



2ND ANNUAL NLU ANTI TRUST MOOT COURT COMPETITION, 2011

In association with:

LAKSHMIKUMARAN & SRIDHARAN
AND
THE COMPETITION COMMISSION OF INDIA

MOOT COURT PROPOSITION

NATIONAL LAW UNIVERSITY, JODHPUR

BEFORE THE COMPETITION COMMISSION OF INDIA

Tridex Pharmaceuticals India Pvt. Ltd. v Cheat'em, S.A. & Others

and

Murali v Cheat'em, S.A. & Others

1. Cheat'em India Pvt. Ltd. is an Indian company incorporated in New Delhi and has its principal place of business in New Delhi. Cheat'em India Pvt. Ltd. was a wholly owned subsidiary of Cheat'em, S.A., a Belgian company whose shares are listed on the Euronext Brussels stock exchange (hereinafter referred to, along with its affiliates as Cheat'em). Cheat'em was originally established in 1885, as a company that manufactures basic chemicals to be used in other manufacturing processes. Within a span of 30 years, Cheat'em became one of the major players in the chemicals sector, manufacturing a number of chemicals and having plants all over Europe.

2. With the success of its business, in the early 1900s, Cheat'em product portfolio included a number of organic molecules. With its growing experience in organic chemistry, Cheat'em slowly expanded its operations into the healthcare sector in the early 1980s by acquiring a number of small players in the European market and a few companies in the USA. Cheat'em is presently at the forefront of R&D in the pharmaceutical sector and is engaged in the manufacture, distribution and sale of branded pharmaceutical products all over the world. In the twelve months ending December 31, 2009, Cheat'em's net worldwide pharmaceutical revenues totaled about Euros 10 billion.

3. Cheat'em has its manufacturing plants for drugs spread over many countries in Europe, including many erstwhile Soviet Union territories. A manufacturing plant in Bangladesh was not set until 2005. These manufacturing facilities catered to all the markets in which Cheat'em had a presence. To supply its drugs to any country without its manufacturing plant, Cheat'em's general methodology was to first establish a wholly owned subsidiary in that country, which will decide on an exclusive distributor for a particular drug for that given country. The subsidiary, on behalf of Cheat'em, will enter into a distributorship agreement with such exclusive distributor for the distribution of that drug. Then, this wholly owned subsidiary would simply import the drugs from the closest manufacturing plant into these countries and distribute them through the exclusive distributor. Cheat'em Pharma India Pvt. Ltd. was set up in India with this business plan and similar subsidiaries existed in Australia and Bangladesh as well.

4. One of the areas that Cheat'em focuses on in the pharmaceutical sector is mental health and it offers a number of prescription medications for the treatment of many psychological disorders,

including schizophrenia and autism. Almost 65% of its worldwide revenue is derived from sales associated with such medications.

5. One of the companies acquired by Cheat'em in the early 1980s, Howe Pharma, S.A., was a company that manufactured one of the most popular anti-psychotic drugs, Gistikol. Gistikol, was first introduced in the European market in 1959 and later introduced in the USA in 1965, after obtaining the required regulatory approvals. After its introduction, many similar drugs followed suit, all of which represented the first generation anti-psychotics developed by pharmaceutical companies. These first generation anti-psychotics, due to the associated signaling pathway within the human body, had a number of common side effects including muscle cramping, tremors and weight gain. There was also significant risk of dyskinesia and fatal neurological disorders. At the time of its acquisition, Howe Pharma was engaged in the research of developing a second-generation anti-psychotic, which was only at the experimental stage.

6. In 1987, the R&D team of Cheat'em involved with the development of anti-psychotics, many of whom were once researchers in Howe Pharma, achieved a breakthrough and ushered in a new era in area of anti-psychotics. The researchers were able to develop a new drug that was as efficacious as any other first generation anti-psychotic and yet, reduced the incidence of the common side effects associated with this class of drugs. Further, this second generation drug was also able to reduce the incidence of more serious and / or fatal neurological disorders. This innovative and first of its kind drug was given regulatory approval in the USA, Australia and in Europe between 1995-1997 and was marketed vigorously under the brand name Colidone. Industry reports indicated that, in total, almost Euros 0.8 billion was spent to bring Colidone into the market. Meanwhile, Cheat'em had applied for various patents relating to the drug, including a patent on the active ingredient used in Colidone, in almost all countries in which Cheat'em sold its products. The patent on Colidone expired in December 2007 in most of the countries in which it had applied for a patent, including the USA, the EU and Australia.

7. At the time Cheat'em developed Colidone, India and Bangladesh did not allow for product patents on pharmaceutical products. Due to this, Cheat'em was only able to procure a patent on the process used to manufacture Colidone, in India and Bangladesh. Domestic pharmaceutical companies in those countries had a free reign to manufacture copycat drugs that were structurally the same as Colidone by simply modifying the process used to manufacture the drugs. These generic versions of Colidone were being sold for a very low price as compared to Colidone. For this reason, Cheat'em was unable to penetrate the market in India and Bangladesh. However, in 1995, both India and Bangladesh became members of the WTO and had to ratify the TRIPs. These international obligations required India and Bangladesh to implement a product patent regime even for pharmaceuticals, by 2005.

8. In 1990, Cheat'em filed a PCT application on the active metabolite of Colidone, designating many countries in its application, including Australia. Three years later, Cheat'em filed a specific formulation patent that claimed the fatty acid ester of the active metabolite suspended in a particular carrier. Later, in 1995, Cheat'em filed a patent application through the PCT route in, inter alia, the

USA, EU and Australia, for a sustained release oral dosage form of the active metabolite. The patent, as well the necessary regulatory approval was granted in these countries for this formulation, which was marketed under the brand name Pantadone. Pantadone was strongly marketed from the beginning of 1999, as a more convenient and more efficacious drug than all other previous versions. As of today, Pantadone is the only second-generation anti-psychotic sold in the Indian market that is available in a sustained release oral dosage form, which results in a number of significant advantages. However, other patented and non-patented drugs belonging to the second-generation of anti-psychotics are available in the market, including in India.

9. Cheat'em moved the corresponding application for the patent covering Pantadone, under the PCT route, to India and Bangladesh as well. The Indian and Bangladeshi applications were moved almost simultaneously in 1997. By this time, India and Bangladesh, as required under the TRIPs mandate, had implemented a "Black Box" system, whereby the patent applications would not to be taken up for examination under the law before 01.01.2005, the day on which the countries were required to comply fully with the TRIPs mandate.

10. As part of the TRIPs mandate, both India and Bangladesh had to provide for a system of temporary exclusivity protection till 01.01.2005 to those who had filed patent applications. Under this requirement, both countries allowed for the filing of applications for Exclusive Marketing right ("EMR") whereby only the applicant would be allowed to market products based on the patent applicant. Based on the patent application, EMR was granted to Cheat'em in both India and Bangladesh, as of 2001. Later, in 2007, after India had fully implemented a product patent regime for pharmaceuticals, the patent application that covered Pantadone was granted in India and a valid patent was issued in Cheat'em's name.

11. However, Cheat'em did not setup any manufacturing plant in India; the facility in Bangladesh provided the necessary supply for Indian market. At this time, there was a growing incidence of mental disorders, especially schizophrenia, in developing and underdeveloped countries. Cheat'em realized that pricing its drug at the same price in all markets results in lower market share of the drug. A sample market survey conducted by Cheat'em in India and Bangladesh showed that a significantly large percentage of the potential users of such products, i.e., 60% in India and 85% in Bangladesh, simply were not able to afford its drug, Colidone/Pantadone, even if it was made available in the market at the same price as in other developed countries. To this extent, Cheat'em believed that it was only losing revenue. Cheat'em, therefore, believed that the marketing plan required comprehensive changes.

12. After long-drawn and intensive internal discussions, Cheat'em decided to enforce a multiple-pricing regime whereby the same drug would have different prices depending on in which country it is being sold. Cheat'em believed that this would only result in additional revenue from that part of the market, which would have otherwise been lost but for the price reduction. It was also around this time that all innovator pharmaceutical companies were drawing fire from all corners for pricing essential drugs so high so as to make them unaffordable for most of the population. Cheat'em believed that its multiple-pricing regime would uplift its image in the market as compared to other

innovator pharmaceutical companies by projecting Cheat'em as a socially responsible company that is willing to sacrifice its profit for enabling access to medicine.

13. Pursuant to this policy, at the time Pantadone was introduced in the market, Cheat'em created three classifications – High Price, Medium Price, Low Price. Each pricing band applies to different economies – developed, developing and underdeveloped, respectively. The said prices were calculated after a rigorous study of the average income in each kind of economy, the market structure in such economies, etc. Seen from this perspective, the markets of Australia, India and Bangladesh neatly fell into the classification system as high, medium and low price countries, respectively. Cheat'em decided that the High Price for Pantadone will be \$600; the medium price will be \$300 and the low price will be \$100. The High Price of Pantadone was 50% more than the price at which Colidone was sold. These numbers were obtained after rigorous internal discussion and calculations, based on the overall market for this class of drugs and was calculated to ensure that Cheat'em will be able to recover its initial cost of bringing the drug to the market. According to a study conducted by Captain Market Studies Pvt. Ltd, a leading Indian company involved in market research in all sectors, including the pharmaceutical sector, sales of Pantadone constituted 35% of the overall sales of anti-psychotics.

14. Similar to how it otherwise operated, Cheat'em, through the relevant local subsidiary, picked certain exclusive distributors in each of its markets and entered into distributorship agreements with them based on the relevant price applicable. For instance, Cheat'em entered into an agreement with X, in which clause 1 declared X to be the exclusive distributor in India for distributing Pantadone within B. Clause 4 of the agreement read as follows:

Notwithstanding anything else contained in this present agreement, the price at which the Drug can be sold within the Territory is \$300 or Rs. 14,000 per 50 tablets, whichever is higher in terms of the exchange rate at the time of distributor obtaining any orders for Pantadone.

Provided however that the price at which the distributor can satisfy orders for other quantities shall be proportionately decided based on the above set maximum price.

15. Clause 2(d) of the agreement defined Drug to “mean and include” Pantadone and clause 2(j) defined Territory to mean and include the territory of India. Clause 2 (e) of the agreement defined the term distributor for the purposes of this agreement to mean X, and its Subsidiaries. The term ‘Subsidiary’ was defined in clause 2(g) as follows:

All entities 50% or more of whose voting stock is directly or indirectly controller by X and includes all those persons who are otherwise controlled by X.

16. Although the term ‘Affiliate’ was nowhere employed in the agreement, clause 2(b) defined the term ‘affiliate’ to mean any legal entity that was associated with X. Clause 12(5) of the agreement also mandated that the contents of this agreement in itself have to be kept confidential and could

not be disclosed to any person, except in accordance with an order or summons from a judicial/quasi-judicial authority.

17. Similarly, Y was made the exclusive distributor in Bangladesh through an agreement executed in 2005, clause 4 of which stipulated that the maximum retail price at which the drug can be resold within Bangladesh would be \$100.

18. Cheat'em realized that with a multiple-pricing system, some form of restriction needs to be placed on a distributor's right to export products sold to it since otherwise the exclusive distributor in one country can take advantage of the price difference the drug has in another country and engage in arbitrage. This would also unnecessarily eat into the market of the other exclusive distributor as well its own revenue from such markets. To prevent this, Cheat'em also issued a circular in 2005 that was circulated to all its distributors world-wide, which contained in clause 4A, the following stipulation:

Distributors are hereby prohibited from satisfying any orders effectively placed from outside their Territory, as defined in their respective agreement, including but not limited to orders placed within the Territory on behalf of persons outside the Territory.

19. After signing the agreement, Y implemented the same until 2008. However, after 2008, Y entered into transactions with certain ad-hoc companies, whereby Y used to sell the drug at the price of \$100 and these ad-hoc companies would, in turn, engage in the export of the drug to India at \$200. The agreement between Y and these ad-hoc companies stipulated that Y would be given a share of 10% of the profit obtained by these ad-hoc companies in selling the drug. Within a span of 2 years, X started realizing that its pending stock of Pantadone was on the rise and that its revenue was consistently decreasing. Market investigation revealed that the imports from Bangladesh were being distributed through another entity in India, which was affecting its ability to market and sell its own stock. X communicated this situation to Cheat'em, in response to which Cheat'em confronted Y in Bangladesh. Y flatly denied such allegations and put Cheat'em in strict proof of the allegations. Cheat'em, which had undertaken its own investigation, issued notice to terminate the distributorship agreement with Y. In response, Y filed a suit for declaration that the notice is illegal and obtained an interim order in its favor against the termination of the contract.

20. The court ordered that till the pendency of the suit, the agreement was to be implemented by the parties on an as is basis. Cheat'em also counter-claimed that Y had committed infringement of patent and breach of contract, but was unable to obtain any interim order in its favor. The suit is currently pending. At the same time, the importer of these drugs from Bangladesh, Tridex Pharmaceuticals India Pvt. Ltd., filed a complaint before the Competition Commission of India ("CCI") alleging that the agreement executed between Y and Cheat'em was in contravention of Section 3 of the Competition Act, 2002 and that Cheat'em was abusing its dominant position in violation of Section 4 of the Competition Act, 2002. This complaint included a copy of the

agreement between Cheat'em and Y, a certified copy of the interim order issued by the Bangladeshi court against Cheat'em, and all other relevant facts and circumstances on affidavit.

21. In the meantime, X was still suffering due to the imports from Bangladesh with a reduction of almost 80% in its revenue. To offset the losses resulting from these parallel imports, and to clear its pending stocks, X adopted a similar approach as Y. X, now set up certain ad-hoc companies in India, whose shares were indirectly held by X itself, which would purchase the products from X at the price of \$300 and export them to Australia for \$450.

22. These imports into Australia significantly affected the revenues of Z, the exclusive distributor of Cheat'em in Australia. Z, under a similar distributorship agreement, was prohibited from selling the drug at a price lower than \$600, the High Price. Australia being a country that follows the international patent exhaustion doctrine, Cheat'em was unable to obtain any sort of infringement claim against such importation into Australia, from the local courts in Australia. Fearing what happened in Bangladesh may repeat in India, Cheat'em believed that immediate action was necessary and that no time could be wasted in court proceedings to decide on whether the agreement was being violated. When rumor spread that Cheat'em was expected to initiate some sort of action to stop exports of Pantadone from India, a number of commentators and bloggers raised questions about the legal validity of its patent covering Pantadone, especially considering Section 3(d) of the Indian Patents Act, 1970.

23. Meanwhile, Jugaad India Ltd., a generic pharmaceutical company based in India filed for a license before the licensing authority established under the aegis of the Drugs and Cosmetics Act to manufacture for sale, a generic version of the Pantadone, under the brand name "Almidone". This application was filed on the basis that Almidone was bioequivalent to Pantadone. Industry reports indicated that Almidone was to be made available in the market at \$100 per unit. When Cheat'em became aware of this application, it immediately filed a writ petition before the Hon'ble Delhi High Court seeking a mandamus to direct the licensing authority not to grant approval to Jugaad since that would allow Jugaad to infringe its patent in India. The High Court dismissed the writ petition on the grounds that there was no legal basis for requiring the drug approval authority to prevent the infringement of a patent by others. An appeal was immediately preferred before a Division Bench of the same High Court. Meanwhile, Cheat'em also instituted an infringement suit against Jugaad, against which Jugaad counter-claimed that the patent covering Pantadone was to be revoked on various grounds, including Section 3(d) of the Indian Patents Act, 1970 and the lack of inventive step. At the same time, Jugaad also initiated revocation proceedings before the Intellectual Property Appellate Board on similar grounds.

24. However, a month later, both Jugaad and Cheat'em released a joint press release stating that the parties had reached a settlement agreement. According to this settlement agreement, Jugaad was given the right to serve as a potential back-up manufacturer for Pantadone, if the need arises. Distribution of all such products manufactured by Jugaad was to be routed solely through Cheat'em. Jugaad was to be paid an annual sum by Cheat'em, withdraw its revocation proceeding and not market Almidone prior to 90 days before the expiry of the Indian patent covering Pantadone. The

parties also agreed to withdraw the various proceedings filed against each other regarding the patent. The exact financial details of the agreement were unknown. The companies refused to disclose further information about this settlement agreement citing a confidentiality obligation under the agreement. Accordingly, both parties moved a joint motion for withdrawal of the revocation application as well the respective infringement suit and counterclaim, which were allowed. The legal guardian of a user of Pantadone, one Mr. Murali, a lawyer, filed a complaint before the Competition Commission of India based on this press release, alleging that the agreement between Jugaad and Cheat'em was in contravention of Section 3 of the Competition Act, 2002.

25. The CCI examined the two complaints filed by Tridex and Mr. Murali, and being prima facie satisfied that there was a contravention of the Competition Act, 2002, referred both the matters for investigation to the Director General under Section 26(1). At the stage of referral no comments were invited from Cheat'em nor was any information sought from other interested parties. The Director General, during the investigation of the complaint filed by Mr. Murali, directed the parties to submit the agreement for examination which was done without any protest. Furthermore, the Director General availed the services of Captain Market Studies Pvt. Ltd. to conduct market research in the area of anti-psychotics. The report submitted by Captain Market Studies indicated that Pantadone constituted 50% of all second-generation anti-psychotics, within India. The report also noted that Pantadone's success is mostly associated with its sustained release oral dosage delivery system, which was unique and was absent in other anti-psychotics in the market. After investigation on both the complaints, the Director General recommended that there was no contravention of any provisions of the Competition Act, 2002. Upon receipt of this recommendation, the CCI invited suggestions and objections from all the parties concerned. While Cheat'em did not raise any objections to the Director General's report on both the complaints, the complainants, i.e., Tridex and Mr. Murali, respectively, raised objections that the conclusions reached by the Director General were incorrect.

26. After consideration of all the evidence and suggestions on record, the CCI disagreed with the recommendations of the Director General and independently initiated its own inquiry on both the complaints and issued notice to the parties concerned. Cheat'em raised a preliminary objection that the CCI does not have the power under the Act to initiate an inquiry if the Director General has recommended that there is no contravention of the provisions of the Competition Act, without there being any additional facts or evidence. Considering that a common preliminary objection was raised in both complaints, the Chairperson directed the matters to be clubbed and heard by the same bench. The bench disposed off the preliminary objection raised by Cheat'em and posted the complaints for final hearing.