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

% **Date of decision: 24th February, 2020**

\+ **CS(COMM) 1119/2016, IA No.10019/2016 (u/O XXXIX R-1&2 CPC), IA No.10020/2016 (u/O II R-2 CPC) & IA No.10021/2016 (u/S 80(2) CPC).**

ROCHE PRODUCTS (INDIA) PRIVATE LIMITED AND OTHERS ..... Plaintiffs

Through: Mr. Gopal Subramanium & Mr. Sandeep Sethi, Sr. Advs. with Mr. Darpan Wadhwa, Ms. Samiksha Godiyal, Mr. Abhishek Tewari, Mr. Tanmay Singh, Ms. Roshni Namboodiry, Mr. Talha Abdul Rehman & Mr. Pavan Bhushan, Advs.

Versus

CADILA HEALTHCARE LIMITED & ORS ..... Defendants

Through: Mr. P. Chidambaram, Sr. Adv. with Ms. Bitika Chattrapati, Mr. Kapil Midha & Ms. Neha Khanduri, Advs. for D-1.

Mr. Sanjay Jain, ASG with Mr. Rishi Kant Singh, Mr. Krishnanu Barua & Ms. Natasha Thakur, Advs. for D-2&3.

AND

\+ **CS(COMM) 540/2016, IA No.6087/2016(u/O.XXXIX R-1&2 CPC), IA No.2698/2017(u/O.VII R-11 CPC) & IA No.2699/2017(u/S. 151 CPC).**

F. HOFFMANN-LA ROCHE LTD & ORS .... Plaintiffs

Through: Mr. Darpan Wadhwa, Sr. Adv. with Mr. Vishal Gehrana, Ms. Deepti Sarin, Mr. Shravan Sahny, Ms. Sonali Jain & Mr. Sanjeet Ranjan, Advs.

Versus

DRUGS CONTROLLER GENERAL OF INDIA & ORS ... Defendants

Through: Mr. Amit Mahajan, CGSC with Mr. Apoorv Singhal, Adv. for UOI.
Mr. Ashish Prasad & Mr. Ashish Virmani, Advs. for D-3.

CORAM:
HON'BLE MR. JUSTICE RAJIV SAHAI ENDLAW

1. CS(COMM) No.1119/2016 has been instituted by the three plaintiffs, namely (a) Roche Products (India) Private Limited; (b) F. Hoffmann-La Roche, AG; and, (c) Genentech Inc., against (i) Cadila Healthcare Ltd. (Cadila); (ii) Drugs Controller General of India (DCGI); and, (iii) Department of Biotechnology (DoB), Ministry of Science & Technology, for

A. declaration:-

(i) that Cadila's drug has not been tested as, and is not, a biosimilar product under applicable law;

(ii) that the approvals dated 30th March, 2012 and 18th September, 2012 by the Review Committee on Genetic Manipulation (RCGM) of the preclinical protocol and preclinical test results respectively of Cadila's drug and Clinical Trials Registry – India (CTRI) registration bearing no.l CTRI/2014/05/004605 and the DCGI's approval dated 10th March, 2014 in relation to clinical trial protocol of Cadila's drug are invalid and are not in accordance with applicable law;

(iii) that the manufacturing authorization dated 28th October, 2015 granted by the DCGI to Cadila for Cadila's drug is invalid; and,

(iv) that the no objection dated 21st January, 2016 for Cadila's drug, for the additional indications i.e. HER2+metastatic gastric cancer and HER2+ early breast cancer, is invalid.

B. Permanent injunction to restrain:-

(i) Cadila from selling, marketing and / or distributing its drug in the Indian market as 'Trastuzumab' or otherwise, pursuant to the manufacturing authorization dated 28th October, 2015 granted by DCGI;

(ii) Cadila from selling, marketing and / or distributing its drug in the Indian market as 'Trastuzumab' or otherwise for the additional indications i.e. HER2+ early breast cancer and HER2+ metastatic gastric cancer pursuant to No Objection dated 21st January, 2016 granted by the DCGI;

(iii) Cadila from representing its drug as 'Trastuzumab';

(iv) Cadila from representing its drug as a biosimilar version of the plaintiffs' 'Trastuzumab' or of HERCEPTIN®, HERCLON™ or BICELTIS® or from claiming similarity and / or comparability with 'Trastuzumab' or with HERCEPTIN®, HERCLON™

or BICELTIS®, until biosimilarity between Cadila's drug and the plaintiffs' 'Trastuzumab' is established pursuant to appropriate tests under the Drugs and Cosmetics Act, 1940 (the Drugs Act), the Drugs and Cosmetics Rules, 1945 (the Drugs Rules) and the Guidelines on Similar Biologics, 2012 (the Biosimilar Guidelines);

(v) Cadila from relying upon or otherwise referring to the plaintiffs' trade marks HERCEPTIN®, HERCLON™ or BICELTIS® or any data relating to the plaintiffs' 'Trastuzumab' marketed as HERCEPTIN®, HERCLON™ or BICELTIS® including data relating to its manufacturing process, safety, efficacy and sales in any press releases, public announcements, package insert, promotional, sales, marketing or other material for its drug; and,

(vi) DCGI from issuing the final package insert approval in relation to Cadila's drug to Cadila.

2. CS(COMM) No.1119/2016 first came up before this Court on 19th August, 2016 when Cadila, being on caveat, appeared through counsel and the counsels were heard at length on the aspect of maintainability of the suit. It was *inter alia* the contention of the senior counsel for Cadila that the approval granted by the DCGI and DoB to Cadila's drug is appealable under Rule 122DC of the Drugs Rules, as under:-

> *"**122DC. Appeal** – Any person aggrieved by an order passed by the Licensing Authority under this Part, may within sixty days from the date of such order, appeal to the Central Government, and the Central Government may after such inquiry into the matter as is considered necessary, may pass such order in relation thereto as it thinks fit."*

It was however felt that the presence of the counsel for the DCGI and the DoB was necessary to adjudicate the aspect of the admissibility of the suit; hence the presence of the Additional Solicitor General (ASG) was sought.

3. On 29th August, 2016, the learned ASG was heard on the aspect of maintainability by the plaintiffs of the appeal under Rule 122DC of the Drugs Rules, against the approval granted by the DCGI and DoB to Cadila and it was enquired from the senior counsel for the plaintiffs, that once the law permits an approval as a new drug to be given to others on account of being biosimilar to the new drug of the plaintiffs, what cause of action on the ground of misrepresentation, passing off, copyright violation and dilution of goodwill, can the plaintiffs have if an approval is given by the Authorities constituted to grant such approval, save as to the validity of the approval. Hearing was adjourned to 26th September, 2016, for the counsel for the plaintiffs to address on the aspect of cause of action if any to the plaintiffs *de hors* the validity of the approval granted by DCGI and DoB to Cadila. Hearing was adjourned from time to time. The senior counsel for the plaintiffs were finally heard on 10th November, 2016 and orders reserved. The senior counsel for the plaintiffs, on that date handed over a note of arguments and liberty was granted to the

counsel for Cadila to also, if so desires, hand over a note of arguments. Written submissions have since been handed over by the counsel for Cadila. However this order remained on back burner for the reasons contained later in this order.

4. It is the plea of the plaintiffs in the plaint in CS(COMM) No.1119/2016, that (i) Genentech INC., in the year 1990, developed a biological drug containing the active ingredient 'Trastuzumab', a humanised monoclonal antibody which binds specifically to the human epidermal growth factor receptor 2 (HER2) protein and is designed to target and block HER2 protein overexpression, and in addition, also triggers an immune response in the body to destroy the particular cell it attaches to, thereby having a two-fold role in containing and curing certain forms of cancer; (ii) between 1992 and 1998, extensive global clinical trials (Phase I, Phase II and Phase III) were carried out by Genentech INC., to test the safety, efficacy and quality of 'Trastuzumab' for the indication, HER2+ metastatic breast cancer; (iii) 'Trastuzumab', after rigorous tests to confirm its safety, efficacy and quality, received manufacturing and marketing approvals worldwide; (iv) the said drug has been sold by the plaintiffs worldwide since 1998 under the trade mark HERCEPTIN® for the treatment of HER2+ metastatic breast cancer and subsequently also for the treatment of HER2+ early breast cancer and HER2+ metastatic gastric cancer; (v) in India, 'Trastuzumab' has been marketed under the brand name HERCEPTIN®, for more than 12 years, as targeted therapy for the treatment of the two additional types of cancer aforesaid; the plaintiffs also import and market the said drug in India under the brand name HERCLON^{TM} and the said drug is also distributed

by one of the plaintiffs under the brand name BICELTIS®; (vi) the import and marketing of the drug in India began after approvals dated 11th October, 2002, 7th August, 2006 and 13th April, 2010 under Rule 122A of the Drugs Rules by the DCGI; (vii) DCGI and DoB, on 15th September, 2012 framed the Biosimilar Guidelines to provide a legal framework for the evaluation and approval of biosimilar drugs in India and to introduce a regime for comparative testing between a purported biosimilar drug and an innovator biological drug; (viii) biological drugs are synthesized by cells of living organisms as opposed to chemical drugs which are produced by chemical synthesis; biosimilars are not generic or bioequivalent drugs and cannot be a generic equivalent of the innovator biological drug owing to the structural and manufacturing complexities involved in the production of biopharmaceuticals; (ix) testing and approval of biosimilar drugs in India is regulated under (a) the Drugs Act, the Drugs Rules and the Biosimilar Guidelines; (b) Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms / Genetically Engineered Organisms or Cells, 1989, notified under the Environment (Protection) Act, 1986; (c) Recombinant DNA Safety Guidelines, 1990; (d) Guidelines for Generating Preclinical and Clinical Data for r-DNA Vaccines, Diagnostics and Other Biologicals, 1999; (e) Central Drugs Standard Control Organisation Guidance for Industry, 2008; and, (f) Guidelines and Handbook for Institutional Biosafety Committees, 2011; (x) Cadila's drug, sought to be marketed in India as a purported biosimilar version of 'Trastuzumab' of the plaintiffs, is a recombinant DNA (r-DNA) drug and which is a 'new drug' under Rule 122E of the Drugs Rules and import and / or

manufacture of 'new drugs' for clinical trials or marketing is regulated under Part XA read with Schedule Y of the Drugs Rules; (xi) the Biosimilar Guidelines provide a detailed and structured process for comparison of the similar biologic with the reference biologic to ensure that the similar biologic is comparable in quality to the reference biologic and can be safely used in the treatment of specified diseases or disorders; (xii) Cadila has filed a suit before the High Court of Bombay seeking to restrain the plaintiffs from interfering with and / or preventing Cadila from launching and marketing its drug; however no interim injunction has been granted to Cadila in the said suit; (xiii) that the plaintiffs have learnt that Cadila, on 30th March, 2012 received permission from RCGM to conduct preclinical toxicity studies on Wistar rats and New Zealand rabbits and results of which preclinical toxicity studies were approved by RCGM on 18th September, 2012, even though Cadila failed to conduct preclinical pharmacology studies in relation to its drug and arbitrarily chose to conduct preclinical studies on Wistar rats and New Zealand rabbits, even though preclinical trials for 'Trastuzumab' were conducted by the plaintiffs on pregnant monkeys with no scientific justification provided therefor and there were other deficiencies / lacunas and owing whereto Cadila's drug is not in compliance with the Drugs Act, Drugs Rules and Biosimilar Guidelines and Cadila has not conducted studies to establish biosimilarity between Cadila's drug and the plaintiffs' 'Trastuzumab'; (xiv) notwithstanding the aforesaid, DCGI has granted manufacturing authorization to Cadila's drug; (xv) though the plaintiffs, in order to obtain information under the Right to Information Act, 2005 made a representation to DCGI, but no adequate response thereto has been

received; (xvi) Cadila's drug purportedly developed for treatment of the same forms of cancer as the plaintiffs' 'Trastuzumab', competes directly with plaintiffs' 'Trastuzumab' and the plaintiffs' apprehend that owing to the lacunas / deficiencies aforesaid in testing the biosimilarity of Cadila's drug with the plaintiffs' 'Trastuzumab', Cadila's drug will not have the same efficacy and result, and thereby dilute the goodwill and copyright of the plaintiffs and their drug 'Trastuzumab; and the same will also amount to passing off and misappropriation by Cadila of the plaintiffs' 'Trastuzumab'; and, (xvii) Cadila, without undertaking the preclinical studies on the relevant animal species and without undertaking the necessary clinical trials will use the data relating to the plaintiffs' 'Trastuzumab' in the package insert for its drug amounting to violation of the rights of the plaintiffs with respect thereto.

5. Though the plaint is replete with details of dissimilarity between the drug of the plaintiffs and the drug of Cadila and the deficiencies / lacunae in terms of the Drugs Act, the Drugs Rules and the Biosimilar Guidelines in grant of approval by the DCGI and DoB to Cadila's drug but on the aspect of considering the maintainability of the suit, there is no need to go into the said details in this judgment.

6. On going through the contents of the plaint, two questions arose in my mind as to the maintainability thereof. Firstly, that once Cadila is entitled under the law to manufacture and market a drug biosimilar to that of the plaintiffs, after obtaining the requisite approvals from the DCGI and DoB and once Cadila had obtained such approvals, whether this Court, in a Civil Suit, could sit in appeal over those approvals so obtained

by Cadila. Secondly, whether the proceedings in the present suit were liable to be stayed under Section 10 of the Code of Civil Procedure, 1908 (CPC) owing to the suit previously instituted by Cadila against the plaintiffs and pending in the Bombay Courts.

7. The senior counsel for Cadila, appearing on caveat on 19th August, 2016, informed and contended that, (i) Cadila's drug had obtained the first marketing authorization on 28th October, 2015 and packaging insert approval on 22nd December, 2015 and had on 25th December, 2015 launched the drug; (ii) marketing authorization was subsequently also obtained on 21st January, 2016 and subsequent packaging insert approval obtained on 3rd March, 2016; (iii) the plaintiffs in the present suit have not sought any interim relief with respect to the marketing authorization already obtained by Cadila; (iv) Cadila has already effected sales worth Rs.17 crores; (v) the suit of the plaintiffs does not qualify as a 'commercial suit' and has been wrongly labeled as such; (vi) Rule 122DC of the Drugs Rules provides for a remedy of appeal against the approvals granted by DCGI and DoB to Cadila; and, (vii) attention was invited to Guidelines 8.4 and 13 (n), (o) and (p) of the Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorisation in India, 2016 filed by the plaintiffs themselves at page 16 of the Part-III Vol-I file, to contend that approvals obtained by Cadila's drug could not have been granted without assessment of safety and the definitions of 'Reference Biologic', 'Similar' and 'Similar Biologic' in the said Guidelines.

8. Per contra, the senior counsel for the plaintiffs, on 19th August, 2016 drew attention to pages 1099 to 1104 of Part-III, Vol-IV file, being

paras 75 to 78 and 84 to 86 of the judgment dated 25th April, 2016 of this Court in CS(OS) No.355/2014 titled ***Roche Products (India) Pvt Ltd. Vs. Drugs Controller General of India*** (later reported as 2016 SCC OnLine Del 2358) to contend that (i) Rule 122DC supra does not cover appeals against approvals granted under Part XA of the Drugs Rules and is limited only to appeals against orders passed by DCGI under Part XA of the Drugs Rules; (ii) thereunder also the remedy of appeal would be available only to a person who is before the DCGI in the first instance; (iii) the said Rules do not protect or enforce the right of the innovator drugs; (iv) the summary procedure of an appeal does not allow complicated questions of fact, on the basis of evidence, to be decided; and, (v) thus the Civil Court has jurisdiction. The senior counsel for the plaintiffs also drew attention to pages 611 and 618 of the Part-III, Vol-III file, to contend that the approvals are pre-trial approvals and the trial was initiated to be completed and is still in phase-III stage.

9. The learned ASG, on enquiry whether the remedy of appeal under Rule 122DC supra is available to the plaintiffs against the grant of approvals by DCGI to Cadila, answered in the affirmative and on specific query whether the appeal, if preferred by the plaintiffs would be entertained or dismissed as not maintainable, after obtaining instructions answered that the appeal would be entertained. On further query whether the limitation of 60 days from the date of the order to prefer an appeal against the order of the DCGI, provided for in Rule 122DC would come in the way of the plaintiffs, the learned ASG stated that the time limit is not sacrosanct and though there is no provision in the Rules empowering for condonation of delay in preferring appeal but since there is no

prohibition also, the Central Government as the Appellate Authority is empowered to extend the time.

10. The following other submissions were made by the counsels on the aspect of maintainability of the suit:-

A. By learned ASG:-

(i) that the drug of Cadila has been held by the DCGI and the DoB to be biosimilar to the drug of the plaintiffs under Rule 122B of the Drugs Rules;

(ii) that a biosimilar drug is a 'new drug' within the meaning of Rule 122E of the Drugs Rules; attention in this regard is invited to explanation (i) to the said Rule;

(iii) that a permission / approval is also an 'order' within the meaning of Rule 122DC and is appealable under the same;

(iv) that Cadila, for the subject drug has approval under Rule 122B(1)(a) of the Drugs Rules;

(v) that Rule 122DC provides for appeal against an 'order' of the DGCI irrespective of whether the order is administrative or *quasi* judicial;

(vi) per Rule 21, a licence is an order;

(vii) that for grant of approval for manufacturing a new drug under Rule 122B, the Licencing Authority has to record its satisfaction;

(viii) that there can be no other meaning of 'order' within the meaning of Rule 122DC, except of grant or refusal of licence / permission sought and the remedy of appeal is available to a third party also;

(ix) a grant or refusal of licence is an 'order'; attention in this regard is invited to Rules 62B(3) and 122M which provide for appeal by any person aggrieved by an order of the DCGI granting or refusing a licence;

(x) Rule 122DC was introduced along with Rule 122DB and both use the word 'order';

(xi) subsequent thereto, Rules 122DAB(3) & (7) were introduced which also use the word 'order';

(xii) the word 'order' is also used in Rule 122DAC(3), which was also introduced subsequently;

(xiii) it matters not whether only approval or license is issued or formal order is issued inasmuch as grant of approval/license is after recording satisfaction and would constitute an 'order';

(xiv) merely because the decision is in the form of a grant of license, and not an 'order' as understood in the courts would not negate the appealability thereof; and,

(xv) attention was drawn to Form 45 and Form 45A to contend that merely because the form of the order is prescribed does not mean that it ceases to be an order.

B. By Mr. Darpan Wadhwa, Advocate for the plaintiffs:-

(i) Part XA of the Drugs Rules had no provision for appeal till December, 2001 when Rules 122DB and DC were added; and,

(ii) that the said Rules have to be read in the context of the other Rules in Part XA and the words 'any person aggrieved' in Rule 122DC can only mean the applicant to the DCGI as others / third parties do not even come to know of the grant or refusal of licence.

(learned ASG responded that approvals by the DCGI are immediately put on the website of the DCGI and come out in the public domain; even otherwise as soon as a new drug surfaces in the market, the public knows of it and it is not as if the launch / marketing of a new drug is hidden from anyone)

(iii) that no hearing is given to third parties before grant or refusal of licence;

(learned ASG referred to ***P.H. Paul Manoj Pandian Vs. Mr. P. Veldurai*** (2011) 5 SCC 214 to contend that the way the Central Government understands Rule 122DC is that there is an appellate provision)

(iv) if permission/approval is refused, there is no appeal under Rule 122DC;

(learned ASG controverted and said it is maintainable)

(v) that the acts of Cadila in any case amount to misrepresentation, passing off, copyright infringement and dilution of goodwill of the plaintiffs and their drug and the suit is maintainable on the said grounds;

(vi) that Cadila is using the proprietary information of the plaintiffs pertaining to the Phase-I and Phase-II trials conducted by the plaintiffs and which have admittedly not been carried out by Cadila; and,

(vii) Cadila cannot tell the public that tests conducted by the plaintiffs are the tests conducted by Cadila as is being done by Cadila.

C. By Mr. Kapil Sibal, Sr. Advocate for the plaintiffs:-

that there is no procedure for the DCGI or the DoB to issue Public Notice of the applications for licence or to give opportunity to third parties to intervene at that stage and once that is so, the remedy of appeal cannot be available to third parties.

D. By Mr. Gopal Subramanium, Sr. Advocate for the plaintiffs:-

(i) the appellate remedy is only for the applicant and not for the innovator;

(ii) innovator can only come to the Civil Court;

(iii) the question for adjudication is whether the drug of Cadila is biosimilar to the drug of the plaintiffs;

(iv) the package insert of the drug of Cadila says that the drug of Cadila is biosimilar to the drug of the plaintiffs;

(v) that the innovator can also initiate *quia timet* action;

(vi) role of Appellate Authority under Rule 122DC is only limited to correct an act of omission and commission of the DCGI;

(vii) that though the patent of the drug of the plaintiffs has expired but Cadila cannot still use the data;

(viii) the right to claim a drug to be biosimilar to the drug of another does not include a right to ride on the reputation and goodwill of the other;

(ix) in a proceeding for claiming a drug to be a biosimilar drug, innovator is a stranger and is not in the picture;

(x) that it is the case of the plaintiffs that there are statutory non-compliances by the DCGI and the DoB and other authorities in grant of permissions to Cadila and such statutory non-compliances are subject to the jurisdiction of the Civil Court; and,

(xi) that intellectual property rights include data rights and the plaintiffs, having rights in the data pertaining to trials conducted by the plaintiffs, are entitled to come to the Civil Court to seek restrain on unfair use thereon by Cadila.

11. The senior counsel for the plaintiffs in his written submissions has referred to:-

(i) ***Ganga Bai Vs. Vijay Kumar*** (1974) 2 SCC 393 – holding that there is a distinction between right of suit and the right of appeal and a right of appeal inheres in no one and an appeal for its maintainability must have clear authority of law;

(ii) ***Secretary of State Vs. Mask and Co.*** AIR 1940 PC 105, ***Dhulabhai Vs. State of MP*** AIR 1969 SC 78, ***Mohammad Din Vs. Iman Din*** 1947 SCC OnLine PC 48, ***State of Kerala Vs. Ramaswami Iyer and Sons*** AIR 1966 SC 1738, ***Ganga Ram Hospital Trust Vs. Municipal Corporation of Delhi*** 2001 SCC OnLine Del 622 (DB), ***Firm Seth Radha Kishan Vs. Administrator Municipal Committee, Ludhiana*** AIR 1963 SC 1547, ***K.S. Venkataraman and Co. Vs. State of Madras*** AIR 1966 SC 1089 – to contend that Civil Court's jurisdiction is not barred if the statutory authority does not act in compliance with the statute or fundamental principles of judicial procedure;

(iii) ***Dhulabhai*** supra to contend that ouster of Civil Courts jurisdiction should not be readily inferred and that while considering the existence of an implied bar, it is necessary to examine the remedies provided under a statute and the scheme of such statute to determine if such remedy would be available to the plaintiff.

(iv) ***Premier Automobiles Ltd. Vs. Kamlekar Shantaram Wadke*** (1976) 1 SCC 496 – to contend that where the suit is to enforce a right under the general law or common law and not merely a right created under a statute, there is no implied bar to jurisdiction, ***Md. Sharfuddin Vs. R.P. Singh*** AIR 1961 SC 1312 and ***State of Maharashtra Vs. Iqbal Mohammed Memon*** 1998 SCC OnLine Bom 482 (DB).

(v) ***Northern Plastics Ltd. Vs. Hindustan Photo Films Mfg. Co. Ltd.*** (1997) 4 SCC 452 on the meaning of 'person aggrieved'.

(vi) ***Dhannalal Vs. Kalawati Bai*** (2002) 6 SCC 16 – to contend that there can be no bifurcation of causes of action.

(vii) ***N.R. Dongre Vs. Whirlpool Corporation*** (1996) 5 SCC 714, ***Bayer Corporation Vs. Union of India*** 2010 SCC OnLine Del 541 (DB), ***K.G. Khosla Compressors Limited Vs. Khosla Extrakting Limited*** 1985 SCC OnLine Del 232 and ***K. Ramdas Shenoy Vs. Chief Officers, Town Municipal Council, Udipi*** (1974) 2 SCC 506 – to contend that passing off action is maintainable.

(viii) ***Erven Warnik Besloten Vs. Townend and Sons*** [1979] A.C. 731, ***B.K. Engineering Co. Vs. UBHI Enterprises*** 1984 SCC OnLine Del 288 (DB), ***Ellora Industries Vs. Banarsi Das Goela*** 1979 SCC OnLine Del 198, ***The Scotch Whiskey Association Vs. Pravara Sahakar Shakar Karkhana Ltd.*** AIR 1992 Bom 294 – on extended passing off action.

(ix) ***T.V. Venugopal Vs. Ushodaya Enterprises Limited*** (2011) 4 SCC 85 – to contend that Cadila is seeking to market its drug 'Vivitra' as 'Trastuzumab' of the plaintiffs.

12. The counsel for Cadila has handed over a compilation of following judgments:-

(i) ***NDMC Vs. Satish Chand*** (2003) 10 SCC 38;

(ii) ***Jasbhai Motibhai Desai Vs. Roshan Kumar, Haji Bashir Ahmed*** (1976) 1 SCC 671;

(iii) ***Rukhmabai Vs. Lala Laxminarayan*** AIR 1960 SC 335;

(iv) ***The State of Uttar Pradesh Vs. Janki Saran Kailash Chandra*** (1973) 2 SCC 96;

(v) ***Rajasthan State Road Transport Corporation Vs. Bal Mukund Bairwa*** (2009) 4 SCC 299;

(vi) ***Ravi Yashwant Bhoir Vs. District Collector, Raigad*** (2012) 4 SCC 407;

(vii) ***State of Assam Vs. Barak Upatyaka D.U. Karamchari Sanstha*** (2009) 5 SCC 694;

(viii) ***National Institute of Mental Health and Neuro Sciences Vs. C. Parameshwara*** (2005) 2 SCC 256;

(ix) ***Prism Entertainment Pvt. Ltd. Vs. Prasad Productions Pvt. Ltd.*** 2006 SCC OnLine Cal 228;

(x) ***Jai Hind Iron Mart Vs. Tulsiram Bhagwandas*** 1952 SCC OnLine Bom 66 (DB);

(xi) ***Dropati Devi Vs. Jaswant Singh*** 2008 SCC OnLine Del 1083;

(xii) ***T. Arivandandam Vs. T.V. Satyapal*** (1977) 4 SCC 467; and,

(xiii) ***Bright Enterprises Private Limited Vs. MJ Bizcraft LLP*** 2016 SCC Online Del 4421 (DB).

13. CS(COMM) 540/2016 was instituted by the same three plaintiffs against (i) DCGI; (ii) DoB; and, (iii) Hetero Drugs Limited (HDL), for

A. declaration:-

(i) that HDL's drug, a purported bio-similar version of the plaintiffs' '*bevacizumab'* drug had not been tested as a bio-similar product under the applicable laws;

(ii) that HDL's CTRI registration No. CTR/2015/05/005757 dated 8th May, 2015, last modified on 4th August, 2015, is invalid and not in accordance with applicable laws;

(iii) that the approval granted on 28th April, 2015 by DCGI to HDL's Clinical Trial Protocol for HDL's drug is invalid and not in accordance with applicable laws;

(iv) that marketing authorization if any, granted by DCGI to HDL's drug is invalid;

B. permanent injunction to restrain:-

(i) HDL from launching, introducing, selling, marketing and/or distributing a bio-similar version of plaintiffs' '*bevacizumab';*

(ii) HDL from representing HDL's drug to be bio-similar to the plaintiffs' '*bevacizumab'*;

(iii) HDL from marketing and/or manufacturing its drug;

(iv) HDL from relying upon data pertaining to plaintiffs' '*bevacizumab'*

(v) HDL from using the name '*bevacizumab'*.

14. CS(COMM) No.540/2016 first came up before this Court on 16th May, 2016 and was adjourned to 24th May, 2016 and 2nd June, 2016. On 2nd June, 2016, the counsels for the defendants, appearing on caveat, took the plea that the suit was not maintainable because of the right of appeal under Rule 122DC of the Drugs Rules. The said suit was also adjourned from time to time for hearing on the said aspect concerning the maintainability of the suit. Ultimately, vide order dated 9th January, 2017, leaving the said question open, summons of the suit were ordered to be issued. Thereafter, HDL filed an application under Order VII Rule 11 of the CPC for rejection of the plaint.

15. At that stage, on 7th December, 2017, CS(COMM) 540/2016 also came up before the undersigned when the counsels stated that part of the controversy for consideration was the same as in CS(COMM) 1119/2016 in which orders had been reserved on 10th November, 2016. Thereafter CS(COMM) 540/2016 was adjourned from time to time to await the orders reserved in CS(COMM) 1119/2016 and during which hearings it was informed that appeals before the Division Bench against the judgment dated 25th April, 2016 in CS(OS) 355/2014 filed by the plaintiffs herein against Biocon Ltd. (Biocon), Mylan Inc. and Mylan Pharmaceuticals Ltd. (Mylan) were pending consideration. In the said judgment, a Co-ordinate Bench of this Court, with respect to maintainability of that suit entailing the same controversy as in CS(COMM) No.540/2016 and CS(COMM) No.1119/2016 i.e. *viz-a-viz* Rule 122DC of the Drugs Rules, had held as under:-

> *"85. 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.

86. 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.

87. 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).''

16. It was felt that a Co-ordinate Bench having held Rule 122DC to be not a bar to the maintainability of a civil suit, though without considering the use therein of the expression "Any person aggrieved" which in ***Municipal Corporation for Greater Bombay Vs. Lala Pancham of Bombay*** AIR 1965 SC 1008, ***Adi Pherozshah Gandhi Vs. H.M. Seervai, Advcoate-General of Maharashtra, Bombay*** (1970) 2 SCC 484, ***Paam Pharmaceutical (Delhi) Limited Vs. Union of India*** 2000 SCC OnLine Del 620 (DB), ***Vinod Kumar Bhalotia Vs. State of U.P.*** 1999 SCC OnLine All 1251 (DB), ***Md. Sharifuddin Vs. R.P. Singh*** 1956 SCC OnLine Pat 94 (DB) and ***B.K. Ramachandra Rao Vs. Kamapalappa*** 1962 SCC OnLine Kar 105 (DB) had been held to have a wide connotation, and the matter was pending before the Division Bench including on the said aspect, the judgment of the Division Bench may be awaited.

17. It was also informed that the same plaintiffs as in these two suits, besides the earlier suit against Biocon and Mylan, had also filed yet another suit being CS(OS) No.3284/2015 against Reliance Life Sciences Pvt. Ltd. (Reliance) and wherein also the same issue i.e. of maintainability of the suit *viz-a-viz* Rule 122DC of the Drugs Rules was raised and vide judgment dated 25th April, 2016 (reported as ***Genentech Inc. Vs. Drugs Controller General of India*** 2016 SCC OnLine Del 2572) the contention with respect to Rule 122DC had been dealt with as in the judgment in the suit against Biocon and Mylan.

18. It was yet further informed that vide the said judgment**s** dated 25th April, 2016 in the suits against Biocon/Mylan and Reliance, certain conditions had been imposed on Biocon/Mylan and Reliance for the manufacture, marketing and advertisement of their respective drugs, pending a final decision in the suits, and the Division Bench, in the appeals aforesaid had stayed the said conditions imposed on Biocon/Mylan and Reliance and position prevailing immediately prior to 25th April, 2016 had been ordered to be continued. It was yet further informed that vide *ad interim* order dated 3rd March, 2017 of the Division Bench in the appeal preferred by Biocon and Mylan, the conditions imposed on Biocon/Mylan vide orders of prior to the judgment dated 25th April, 2016, were also vacated and against which order the plaintiffs herein and therein had preferred SLP(C) No.015532-015537/2017 but which were withdrawn on 11th August, 2017. It was yet further informed that the Division Bench, vide *ad interim* order dated 18th September, 2019 in the appeal preferred by Reliance had also set aside the conditions imposed on Reliance and against which SLP(C) No.24727/2019 had been preferred by the plaintiffs herein and therein and in which notice had been issued and the order of the Division Bench vacating the conditions imposed by the Single Judge on Reliance had been vacated.

19. On 27th January, 2020, the counsel for the plaintiffs mentioned these two suits for listing owing to subsequent developments in the matter and the suits were accordingly listed on 31st January, 2020.

20. On 31st January, 2020, it was informed that the Supreme Court vide judgment dated 17th December, 2019 in SLP(C) No.24727/2019 had set aside the *ad interim* order of the Division Bench in the appeal preferred by Reliance vacating the conditions imposed on Reliance vide judgment dated 25th April, 2016, and had restored the order dated 25th April, 2016.

21. A perusal of the judgment dated 17th December, 2019 of the Supreme Court however did not show the Supreme Court to have dealt with the aspect of maintainability of the suits in the light of Rule 122DC of the Drugs Rules and the Supreme Court in the said judgment, was only concerned with the orders of the Division Bench of this Court vacating the conditions imposed on Reliance by the Single Judge vide judgment dated 25th April, 2016, and which have been ordered to continue.

22. Being of the view that the Co-ordinate Bench in the judgments dated 25th April, 2016 in the suits against Biocon/Mylan and Reliance, though had dealt with Rule 122DC but not in its entire perspective and that the Supreme Court also in the judgment dated 17th December, 2019 had not touched upon the said aspect, after 31st January, 2020, I started working on the judgment scheduled for pronouncement on 24th February, 2020. However, while working on the said judgment, orders, both dated 11th February, 2020, of the Division Bench of this Court in the appeal arising out of the Reliance suit and the appeal arising out of the Biocon/Mylan suit came to the notice of the undersigned. Vide order dated 11th February, 2020 concerning the

appeals by the plaintiffs herein arising out of the suit filed against Reliance, the Division Bench, in view of paragraph 28 of the judgment dated 17th December, 2019 of the Supreme Court in SLP(C) No.24727/2019 as under:

> *"3. Para 28 of the order dated 17th December, 2019 of the Supreme Court reads as under:*
>
> > *"28. In view of the aforesaid, the impugned order is set aside and appeal is allowed. The interim direction given by the learned Single Judge on 25.4.2016 is accordingly made operational. At the same time, as the Reliance's suit is pending since 2016, the High Court is requested to dispose of the CS (OS) No. 3284/2015 expeditiously and preferably within 12 months of receipt of this order, In the meantime, to avoid prejudice to respondent No. 3, whenever government procurement is proposed for the drug by its generic name 'Trastuzumab', the Reliance should be allowed to participate with their biosimilar product, without any impediment. It is made clear that the views expressed here is only for the purpose of this appeal and should have no bearing in the proceeding pending in the High Court.""*

held as under:-

"*4. Having considered the submissions of Mr. Sethi, and having read the aforesaid order dated 17th December, 2019 of the Supreme Court as a whole, the Court is not persuaded that the Supreme Court did not uphold the order dated 25th April, 2016 of the learned Single Judge in its entirety. The Court notes that the Supreme Court specifically directed that the said order "is accordingly made operational" and also requested that the suit itself to be disposed of "expeditiously and preferably within 12 months of the receipt of this order." If the issue regarding the deletion of the DGCI as a*

party defendant were to be left open to be adjudicated upon by this Court i.e. the Division Bench, it would inevitably result in further delaying the disposal of the suit itself. Clearly, that result was not envisaged by the directions of the Supreme Court reproduced hereinabove.

5. For the aforementioned reasons, the Court is unable to agree with Mr. Sethi that any aspect of the interim order dated 25th April, 2016 of the learned Single Judge in CS (OS) 3284/2016 remains to be adjudicated upon by this Court.

6. Consequently, FAO (OS) 227/2016 is also disposed of as having been rendered infructuous as a result of the order dated 17th December, 2019 of the Supreme Court in C.A. No. 9491/2019. The pending applications are also disposed of."

23. However vide order dated 11th February, 2020 of the Division Bench in the appeal filed by Biocon against the judgment dated 25th April, 2016 of the Single Judge, the appeal was adjourned for hearing to 16th July, 2020 observing as under:-

"3. The issue whether the suit was maintainable has been raised as a ground in the appeal itself. The Court therefore does not see any reason to separately entertain an application for considering the said issue. Accordingly, the application is disposed of."

24. In the light of order dated 11th February, 2020 of the Division Bench in the appeal filed by the plaintiffs herein against the order dated 25th April, 2016 in the suit filed against Reliance, holding that the Supreme Court vide judgment dated 17th December, 2019 had upheld the order dated 25th April, 2016, also dealing with Rule 122DC, in entirety, it was felt that after the said order it is not open to

the undersigned to foray into the said aspect. The counsels were accordingly informed and asked to appear on 20th February, 2020.

25. On 20th February, 2020, while it was the contention of the senior counsels for the plaintiffs that had the Supreme Court felt the suit to be not maintainable in view of Rule 122DC, it would not have, vide judgment dated 17th December, 2019, vacated the order of the Division Bench staying the conditions imposed on Reliance vide judgment dated 25th April, 2016, it was the contention of the senior counsel for the defendants that in light of the order dated 11th February, 2020 in the appeal preferred by Biocon, the question is still very much open before the Division Bench.

26. However the need for the undersigned to adjudicate the said rival contentions also is not felt because the senior counsel for the plaintiffs has also handed over in the Court a notification dated 19th March, 2019 of the Ministry of Health and Family Welfare (Department of Health and Family Welfare) notifying the New Drugs and Clinical Trial Rules, 2019 (the New Rules). The senior counsel for the plaintiffs contended that in the New Rules, there is no equivalent of Rule 122DC supra.

27. On enquiry, whether any provision has been made qua pending appeals, the senior counsel for the plaintiffs states that there is no such provision and there were no pending appeals.

28. The senior counsel for the defendants have not controverted.

29. I have perused the New Rules. Rule 97 thereof inserts the following Rule after Rule 122DA of the Drugs Rules.

> *"**122DAA. Non-application of certain rules for new drugs and investigational new drugs for human use. -** Part XA and Schedule Y shall not be application in respect of new drugs and investigational new drugs for human use from the date of coming into force of the New Drugs and Clinical Trials Rules, 2019, and the references in respect of human use made in the these rules shall respectively be omitted, and the construction thereof shall be construed accordingly and shall stand amended with all cogent meaning of the grammar."*

30. I also find the New Rules to be, though, in Rules 53 and 60 thereof in Chapter VIII titled "Manufacture of New Drugs or Investigational New Drugs for Clinical Trial, Bioavailability or Bioequivalence Study or for Examination, Test and Analysis" and in Rule 68 thereof under Chapter IX titled "Import of New Drugs and Investigational New Drugs for Clinical Trial or Bioavailability or Bioequivalence Study or for Examination, Test and Analysis", providing for a remedy of appeal against the decision of the DCGI to the Central Government as under Rule 122DC supra but, as distinct from the expression "any person aggrieved' used in Rule 122DC supra, using the expression "an applicant who is aggrieved by the decision of the Central Licencing Authority". It is thus clear that under the New Rules the remedy of appeal is confined to the applicant before the DCGI and is not available to others such as the plaintiffs herein.

31. With the deletion of the provision of appeal, on account whereof the maintainability of the suit was challenged, the said challenge has become infructuous.

32. Resultantly, the suits have to proceed.

33. I clarify that I have in this order/judgment not dealt with the aspect of stay of proceedings in CS(COMM) No.1119/2016 owing to the suit previously instituted by Cadila against the plaintiffs and pending in the Bombay courts and on which aspect arguments were not heard during the hearings aforesaid.

34. Pleadings in the two suits, if not completed, be completed with written statement/reply being filed within 30 days and replication/rejoinder thereto within further 30 days thereafter.

35. List for framing of issues, if any and for hearing of other pending applications, on 12th May, 2020.

RAJIV SAHAI ENDLAW, J.

FEBRUARY 24, 2020
'pp/AK'..