The US patent holdings of homegrown Indian biotech and pharma companies

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We have analysed all United States (US) patents of all homegrown Indian pharma and pharma biotech companies granted up to, and including, 2007. Only 57 companies (and associated foundations) have US patents. They hold a total of 19 biotech and 425 pharma patents. The patents protect both processes and 'products'. Pharma patents have been obtained since 1990, but biotech patents since 2001. A mere 11 patents have been cited ten or more times. This study serves as a baseline to track the evolution of the US patent landscape of the Indian biotech and pharma industries in the years to come.

Keywords: Biotech and pharma industries, industrial R&D, patents.

AN ambitious company from India, seeking a foothold in the United States (US) – the biggest pharma market – seeks patent protection for its inventions in that territory. US patents therefore serve to reflect the technical and financial strengths of the concerned company and also its preparedness to engage with foreign regulatory systems. In order to map these strengths more precisely, we have analysed the US patents of all homegrown Indian pharma biotech (hereafter biotech) and pharma companies. The India-based units of large multinational corporations are not included in this study.

Methodology

We adopted the following process to identify all the US biotech and pharma patents granted to homegrown Indian companies. From a variety of sources, including the trade magazine *BioSpectrum* and relevant sites on the internet, we drew up an exhaustive list of 424 biotech and pharma companies in India. The list included homegrown biotech and pharma companies of interest to this study. It also included Indian subsidiaries of foreign companies and agriculture-related companies dealing with insecticides or pesticides, neither set of which was of interest.

We focused almost solely on homegrown biotech and pharma companies. The few exceptions are detailed below. In order to determine the patent holdings of individual companies of interest, each company was looked up at the 'Issued Patents' section of the US Patent and Trademark Office (USPTO) database, under 'Quick Search'. The search was done for 'Name of company' as 'Assignee name'. Only those patents issued up till 31 December 2007 were considered. We considered all the relevant patents of Indian companies, even if a foreign company was a co-assignee. We have not considered the holdings of Nobex, a company acquired by Biocon for its patent holdings. All patent data were collected in May and June 2008.

It was found that in several cases patents have been granted to companies with closely related names. In each case, the pairs of names were investigated to establish whether the company name had changed over time or whether there was some other relationship between the companies. Biocon India Limited and Biocon Limited, Sami Chemicals & Extracts and Sami Labs, and Themis Medicare and Themis Chemicals Limited are examples of change of name. In these three cases, the patents have been pooled for each pair of company names.

There were a few instances where variations in name genuinely reflected different organizations. In five cases a research entity was one of the pair: the Dabur Research Foundation is associated with Dabur Limited and Dr Reddy's Research Foundation (DRRF) with Dr Reddy's Laboratories (DRL). Kopran Research Laboratories is a 100% subsidiary of Kopran Limited, and Lupin Laboratories is a wholly owned subsidiary of Lupin Limited. Sun Pharmaceutical Advanced Research Centre (SPARC), perhaps since closed, was associated with Sun Pharmaceutical Industries (although we note that a new entity called Sun Pharmaceutical Advanced Research Company Limited has been registered in 2007). Although we have not studied other independent foundations, since the above-mentioned foundations are closely related to the companies concerned, we have included them in this analysis. Each organization is a distinct legal entity and

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so the holdings of each member of a pair have been listed separately, although sometimes discussed together. We have confirmed that no patent is co-assigned to both members of a pair. Although the Vittal Mallya Scientific Research Foundation was set up to honour the founder of United Breweries, it is a stand-alone institution and the research does not appear to have much of a relationship to the company. Its patents have therefore not been considered.

There were two other cases of companies with similar names. Cadila Laboratories split into Cadila Healthcare (later acquired by Zydus to form Zydus Cadila) and Cadila Pharmaceuticals. The holdings of these three companies have not been pooled. Strides Research and Specialty Chemicals Limited was a 100% subsidiary of Strides Arcolab Limited, from which the latter has now exited, and therefore the patents of these two companies have also been considered separately. There was one case where an Indian professional in the US, Mohammed Majeed, set up a company (Sabinsa Corporation) there. He went on to set up another company (Sami Labs) in India. The holdings of Sami Labs have been considered, but not those of Sabinsa Corporation.

Subsequently, as we searched the USPTO database for the holdings of specific companies, we came across patents that belong to the foreign arms of three Indian companies. In the case of each of these foreign subsidiaries (Reddy US Therapeutics, Strides, and Wockhardt Europe), we examined the inventors on their patents. In each case, we totalled the number of inventors on all patents (and had multiple counts for inventor 'repeats'). For each company more than half the inventors were based in India. Likewise, the stand-alone company Gangagen Biotechnologies is registered in the US, but more than half the inventors are based in India. We therefore included these companies in our list. In each case the companies are listed separately, and have not been clubbed with their parent organization (where applicable).

Finally, it was found that there are errors in the USPTO database in terms of company names. The four patents of J. B. Chemicals and Pharmaceuticals were represented by three spelling variations. Panacea Biotec was represented as Panacea Biotic once and Panacea Biotech twice. A patent was found assigned to Banbaxy Laboratories Limited that actually belongs to Ranbaxy Laboratories Limited (Ranbaxy). Likewise, RPG Life Sciences was represented as RGP Life Sciences in one document. In one case each, DRL was represented as Reddy's Laboratories Limited, DRRF as Redd's Research Foundation, Sun Pharmaceutical Industries as Sun Pharmaceuticals Industries and Wockhardt as Wockhart. Extensive searches were done to ensure that every patent of each company was identified. After double checking that these were typographical errors and not different companies, all such variations were pooled with the rest of the patents of the concerned company to get a complete picture of its holdings.

Results

Identifying and analysing the patents

We detail above the process by which we identified the companies that hold biotech and pharma patents. Of the 424 companies and associated foundations investigated, only 53 were found to have US patents. Subsequently, we found that the foreign arms of three Indian companies and one foreign-registered company (Gangagen Biotechnologies) were also included. The 57 companies (and associated foundations) and their holdings are listed in Table 1.

We have restricted our analysis to granted patents. Overall, till the end of 2007, the Indian industry has been issued 444 US patents. Of the 57 companies (and related foundations) with these holdings, only 13 have ten or more patents. These are Ranbaxy (84), DRRF (44), DRL (34), Dabur Research Foundation (31), Orchid Chemicals and Pharmaceuticals (22), Biocon (19), Panacea Biotec (16), Wockhardt (14), Lupin Laboratories (13), Reddy US Therapeutics (12), Sami Labs (12), Sun Pharmaceutical Industries (10) and Torrent Pharmaceuticals (10). The assets of these groups are further enhanced as follows: Dabur India (6) and Dabur Pharma (1) add to the holdings of Dabur Research Foundation; Lupin (4) adds to those of Lupin Laboratories; Wockhardt Europe (3) adds to those of Wockhardt and SPARC (1) adds to those of Sun Pharmaceutical Industries.

In order to understand the patents, we first determined whether each was for a biotechnological or pharmaceutical invention. Each document was examined and accordingly classified as 'biotech' or 'pharma'. A patent was classified as 'biotech' if it protects (a) a recombinant enzyme; (b) a reaction carried out by an enzyme or a method to detect enzymatic activity; (c) a method to detect whether a molecule (such as a cytokine) affects the activity of, or the expression of an enzyme; (d) a bio-reactor or fermentor, or the produce from use of such a device; (e) bacteriophages, or bacteria infected by such phages, as products or methods of their use; (f) an algal strain and the process of culturing it; (g) stem cells and methods of growing them and (h) a design patent covering an umbilical cord collection bag (an invention related to the use of stem cells). Patents classified as 'pharma' cover those that involve non-biological chemical processes or chemical compounds.

The number of biotech patents, at 19, is low, whereas that of pharma, at 425, is over 20-fold greater. Interestingly, we found that several companies with biotech- or life science-related names have a high proportion of pharma patents. Thus, the holdings of Indus Biotech, Panacea Biotec, RPG Life Sciences and Suven Life Sciences are exclusively pharma. In fact, about two-thirds of the patents of Biocon are categorized as pharma. We also examined the converse, but found that only one pharma company, Reddy US Therapeutics, has (3) biotech patents.

Table 1. All homegrown Indian companies holding US biotech or pharma patents, and a broad categorization of these patents

Company	Biotech patents						Pharma patents						Total
			Utility patents			Design patents			Utility patents			Design patents	
	Number	Percentage	Product	Process	Product and process		Number	Percentage	Product	Process	Product and process		
Alembic	0		–	–	–	–	5	1	–	4	1	–	5
Aurobindo Pharma	0		–	–	–	–	9	2	–	6	3	–	9
Bharat Biotech International	2	11	–	–	2	–	0		–	–	–	–	2
Bharat Serums and Vaccines	0		–	–	–	–	3	1	–	–	3	–	3
Biocon	6	32	1	4	1	–	13	3	4	6	3	–	19
Cadila Healthcare	0		–	–	–	–	4	1	–	1	2	1	4
Cadila Laboratories	0		–	–	–	–	1		–	–	1	–	1
Cadila Pharmaceuticals	0		–	–	–	–	1		–	–	1	–	1
Chemintel India	0		–	–	–	–	3	1	–	2	1	–	3
Cipla	0		–	–	–	–	4	1	–	3	1	–	4
Dabur India	0		–	–	–	–	6	1	–	3	3	–	6
Dadur Pharma	0		–	–	–	–	1		–	–	1	–	1
Dabur Research Foundation	0		–	–	–	–	31	7	7	8	16	–	31
Dr. Reddy's Laboratories	0		–	–	–	–	34	8	6	11	17	–	34
Dr. Reddy's Research Foundation	0		–	–	–	–	44	10	4	4	36	–	44
Emcure Pharmaceuticals	0		–	–	–	–	1		–	1	–	–	1
Fermenta Biotech	0		–	–	–	–	1		–	–	1	–	1
Fortune Bio–tech	0		–	–	–	–	1		–	1	–	–	1
Gangagen Biotechnologies	3	16	–	–	3	–	0		–	–	–	–	3
Glenmark Pharmaceuticals	0		–	–	–	–	7	2	1	2	4	–	7
Indian Herbs and Research Supply Company	0		–	–	–	–	8	2	2	2	4	–	8
Indus Biotech	0		–	–	–	–	2		1	1	–	–	2
Ipca Laboratories	0		–	–	–	–	1		–	1	–	–	1
J. B. Chemicals and Pharmaceuticals	0		–	–	–	–	4	1	2	–	2	–	4
Jai Surgicals	0		–	–	–	–	1		1	–	–	–	1
Jubilant Organosys	0		–	–	–	–	5	1	–	5	–	–	5
Kopran	0		–	–	–	–	1		–	1	–	–	1
Kopran Research Laboratories	0		–	–	–	–	2		–	–	2	–	2
Lekar Pharma	0		–	–	–	–	1		1	–	–	–	1
Lupin	0		–	–	–	–	4	1	–	3	1	–	4
Lupin Labs	0		–	–	–	–	13	3	2	9	2	–	13
Max India	0		–	–	–	–	3	1	–	3	–	–	3
Natco Pharma	0		–	–	–	–	1		–	1	–	–	1
Natural Remedies	0		–	–	–	–	1		–	–	1	–	1
Nicholas Piramal India	0		–	–	–	–	4	1	–	2	2	–	4
Orchid Chemicals and Pharmaceuticals	0		–	–	–	–	22	5	–	14	8	–	22
Panacea Biotec	0		–	–	–	–	16	4	5	1	10	–	16
Proalgen Biotech	1	5	–	–	1	–	0		–	–	–	–	1

(*Contd.*)

Table 1. (*Contd.*)

Company	Biotech patents						Pharma patents						Total
			Utility patents			Design patents			Utility patents			Design patents	
	Number	Percentage	Product	Process	Product and process		Number	Percentage	Product	Process	Product and process		
Ranbaxy Laboratories	0		–	–	–	–	84	20	13	53	18	–	84
Reddy US Therapeutics	3	16	–	3	–	–	9	2	9	0	–	–	12
Reliance Life Sciences	4	21	1	2	–	1	0		–	–	–	–	4
RPG Life Sciences	0		–	–	–	–	3	1	1	2	–	–	3
Sahajanand Biotech	0		–	–	–	–	2		2	–	–	–	2
Sami Labs	0		–	–	–	–	12	3	1	8	3	–	12
Shasun Chemicals and Drugs	0		–	–	–	–	1		–	–	1	–	1
Strides	0		–	–	–	–	2		–	1	1	–	2
Strides Arcolab	0		–	–	–	–	1		–	–	1	–	1
Strides Research and Specialty Chemicals	0		–	–	–	–	1		–	1	–	–	1
Sun Pharmaceutial Advanced Research Centre	0		–	–	–	–	1		1	–	–	–	1
Sun Pharmaceutical Industries	0						10	2	2	5	3	–	10
Suven Life Sciences	0		–	–	–	–	1		–	–	1	–	1
Themis Medicare	0		–	–	–	–	2		–	–	2	–	2
Torrent Pharmaceuticals	0		–	–	–	–	10	2	1	2	7	–	10
Tsar Health	0		–	–	–	–	2		–	–	2	–	2
USV	0		–	–	–	–	9	2	–	4	5	–	9
Wockhardt	0		–	–	–	–	14	3	1	2	11	–	14
Wockhardt Europe	0		–	–	–	–	3	1	–	2	1	–	3
Subtotal	19	100	2	9	7	1	425	100	67	175	182	1	
Total					19						425		444

The reputation of the Indian pharma industry is primarily based on its skills in process chemistry. In order to examine this more closely, we next looked at whether the inventions are covered by utility or design patents, and amongst the former, whether they are for compositions of matter (hereafter, products) or processes. The utility patents were classified into 'product', 'process' or 'product and process'. We find that a surprisingly large fraction of both biotech and pharma patents have product claims (Figure 1). Among those categorized as biotech, 2 (11%) cover only products, 9 (47%) only processes, 7 (37%) both products and processes, and 1 (5%) is a design patent. Amongst the pharma patents, 67 (16%) are for products, 175 (41%) for processes, 182 (43%) for both products and processes, and 1 (less than 1%) is a design patent. Thus, a total of 48% of biotech and 59% of pharma patents protect products, either alone or together with processes.

Keeping in mind the issue of protection of products and processes, we looked at the two categories of patents in more detail. We first considered the biotech patents, briefly outlined in Table 2. As mentioned above, these cover a range of subject matter, from a fermenter to a bacteriophage, and reflect some of the homegrown competencies in the country. Notably, there is not a single patent related to generic biologicals or 'bio-similars'.

Coming to pharma, we found that both products and processes have been protected in good numbers, either separately or together. The large number of process patents are due to the reverse engineering capabilities of the companies, which cover methods of synthesis, purification procedures, producing optically active forms of compounds and so on (Table 2). Interestingly, several process patents cover novel drug-delivery technologies.

Aside from utility patents with product and process claims, we also considered design patents. Out of a total of 444 patents, only two (an umbilical cord storage bag of Reliance Life Sciences, and an inhalation device of Cadila Healthcare) fall in this category.

Patenting trends over time

Aside from the types of patents and their numbers overall, we have also tracked their numbers over time. As shown in Figure 2, these have been rising steadily. The first two for pharma were granted in 1990. Between 1990 and 1995, only 8 were awarded, and all of these (for tetracyclines and cephalosporins) were to Ranbaxy. Since then, the total number of pharma patents has, with a couple of exceptions, risen each year and 68 were awarded in 2007. Biotech patents have been granted since 2001. Their rise has happened more recently, from 2003, and has been to a smaller extent. Also, although their numbers have increased in the past few years, there has not been the same year-on-year consistency.

We also examined how many companies received their first US patent in a given year. For this analysis, we pooled all the companies (holding biotech and/or pharma patents). The first company to acquire a US patent was Ranbaxy in 1990. Although no other company acquired a patent till 1996, since then, the number of companies has shown an overall increase over the years. However, this rise was uneven, with dips in 1998, 2002 and 2007, a steep spike in 2003 and no change in 2001, 2005 and 2006 (Figure 3).

Citation analysis of the patents

Having examined the nature of the patent holdings and their numbers over the years, we went on to evaluate their innovativeness by doing a citation analysis. This was done using the patent number as a search term under 'referenced by' in the 'Quick Search' option of the USPTO database. Patents with ten or more citations belong to DRRF (5), Panacea Biotec (2), Cadila Laboratories (1), Dabur Research Foundation (1), Ranbaxy (1) and Sami Labs (1). These citations were divided into those by 'self or associated companies' and 'others'. It was observed that only 33% was self citations and 67% was by others. The patent (5616593) with the highest citations belongs to Cadila Laboratories. It has 19 citations, all of which are by others. Most patents have been cited less than ten times; those with ten or more are listed in Table 3.

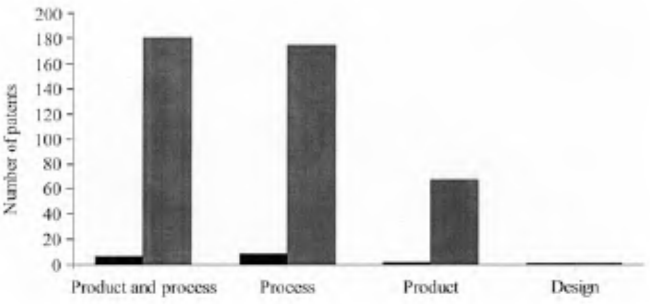

Figure 1. The number of patents that protect products and processes, processes, products or designs, shown separately for biotech (in black) and pharma (in grey) inventions.

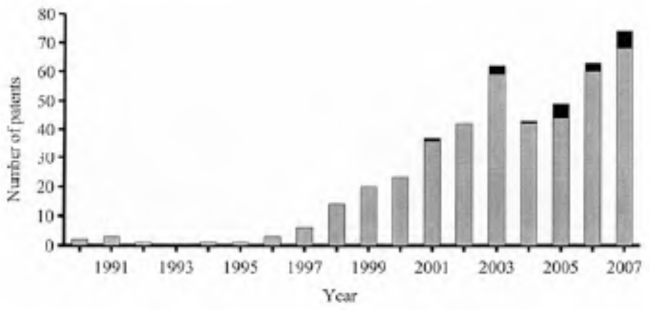

Figure 2. Growth of US biotech and pharma patents of Indian companies over the years. The grey portions refer to pharma, and the black portions to biotech patents.

Table 2. An outline of the protection offered by the US patents awarded to Indian biotech and pharma companies

Patent no.	Assignee	Title of invention
Each of the 19 biotech patents		
7105327	Bharat Biotech International	Recombinant streptokinase
6897041	Bharat Biotech International	Expression of recombinant mature lysostaphin
7189558	Biocon	Process for producing pravastatin sodium salt using *Streptomyces flavidovirens* dsm 14455
7176001	Biocon	Manufacture and purification of cyclosporin A
6927047	Biocon	Manufacture and purification of mycophenolic acid
6709846	Biocon	Methods of producing esters of mycophenolate
6664095	Biocon	Solid state fermentation
6197573	Biocon	Solid state fermentation
7087226	Gangagen Biotechnologies	Lysin-deficient bacteriophages having reduced immunogenicity
6913753	Gangagen Biotechnologies	Incapacitated whole-cell immunogenic bacterial compositions
6896882	Gangagen Biotechnologies	Lysin-deficient bacteriophages having reduced immunogenicity
6936459	Proalgen Biotech	Medium for the production of betacarotene and other carotenoids from dunaliella salina (ARL 5) and a strain of dunaliella salina for production of carotenes using the novel media
7273712	Reddy US Therapeutics	Methods and compositions for detecting compounds that modulate inflammatory responses
6900041	Reddy US Therapeutics	Methods and compositions for the treatment of inflammatory diseases
6656699	Reddy US Therapeutics	Methods and compositions for glycosidase assays
7294508	Reliance Life Sciences	Isolation of inner cell mass for the establishment of human embryonic stem cell (hESC) lines
7179643	Reliance Life Sciences	Device and a process for expansion of haemopoeitic stem cells for therapeutic use
7060494	Reliance Life Sciences	Growth of human Mesenchymal Stem Cells (hMSC) using umbilical cord blood serum and the method for the preparation thereof
D481793	Reliance Life Sciences	Umbilical cord blood collection bag

Products and processes protected by the 425 pharma patents.

Patents protecting processes: The processes protected include new or more efficient (i) synthetic routes for a wide variety of compounds, including analogs and (ii) methods for crystallizing specific compounds, preparing particular salts or solvates, isolating or purifying compounds, solubilizing therapeutic compounds, producing optically active forms of a compound and stereospecific synthesis.

Patents protecting products: Product claims cover compounds with therapeutic effects, intermediates, formulations, stereoisomers, tautomeric forms, polymorphs, crystalline forms, analogues or derivatives of known therapeutic compounds, compositions with increased bioavailability, catalysts, capsules, dental formulations, synergistic compositions, herbal compositions with therapeutic effects and nutritional supplements. All peptides, including insulin, have been classified as pharma patents as they were all synthesized chemically. An inhalation device is covered by a design patent.

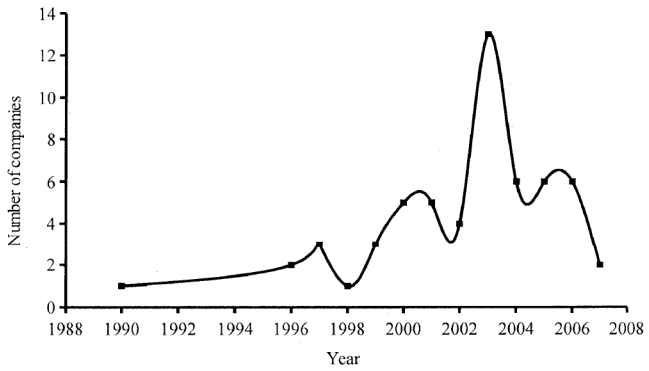

Figure 3. The number of companies that received their first US patent in a given year versus year.

Discussion

In our analysis of the pharma-related patents of home-grown Indian companies, we found that only 53 out of the 424 companies investigated have US patent holdings. This is less than 15% of the total. Although this is a low percentage, most of the companies have acquired patents in the last decade, which indicates a certain maturing of the

Table 3. US patents of Indian biotech and pharma companies cited ten or more times

Company	Patent number	Date of grant of patent	Number of citations	By self or associated company	By others
Cadila Laboratories	5616593	1 April 1997	19	0	19
Dabur Research Foundation	6048847	11 April 2000	12	3	9
Dr Reddy's Research Foundation	6054453	25 April 2000	17	11	6
Dr Reddy's Research Foundation	5985884	16 November 1999	13	7	6
Dr Reddy's Research Foundation	5889025	30 March 1999	16	5	11
Dr Reddy's Research Foundation	5885997	23 March 1999	13	10	3
Dr Reddy's Research Foundation	5801173	1 September 1998	11	5	6
Panacea Biotec	5858371	12 January 1999	15	0	15
Panacea Biotec	5716609	10 February 1998	11	3	8
Ranbaxy Laboratories	5763646	9 June 1998	13	1	12
Sami Labs	5861415	19 January 1999	17	0	17
		Total number of citations	157	45	112
		Percentage of citations	100	29	71

capabilities of the biotech and pharma industries. One can therefore expect this percentage to rise in the coming years.

The largest number of patents protects pharma inventions. This is a reflection of the importance of this industry, which has had many high-value international deals. The number of biotech patents, however, is much smaller. Also, although the biotech numbers have increased in the past few years, there has not been the same year-on-year consistency, which is not surprising given the small numbers. The small number of these patents reflects the fact that as elsewhere, the Indian biotech industry is younger and smaller than its pharma counterpart. Following a worldwide trend, major Indian pharma companies have entered the area of biologics recently and some products, such as Reditux (generic Rituximab) and Filgrastim from DRL, and Interferon alpha 2B from Wockhardt are already on the Indian market. The lack of patents pertaining to biosimilars is due, in particular, to the lack of a clear regulatory pathway for such molecules in the US at present. Major biologics worth about US$ 10 billion are coming off patent[1] by 2009 and the US Senate is discussing ways to bring biosimilars to the US market in the next few years. We therefore expect innovation, and US patents (as for expression systems or bio-manufacturing processes) in this area to increase in the years to come, as this market becomes increasingly important for some Indian companies.

Medical device companies are more likely to have design patents than, say, therapeutics companies, and the negligible number of design patents is indicative of the lack of certain types of cross-disciplinary skills in the area of medical devices and instrumentation in India. This situation is also reflected in the fact that India meets 85% of its needs in these areas through imports[2]. The recently launched Stanford-India Biodesign Program will bring engineers and doctors together to explore needs in the areas of implants, devices and bio-instrumentation. The numbers of design patents granted to Indian companies should increase in the future.

Coming to the matter of patent citations, in general, the higher the number of citations of a given patent, the more valuable it is as a basis for future work. This is illustrated by the large number of citations received – up to the end of 2007 – by certain (non-Indian) fundamental patents granted by the USPTO; 553 for 4816567 (Old Cabilly), 257 for 4399216 (Axel patent) and 138 for 5225539 (Winter patent). A few patents from India are cited several times: it appears that so far there are no patents that represent fundamental innovations or high-impact technological breakthroughs.

Current patent holdings reflect work done in the past. What does the future look like for Indian biotech and pharma companies? First, R&D funding is on the rise. Between 1995 and 2004, the Indian pharma industry saw a greater than six-fold increase in R&D expenditure, with consistent year-on-year increases[3]. Ranbaxy spends the most on R&D. However, the company with the highest R&D intensity – the ratio of amount spent on R&D to sales – is DRL (12.3%). Sun Pharmaceuticals (11.4%) and Glenmark (9.7%) also have a higher proportionate investment in R&D than Ranbaxy (9.3%)[3]. Furthermore, the recent acquisition of the Ranbaxy promoters' stake by Daiichi Sankyo (www.biospectrumasia.com/Content/110608IND6368.asp) raises questions about the future direction of growth of the company. The R&D intensity of the top Indian companies compares reasonably well internationally, since the top ten 'big pharma' are at 13–15%, and some of the Indian investment has been in original drug discovery. Second, there are also more varied collaborations. Partnerships with multinational companies, with the Bill & Melinda Gates Foundation and other international non-profit organizations, and with both Indian and foreign academic institutions have risen. Third, new gov-

ernment initiatives such as the Small Business Innovation Research Initiative of the Department of Biotechnology will benefit industrial R&D. All of these steps bode well for the R&D of Indian companies in the years to come.

Conclusion

In this study we have analysed all the US patents of homegrown Indian biotech and pharma companies. The current patents overwhelmingly relate to pharma rather than to biotech inventions, but both are growing. The industry does not have many design patents. Although the current patents largely reflect the capabilities of generic companies, R&D has recently been spurred by increases in funding and partnerships, some of which are directed at original drug discovery. This will show up in patents granted to Indian companies in the years to come.

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ACKNOWLEDGEMENTS. We thank V. Rama Chandra Reddy for preliminary work and Sanket Godha for assistance. Financial support from the Wadhwani Foundation is acknowledged.

Although none of the authors was directly supported by industry, the Institute of Bioinformatics and Applied Biotechnology (IBAB), Bangalore has received support from, and has collaborations with, biotech and pharma companies. As far as the companies listed in this article are concerned: the institute has received a faculty chair from Biocon. Also, Kiran Mazumdar-Shaw, Chairman and MD, Biocon, is on the Governing Body of IBAB.

Received 25 June 2008; revised accepted 12 November 2008