

Report on Interaction & Discussions Competition Issues in Health & Pharma Sector in India: Diagnosis & Prognosis

Venue: YMCA, 1- Jai Singh Road, New Delhi-110001

A focussed interaction was organised by CUTS Institute for Regulation & Competition on 25th September 2014 on the theme ‘Competition Issues in Health & Pharma Sector in India: Diagnosis & Prognosis’, focussed on regulatory and competition issues hindering development of competition culture in the health care and pharma sector. The programme had three officials from US-FTC sharing their experiences with the participants; Nicholas J. Franczyk is a Counsel for International Technical Assistance in FTC’s Office of International Affairs; Lynda Lao is a staff attorney in the Mergers I Division of the FTC’s Bureau of Competition and Steve Vieux who practices antitrust law with the FTC’s Bureau of Competition in its Health Care Division.

The agenda of the programme was to share the experiences of FTC and various projects undertaken by CUTS & CIRC in this sector and provide a platform for open interaction and discussion. There were some 25 participants representing law firms, think tanks, industry and regulators.

The programme started with a welcome address by Mr. Arun Talwar, COO of CIRC. He welcomed the officials from the FTC as well as the participants. He took the opportunity to highlight the various activities of CIRC such as training programmes and courses on Competition Policy and Law and other economic legislations.

Session I: Presentations by US FTC Experts

The first speaker Mr. Nicholas gave an overview of U.S. - India Competition Law Relationship. He announced that FTC was celebrating its centenary and September 26, 2014 marks the 100th year anniversary of the organisation. He said that the FTC had been playing the role of a matured organisation involved actively in competition advocacy activities. Since the past 25 years, the FTC has undertaken the task to aid and assist new countries/states adopting a new competition regime. This included advising various governments including India in framing its Competition Act. He also thanked CIRC for providing this platform to share some emerging competition issues in the health care sector.

The second speaker Ms. Lynda dealt with Competition Issues in Health Care Markets. She focussed on competition issues emerging from Agreements in Restraint of Trade; Monopolisation or Abuse of Dominance and Mergers and Acquisitions. Talking about horizontal and vertical agreements, she said the course of analysis for each type of agreement is different as it raises different issues. The FTC has undergone changes in terms of enforcement actions, it has moved away from the per se rule, with some exceptions. She cited few cases from the US. The *FTC vs. Actavis* case, Actavis was accused of using reverse payment settlements to keep its generic drug out of the market. Again in *FTC vs. Cephalon*, the FTC claimed that Cephalon, Inc. paid an excess of \$200 million dollars to generic drug companies in an effort to induce them to abandon their patent challenges against Provigil, a prescription medicine used to improve wakefulness in adults, and to dissuade the generic companies from selling generic version of Provigil. On competition issues of hospital mergers, she cited Phoebe Putney Hospital

Merger case, wherein the FTC argued that the merger would significantly reduce competition in the market for acute -care hospital services sold to commercial health plans in Albany, Georgia and surrounding areas – raising prices, harming patients and their employers.

In Mylan, Inc. case, FTC asked the company to divest 11 generic injectable drugs as a condition of allowing Mylan's proposed acquisition of Agila from Strides Arcolab Ltd. According to FTC analysis, in each of these 11 markets, Mylan and Agila are two of only a limited number of current or likely future competitors. Hence the possibility of merger harming competition and ultimately leading to price rise was evident.

Lynda concluded her session by saying that there are about 10 major global players in the pharma industry, any merger or acquisition activity whether horizontal or vertical between these players in the sector will affect the market dynamics. Health which includes pharma sector is a major concern in most competition regime, given the legitimate concerns for patient health and safety. Further, the number of suppliers in generic pharmaceutical markets matters because prices generally decrease as the number of competing generic suppliers increases.

The third speaker Mr. Steve covered the regulatory mechanisms/ activity that affect Competition in Health Care. His brief session covered the Scope of Practice; Professional Licensing Boards and Certificate of Need (CON). He pointed out that the biggest impediments of regulation or over regulation is that it prevents responses to changes in the industry and the market. The other impediments include increase in administrative costs and limitations on innovation.

There are parallel laws and regulations that adversely act on each other. There are evidences that industry participants lobby for parallel regulation in order to avoid competition. Regulation may be inappropriate when requested merely to protect industry incumbents from competitive entrants. For several years the FTC also has been fighting with laws that impede competition. The FTC recently issued a policy paper dealing with proposed state-level changes to statutes and rules governing the scope of practice of Advance Practice Registered Nurses (APRNs).

Session II: CUTS/CIRC research showcase demonstrating competition issues in health care in India

The session on CUTS & CIRC research demonstrating competition issues in health care in India was done by Saket Sharma, Jr. Fellow at CIRC. In his presentation he showcased the various projects of CUTS and CIRC in this sector. (1) CUTS project on Unholy Alliances in Healthcare Services Collusive Behaviour in Healthcare and Impact on Consumers: Evidence from Assam and Chhattisgarh (COHED Project); (2) CIRC research study on Competition Distortions in Pharmaceutical Sector, 2012 (for GOI) and (3) CIRC research study on Competition Distortions in Health Care Sector, 2012 (for GOI). The project reports states that over regulation is also a major hurdle to competition in this sector. Some of the factors reported were; lack of an appropriate regulator that spans all segments of the sector, possibility of collusion among the different players at different levels and consumer ignorance or misinformation. He cited examples such as incentives to doctors to mis-prescribe and free samples of medicines being sold. He also referred to the draft - National Competition Policy which never saw the light of the day and further added adopting a competition policy may correct the policy paralysis in this sector.

Session III: Moderated discussion with all stakeholders

After the floor was opened for debates and question- answers, participants raised some interesting topics for discussions.

One of the participants Mr. MM Sharma (Head Competition Law practice at Vaish Associates) asked the FTC experts to comment on the data exclusivity issues charges by US against India, especially referring to the US Special 301 (in which India is criticised for not protecting US patents in India).

Mr. Nicholas answered to this question by saying that there can be laws which are anti-competitive in nature. Further, he added that he is not the best person to answer to this question as it pertains to U.S. Food and Drug Administration (FDA).

Another participant Mr. Manas Kumar Chaudhuri (Partner, Khaitan & Co.) asked the experts from FTC to comment on the exclusivity agreement between a scientist (whose patent is not registered) and pharma company to exploit the patent. What is the fate of the license agreement between the scientist and the company in case they have fallout?

To this Mr. Steve replied even in those pay for delay cases, it is not really a competition issue but a breach of contract issue. If one party to the contract is violating the terms of the contract, it amounts to breach only and not a competition issue.

Deliberating in detail he added that there are all sorts of agreements between scientist and pharma companies to exploit a particular patent after entering into license agreements. In case the theory of competition harm is not established, any contract between any stakeholders does not amount to anti-competitive.

Mr. Gautam Shahi (advocate at JSA), a participant asked for the FTC view in determining relevant market in the context of medical tourism. He referred to the speciality section of a medical care in the range of medical (health) tourism.

This question was answered by Mr. Steve saying that in country like US, it is easy to rely on the data available at the hospitals as it can go down to the minutest of details like bank accounts and ZIPCODE of the area from where the patients have come from. A bank account and a ZIPCODE can give away a lot of information on the type of relevant market for a particular segment of patients.

Obviously in India due to the paucity of data of relevant market is a big challenge. Here, Mr. Vijay Kumar (Dy. Director of CCI) added by saying that the one factor to determine relevant market in this context is the treatment charges. The consultation and the treatment charges under the health tourism is very different from the regular charges availed by the local patients in India. Hence, relevant market will be different in such case.

Vaibhav Choukse (advocate at Vaish Associates) referred to the EU cases on pay for delay cases, where dominant firms can defend on grounds of objective justification. Following the US trend, even the EU- commission has started busting the pay for delay anti-competitive agreements. Such as the Servier case in which the company was fined €331 million (\$450 million), the company has condemned the EC decision as “absurd” and “detrimental to patients” because it would limit its research efforts.

To this Nicholas replied by saying that under the US antitrust regime, rule of reason is applied in almost all cases. While assessing any case, the rule of reason would be applied even in patent litigation and pay- for -delay cases.

The programme ended with a vote of thanks from CIRC and Mr. Arun Talwar, COO presented mementos as a token of appreciation to the experts.

PROGRAMME AGENDA

15.00 – 15.30	Registration and Networking
15.30 – 15.40	Welcome and Programme Introduction (CIRC)
15.40 – 16.40	Presentations by US FTC Experts Overview of U.S. India Competition Law Relationship (Nick Franczyk, US FTC) Competition Issues in Health Care Markets (Lynda Lao, US FTC) Considering Competitive Effects of Regulation (Steve Vieux, US FTC)
16.40 – 17.00	CUTS/CIRC research showcase demonstrating competition issues in health care in India (Saket Sharma, CIRC)
17.00 – 17.30	Moderated discussion with all stakeholders Networking Tea

Brief Profile of Experts

NICHOLAS J. FRANCYK

Nicholas J. Franczyk is Counsel for International Technical Assistance in the **US Federal Trade Commission’s Office of International Affairs**. He has been an attorney with the Federal Trade Commission since 1987, where he has worked on various antitrust (both merger and conduct) and consumer protection matters. As Counsel for International Technical Assistance, he is responsible for providing various assistance and training to foreign agencies in the areas of competition and consumer protection law and policy, including training of personnel in substantive legal principles, analytical framework, and investigative techniques. He has also provided comments on various draft competition laws, guidelines, regulations, and policies. His primary responsibilities include India and Sub-Saharan Africa.

He has served as long-term resident advisor to the South African Competition Commission (2004 and 2008) and to the Indonesian Business Competition Supervisory Commission (2004). He has participated in more than 50 short-term technical assistance training programmes for competition and consumer protection authorities in Colombia, COMESA, Egypt, Gambia, India, Indonesia, Kenya, Mexico, Mozambique, the Philippines, Russia, South Africa, Tanzania, Vietnam, and Zambia, and various regional programmes in Africa, Southeast Asia, and Southeast Europe. He has also conducted

commercial law assessments in Indonesia, Kenya, and Tanzania for the United States Agency for International Development.

LYNDA LAO

Lynda Lao is a staff attorney in the Mergers I Division of the US Federal Trade Commission's Bureau of Competition. The Mergers I Division's primary area of responsibility is reviewing transactions in health care-related industries, such as pharmaceuticals and medical devices, as well as matters involving defense, scientific, industrial, technology, and consumer products. Lynda joined the FTC after graduating from law school in 2008. Lynda earned her law degree from Loyola University Chicago School of Law in Chicago, IL and received undergraduate degrees in economics and history from Stanford University in Palo Alto, CA.

STEVE VIEUX

Steve currently practices antitrust law with the US FTC's Bureau of Competition in its Health Care Division. Steve has been with the Health Care Division since 2001, where he has played a leading role in numerous investigations and litigation matters concerning anti-competitive conduct and combinations in the health care and pharmaceutical industries. Before that, he briefly worked in the FTC's Office of General Counsel where he assisted FTC staff on various competition, consumer protection, and administrative law matters. He has received the FTC's Janet D. Steiger award for contributions to the litigation teams in *FTC v. CSL Limited* and *In the Matter of Schering-Plough Corp.* Steve is also a member of the Steering Committee for the Antitrust and Consumer Law Section of the D.C. Bar Association. Steve received his law degree from the University of Pennsylvania, and he graduated with a B.S. in Industrial & Labor Relations from Cornell University.

SAKET SHARMA

Saket works as a Jr. Fellow in CUTS Institute for Regulation & Competition (CIRC). CIRC, established in 2009, is a training and capacity building research institute working in areas related to regulatory and competition law (www.circ.in). His work profile includes supervising, managing and researching in areas related to competition law; developing courses related to regulatory sphere and competition law and organising training programs in related areas. His specific research interests revolve around the interface of IP and competition law, competition law and innovation. He holds Masters in Law from Faculty of Law, University of Delhi. He has to his credit various academic achievements including Prof. Sivasubramaniam Gold Medal and University Prize for being the overall Topper in LLM/MCL batch being awarded at 87th Convocation of University of Delhi in 2009. He has worked on various research projects with government bodies, universities and other reputed research organisations like UGC, ICSSR, IICA, IGNOU, GIZ. He is a regular speaker in events related to the above given themes and also writes on these issues.