 and rules framed under the Drug Act. The final finding in this respect is yet to be arrived after the present suit is heard upon completion of the trial. Pending the final outcome of the suit, there is a need to arrive at interim measure by working out certain terms between the parties by passing the following directions:

a) The defendants No.2 to 4 may continue to manufacture, market and advertise their product under the name CANMAb or Bmab-200 or Hertraz on the basis of the approvals already granted to defendant No.2 without calling their product as “bio similar” and/ or “bio similar to HERCEPTIN, HERCLON, BICELTIS” or in any way ascribing any bio-similarity with that of the plaintiffs products HERCEPTIN, HERCLON, BICELTIS in any press releases, public announcements, promotional or

other in printed form and from relying upon or referring the plaintiffs' names.

b) The defendants No.2 to 4 may also manufacture and market the drug by qualifying the INN name Trastuzumab but not to use the said name stand alone on the carton or package insert as a brand name. The defendants No.2 to 4 can use the INN name as Biocon's Trastuzumab or Mylan's Trastuzumab wherever applicable to describe the composition of molecule on the product as well as in its insert and not in a prominent manner. The said expression shall be used at the bottom part of the carton and should be in small size letters than their respective brand names.

c) In view of prima facie findings that the use of the data by the defendants No.2 to 4 in the product insert without undergoing the entire process of the trials is misleading, the defendants No.2 to 4 are also restrained from using the data relating to manufacturing process, safety, efficacy and tests conducted for the safety of the drugs as complained of by the plaintiffs till the time the final decision on the issue of the bio similarity is made in the present suit.

d) In the event, the defendant No.2 intends to claim bio similar as a description of its product or part of its promotional campaign or otherwise in any other form, the defendant No.2, if so advised, can re-apply the said license before the relevant authorities including defendant no. 1 and in which case, the defendant No.1, the authorities and committees framed therein shall decide the said approval application in accordance with the Rules and Guidelines of 2012 and also the observations made by this court in the present order. In the alternative, the defendant No.2 may await the outcome of the present suit and can continue with the present arrangement as an interim measure.

e) This interim measure is made only in view of the peculiar facts in the present case wherein the defendant No.2 is already in possession of approvals granted rightly or wrongly validity of which is questioned in this suit. All the decisions made by the defendant No.1 and authorities and committees made therein in connection with future approvals shall take into consideration the guidelines of 2012 and also the findings arrived at in the present order by this court.

335. The findings made herein above are all tentative in nature and shall have no bearing when the main suit would be decided after trial on merits.

336. Both the abovementioned applications are accordingly disposed of.

337. No costs,

CS(OS) No.355/2014

List on 2nd June, 2016 before the roster Bench.

(MANMOHAN SINGH)
JUDGE

APRIL 25, 2016/jk