



25.09.2014

**SUBMISSIONS BY CUTS UNDER SUB-SECTION (3) OF SECTION 29 OF THE
COMPETITION ACT, 2002 REGARDING THE PROPOSED MERGER
BETWEEN SUN PHARMA AND RANBAXY**

I. Background

- 1.1 This is in response to the notice¹ (dated 04/09/2014), published by the Competition Commission of India (Commission) inviting comments/objections/suggestions, from any person(s) adversely affected or likely to be affected by the combination. Consumer Unity and Trust Society (CUTS), pursuant to its pro forma notice (dated 02/08/2014 sent via email to the Secretary, Commission and copied to Chairman, Commission), as an informed stakeholder intends to raise certain points which the Commission might consider while assessing the proposed combination between Sun Pharma and Ranbaxy (Combination Registration No.C-2014/05/170) in the interest of the public, patients and healthy competition in the pharmaceutical industry.
- 1.2 It is well noted by CUTS that the Commission, on a prima facie opinion that the combination is likely to have an appreciable adverse effect on competition, directed the parties under section 29(2) of the Competition Act, 2002 (Act), to publish details of the combination within ten working days for bringing the combination to the knowledge or information of the public and persons affected or likely to be affected by such combination. The parties were asked to publish the details of the merger combination and also to host the same on their respective websites. CUTS has also reviewed the details submitted by the parties under Form IV as required by the Commission under the Act.
- 1.3 These submissions are based upon the information available under the public domain and Form IV submitted by the parties. Our altruistic objective is to aid and assist the Commission in assessing the said merger in view of larger public interest, promote

¹ Available at <http://cci.gov.in/May2011/PressRelease/C-2014-05-170-Press-Release.pdf><http://cci.gov.in/May2011/Home/C-2014-05-170-Form-IV.pdf>; (last visited on 2014.09.11)

healthy competition in the pharmaceutical sector and to boost the economy of the country.

- 1.4 World over, competition authorities take into consideration the merging parties, size, business and their market shares while assessing mergers from the competition perspective. As per details submitted by the parties, the first party i.e. Sun Pharma, is an internationally established pharmaceutical company with a total of 26 manufacturing facilities worldwide. It has manufacturing facilities in India, US, Canada, Brazil, Mexico, Hungary, Israel and Bangladesh. In India, the key therapy areas of Sun Pharma are CNS, Cardiology, Orthopaedics, Ophthalmology, Gastroenterology, Nephrology, with focus on complex, difficult to manufacture generic products and chronic therapies. Ranbaxy is the second party which is also a pharmaceutical company producing affordable generic medicines. Ranbaxy's key therapies in India include anti-infectives, cardiovascular, pain management, respiratory, dermatology, orthopaedics, nutritionals and urology. Ranbaxy has begun investing in Biotech and Vaccines as well.

II. Relevant Market

- 2.1 The parties have indicated a combined presence in: (i) 18 Therapeutic Areas; (ii) 127 Therapeutic Groups; and (iii) 246 Molecules. As per para 20 of Form IV, the parties have identified overlap in 37 molecules out of 246 molecules, where the combined market share post-merger would be greater than 15 percent. Of the 37 overlapping molecules, there are two molecules i.e., ATORVASTATIN and LOSARTAN which are under National List of Essential Medicines (NLEM). In order to understand impact of competition, it is a prerequisite to correctly define the relevant market². Two markets are involved in the present matter, viz; the molecular market³ and the medicine/drug market⁴. The same are discussed as under:

2.1.1 Market Share in molecular market

- Sun Pharmacy and Ranbaxy manufacture medicines by synthesising the molecules or combination of molecules as inputs. One of the key concerns with regards to the said merger are the 37 molecules cited as overlapping products by the parties (as per the

² A relevant market is a market in which a particular product or service is sold.

³ Molecules formulated by the pharmaceutical entities through research and development that are used to manufacture drugs come under the molecular market.

⁴ The medicine/drug marketed, developed, or produced by pharmaceutical entities come under drug market.

details given on pages 6-9 of the Form IV disclosure). Investigation must to be conducted by the Commission into the market share of the combined entity in the molecule market. For instance, the market shares of molecule ROSUVASTATIN+EZETIMIBE and LEUPRORELIN are 91.7 percent and 85.8 percent respectively, which seems quite substantial to affect the molecular market. The combined entity in the market for molecules (being the input to make drugs) might have dominant position, and incentive to abuse the same, without any checks.

2.1.2 *Market share in the drug market*

In addition to the development of molecules, the combined entity will also develop and sell drugs in the market. Consequently, the overlapping products have to be analysed to understand the implications of this merger in the pharmaceutical industry. For analysing this merger, output market (drugs market) has to be studied. To elaborate further on the drugs market, cited below are examples of a few products:

- Use of the STATINS drug can treat hypercholesterolemia but it might not control LDL-C level. As per reports, a synergistic effect can be obtained by concomitant administration of the cholesterol absorption inhibitor EZETIMIBE and STATINS. However, in patients with Type 2 diabetes who are already being treated with STATINS, it remains unclear whether it is more effective to add EZETIMIBE or to increase the STATINS dose. As per the information given by Lipid world, the drug developed by combination of ROSUVASTATIN and EZETIMIBE (molecule by Sun/Ranbaxy) not only achieves quantitative but also qualitative improvement of serum lipid levels in Type 2 diabetic patients, suggesting that this combination could suppress the progression of atherosclerosis.⁵ This indicates greater utility of the drug produced by the combined entity. This might result in combined entity achieving dominant position in the market of such drug. Moreover, it might also be possible that due to better results, the drug might create a unique market of its own, in which the combined entity might enjoy near monopoly.
- Analysing another molecule i.e. LEUPRORELIN which is used for the treatment of hormone-responsive cancers such as prostate cancer or breast cancer, estrogen-

⁵by Yosuke Okada, Yoshiya Tanaka, Kenichi Tanaka, et al , Efficacy of combination of Ezetimibe 10 mg and Rosuvastatin 2.5mg.; Available at <http://www.lipidworld.com/content/12/1/137/#ins1> (last visited on 2014.09.09)

dependent conditions (such as endometriosis or uterine fibroids) and to control ovarian stimulation in In vitro Fertilization (IVF), is manufactured by 8 companies. Although post-merger the number of manufacturers, including Sun and Ranbaxy, would merely reduce from eight to seven, it is indicated that market share of the combined entity might be as high as 85.8 percent, which could disturb the relevant product market, owing to the dominant position.⁶

- Similarly, there are only 10 manufacturers of TERLIPRESSIN which is used to treat hypotension (low blood pressure) in India⁷. It is emphasised that although the post-merger market would eliminate only one manufacturer of this molecule, the combined entity would still have 69.4 percent market share which is significant to influence the pharmaceutical market. With this percentage of market share post-merger, it is possible that there might be abuse of dominant position. In case the Commission detects abuse of dominance post-merger, damage would have been already caused. With the present price of each brand at around INR 1500, it could be presumed that dominance can lead to a price rise unaffordable by consumers.

It is submitted that the Commission must review the input market (molecular market) as well as the output market (drug market) together, and not in isolation, for the purpose of assessing this proposed merger. It is to be noted here that the molecules manufactured by the parties result in the drugs that are to be sold in the market. Expenditure done by the pharmaceutical companies in developing/procuring those molecules is added to the price of the drugs to be sold. Assuming that the combined entity has a dominant position in different molecular markets (as analysed above), there arises a possibility of abuse of such position by raising the price of such molecules abnormally, which might ultimately result in distortion of the price of final product. Further, as Sun Pharma and Ranbaxy produce drugs through these molecules, there is a possibility that they might prefer their group entities (that are manufacturing such drugs) for supply of molecules, over third parties. These group companies might get the molecules at a lower price than a third party. There also exists a possibility that the parties might restrict the supply of molecules to their group entities thereby eliminating the number of players in that

⁶ Available at <http://www.drugupdate.com/brand/showavailablebrands/258> (last visited on 2014.09.09).

⁷ Available at <http://www.drugupdate.com/brand/showavailablebrands/864> (last visited on 2014.09.09)

relevant market. It can therefore be a possibility that when it comes to manufacturing the drugs to be sold in the market, the group entities of Sun/Ranbaxy, are at an advantageous position over other players. Eventually, a situation might occur when the final drug by a group entity of Sun/Ranbaxy is sold at a lower price than that of third parties. Finally, this difference in pricing of the same drug could lead to elimination of third parties from the market.

As price of majority of the molecules are controlled by manufacturers, the dominance of the combined entity in the molecular market would subsequently affect the final product i.e., drugs' prices, which could be quite high, becoming an issue of concern for consumers. It is therefore requested to the Commission that the market share of the combined entity in the drug market along with the molecular market must be carefully examined.

III. Role of NPPA

3.1 In the proposed merger of Sun and Ranbaxy, role of National Pharmaceutical Pricing Authority (NPPA) becomes significant as this authority was established for fixing pricing and availability of drugs in the country. The pharmaceutical companies on account of the vulnerability of patients and the market potential of these therapeutic groups have introduced expensive drugs in the Indian market⁸. The Commission and the NPPA can work in tandem to ensure that the drugs available or to be sold in the market are available at a competitive price for the public.

3.2 It is further submitted that the Department of Pharmaceuticals vide its notification in September 2014 has withdrawn the power to cap the prices of non-essential drugs, from NPPA. This raises concern as the discretion to fix drug prices now solely rest on the pharmaceutical companies. With Ranbaxy and Sun having a mammoth market share of 93.7 percent in the TAMSULOSIN+TOLTERODINE molecular market, and 91.7 percent in the ROSUVASTATIN+EZETIMIBE molecular market, there is likelihood that the dominance could be abused by raising prices of drugs.

As NPPA deals with the legal matters and has thorough expertise on pharmaceutical sector; it is therefore suggested that the Commission can take assistance from NPPA to

⁸ P A Francis, 108 Drugs More Under DPCO, available at <http://www.pharmabiz.com/ArticleDetails.aspx?aid=83102&sid=3> ((last visited on 2014.09.18)

gather relevant information that could be helpful to take a stand on the combination application.

IV. Competition Authorities determining relevant market

4.1 While it is for the first the Commission has invited a public comment, similar kind of public consultation or stakeholder consultation by the Competition Authorities has been much applauded worldwide.⁹ In determining the dominance caused by this proposed merger, it is pertinent that the relevant market is determined accurately. Given below are few cases which might be taken into consideration while deciding the fate of the present one. In the *Pfizer – Wyeth* transaction, Pfizer formally submitted commitments to the EC¹⁰ in 2009, which were modified thrice. In this particular case, for the purpose of defining a relevant market, the pharmaceuticals market was subdivided into various therapeutic classes as per Anatomical Therapeutic Chemical classification. The Commission also conducted investigation into the molecular level. In another case of Novartis AG/Hexal AG, the relevant product market were divided into three kinds; subdivision of medicines therapeutic classes, prescribed/non-prescribed and originator/generic medicines.¹¹ In Baxter International Inc/Wyeth Corporation acquisition, the Commission alleged that the acquisition would reduce competition in five distinct markets¹². One market was defined as the manufacture and sale of Profol which is used as a sedative. The agency found unique characteristics about this product compared to others, thereby making it superior to others. Rest markets were divided according to the manufacture and sale of various drugs.

To conclude, it is submitted that the Commission might refer to the above cases while determining relevant market in the proposed merger.

⁹ Available at <http://www.jftc.go.jp/en/pressreleases/yearly-2014/September/140903.html> (last visited on 2014.09.14)

¹⁰ Case No COMP/M.5476-PFIZER/WYETH; available at http://ec.europa.eu/competition/mergers/cases/decisions/m5476_20090717_20212_en.pdf (last visited on 2014.09.10)

¹¹ Case No COMP/M.3751; available at http://ec.europa.eu/competition/mergers/cases/decisions/m3751_20050527_20212_en.pdf (last visited on 2014.09.10)

¹² Baxter International Inc/Wyeth, Retrieved from <http://www.ftc.gov/sites/default/files/documents/cases/2002/12/baxterwyethcomplaint.pdf> (last visited on 2014.09.18)

V. RECOMMENDATIONS by CUTS

The information submitted by the parties in Form IV is according to the survey conducted by AIOCD-AWACS. As Sun Pharma and Ranbaxy Laboratories are members of AIOCD, it might be possible that the reports submitted by the parties are not entirely true. In light of this, CUTS puts forward the following recommendations:

(i) *Assessment of market survey by an Independent Committee.*

As the report submitted is entirely conducted by AIOCD-AWACS, the Commission is requested not to solely rely on information mentioned under Form IV. The merger will create India's biggest drug maker with a market share of 9.2 percent which is not significant in itself but the substantial market share of the combined entity in several popular medicines would require assessment.¹³ It is therefore submitted before the Commission to get the report assessed by a third party, preferably an independent committee, that could meticulously conduct market survey and submit a separate independent report making recommendations on the proposed Sun Ranbaxy deal.

(ii) *Role of the Director General (DG)*

Section 29-1(A) of the Act empowers the Commission to call for a report from the Director General (DG) after the receipt of response of parties to the combination under section 29(1). Such report is required to be submitted by the DG within such time as directed by the Commission. This provision introduced in the 2007 amendment was a discretionary step, which the Commission could have invoked after receiving the present combination application. It is therefore submitted that the Commission may call for the investigation by the DG in the present application as it might be helpful in the discovery of relevant data thereby determining relevant market, and actual market share which is crucial in ascertaining the likely appreciable adverse effect on competition.

(iii) *Form- IV: Need for further information*

The information submitted by the parties under Form IV appears to be incomplete. Apart from acquiring Ranbaxy, Sun Pharma would be indirectly acquiring Ranbaxy's shareholding (46.79 percent) in Zenotech Laboratories Limited ("Zenotech"). As per FORM IV disclosure, Sun Pharma was expected to disclose the open offer of

¹³Available at <http://m.economictimes.com/industry/healthcare/biotech/pharmaceuticals/sun-ranbaxy-combine-to-control-over-40-market-for-25-drugs/articleshow/39642982.cms> (last visited on 2014.09.17)

purchasing 28.1 percent shares of Zenotech. However, this is the only detail given by the parties of Zenotech Lab, there are no further details regarding this company. The Commission may call for more details from the parties regarding this company as without it the merger assessment would be incomplete. Further, the parties have merely stated examples of molecules like ESOMPRAZOLE and PRASUGREL in paragraphs 22 and 24 of Form IV which have combined market share of 25.2 percent and 36.4 percent respectively thereby eclipsing molecules like TAMSULOSIN+TOLTERDINE and ROSUVASTATIN+ EZETIMIBE which have a post transaction market share of 93.7 percent and 91.7 percent respectively. The Commission may enquire into the matter for more information from the parties regarding the above as the merger assessment could be incomplete without it.

(iv) *Determination of Relevant Product Market*

The most challenging issue for the Commission would be the determination of relevant product market. As each therapeutic line (molecules/combination of molecules) of medicine is not substitutable, the relevant product market for each therapeutic line could be different. While conducting the investigation, the Commission would need to closely examine each therapeutic line (molecules/combination of molecules) in which the combined entity will have a post transaction market share of more than 50 percent. As molecules are synthesised to produce the medicines, it is pertinent to take into consideration certain molecules of Sun/Ranbaxy with a market share of around 90 percent, as steep rise in molecules price might ultimately lead to the price rise in the resultant drug. Going by the deductions and analysis of some of the drugs, there is a likelihood of dominance of some drugs post- merger and consequent possibility of abuse.

(v) Pursuant to a notification dated 29 May 2014, the Department of Pharmaceuticals gave power to NPPA to cap prices of drugs that are not on the essential list. In July 2014, NPPA invoked this power and capped the price of 108 formulations including anti-diabetics and cardiac drugs. On 22 September, 2014 the Ministry of Chemicals and Fertilizers vide its notification withdrew the guidelines issued on 29 May 2014 thereby withdrawing the power from the drug pricing authority to impose price caps on non-essential drugs¹⁴. Such a notification has given ability to the pharma companies to

¹⁴ <http://www.nppaindia.nic.in/order/withdrawguideline-22-9-14.pdf> (last visited on 2014.09.25)

decide on the prices of these drugs. Sun and Ranbaxy being major players in the Indian pharmaceutical market with the potential to have a dominant position in the relevant drugs market, there arises a probability that post combination, the prices of drugs under consideration might be arbitrarily set, thereby harming competition and consumer's/patient's interest. As the price capping has been removed, the present merger application needs thorough inquiry by the Commission. It is therefore submitted to the Commission to conduct investigation on the impact of the September notification by the Department of Pharmaceuticals on the drug prices.

- (vi) Also, the Commission while determining relevant market in the proposed merger of Sun-Ranbaxy may take into reference the aforementioned cases decided by Federal Trade Commission and European Commission, in determining relevant market while reviewing mergers in pharmaceutical sector. It is also submitted that while assessing pharmaceutical mergers competition authorities have considered divestiture¹⁵ of overlapping businesses. This approach might be taken into consideration by the Commission while evaluating the present merger application.
- (vii) Finally, while analysing the application, the Commission is requested to examine the effect of the said merger on the 'innovation market'; i.e., whether Sun Pharma and Ranbaxy merger deal would reduce the research and development expenditure or not? There is a major concern regarding growing trend in the pharmaceutical industry whereby companies make acquisitions, eliminate drug pipelines, reduce research and development costs, and arbitrage location headquarters. Showing concern on market concentration of pharmaceutical industry in the USA, US Senator Dianne Feinstein suggested the Federal Trade Commission in Valeant Pharmaceutical Inc/Allergan merger,¹⁶ to examine whether this merger would remarkably reduce the research and development taking place post-merger. Also, in Genzyme Corporation/Novazyme merger, the FTC assessed the reduction of research and development expenditure post-

¹⁵ Divestiture is the partial or full disposal of a business unit through sale, exchange, closure or bankruptcy. During divestitures, an organization sells a division of itself to another company. When huge pharmaceutical entities enter into horizontal mergers, the competition authorities recommend divestiture of specific overlapping product lines as a structural remedy. For example: In the acquisition of Wyeth by Pfizer Inc, consent agreement was signed between Bureau and the parties for the divestiture of a significant number of animal pharmaceuticals and vaccine products.

¹⁶ <http://www.feinstein.senate.gov/public/index.cfm/press-releases?ID=25db5525-b8c0-4ad0-a243-522a1479dd19> (last visited on 2014.09.19)

merger.¹⁷ Emphasizing on the international scenario, it is hereby proposed that the Commission refers to these cases and conducts comprehensive research to analyse implications on research and development costs in India post Sun Ranbaxy merger.

¹⁷ <http://www.ftc.gov/news-events/press-releases/2004/01/ftc-closes-its-investigation-genzyme-corporations-2001> (last visited on 2014.09.19)