



## Director's Message



IP commercialisation is one of the most crucial aspect of IP management. It implies the real marketing of the IP by realising its commercial value. There are different mechanism of commercialisation and involves strategic and policy decision of the management. If the management has capital support and manufacturing facility it may commercialise the IP in house and in other cases it may decide to go through the process of marketing either by licensing or by assignment. In case of licensing,

the owner of IP may decide to give up the right of commercialising or manufacturing but not the ownership but in case of assignment, the owner does not retain any right of ownership. In case of licence, the owner gets royalty, which can be calculated in different ways and in case of assignment the sale price may be determined by way of IP valuation through experts.

IP licensing can be either exclusive or non-exclusive. The exclusivity may be for the product, field or territory or the combination of any of these. The owner of IP may also look for other mode of optimizing the revenue by retaining the right to manufacture and to grant exclusive right of marketing or by licensing manufacturing right to one party and marketing right to another and for selling right to yet another party. There can be other mode of commercialisation through venture capitalists or through a joint venture. Franchising is another mode of licensing where each licence is a part of a larger network with uniformity in application of technology or the brand. The franchisee right can itself be sold or assigned to a third party at any stage of its creation.

IP commercialisation can be undertaken by the IP owner himself or to outsource through IP Exchange or through IP auction or through some IP broking company. There are several companies which conduct IP auction of patent at periodic intervals. Ocean Tomo is one of the renowned name in the field but many others are emerging in European market. ITAG has developed association with some of such internationally acclaimed agencies for IP commercialisation of its valued clients and more details are available at [www.ipcommercialisation.com](http://www.ipcommercialisation.com).

IP commercialisation involves a number of steps including valuation, taxation implication, drafting of agreement for licensing or for assignment. It is very important for a research based organization to identify and maintain a track record of its various technologies and in order to harness the proper return on investment, it should develop a proper IP policy and strategy for IP commercialisation which can not only offset the cost of costly research activities but can become a profit center for the organization. The role of R&D centers in the present era of competition also help management to do a competitive intelligence exercise through IP analysis and technology landscaping and to resort to freedom to operate (FTO) and cross licensing to avoid IP litigation. Thus the job of R&D center is very crucial in the overall IP management of an enterprise and it is possible only through an efficient IPR cell in the center which can function under the able advice and in conjunction of an expert team of dedicated IP consultant who has the expertise of legal, technical and commercial team in their organization. ITAG is a unique company in this field where one can find all three expertises at one place. ITAG has also developed strategic alliances with different expert and reputed organization at global level to provide world class services under one roof.

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- Dr. D. R. Agarwal

## IPR NEWS - INDIA

### INDIAN COURT DISMISSES BAYER'S PATENT CLAIM

The Delhi High Court has dismissed Bayer's petition aiming to block Cipla from getting approval for the generic version of Nexavar from Drug Controller General of India (DCGI). Nexavar is a patented drug of Bayer's and is used to treat kidney cancer.

Cipla, based in Mumbai usually launches generic version of various patented medicines both in India and abroad. Bayer and its Indian unit Bayer Polychem had filed a petition last year after the DCGI approved Cipla's generic sofefenib tosylate, Soranib.

Bayer had patent for the drug in India since March 2008, giving it marketing exclusivity for 20 years and if Cipla launches a generic version of the kidney cancer drug, it would have infringed on Bayer's patent. Both the companies and the DCGI have been asked to wait for further orders by the court. The HC dismissed Bayer's plea since unpatented drugs are not spurious drugs and Bayer's petition was an attempt to bend public policy. Bayer will have to pay Rs 6.75 lakh to the Indian government and Cipla as legal cost.

### CLEAN CHIT FOR TCS

The Madras High Court has dismissed applications seeking an interim injunction restraining Tata Consultancy Services (TCS) for infringing the applicants copyright and patent in the invention 'FLYGUARD' under the title e-passport (Smartcard) and as TCS e-passport solution.

S Paul Raj, the applicant, a computer science graduate, said he had identified several areas in daily life, which could be simplified with technological intervention. He claims to have invented the concept of a travel document, which would be the substratum for the traveler's information. He said he was the owner of the IP regarding the invention in the written form of the project concept.

In its response, TCS submitted that the idea was neither original nor new and involved technologies that were already in public domain for a long time. The applicant had not put his idea into use nor there was any patent registration in his name. In his order, Justice K Chandru said the applicant had neither made out any prima facie case nor the balance of convenience was in his favour for the grant of any interim order.

## IPR NEWS-AROUND THE WORLD

### SANDISK WINS REVIEW OF PATENT

SanDisk Corp., the world's largest maker of cards which store digital pictures, won a second chance to argue that more than a dozen companies infringe its patents for flash-memory technology. Flash-memory chips are used to store data in digital cameras, cell phones and MP3 players.

SanDisk had claimed that 25 companies, including LG Electronics Inc. and Imation Corp., infringed its patents.

The U.S. International Trade Commission in Washington has agreed to review part of an ITC judge's findings that SanDisk had lost in April. If any abuse is observed,

### OFF-PATENT DRUGS FROM US TO PROFIT INDIAN PHARMA COMPANIES

As over \$70 billion worth of drugs are expected to go off patent in the US, the world's largest pharma market, the Indian drug industry is likely to make profit in the near future. Drugs worth around \$50 billion went off-patent in the US, in the past five years which, along with a doubling of generic alternatives in the market, has led to a rise in the generic share by volume to 68%.

Indian pharma companies are being presumed as one of the most competitive generic firms globally with a large FDA approved product pipeline, coupled with a strong research and development foundation. Indian companies have filed more than 900 abbreviated new drug applications (ANDA) which is the first stage approval for launching the drugs with United States health regulator in 2008 alone and has got around 300 approvals in the last year.

### INDIA TO COMPLAIN AGAINST EU WITH WTO

India will file a complaint with the World Trade Organization against the EU which allowed customs agencies to detain generic drugs in transit to developing countries.

Since November last year, border inspectors in the Netherlands and Germany have held up Indian medicines used to treat AIDS, Alzheimer's disease, heart conditions and other ailments, saying they violated patent laws in the EU, though the drugs were not meant for sale there. The drugs were detained for long periods at the request of big pharma companies including Sanofi-Aventis SA, Novartis AG and Eli Lilly & Co. Indian generics makers had to divert shipments at higher cost and had to hire lawyers to defend their right to have the drugs shipped to their destination.

Cipla Ltd.'s shipment of a schizophrenia medicine seized in November is still with the Dutch customs officials. Rajeev Kher, joint secretary of commerce in India, is preparing a complaint that India will file at the WTO, after which the WTO could dismiss the case, or rule that India has the right to impose retaliatory tariffs on the import of goods from the EU.

imports of any products that infringe the SanDisk patent would be banned.

### MERCK SUED OVER ALLERGY DRUG PATENT

Singulair, the best-selling allergy and asthma drug of one of the world's largest drug makers, Merck and Co.'s is in a patent dispute with a group of drug distributors and health insurers. Sales of Singulair are expected to be \$4.4 billion to \$4.7 billion this year.

The companies allege in the lawsuit that Merck kept a monopoly on the drug, and consequently they have overpaid for Singulair over the last six years. The claimants are Louisiana Wholesale Drug Co., Burlington

## IPR NEWS-AROUND THE WORLD Contd.....

Drug Co., Miami-Luken Inc., District Council 37 Health & Security Plan and The Guardian Life Insurance Co. They say that Singulair's chemical composition was obvious and it could have been discovered by any other researchers. Patents are not given to drugs that are deemed obvious, and obviousness is one reason for a patent to be invalidated.

The drug was approved in the U.S. in February 1998, and the related patents of the drug are to expire in 2012.

### MILESTONE SCIENTIFIC RECEIVES NOTICE OF ALLOWANCE FOR DISPOSABLE HAND PIECE FOR FLUID ADMINISTRATION

The USPTO has issued a Notice of Allowance for Milestone Scientific Inc.'s patent application for the use of its disposable hand piece for fluid administration. This award-winning hand piece is being used in conjunction with the Company's commercially available Computer-Controlled Local Anesthetic Delivery (C-CLAD) systems, including the STA Single Tooth Anesthesia System(TM), CompuDent(R) and CompuMed(R).

A Notice of Allowance generally completes the substantive examination of a patent application. Milestone has been awarded a total of 21 U.S. utility and design patents relating to its C-CLAD technologies till now.

### US PATENT FOR NOVEL FOAM TECHNOLOGY

Foamix Ltd., a leading developer of topical foams for dermatology and gynecology, has been awarded a US Patent which covers unique foam compositions, useful in the treatment of heat and chemical burns, wounds, bacterial, fungal and viral infections.

Foamix Ltd., headquartered in Ness Ziona, Israel is a leading developer of topical foams for dermatology and gynecology. The Company's CEO said that the novelty of foam technology platform is that it enables facile delivery of active agents to the affected site. The foams are breakable and can be easily applied to the wounds and burns and they are absorbed readily.

To date, Foamix has five issued U.S. patents covering its OilGel and topical foam technology platforms.

### CISCO, AVAYA SUED BY KLAUSNER OVER VOICEMAIL PATENT

Klausner Technologies Inc., a Patent holding company has sued Cisco Systems Inc. and Avaya Inc. for infringement on a visual voicemail patent. The suit was filed in federal court in Texas by the law firm of Dovel & Luner.

Last year Klausner had settled a lawsuit with Apple and AT&T Inc. over the same issue.

Apple and AT&T had agreed to take out licenses on the technology, joining eBay Inc.'s Skype division.

Klausner has 24 visual voicemail patent licensees.

## GLIMPSES OF JUDGMENT ON IPR

### CIPLA WINS OVER GENERIC CANCER MEDICINE CASE (BAYER CORPORATION V. UNION OF INDIA, DCGA & CIPLA)

**Facts:** This WRIT Petition was brought by German drug major Bayer Pharmaceuticals to restrain grant of drug license in favor of the Respondent no.3 ('Cipla') to manufacture, sell and distribute its drug called 'Soranib' as a brand name. Indian Patent Office had granted patent to Bayer on 3rd March, 2008 in respect of a drug named 'Nexavar' for the treatment of cancer. The DCGI approved the Cipla's application for license for the production, distribution and sale of the said generic drug.

Bayer the owner of the Patent argued that this generic drug is a 'spurious drug' under section-17B of the Drugs and Cosmetics Act (amended), 1982 and section-2 of the Drug Act have to be read in conformity with section-48 of the Indian Patent Act (amended), 1970. It is also argued that Drug Controller's (Respondent no.2) decision over licensing and marketing issues over the drug should not derogate from any other law for the time being in force in India. Section-2, 17B, 18 of the Drug Act read with Form-44, Appendix-1 to Schedule Y of the Drug Rules for 'chemical & pharmaceutical information' has to be filed by Cipla to the licensing authority for the disclosure of manufacturing of the Drug.

**Issues:** Whether the 'Patent Linkage' concept evolved from Hatch-Waxman Act is applicable in India? Whether the drug is a 'Spurious drug' under section-17B of the Drugs and Cosmetics Act? Whether the Drug Controller exceeds his jurisdiction and ultra vires chapter-IV of the Drugs Act?

**Judgment:** Justice S. Ravindra Bhatt while pronouncing the judgment opined that Section-2 of the Drugs Act and Section-156 of the Patents Act do not establish the patent linkage that is sought for by the petitioner. The Court said that it cannot conclude that unpatented drugs are spurious drugs. The Court also said that DCGI was right in the decision over the licensing issue. The Judge awarded a cost of Rs 6, 75,000 payable in equal shares to the Union of India, and Cipla, stating that 'the filing of the petition attempted to twist the public policy as it could stall the manufacture of an important drug'.

## EVENT AT ITAG



On 10th August, ITAG has entered into a strategic alliance with FoxMandal Little, India's largest and oldest Legal cum IP firm and an LPO at Noida and having its operation in several cities in India and London.

## SNAPSHOT

### Distribution by International Searching Authorities

The chart below shows the number of PCT international applications filed according to their selected ISAs.

International Searching Authorities	2004	2005	2006	2007	2008	2008 Share	2008 growth
European Patent Office	63,223	67,113	71,535	75,388	77,746	47.5%	+3.1%
Japan	18,695	23,020	25,146	25,946	27,499	16.8%	+6.0%
United States of America	26,896	28,626	30,543	30,499	21,379	13.1%	-29.9%
Republic of Korea	3,211	4,230	6,670	10,236	19,167	11.7%	+87.3%
China	1,650	2,482	3,890	5,492	6,262	3.8%	+14.0%
Australia	2,503	2,737	2,752	2,809	2,777	1.7%	-1.1%
Canada	840	2,103	2,314	2,524	2,473	1.5%	-2.0%
Sweden	3,400	3,381	3,191	3,134	2,371	1.4%	-24.3%
Spain	772	986	1,063	1,142	1,202	0.7%	+5.2%
Austria	824	915	1,097	1,172	1,131	0.7%	-3.5%
Russian Federation	616	723	805	853	821	0.5%	-3.8%
Finland		426	642	718	669	0.4%	-6.8%
Nordic Patent Institute					102	0.1%	
<b>Total</b>	<b>122,630</b>	<b>136,742</b>	<b>149,648</b>	<b>159,893</b>	<b>163,600</b>	<b>100%</b>	<b>+2.3%</b>

Source: WIPO Statistics Database

- The patent Offices acting as ISAs that experienced the largest growth rates compared to 2007 are the Offices of the Republic of Korea (+87.3%), China (+14%) and Japan (+6%).
- Since 2006, the Korean Intellectual Property Office has been acting as an International Searching and Preliminary Examining Authority for PCT international applications filed with the United States Patent and Trademark Office acting as the receiving Office.



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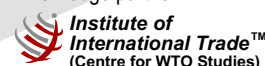
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