

# **STRATEGIC OPPORTUNITIES IN MANAGING IPRs: BIODIVERSITY, DRUG INDUSTRY AND EMERGING OPTIONS<sup>1</sup>**

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Indian drug industry provides an outstanding example of its distinctive contribution in adapting global technologies for domestic demand through adaptive research in formulation of drugs. This has meant availability of large number of drugs at low cost. Having developed an expertise in reverse engineering, somehow we started to believe that we were capable of being outstanding only in this field of knowledge. Developing new drugs not just for Indian but global market apparently was beyond our reach. Consequently, a dominant opinion against product patent regime got developed in our country. However, success of Dr.Reddy's lab and Ranbaxy in vying for global space for the locally developed technologies has started to change the mind set. Simultaneously, new partnerships between academic and commercial organisations within and outside the country have started emerging. Many small companies believed that given their limited resources, it will be almost impossible for them to do world class R&D and pursue the path of prosperity through protection of intellectual property rights.

In this paper, I first discuss the key concept of IPR and its relevance for our conditions. I then review the recent trends in filing patents based on herbal resources in US Patent Office during last two years compared to the trends apparent in 1992.

In part two I review the inter-organisational strategies for R and D drawing upon the excellence in informal sector as well as formal sector. Finally, I summarise the strategy that Indian pharmaceutical industry could pursue for global competitive advantage through protection of IPRs without compromising with the goal of universal health for all.

## **PART I**

### **The basics of IPR**

Patent granted by government to an inventor/s signify a contract. In lieu of disclosing the invention, the society allows the inventor to monopolise the commercial returns from the application of the invention for 17 - 20 years. If the inventor chose to use trade secret route of commercialising one's innovation, the growth of the ideas may suffer. Further, simultaneous development of innovations similar to one's own may emerge and be protected affecting the interest of the company or the inventor having the trade secrets. Further patenting does not necessarily imply that one should commercialise the applications. There are examples where companies as well as individuals have given away the rights for wider application of patented technology to WHO or to some other institutions. Thus, if someone opposes patent on ground of its excludability, then one should be clear as to whether the exclusion is deliberate or is it inherent in the nature of instrument. Patents can exclude anybody else from benefiting from the protected technology without a proper licence from the patentee. But this exclusion is subject to the wish and preference of the inventor.

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<sup>1</sup> Modified version of the paper presented at the 49th Indian Pharmaceutical Congress in Trivandrum on 20th December, 1997.

Does patenting inhibit research and development? It could if some of the important processes and products crucial for derivative R&D are sought to be used without due authorisation. Otherwise, the only restriction a patent would impose on derivative R&D is to ensure that either the improvement is made available to the original patentee through a cross licence. Or it should be proved that improvement can be operationalised without infringing the rights of the original patentee - a case very difficult to prove. In the case of Zantac discussed separately, similar dispute had arisen.

### What can be patented?

Any product or process or design, which involves an inventive, novel and non-obvious step capable of industrial application, can be patented.

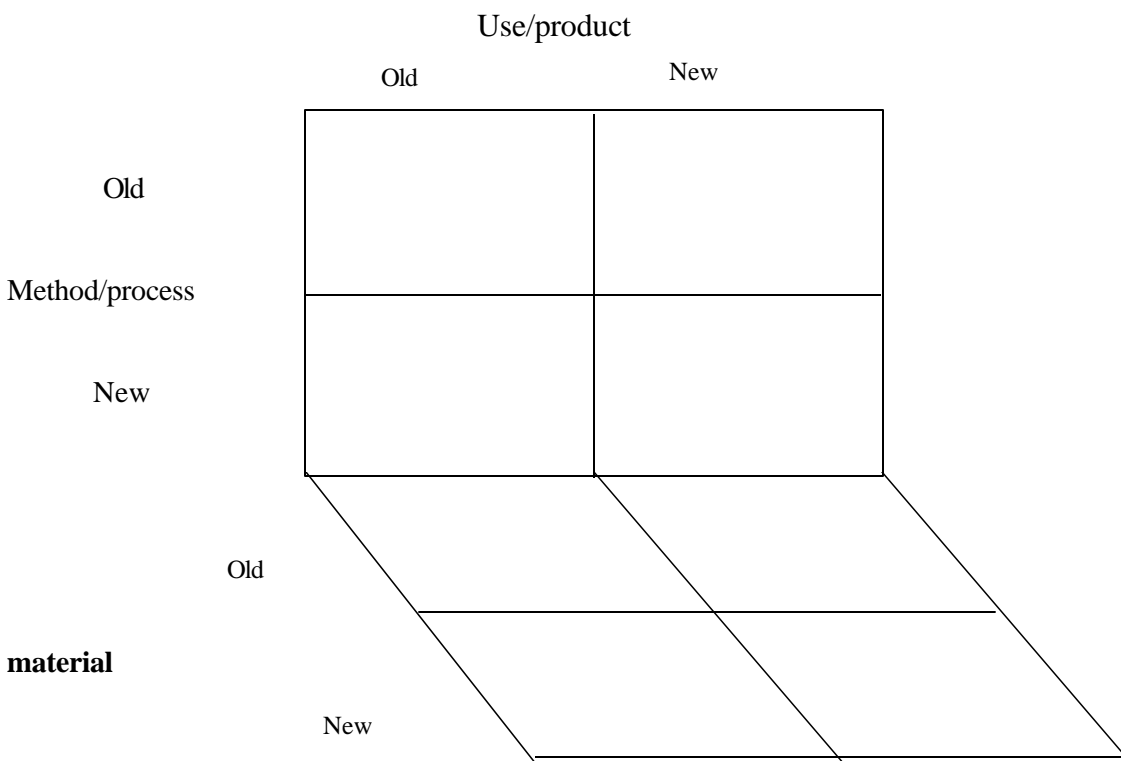


Figure 1

( Gupta, 1989, 1995, Gupta et al, 1996)

At least one cell out of the six should be new. That is, a known compound extracted or developed by known method but for a new use can be patented for that purpose. Therefore if a *known compound* from neem, say azadirachtin extracted by a *known process* has been used for curing cancer - an *unknown use*, the patent can be granted for that purpose.

*Where does our competitive edge lie?*

*Building Upon Biodiversity and Associated Knowledge Systems:*

India has about ten percent of the world's biodiversity wealth but its share in total world trade based on biodiversity as per the recent Exim Bank report (1997) is negligible. Ayurvedic medicines export seems also to fluctuate. In 1993-94, our major exports were aimed at USA but in 1994-95 it was Russia which imported the maximum from us. Our exports have steadily increased at about 30 per cent per annum while imports have recently come down (Exim Bank Report, 1997). The expenditure on R & D by Indian companies has been abysmally low, exceptions apart. As against world average of 12-15 per cent of expenditure on R & D, Indian companies hardly spend about 1-2 per cent on an average. No intellectual property worth anything can be generated with this kind of investment.

Discussions with Keith Richardson of Derwent Patent Data bases (one of the leading patent information providers on internet) revealed some interesting problems in analysing the situation with regard to patents on herbal drugs. None of the classification systems used by them (US,IPC,Derwent Classifications) have a classification for this category of knowledge. There is no way to reliably search via keyword.

Richardson searched on patents mentioning the words "herb# or herbal# or herbal medicine or herbalism or (traditional and (medicine or remedy). He stressed that it was unclear whether a patent containing one of these words actually was a herbal or traditional medicine patent. Nor would every herbal/traditional medicine patent mention one of these words - they might fail to mention any history of the technology in order to obtain exclusive rights. In any case, for getting a general trend he ran the search. There were 4328 patent records mentioning these words in Derwent's World Patents Index (available via the telnet online hosts - STN, Dialog, Orbit or Questel; also available for searching via the Derwent Search Service US703-706-4220). The World Patents Index covers 40 patent-issuing authorities, including the US, EP, PCT, Japan, China, etc. Derwent translate over 16,000 patents a week into English (from over 30 languages).

***A: . Ownership of patents that mention the words "herb# or herbal# or herbal medicine or herbalism or (traditional and (medicine or remedy)"<sup>2</sup>***

It seems to be mostly individual inventors (last names followed by first initial) There are not many corporate names in this list of the top 100 patent holders compared with other areas of technology. First twenty in the list are given here in Table one.

**Table one**

RANK	# OCC	# PATS	% PATS	PATENT ASSIGNEE
1	28	28	0.65	TSUMURA & CO
2	24	24	0.55	WANG Z
3	22	22	0.51	INT FLAVORS & FRAGRANCES INC
4	20	20	0.46	LI Y
5	20	20	0.46	NISSHIN FLOUR MILLING CO
6	20	20	0.46	TSUMURA JUNTENDO KK

<sup>2</sup> The discussion and tables under point A to D are quoted from the personal communication from Keith Richardson of Derwent Patent Search services, USA. I am extremely grateful to him for doing such a thorough search on complimentary basis to strengthen the arguments in this paper. Responsibility for any errors in quotation or interpretation is mine : Anil K Gupta

7	16	16	0.37	UNILEVER NV
8	16	16	0.37	WANG Y
9	15	15	0.35	CHEN J
10	15	15	0.35	UNILEVER PLC
11	14	14	0.32	WANG J
12	14	14	0.32	ZHANG Z
13	13	13	0.30	HASEGAWA CO LTD
14	13	13	0.30	KANEBO LTD
15	13	13	0.30	KAO CORP
16	13	13	0.30	LIU Y
17	12	12	0.28	BASF AG
18	12	12	0.28	FIRMENICH SA
19	12	12	0.28	LION CORP
20	12	12	0.28	NITTO ELECTRIC IND CO

***B. THE AVERAGE INVENTOR/COMPANY APPLIES TO ONE COUNTRY ONLY***

Derwent updates each patent record each time a patent is published in a new country - giving reliable patent family information.

In 1987 there were 164 patent records containing the words "herb# or herbal# or herbal medicine or herbalism or (traditional and (medicine or remedy)" and 69.51% of them only applied to one country. in 1996 there were 522 patents containing either of these words. 83.72% applied in only one country. But notice some of the higher numbers here compared to 1987 - some of these patents were applied for in 60+ countries. This would seem to indicate the technology is getting more important. It is very expensive to patent in that many countries - the patentee must feel there is long term viability.

***C. IN 1996 CHINA PATENTED THE MOST OF THESE PATENTS - 239 PATENTS OR 45.79% OF THE 522. HERE ARE ALL THE COUNTRIES IN THE GROUP FROM DERWENT'S DATABASE.***

**Table two**

RANK	# OCC	# PATS	%PATS	PUBLICATION COUNTRY
1	240	239	45.79	CN CHINA
2	132	106	20.31	JP JAPAN
3	62	62	11.88	RU RUSSIAN FEDERATION
4	95	60	11.49	EP EUROPEAN PATENT OFFICE
5	54	51	9.77	US UNITED STATES
6	69	50	9.58	AU AUSTRALIA
7	49	47	9.00	WO WORLD PATENT OFFICE
8	55	45	8.62	DE GERMANY
9	28	22	4.21	ES SPAIN
10	24	22	4.21	CA CANADA
11	21	17	3.26	HU HUNGARY
12	16	16	3.07	ZA SOUTH AFRICA
13	14	10	1.92	FR FRANCE
14	15	9	1.72	GB ENGLAND
15	11	8	1.53	CZ CZECH REPUBLIC
16	8	7	1.34	BR BRAZIL
17	7	7	1.34	RO ROMANIA
18	6	6	1.15	PT PORTUGAL

19	8	5	0.96	NO NORWAY
20	5	5	0.96	IT ITALY
21	5	5	0.96	SK SLOVAKIA
22	7	4	0.77	FI FINLAND
23	4	4	0.77	TW TAIWAN
24	6	3	0.57	AT AUSTRIA
25	3	3	0.57	CH SWITZERLAND
26	3	3	0.57	IE IRELAND
27	3	3	0.57	IL ISRAEL
28	2	2	0.38	BE BELGIUM
29	2	2	0.38	NZ NEW ZEALAND
30	2	2	0.38	SU SOVIET UNION
31	2	1	0.19	CS CZECHOSLOVAKIA
32	1	1	0.19	DD GERMANY
33	1	1	0.19	DK DENMARK
34	1	1	0.19	RD RESEARCH DISCLOSURE

**D. IN 1992 THE COUNTRY RANK WAS VERY SIMILAR**

The data from Exim Bank and the trends indicated here seem to suggest that we have to be careful in developing our future strategy. China, Japan and Russia are the major countries which seem to show major intellectual Property protection activity. Given the direction of our herbal exports, it seems to corroborate the trend in patenting. Except that China does not need to import herbs from us and instead, it relies on its internal supply.

But if China can become a world leader in herbal drug patents, why can not India ? One obvious answer is that we seem to be more concerned about the adverse effect of product patent regime on our common people than China which incidentally has achieved much higher growth in per capita income in recent years. It is not just the domestic supply of herbal drugs in which China leads but its share of the world trade also is significant. China produces about US\$ 10 billion worth of drugs of which US\$3 billion worth drugs are exported (Exim Bank, 1997). I disagree with the suggestion of Exim Bank report (1997:33) that given the high costs of developing new drugs, Indian companies can play major role in just "carrying out clinical trials, collecting and analysing test data from other centres". This is the same story as in software industry. We claim to provide some of the best software programmers in the world but we seem to be satisfied with servicing other's needs at low level of margins. We do not seem to gather will to introduce our own branded products in global markets. Drug industry can go the same way if our strategy remains what it is at present. Ranbaxy is planning to enter US market under its own brand name next year and that shows its confidence in its ability to deliver.

While the potential of biodiversity based knowledge systems and herbal supply is well recognised, we do not have any national or industry level strategy even in this field. Let me illustrate:

***Lack of Strategy in Biodiversity Conservation and Prospecting:***

- a) No major company whether ayurvedic or allopathic, national or international seems to have any plan of sustainable extraction of wild herbs from forest or elsewhere.

- b) Given an extraordinary high price spread from field to firm, the wages paid to local herb collectors are so low that even they do not have any incentives to conserve diversity
- c) the conservation of biodiversity I have repeatedly argued can not be ensured by keeping people poor. After all, most poor people do inhabit the regions which otherwise are rich in biodiversity of different kinds (Gupta, 1990-1996).
- d) there is no national mission to achieve strategic leadership in either certain drug areas in which we have raw material advantage or in which we have domestic unmet demand (and where our imports are maximum) or in areas in which we have research advantages.
- e) despite public pronouncements, partnership between public, private and NGOs and communities of herbalists have not come about to give us a strategic advantage in conceptualising the heuristics of research. After all, the *cost reduction* as well as higher *hit rate* can only be achieved by using different heuristics and not just by doing the more of the same.<sup>3</sup>
- f) The effort in the earlier draft of national Legislation on biodiversity conservation to regulate the access by only international biodiversity prospectors leaving domestic users to have a free run over resources was neither prudent nor sustainable. The need for domestic as well as international companies to have minimal responsibility towards local communities who conserve biodiversity has been realised in the latest draft of the bill on the subject. There should be some agreement on benefit sharing protocol between local herbalists and their communities and external prospectors.
- g) Data bases like NAPRALERT having 130,000 references on more than 40,000 species with all the information on local names, purposes for which screened, compounds present, activities present etc., are not widely accessible to users with in India. Though this data base is accessible electronically through email to users in third world without any cost, there are a large number of companies, research institutions, pharmacy colleagues and other leading labs which do not either have access or do not use for whatever reasons. National Data bases developed by CSIR are also not widely accessible to common researchers. Obviously this means lot of low quality research some of which is also highly repetitive.
- h) Despite repeated pleas to national scientific leaders for developing high throughput screening robotics systems, we still do not have any time bound program to do so. The result is that it takes months to screen just a few plants or scores of micro-organisms. We took up a study on microbial diversity map of Gujarat under the auspices of SRISTI (an NGO, [Http://csf.colorado.edu/sristi](http://csf.colorado.edu/sristi)) in collaboration with IISc, MS University, GAU and many other institutions. Out of 760 samples, we could hardly analyse about 60 samples for basic microbial diversity in a year. The taxonomic identification of new cultures was even more difficult.
- i) Taxonomy is a dying discipline and there is no corporate investment in chairs on taxonomy.

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<sup>3</sup> Early this year, I had the opportunity to serve on an evaluation panel of a major international program by National Science Foundation, National Institute of Health, USA involving some of the leading drug companies on Biodiversity Conservation and exploration through Drug Discovery. It became quite obvious that for most major companies, a herbal extract had to fit in the existing models of disease inhibition or control even if the local herbalist suggested an alternative route of controlling the same disease. Further, even the method of application or use of the given herbal drug was not pursued as per the method perfected by herbalists. This is an area in which India can break new ground by devising new imaginative heuristics and thus achieving higher hit rate in screening plants or micro-organisms for drug discovery.

The tragedy is that national apex institutions such as Botanical Survey of India as well as Zoological Survey of India do not have experts in many fields of plant and animal kingdom. There is no strategy to build capacity and retain the skills that we have.

- j) Honey bee network has one of the largest data bases on local knowledge and innovations in the field of herbal use for various purpose. More than 9000 innovations with the name and addresses of the innovators from over 2300 villages are already recorded. The purpose is to augment local repertoire of such knowledge. One can not conserve such a rich knowledge systems only by recording it in books. One has to conserve it in situ .
- k) However, unless we have an *innovation patent system* akin to *petty patent system* in vogue in many countries but particularly in Australia, we will not be able to provide incentives to local communities as well as herbalists to disclose their knowledge unhesitatingly. After all, no herbal company has invested any thing in their well being so far. The proposal on INSTAR (International Network on Sustainable Technologies Applications and Registration) aims to provide limited period protection to local communities as well as herbalists. The advantage of national and global data base of local knowledge systems and herbal; drugs will be that small entrepreneurs form one part of the world may source innovation from another part and seek investment funds from third place and set up an enterprise in any one of the places. Golden Triangle of Innovations, Enterprise, and Investment has been operationalized through a venture promotion funds called as GIAN (Gujarat Grassroots Innovation Augmentation Network) set up in collaboration with Gujarat Government with an initial proposed corpus of Rs 10 million of which about sixty per cent has already been mobilised. Idea is to upscale small innovations and help in building bridges between local herbalists and corporations interested in developing products such as drugs and act as an honest brokers.
- l) Even the large firms have considerable patent illiteracy in India and there is a need for an urgent program aimed at building not only awareness but also capacity to deal with complex IPR related issues.

## **Part Two: Inter-Organisational Strategy for R & D and patent advantages**

There are several implications that follow from the analysis of the lack of strategy towards deriving competitive advantage in drug industry. I summarise the key arguments here:

- a) No one department or discipline can really research all the dimensions of drug discovery and formulation. And yet there is no way one can develop a globally competitive product or nationally advantageous product without developing Knowledge Networks (KNs).
- b) KNs should link not only experts in various departments but also in the villages and slums who may be reached only through vernacular media. It is the blend between excellence in informal and formal sector that real breakthrough will come.
- c) We have to remember that we can not win this struggle by doing more of the same or what every body much better endowed than us is doing already.
- d) We should remember that out of about 1500 plants recorded in various texts, hardly 600 are used extensively. There are supposed to be 43000 species in India and if we include about 7000 plants of which folkloric uses have been recorded by Ethnobotanical surveys( without ever sharing any knowledge or returns back with the providers of knowledge), there still remains a great deal of knowledge still to be documented, tried and tested. Will we just let this opportunity slip by our finger as in past?
- e) The networks will evolve only when there is a room for imagination, long term perspective, mutual faith and willingness to fail in good faith i.e. to take risks and not feel too bad on failure. It is not impossible to work together without any formal agreements. SRISTI has worked with private as well as public sector labs and in many cases has been frustrated while

in other cases, has received very significant results. At least it is possible to have collaborations when one knows that cause is clear, no attempt is made to take credit for each other's work, and resources are shared.

- f) The networks that will lead to creation of Knowledge Organisation and Knowledge Networks will require dynamism and real time connectivity across cultural, disciplinary and sectoral spaces.

### **Part Three: Where do we go from here?**

IPRs are a means of helping society make a transition towards a meritocratic systems. The possibility of Knowledge Rich economically poor communities, nations and individuals making difference is clear. My faith stems not only from what I have seen but also from what I see as possible. There are hardly any patents on neem for instance which do not quote an Indian work and yet how many commercializable patents did we file on neem itself? There are examples where individual researchers have generated tremendous wealth through small scale research.

On one hand we have attempts to extend the life of existing patents as long as possible so that profits of large corporations continue. If a bill pending before US congress gets passed in next few months, pharmaceutical companies may be able to extend the protection for brand name products by as much as ten years by paying three per cent royalty to government. On the other hand we have recent decision of Australian government to introduce a modified petty patent system called as Innovation Patent System with 8 year protection and limited inquiry of novelty, only five claims per application and low costs. The idea is that small and medium enterprises might benefit most from such a system for quick registration of innovations at low cost. It will help reduce cost of gaining and thus commercialising the intellectual property.

We have to devise our strategies keeping our strength in view. Our domestic industry can be wiped out if we do not generate opportunities for new ways of collaboration among small and big, informal and formal and national and international actors. We should not just think of a few options which seem popular at present such as joint ventures with large corporations. That may be a way of gobbling up national partners. But we should think of making our small scale sector more inventive, and make public R and D system more closely aligned with the industry so that user perspective can be brought into every day decision making system. At the same time, we need to augment the capabilities of individual herbalists in villages who despite remaining poor have conserved this knowledge so that they become partners in the new wealth creation process.

Once the knowledge is lost, diversity will be like a library without a catalogue. Do we want to create such a situation. If not, how will a national campaign be generated to make IPRs and INSTAR as central instruments of creating wealth.

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