



The Real Challenge Is Access To Healthcare: Mr. Ranjit Shahani, President, OPPI

December 30, 2009, Financial Express

<http://www.financialexpress.com/news/the-real-challenge-is-access-to-healthcare/561190/2>

During the past year, the Indian economy relatively withstood the global downturn. Since then, it has emerged as one of the fastest-growing economies in the world, with a projected growth of 7-7.5% in 2009-10. The financial meltdown in the developed world started impacting the business environment of the country from the third quarter of the previous year—however, not as much as the western world has suffered. It is interesting to note that in the Servcorp International Business Confidence Survey, India was ranked the third-most promising country to survive the economic crisis.

The manufacturing and construction sectors recorded the strongest growth, while the weakest was agriculture, which showed growth of just 0.9%. This was aggravated by the poor monsoon this year. The inflationary trend, though, which was brought well under control during the year, has now started showing an ascending trend, especially in food prices. This is indeed a major cause of concern as food price inflation hits the poorest the hardest.

The pharmaceutical industry in India remained insulated from the global financial crisis, registering a growth rate of 14% during the year. India now accounts for 8% of global production and 2% of the world pharmaceutical market. In 2009-10, the finance minister brought the industry some relief with the abolition of the fringe-benefit tax and commodity transaction tax.

Simultaneously, the planned introduction of a goods & services tax and extension of provisions relating to weighted deduction of 150% on expenditure incurred on

in-house R&D to all manufacturing businesses augur well for the industry.

Proposals for the improvement of healthcare infrastructure under the National Rural Health Mission and coverage of all below-poverty line families under the Rashtriya Swasthya Bima Yojana with an increase in allocation by 40% will help improve healthcare access to the common man.

The decision to cut basic customs duty on raw materials for lifesaving drugs, vaccines and medical devices, the total exemption of basic customs duty on influenza vaccine and nine other specified lifesaving drugs used for the treating breast cancer, hepatitis B, rheumatic arthritis, etc, and the tax incentives to set up and operate cold-chain facilities were welcomed by the industry.

In the larger frame, though—in my view—the following areas, if not addressed speedily, may throw up a tough challenge to the Indian economy in the near future:

- * Rising prices, particularly food price inflation
- * Low public spend on education and health
- * Long overdue reform in labour laws
- * Deterioration in balance of payments
- * High levels of debt
- * Large Budget deficit
- * Delay in completion of various infrastructure and socio-economic projects, and
- * Inequitable distribution of the economic growth.

Even though India has the highest levels of mortality and morbidity in the world, the 1% of GDP spent on healthcare is one of the lowest compared even with developing countries in Asia. The real challenge is not access to medicine, but access to healthcare. In India, we have the lowest-priced medicines, however delivery systems outside the cities just do not exist, denying over

65% of the population access to modern healthcare. That is the challenge....

Small Drug Firms Cry Foul Over Ethics Code

December 27, 2009, Business Standard

<http://www.business-standard.com/india/news/small-drug-firms-cry-foul-over-ethics-code/380840/>

common 'ethical marketing practices code' for drug makers in the country is unlikely in the near future despite the latest attempts of the government's department of pharmaceuticals to evolve such a code.

The smaller players in the business – combined under the Small Pharmaceutical Industries Confederation (SPIC) – have raised objections to the proposed Uniform Code of Pharmaceutical Marketing Practices (UCMP).

This code has been finalised at the behest of the department of pharmaceuticals by industry associations such as **Organisation of Pharmaceutical Producers of India (OPPI)** and Indian Drugs Manufacturers Association (IDMA).

The department of pharmaceuticals initiated the latest move after taking note of a series of complaints against unhealthy marketing practices of pharmaceutical companies. After preliminary discussions with industry associations, the department asked OPPI to consult other stakeholders and prepare a common code of conduct to be followed voluntarily.

The OPPI submitted UCMP last month, among complaints by some stakeholders that they had not been consulted. The code proposes a bar on incentives to doctors to prescribe medicines. It also puts a check on foreign junkets, disguised as scientific conferences, for doctors. SPIC has objected to the draft code prepared by other stakeholders saying that it is unworkable in its current form.

"In spite of the code, there are complaints about marketing practices. What we require is not a fresh code that is voluntary but a code that is legally binding," says Jagdeep Singh, secretary general of SPIC. The small players also feel that the code is just an "eye wash" as there are already codes of ethics announced by individual organisations.

For instance, OPPI, the lobby of multinational pharmaceutical firms in India, has adopted the code put out by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the global entity of which OPPI is an affiliate.

UCMP, compiled by OPPI, is a watered down version of the IFPMA code, industry observers say. Other organisations, such as, IDMA and Confederation of Indian

Pharmaceutical Industries (CIPI) have also their own codes for a long time.

SPIC wants the government to stop giving income tax sops to all promotional expenses to medicines that have been in the market for more than five years. It also wants a ban on the change of ingredients under a brand name. These two, Singh says, indirectly aid high promotional expenses which then get reflected in the prices of medicines.

Senior ministry officials did not comment on the status of a common code, but expressed the hope that the associations will reach at a consensus.

Uniform Code On Pharma Marketing Practices Ineffective With No Binding Clause On Cos

December 11, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=53032§ionid=>

The proposed Uniform Code of Pharmaceutical Marketing Practices (UCMP), claimed to have been unanimously agreed by all prominent pharma bodies to discourage freebies to doctors but became a bone of contention between the associations, may not make any desired impact in curbing the existing unethical trade practices in this industry.

Voluntary by nature, the joint code presented at the meeting on Wednesday, will not be binding on the companies, though some associations like SME Pharma Industries Confederation have been pressing for some 'legal teeth' to arrest the unethical practices. Though organizations like **Organisation of Pharmaceutical Producers of India (OPPI)** had such a code for years, it did not bring in any desired effect as it was voluntary.

OPPI, IDMA Oppose Legally Binding Marketing Code At DOP Meet To Evolve Uniform Code

December 10, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=53011§ionid=>

The Department of Pharmaceuticals (DoP)'s efforts to evolve a uniform code of marketing practices (UCMP) to

arrest the unethical marketing practice of bribing doctors for prescribing drugs proved to be a damp squib as major differences cropped up among the industry associations, especially between the big and small players in the field. Due to the sharp differences between these associations, no major decision was taken in today's meeting on the issue convened by the DoP.

While the industry associations like **OPPI and IDMA**, representing by and large big and medium pharma companies, wanted a uniform code of marketing practices which is not binding on the industry, the associations like SPIC, which claims to represent around 5000 small pharma companies, pleaded for a uniform code which is legally binding on the companies. The SSIs pleaded in the meeting in favour of a legal document, on the same lines of such documents in the developed countries, and the violation of the code should invite punishments both in terms of money and jail term for the violators, sources said.

Besides, the SPIC forcefully pleaded for a clause in the code barring the companies from adding promotional expenses to a drug which has been in the market for five years. "Five years is a sufficient time to promote a drug after which the drug should not be promoted," a SPIC spokesman said.

When contacted, SPIC secretary general Jagdeep Singh said that the SSIs are working for the prices of drugs to come down. "We request the IDMA not to let down the SSIs as it has done in case of Schedule M and MRP-based excise," Singh said.

Docs Told Not To Accept Gifts From Drug Cos

November 16, 2009, The Economic Times
<http://economictimes.indiatimes.com/news/news-by-industry/et-cetera/Docs-told-not-to-accept-gifts-from-drug-cos/articleshow/5233709.cms>

The global association of doctors World Medical Association (WMA) has asked physicians to refrain from taking gifts, including hard cash from drugmakers, as an incentive to promote their medicines to the patients. It is part of a resolution passed by WMA outlining the guidelines for doctors to follow while dealing with pharma companies.

The advisory issued during a recent WMA meeting in Delhi comes at a time when the domestic pharma companies and medical bodies are in the process of finalising a detailed marketing code of conduct to curb the practice of pharma companies paying doctors to prescribe their medicines. The Indian government had recently asked the drug industry to self regulate so that the interests of the patients are not compromised.

The Rs 36,000-crore Indian drug retail market is fiercely competitive, with the largest player having a meagre 5% market share. Globally, drugmakers are not allowed to advertise their prescription drugs, or medicines that can only be bought on a doctors prescription. As a result, the success of a medicine largely depends on the recommendation of doctors.

The WMA guidelines has asked doctors to refrain from taking expensive personal gifts designed to influence clinical practice, payments in cash or cash equivalents from companies, payment to cover travelling expenses or room for conference or compensation for their time, and declare financial support they get from companies.

The Indian Medical Association (IMA), representing doctors in the country, and the domestic drugmakers associations say they agree with the WMA resolution in-principle. IMA secretary general Dharam Prakash said: "Once you take a gift or travel at somebody's expense, you would be obliged to return the favour, which means promoting a company's brand. The resolution should curtail the practice of drugmakers to unethically promote their drugs."

"In many areas, the WMA statement is similar to our code of conduct for marketing practices. This is a good step in the right direction," said Tapan Ray, director general at the **Organisation of Pharmaceutical Producers of India**, a group that represents the interests of large drugmakers in the country.

Most doctors in the country accept gifts and incentives in various forms to promote a particular company's products. Industry experts such as CM Gulati, a veteran with medical regulations, feels the resolution will be ineffective and it is an attempt by the medical fraternity and industry bodies to prevent the government from regulating the drugmakers marketing practice.

"Both the doctor and industry are interested parties who benefit from the current practice, the consumers interest is not represented. The industry bodies are toothless and can't take any punitive action, so the question of self-regulation is a hogwash," he says.

On Prescriptions Without Motives

November 16, 2009, Businessworld
http://www.businessworld.in/bw/2009_11_07_On_Prescriptions_Without_Motives.html

A code of conduct alone is not enough to check unethical drug marketing Pharmaceutical industry associations will present a code of ethics governing their marketing practices to the Department of Pharmaceuticals by the end of this month. Dubbed the Uniform Code of Marketing Practices (UCMP), the move is a response to a government directive to the drug industry following media reports of unethical inducements to doctors such as foreign junkets, expensive gifts etc. "It is expected that all stakeholders will help maintain its sanctity to address this public, sensitive issue, effectively," says **Tapan Ray, director-general of the Organisation of Pharmaceutical Producers of India (OPPI)**.

Generics Gateway

November 9, 2009, Financial Express

<http://www.financialexpress.com/news/Generics-Gateway/538875/>

If generics are the gateway of growth for global pharmaceutical giants such as AstraZeneca, Pfizer, Sanofi-Aventis, Novartis, Merck and GlaxoSmithKline, there is a clear and renewed thrust on the \$17 billion Indian pharmaceutical market. Market is abuzz with acquisition talks as global pharmaceutical majors scan the Indian market for potential buyouts.

Ranjit Shahani, managing director of Novartis India and current president of Organisation of Pharmaceutical Producers of India (OPPI) is quick to endorse the global pharmaceutical majors' move to grow in India. "Markets in the developed world are growing at low single digit; developing countries like India are expected to grow at double digits. With its growing middle class, India represents an opportunity for geographic expansion and a fertile ground for big pharmaceutical companies," he stresses. **Tapan Ray, director-general, Organisation of Pharmaceutical Producers of India** says, the global pharmaceutical companies are resorting to an interesting strategy, combining both traditional and the new business strategies.

Low Imports From China Lead To 15% Shortage In Drugs

November 6, 2009, DNA

http://www.dnaindia.com:80/money/report_low-imports-from-china-lead-to-15pct-shortage-in-drugs_1203849

India sources 80% of its APIs from China The current financial crisis has sent stress levels soaring. Can illnesses be far behind? But don't expect much relief from the medical store close-by. Medicines are somewhat scarce in the market.

J S Shinde, president of the All India Organization of Chemists & Druggists (AIOCD), the apex body of 5.5 lakh chemists in the country, said chemists and druggists across India are seeing a 10-15% shortfall in medicines, especially antibiotics. "The flow of medicines has slowed down," he said.

The shortfall is in commonly-used drugs with active raw materials such as paracetamol (for fever and pain), cephalosporin (antibiotic), chloramphenicol (typhoid, cholera), betamethasone (anti-inflammatory for eczema), cefalexin (antibiotic for urinary and respiratory tract infections), methylprednisolone (bronchitis, arthritis), and prednisolone (asthma, rheumatoid arthritis).

Prasad Danave, honorary general secretary of Retail and Dispensing Chemists Association, said, "The shortage has led to chemists losing about 10% of their business."

The main reason for this shortfall is the decreased import of active pharmaceutical ingredients (API) - the raw materials used for manufacturing drugs - from China. India imports as much as 80% of its APIs from China as they are 10-50% cheaper than India-made ones.

But China clamped down on its manufacturing units during the Beijing Olympics to address concerns over pollution. Due to this, the supply of APIs to India was hit and prices shot up by 50-100%, said industry experts. AIOCD's Shinde said, "The scene during the Olympics was bad and though it's been long over, imports have still not stabilised. In August we had predicted the shortage to be around 30% by October-November. But it is about 15% now."

Tapan Ray, the director general of pharma body Organization of Pharmaceutical Producers of India (OPPI), said that the price of paracetamol is more than 100% higher than the December 2007 levels. Ranjit Shahani, vice chairman and managing director of Novartis India, said antibiotics such as azithromycin and clarithromycin are still up by 30-50% over the 2007 prices. "The depreciation of rupee against the dollar has also played a role in the API issue," he said.

According to Daara Patel, secretary-in-chief, Indian Drug Manufacturers Association (IDMA), the fall of rupee to Rs 49 against the dollar has upped the prices of raw materials by 25%.

Locally-produced APIs such as diclofenac (painkiller), carbamezapine (for epilepsy) etc, which depend on Chinese intermediates used for making drugs, are 15% above their 2007 price. According to Ranjit Kapadia, head (research), private client group at broking firm Prabhudas Lilladher, another factor that has caused API price rise is that the Chinese government has reduced export incentives to manufacturers by 7-13%. The price of packaging material has gone up too, say experts.

Healthcare Marketing - The New Focus

November 1-15, 2009, Express Pharma

<http://www.expresspharmaonline.com/20091115/market13.shtml>

Despite the global economic downturn, healthcare sector remains one of the fastest growing and steady sector globally. As many drugs are going off-patent and more and more generic drugs are making their way into the market, there are several points that need to be addressed in general public interest. In India, with the rise in health consciousness pharmaceutical companies are increasing their line-up of over-the-counter (OTC) products. Cosmetic surgery and dentist services are increasingly being availed by people today as they no

longer want to be perceived as just healthy, but also as being fit. To address these issues, a Health Marketing Conclave, the first of its kind in India, was recently held in Mumbai with an aim to promote awareness about health.

The conference had speakers from different sectors related to healthcare, eg, Vinita Bali, MD, Britannia Industries; Shrijeet Mishra, Executive Director, Foods, HUL; Saugata Gupta, CEO, Marico Industries; Vishal Bali, CEO, Wockhardt Hospitals Group; Dr Ajay Thakker, CM and CEO, Jupiter Hospital; Sudarshan Jain, Director, Healthcare Business, Piramal Healthcare; A Vaidheesh, MD, J&J Medical India; J S Pai, Executive Director, Protein Foods and Nutrition Development Association of India; **Tapan Ray, Director General, OPPI**; Rinita Singh, MD, Qantum Group; Kinjal Medh, COO, Cogita Consulting; and Abhijit Desai, Cosmetic Dermatologist and MD, Evolve Med Spa.

DoP to Convene Third Meeting on Unethical Marketing Practices

October 28, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=52320§ionid=>

The department of pharmaceuticals (DoP) will soon convene the third round of meeting between the government and the industry on the issue of evolving a common mechanism to discourage drug companies from bribing doctors for favours. Early this year, the DoP had initiated the move to implement strictly the code of pharmaceutical marketing ethics in the wake of increasing instances of inducements to doctors for favours and a series of media reports in this regard.

Secretary, DoP, Asok Kumar said that the department will soon convene the third meeting in this regard to find an amicable solution to the issue. Most probably, it will be held in the first week of November, he said. In the last meeting, Asok Kumar had asked the **Organisation of Pharmaceutical Producers of India (OPPI) to evolve a joint code of ethics for the industry** in a bid to curb the growing unethical trade practices. In the meeting, the OPPI is expected to submit the joint code ethics for the consideration of the government.

The second meeting on this issue was held on April 15. Though different pharma associations like OPPI, IDMA and SPIC had their own marketing code for their members, the DoP in the last meeting asked the associations to come out with a common code to be adhered by all companies belonging to different associations. **The task was then given to the OPPI to consult and compile these codes and hammer out a joint one.**

Generics Face Uniform Patent Norms Threat

October 17, 2009, DNA

<http://epaper.dnaindia.com/epapermain.aspx?queried=7&username=Masood&useremailid=masood18762%40gmail.com&parenteditioncode=9&eddate=10%2f17%2f2009>

Move to push uniform patenting norms at WIPO may whittle down pre-grant opposition. Patients suffering from swine flu in India have a choice of buying the medicine oseltamivir from Natco Pharma, Hetero Drugs and Strides Arcolab, etc all of whose brands are available in the market. This would not have been possible had the Delhi Patent Office in April granted a patent to the US based Gilead Science Inc's oseltamivir, which is marketed as Tamiflu

However, the multinational pharma lobby, **Organisation of Pharmaceutical Producers of India (OPPI)** feels that in order to facilitate India's further integration into the international economy while at the same time protecting our national interests, the government should support efforts for reforms at the WIPO. Says **Ranjit Shahani, president, OPPI**, "IP harmonisation could possibly make available almost parallelly all new global introductions related to niche indications (unmet medical needs) to Indian patients. Moreover, possibilities of Big Pharma investing in R&D infrastructure for TB, leprosy, would increase if there is meaningful implementation and harmonisation of IP."

Opportunities And Challenges In The Health Marketing Space

October 14, 2009,

<http://www.paperarticles.com:80/2009/10/opportunities-and-challenges-in-health.html>

Session IV:

Differentiating the 4 Ps of Health Marketing

The traditional 4 Ps of marketing cannot completely address the needs of health marketing. There are ways to sharpen the marketing mix for health related brands. The last session of the ET Health Marketing Conclave concentrated on the various strategies employed to differentiate health brands from brands of other consumer goods and services through case study examples.

Ms. Sukanya Kripalu, a strategic marketing consultant, moderated the session which had Mr. Neal Cavalier Smith, Managing Director, Healthy Marketing Team, **Mr. Tapan Ray, Director General, Organisation of Pharmaceuticals Producers of India (OPPI)**, Mr Kinjal Medh, Chief Operating Officer, Cogito Consulting and Dr Abhijit Desai, Cosmetic Dermatologist and Managing Director of Evolve Med Spa as panelists.

Mr. Smith presented the Wennstrom's Four Factor Model. According to this model, a marketer of a product needs to seek answers to four pertinent questions: who needs the product? Does the consumer understand the benefit of the product? Does she accept the ingredients of the product? And lastly but importantly, does she trust the product?

Mr. Ray put forth a classification of various health foods and pointed out the key growth drivers and challenges in health food market. He classified health foods into functional foods, dietary supplements, medicinal foods, nutraceuticals, phytochemicals, organic foods and sports nutrition. He noted that consumer awareness, surge in lifestyle-oriented diseases and ageing population were the key drivers for growth in the health foods market. Against this, lack of standardization in case of plant-based products is a major challenge for the industry.

The discussion during the session also highlighted the challenges and opportunities faced while distributing health related products and services, innovation in delivery mechanism to exploit the changing attitudes and motivations of consumers towards health and wellness.

In his discussion, Mr. Medh spoke of being a witness to a gradual change in the health market landscape. From calcium tablets to beauty products to wellness systems now, the change has been more and more inclusive. According to him, while the fundamentals of the four Ps won't change in case of health marketing, the way they are put into practice will and has undergone change. "As a service provider, we are in the process of learning the 4 Ps", said Dr Abhijit Desai from Evolve Med Spa. According to him, service providers need to explain the feature of the product to the consumer.

Patent Experts Pool Being Set Up To Advise Courts

October 7, 2009, Mint

<http://www.livemint.com/2009/10/07232135/Patent-experts-pool-being-set.html>

India's patent office last week launched an initiative to create a panel of independent experts who will, in turn, act as advisers to courts of law across the country in patent-related cases. The reasoning behind the move is that the Indian judiciary is still not fully conversant with the fine print of an evolving patents regime.

The decision follows a number of delayed or overturned judgements in courts across India due to the technical aspects of the law. While it is the patent office that has taken the initiative in this instance, the judiciary itself hasn't been hesitant to seek expert assistance in complex areas.

In 2002, it appointed N.C. Saxena and S.R. Sankaran as commissioners to advise it on issues related to a right-to-food litigation. And in 2008, it appointed an expert panel that includes environmentalist R.K. Pachauri to advise it on the controversial Sethusamudram project litigation.

"The need for maintaining a panel of experts for ready reference was felt after the court was even seeking advice from patent examiners and controllers to interpret the technologies," said a senior official from office of the controller general of patents, pointing to an obvious conflict of interest. He asked not to be identified because he is not authorized to talk to media.

The patent office's move has been welcomed by both lawyers and the pharmaceuticals industry, which is responsible for a significant volume of patent litigation.

"It will significantly help the judiciary to fairly understand the technical aspects of an intellectual property-related matter, which is comparatively difficult for a judge who doesn't have a technical background," said Pravin Anand, a patent lawyer and partner at Delhi-based law firm Anand and Anand.

An industry lobby of foreign drug makers present in the country expressed the hope that the process would be "transparent". "Improper selection of experts for this panel having a biased outlook could prove to be counterproductive, creating a protracted litigation process," said **Organisation of Pharmaceutical Producers of India director general Tapan Ray**.

Interestingly, an amendment made to India's patent laws in 2003 (Rule 103) requires a roster of advisers to be maintained and updated annually; however, this is the first time that the rule would be actually implemented.

The Controller General of Patents, Designs and Trademarks of India has invited applications from qualified persons for the department's scientific advisers panel. The advisers will appear before a court to assist it in patent infringement or other patent-related cases, where technical explanation of the patent is found necessary to resolve the matter. The courts are, however, not bound to seek advice from the expert panel and can call an independent expert of their own choosing.

Still, the patent office's move could only help things, said Anand. "It is difficult to locate technical talent in specialized areas of technology quickly, and to train them to understand the court process, which can be quite overwhelming," he said.

The Delhi high court had in 2008 appointed a professor of Indian Institute of Technology for advice on a product patent challenge filed by Imco Alloys Pvt. Ltd against a patent for a sugarcane crusher awarded to Polytech Pvt. Ltd. The scientific adviser's report, which was submitted

last month, suggested invalidating the patent granted by the Delhi patent office.

Several interim orders passed by lower courts in recent patent-related cases involving drug makers Novartis AG and Bayer AG, and automobile firm Bajaj Auto Ltd, among others, have invited serious criticism from patent and industry experts.

The patents office will have to pay the advisers selected by the court for their work.

PCT Reforms at WIPO Will Benefit Indian Innovators, Exporters: OPPI

October 5, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=51964§ionid>

The **Organisation of Pharmaceutical Producers of India (OPPI)**, which represents multinational pharma companies in the country, has joined issue with the forces who are opposing the efforts of the developed nations at WIPO for the patent harmonization which is feared to undermine the flexibilities available under TRIPS. While several public interest organisations have urged the government to oppose any move on harmonization of patent administration as it can fundamentally change the way in which substantive decisions about granting patents are taken by the patent offices in developing countries, the OPPI argues that the proposed changes in the PCT (patent cooperation treaty) are an opportunity for countries like India. Hence, the OPPI has urged the Indian government to continue its support for efforts such as 'WIPO PCT Reform' that seek to facilitate India's further integration into the international economy while at the same time protecting Indian national interests.

Criticising those who oppose the move, **OPPI director general Tapan Ray** said that the proposed changes in the PCT have indeed important ramifications for countries like India, as they represent the greater opportunities that the PCT changes will provide Indian commercial interests through an improved international patent search and examination process. "As the third largest user among developing countries of the PCT system, India has a particular interest in ensuring that the PCT system supports its innovators and exporters in the most efficient manner possible," he said.

Patent Bill to Hurt Public Interest: Expert

September 21, 2009, Mint

A patent and intellectual property rights Bill modelled on a 1980 Act of the US Congress and due to be tabled in the Parliament's December session is drawing criticism from researchers and academics for not addressing key issues and jeopardizing public interest.

Tapan Ray, director general, Organisation of Pharmaceutical Producers of India, an industry body that represents foreign drug firms operating in India, said, "The core concept of the Bill encourages innovation and ensures protection of patents and other forms of IP rights of the government-funded R&D outcomes, where the owner of the intellectual property will be the government grant recipient or the government.

Presentation on "Fight against Counterfeit Goods and why it matters to us?" by Mr. Tapan Ray on September 15, 2009 at New Delhi

Mr. Tapan Ray, Director General, OPPI, addressed the Seminar on "Counterfeit Products & their Impact on Consumer Safety" held in New Delhi on 15th September, 2009. The Seminar was organised by the United States Patent and Trademark Office, U.S. Embassy in collaboration with the Council of the European Union, the British High Commission, the International Federation of Spirits Producers (IFSP) and OPPI. Mr. Ray made a presentation on "Fight against Counterfeit Goods and why it matters to us?"

Presentation on "Overview of the Pharmaceutical Industry" by Mr. Tapan Ray on September 11, 2009 at Mumbai

Mr. Tapan Ray, Director General, OPPI, was invited to address the DHL Leadership Dialog - Life Science & Healthcare Conference held in Mumbai on 11th September, 2009. The event was a gathering of key experts collaborating to discuss major developments in supply chain management in order to provide an unparalleled environment for networking, learning and sharing of best practices. Mr. Ray presented an "Overview of the Pharmaceutical Industry" covering Healthcare Environment, Indian and Global Pharmaceutical Market, Healthcare Policy, Pricing & Financing, etc.

Patent Laws Affect Drug Innovation

August 27, 2009, Hindustan Times

India's patent laws are stifling incremental drug innovation, according to a report prepared by the United States India Business Council (USIBC) supported coalition for healthy India, White & Case and Dua Consulting.

Ranjit Shahani, President of Organisation of Pharmaceutical Producers of India who is also the Vice Chairman & Managing Director of Novartis, said the industry is in talk with the government for bringing changes in Section 3 (d) of the Indian Patent Act.

Big Pharma Companies Join Outsourcing Queue

August 17, 2009, Business Standard

<http://www.business-standard.com/india/news/big-pharma-companies-join-outsourcing-queue/367178/>

India emerging as a big global destination for contract manufacturing, unlike R&D outsourcing Ahmedabad-based Dishman is a specialist contract manufacturing company. So is Jubilant Organosys. Revenues of both companies from their contract research and manufacturing services (Crams) went up by 29 per cent and 41 per cent, respectively, in the last financial year.

That hasn't escaped the attention of even formulation manufacturers such as Dr Reddy's Laboratories, Aurobindo, Lupin and Wockhardt. All of them have started giving more focus to securing outsourcing contracts from Big pharma.

There are many reasons why India is emerging as an inviting destination for outsourcing drug production. **A report by Ernst & Young and the Organisation of Pharmaceutical Producers in India** said that over 80 per cent of the 38 big and medium-sized pharma companies across the world rated India higher than China, Eastern Europe, Puerto Rico, Singapore and Ireland.

E&Y estimates the Indian drug production outsourcing industry to grow over 43 per cent annually, thrice the global growth rate. Research agency Frost & Sullivan estimated this segment for the Indian industry to reach over \$6.5 billion by 2013.

Pharma Outsourcing to Touch \$2.3b

August 15, 2009, The Economic Times

Riding over lower manufacturing costs and availability of quality manpower with technical capabilities, the Indian pharmaceutical outsourcing industry is expected to touch \$2.3 billion by the end of the 2010, **according to a report, jointly prepared by global consultancy firm Ernst & Young and industry body OPPI**, said Indian pharmaceutical contract manufacturing industry is growing at thrice the rate of the global outsourcing market, and is expected to reach \$2.3 billion from \$1.1 billion in 2008. "India scores well on its ability to create a differentiating cost value proposition, powered by its lower manufacturing cost and manpower and technical capabilities, but it needs to improve on its culture of environment and health safety compliance and infrastructure," the report said

Three NIPER Faculty Bag OPPI Awards for 2009

August 14, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=51209§ionid=5>

Professor P V Bharatam, Department of Medicinal Chemistry and Dr Sanyag Jain, assistant professor, Department of Pharmaceutics of National Institute of Pharmaceutical Education and Research (NIPER), SAS Nagar have bagged the prestigious OPPI scientist and Young scientist Awards for the year 2009, respectively. Further, Dr Shyam S Sharma, associate professor, Department of Pharmacology & Toxicology will receive the prestigious Indian Council of Medical Research (ICMR) Shakuntala Amir Chand Prize for the year 2008 for his significant contribution in the area of stroke research.

The Organisation of Pharmaceutical Producers of India (OPPI), Mumbai has instituted 'Scientist Awards' in collaboration with NIPER, as a part of its Public Private Partnership initiative to honour outstanding Research Scientists working in India to encourage scientific culture. The award has been set-up with the objective to recognize scientific contributions of significance from scientists in India in the field of human healthcare. Each award carries a cash prize of Rs 1, 00,000, Citation and a Trophy.

India To Grow Faster in Pharma Outsourcing Among Emerging Markets, E&Y-OPPI Study

August 12, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=51153§ionid=5>

The pharma outsourcing industry, both the custom manufacturing and contract research, are poised to grow thrice the global market rate in near future with more global pharmaceutical companies opting strategic partnership with Indian companies when compared to other emerging pharma markets, according to a study.

The study, 'Taking Wings-Coming of age of the Indian pharmaceutical outsourcing industry', released by **the leading professional services firm Ernst & Young (E&Y) and the Organisation of Pharmaceutical Producers of India (OPPI)** states that the custom manufacturing outsourcing in India is growing at a rate of 43 per cent that is thrice the global market. The growth is driven by the Indian companies' ability to create a differentiating cost value proposition powered by its lower manufacturing costs, skilled manpower and strong technical capabilities.

In a survey conducted to assess relative attractiveness in custom manufacturing outsourcing of six countries - India, China, Eastern Europe, Puerto Rico, Singapore and Ireland with 38 respondents across 17 big and medium pharma companies, 67 per cent of respondents rated India as an excellent destination for cost efficiency in manufacturing outsourcing. India is offering manufacturing services with cost around 35-40 per cent of the cost of manufacturing in the US.

DoP Plans Major Projects to Boost Pharma Manufacturing, R&D and Medical Devices Sector

August 11, 2009, Pharmabiz

The Central government, through the Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilisers, is contemplating major projects including establishment of two pharma clusters, a pharma city, a vaccine development centre and four R&D hubs in the country to augment the manufacturing and R&D capacity of the Indian pharmaceutical sector.

As the first phase of the proposed Pharma India Vision 2020, which emphasises on developing adequate infrastructure to support the expected growth in the India pharma industry, the department will set up a Pharma City in Andhra Pradesh. The DoP is in talks with the Andhra Pradesh Industrial Infrastructure Corporation to develop an 800 to 900 acre cluster in Hyderabad, said Ashok Kumar, secretary, DoP on the sidelines of **the 43rd Annual General Meeting of Organisation of Pharmaceutical Producers of India (OPPI) in Mumbai.**

Pharma Sector in for an R&D Boost From Govt

August 10 2009, The Times of India

<http://economictimes.indiatimes.com/News/News-By-Industry/Healthcare-Biotech/Pharmaceuticals/Pharma-sector-in-for-an-RD-boost-from-govt/articleshow/4875505.cms>

The pharmaceutical industry in India is likely to see added stimulus in coming months. The department of pharmaceuticals (DoP) has put forth a number of proposals to the government which will help boost the pharma sector in the country, said Ashok Kumar, secretary of DoP, on Saturday **at the AGM of the Organisation of Pharmaceutical Producers of India (OPPI).**

One of the proposals includes setting up of 800-900 acre pharma city in Hyderabad, for which talks are already under way with the Andhra Pradesh Industrial Infrastructure Corporation (APIIC) – the organisation that developed the Pharma City at Vishakapatnam.

“Talks are on with APIIC and once a memorandum is signed, work will start. However, this is still in the initial stages and should take about two years,” Mr. Kumar said. The idea behind developing a pharma city in Hyderabad was strengthened by the presence of the National Institute of Pharmaceutical Education and Research (NIPER), which could take care of the human resource needs of the companies.

The department has also proposed developing Chennai, Pune, Mumbai and Kolkata as R&D centres and plans to provide the required infrastructure to attract both MNC and Indian companies to set up their research facilities there to promote innovative research.

The government’s Jan Aushadhi programme to set up generic drug stores in each district of the country is spreading its reach after a successful start in Punjab, Haryana and Rajasthan. The government now plans to open centres in Orissa, Delhi and Andhra Pradesh. “Four centres have been identified in Orissa and four hospitals in Delhi have offered us space to set up the store,” Mr Kumar added.

The government is also in talks with some vaccine companies for the vaccine development centre, Mr Kumar said. “We want contemporary vaccines to be made here. We are not interested only in manufacturing. If you don’t have a manufacturing plant in India you can import it. We want the R&D centre to be here and it can be done exclusively by the company or in partnership with the government.

At present, we have spoken to two companies about this,” he said. With all these initiatives being proposed by the government to boost the pharma sector and showcase India as an ideal place to conduct end-to-end research, APJ Abdul Kalam said: “It has been predicted that the Indian pharma industry will touch \$50 billion by 2015. I think it is possible for the industry to touch \$100 billion by 2015 if you start work now.”

India to Turn Pharma Hub

August 9, 2009, Asian Age

<http://trak.in/india/india-to-turn-pharma-hub/india-16665/>

The department of pharmaceuticals will soon chart a roadmap for the Indian pharmaceutical industry towards becoming a global power by the year 2020. The government will give an impetus to the industry to help make India a global hub for end-to-end pharma discovery.

The recognition of India’s technical skills and low costs by MNCs is believed to be the reason behind such an ambitious plan.

Vision 2020, which was presented by Mr Ashok Kumar, secretary, the department of pharmaceuticals, **at the 43rd AGM of Organisation of Pharmaceutical Producers of India (OPPI) in Mumbai,** will cover various programmes to increase India’s share in the research and development business.

OPPI to Come Up with 4 Research and Development Hubs in Major Cities

August 9, 2009, UNI News

<http://www.newkerala.com/nkfullnews-1-88601.html>

Organisation of Pharmaceutical Producers of India (OPPI) today said that it will create four Research and Development (R and D) hubs each in Pune, Mumbai, Chennai and Kolkata by next year.

Talking on the sidelines of the 43rd Annual General Meeting here, Union Ministry of Chemical and Fertilisers, Department of Pharmaceutical Ashok Kumar said the Indian pharmaceutical companies were competent enough to produce cost effective and quality pharma products.

Quoting a McKinsey report, Mr Kumar said the Indian Pharma market would reach USD 25 billion in 2010 and USD 50 billion by 2015 adding that the sector should work hard to achieve USD 100 billion by 2020.

Present on the occasion was former President Dr APJ Abdul Kalam, who said the global production of pharmaceuticals, both branded and generics, was USD 70 billion and India contributes over USD 17 billion of generic products for both domestic and international market.

Dr Kalam, on behalf of OPPI, presented various awards like, OPPI Scientist Award and OPPI Young Scientists Award, to recognise, honour and encourage outstanding performance in the pharmaceutical sector.

The organisation also announced its collaboration with two premier R&D oriented institution-- National Institute of Pharmaceutical Education and Research (NIPER) and Council of Scientific and Industrial Research (CSIR)-- as part of its Public-Private Partnership (ppp) initiative to encourage innovativeness in research work. --- UNI

Low Costs A Draw for Foreign Drug Makers

August 9, 2009, Livemint

<http://www.livemint.com/2009/08/09220823/Low-costs-a-draw-for-foreign-d.html?d=2>

Low costs, high technical capabilities and a skilled work force are making India an attractive destination for research and contract manufacturing of drugs

In spite of concerns over intellectual property rights and data protection, overseas drug makers now see India as an attractive destination for research and contract manufacturing.

This is mainly because of low costs, high technical capabilities and a skilled work force, a report released

on Saturday by industry lobby group **Organisation of Pharmaceutical Producers of India (OPPI)** and consultancy firm **Ernst and Young** has found.

As many as 67% of at least 50 respondents from 30 pharmaceutical firms in the US, Europe and Asia rated India as an excellent destination for contract manufacturing, according to the report "Taking Wings: Coming of Age of the Indian Pharmaceutical Outsourcing Industry".

The respondents cited cost efficiency, which is about 35-40% of those incurred in the US, as one of the main reasons for this.

"The country will see several new partnership deals between large-scale drug makers from across the world and local players coming up in this segment in the next few years," said Ajit Mahadevan, partner, health sciences practice, Ernst and Young.

Ranjit Shahani Elected OPPI President

August 8, 2009, Samaylive

<http://www.samaylive.com/news/ranjit-shahani-elected-oppi-president/644727.html>

Organisation of Pharmaceutical Producers of India (OPPI), today elected Novartis Vice-Chairman and Managing Director, Ranjit Shahani, as its President.

He takes over from Wyeth MD, Ranga Iyer. His election was announced at OPPI's 43rd Annual General Meeting held here today. He would be President for two years.

Pharma Secretary, Ashok Kumar, who gave the key note address, said the department has identified two clusters for development of clean technology.

How Real is the Threat of Counterfeit Medicines?

July 21, 2009, The Economic Times

<http://economictimes.indiatimes.com/Opinion/ET-Debate/How-real-is-the-threat-of-counterfeit-medicines/articleshow/4801127.cms?curpg=2>

Incidence high in countries where access to medicines is poor

Tapan Ray, Director-General,

Organisation of Pharmaceutical Producers of India

It's an MNC agenda to prevent competition

Anand Grover, Director, Lawyers' Collective HIV/AIDS Unit

A study by the WHO's International Medical Products Anti-Counterfeiting Taskforce (IMPACT) indicated in 2006 that in countries like the US, EU, Japan, Australia, Canada and New Zealand, the incidence of spurious/counterfeit drugs is less than 1%. On the other

hand, in parts of Asia, Latin America and Africa, more than 30% of the medicines are counterfeits.

In south-east Asia, estimated prevalence of counterfeit Artesunate for malaria is 33-53%. It appears that in all those countries where access to modern medicines is poor, incidence of counterfeit medicines, ranging from anti-malarial, anti-hypertensive, anti-tubercular, anti-retroviral to cardiovascular and other life-saving and life-style drugs, are higher.

As per an estimate, the value ascribed to counterfeit medicines across the world will reach \$75 billion by the end of 2010, up 90% over the 2005 level. WHO said incidence of detection of counterfeit medicines in 2007 had increased to more than 1,500, ten times that in 2000. It also indicated that in 2005-06 the volume of counterfeit drug seizures included 2.7 million articles and the main countries where these articles originated from were India: 31%, UAE: 31% and China: 20%.

So, enough data are available to establish that counterfeit drugs are posing a growing menace to the humanity. All stakeholders should join hands to address this public health issue, leaving aside petty commercial interests, be it generic companies or R&D-based ones. Otherwise, thugs and criminals who are running to their banks, more often than ever before, with sacks full of money from this illicit trade, at the cost of the innocent patients, will keep going almost scot-free, for ever.

The concern of IPR being extended to the definition of counterfeit medicines is misplaced. As even in India, 'misbranding' though an integral part of IPR, is considered as a public health issue and is an offence under the Drugs and Cosmetics Act. The magnitude of this problem is anybody's guess. Earlier, a WHO-sponsored study by SEARPharm reported that only 0.3% drugs in Indian market were spurious and 3% of drugs were counterfeits.

The Drugs Controller General of India has initiated a study with 61 popular brands from nine therapeutic categories for testing 24,000 samples. The study is expected to cost Rs 5 crore and is expected to be published soon.

Weighing The Verdict

July 16-31, 2009, Express Pharma

<http://www.expresspharmaonline.com/20090731/managment01.shtml>

It is the time of the year when the whole industry is busy analysing the effects of the budget, finding out on how much of their demands have been met with and which ones were overlooked. Suja Nair gets the reactions from the industry

Thumbs up

Giving his reaction to the budget **Tapan Ray, Director General, Organisation Of Pharmaceutical Producers Of**

India feels, "The Finance Minister has rightly focused on improvement of the healthcare infrastructure by increasing allocation under National Rural Health Mission (NRHM). The budget proposal of covering all BPL families under Rashtriya Swasthya Bima Yojana (RSBY) with an increase in allocation by 40 percent will help in improving healthcare access. Though reduction of customs duty for drugs used for heart diseases, influenza vaccine, breast cancer, hepatitis B, rheumatic arthritis and also for bulk drugs used for the manufacture of such drugs from 10 percent to five percent and total exemption of excise and countervailing duty for these drugs is a positive move, the industry expected that Government will take similar action for all life-saving drugs."

The Economic Survey 2008-09 highlights that the economy of the country has grown by 6.67 percent despite global economy meltdown. For the pharma industry, the Economic Survey comments that the drugs price control should be limited to essential drugs in which there are less than five producers. All others should have been decontrolled. OPPI hopes that this issue will be addressed in subsequent policy announcements by the Government.

Enjoining with Ray, Ranga Iyer, President, OPPI says, "The healthcare needs of the country have been given importance in the Union Budget proposals for 2009-10 and the proposals will help in improving the healthcare needs of the country."

It's A Mixed Bag for Pharma; FBT Removal to Help

July 8, 2009, Financial Express

<http://www.financialexpress.com/news/its-a-mixed-bag-for-pharma-FBT-removal-to-help/486325/>

The Indian pharmaceutical industry, which had high hopes from the Budget, was again forced to be contended with typical custom duty cuts and extension of weighted deduction for R&D projects, as it has not got any major support from the government. Moreover, the industry is concerned about the increase of the Minimum Alternate Tax (MAT) to 15% from 10%, which is expected to hit them hard.

Customs duty cut on 10 specified life-saving drugs/vaccines and bulk drugs from 10% to 5% with nil CVD (by way of excise duty exemption) and customs duty cut on specified heart devices, namely artificial heart and PDA/ASD occlusion device, from 7.5% to 5% are the major aids given to the industry. Allocation under the National Rural Health Mission (NRHM) increased by Rs 2,057 crore over Rs12,070 crore allocated in the interim budget 2009-10. Allocation for all BPL families under the Rashtriya Swasthya Bima Yojana has been increased by 40% over previous allocation to Rs 350 crore. Also, the fringe benefit tax (FBT) was abolished.

Though **Tapan Ray**, director general, **Organisation of Pharmaceutical Producers of India** welcomed the benefits allowed for the industry, he said the government should announce tax cut for all the life-saving drugs....

Pharma Sector Welcomes Customs, Excise Cuts

July 7, 2009, Hindustan Times

http://enews.ttnet.net/cgi-bin/enews.cgi?date=20090707&src=_t0707007.5ke&chap.html

The pharmaceutical industry has largely welcomed the proposal from the finance minister to reduce excise and customs duties on life-saving drugs and devices. The mood in the industry was largely upbeat following the minister's announcement focussing on rural healthcare. Industry leaders, however, said important sops, particularly on price control and sops to research-focused companies, were missing.

Tapan Ray, director general, **Organisation of Pharmaceutical Producers of India (OPPI)**, said the budget failed to take into account a critical comment from the Economic Survey published last Thursday which said, "The drugs price control should be limited to essential drugs in which there are less than five producers. All others should have been decontrolled".

Major Pharma Industry Bodies Welcome Union Budget for 09-10

July 6, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=50566§ionid=>

The pharma industry has by and large welcomed the Union budget presented in Parliament today by finance minister Pranab Mukherjee. While the industry is happy with continuation of excise duty at 4 per cent, a section of the industry had anticipated more from the finance minister.

Welcoming the budget, **OPPI director general Tapan Ray** said that the reduction of customs duty for drugs used for heart diseases, influenza vaccine, breast cancer, hepatitis B, rheumatic arthritis and also for bulk drugs used for the manufacture of such drugs from 10 to 5 per cent and total exemption of excise and countervailing duty for these drugs will help reduction of transaction costs of these medicines.

When we Think Of Pharmaceutical and Biotechnology Industry One Issue that Comes to Our Mind is Patent Protection. How Are Companies

Coping with Evolving Patent Laws? Ms. Suja Nair Reports.....

May 16, 2009, Express Pharma

Is Protectionism a matter?

In both cases, the ruling was against the MNCs and in favour of generic companies. Both cases have been high-profile cases where landmark decision was given. Is this a show or protectionism on the part of Indian Judicial system towards generics?

Expressing his views, **Mr. Tapan Ray**, Director General, **OPPI**, opines, "In its current form the patent laws appear to be somewhat protective in nature towards the domestic generic companies. Absence of data protection and less than adequate patent enforcement mechanism within the country will bear testimony to this fact. Probably because of all such reasons, in the Pharma space, India is attracting much lesser foreign direct investments than China, in the post IPR regime."

It seems that at present India needs a robust enough patent management systems and procedures within the country, for the countries own interest. Such world class patent management systems will be able to protect the long term interest of the innovators of India and not just for the acceptability by the West. Ray points out.

Take on patent law in India.....

Mr. Tapan Ray informs, "The patent management strategies in our country are evolving and may be for that reason, are not robust enough, as yet. When we compare India with China, it can be noticed that there is still some work needed to be done. For instance there is a big gap within the patent management system which undoubtedly shows the absence of regulatory data protection.

Dept of Pharma to Organise International Meet on Pharma Industry in Mumbai in Nov.

May 16, 2009, Pharmabiz

The Department of Pharmaceuticals, in association with FICCI and other pharma organisations, is organising an international conference on pharmaceuticals in Mumbai on November 30, ahead of the proposed CHI happening from next day, to showcase strength of Indian companies.

A meeting, called by Pharma secretary Ashok Kumar recently, decided to organise the event in a bid to lure the big traders from the developed countries and thereby giving a fillip to the exports from the country by showcasing the strengths of the domestic industry. The meeting was attended by joint secretary Arun Jha, deputy secretary Paresh Johri, representatives from organisations like SPIC, IDMA, BDMA and **OPPI**, experts

from UNIDO, Pharmexcil and CPhI organisers to chalk out the detailed plan for the event.

OPPI Calls Meeting of Pharma Bodies on May 12 to Evolve Code of Ethics for Marketing

May 4, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=49518§ionid=43>

As desired by the Department of Pharmaceuticals, the Organisation of Pharmaceutical Producers of India (OPPI) will hold a brainstorming session in Mumbai on May 12 with other pharma associations to evolve a joint code of ethics for the industry in a bid to curb the growing unethical trade practices.

The joint meeting is expected to be attended by different organisations representing small and large pharma sectors and it will work out a common code of ethics to be submitted to the department for final clearance and implementation with a view to reign on the sales promotions and increasing unethical practices like inducing doctors, sources said. Invitations have been sent to all the concerned associations.

The department wanted the associations to bridle own members and warned that the department would intervene if the organisations failed to do so. Two meetings were already held by pharma secretary Ashok Kumar with the pharma associations and finally entrusted the job of compiling the **common code with OPPI which was one of the pioneers to introduce guidelines to its members**

DCGI, Ranga Iyer, Anji Reddy Among 40 Most Powerful Pharma People

April 30, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=49490§ionid=17>

DCGI Dr Surinder Singh, **OPPI President Ranga Iyer**, and Reddy's Laboratories chairman Dr Anji Reddy have been selected as among the 40 most influential personalities of the global pharma industry by the World Pharmaceutical Frontiers.

The annual list of 2009, judged by their contributions to the pharma industry, is led by US president Barack Obama. It also has some other well-known names like Bill and Melinda Gates, former US president Bill Clinton, WHO director general Margaret Chan among others including the heads of a number of global pharma majors. But there are only a very few from Asian region and all the three Indians in the list have made it this time as new entrants, while many of others were there in the previous list also.

Common Ethical Code for Sales Promotion Planned to Check Inducements to Docs

April 20, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=49311§ionid=43>

A common ethical code of conduct for all pharmaceutical companies, instead of separate guidelines by different organisations for their members, is likely to be framed to check the increasing unethical trade practices in the name of sales promotions.

A meeting convened recently by the Department Secretary, Ashok Kumar and attended by different pharma organisations and CEOs of member companies have decided to entrust the **OPPI** to take the lead in framing the common ethical code for marketing. A brainstorming session, involving experts and representatives of the industry, will be held by the end of May in Mumbai in the run-up to framing the code and the **OPPI** will compile the common code by obtaining guidelines from other associations.

Pharma MNCs Vie for the Indian Pie

April 13, 2009, DWS Pill Scribe

<http://www.dancewithshadows.com/pillscribe/pharma-mncs-vie-for-the-indian-pie/>

Pharma multinationals are getting more aggressive about India despite patent concerns. The Indian pharma market is high on the radar of global pharma MNCs, as they continue their push into emerging markets. More and more pharma giants from the top league are seeing greater opportunities in the developing economies as they find their revenues in major markets stall.....

In addition to a large consumer base, a higher level of sophistication in manufacturing and research achieved by the Indian firms is another lure for the MNCs. "Big pharma is tapping into India's research skills for new drug discovery and trying to cut down the time to market through 24/7 operations," explained **Mr Ranga Iyer, president, Organisation of Pharmaceutical Producers India** - the representative body for MNCs.

DBT Planning Separate Guidelines for Pre-Clinical Approval of Biologicals

April 7, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=49115§ionid=3>

The Department of Biotechnology (DBT) has started the process of framing a set of guidelines for the biologicals upto the clinical stage so that the process of approvals could be simplified and made more transparent.

The Organisation of Pharmaceutical Producers of India (OPPI), sometime back, had submitted a detailed representation to DCGI to consider classifying all biosimilar products as new products enforcing all the procedures needed for the approval of a new product in the market. The biosimilars vary from the innovators due to their nature and complexity of manufacturing process, though the sameness of molecular structure in chemistry based generic medicines is very much defined.

Any alteration to the manufacturing process of biological drugs may result in a completely different product and it should not be considered as a similar product to the original biopharmaceutical product from the innovator company, **according to OPPI**.

Protect Or Perish

March 22, 2009, Business Today

http://businesstoday.intoday.in/index.php?option=com_content&task=view&id=10393&Itemid=1&issueid=51§ionid=25&latn=2&limit=1&limitstart=1

Perhaps the most contentious debates and legal disputes that have taken place so far are in the pharmaceutical industry. Here, big money is at stake as foreign pharmaceutical companies, anxious to avail of the Indian market as well as talent for their R&D efforts, are increasingly flocking to the country. However, they have also encountered companies such as Cipla, who regularly introduce generic—and far cheaper—versions of the foreign firms' drugs into the local market, and export them to countries like South Africa, which receive a large quantity of Cipla's HIV drugs. "What is at stake is the debate on one hand that India should be giving weight to a development issue that seeks to offer medicines at affordable cost, and on the other that India should strictly adhere to the patent protection and preserve the cause of innovation," says a top attorney, who did not wish to be named.

While that debate may not have a resolution anytime soon, what is a certainty, however, is the rash of lawsuits that have and will continue to take place in the industry, primarily over patent infringement. Much of the controversy rests on a provision known as Section 3 (d) of the Indian Patent Act that says that derivatives of a known substance are not considered worthy of a patent unless they enhance the efficacy of that substance—done in order to prevent western drug companies from making superficial changes in the drug in order to extend the run of their expensive, blockbuster products.

The Generic Argument

March 22, 2009, Business Today

http://www.businesstoday.intoday.in/index.php?option=com_content&task=view&id=10393&Itemid=1&issueid=51§ionid=25&latn=2&limit=1&limitstart=1

Point: Mr. D.G. Shah, Secretary General, Indian Pharmaceutical Alliance

- Under the Trade Related Intellectual Property Rights (TRIPS) Agreement, India decided to protect against "evergreening"—where new forms of a known substance are not granted patents.
- However, several pharma patents have been granted to new forms of known substances and combinations of old drugs.

Counterpoint: **Mr. Tapan Ray, Director General, Organisation of Pharmaceutical Producers of India**

- One of the major drawbacks of the new patent regime is the lack of effective product patent enforcement. A major issue is how the same government which grants patents to innovators gives marketing approval to generic equivalent of the same molecule.
- Patent enforcement should not be linked with "affordability" of medicines.

Indian Industry Divided Over Review of 86 Patents

March 20, 2009, SCRIP

A recent request by Indian companies seeking the re-examination of 86 local patents for reasons such as inadequate scrutiny has evoked strong reactions across industry.

The Organisation of Pharmaceutical Producers of India (OPPI), which represents multinational companies, said that India's existing patent system offers adequate opportunity to challenge patents that have allegedly been granted wrongly.

"After publication of the patent applied for in the patent journal, one can file a pre-grant opposition. Assuming someone has missed this opportunity, the provision for filing post grant opposition will still be there", **Tapan Ray, Director General of OPPI**, told Scrip.

FMHG Market in India - A Close View (Industry Lobbying)

March 16-31, 2009, Express Pharma

The Organisation of Pharmaceutical Producers of India (OPPI) has submitted a list of 11 molecules to the DCI to be excluded from Schedule H paving way for the initiation of responsible self medication as the first line of health management.

New 'Cold Chain' Facility for Delhi Airport

Friday, Mar 13, 2009, Hindu Business Line
<http://www.hindu.com/2009/03/13/stories/2009031356790400.htm>

Drugs are complex entities and many of them are temperature-sensitive in nature'Mumbai airport has already installed four new cold rooms for pharmaceuticals

With the objective of maintaining precise and continuous temperature conditions in transit in order to retain potency and resultant efficacy of life-saving drugs and vaccines, the **Organisation of Pharmaceutical Producers of India (OPPI)** has tied up with Delhi International Airport Limited (DIAL) to overhaul and add to the existing cold chain facility in the Capital.

Problems

"The Government on its part should ensure proper cold room facilities at airports. It is unfortunate that the pharmaceutical industry is facing such problems despite giving substantial revenue to the Government in exports and imports of goods," added Mr. Ray.

Indian Industry Divided Over Review of 86 Patents

Published Online: 10/03/2009 By Anju Ghangurde

A recent request by Indian companies seeking the re-examination of 86 local patents for reasons such as inadequate scrutiny has evoked strong reactions across industry.

The Organisation of Pharmaceutical Producers of India (OPPI), which represents multinational companies, said that India's existing patent system offers adequate opportunity to challenge patents that have allegedly been granted wrongly. "After publication of the patent applied for in the patent journal, one can file a pre-grant opposition. Assuming someone has missed this opportunity, the provision for filing post grant opposition will still be there," **Tapan Ray, director general of OPPI**, told *Scrip*.

If both the opposition opportunities are missed, there still exists the option of going to court to invalidate such patents, OPPI added. "In the absence of any of the above measures not being taken, the reasons and motive behind allegations that Section 3d is being violated, are indeed very difficult to understand," Mr Ray said.

Keynote Address by Mr. Ranga Iyer, President, OPPI, & Managing Director, Wyeth

'Globalization - Leveraging Opportunities in Pharmaceuticals'

Pharma World Expo 2009, February 13, 2009, Mumbai

Talking about globalization of the Indian pharmaceutical industry is like carrying coal to Newcastle, as the English saying goes. I'd say it is like carrying sandalwood to Mysore!

The pharmaceutical industry is among the most globalized industries in India. Statistics show that globalization is accelerating with each passing year. Indian companies have filed more than 240 DMFs with the US FDA - more than any other country. India has more than 100 FDA-certified manufacturing plants - the largest number of FDA approved plants outside North America. US FDA now has its office in India.

There was a time when globalization meant exports out of India. That was only the baby step in globalization. India's ambitious entrepreneurs have invested more than \$ 2 billion in recent years in outbound mergers and acquisitions, creating Indian-owned multinationals. Chances are that some of the generic medicines you may purchase anywhere in the world today may have an Indian connection. Exports of pharmaceuticals today are equivalent to the total domestic sales.

.....
 Most of the multinationals increasingly prefer China over India. GSK is making big ticket investment in China, betting that the future of drug development will be led by China. In his keynote address titled "From Made in China to Discovered in China" at the China Trials 2008 Global Clinical Development Summit in Shanghai, Perry Nisen, senior vice president, cancer research at GSK, emphasized the importance of China with regard to GSK's global strategy. He said that if GSK's China initiative is not successful, it is going to hurt the company because it has invested so much there.

GSK is not the only Big Pharma to set up R&D centre in China. It is followed by Roche, Pfizer, AstraZeneca and Novartis and Ely Lilly.

The Big Pharma is increasingly more comfortable in China than in India. Much of that comfort comes from an increasing trust in China's patent laws which have been getting stronger. China moved late in 2006 to protect the intellectual property of Pfizer's Viagra, while Novartis lost a patent case in India over a cancer drug on the ground that it was only an incremental innovation.

.....
 Henry Kissinger said that a nation has no permanent friends or enemies -- it has permanent interests. It is in India's interests, and in the interest of the patient, that we seize global opportunities in pharmaceuticals to emerge as the choice destination for the world's leading companies - Indian as well as foreign - to conduct research and manufacture in India for the world at large.

Let us capitalize on the opportunities thrown up by the global recession.

OPPI'S Initiative Results in Improving Cold Chain Facilities at Major Airports

January 29, 2009, IndiaPRwire.com

Drugs are complex entities and many of those are temperature sensitive in nature. This entails them requiring precise and continuous temperature conditions in transit in order to retain their potency and resultant efficacy. Life saving drugs and products like vaccines are very sensitive to proper cold chain. Any slippage in cold chain can lead to immediate denaturing or deterioration in quality of the product. It is imperative that a careful consideration is given by the authorities while providing storage space at the airport warehouses before drugs find their way into the distribution channels run and controlled by the Drug companies.

With a view to take the initiative to improve the Cold Chain Management at Mumbai and New Delhi airports, OPPI has taken up this cause with major stakeholders, particularly, Mumbai International Airport Pvt. Ltd. (MIAL) and Delhi International Airports Ltd. (DIAL), where 80-90% of the export & import trade of pharmaceuticals take place. OPPI delegation met with the Senior Officials of GVK in Mumbai and GMR in Delhi, who are the custodians of the respective airports.

To bring in learnings in this area, OPPI organized a seminar with support from MIAL on, "Cold Chain Management of Pharmaceutical Products" at Sahar Air Cargo Complex, Mumbai, for various stakeholders, including porters and supervisors. This was followed by a visit of Supervisors and Managers to Roche Distribution Centre, Mumbai.

OPPI plans to make this an ongoing exercise to partner continually with Port authorities and also provide training to the handling staff to ensure proper compliance. The coming months will see a major boost in cold room infrastructure and better facilities at the Mumbai & Delhi airport due to the initiatives taken by OPPI.

WHO Won't Redefine Fake Drugs

January 27, 2009, The Economic Times, Sushmi Dey & Khomba Singh, ET Bureau

<http://economictimes.indiatimes.com/rssarticleshow/4034234.cms?prtpage=1>

In a major victory for India's cheap but high quality generic drug industry, the World Health Organisation (WHO) has decided to shelve its plans of redefining counterfeit medicines a move that could have posed a threat to sale and export of legitimate generic medicines, a government official said.

Strong opposition by a large number of developing countries, led by India and Brazil, to the proposed move finally made the WHO give up its attempt at redefining counterfeits in a recent meeting in Geneva, the official said. The decision is yet to be made official. This means generic drug makers such as Ranbaxy, Cipla, Lupin and Dr Reddy's may continue to sell medicines in foreign markets without a hitch.

Organisation of Pharmaceutical Producers of India (OPPI), representing global drugmakers, had earlier this month written to the Drug Controller General of India (DCGI) to endorse the new definition. "OPPI re-affirms the proposed WHO-IMPACT definition is a step in the right direction and we remain aligned to the changes that are being proposed by WHO-IMPACT," OPPI director general Tapan Ray said.

HC Allows CPAA to Join Bayer-Cipla Case

January 21, 2009, The Economic Times

The Delhi High Court (HC) has allowed cancer patient group Cancer Patient Aid Association (CPAA) to join the Bayer AG and Cipla case. The German drugmaker Bayer AG had sued the Indian government. Its drug regulator and domestic drug company Cipla for giving marketing approval to Cipla for Bayer's patented cancer drug Nexavar.

"The court has recognized that public interest is at stake. Therefore, CPAA should also have an opportunity to protect the interest of cancer patient which is at risk if marketing approvals are linked with patents," CPAA chairman and CEO Y.K. Sapru told ET.

Mr Sapru said a kidney cancer patient will have to shell out Rs 2.85 lakh for a monthly dosage of 120 tablets of Nexavar. Linking marketing approvals with patents would stop entry of low-cost medicines in the country, making cancer treatment unaffordable for most people in developing countries.

The court also clarified that its order is limited to Nexavar drug alone and should not be interpreted for all similar marketing generic applications, law firm Singh & Singh's Prathiba Singh representing Cipla in the case said. The HC in its interim order, last month, asked the Drug Controller General of India (DCGI) not to grant marketing approval to Cipla for Bayer's patented drug Nexavar, indirectly linking marketing approvals with patents.

But, multinational drugmakers say patent protection and affordability of medicines are two different things.

"Allowing or encouraging violation of patent is not the right and desirable way to improve access to affordable modern medicines to the common people. Patent enforcement is the responsibility of the government.

When it fails to protect it, the same gets converted

into a legal issue, whereas 'affordability' is an economic issue " Organisation of Pharmaceutical Producers of India (OPPI) director general Tapan Ray said.

Pharmaceuticals Families of India - Towards A New Dawn

January 16-31, 2009, Express Pharma

<http://www.expresspharmaonline.com/20090131/market01.shtml>

Tapan Ray, Director General,
Organisation of Pharmaceutical Producers of India (OPPI)

Is there any institution more enduring or universal than a family business? Before the multinational corporations, there was family business. Before the Industrial Revolution, there was family business. Before the enlightenment of Greece and the empire of Rome, there was family business, but the question is does this prevail in today's changing times?

In many of our most productive countries, like, the United States, Germany, Spain and China, to name just a few, families control up to 90 percent of the businesses and contribute more than 50 percent of the gross domestic product. In the emerging economies, families are the developmental foundation for new business and future prosperity. Until now, the focus on ensuring prosperity through family businesses was to help them preserve wealth and survive from one generation to the next. But with changing times, the families have come to understand the requirements for long-run growth and productivity that can generate prosperity for many generations to come. A critical facet of all thriving businesses and growing economies is no secret entrepreneurship.

The family run Pharmaceutical Companies in India should take a note of the changing dynamics of the professionally managed global pharmaceutical business while selecting the helmsman and may wish to get some message out of those newer trends, as and when they would decide to pass on the baton to a professional CEO reporting directly to a well competent professional board of directors.

Govt May Ask Pharma Cos to Curb Unethical Promotion of Drugs By Inducing Doctors

January 15, 2009, Pharmabiz

A set of common guidelines binding on all pharma companies or a joint mechanism of the sort by the industry may be evolved soon to curb the unethical trade practices of inducing doctors for favours by some companies, thanks to a belated but strong resolve by the government to reign in on the practice.

Stung by public criticism and concern by the government, the leading pharma associations have agreed to come up with more effective ethical guidelines and discuss the matter again in a bid to draft some common guidelines or joint mechanism in this regard. At a meeting called by the pharmaceutical department secretary other day and attended by all associations and CEOs of some major companies, they have decided to meet again sometime in April to thrash out common guidelines, it is learnt.

In the wake of recent media reports which prompted the government to call the meeting, pharma secretary expressed strong concern on the practice and government desire to see the industry taking some voluntary steps to curb it. Indian Drug Manufacturers Association (IDMA) and **Organisation of Pharmaceutical Producers of India (OPPI)** had said that they have a code of ethics for the members and the promotional expenses by them were below 9 per cent on an average. The same was spent on promotion on products.

OPPI, IDMA Come Out With Contrasting Views on Definition of Counterfeit Drugs

January 14, 2009, Pharmabiz

While the government and the industry thrashed out a semblance of consensus on India's viewpoint on the definition of counterfeit drugs that will be presented at the WHO executive board meeting later this month, two major industry associations in the country, **OPPI and IDMA**, took a totally contrasting view on this controversial issue.

While the OPPI wholeheartedly supported the WHO initiative, saying "The proposed WHO-IMPACT definition is a step in the right direction and we remain aligned to the changes that are being proposed by WHO-IMPACT," the IDMA opposed it tooth and nail saying that "...we earnestly urge the government to oppose the IMPACT definition as it stands today. Both the original definition as well as the one arrived at Bonn (25-26 Nov 2008) are totally unacceptable being against the developing countries and the generic industry. They seem to be part of MNC's IPR enforcement agenda through back door."

The IDMA further pleaded with the authorities that instead of confining itself to health hazard aspect of counterfeit drug problems, IMPACT is trying to expand the definition of counterfeit to include IPR and other (so called) violations. "We are unable to accept this approach because the criminality aspect or 'mens rea' associated with health issues do not apply in cases of IPRs or regulatory matters. IPR issues are commercial matters and regulatory matters are administrative matters unconnected with public health crimes. Therefore, they have to be dealt with accordingly. We feel that such expanded meaning will hurt the broad public interest; generic industry and its legitimate

international trade. That will also be against the objectives of WHO and WTO," the IDMA said.

Meanwhile, the OPPI pointed out that "Section 17b of the Drugs and Cosmetics Act gives a fairly exhaustive and well thought through definition of 'spurious' drugs that is much broader than what is being proposed by WHO-IMPACT or for that matter what is being debated at various forums here. A careful reading of the proviso provides us an insight into the mindset of the lawmakers who had worked to encompass the various angles that any unscrupulous element could adopt while peddling spurious/counterfeit drugs. This definition is aimed at taking adequate measures to protect the interests of the patients, industry and the public at large."

Ex Parte Order To Bristol-Myers Setback To Indian Drug Industry?

January 12, 2009, Mint

<http://www.livemint.com/2009/01/12230042/Ex-parte-order-to-BristolMyer.html>

Legal experts, health care activists question decision against Hetero; claim move violates Drugs and Cosmetics Act

Mumbai / Delhi: A recent order by the Delhi high court in favour of US drug maker Bristol-Myers Squibb Co. (BMS) will effectively link India's drug regulatory process with its patent regime, throwing the country's huge and profitable generics or off-patent drugs industry into a tizzy.

Legal experts and health care activists have raised questions on the so-called ex parte injunction—a court order that will remain in place until the actual hearing, in this case in March—that the court issued against Hyderabad-based generic drugs maker Hetero Drugs Ltd.

Apart from the wisdom of linking the process of granting regulatory approval to a drug with the status of its patent, the experts and activists claim the court's decision goes against India's Drugs and Cosmetics Act, which doesn't say marketing approval should be withheld because some other company holds a patent.

Although the US and a few other countries such as Chile and Singapore link regulatory approvals to the status of the patent, this isn't mandated by the World Trade Organization (WTO). This so-called TRIPS-plus (TRIPS stands for trade related intellectual property rights and is part of the WTO process) provision isn't recognized by any European country and experts say that even in the US, the capability of the drug regulatory authority to evaluate the validity of patents is suspect.....

Tapan Ray, director general of OPPI, said: "The broad issue is how can the same government, which is granting a patent to the innovator, give marketing approval of a

generic equivalent of the same patented molecule, paving the way for blatant patent infringement?"

DCGI's Plan on Patent Linkage Gets HC Booster

January 8, 2009, The Economic Times

The Delhi High Court (HC) has directed the drug controller general of India (DCGI) not to give marketing or manufacturing permission to generic drugmakers for drugs that have already been granted patent in India. The court gave this order last month while preventing Hyderabad-based drug company Hetero Drugs from manufacturing or selling its low-cost version of Bristol-Myers Squibb's (BMS) patented Leukemia drug, Dasatinib.

The order added that Hetero should restrain from manufacturing, selling, distributing, advertising, exporting, offering for sale that would directly or indirectly infringe upon BMS's drug Dasatinib. The next hearing will be held next month.

ET had reported last May that the DCGI was planning to link marketing approval to patents. Indian generic companies had strongly opposed such a policy while patent experts said the DCGI does not have the mandate to do so but the court order could bolster the DCGI's initiative.

Organisation of Pharmaceutical Producers of India (OPPI) director general Tapan Ray said: "OPPI has been trying to impress upon the need of 'patent linkage' to the government, since quite sometime. In April last year, the DCGI acceded to our request. Unfortunately, due to some reason, this assurance did not get translated into reality. We are delighted to know about this Delhi HC order, specially at a time when we are still discussing this issue with the government."

Delhi HC Directs DCGI Not To Permit Generic Drugmakers For Drugs Already Patented

January 7, 2009, The Economic Times

http://www1.economictimes.indiatimes.com/Pharmaceuticals/Delhi_HC_directs_DCGI_not_to_permit_generic_drugmakers_for_drugs_already_patented/articleshow/3948311.cms

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The court gave this order last month while preventing Hyderabad-based drug company Hetero Drugs from manufacturing or selling its low-cost version of Bristol-Myers Squibb's (BMS) patented Leukemia drug, Dasatinib.

In its ex parte interim injunction order, the court said, "It is expected that the DCGI while performing statutory functions will not allow any party to infringe any laws and if the drug for which the approval has been sought by Hetero Drugs is in breach of the patent of the BMS, the approval ought not to be granted to the Hetero."

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Patent expert and professor in Intellectual Property Shamnad Basheer said the Delhi HC's decision has transgressed existing laws and regulations, besides giving legal mandate to the DCGI to link marketing approval with patents.

"The order contravenes the Drug and Cosmetics Act under which the mandate of the DCGI is limited to examining the safety and efficacy of drugs" he added.

Indian Pharmaceutical Association's (IPA) secretary general D G Shah said the order grants unlimited data exclusivity to the patent holder as the HC has asked Hetero not to pursue its marketing application.

The order also invalidates the bolar expression of the Indian patent law which allows generic companies to pursue regulatory process of patented drugs to expedite the launch of their own drugs. They can even 'launch their drugs at risk'.

Global discovery drugmakers who have been demanding to link patent with marketing approvals alleging generic companies of infringing on their patents has welcomed the order.

Organisation of Pharmaceutical Producers of India (OPPI) Director General Tapan Ray said, "OPPI has been trying to impress upon the need of 'patent linkage' to the government, since quite sometime. In April last year, the DCGI acceded to our request. Unfortunately, due to some reason, this assurance did not get translated into reality.

We are delighted to know about this Delhi HC order, especially at a time when we are still discussing this issue with the government."

It may be recalled that there has been a few cases where Indian generic drug companies launched their low-cost versions of patented drugs in India, notably Cipla's launch of Roche's patented drugs Tarceva and Valcyte.

Roche has dragged Cipla to court in both the cases and awaiting final order from the court.

More Knocks Than Praise As Transparency Remains Key Issue

January 3, 2009, Mint

<http://www.livemint.com/Articles/PrintArticle.aspx?articleid=868AF7BE-D8DA-11DD-878C-000B5DABF636>

Product patenting is strewn with allegations of ambiguous laws, shortage of examiners and piling complaints

Three years since the country passed a comprehensive Patents (Amendment) Act 2005, as part of its obligation to the Trade-Related Intellectual Property Rights (TRIPS) regime, the product patenting landscape is strewn with allegations of ambiguous laws, lack of transparency, shortage of examiners and a stack of complaints.

This was not how it was meant to be.

When India became a member of the World Trade Organization (WTO), it was obligated to install a new patent law that would be in line with global practices. Instead, it dithered until the last minute, unveiling the law hastily in January 2005, to avoid being slapped with sanctions by the world body.