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Biotechnology in India:

Its Policy and Normative Framework

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FOREWORD

I

In many regards India is a country in transition, a characteristic which partially explains the contrasts found in several social, economic and scientific sectors. For instance, a significant percentage of the Indian population lives under the poverty line but manages to coexist with a growing wealthy class. Also contrasting are certain features of India's economy: subsistence agriculture coexists with high-tech clusters of information and communication technologies as well as biotechnology. Moreover, industrialization and the services sector are progressing steadily and have made of India one of the world's most dynamic economies. Education also presents sharp disparities. Although illiteracy remains a critical problem, India can rely on one of the world's largest pools of and postgraduate professionals as well as PhDs.

The list of the contrasts could continue. This may not be surprising since India is the world's largest democracy and it is second most populated country in the world, with more than a billion inhabitants. When referring to India, statistics and numbers pertain to a distinct dimension. Biotechnology as a sector exemplifies the aforementioned disparities. It is one of the most modern and developed sectors of the Indian economy, and it has been one of the engines of the present prosperity of cities such as Hyderabad and Bangalore, as well as the Mumbai/Pune area. And although already thriving, it is easy to foresee that it's grow is nothing in comparison to what it will be in the near future.

Biotechnology has a broader societal dimension in India. It is not regarded only as a private profiting activity, but also as a tool to foster national development. In fact, India quickly identified the potential biotechnology had for the promotion of national development. The Sixth Five Year Plan, 1980-1985, singled out biotechnology as a useful means to meet the health and agriculture needs of the Indian population.[1] Since then, technology in general, and biotechnology in particular, have been at centre stage of Indian national development strategy.

Efforts have been undertaken to turn innovation into goods accessible to the large Indian public and adapted to local conditions. In achieving this goal, Indian innovation also benefits numerous developing countries that share Indian climatic and economic conditions. These benefits are indeed clear with regards to green and, particularly, red biotechnology. This last is due to the fact that the Indian biotechnological sector is largely concentrated in healthcare biotechnology, with particular emphasis in the fields of vaccines and recombinant products: revenues generated by biopharmaceuticals are five times greater than those generated by bioservices (the second area of specialization) while the number of biopharmaceutical firms is double that of bioservices.[2]

The growth of the biopharmaceutical sector has been so important that some foresee that it will not only be able to equal or increase the economic revenues generated by the Indian conventional pharmaceutical generics industry, but also to cause a major paradigm shift from the development of chemistry-driven medicines to biopharmaceuticals. It is too soon to ascertain whether this will be true or not, but it indeed reflects the rapid development that the biopharmaceutical sector has achieved.

1. More precisely, it identified "tissue culture application for medicinal and economic plans; fermentation technology and enzyme engineering for chemicals; (…) emerging areas like genetic engineering and molecular biology". See Planning Commission, *Sixth Five Year Plan*, Government of India, New Delhi, 1981. In link (*accessed May 2010*).
2. In the biennium 2006-2007, the revenues generated by biopharmaceutical amounted to 1482 US$ million; bioservices 273; agricultural biotechnology 229; industrial biotechnology 98; and bioinformatics 35. 142 biopharmaceutical firms and 74 of bioservices firms were identified. Biospectrum, *India boosts CRAMS Sector*, 2008.

II

The European Union and India have had a privileged relationship since adopting the 2004 *India-EU Strategic Partnership*. Annual high-level summits strengthen the political ties, while the economy makes the relationship especially important for both sides: the European Union is India's main trading partner and India is number nine on the list of the EU's partners, accounting for almost 2 per cent of EU exports and imports. Almost a decade ago the Euro-Indian relationship became also stronger in the scientific and technological area thanks to the 2001 *Science and Technology Cooperation Agreement*. This treaty encourages cooperative research and development activities in science and technology fields of common interest between the EU and India.

The abovementioned political, commercial and scientific strong relationships, added to the facilities that in the last decade India has given to foreign direct investment, help to explain the European interest and presence in the Indian biotechnology sector. On the other hand, the size and dynamism of some Indian biotech companies leads these companies to invest in Europe and even take over some European firms. Therefore, strategic alliances between European and Indian companies are not surprising anymore, while outsourcing of bioservices from Europe to India is steadily growing. In this context, the potential conclusion of an association agreement between the European Union and India, covering issues such as services, intellectual property and investment, becomes of the utmost relevance.

III

When assessing the Indian legal framework for biotechnology, attention must be paid both to international compromises and internal norms. India is party to several international treaties that directly impact biotechnology regulation and management. These treaties pertain to several public international law regimes, such as international trade law, international environmental law, intellectual property law and international human rights law. On the other hand, the national normative framework is the outcome of a relatively unsystematic evolution which has its origin in the 1986 Environment (Protection) Act. The norms of the Environment (Protection) Act provide the legal background to the Rules for Manufacturing, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, which are the other key pieces of legislation.

The majority of the agencies that enact rules and control activities in the biotechnology field pertain to four ministries of the central government. The Ministry of Science and Technology controls the Department of Science and Technology, the Department of Scientific & Industrial Research and the Department of Biotechnology. The Ministry of Health governs the Indian Council of Medical Research. The Ministry of Agriculture controls Indian Council of Agriculture Research. The Ministry of Human Resource and Development control the University Grants Commission. Finally, the Department of Scientific & Industrial Research funds the Council of Scientific and Industrial Research (both of whom directly fund biotechnology).

A series of committees set up a multi-tiered regulatory framework aimed at ensuring the biosafety of genetically engineered organisms in India. These agencies are the Review Committee on Genetic Manipulation, the Genetic Engineering Approval Committee, the Recombinant DNA Advisory Committee, the Institutional Biosafety Committee, the State Biotechnology Coordination Committee and the District Level Committees. In the biopharmaceuticals domain, these bodies work together with the Central Drugs Standard Control Organization and the Drugs Controller General of India, which have a broader mandate covering all pharmaceuticals.

The multiplicity of regulatory agencies and the complex approval procedures have been identified as factors that negatively affect the functioning of the Indian biotech sector. In response to sector specific reports time-frames for approval of biotech products have been streamlined, but the implementation of other proposed reforms, such as the establishment of a single-window agency, is still pending. If created, the National Biotechnology Regulatory Authority will regulate the research, manufacture, import and use of genetically engineered organisms and products derived thereof.

IV

Indian patent law underwent significant changes during the last fifteen years. The main driver of these changes has been the need to adapt Indian law to the TRIPS Agreement. The Patents (Amendment) Act, 2002 introduced significant changes with regard to the patentability of biotechnological inventions. By specifically allowing for the patentability of microorganisms, the law complied with the requirement of article 27.3(b) of the TRIPS Agreement. The exclusion of inventions which represent the 'discovery of any living thing or non-living substance occurring in nature', consists of 'traditional knowledge' or of 'known properties of traditionally known components' would lead to the exclusion from patentability of some biotechnology-based inventions. One of the key issues is whether a merely isolated (unmodified) biological material may be deemed as not 'occurring in nature'. The Indian law seems to provide that only materials, including microorganisms and genes, that are the result of human intervention would be patentable.

The Patents (Amendment) Ordinance, 2004, later replaced by the Patents (Amendment) Act, 2005 (Act 15 of 2005) introduced the third set of amendments to the 1970 Patent Act. The key modification was the introduction of product patents for fields of technology previously excluded from protection. This Amendment introduced a new provision (section 3(d)) aimed to prevent the grant of patents on 'minor' or 'frivolous' inventions. Although the main objective of Section 3(d) has been the avoidance of what have become common 'evergreening' practices in the pharmaceutical industry, this provision has apparently not been an absolute barrier against the patenting of variants of existing products, such as polymorphs.

There have been concerns about the extent to which public investment in R&D translates itself into innovations effectively leading to new production processes and products. Some institutions have put in place active policies to increase the transfer of R&D results to industry, including by promoting the patenting of inventions eventually obtained by their researchers. The Protection and Utilization of Publicly Funded Intellectual Property Bill was introduced to the Indian Parliament in 2008, with the goal of encouraging patenting by universities and autonomous research institutions that are government funded. In assessing this Bill, it has been held that "[O]verall, data from the U.S. experience suggest it is unlikely that Indian institutions will earn much money, or even cover costs, from these activities. If income is the goal of the new legislation, the game is probably not worth the candle". Other commentators, however, have welcomed the initiative as 'a step in the right direction' that may 'encourage and motivate inventors and institutes and provide a legal framework for better interaction between industry, academia and government'.

I. INTRODUCTION

1. DEFINING BIOTECHNOLOGY

Given the different approaches existing on the definition of 'biotechnology', and the plurisemic use of the term, it seems necessary to briefly introduce its potential different meanings. Biotechnology makes reference to the activity consisting of the utilization or manipulation of living organisms for obtaining products or implementing processes, generally by means of the integration of natural and engineering sciences.

Biotechnology can be approached from different angles. Some describe it as "a field of technological activity in which biochemical, genetic, microbiological, and engineering techniques are combined for the pursuit of technical and applied aspects of research into biological materials and, in particular, into biological processing",[3] such as "the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for production of knowledge, goods and services."[4] Under a wide approach based on the biological nature of the products and processes involved, old techniques, such as fermentation processes, as well as the newest ones, such as biomolecular engineering may be included in the range of activities falling in the field of biotechnology.

It is probably due to the wide-encompassing nature of the term "biotechnology" that some confusion regarding its use can be perceived. Thus, it has become frequent to use "biotechnology" to allude to "modern biotechnology" only. This greatly reduces the scope of biotechnology as a technological activity, and excludes important and traditional fields of biotechnology from its scope. It is therefore important to properly define "modern biotechnology".

According to the Indian draft National Biotechnology Regulatory Bill 2008, modern biotechnology is "the application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells; or organelles, or fusion of cells beyond the taxonomic family that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection. It excludes: *in vitro* fertilisation; natural processes such as conjugation, transduction, transformation; polyploidy induction; and accelerated mutagenesis".[5]

The manipulation of genetic material through techniques of modern biotechnology permits to develop genetically-modified organisms (GMO), which can be living genetically modified organisms (LMO) and non- living genetically modified organisms. GMO can be grouped into the following categories: transgenic crops, recombinant pharmaceutical products, genetically modified microorganisms, transgenic animals and industrial products.

A more comprehensive categorization of biotechnology, based on its end-use has also been proposed. In this classification products are adscribed to one of the following biotechnology thematic subsets: healthcare biotechnology, agricultural biotechnology, industrial biotechnology and environmental biotechnology. Each one of these broad categories encompasses a range of products, activities and techniques:

3. R. Cammack (et al.), *The Oxford Dictionary of Biochemistry and Molecular Biology*, Oxford University Press, 2008.
4. OECD, *OECD Biotechnology Statistics 2009*, 2009, p. 3.
5. Draft National Regulatory Bill, 2008, art. 2(k), See in link (*Accessed March 2010*).

- Healthcare biotechnology: medicines, vaccines, diagnostics and gene therapy.

- Agricultural biotechnology hybrid seeds, biopesticides, biofertilizers and plant extraction.

- Industrial biotechnology: industrial enzymes, polymers, biofuels and fermentation products.

- Environmental biotechnology: effluent and waste water management, bioremediation, biosensors and creation of germoplasms.

Similarly, diverging approaches exist also in respect of the meaning of certain bioproducts, such as biopharmaceuticals. Although 'biopharmaceutical' is a widely used term, it is not always employed with the same meaning. There are several possible notions of what a biopharmaceutical is.[6]

- The first definition, which is the most widely accepted, alludes to biopharmaceuticals as medicinal products, therapeutics, prophylactics and *in vivo* diagnostics with active ingredients inherently biological in nature and manufactured using biotech.

- A second definition limits biopharmaceutical products to those fulfilling the first definition and involving genetic engineering. This corresponds to what has been named "new or modern biotech", which is a subset of the abovementioned notion. Since the early eighties, when recombinant DNA and hybridoma technology were developed, the recourse to this notion has become more and more usual. This was, for instance, the definition used by the Federal Trade Commission in its 2009 report on biosimilars. According to the Federal Trade Commission, "*biologic* drugs are protein-based and derived from living matter or manufactured in living cells using recombinant DNA biotechnologies".[7] As it can be observed, this approach limits the concept of 'biologic drugs'.

- Another definition of 'biopharmaceutical' implies a *contagious* use of the term. This can be observed when any health-care product that is loosely related to biotechnology is deemed to be a 'biopharmaceuticals'. For instance, all products manufactured by a company that produces biopharmaceuticals would be considered biopharmaceutical products.

- Finally, another possible approach, widely used among those working in the commercial and media areas of the pharmaceutical industry, employs the term 'biopharmaceutical' as a synonym of anything that is pharma-related.

The third and fourth definitions are market-oriented rather than science-based notions. This is why, on the one hand, it is advisable to exclude them from technical or scientific documents and, on the other, caution must taken when reading biotechnology statistics. Consequently, this document follows the first and second notions, particularly the latter, and uses the term 'modern biopharmaceuticals'. Although the scope of the first definition is more accurate, the second one is useful due to the fact the products covered thereunder generate more controversies from the point of view of its sanitary approval. That is, most of the present challenges have to do with modern biopharmaceuticals. Therefore, although references are made to immunoglobins, sera, vaccines, non-engineered insulin and other biopharmaceuticals that fall under the first definition, most problems arise in relation to modern biotechnological products which, hence, frequently are the focus of attention.

6. See in detail R. A. Rader, "(Re)defining biopharmaceutical", *Nature Biotechnology*, vol. 26, nº 7, 2008, p. 747.
7. FTC, *Emerging Health Care Issues: Follow-on Biologic Competition,* 2009, p. I, link (*Accessed March 2010*).

2. CONTEXT

2.1 Biotechnology and development in India

India has placed great importance on the development of a strong scientific sector since its early days as an independent country. Technology and science have been associated not only with culture, social progress and the import substitution paradigm, but also with political pre-eminence and even national pride. P. Ghosh affirms for instance that the commitment of the Indian government in the biotech field "emerges out of compulsions and social commitments to minimize foreign dependence".[8]

As early as in 1983, the Long Term Plan in Biotechnology identified as top priorities self sufficiency in food, housing and clothing, as well as a balance in international trade. If statistics and forecasts on the percentage of imports are taken into account, India would be on the right track to fulfil those goals, since it has almost overcome its previous dependence. It is foreseen that in 2012 only 10.95% of local consumption of biotechnological products will be imported.[9]

Thanks to decades of important and constant efforts on the part of Indian society, nowadays India is acknowledged for having a thriving knowledge-based sector and world-class scientific centres. What once were buoying but isolated sectors, such as those based on information and communication technologies, are presently accompanied by other dynamic sectors. At present biotechnology is a fast growing field and one of the most successful scientific and economic areas in the Indian economy.

In a country where poverty is still a daunting reality,[10] investing in science and technology is a deliberate pro-development choice. Although Indian knowledge-based industries do not present notable differences in terms of management and goals when compared to Western companies, in India efforts are also undertaken to turn technological innovation into goods and services which are not only useful to the economic development of the country but also accessible to the Indian public and adapted to local conditions. As the *Annual Report* of the Department of Biotechnology states, in India, "balancing needs of economic competitiveness with affordable products continues to engage policy makers and the industry".[11]

The equilibrium India tries to achieve between innovation and access is important to the entire developing world. At present Indian innovation benefits numerous developing countries that share Indian climatic, logistic and economic characteristics. This has been seen particularly in the field of information and communication technologies, and in the area of pharmaceutical products. An outstanding challenge is to replicate the same success in the field of biotechnology, two good candidates being biopharmaceutical products and bioinformatic services.

The need to link Indian technological development with the economic and human development of the country has been emphasized in several relevant reports. For instance, in the specific field of biotechnology the 2004 *Report of the Task Force on Application of Agricultural Biotechnology* stated that biotechnology offers opportunities for converting India's biological wealth into economic wealth and new employment opportunities on an environmentally and socially sustainable basis.[12] Even more

8. K. Ghosh, "Indian Efforts for Developing Biotechnology", *Asian Biotechnology and Development Review*, vol. 11, nº 1, 2008, p. 36.
9. *Ibid*. p. 43.
10. In 2005 42 per cent of the Indian population still lived below the poverty line, that is, with less than 1.25 US$ per day. See World Bank, "New Global Poverty Estimates - What it means for India", link (*Accessed April 2010*) 456 millions in 2005)
11. Department of Biotechnology, *Annual Report 2008-2009*, 2010, p. 1.
12. Task Force on Agricultural Biotechnology, *Report of the Task Force on Application of Agricultural Biotechnology* by: M. S. Swaminathan Chairman, Task Force on Agricultural Biotechnology, May 2004, Ministry of Agriculture, India, p. 6.

clearly, it has been stated that "for Indian policy makers it is paramount not only to encourage excellence in high tech industries but also further inclusive pro-poor innovation".[13]

These statements are not anecdotal. In India there is an open debate on what the priorities of the research should be. This is a debate that, in fact, requires to consider whether Indian innovation should be different -and if so, to what extent- from the innovation generated in countries pertaining to the Organisation for Economic Cooperation and Development (OECD). In a related way but at the other extreme of the innovation chain, questions also are posed with regard to accessibility. Thanks to countries such as China and India, products such as electronics and pharmaceuticals have become accessible to masses of people all over the world. Personal computers for less than 80 US$ or AIDS generic medications with prices ten-fold lower than branded antirretrovirals have improved or saved the lives of tens if not hundreds of millions of people. It would be naïve to affirm that Indian manufacturers produce these goods at highly competitive prices with the sole goal of fostering the well-being of the masses. Nevertheless, it would also be erroneous not to establish a balance between the price of the invention and the economic possibilities of those willing or needing to consume the invention.

As a subset of science and technology, India quickly identified the potential biotechnology had for fostering national development. The Sixth Five Year Plan, which set out the developmental priorities of India for 1980 - 1985, signalled out biotechnology as a useful tool to meet the health and agriculture needs of the Indian population. More precisely, it identified "tissue culture application for medicinal and economic plans; fermentation technology and enzyme engineering for chemicals; (…) emerging areas like genetic engineering and molecular biology".[14] The Council for Scientific and Industrial Research was indentified as the body in charge of guaranteeing the coordination of the biotechnological initiatives undertaken by different departments.

In 1982 the National Biotechnology Board was created. This was a small division within the Department of Science and Technology devoted to the management of biotechnology. More specifically, it was established to signal out priorities and oversee and plan for required manpower, integrated industrial development and large scale use of biotechnology products and processes.[15] This inter-departmental body drafted and issued in 1983 the *Long Term Plan in Biotechnology for India*, which mapped the priorities in that field for the years to come. The document was drafted taking as a reference the developmental needs of the country.

Four years later, in 1986, a Department of Biotechnology was founded.[16] In fact, this new department within the Ministry of Science and Technology resulted from the upgrading of the National Biotechnology Board. This was coincidental with the first experimental release of a genetically engineered organism into the environment as well as with the production of the first transgenic farm animal.

Since those early beginnings of biotechnology in India, it has been regarded as fundamental for the development and placed at the centre stage of the Indian development strategy. In 2001 the Vision Statement on Biotechnology affirmed that the goal of the Indian biotechnology policy was "attaining new heights in biotechnology research, shaping biotechnology into a premier precision tool of the future for creation of wealth and ensuring social justice –specially for the welfare of the poor".[17]

13. J. P. Wogart - CREST OMC Working Group, *Country report India: An Analysis of EU-Indian Cooperation in S&T*, 2008, p. 20.
14. See in particular Planning Commission, *Sixth Five Year Plan*, Government of India, New Delhi, 1981. In link (*Accessed May 2010*).
15. S. Chaturvedi, "Emerging Indian entrepreneurship in biotechnology and National Innovation System: exploring linkages and prospects", *International Journal of Technology and Globalisation*, vol. 5, nº 1/2, 2010, p. 78.
16. See P. M. Bhargava, "Biotechnology in India: The beginnings", *Biotechnology Journal*, vol. 4, 2009, pp. 313-318.
17. Department of Biotechnology, *Biotechnology – A vision (Ten Year Perspective)*, 2001, link (*Accessed April 2010*).

2.2 Indian scientific and technological research system

Before focusing the attention on the bodies and institutions most directly related to biotechnology, the broader Indian scientific and technological research system is briefly introduced in this section. This is important for at least two reasons. Firstly, it is in the overall framework of the Indian science and technology system that bodies which are specialized in biotechnology operate. It is, therefore, important to present the key elements of that framework. Secondly, this overall picture is also necessary because agencies pertaining to different areas of expertise promote and participate in biotechnology-related activities. That is, not only institutions with the 'biotechnology' tag in their name perform biotechnology-related activities.

Numerous Indian ministries, public agencies and institutions deal with science and technology. Most of these agencies belong to the central government, which both from a political and economic point of view is the major player in the Indian innovation system. In effect, the scientific and technological research system in India is managed by the central government, although state governments, independent research institutions, universities, private companies and non-governmental organizations play relevant roles as well.

The central government concentrates the authority and leadership in the field of science and technology. An important part of the research and development programmes are promoted by ministries, departments and committees which are under the authority of the central government. The key role of the central government is also reflected in terms of funding, since it finances two thirds of public research.

Most of the scientific initiatives are promoted by the central government through several ministries. The ministries with competences in the science and technology field are the Ministry of Science and Technology, the Ministry of Health and Family Welfare, the Ministry of Agriculture and the Ministry of Human Resource Development. Within each one of these ministries several departments conduct science and technology-related research.

- Within the Ministry of Science and Technology, two departments are crucial: the Department of Science and Technology and the Biotechnology Department. The Department of Science and Technology formulates policies on science and technology, supports the research conducted in India and coordinates international relations in the area of science. Other departments working intensively in science and technology in the same ministry are the Department of Atomic Energy, the Department of Ocean Development, the Department of Space and the Department of Scientific and Industrial Research.

- Most of the biomedical research is promoted by the Ministry of Health and Family Welfare, which controls the Indian Council of Medical Research, a key institution in that field.

- Agriculture, agroforestry, animal husbandry, dairy and fisheries are concerned is under the authority of the Ministry of Agriculture whereunder several departments and institutions operate. Among them, the Indian Council of Agricultural Research is prominent.

- Finally, the Ministry of Human Resource Development plays an important role in the management and research of relevant scientific institutions, such as the Indian Institutes of Technology and the Indian Institute of Science. It also controls the University Grants Commission.

Due to the ties between education, science and technology, and given the role attached to science and technology for the promotion of the Indian development, the Indian government has considered

education as a crucial development tool.[18] This was emphasised since India became an independent State. The All-India Council of Technical Education was created in 1945, and in 1947 the Report of the Scientific Manpower Committee was adopted. Both were crucial to initiate and foster engineering and technological education. Despite the development hurdles, India has made an effort to devote all possible resources to improve scientific education. At present, the university system is an essential component for the promotion of science and technology in India. Around 350 universities exist in the country. Some are financed and managed by the central government, others are under the control of state governments or privately funded.

The importance attached to education can also be seen in respect of biotechnology. In 1984, the National Biotechnology Board launched an integrated short-term programme in the field of biotechnology. Shortly after, the Department of Biotechnology started its activities to satisfy the demand of human resources in the field of biotechnology. Post-graduate education in biotechnology, boosted by the Department of Biotechnology, started in 1986 with a model system of post-graduate teaching in biotech. Later on, in 1988, specialized MSc courses on marine and agricultural biotechnology were organized. Among the tasks that the Department of Biotechnology currently performs is the support of education programs in biotechnology. It supports more than thirty courses on General Biotechnology, seven in Agricultural Biotechnology, one in Healthcare Biotechnology, three in Neurosciences and two in Marine Biotechnology. Around 1000 students participate annually in courses organized or supported by the Department of Biotechnology.[19]

In addition to universities' research centres, there are many scientific institutions conducting research in India. The most prominent among them are the seven Indian Institutes of Technology, the Indian Institute of Science, the Institutes of Information Technology and the All India Institute of Medical Sciences. Regarding the Indian Institutes of Technology and the Indian Institute of Science, it has been highlighted that "The formation of higher educational institutions, such as the Indian Institutes of Technology (IITs) and the Indian Institutes of Management (IIMs), was part of a policy to create a modern Indian state".[20] With regard to biotechnology, the Delhi Indian Institute of Technology launched a five-year integrated programme in Biochemical Engineering and Biotechnology as soon as in 1992. The Indian Institute of Science located in Bengaluru is a leading research organization both in India and South Asia and accounts for almost 10 per cent of India's total scientific output in terms of scientific publications, has several hundreds of faculty members and an important percentage of its students pursue doctoral degrees.

As far as biotech infrastructure is concerned, India has developed world class facilities for numerous biotech activities and techniques: "facilities for DNA sequencing, protein engineering, bioprocessing, crystallography, molecular graphics and modelling, PL3 and PL4 level containment for work on dangerous pathogens, prescribed glass/animal houses for transgenic animal/plant research, repositories of microorganisms important in agriculture, healthcare and industry, ex-situ and in-situ gene banks for crops and endangered medicinal and aromatic plants, medium and high throughput screening facilities for drugs and pharmaceuticals, biosensors, nuclear magnetic resonance machines, different mass spectrometers for various purposes, GM testing labs and recently micro arrays, automated DNA sequencing as well as robotic plasmid isolation equipment".[21]

18. J. P. Wogart-CREST OMC Working Group, op. cit.
19. S. Chaturvedi, op. cit., p. 83.
20. J.P. Wogart-CREST OMC Working Group, op. cit.
21. S. Rao, "Indian Biotechnology Developments in Public and Private Sectors – *Status* and Opportunities", *Asian Biotechnology and Development Review*, p. 3. link (*Accessed June 2010*).

2.3 Funding science, funding biotech

Since its independence, India has tried to foster its economic and social development through the organization of public policies and activities in five-year plans. Presently, the Eleventh Five-Year Plan is being implemented. This plan dramatically increases the funding for science and technology, a projected outlay of 73.304 Crores which almost triples the sum devoted to science and technology in the previous five-year plan.[22] As in previous plans, science and technology play an increasingly important role, and the Five-Year Plan emphasizes the need to promote an enhanced interaction between scientific institutions and the industrial sector.

From both the political and economic points of view, the major player of the Indian innovation system is the central government. On one hand, most of the research and development programmes are promoted by ministries, departments and committees which are under the authority of the central government. On the other hand, the government funds two thirds of public research.

In the biennium 2005-2006, the share of the central government and public enterprises in the overall research and development expenditure was 62 per cent; State governments accounted for 7.7 per cent, higher education 4.4 per cent and the private sector 25.9 per cent.[23] That is, 74.1 per cent of the total research and development expenditure was funded with public resources.

If public and private expenditures are taken together, 0.89 per cent of the Indian Gross National Product is devoted to research and development.[24] This percentage is still far from the 2 per cent that most developed countries invest in research and development; however it is higher than in most developing countries. In total, in the biennium 2005-06 India devoted 1994665.23 Rs. Lakhs to research and development.

Given the importance attached to biotechnology as a tool to foster national development, biotechnology research and development has become a cross-cutting objective in the Indian public sector. Although a particular department (the Department of Biotechnology) is entirely devoted to biotechnology, different ministries, departments and councils also allocate funds to biotech-related activities.[25] Among the latter the most prominent probably are the Department of Science and Technology, the Council of Scientific and Industrial research, the Indian Council for Medical Research, the Indian Council of Agriculture Research, the University Grants Commission and the Department of Scientific and Industrial Research. In fact, it is likely that the share of research and development expenditure corresponding to the Department of Biotechnology is relatively low: only 2 per cent of the total funding, despite the fact that since the nineties the budget of the Department of Biotechnology has been increased (see *Figures 1* and *2*).[26]

In fact, in terms of funding, the Department of Biotechnology ranks number 8 out of 13 departments/ institutions. Moreover, it has to be taken into account that the five major agencies concentrate 83.9 per cent of the total research and development expenditure incurred by Indian scientific agencies.[27] Recent plans have attracted more funding: in 2009, Rs 18 billion (351 U$S billion) were allocated to biotech R&D in order to foster the NBDS.[28] In addition, it has been reported that "[T]he biotechnology

22. In effect, the Tenth Five-Year Plan projected 25.301 Crores to science and technology. S. Aggarwal, "11th Plan triples allocation for science and technology", *Indian Express*, 28/12/2007. link (*accessed January 2010*).
23. Department of Science and Technology, *Research and Development Statistics 2007-2008*, New Delhi: Department of Science and Technology, 2009, p. 4.
24. *Ibid*., p. 3.
25. See, P. K. Ghosh, op. cit., p. 36.
26. Department of Science and Technology, op. cit., p. 26.
27. *Ibid*., p. 7
28. E&Y, "Nurturing growth", E&Y, *Beyond Borders. Global Biotechnology Report 2009*, 2009, p. 114.

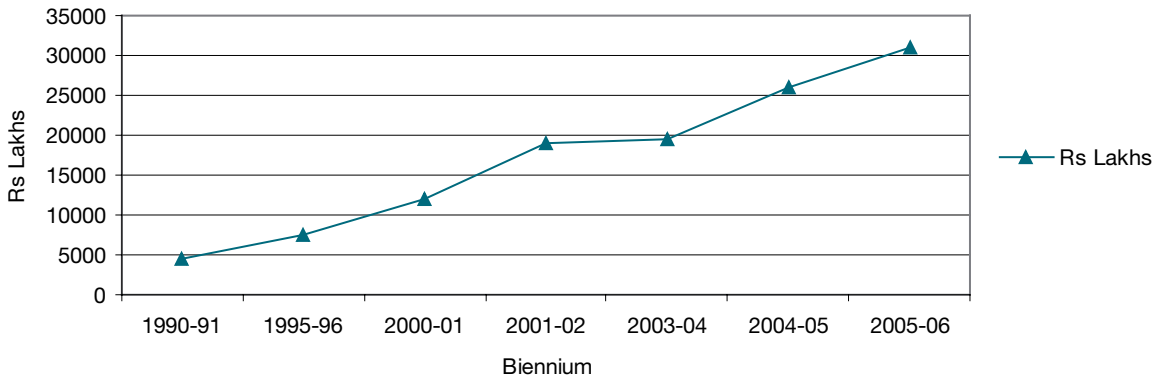
department has a good record in supporting industrial projects, spending around US$200 million (€142 million) a year to develop biotechnology initiatives".[29]

Figure 1: **Financial progress for the Department of Biotechnology in the eight, ninth and tenth plan period**

	Outlay (Rs. Crores)	Anticipated Expenditure (RS. Crores)
8th Plan (1992-1997)	265.00	395.84
9th Plan (1997-2002)	675.00	621.71
10th Plan (2002-2007)	1450.00	1649.66
11th Plan (2007-2012)	6389.00	

The number of extramural research and development projects and the funds approved by the Department of Biotechnology confirms the positive evolution of public investment in biotech research. During the 2003-2004 biennium there were 249 approved projects with an approved cost of 60.01 Crores, these figures were doubled and tripled, respectively, in the 2005-2006 biennium: 422 approved projects with a cost of 174.73 Crores.[30] The institutions benefiting from these projects and funding were universities and colleges (54%), deemed universities (6%), institutes of national importance (12%), national laboratories (17%) and other institutions under state governments, non-governmental agencies and registered societies (11%).[31]

Figure 2: **Department of Biotechnology expenditure on research and development**[32]



29. "Indian firms may well take large slice of global biosimilars pie", *Scrip*, 5/8/2009, link (*Accessed February 2010*).
30. Department of Science and Technology, op. cit., p. 70.
31. *Ibid*., p. 70.
32. Data extracted from Department of Science and Technology, op. cit., p. 78.

3. INDIA AND EU COOPERATION IN THE FIELD OF SCIENCE AND TECHNOLOGY

3.1 Evolution

Indian scientists and technological entrepreneurs have had a record of fruitful collaboration with their European peers, and some EU Member States have strong bilateral relations with India in the field of science and technology. This is the case, in particular, of France, the United Kingdom and Germany. Nevertheless, if the present cooperation record in the field of science between the EU and India is compared to that of the EU and other emerging economies, such as China or Brazil, it is clear that the Euro-Indian relationship has yet a long way to go. To increase the cooperation in the field of science and technology, several difficulties must be overcome. According to European entrepreneurs, the most significant difficulties are the lack of information about the Indian science and technology system and the complexity of the Indian system itself.[33]

In 1962 India and the European Economic Communities established diplomatic relations. Since then, several legal and political instruments have framed the Euro-Indian relationship. Between 1973 and 1985 several commercial agreements were adopted, and in 1991 the European Community Investment Partners scheme in India was launched to provide funding and facilitate joint ventures among small and medium companies.

The present framework for cooperation was set up in the early nineties, when the *Joint Political Statement* (1993) and the *Cooperation Agreement between the Community and India on Partnership and Development* (1994) were adopted. These texts set up the institutional basis for the EU-India political interaction. In 2000 the first EU-India summit was held in Portugal. This was an initial meeting of paramount importance; since then similar meetings have been regularly held.

All the Euro-Indian political summits have highlighted the importance of the cooperation in the field of science and technology. At the meeting held in The Hague in 2004, the Euro-Indian relationship was strengthened with the adoption of the *India-EU Strategic Partnership*. India became one of the selected EU's 'strategic partners', an Action Plan was adopted and several areas of collaboration were identified. The Sixth EU-India summit, held in 2005, endorsed the *EU-India Joint Action Plan*, aimed at strengthening the Euro-Indian partnership in key areas of interest for India and the EU.[34] This was a major step towards the identification of specific areas of collaboration. The importance of the ongoing cooperation in the field of science and technology was also emphasized in the 2006 Helsinki Euro-Indian political summit.

In the specific field of technology, the EU and India have a strong cooperation record. The *India-EC Science and Technology Cooperation Agreement* was signed in 2001 and came into force on 14 October 2002. This treaty was aimed at promoting collaborative activities and research projects in five areas, including genomics and biotechnology for health. Although the *Science and Technology Cooperation Agreement* was a milestone, the potential for a broader collaboration in emerging high-tech areas is substantial, as affirmed in the first EU-India Ministerial Science Conference, held in New Delhi in 2007. At this landmark event, the importance for the EU of the collaboration with India regarding science and technology was stressed. In fact, this was the first summit the EU and its Member States had ever held outside the European territory at a science ministerial level. 22 out of the 27 EU States sent ministers or high-level representatives pertaining to science related fields to meet with the Indian Ministry for Science and Technology, Earth Sciences and the Indian Ministry for Research. Academic and economic representatives were also present and a special meeting gathering professionals from both sides was held.

33. J. P. Wogart - CREST OMC Working Group, op. cit., p. 32.
34. See these areas in link (*Accessed August 2010*).

Presently, India is prioritized for collaboration under the international dimension of the EU's Seventh Framework Research Programme (FP7). This program and the EU-India *Science and Technology* Agreement are the main triggers for the scientific collaboration between India and the EU. The Tenth India-European Union Summit held in New Delhi on November 2009 welcomed the India-EU efforts to support joint research projects in the field of solar energy which were launched within the FP7. The Tenth India-European Union Summit also welcomed the abovementioned *India-EC Science and Technology Cooperation Agreement* as an important step to strengthen strategic cooperation.

Despite the progress in the Indian science and technology, there still exists an important gap between India and Europe in this field. Existing differences explain the potentially diverging views and interests in some technological fields and regulatory aspects. Nevertheless, according to the political principles endorsed at the India-EU Ministerial Science Conference in 2007 the relationship between India and Europe should be based on the principles of "symmetry, reciprocity, mutual benefit and, where appropriate, the co-investment of resources and joint actions".[35] These are principles that should be taken into account in all areas that may have an impact on scientific and technological development.

Since 2007, the EU and India has been negotiating the conclusion of a comprehensive association agreement which would cover issues such as trade, services, investment and intellectual property. As it has been said, "while there are a plethora of preferential trade agreements (..) there has been nothing to rival the ambition of the Euro-Indian trade agreement that is currently being contemplated".[36] The agreement, if concluded, would regulate a market comprising the fifth of the world's population: more than one billion of Indians and 500 hundred millions of Europeans.

This treaty is important for both parties since trading between India and the EU has doubled and investments have risen ten-fold in the past five years. The treaty could not be more important for India, since the EU is its main trading partner and India is number nine on the list of the EU's partners, accounting for almost a 2 per cent of EU exports and imports. The total trade between India and EU increased from 46 billions of Euros in 2006 to 55 billion in 2007.

With regards to the prospects of concluding the treaty, there are coincidental points that raise the probability of concluding the agreement. Both India and the EU attach great importance to the role of the State in the economy, "Thus, it may be easier to come to agreement on the degree the state can intervene when trade flows will be affected."[37] On the other hand, India and the EU may have a coincidental interest in excluding some sectors form the liberalization, such as agriculture and automobiles, since they are heavily protected and strategic both in India and in the EU.[38]

The effects of the text -and particularly of the intellectual property and services chapters- on technology-intensive areas such as pharmaceutical products could be far-reaching. In fact, it seems that non-tariff barriers will likely be the most contentious issue in the negotiations.[39] Additionally, given the role of India as world supplier of accessible products, such as medicines, the treaty must be viewed in a broader international and social context.[40]

35. *The New Delhi Communiqué*, India-EU Ministerial Science Conference, 7-8 February 2007, New Delhi.
36. S. Khorana, N. Perdikis, M. T. Yeung, W. A. Kerr, *Bilateral Trade Agreements in the Era of Globalization. The EU and India in Search of Partnership*, Cheltenham: Edward Elgar, 2010, p. xv.
37. *Ibid*., p. 10.
38. *Ibid*.
39. *Ibid*., p. 69.
40. See below IV.2.

3.2 The Science and Technology Cooperation Agreement

With the objective of fostering cooperative research and development activities in the field of science and technology, the European Community and India signed the first agreement on this specific area on 23 November 2001. The *Science and Technology Cooperation Agreement* (STCA) was concluded in the context of the cooperation and information exchange in science and technology under the abovementioned 1994 *Cooperation Agreement between the Community and India on Partnership and Development*. The STCA was established for a five-year period and covers all research and technological development activities; it also includes an annex on the protection of intellectual property rights. The Agreement renewing the *Agreement for scientific and technological cooperation between the European Community and the Government of the Republic of India*[41] was signed in 2007, as anticipated in the EU-India Summit held in Helsinki in October 2006, and foreseen in article 11 of the STCA.

The purpose stated both in the STCA and 2007 agreements is to "encourage and facilitate cooperative research and development activities in science and technology fields of common interest between the Community and India". This cooperation may cover activities of research, technological development and demonstration, and shall be guided by the following principles: *i*) partnership for balanced mutual benefits; *ii*) reciprocal access to the activities of research and technological development; *iii*) exchange of information affecting cooperative activities; *iv*) protection of intellectual property rights.[42]

Article 5 of both agreements identifies the possible forms that cooperative activities may adopt. Among the activities foreseen in the non-exhaustive list are the participation of research entities in projects promoted by each one of the parties, joint projects in the activities covered by the agreement, mobility of scientists and technical experts, joint organization of symposia, workshops and conferences, sharing of equipment and materials and dissemination of information on practices, laws and programmes relevant to scientific cooperation.

Politically, the STCA is under the control of the Indian Department of Science and Technology and the EU Directorate General for Science, Research and Development. Remarkably, the STCA created a Steering Committee on Science and Technology Cooperation. An equal number of representatives of each party make up the committee, which holds a meeting at least once a year. This committee was entrusted with the tasks of promoting and overseeing the collaborative activities mentioned in the treaty as well as those which could affect the collaboration under the agreement; facilitating the development of joint scientific and technological projects, identifying priority sectors, proposing the pooling of projects, reviewing the efficiency of the treaty and reporting to the Parties on the cooperation undertaken under the Agreement. The Steering Committee on Science and Technology Cooperation held its first meeting on March 2004, when five thematic priorities for cooperation were identified: surface transport, nanotechnology and multifunctional materials, health, climate change and information and communication technologies. Although the Steering Committee has organized numerous activities and has met four times, monitoring on the implementation of its decisions have allegedly been weak.

After the initial four years of the implementation of the STCA, an evaluation of the agreement was conducted. The assessment concluded that in a short period of time the STCA had positively contributed to the promotion of joint collaborative scientific activities and had had a positive impact on policy, but a more limited impact on the economy.[43] Nevertheless, it also mentioned several areas that should be reinforced, such as the participation of EU scientists in Indian research programmes, the promotion of mobility of scientists, the preparation of joint calls for proposals in the context of EU framework programmes, the awareness-raising on the opportunities offered by the Agreement and the role of the Steering Committee.[44]

41. *Official Journal of the European Union,* L 171/19, 1.7.2009.
42. See articles 4 and 3 of each one of the Agreements.
43. V. Pandey, *Impact assessment of the Scientific and Technological Cooperation Agreement concluded between the European Community and the Government of the Republic of India*, 2006, p. 23.
44. *Ibid*., p.5

3.3 Fields and mechanisms of collaboration

3.3.1 Framework cooperation programmes

The STCA does not set up specific obligations as far as funding for science and technology cooperation is concerned. By contrast, under the STCA each Party commits itself to allocate funds on a specific case-by-case basis, taking into consideration the applicable regulations and policies. For the EU, the principal tool to fund science and technology activities between India and Europe is the Framework Programme (FP).

The FP is the main EU mechanism for funding scientific research. It is open to companies, non-governmental organizations, universities, research centers and individuals of all countries, both European and non-European, under certain conditions. The seven consecutive FPs have traditionally been a good instrument for international science and technology partnerships. In effect, since 1984 these four-year programmes have supported research in science and technology taking place in third countries. Increasingly, FPs have included projects conceived in emerging economies -"third country participants"- such as Russia, China, India and Brazil. As far as their relevance for the Euro-Indian cooperation is concerned, it should particularly be highlighted the importance of the last two FPs: the 6th and the 7th.

The 6th Framework Programme (FP6) lasted from 2002 to 2006. It represented a major boost for scientific cooperation between India and Europe if the relatively low number of projects financed in previous FPs is taken into account. Between 2002 and 2006, 72 projects involving Indian researchers were financed by FP6.[45] It almost doubled the Indian share compared to FP4 (33 projects with Indian participation were funded)[46] and FP5 (32 projects with Indian participation were funded). In the context of FP6 more than 100 Indian institutions were somehow involved in EU funded projects, exceeding 250 million Euros. Although the focus was on sustainable development and climate change, biotechnology for health was also found among the main areas of collaboration.[47]

In 2007 FP7 was initiated, and it will run until 2013. Although Euro-India cooperation in the field of science and technology has lasted for a long time, the FP7 shows a dramatic increase in the level of cooperation. The success of the first call for proposals was already remarkable: more than 400 Indian research institutions responded to that call, which opened a new period of enhanced scientific collaboration. Of these proposals, 139 (37%) were health-related proposals, followed by information/communication technology (92, which represented 24%) and environment (50 proposals, 13%).[48] At present, more than 90 projects with at least one Indian partner have been funded by the FP7.[49]

3.3.2 Workshops, human resources and other cooperation initiatives

In 2007, the EU-India Ministerial Science Conference decided to celebrate several "EU-India Strategic workshops" on key areas, such as climate change, health, clean energies and combustion.[50] During

45. See the projects in link *(Accessed April 2010).*
46. V. Pandey, op. cit., p. 16.
47. See the list of all projects funded, classified by topics, in link (*Accessed April 2010*).
48. J. P. Wogart - CREST OMC Working Group, op. cit., p. 25.
49. See the list of projects in link (*Accessed April 2010*).
50. Among the meetings celebrated since then are the following: Workshop on cultures of governance and conflict resolution; workshop on clean coal technologies; a series of targeted information seminars on opportunities for cooperation between Indian and European Union Researchers and Research Organizations; Workshop on Renewable Energy Research and Technology Development, European Union India Day at the Nutraceutical Summit, Research Cooperation Opportunities in Nanosciences and Materials Research; First EU-India Strategic Workshop on Climate Change Research Needs.

the FP6 period, the Indian Department of Science and Technology and the EU Directorate General for Research convened seminars on several issues: information society, road transport research, nanotechnology, functional materials and climate change and natural disasters.[51] In addition to scientific exchange, the joint projects conceived at these workshops have been, in some cases, awarded funding in the corresponding FP.[52] These workshops have dealt with 'green' and 'red' biotechnology. Interesting initiatives have been, for instance, those resulting in the celebration of a workshop on infectious diseases of the poor and immuno-compromised individuals, in June 2006 in Bangalore, and a workshop on genomics and health biotechnology, in April 2005 in Delhi.

Additionally, different programmes and initiatives are aimed at promoting the mobility of researchers between India and the EU. If certain conditions are met, Indian researchers can benefit from (as any other non-EU national) the so-called 'researchers visa', which facilitates the movement across EU territory. Programmes, such as the Marie Curie, Erasmus Mundus and India Window need to be mentioned.

The Marie Curie Programme is a mobility programme for scientists. It distinguishes between 'International Outgoing Fellowships for Career Development' and 'International Incoming Fellowships'. An assessment of the Marie Curie programme focused on the Euro-Indian relationship has proved that incoming international fellowships (the ones open to foreign scientists to do research in Europe) are much more successful than outgoing fellowships (the ones awarded to European researchers to undertake research abroad).[53] That is, many more Indian scientist conduct research in Europe thanks to the Marie Curie programme than European researchers do in India.

Other programmes to be taken into account in this context are the Erasmus Mundus Program and the India Window Program. Erasmus Mundus provides scholarship to students willing to fulfil master studies in Europe in very different fields. The India Window programme reinforces the Erasmus Mundus program, funding it with 33 million of Euros for the 2005-2009 period. As a result of both programs, highly qualified students can follow post-graduate courses in Europe.

The 2007 EU-India Ministerial Science Conference recommended establishing a number of joint EU-India nodes for networking innovation systems in different regions of India and Europe, a new program for promoting cooperation in the field of science and technology, the promotion of mobility, and to undertake efforts for building up joint infrastructures.[54] The same conference decided that India and the EU shall annually invest 5 millions of Euros in joint research. Since then, two joint calls for proposals have been launched. The first call for proposals was launched with the Department of Science and Technology, and focused on computation materials science. It attracted 25 proposals, of which 6 were funded. The second call for proposals was prepared together with the Department of Biotechnology and it funded 2 out of 25 proposals on food, health and well being.

3.4 The way forward

The Euro-Indian relationship and strategic partnership in the scientific area of science and technology still has a long road ahead. Although there is an increasing number of academic collaborations and the European funding for collaborative research has grown, European attention to Indian science and technology still lies behind the efforts the EU devotes to other major developing economies such as Brazil and China.[55]

51. J. P. Wogart - CREST OMC Working Group, op. cit., p. 24.
52. V. Pandey, op. cit., p. 16.
53. *Ibid*., p. 18.
54. *The New Delhi Communiqué,* op. cit.
55. J. P. Wogart - CREST OMC Working Group, op. cit., p. 32.

In December 2008, a report of the CREST OMC Working Group analysing the EU-Indian cooperation in science and technology delivered a set of recommendations for enhancing cooperation. Detailed and ready to implement actions were proposed under the following headings:

> *i*) fostering a knowledge-based strategic agenda-setting; *ii*) offering an optimum framework for science and technology cooperation and removing barriers; putting emphasis on the 'human dimension' through brain-drain circulation; *iii*) putting emphasis on the "human dimension" through brain-circulation; *iv*) strengthening brainpower attraction and circulation; enhancing strategic science and technology cooperation and advancing the instruments and institutions.[56]

Among the recommendations made by the CREST OMC Working Group there was a constant reference to the need to improve information on Indian science and technology policies and key institutions. References were also made to the necessary simplification and harmonization of procedures, and to lowering or eliminating Indian taxes affecting science and technology. Regarding brain-circulation, one of the most tangible recommendations of the CREST OMC Working Group was to offer return-fellowships for Indian researchers. This should be done by the EU and Member States and, in fact, would complement already existing Indian actions in this regard.

56. *Ibid*., pp. 37-40.

II. INSTITUTIONAL AND NORMATIVE FRAMEWORK FOR BIOTECHNOLOGY IN INDIA

1. NORMATIVE FOUNDATIONS

1.1 International

India is party to several international treaties that directly impact on biotechnology regulation and management. These treaties pertain to several public international law regimes, such as international trade law, international environmental law, intellectual property law and international human rights law.

In the field of international trade law, Indian is signatory to the Agreement establishing the World Trade Organization (WTO); therefore attention must be particularly paid to the WTO covered agreements and, among them, particularly to two agreements: 1) the Technical Barriers to Trade Agreement, which prescribes the adjustment of national regulations to international standards, something which can be of relevance in case of standards aimed at safeguarding the quality, biosafety and efficacy of biotechnological products; and 2) the TRIPS agreement, which prescribes the patentability of inventions in any field of technology, including microorganisms.[57] A third relevant treaty to be borne in mind is the Sanitary and Phytosanitary Agreement, which establishes WTO rules on food safety and animal and plant health measures.

India is also party to the 1992 Convention on Biological Diversity (CBD). Article 15.1 recognises the States sovereign rights over their resources and confers on them the "authority to determine access to genetic resources". Article 15.4 subjects access to foreign resources to "mutually agreed terms", while article 15.5 conditions it to the prior informed consent of the Party providing those resources. Article 15 also requires States to adopt measures to share in a fair and equitable way with the Party providing the genetic resources the results of research and development and the benefits deriving from their commercialization and other uses.[58] Hence, disclosure of origin is an important element of the CBD access and benefit-sharing regime, and reflects the interrelationship of the CBD regime with the international intellectual property law system.[59] Proving this interrelationship, in India, failure to disclose the source and origin can result in the invalidation of the patent.[60]

India is party to the 1977 Budapest Treaty on the Deposit of Microorganisms. Signatory States to this Treaty are obliged to recognise the deposit of a strain or sample of a microorganism claimed in a patent as disclosure of the invention. Patent applicants must deposit the material in an international depository authority. Article 10(4)(ii) of the *Patents Act* 1970 alludes to the Budapest Treaty, and sets out the conditions governing the deposit of microorganisms. The Microbial Type Culture Collection and Gene Bank is a national facility established in 1986 which, since 2002, has become one of the international depository authorities capable of receiving strains or samples of microorganisms.

Indian commitments in the field of International human rights law are also of relevance in respect of biotechnology. Several rights, such as the right to health or the right to food are of relevance when

57. See below IV.1 1. The TRIPS Agreement and the Patents Act successive amendments.
58. C. Correa, J. Sarnoff, *Analysis of options for implementing disclosure of origin requirements in intellectual property applications,* Geneva: UNCTAD, 2006, UNCTAD/DITC/TED/2004/14.
59. *Ibid*., p. 5.
60. See below IV.2.2. *Disclosure of origin*.

considering both the development and access to biotechnological inventions. Intellectual property management and clinical trials development have to duly take into account Indian international obligations to respect and protect diverse human rights. In a case related to the patentability criteria that reached the High Court of Judicature at Madras, judges stated that to take a decision on the case they had "borne in mind the object which the Amending Act wanted to achieve namely, to prevent evergreening: to provide easy access to the citizens of the country to live-saving drugs and to discharge their constitutional obligation of providing good health care to its citizens".[61] That is, intellectual property shall be applied within a broader normative framework having in mind other superior legal interests.

1.2 National

The current Indian norms and web of agencies that deal with biotechnology do not follow an exhaustively defined plan. By contrast, the present normative and institutional framework is the outcome of a relatively unsystematic evolution which has in its origin the 1986 Environment (Protection) Act.

The Environment (Protection) Act contains the legal foundations of the Indian biotechnology system. Sections 6, 8 and 25 are worth noting: Section 6 enables the Indian government to enact rules on procedures, safeguards, prohibitions and restrictions for the handling of hazardous substances; Section 8 subjects the handling of hazardous substances to safeguards and procedures; and Section 25 empowers the government to continue this task and adopt specific rules and guidelines in the field of biosafety.[62]

The norms of the Environment (Protection) Act provide the legal background to the Rules for Manufacturing, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells.[63] This is a key piece of the Indian legislation on biotechnology, which is also known as Biosafety Rules or, simply, *the Rules* of 1989. The Biosafety Rules deal with the research, manufacturing, importation, usage and storage of microorganisms, gene technology products and products made out of genetically modified microorganisms.[64] They were adopted with the view of protecting the environment, nature and hea1th. They are accompanied by a "Schedule", which is a list that identifies and categorises animal and human pathogens according to their risk profile. The Schedule includes animal and human pathogens, and distinguishes between risk group II and III for the following categories: bacterial, fugnal, parasitic and viral rickeistial and chaimydial. Finally, it also includes special categories of bacteria, viral rickeistial and chaimydial and plant pests.

Rule 9 of the Biosafety Rules establishes that unless special permission by the Genetic Engineering Approval Committee is granted, it is prohibited the unintentional and deliberate release of genetically-modified organisms and cells covered under the schedule for experimental purposes. It clarifies that "deliberate release" means intentional transfer of GMO/hazardous, microorganisms or cells to the environment or nature. According to rule 7, the Genetic Engineering Approval Committee must also approve the import, export, transport, manufacture, process, use or sell of any hazardous microorganisms of GMO/substances or cells. On the other hand, in rule 4 the responsibilities of several biotech authorities are identified, and the Review Committee on Genetic Manipulation is tasked with the

61. The High Court of Judicature at Madras, W.P. NOS 24759 of 2006 and, 24769 of 2006, 6/8/2007, p. 89.
62. The Environment (Protection) Act, 1986 (Nº 29 of 1986, 23 May 1986).
63. Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells (New Delhi: Ministry of Environment & Forests, GSIR 1037 (E), 5 December 1989). *Gazette*, nº 621 dt. 5-12-1989.
64. The activities identified in art. 2 are sale, offer for sale, storage for the purpose of sale, offer and any kind; exportation and importation; production, manufacturing, processing, storage, import, drawing off, packaging and repacking; production, manufacture etc. of drugs and pharmaceuticals and food stuffs distilleries and tanneries, etc. which make use of micro-organisms genetically engineered micro-organisms one way or the other.

adoption of further guidelines. The level of comprehensiveness of the 1989 *Rules* and the time of their adoption, have led some to state that "in the matter of biosafety laws and policies, India was one of the early movers in the developing world".[65]

In 1990 the Department of Biotechnology enacted the Recombinant DNA Safety Guidelines supplementing the Biosafety Rules.[66], which have been revised on two occasions (1994, Revised Guidelines for Safety in Biotechnology and 1998, Revised Guidelines for Research in Transgenic Plants).[67] These guidelines are crucial for conducting rDNA research activities, experimentation, quality control and importation of products resulting from biotechnology.

Consumer groups have criticized biosafety regulations, stating that they are neither capable nor able to control or avoid the introduction of harmful products. By contrast, industry associations consider current biosafety regulations an impediment to their growth and economic expansion. Both the industry and the civil society have put forward proposals to amend the legal framework for biotechnology.[68]

Regarding importation, biotechnological products do not have, per se, a specific tariff classification, but are included in various codes pursuant to the World Customs Organization' Harmonized Commodity Description and Coding System, that the 1985 Customs Tariff Amendment Act fully adopted.[69]

In some specific fields of biotechnology, such as those related to biopharmaceutical and agrobiotechnological products, other norms coexist with the abovementioned regulations. Depending on the precise phase of development of the product, the norm to be applied will be one of said general rules or some other more theme-specific norms. Both living and non-living genetically modified organisms can only be marketed once it has been proven that they are safe for human beings, animals and the environment.

The National Biodiversity Act 2002 and the Biological Diversity Rules aimed at implementing the CBD. The National Biotechnology Act states that its goal is the conservation, sustainable utilization and equitable sharing of the benefits that result from genetic resources. In order to achieve its goals, the Act provides for access and benefit sharing mechanisms (including the disclosure of origin of the genetic material) and incorporates conservation principles. The Act also created a new Institution: the National Biodiversity Authority.

Other important norms influencing activities in the biotechnology field are the Protection of Plant Varieties and Farmers' Rights Act 2001 (provides plant breeders with rights over new plant varieties), the Indian Patent Act (particularly important Section 3(d), regarding patentability criteria), Biosecurity Regulations, the Seed Act and Prevention of Food Adulteration Act.

2. POLICY AGENCIES

It has already been mentioned that biotechnology is a cross-cutting inter-ministerial activity, since several ministries conduct activities in the biotech field: the Ministry of Science and Technology, the Ministry of

65. A. Damodaran, "Re-engineering Biosafety Regulations in India: Towards a Critique of Policy, Law and Prescriptions", *Law, Environment and Development Journal*, vol. 1, nº 1, 2005, p. 3. See. link (*Accessed March 2010*).
66. K. I. Varaprasad Reddy, "Biotech regulation in India: Problems and promises", *Biotechnology Journal*, vol. 4, 2009, p. 306.
67. Revised Guidelines for Research in Transgenic Plants (New Delhi: Department of Biotechnology and Government of India, 1998).
68. A. Damodaran, op. cit., p. 8. of India, 1998).
69. For instance, HS code 30 refers to pharmaceutical products, HS code 31 includes fertilizers, and HS code 35 albuminoidal, sub, starches, enzymes, glues.

Agriculture, the Ministry of Health and the Ministry of Human Resource and Development.[70] Among the agencies under the authority of those ministries the Department of Biotechnology, the Indian Council of Medical Research, the Council of Scientific and Industrial Research, the Indian Council of Agricultural Research and the National Biodiversity Authority.

2.1 Department of Biotechnology

The Department of Biotechnology is the nodal agency under the Ministry of Science and Technology entrusted with the task of formulating policies in this specific field of science In biotechnology Established in 1986, the Department of Biotechnology provides support to researchers and national industry through facilities, human resource development and bioinformatics programs.[71] Also in the research field, the Department of Biotechnology supervises the activities of the National Centre for Cell Sciences, the National Brain Research Centre, the National Centre for Plant Genome Research, the National Institute for Immunology and the Centre for DNA Fingerprinting and Diagnosis.

The Department supports numerous courses in several fields of biotechnology: general biotechnology, agricultural biotechnology, marine biotechnology, medical biotechnology, molecular and biochemical technology.[72] In response to the increasing relevance of the Department, and in view of the promising future attached to this sector, plans have been presented to upgrade the Department of Biotechnology to the status of a full-fledged ministry.[73]

2.2 Indian Council of Medical Research

Another important body in the biotechnology field is the Indian Council of Medical Research. It was created at the beginning of the XXth Century and at present is under the responsibility of the Ministry of Health and Family Planning. The Indian Council of Medical Research is responsible for all biomedical research in India related to human health. It formulates, promotes and coordinates medical research in a way that matches national health priorities.[74] The Council also supervises a broad network of research centres and institutes: 22 national research institutes and 6 regional medical research centres are under its control.

The Indian Council of Medical Research also conducts normative functions and has adopted guidelines on different matters.[75] In the specific field of modern biotechnology, it adopted guidelines for stem cell research and therapy and, in view of their potential impact on health, on biotechnology and genetically-modified seeds and food.

70. See 2.2 Indian scientific and technological research system.
71. N. K. Kumar *et al*., "Indian biotechnology –rapidly evolving and industry led", *Nature Biotechnology*, vol. 22, supplement, 2004, DC32.
72. S. Chatuverdi, op. cit., p. 84.
73. "Biotechnology may get separate ministry in India", 18/3/2008, link (*Accessed January 2010*).
74. In its institutional web, the ICMR identifies as targets of its research activities: communicable diseases, fertility control, maternal and child health, nutritional disorders, developing alternative strategies for health care delivery, environmental and occupational health problems; major non-communicable diseases like; mental health research and drug research.
75. Among others National Guidelines in the Management of Retinoblastoma, Guidelines for Good Clinical Laboratory Practices, Guidelines for Stem Cell Research and Therapy, Guidelines for Management of Type 2 Diabetes, Ethical Guidelines for Biomedical Research on Human Participants and National Guidelines for Accreditation, Supervision & Regulation of ART Clinics in India.

2.3 Council of Scientific and Industrial Research

Founded in 1943 and attached to the Department of Scientific and Industrial Research, is the Council of Scientific and Industrial Research. It is the largest network of Indian research institutions. Forty institutes and around one hundred field stations belong to this network. The Council of Scientific and Industrial Research also implements support programmes for small and medium enterprises. In this connection, the New Millennium India Technology Leadership Initiative was launched to fund innovative Indian companies and improve their leadership in some selected areas. Ascribed centres conduct research in numerous fields, some of them in the biotechnological sphere. Six laboratories belonging to this network carry out publicly funded biomedical research: the Central Drug Research Institute, the Indian Institute of Chemical Technology, Institute of Chemical Biology the Institute of Microbial Technology, Central Food Technological Research Institute, the Centre for Cellular and Molecular Biology and Centre for Biochemical Technology.

2.4 Indian Council of Agricultural Research

Indian Council of Agricultural Research is under the authority of the Ministry of Agriculture and attached to the Department of Agricultural Research and Education. Its origins date back to 1929, when the Imperial Council of Agricultural Research was established. It has a tremendous importance, since it coordinates and manages research and education in agriculture, animal sciences and fisheries, activities of the utmost importance in India.

On September 2009, under the Council's guidance there were 45 research institutes, 4 deemed universities, 17 national research centers, 6 national offices and 25 directorates. In the biotechnology field, the Indian Council of Agricultural Research controls the National Bureau of Plant Genetic Resources and is responsible for the control of the importation and quarantine of transgenic planting material.

2.5 National Biodiversity Authority

The National Biodiversity Authority was created in 2003 pursuant to Section 8 of the National Biodiversity Act. It has both and advisory and regulatory role, since it advises the government of India on biodiversity preservation and equitable sharing of benefits and, on the other hand, regulates access to biological resources for research and/or commercial purposes.

The National Biodiversity Authority has issued important documents, such as guidelines on Access and Benefit Sharing, Intellectual Property Rights, Prior and Informed Consent and Mutually Agreed Terms. Moreover, it also intervenes on behalf of the Indian Government in patent-opposition procedures in cases of patents applied for or obtained without prior informed consent and on mutually agreed terms. It also provides technical guidance and financial assistance to State Biodiversity Boards as well as local Biodiversity Management Committees.

3. REGULATORY AGENCIES

In India there are various federal committees and state agencies in charge of the approval of biotechnological products. In August 2010, while pending the final approval of an important institutional reform, the most important bodies performing this task are the Genetic Engineering Approval Committee, the Review Committee on Genetic Manipulation and the Recombinant DNA Advisory Committee. Additionally, *ad-hoc* committees are also regularly created and must be added to the

Institutional Biosafety Committee, the District Level Committees and, in the pharmaceutical field, the Drugs Controller General of India.

The following sets of bodies constitute a multi-tiered regulatory framework aimed at ensuring the biosafety of genetically engineered organisms in India.

3.1 Review Committee on Genetic Manipulation

The Review Committee on Genetic Manipulation (RCGM) is a body created in 1989 in accordance to the *Biosafety Rules*. It works in the Department of Biotechnology, and includes representatives from the Department of Biotechnology, the Indian Council of Medical Research, the Indian Council of Agricultural Research, the Council of Scientific and Industrial Research and persons who are appointed as experts in their individual capacities.

The RCGM mission is to monitor the safety aspects of ongoing recombinant DNA research projects and activities that involve genetically engineered or hazardous organisms. Making use of its power to establish sub-committees, the RCGM has created six *ad-hoc* sub-committees:

- Sub-Committee for finalizing the protocols for biosafety studies on transgenic brinjal, okra, tomato, cauliflower and cabbage.
- Sub-Committee for review and finalization of the protocol on safety (toxicity and allergenicity) studies on new transgenic crops in regulatory pipeline.
- Sub-Committee for finalizing the protocols for biosafety studies on transgenic corn.
- Sub-Committee for finalizing the protocols for biosafety studies on legumes (groundnut, redgram, pigeonpea, chickpea and other pulses).
- Sub-Committee for formulation of detailed biosafety guidelines for millets.
- Sub-committee for finalizing the protocols for genotype ID through DNA fingerprinting and prescribing standard molecular markers for cotton hybrids for inventorization & assessment for field trials based on parental lines, and for biosafety assessment for various vegetable crops.

The activities of the RCGM are numerous. In order to ensure that precautions and containment conditions are complied with, the RCGM overviews confined field experiments and high risk category projects.[76] With the objective of guaranteeing environmental safety, the RCGM regulates and establishes procedures on the research, production, sale, import and use of genetically engineered organisms. The RCGM also drafts manuals and guidelines regarding regulatory processes with respect to activities involving genetically engineered organisms, and lays down proposals for capacity building and training courses in biosafety. The RCGM reviews the applications to conduct confined field trials, proposes studies aimed at obtaining data for biosafety evaluation and issues permissions for the importation or exchange of biologic material for research use. It may also appoint special experts on a case by case basis, and may visit the experimental sites where r-DNA projects and activities involving genetically engineered organisms and hazardous microorganisms are conducted to ensure that adequate safety measures have been taken.

76. This is a task that it performs taking as a reference the Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered (GE) Plants, enacted by the Department of Biotechnology. *See* link

3.2 Genetic Engineering Approval Committee

The Genetic Engineering Approval Committee (GEAC) is a statutory body in the jurisdiction of the Ministry of Environment and Forests, although its board also includes representatives from the Ministry of Commerce and Industry, the Ministry of Food Processing Industries, the Ministry of Foreign Affairs, the Ministry of Health & Family Welfare, the Department of Biotechnology, the Indian Council of Agricultural Research, the Drug Controller General of India, the Indian Council of Medical Research, the National Botanical Research Institute, the Central Institute For Cotton Research, several university representatives, the Industrial Toxicology Research Centre, the International Centre for Genetic Engineering and Biotechnology and the Institute of Genomics and Integrative Biology.

In accordance with the Biosafety Rules the GEAC has broad powers. Among others, it controls the approval from an environmental angle of activities that involve the large scale use of hazardous microorganisms and recombinants in research and industrial production.[77] It is also in charge of approving proposals relating to the release of genetically engineered organisms into the environment, as well as of approving the production in which genetically engineered organisms or cells or micro-organisms are generated or used. The GEAC controls foreign trade in these products, field trials and the commercial use of genetically modified plants. It is also responsible for approval of proposals involving the use of living modified organisms above certain risk categories in the manufacturing or importation of recombinant pharmaceutical products, or where the end product of the recombinant pharmaceutical product per se is a living modified organism. The GEAC can also appoint expert committees to undertake specific activities related to biosafety compliance, and is in charge of granting licenses to persons operating or using regulated genetically engineered organisms/microorganisms for scale up or pilot operations.

3.3 Recombinant DNA Advisory Committee

The Biosafety Rules established that the Recombinant DNA Advisory Committee should be created in the Department of Biotechnology. As its name suggests, it has an advisory role. It is entrusted with the task of reviewing national and international developments in biotechnology and recommending safety regulations in r-DNA research, use and applications.

3.4 Institutional Biosafety Committee

The Institutional Biosafety Committee is a body created to ensure that the activities of institutions engaged in research and development or manufacture recombinant DNA-based products comply with biosafety rules. It has both an advisory and regulatory role, and periodically reports to the RCGM. In accordance with Rule 7 of the Biosafety Rules, it also controls certain experiments for the purpose of education within the field of gene technology or microorganism. All the institutions involved in research on recombinant technology are represented in the Institutional Biosafety Committee, a body that also prepares site specific plans for use of genetically engineered microorganisms.

3.5 State Biotechnology Coordination Committees

The Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells establish that “wherever necessary” there shall be a State

77. Article 4.4 of the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms Genetically Engineered Organisms or Cells, op. cit.

Biotechnology Coordination Committee in the States. These committees shall have powers to inspect, investigate and take punitive action in case of violations of safety and control measures in the handling of genetically engineered organisms. The Committees have supervisory powers and periodically review the safety and control measures both in industries and institutions handling genetically engineered organisms or hazardous microorganisms.[78]

3.6 District Level Committees

The district level committees perform supervisory functions headed by the District Collector. They have powers to inspect, investigate and report to the State Biotechnology Coordination Committee or to the Genetic Engineering Approval Committee about compliance with r-DNA guidelines or violations under the Environment Protection Act. They also act as a nodal agency at district level to control damages resulting from the release of GMOs and to take on site control measures.

4. FUNCTIONING

Pre-research, research, release and post-release are the four stages involved in the life-cycle of a biotech product. Several organizations/bodies intervene in these different phases:,

> "The RDAC is in the pre-research domain as it triggers research through its initial approval mechanisms. The RCGM functions in the research domain, closely monitoring the process of research and experimental releases. Commercial releases of organisms or biotech products containing GMOs come under the purview of the GEAC, a body that dominates the release domain. The Monitoring and Evaluation Committee and the State Biotechnology Coordination Committee and the District Level Committees basically occupy the post-release domain (…). The Institutional Biosafety Committee undertakes monitoring and implementation of safeguards at the R&D sites".[79]

The lack of participation of some stakeholders in these procedures is noteworthy. In particular, the absence of provisions enabling relevant participation of consumer groups and industry representatives has been underscored and tried to change in proposals for streamlining biosafety norms.[80]

5. SPECIFIC FIELDS OF EXPERTISE

5.1 Agricultural biotechnology

Risks associated with experiments in the field of plant biotechnology obligate authorities to subject them to rigorous control. Since 1989 there is in India a regulatory framework for the monitoring of experiments in plant biotechnology, which was developed under the provisions of the 1986 Environment Protection Act.

To guide applicants seeking approval for the environmental release of genetically engineered (GE) plants under the 1989 Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms and Genetically Engineered Organisms, several protocols have been adopted.

78. Article 4.5 of the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms Genetically Engineered Organisms or Cells.
79. A. Damodaran, op. cit., pp. 3 and 5.
80. Ibid., p. 8.

These protocols address the safety of foods and livestock feeds potentially resulting from genetically engineered crops.[81] In 1990, the biosafety guidelines to monitor all experiments (both indoor and outdoor) that use genetically modified plants were enacted. These guidelines were updated in 1994 (Recombinant DNA Safety Guidelines; Revised Guidelines for Safety in Biotechnology) and in 1998 (Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts).

In order to address the human health safety of foods derived from genetically engineered plants, the Indian Council of Medical Research formulated the Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants in 2008, which were adopted using the international Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants as reference.

In 2008 the Supreme Court lifted a ban on approvals of genetically modified crops for field trials, and that same year a joint effort undertaken by the GEAC and the RCGM resulted in guidelines to conduct field trials of genetic engineered organisms (Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated Genetically Engineered (GE) plants.[82] The massive use of some GM crop contrasts with the persistence of social controversies regarding its environmental and social implications.

The 2003 Plant Quarantine Order, adopted by the government in exercise of the powers conferred by the Destructive Insects and Pests Act 1914, contains the rules governing the import of, among others, genetically modified crops.[83]

The aforementioned committees play a role in the regulation of agricultural biotechnology and the management of genetically engineered material. Particularly important are the RCGM and the GEAC. The former because it is responsible for the Biosafety Research Level I trials, the latter because it is responsible for the Biosafety Research Level II trials. Under the supervision of the RCGM, the Monitoring and Evaluation Committee operates, which designs field experiments as well as methods for collecting scientific information on plants grown in containment, as well as in limited field trials.[84] Another institution, the National Bureau of Plant Genetic Resources, controls the importation of transgenic seeds and plants for research purposes. Nevertheless, this institution can only issue a permit if an import has already been cleared by the RCGM.

5.2 Medical Biotech

5.2.1 Institutions dealing with biopharmaceuticals

In the particular field of biopharmaceutical products, the aforementioned bodies coexist (and work together) at the federal level with the Central Drugs Standard Control Organization (CDSCO) and the Drugs Controller General of India (DCGI), which are the agencies responsible for the approval of clinical trials, drug applications and applications for the importation of drugs.

The approval of modern biopharmaceuticals is primarily controlled by the DCGI, although previously they must be cleared by the RCGM, while manufacturing licences are given by each one of the State's drug controllers. The DCGI is the authority in charge of authorising the clinical trials with recombinant

81. Until 2008 adopted protocols included: Acute Oral Safety Limit Study in Rats or Mice, Subchronic Feeding Study in Rodents, Protein Thermal Stability, Pepsin Digestibility Assay, Livestock Feeding Study. See. Department of Biotechnology, Protocols for Food and Feed Safety Assessment of GE crops, 2008, link (*Accessed June 2010*).
82. link (*Accessed May 2010*).
83. link (*Accessed May 2010*).
84. G. J. Randhawa, R. Chabra, "Import and commercialization of transgenic crops: an Indian perspective", *Asian Biotechnology and Development Review*, vol. 11, nº 2, 2009, p. 117.

products that are conducted in humans. It also controls the results of these trials and authorises the release for human consumption of the biopharmaceutical products. However, these products must also receive final clearance from the GEAC due to concerns about their potential environmental harm.[85]

The creation of a unified Central Drug Authority (CDA) has been proposed on several occasions. The *Mashelkar Report* put forward a proposal in that direction in 2006, and it was foreseen that in 2008 the CDA would be created. If established, this institution would assume the inspection, licensing and evaluation functions, replacing almost all other existing agencies (mainly state and local). As it was conceived, the CDA was planned to be autonomous and to have several departments dealing with different products and activities. Among the foreseen departments, there would be one responsible for clinical trials and another one for biologics. In 2007, a Central Drug Authority (CDA) draft Bill was released. It effectively foresaw the transfer of the licensing powers currently in the states, including drug manufacturing permits of existing and new medicines. Nevertheless, complaints from state administrations and local companies claiming that a unique authority in Delhi would mean that manufacturers located in distant states would have to incur additional expenses,[86] apparently led to abandon the proposal for a CDA.

The regulatory process for the approval of a biopharmaceutical product is governed by several bodies:

i) The Department of Biotechnology is in charge of the approval of protocols for animal toxicity studies.
ii) The Drug Controller General approves the clinical trials with humans, as well as the granting of marketing approval.
iii) The GEAC is responsible for the approval of proposals involving the use of living modified organisms above certain risk categories in the manufacturing or importation of recombinant pharmaceutical products, or where the end product of the recombinant pharmaceutical product *per se* is a living modified organism.

5.2.2 Regulatory standards for biopharmaceuticals

Regarding biopharmaceuticals in its ample meaning, the Central Drugs Standard Control Organization has adopted several guidelines:

- Guidance for Industry Requirements for Permission of New Drug Approval.
- Preparation of the Quality Information for Drug Submission for New Approval: Biotechnological/ Biological Products.
- Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy.
- Post Approval Changes in Biologic Products: Quality, Safety and Efficacy Documents.

a) Guidance for Industry Requirements for Permission of New Drug Approval.[87]

This Guidance contains the information the manufacturer has to provide either to import or to manufacture a new biologic drug. It applies to biologicals for human consumption, regardless of where they are manufactured and whether they are licensed in the country of origin or not.

85. N. K. Kumar *et al*., op. cit., DC34.
86. *P.T. Jyothi Datta*, "Central Drug Authority proposal shelved", *Business Line*, 1 February 2009, link (*Accessed January 2010*).
87. See in CDSCO, Guidance for the Industry, CDSCO, pp. 38-76.

The Indian Drugs and Cosmetic Act 1940 and Drugs and Cosmetic Rules 1945 prescribe the obligation to submit an application on Form 44 for permission of New Drug Approval. The *Guidance* for Industry Requirements for Permission of New Drug Approval simplifies the submission requirements to obtain marketing approval of biologicals. On most occasions, non clinical and clinical trial requirements remain the same as per Schedule Y of the Drugs and Cosmetic Rules 1945.[88]

The Guidance has five parts, or modules, which respectively refer to administrative and legal information, summaries, quality information, non-clinical information and clinical information.

b) Preparation of the Quality Information for Drug Submission for New Approval: Biotechnological/ Biological Products.[89]

This text, adopted in July 2008, is a final guideline on abbreviated licensing pathways for biosimilars. Apart from this specific guidance, there are no overarching regulatory guidelines for biosimilars in India. It is said that this is the reason why Indian biogeneric companies might not be "following uniform measures to establish comparability with the innovator's product".[90] Nevertheless, a product specific monograph for six recombinant proteins in the Indian Pharmacopoeia does exist and should be followed by all those marketing those products. These products are: EPO, G-CSF, HBsAg, Interferon-alfa, Factor VIII and Streptokinase. However, the enforcement of the standards laid down for these products is allegedly deficient.[91]

c) Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy.[92]

This Guidance deals with the submission of applications for clinical trials. Firstly, it alludes to phases I and II clinical trials, and establishes the general information that has to be provided, the information regarding chemistry manufacturing control, the nonclinical data, and the proposed phases I and II studies. Regarding the nonclinical data and the phases I and II studies, the guidance refers to other already existing rules: the *Schedule Y*, amendment version 2005 of the *Drugs and Cosmetics Rules 1945*, the *GCP guidelines* published by CDSCO and the *Ethical Guidelines for Biomedical Research on Human Subjects*.

Secondly, it deals with phase III trials and, also in four sections, lays down the general information that has to be provided, the information regarding chemistry and manufacturing control, the nonclinical data and the proposed phase III studies. Again, regarding the nonclinical data and the phase III studies the guidance refers to the *Schedule Y*, amendment version 2005 of the *Drugs and Cosmetics Rules 1945*, the *GCP guidelines* published by CDSCO and the *Ethical Guidelines for Biomedical Research on Human Subjects*. In this context, several specific references are made to recombinant products. They range from the need to provide the RCGM and GEAC committees' approvals, the specific physicochemical characterization of recombinant products and validation studies for phase III trials.[93]

d) Post Approval Changes in Biologic Products: Quality, Safety and Efficacy Documents.

The aim of this guidance is to assist with the classification of changes made to already approved biological products and to provide applicants with recommendations on the data considered sufficient enough to determine the impact of the change on the quality of the approved products as it relates

88. *Ibid*., p. 39.
89. *Document No. – QI/71108, Version 1.1*
90. R. Mody, V. Goradia, D. Gupta, *How similar are biosimilars in India? A blind comparative study,* link (*consulted April 2010*)
91. *Ibid.*
92. Document No. –CT/71108, Version 1.1
93. See pp. 35-36.

to safety, efficacy and/or effective use of the products.[94] According to their relevance, the guidance distinguishes among three different categories of changes: major quality changes, moderate quality changes and minor quality changes.[95]

5.2.3 Challenges

Patient safety, patent protection, test data protection and the economic impact of biopharmaceuticals are controversial as well as strategic topics in the global health agenda. This is also the case in India, as in many other countries, both developed and developing. The relative novelty of modern biopharmaceuticals and the complexity of the issues they raise explain the important differences that exist among national regulations.

Although the inherent complexity of issues relating to biopharmaceutical's patent and test data protection, patient safety and economic impact requires an analysis of each one of these topics separately, it is also necessary to take their interconnectedness into account. In this regard, it has to be noted that the test data for which protection is sought permits an applicant to prove the safety and efficacy of the drug. The generation of the data requires numerous tests and incurring in the corresponding costs, which must be added to the costs necessary to develop the product. The accumulation of these costs is the argument put forward to justify the need for patent protection and data exclusivity. While these issues have been lengthy debated in respect of conventional pharmaceuticals, biotechnological products add another (related) dimension. Given the intrinsic complexities of biopharmaceuticals -resulting from their macromolecular characteristics- once exclusivity periods expire, the question arises as to whether competition of equivalent (or 'similar') biopharmaceuticals is possible and at what cost.

Important questions currently discussed in India refer to test data protection and the data required for granting marketing approval to follow-on biotechnologicals. Test data protection and patent protection for biotechnological products are dealt with later on in this report. What follows is an introduction to questions to be taken into account when regulating biosimilars, which may be useful to consider in the context of current debates in India.

Terms such as 'biogenerics', 'biosimilars', 'follow-on-drugs', 'subsequent entry biologics' and 'similar biotherapeutic product' allude to products that fulfil the same function as the licensed originator product and have the same mechanism of action. Nevertheless, their origin (biologic material), manufacturing process, molecular characteristics and therapeutic modes of action impede the existence of exact replicas to the reference product.[96] The difficulty in showing identity between the reference product and its follower, together with the potentially severe inmunogetic effects of apparently unimportant differences, are the reasons why the biosimilars' approval process is much more complex than the one for small-molecule generics. Consequently, biosimilar producers may have, in comparison to originators, less pre-clinical and clinical testing expenses, but would generally need to incur in much larger expenses than those required to prove bioequivalence between two small molecule drugs. Nevertheless, and by contrast to what is usual regarding small molecule drugs, the additional data that biosimilar producers will be asked to produce is highly contingent on the specific product characteristics and on the particular requirements of the national legislation applicable to the approval of these products.

94. See p. 79.
95. This must be read together with the Clarification & Amendments in guidance for industry with respect to Post Approval Changes in Biologicals Products, adopted by the CDSCO on 5th August, 2010.
96. *See*, in this sense, WHO, "Challenges in Biotherapeutics", *WHO Drug Information*, vol. 22, nº 1, 2008, p. 4.

Countries have followed different legislative and administrative approaches to grant marketing approval to biosimilar products:

1) Presently, the majority of countries have no special regulatory mechanism for the approval of biosimilar products. Hence, applicants are obliged to perform all tests and processes as if the products were brand-new.

2) Other countries follow a comparability approach, which requires a thorough comparability exercise to prove similarity, in terms of quality, safety and efficacy, of the biosimilar product with the reference product. The type and scope of data to be generated for this exercise depend on the characteristics of the products.

3) Under a third approach, a comprehensive comparability exercise is not necessary: it is enough for the applicant to rely on publicly available information coupled with non-clinical and clinical studies to demonstrate the similarity.[97]

Both the second and the third approaches raise the issue of how much information is needed to show the biosimilarity. In following the third approach, countries, and particularly developing countries, could consider granting automatic marketing approval to biosimilar products that have already been granted such authorization in another country with adequate requirements and reliable procedures for the marketing authorization of such products. Another option that countries might consider is to enter into agreements for empowering one of their drug authorities to grant marketing approval, at least for some complex products. This was the case in the nineties in Europe, when procedures for the marketing approval of biotechnological products were centralized at the European Medicines Agency.

The marketing approval of a product as a biosimilar, as mentioned, generally requires proof of similarity to a reference product in terms of quality, pre-clinical and clinical parameters. It is necessary to characterize and evaluate the quality attributes of the product. There is significant consensus on the fact that "comprehensive characterization and comparison at the quality level are the basis for possible data reduction in the non-clinical and clinical development".[98] This characterization provides the basis to establish whether the clinical safety and efficacy profile of the reference product apply to the biosimilar; if so, it is not necessary to present the entire set of data again. Therefore, manufacturers of biosimilars should be requested to present the complete characterization of their product in a full quality dossier.[99]

If a high degree of similarity is proven, the non-clinical and clinical data set to support the application for market authorization will be reduced. Whenever differences are found between the originator and the follower, it is necessary to investigate what the reasons causing such differences are, and to infer their impact on safety and efficacy. The WHO Expert Committee on Biological Standardization has recently adopted guidelines on the evaluation of biosimilars, which deal with the non-clinical[100] and

97. With regards to this last approach, "it is considered that further clarity and real examples are needed". See, for all them, WHO, "Challenges in Biotherapeutics", *op. cit*., p. 4.
98. Expert Committee on Biological Standardization, *Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs)*, October 2009, WHO/BS/09.2110, pp. 8 and 10.
99. *Ibid*., p. 9.
100. Regarding non-clinical evaluation, that is, the pharmaco-toxicological assessment of the biosimilar, the similarity between this product and the product of reference will reduce the need to generate new information since the originator "will already have a significant clinical history". Nevertheless the specific information that has to be provided will be dependent on quality related factors, and on factors related to the pharmaco-toxicological properties of the active substance. The variability of these factors will oblige to identify on a case-by-case basis what are the additional data that the biosimilar producer will be required to provide. In this regard, the WHO recommends following the ICH6 guideline. Expert Committee on Biological Standardization, op. cit., pp. 22, 23.

clinical evaluation.[101] India may find some useful guidance in those guidelines , although it is necessary to note that the guidelines adopt positions on some specific aspects that are still debated over, and they also include confusing references to intellectual property matters, which are unrelated to quality, safety and efficacy.

The issue of interchangeability of biopharmaceuticals directly impacts the Indian biosimilars sector . The impossibility of replicating exactly the same manufacturing process justifies the argument that biogeneric interchangeable products cannot be obtained. In accordance with this view, only similar but not identical products would be possible. This is the assumption that underpins regulations establishing the need to prove that the function and structure of the biosimilar drug are comparable to that of the innovator and that differences have no negative influence.[102] However, even after performing tests to show the absence of negative effects, the possibility of substituting a reference biotherapeutic product by a biosimilar generates debate. The crux of the matter is found in immunogenicity, that is, the stimulation of an immune response or reaction, such as an allergic reaction or the development of specific antibodies. The fact that the substitution is not made with an exact copy could mean that patients could react differently to the treatment and, therefore, clinical consequences could exist. And all this despite the fact that the product has shown acceptable comparability and that immunogenicity tests have been performed. Available methodologies do not permit yet to determine whether a biosimilar product is interchangeable with the reference product in all circumstances and for all people, particularly due to uncontrollable genetic factors.

The current uncertainty has caused intense debates on whether interchangeability should be allowed or not in this field. The legislation of some European countries forbids interchangeability despite the fact that a specific and highly-demanding regulatory pathway for biosimilars exists.[103] On the contrary, other European countries do not forbid interchangeability. Recently a WHO expert group has stated that "The decision to allow automatic substitution of a SBP (similar biotherapeutic product) for a RBP (reference biotherapeutic product) should be made on a national level taking into account potential safety issues with the product or class of products. Decisions on interchangeability should be based on appropriate scientific and clinical data and is beyond the scope of this document."[104] At the extreme end of this debate, some originator companies try to emphasize the differences between their biopharmaceuticals and the corresponding biosimilars. In some countries companies have proposed adding warnings on labels that inform about the non-identity, and to require biosimilars to have their own brand name and ensure that patient prescriptions specify the brand name. Trade law may become, therefore, of relevance in this specific field. In spite of the increasing pressure, the WHO and the European Medicines Agency have refused the demands of some biopharmaceutical originators to forbid the use of international non-proprietary names for the marketing of biosimilars.

In addition to proposing general requirements, it is necessary to establish the conditions for specific classes and even specific products, since much depends on the type of molecule and the complexity of the product.[105] In Europe, for instance, the requirements for EPO are more stringent than for other recombinant proteins. This can be explained because of its molecular complexity and clinical history

101. As far as clinical evaluation is concerned, according to the Expert Committee on Biological Standardization it will be necessary to conduct pharmacokinetic and pharmacodynamic studies, as well as clinical trials to prove that the biosimilar product has similar efficacy to the originator. In some cases, comparative pharmakonetic and pharmacodynamic studies may be appropriate and replace clinical studies to demonstrate similar efficacy between the biosimilar and the originator. Dosage studies could be avoided, because the demonstration of comparable potency, pharmakonietics and pharmacodynamics suffices to accept the dosage instructions of the reference product. Expert Committee on Biological Standardization, op. cit., p. 30.
102. R. Mody, V. Goradia, D. Gupta, (op. cit.).
103. This is the case of Spain and Germany.
104. Expert Committee on Biological Standardization, op. cit., p. 8.
105. Health Canada, *Consultation on the Regulatory Framework for Subsequent Entry Biologics – Summary Report*, 5-6 June 2008, p. 6.

(for instance, pure red cell aplasia cases).[106] This is, in fact, the approach followed by the EMA, which requires more or less data to certify the quality, safety, efficacy and similarity, depending on the complexity of the molecule and its development. Some analysts consider that, given that biotech proteins will present a large range of variations and levels of complexity, regulatory authorities should enjoy an ample margin of discretion.[107]

106. EGA, *EMEA similar guidelines*, 28/9/2009.
107. R. G. Frank, "Regulation for Follow-on Biologics", *The New England Journal of Medicine*, vol. 357, nº 9, 2007 p. 843.

III. REGULATORY REFORMS

1. PERCEIVED PROBLEMS

It has become a common place identifying the multiplicity of regulatory agencies as one of the factors that negatively affects the functioning of the Indian biotech sector. A barrier that, according to some commentators, is so important that it could hinder the development of biotechnology in India.[108]

Among the most prominent problems resulting from this multiplicity is the alleged lack of coordination of the several agencies that play a role in the Indian biotech regulatory framework. These agencies are often placed under the control of different ministries, and operate at very different administrative levels. This makes it difficult to guarantee the consistency of their work and affects those who take part in the approval process of biotechnological products. In this sense, it has been noted that "in dealing with several agencies, companies experience an approval process that causes significant confusion and delays in commercialization",[109] because biologics manufacturers in India "must seek approval from multiple state, district, and federal agencies for routine activities".[110] Allegedly, sometimes these authorities reach different conclusions regarding the approval of the same product,[111] thereby leading to confusion and lack of confidence in the Indian regulatory system.

Together with the multiplicity of authorities, the tedious and complex approval procedures have also been identified as challenges.[112] The need for simplification and streamlining of procedures has already been acknowledged. In the specific field of agrobiotechnology, a Task Force created in 2003 came to the conclusion that the system needed "review and rationalization", as well as a "reduction in the levels and number of steps required in evaluation and environmental clearance of GM products/transgenics" and "transparency and professionalism in the regulatory process".[113]

In addition to structural problems, some companies and scholars have criticised the alleged lack of expertise regarding biologicals on the part of some regulatory agencies,[114] while others have pointed out staffing problems.[115] Some sources state that the shortage of personnel and the alleged lack of expertise are the reasons why Indian companies seek the approval of their products abroad. It is said that the approval of the Indian products by foreign drug regulatory agencies, or international organizations such as the World Health Organization regarding pharmaceuticals, gives an extra credibility to Indian products.[116] An opposite phenomenon has also been described. According to some authors, an internal race to the bottom may also exist. The reason would be found in a sort of forum-shopping by companies that seek the lowest regulatory surveillance levels existing in Indian States to

108. In this last instance, it has been stated that "multiple regulatory agencies delay commercialization" S. E. Frew et al., "India's health biotech sector at a crossroads", *Nature Biotechnology*, vol. 25, nº 4, 2007, p. 413.
109. *Ibid*.
110. E. Lager, "Biologics regulation in India", *BioPharm International*, March 2008, p. 26, link (*Accessed January 2010*).
111. K. Satyanarayana, "Current IP Management Issues for Health and Agriculture in India", A. Kratiger, R.T. Mahoney, L. Nelsen *et al*., (Eds.) *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, Davis-Oxford: PIPRA-MIHR, 2007, p. 1605.
112. J. Wong et al., *Harnessing the power of India. Rising the Productivity Challenge in Biopharma R&D*, BCG, May 2006, p. 6, link (*Accessed January 2010*).
113. *Report of the Task Force on Application of Agricultural Biotechnology* op. cit., p. 38.
114. This criticism is reflected in a report comprising a series of interviews with Indian and non-Indian actors operating in India. S. E. Frew et al., op. cit., p. 413; see also E. Lager, "Biologics regulation in India", *BioPharm International*, March 2008, p. 26, link (*Accessed January 2010*).
115. E. Lager, "Biologics regulation in India", op. cit. p. 26.
116. This criticism is reflected in a report comprising a series of interviews with Indian and non-Indian but operating in India biotech actors. S. E. Frew *et al*., op. cit., p. 413.

locate their activities.[117] P. K. Ghosh states, with an apparently less radical view, that "while a rationale regulatory structure is in place, there is a need to invest for creating more competence for testing and assessing the safety of GMOs in publicly funded institutions".[118]

Several initiatives have been undertaken to counteract the questioning of the quality of the Indian products. In the field of the pharmaceutical and biopharmaceutical products, the Indian Government has insisted on the mandatory compliance with good manufacturing practises while, on the other hand, numerous Indian companies have sought to obtain an international certification that they meet internationally guidelines.

The 2005 amended revision of the *Drugs and Cosmetics Act of 1940* alludes in numerous occasions to the obligation to apply good manufacturing practices (GMPs), and makes reference to the *WHO Good Manufacturing Practices*. Schedule M contains the norms on *Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products*. Previously, Sections 71.7, 74 (o), 76.8, 78 (p) and 79 of the *Drugs and Cosmetics Rules, 1945*, indicate the need to certify compliance with GMPs in order for different licenses to be granted or renewed. Additionally, Schedule D(I) 2.3 deals with the information and undertakings required to be submitted by the manufacturer or his authorised agent with the application form for a registration certificate. For the registration of drugs, a copy of a GMP certificate "as per WHO-GMP guidelines, or Certificate of Pharmaceutical Products (CPP), issued by the National Regulatory Authority of the foreign country concerned" is required. As a result of these norms and commercial interest there are currently in India 817 manufacturing facilities that fulfil WHO Good Manufacturing Practices[119] whereas seventy pharmaceutical and biopharmaceutical facilities have been approved by the US FDA.[120]

Although this is a positive move, changes to the Indian regulation are not always welcomed by all concerned parties. For instance, US FDA rules inspired the abovementioned Schedule M of the *Drugs and Cosmetics Act*. Although the change was strategically done to facilitate the entrance of Indian pharmaceuticals into the United States of America (USA) market and to counteract the criticism on the alleged Indian quality, safety and efficacy shortcomings, not all companies were equally affected. In fact, local companies without exportation capabilities and with limited resources have criticized the new regulation and, particularly, the lack of transitional periods to adjust to the new regulatory framework.

2. REACTIONS IN THE PHARMACEUTICAL AND AGRICULTURAL FIELDS

The need to introduce some adjustments to the regulatory framework has been recognised in the fields of pharmaceutical and agrobiotechnological products. Regarding the former, as early as in 1999, the Pharmaceutical Research and Development Committee criticised the "inadequate framework for clearance of new drug investigation and registration",[121] and recommended enhancing the resources available to the Central Drugs Standard Control Organisation. In 2004, in order to streamline the regulatory framework for the use in the pharmaceutical industry of living modified organisms during the R&D, testing, manufacture and import of LMOs as drugs, the Ministry of Environment and Forests promoted the creation of a task force. One year later, in June 2005, the Task Force delivered a report, the *Recombinant Pharma Task Force* (also known as the *Mashelkar Committee Task Force Report*) containing recommendations that were adopted in 2006 by the Indian Government.[122]

117. According to E. Lager "Manufacturers that set up operation in states where regulatory oversight and enforcement are weakest can then market their drugs in the rest of the country". E. Lager, "Biologics regulation in India", op. cit. p. 26.
118. P. K. Ghosh, op. cit., p. 38.
119. CDSCO, *Manufacturing units having WHO GMP certification*, link (*visited April 2010*).
120. Biospectrum-ABLE, *One billion industry*, 2005.
121. Pharmaceutical Research & Development Committee, *Transforming India into a Knowledge Power*, link (*Accessed January 2010*).
122. More specifically, on 23rd January 2006 by Ministry of Environment and Forests, Department of Biotechnology, Drugs Controller General of India And Ministry of Health.

The *Mashelkar Committee Task Force Report* tried to simplify the procedures for approval of biopharmaceuticals (*See Figures 3 and 4*). It proposed several new and faster processes that should be applied to different categories of products, depending on their nature and the inherent risks associated to them. Moreover, the creation of a single authority (the National Biotechnology Regulatory Authority) was proposed in order to overcome the alleged lack of coordination and organizational shortcomings. In response to the report, specific time frames for decisions by the regulatory authorities were adopted: 45 days for the RCGM to approve pre-clinical animal studies; 45 days for the DCGI to approve a human clinical trials protocol; 90 days also for the DCGI to revise and approve clinical trial data; in addition, parallel decisions by the DCGI and GEAC are to be adopted in 45 days.[123]

In the agriculture field, a task force was also set up in 2003. Chaired by Professor Swaminathan, it was asked to examine the challenges that biotechnology posed to agriculture. The constitution of this task force was particularly timely. Although not new, controversies regarding the authorisation of GM foods were particularly strong in 2002. That year the GEAC approved the first GM modified crop, and numerous applications started to be granted. In addition to the moral, safety and religious concerns generated by the use of GM crops in India, NGO, scientists and farmers complained for what they claimed to be a lack of transparency and for the risks arising from field trials. Reports on negative health impacts on animals grazing in *Bacillus thuringensis* (Bt) insect-resistant cotton fields were also released.[124]

Genetically modified food crops are still the centre of important controversies in India. The first GM food crop intended to be introduced into the Indian market was a Bt variety of aubergine, for which field trials were authorised in 2007. On 13 February 2008 the Supreme Court of India lifted restrictions on field trials and commercialisation of biotechnological crops. Although GEAC recommended the approval of the Bt Brinjal in October 2009, and the Ministry of Environment endorsed the safety assessment and the introduction of the Bt Brinjal onto the Indian food market, protests forced the Ministry to step back and announce the withdrawal of the authorisation.[125] The reasons invoked by the Ministry of Environment included the lack of a unique regulatory authority and of scientific consensus regarding the potential problems arising from genetically modified food.

In connection with the risks posed by biotechnology, the *Swaminathan report* stressed the importance of a regulatory mechanism that helped to strengthen public confidence. For the Task Force, "the bottom line for any biotechnology regulatory policy should be the safety of the environment, the well being of farming families, the ecological and economic sustainability of farming systems, the health and nutrition security of consumers, safeguarding of home and external trade, and the biosecurity".[126] It also made suggested that the "transgenic approach should be considered as complimentary and resorted to when other options to achieve the desired objectives are either not available or not feasible."[127] Additionally, it added that the transgenic approach should be excluded when it affected the trade of well-know Indian products. Its considerations on the priorities of research were also interesting, since they anticipated similar debates that took place later on in the field of public health. Among other things, the report stressed the importance of the research sensitiveness to the biodiversity conservation and the socio-economic context, and that public investment in the area of biotechnology, particularly in recombinant DNA technology, should be aimed at addressing socially and ecologically relevant problems. Finally, the *Swaminathan* report proposed the creation of a single-window agency, an autonomous and professionally-led National Biotechnology Regulatory Authority.

123. *Notification regarding the adoption of the recommendations of the task force on r-pharma under the chairmanship of Dr. R A Mashelkar, DG-CDIR with effect from 1.4.2006*
124. K. I. Varaprasad Reddy, op. cit., p. 307.
125. The Minister mentioned the lack of clear consensus among the scientific community, opposition from Brinjal-producing States, questions raised about the safety and testing process, the lack of an independent biotechnology regulatory authority, negative public sentiment and fears among consumers and the lack of a global precedent. *The Hindu*, "Moratorium on Bt Brinjal", 10 February 2010.
126. Task Force on Agricultural Biotechnology, op. cit., pp. 4, 6.
127. *Ibid*., p. 22.

Figures 3 and 4: **Regulatory protocols proposed by the Mashelkar Task Force**

Figure 3: Protocol - I

Indigenous product deveopment, manufacture and marketing of pharmaceutical products derived from LMOs but the end product is not an LMO.

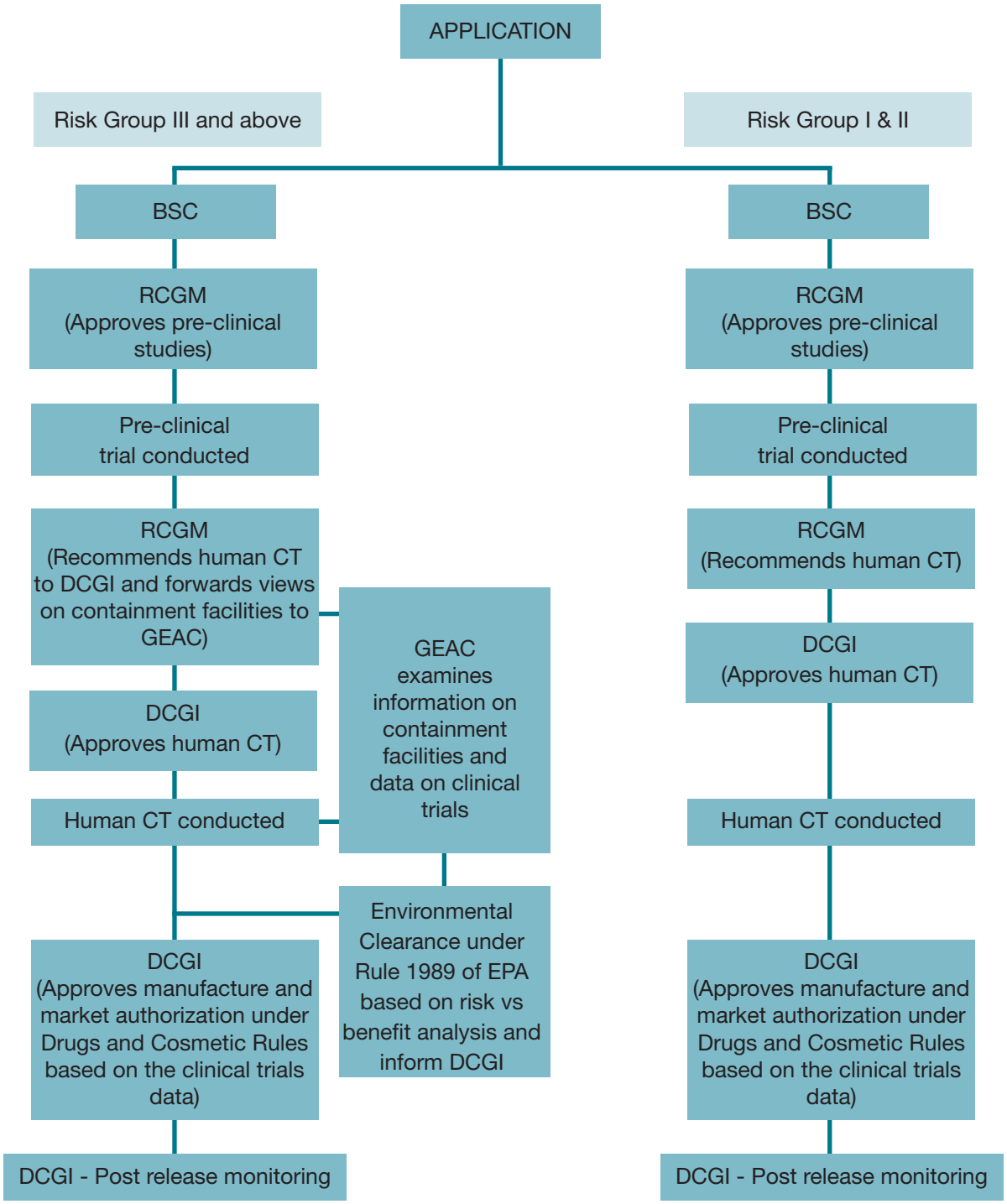
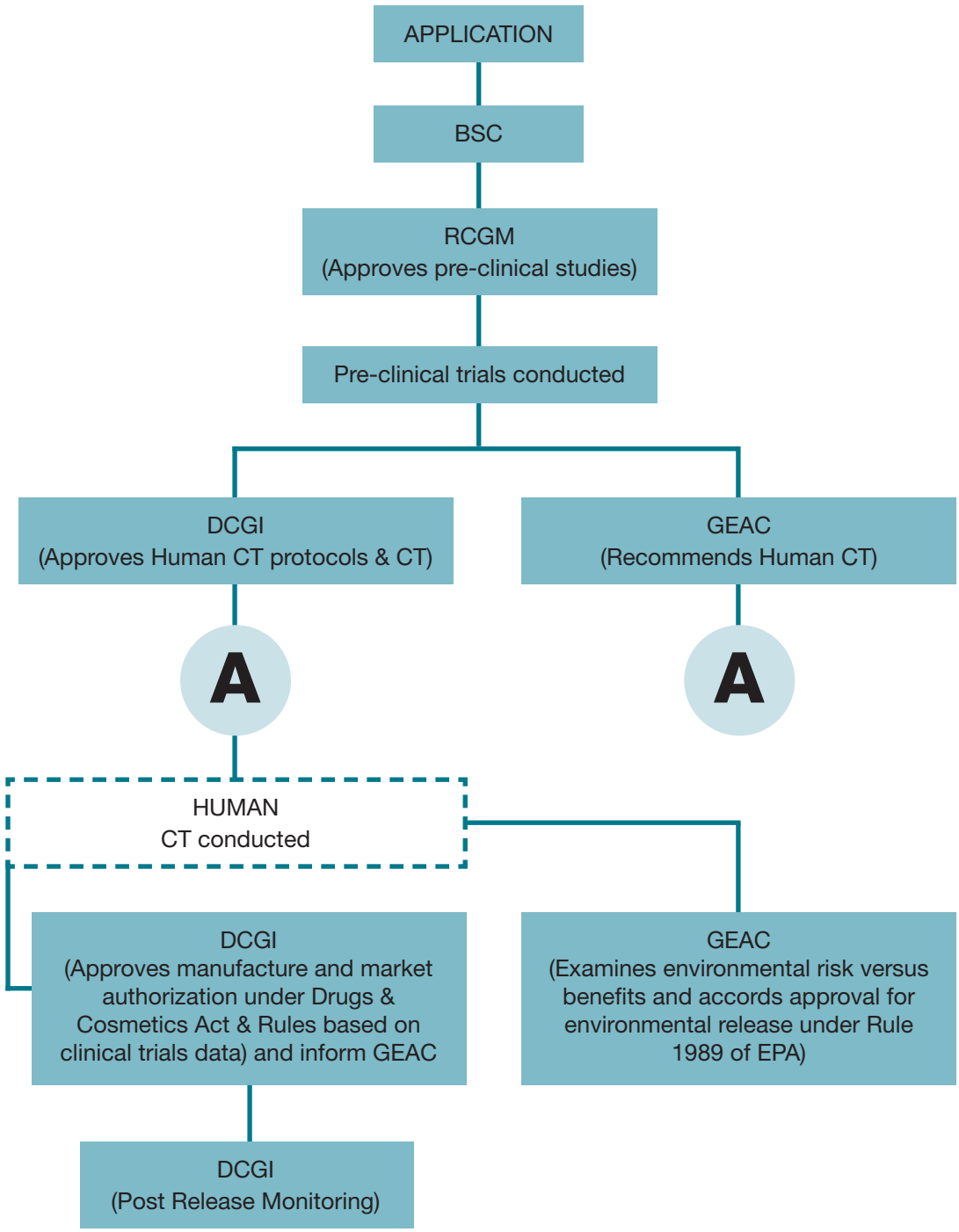


Figure 4: Protocol - II

Indigenous product deveopment, manufacture and marketing pharmaceutical products where the end product is an LMO



3. THE WAY FORWARD: THE NATIONAL BIOTECHNOLOGY DEVELOPMENT STRATEGY, THE (DRAFT) NATIONAL BIOTECHNOLOGY REGULATORY BILL AND THE (ENVISAGED) NATIONAL BIOTECHNOLOGY REGULATORY AUTHORITY

3.1 The National Biotechnology Development Strategy

In November 2007, the Indian government approved the National Biotechnology Development Strategy (NBDS). It was an eagerly awaited policy document, which devised a comprehensive ten year road map for the Indian biotech sector, and put forward proposals that could greatly change the Indian biotechnology regulatory landscape. The NBDS was the outcome of two years of consultations with several stake-holders. The government held meetings with private companies, research institutes, several ministries, universities, international bodies and consumer associations.[128]

The NBDS defined three general goals: development of human resources, strengthening of the infrastructure and promotion of trade and industry. To fulfil these goals, the NBDS identified several actions, probably the most important amongst them was the creation of a new National Biotechnology Regulatory Authority, whose characteristics will be described in detail below.

The NBDS contained important proposals regarding higher education and research centres. In this respect, the NBDS identified several goals and measures such as the creation of new research centres in universities, the design and entry into operation of new PhD programs in the biotech field and the provision of incentives to facilitate the return of Indian expatriate scientists to India.

As far as budgetary issues are concerned, the NBDS targeted the financial and structural aspects of the biotech policy. Regarding the former, the available funds for the Department of Biotechnology through the 11th plan – which will implement the NBDS- would amount to 6500 Crores (almost 1.3 billion Euros).[129] According to official sources, the majority of the items contemplated in the NBDS were included in the budgetary allocation of the first trimester of 2009. This resulted in an almost five-fold increase in the biotech budget in India.[130]

Finally, as far as organizational and administrative issues are concerned, the NBDS made of the coordination among ministries and bodies working in biotech issues a distinct priority, and stressed the need to foster partnerships between private biotechnology ventures and academic research centres.

3.2. The (envisaged) National Biotechnology Regulatory Authority

Among the proposals set forth in the NBDS, the creation of the National Biotechnology Regulatory Authority (NBRA) is prominent. This will be an independent statutory body with wide-encompassing functions relating to the bio-safety approval of genetically modified products and processes. According to the 2004 *Task Force on Application of Agricultural Biotechnology* report, the establishment of the NBRA "is a must" if India is "to derive full benefit from this fast growing area of science including fields like functional genomics, proteomics, bioinformatics and nano-biotechnology, in a safe and responsible manner."[131] In fact, in accordance to the report, the establishment of the NBRA was "essential for generating the necessary public, political, professional and commercial confidence in the science based regulatory mechanisms in place in the country".[132]

128. Department of Biotechnology, *National Biotechnology Development Strategy. Key Elements*, link (*Accessed August 2010*).
129. *Ibid*., 12.
130. Interview with M. K. Khan, Secretary to the Government of India, Department of Biotechnology, in E&Y, *Beyond Borders. Global Biotechnology Report 2009*, E&Y, 2009, p. 108.
131. Task Force on Application of Agricultural Biotechnology, op. cit., p. 4.
132. *Ibid*., p. 8

Some months later, in July 2008, the National Biotechnology Regulatory Act was drafted to establish the NBRA under the Department of Biotechnology. This piece of legislation identified as the core goal of the agency to safeguard "the health and safety of the people of India and to protect the environment by identifying risks posed by, or as a result of, modern biotechnology, and managing those risks through regulating the safe development and deployment of biotechnology products and processes".[133] By April 2010, the NBRA had not been created, although the Indian government affirmed that it could be established by the first quarter of 2010.

In accordance with the National Biotechnology Regulatory Act, the NBRA will be entrusted with the responsibility of regulating the research, manufacture, importation and use of genetically engineered organisms and products derived thereof. Once the NBRA starts working, it will be responsible for controlling the approval of genetically modified food, crops, recombinant biologics, recombinant gene therapy products, vaccines, and recombinant and plasma-derived products, while the DCGI will retain the approval of recombinant therapeutic proteins.[134]

The NBRA will be the first body in full control of almost all aspects of biotech regulation. The need for this agency arises from the lack of uniformity that results from the present institutional framework for biotechnology. Although coordination mechanisms among the aforementioned committees have been established, the lack of uniformity has caused confusion. Consensus has emerged in the sense that regulatory approvals need a consistent and unique mechanism, and a "more uniform and consistent approach to address the safety of biotechnology products and processes in a scientific and transparent manner".[135] In order to fulfil this mission, a single-window clearance system under the authority of a unique agency would be established. In doing so, the creation of the National Biotechnology Regulatory Act would provide a response to the demands by both the private sector and the government commissioned task forces.[136]

The NBRA will be an autonomous body with an independent legal status with head offices in New Delhi. The *Draft National Biotechnology Bill* lays down the basis for the creation of the National Biotechnology Advisory Council and the Inter-Ministerial Advisory Board. The former shall provide the NBRA with independent, strategic advice from several stakeholders on developments in modern biotechnology, while the latter seeks to foster coordination among Central Government ministries in the implementation of India's national biotechnology regulatory system.

The First Schedule of the National Biotechnology Regulatory Bill identifies the products to be dealt with by each one of the three branches that will integrate the NBRA. It may establish measures to regulate issues such as clinical trials, containment and release of genetically modified products and the accreditation and notification of facilities that perform research.[137] Other responsibilities confirm the central role attributed to the NBRA. It will provide scientific advice to central and state authorities when designing policies and rules related to biotechnology; it will also be a point of contact for international policy and regulatory activities related to biotechnology, develop guidelines for risk assessment methodologies, and control the safety of modern biotech products and processes. The NBRA must also guarantee transparency of its activities and, in particular, inform about clinical and field trials and about the Authority's mandate and programmes.

From the institutional point of view, the NBRA shall be directed by a Chairperson. Under his/her authority, three chief regulatory officers will direct the activities of the Authority in three specific biotechnology fields: *i*) agriculture, forests and fisheries; *ii*) human and animal health; and, *iii*) industrial and environmental applications. This is not a *numerus-clausus* list: in the future, other fields may be specified and other branches created accordingly. Combination products will be assigned to an authority for review and regulation in accordance with its primary mode of action.

133. Establishment Plan for the National Biotechnology Regulatory Authority, p. 3.
134. E&Y, op. cit., p. 114.
135. NBRB 2008, preamble.
136. Task Force on Application of Agricultural Biotechnology, op, cit., , pp. 46-48, 51-53.
137. Article 9.1 and 9.2

Chapter IV of the *Draft National Biotechnology Bill* 2008 is devoted to genetically modified organisms. In accordance with this chapter, to undertake research, import, manufacture or use genetically engineered organisms and derived products,[138] it will be imperative to submit an application that specifies the details of those activities and obtain an authorisation from the Chairperson. The application will be scientifically evaluated by the Risk Assessment Unit of the Authority, which will submit an opinion on safety to the –also newly-established– Product Rulings Committee.[139] The latter will be composed by the Chairperson and the Chief Regulatory Officers of the regulatory branches, and could be enlarged with additional members. In its periodic meetings, the Product Rulings Committee may approve the pending authorizations, refuse to authorise the proposed undertakings or impose conditions for risk management.[140] The decision may be appealed before the National Biotechnology Regulatory Appellate Tribunal, another new body that shall consist of one judiciary member and two technical members, one from the healthcare field and one from the agriculture and related fields.[141]

3.3. Doubts and challenges

The proposed scope of the NRBA activities has raised criticism. As conceived, it seems that the NRBA would deal with applications relating to biotechnology in plants, animals and humans. Nevertheless, this argument has been questioned.[142] In fact, in accordance with the National Biotechnology Regulatory Act, the NRBA will devote most of its efforts to activities involving genetic engineering. Biotechnology is a broad term covering activities that do not -or may not- imply genetic engineering, such as fermentation processes or the elaboration of vaccines. Some have criticized the limitation of the concept of 'biotechnology' to genetic engineering and, more precisely, the limitation of the activities of the NRBA to those involving genetic engineering. It is held that this simplification responds to the economic and technical importance of this subset of biotechnology, but such a decisive move as the creation of an authority exclusively devoted to biotechnology could have been reinforced if the resulting authority covered all areas of biotechnology.

Another potential focus of controversy is article 9.3(n). This provision makes reference to the responsibility of the Authority to achieve consistency between national and international standards. More precisely, it establishes that the Authority shall "promote consistency between international technical standards and domestic standards related to the regulation of biotechnology products and processes while ensuring that the level of protection adopted in the country is not reduced." The immediate question that arises is which international standards could be considered when adopting national regulations.

Firstly, it would be necessary to determine whether "international standards" refer to other countries' standards (such as those adopted in the USA, Japan or the EU) or only to those adopted by international organizations. The latter seems to be the correct interpretation, Secondly, it is necessary to bear in mind that several organizations are working in the adoption of standards for biotechnology. In the pharmaceutical field, for instance, there is a growing convergence between the standards endorsed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and those adopted by the World Health Organization. In fact, the WHO seems to have delegated its standard/setting role in favour of the ICH "process". However, there are also differences and there is no guarantee that the views of both organizations will coincide in the future. Moreover, other standards do exist, for instance, those of the World Medical Association regarding the performance of clinical trials. These standards are different from and more protective of the human being than those adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

138. As stated in the First Schedule.
139. 11.4
140. 11.5
141. 20
142. K. I. Varaprasad Reddy, op. cit., p. 308.

IV. INTELLECTUAL PROPERTY

1. THE TRIPS AGREEMENT AND THE PATENTS ACT SUCCESSIVE AMENDMENTS

The Indian patent law underwent significant changes during the last fifteen years. Rather than local demands, the main driver of such changes has been the need to adapt Indian law to the TRIPS Agreement. This Agreement required WTO members, *inter alia*, to recognize process and product patents in *all* fields of technology.

The TRIPS Agreement provided for a number of transitional periods (article 65) which allowed economies in transition, developing countries and Least Developed Countries (LDCs) some time to introduce into their intellectual property regimes the reforms needed to comply with the detailed obligations imposed by the Agreement. The general transitional period for developing countries ended on December 31, 1999.

India was one of the few developing countries that enjoyed (until January 1, 2005) the totality of the transitional period established by the TRIPS Agreement for countries that did not recognize product patent protection in certain fields of technology by January 1, 2000 (article 65.4). Although the transitional period without product patents on pharmaceuticals[143] was of particular importance for the development of the local pharmaceutical industry, such a period was also applicable to other fields, including biotechnological products (such as food) also excluded from product patent protection.

While the first patent legislation was introduced in India in 1856 by the UK, it was only in 1911 that the Indian Patents and Designs Act put patent administration under the management of the Controller of Patents of India. This Act was amended for the first time after independence in 1950, when grounds for compulsory license/revocation due to lack or insufficient working were introduced. Later, the 1970 Patent Act made significant changes to the patent legislation, which distanced the Indian law from the legal standards prevailing in most European countries at that time. Among the changes introduced by the 1970 Act the following are to be noted:

- No product patents were allowed for substances intended for use as food, drugs and medicines including the product of chemical processes.
- Codification of certain inventions as non-patentable.
- Mandatory furnishing of information regarding foreign applications.
- Adoption of absolute novelty criteria in case of publication.
- Expansion of the grounds for opposition to the grant of a patent.
- Exemption of certain categories of prior publication, prior communication and prior use from anticipation.
- Provision for use of inventions for the purpose of Government or for research or instruction to pupils.
- Reduction in the term of patents relating to process in respect of substances capable of being used as food or as medicine or drugs.

143. During this period, however, WTO members were obliged to receive patent applications, to be kept in a 'mail-box' until the end of the period.

- Enlargement of the grounds for revocation of a patent.
- Provision for non-working as ground for compulsory licenses, licenses of right, and revocation of patents.
- Additional powers to Central Government to use an invention for purposes of government including Government undertakings.
- Prevention of abuse of patent rights by making restrictive conditions in license agreements/ contract as void.[144]

Several aspects of the 1970 Patent Act required amendment when the TRIPS Agreement was adopted. In order to comply with the transitional provisions of the Agreement, an Ordinance was issued on 31st December 1994 which, in the absence of Parliament's approval, lapsed after six months. As a result, the USA and the European Communities submitted complaints against India under the dispute settlement rules of the WTO arguing that India had failed to comply with the 'mail box' obligations under article 70.8 of the Agreement. In both cases India was found in violation of the Agreement.[145] A new Ordinance was issued in 1999, later replaced by the Patents (Amendment) Act, 1999, which implemented the filing of patent applications on pharmaceuticals.[146]

Subsequently, the Patents (Amendment) Act, 2002[147] introduced a number of important changes aimed at aligning the patent law with the TRIPS Agreement, such as the 20-year patent term, the reversal of burden of proof in case of infringement of process patents, and the patentability of inventions related to microorganisms.[148] The Amendment also introduced several 'flexibilities' allowed by the TRIPS Agreement:

- Identification of non-patentable inventions.
- Regulation of compulsory licenses.
- Parallel imports.
- Exemption from infringement of the use of a patented invention for obtaining regulatory approval.

In addition, the Patents (Amendment) Act, 2002 introduced provisions to protect biodiversity and traditional knowledge and incorporated a number of procedural changes regarding the Appellate Board, the introduction of a system of deferred examination and the publication of applications after 18 months from the date of filing.

144. See Controller General of Patents, Designs & Trade Marks, India, *Manual of Patent Practice and Procedure, the Patent Office*, India, 2008.
145. See Report of the Appellate Body, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (1998), and Report of the WTO Panel, *India- Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS79/R (1998).
146. Act 38 0f 2002, available at link. The Act was retrospectively applied as of 1st January, 1995, but patent applications relating to pharmaceutical products were examined only after January 1st, 2005, consistently with the TRIPS Agreement. Meanwhile, applicants could obtain Exclusive Marketing Rights (EMRs). Novartis, for instance, obtained in 2004 EMRs in respect of its anti-cancer drug Imatinib mesylate ('Glivec').
147. The Act came into force in May, 2003 with the introduction of the new Patents Rules (which replaced the Rules issued in 1972).
148. What has been termed the 'biotech exception' contained in article 27.3(b), allowed WTO members to exclude from patentability plants and animals, including essentially biological processes for the production of plants and animals. Non-biological and microbiological processes, as well as microorganisms, instead, must be patented if they meet the prescribed patentability requirements. With regard to plant varieties, the Agreement obligated Members to provide for their protection 'either by patents or by an effective *sui generis* system or by any combination thereof' (article 27.3(b)).

This Amendment also made some significant changes with regard to the patentability of biotechnological inventions. Section 3.4 stipulated the non-patentability of:

- the "discovery of any living thing or non-living substance occurring in nature";
- "plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals";
- "an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components"

By specifically allowing for the patentability of microorganisms, the law complied with the requirement of article 27.3(b) of the TRIPS Agreement. The exclusion of inventions which represent the 'discovery of any living thing or non-living substance occurring in nature', consists of 'traditional knowledge' or of 'known properties of traditionally known components' would lead to the exclusion from patentability of some biotechnology-based inventions. Of particular importance is the interpretation given by the patent office and the courts to the concept of 'occurring in nature'. The Manual of Patent Practice and Procedure of the Patent Office clarifies that:

> "There is a difference between discovery and invention. A discovery adds to the amount of human knowledge by disclosing something already existent, which has not been seen before, whereas an invention adds to the human knowledge by creating a new product or processes involving a technical advance as compared to the existing knowledge (para 4.4.1)."

It further indicates that

> "…the fact that a known material or article is found to have a hitherto unknown property is a discovery and not an invention. But if the discovery leads to the conclusion that the material can be used for making a particular article or in a particular process, then the article or process could be patentable (para. 4.4.3)."
>
> Similarly, finding of a new substance or micro-organism occurring freely in nature is a discovery and not an invention e.g. in *Kirin-Amgen v. Hoechst Marion Roussel* [2005] RPC 9] (para. 4.4.4).

One of the key issues is whether a merely isolated (unmodified) biological material may be deemed as not 'occurring in nature'. In the USA and EU, for instance, isolated genes for which the patent applicant identifies at least one function may be patentable. The Indian law, however, seems to provide that only materials, including microorganisms and genes, that are the result of human intervention[149] would be patentable.

Since the TRIPS Agreement does not define what an 'invention' is, it is within the room for maneuver left to WTO Members to determine whether substances found in nature, even if isolated, are patentable. Brazil and other developing countries do exclude such substances from patentability. Interestingly, in a recent decision[150] the U.S. District Judge Robert Sweet invalidated seven patents related to the genes BRCA1 and BRCA2, whose mutations have been associated with breast cancer, on the argument that DNA's existence in an isolated form does not alter the fundamental quality of DNA as it exists in the body nor the information it encodes. 'The "isolated DNA, he said, is not markedly different from native DNA as it exists in nature".[151] He joined those 'including scientists in the fields of molecular biology and genomics' who have considered the practice of patenting 'isolated' DNA 'a 'lawyer's trick' that

149. For instance, synthetic genes, vectors, recombinant products such as vaccines, enzymes, hormones, etc. See link.
150. In *Association for Molecular Pathology, et al. v. USPTO, et al.*(case no. 09-CV-4514 (S.D.N.Y. Mar. 29, 2010). See http://www.aclu.org/files/assets/2010-3-29-AMPvUSPTO-Opinion.pdf.
151. *Ibid*..

circumvents the prohibitions on the direct patenting of the DNA in our bodies but which, in practice, reaches the same result".[152]

The Patents (Amendment) Ordinance, 2004, later replaced by the Patents (Amendment) Act, 2005 (Act 15 of 2005)[153] introduced the third set of amendments to the 1970 Patent Act. The key modification was the introduction (as required by the TRIPS Agreement) of product patents for fields of technology (including food, chemicals and pharmaceuticals) previously excluded from protection. The Act revised the definition of 'inventive step',[154] implemented the WTO Decision of August 30, 2003 in India (by incorporating a provision for the export of medicines under a compulsory license to countries with insufficient or no manufacturing capacity in pharmaceuticals) and introduced, *inter alia*, modifications to the opposition procedures before the Patent Office (both pre-grant and post-grant oppositions were allowed). This Amendment introduced a new provision (section 3(d)) aimed to prevent the grant of patents on 'minor' or 'frivolous' inventions. Section 3(d) reads as follows:

> "*(d)* the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
> *Explanation*.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;".

Although the main objective of Section 3(d) has been the avoidance of what have become common 'evergreening'[155] practices in the pharmaceutical industry, this provision has apparently not been an absolute barrier against the patenting of variants of existing products, such as polymorphs.[156] The total number of pharmaceutical patents granted in India increased between 2004-05 (when the new section 3(d) was introduced) and 2008-09, from 765 to 2373.[157] This trend may be regarded as 'indicative of the fact that the Patents Act, as it exists today, accommodates incremental innovations, since the patents granted are not only for new molecules but also for new processes as well as new uses, combinations and dosage forms'.[158]

Some of the guidelines contained in the *Manual of Patent Practice and Procedure* of the Patent Office of India may be of particular relevance for the assessment of patent applications relating to biotechnological inventions (see Box 1).

152. In addition, 'the judge held that 'Myriad's suggestion that invalidating the patents-in-suit would constitute an unconstitutional taking in violation of the Fifth Amendment of the Constitution or a violation of the United States' obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") is unpersuasive'. He considered that the decision to revoke the patents based on the non-patentability of the subject matter was, in particular, consistent with articles 8.1 and 27.3 of said Agreement' (*Ibid*, at. p. 106-107).
153. See link (*Accessed June 2010*).
154. Section 2(1)(ja): "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art'.
155. 'Evergreening' describes the practice by brand name pharmaceutical companies of filing patents on attributes or variants of existing products that are about to fall or have fallen in the public domain, in order to delay the entry of generic competitors.
156. See, e.g., IN201140, IN202128, IN201649 and IN210420. However, a patent application on a polymorph of Novartis' Imatinib mesylate ('Gleevec') was rejected by the Intellectual Property Appellate Board (IPAB)in July 2009 under the 'higher' inventive step required by section 3(d). See , e.g., link.
157. T C James, *Patent Protection and Innovation. Section 3(d) of the Patents Act and Indian Pharmaceutical Industry,* 2009, p. 13. link (*Accessed July 2010*)
158. *Ibid*..

Box 1: Guidelines on patentability with potential impact on the assessment of biotechnological inventions in India

(viii) Purification Compounds:
Mere purification of known material is not patentable as they are considered the purified compound. However the purification process or the purified compound which never existed before due to inherent long standing problem can be considered patentable.
4.5.8 Mere discovery of new property of a known substance: - A mere discovery of a new property of known substance is not considered patentable. For instance, the paracetamol has antipyretic property. Further discovery new property of paracetamol as analgesic can not be patented. Similarly ethyl alcohol is used as solvent but further discovery of it new property as anti knocking thereby making it usable as fuel can not be considered patentable

4.5.9 Mere discovery of any new use of known substance:- A mere discovery of new property of known substance is not considered patentable. For instance new use of Aspirin for treatment of the cardiovascular disease, which was earlier used for analgesic purpose, is not patentable. However, a new and alternative process for preparing Aspirin is patentable. Similarly the New use of methyl alcohol as antifreeze in automobiles- The Use of methanol as a solvent is known in the prior art. A new use has been claimed in this claim as antifreeze which is not allowable Further, a new use of Chloroquine for Sarcoidosis (a fungal disease) and for Infectious mononucleosis (a viral disease) and for Diabetic neuritis (inflammation of nerves) is not patentable.

3*(h) A method of agriculture or horticulture.*

4.8.1 A method of producing a new form of a known plant, even if it involved a modification of the conditions under which natural phenomena would pursue their inevitable course, is not patentable. (N.V. Philips Gloeiammpenfabrieken's Application 71 RFC 192).

4.8.2 A method of producing improved soil from the soil with nematodes by treating the soil with a preparation containing specified phosphorathioates was held not patentable (Virginia Carolina Chemical Corporation application 1958 RFC 38).

4.8.3 A method of producing mushroom plant (64/Cal/79) and a method for cultivation of an algae (445/Del/93] were held not patentable respectively.

3*(j) Plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.*

4.10.1 As per this sub-section, while plants and animals, or any part of the plant or animal is not patentable, an exception is made in the case of micro-organisms. However, any discovered micro-organism from the nature is not patentable.

4.10.2 In Dimminaco – A.G vs. Controller of Patents & Designs and others (AID No.1 of 2001) the issue involved was the patenting of the process for preparation of infectious bursitis vaccine, which is invented for protecting poultry against infectious bursitis. The Controller held that the process of separation of the vaccine which has living entity cannot be considered a manufacture and hence not patentable under section 2(1)(j)of the Patents Act. He also held that since the vaccine contains living organism it cannot be patented. The court held that the matter involved is of a *new* process of preparation of vaccine under specific scientific conditions and the said vaccine is *useful* for protecting poultry against

contagious bursitis infection and there is no statuary bar to accept a manner of manufacture as a patentable even if the end products contain living organism.

4.10.3 Plant varieties are provided protection in India under the provisions of the Protection of Plant Varieties and Farmers' Rights Act, 2002.

3*(p) An invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components;*

4.16.1 Traditional Knowledge, being knowledge already existing, is already in public domain, and hence, not patentable, for example: Wound healing property of turmeric. The anti-septic property of turmeric for wound healing. The pesticidal, insecticidal properties of neem.

Although some of this criteria are comparable to those applied in the European context and there are some coincidences (e.g. the non-patentability of animal and plant varieties), a comparison between the Indian law and the EU regime applicable to biotechnological inventions[159] reveals several important possible divergences regarding the admissibility of patents over substances found in nature.[160] The Manual of Patent Practice and Procedure, however, often relies on EPO decisions to provide guidance for the examination of various types of patent claims, such as T 0814/04 on a process for the production of trypsin in a filamentous fungus of an Aspergillus species, T 303/86 (CPC Int. [1993] EPOR 241) regarding a process for making flavour concentrates from vegetable or animal substances, and T 455/91 (OJ 1995, 684) defining the skilled person's likely attitude to possible changes, modifications or adjustments in known products (e.g. a plasmid) or procedures.

Some foreign biotechnological firms have been critical about the protection conferred in India to biotechnological innovations. Thus, it has been argued that the reforms of the patent law led to a 'dilution of biotechnology patentability' and that the Biological Diversity Act (2002) and Regulations (2004) 'restrict genetic resource patent rights' since they would create major hurdles for bio-prospecting in India, cloud patent rights gained abroad, deny national treatment, limit patentability for biotech inventions and provide additional grounds to challenge and revoke patents.[161] More specifically, criticism has focused on the following provisions:

2002 Patents (Amendments) Act:

– Every complete specification shall… disclose the source and geographical origin of the biological material in the specification, when used in an invention.

– Two new grounds for revocation:

- The complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention.

- The invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.

159. As codified in the Council Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions.
160. In accordance with article 3.2 of the Directive '[B]iological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature'; article 5.2 further provides that '[A]n element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element'.
161. Presentation by Susan Finston, available at link (*Accessed August 2010*).

2002 Biological Diversity Act:

– Requires all inventors to obtain consent of National Biodiversity Authority (NBA) before applying for patents where the invention is based on any biological resource.

– Grants NBA power to impose benefit sharing fee (or royalty) or conditions, such as the sharing of financial benefits arising out of commercial utilization.[162]

Moreover, the Biotechnology Industry Association (BIA) requested the US Trade Representative (USTR) on February 11, 2008, to keep India under the USTR 'watch list' arguing:

- lack of clarity about the patentability of biomolecules like polypeptides and nucleic acids;

- that the Indian Patent Act 'disallows patents for known products unless they result in significant enhancement of the known efficacy';

- lack of exclusive protection for test data for pharmaceuticals;

- the 'unreasonable burdens on patent applicants, subjecting valuable patent rights to uncertainty' allegedly resulting from the applicants' obligation to disclose the source and geographical origin of biological materials used for invention.[163]

However, the USTR report for 2009 on Special Section 301 did not reflect these complaints, except with regard to the more general issue of test data protection. In that report, USTR continued to 'urge India to improve its IPR regime by providing stronger protection for copyrights and patents, as well as effective protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for pharmaceutical and agrochemical products'.[164]

In addition, an academic study has found that:

"[R]ecent enhancements to India's patent laws, a new acceptance of biotechnology patents by the Indian judiciary, and an expanding global demand for generic bio-pharmaceuticals all predict a surge in biotechnology process development and patenting in India… The TRIPS-mandated term extension of Indian chemical (including biotechnological) process patents from seven to twenty years from filing, coupled with a shifted burden of proof for alleged infringements of process patents, will work in concert with the Indian biotechnology industry's desire to lead the world in supplying generic biologics. As multiple Indian companies compete to sell the same biotechnology product, each firm's need to distinguish itself by process development increases. Stronger process patent protection will facilitate competitive advantage among Indian biotechnology companies"[165].

162. See link.
163. J. C. Mathew, 'Biotech firms want changes in patent law', New Delhi February 21, 2008, available at link
164. See link.
165. J. M. Mueller, "Biotechnology Patenting in India: Will Bio-Generics Lead a 'Sunrise Industry' to Bio-Innovation?", *University of Missouri-Kansas City Law Review*, vol. 75, nº 2, 2008, abstract available at link.

2. ONGOING NEGOTIATIONS FOR THE CONCLUSION OF A FREE TRADE AGREEMENT BETWEEN THE EU AND INDIA: MAIN TOPICS ON INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER

2.1 EU objectives

India and the EU have launched negotiations for the possible adoption of a free trade agreement (FTA) that includes – in line with the policies deployed by the EU and the United States in the last ten years – a comprehensive chapter on intellectual property rights (IPRs).[166] The objectives of the IPRs chapter, as proposed by the EU, would be to facilitate the production and commercialization of 'innovative and creative products between the Parties' and to achieve 'an adequate and effective level of protection and enforcement' of IPRs.[167]

The negotiation of this FTA has attracted significant attention in Indian business circles and non-governmental organizations (NGOs), given the far reaching implications that the adoption of new standards on IPRs may have in different sectors, particularly the pharmaceutical industry. Several international NGOs have also expressed concerns about the outcomes of the negotiations, having in view that India has become a major world supplier of low cost medicines and active ingredients.[168]

Article 2.1 of the EU-India draft FTA explicitly indicates that 'this chapter shall complement and further specify the rights and obligations between the Parties *beyond* those under the TRIPS Agreement and other international treaties in the field of intellectual property to which they are parties'.[169] The draft FTA includes, in effect, a large number of TRIPS-plus standards. The EU-India draft FTA practically covers all areas of IPRs. It is clear that the EU seeks levels of IPRs protection that exceed those currently available under Indian domestic legislation as well as those mandated by the TRIPS Agreement.[170]

India is in a particular situation as regards to the formulation of IPRs policies that may affect the development of the biotech and other sectors. On the one hand, innovative activities have increased in a context of economic growth and strengthening of the country's research and development infrastructure. The country is today considered one of the few 'innovative developing countries' that have started to reap benefits from years of investment in R&D and training of human resources.[171] *On the other, many companies within the biotech sector and in other sectors still depend on reverse engineering and imitation, and around 42% (i.e. about 456 million) of the Indian population is below the poverty line.*[172] *These contrasts are likely to create serious dilemmas*[173] *to policy makers in designing IP laws and negotiating the FTA with the EU and other partners.* Increasing the levels of IPRs protection

166. The following analysis is based on the draft IPR chapter of the EU-India FTA in its status before the 6th round of negotiations held from 17 to 19 March 2009 in Delhi. See, link (*Accessed June 2010*).
167. Significantly, no reference is made to the need of balancing the interests of IPRs holders and users nor to the contribution that IPRs should make to social and economic welfare (see, for example, article 7 of the TRIPS Agreement). This is noteworthy in the light of the Indian position on IPRs in international fora, such as WIPO and WTO, and of the involvement of both India and the EU in the discussion of the Development Agenda within WIPO. See, e.g. M. Khor, *Strong support from South for WIPO development agenda*, available at link (*Accessed July 2010*).
168. See, e.g., link.
169. Emphasis added.
170. The European Parliament, however, has repeatedly called on the European Commission not to seek TRIPS-plus standards of protection in developing countries, particularly as they may affect access to medicines. See, e.g., the European Parliament Resolution of 12 July 2007 on the TRIPS Agreement and access to medicines which calls on the European Council 'to meet its commitments to the Doha Declaration and to restrict the Commission's mandate so as to prevent it from negotiating pharmaceutical-related TRIPS-plus provisions affecting public health and access to medicines, such as data exclusivity, patent extensions and limitation of grounds of compulsory licences, within the framework of the EPA negotiations with the ACP countries and other future bilateral and regional agreements with developing countries' (para. 11), available at link.
171. See C. Morel, *et al*., "Health Innovation Networks to Help Developing Countries Address Neglected Diseases", *Science*, vol. 309, 15 July 2005, p. 401.
172. World Bank, *New Global Poverty Estimates. What it means for India*, link (*Accessed August 2010*).
173. One of the limitations that policy makers face is that the non-discrimination clause contained in article 27.1 of the TRIPS Agreement would not allow, in principle, to establish different standards of patent protection in different fields of technology.

might benefit some innovative local companies, particularly in the area of biotechnology, but it may negatively affect companies that are at an early stage of technological development as well as a large part of the population in respect of access to the outcomes of innovation.

Some of the standards of IPRs protection under discussion are examined in more detail in the following sections.

2.2 Disclosure of origin of biological materials

The draft FTA requires the Parties to adhere to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977, amended in 1980). This obligation would not entail changes in Indian legislation, since this Treaty is in force in India since December 2001. However, the draft FTA obligates the Parties to accede to the Patent Law Treaty (Geneva, 2000) which harmonizes certain procedural aspects of patent law. This Treaty has not been adhered to by India so far and its eventual implementation might impose some restrictions on national law, particularly in respect of the obligation to disclose the origin of biological materials used in claimed inventions.

India has been at the forefront of initiatives aiming at curbing the misappropriation ('bio-piracy') of genetic resources and associated traditional knowledge, through the establishment of an obligation to disclose the origin of biological materials claimed in patent applications.[174] The Patent (Second Amendment) Act 1999 made incumbent upon patent applicants to disclose the source of origin of the biological material used in the invention. In addition, the law incorporated the non-disclosure or wrongful disclosure of the source of origin of biological resources as one of the grounds for rejection of a patent application, as well as of revocation of a granted patent (§ 10(a)(4)(d)(ii)(D)). Further, the Indian Biodiversity Bill establishes a series of measures aiming to ensure an equitable sharing of benefits arising from the use of biological resources and associated knowledge originating from India. Section 6 of the Bill provides that anybody seeking any kind of intellectual property rights on a research based upon biological resource or knowledge obtained from India, need to obtain prior approval of the National Biodiversity Authority (NBA). The NBA will impose in these cases benefit-sharing conditions. Section 18 (iv) of the Indian Biodiversity Bill, in addition, stipulates that one of the functions of NBA is to take measures to oppose the grant of IPRs in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource.

The absence in the draft FTA of provisions safeguarding the disclosure of origin obligation is a noticeable gap.[175] India may have deliberately opted to leave this issue outside the FTA negotiation in order to fully preserve its capacity to regulate the matter at the national level. However, if India accepted the requirement to adhere to Patent Law Treaty, questions may arise about the possibility of revoking a patent in cases of non compliance with the obligation to declare the origin of biological materials, in the light of the provision of the Patent Law Treaty that only allows for revocation or invalidation of a patent in those cases 'where the non-compliance with the formal requirement occurred as a result of a fraudulent intention'.[176]

174. See, e.g., Elements of the obligation to disclose the source and country of origin of biological resources and/or traditional knowledge used in an invention, submission from Brazil, India, Pakistan, Peru, Thailand, and Venezuela, IP/C/W/429 of September 21, 2004.
175. It is worth mentioning that CARIFORUM-EU Economic Partnership Agreement (EPA) included provisions on this subject. Article 150.4 provides that the Parties 'may require as part of the administrative requirements for a patent application concerning an invention which uses biological material as a necessary aspect of the invention, that the applicant identifies the sources of the biological material used by the applicant and described as part of the invention'.
176. Article 10 "*Validity of Patent; Revocation*".

It is worth noting that while the EU has generally accepted[177] the introduction of a disclosure obligation, it considers that non-compliance should not be penalized with the revocation or non-enforceability of the granted patent, but by means of other measures that do not affect the validity or enforceability of the patent.[178]

2.3 TRIPS-plus protections potentially affecting biotech products

Article 9.3 of the draft FTA, if accepted, would compel India to extend the exclusive rights accorded by a patent for up to five additional years in order to compensate for the time required for the marketing approval of a medicinal product.[179] This provision is modeled on the concept of 'supplementary protection certificate' applied in the European context.[180] The grant of such certificates would, in practice, delay the entry of generic products. There is no empirical evidence supporting that such an extension in India is needed to ensure that the patent owner recovers its R&D investment, since this is probably done through sales in developed countries themselves. An exceptional case could arise when a product is only or principally destined to treat diseases prevailing in India and other developing countries. Alternative mechanisms to stimulate investments in these situations may be devised.[181]

EU proposal also includes the establishment of exclusive rights for the test data on the efficacy and safety of drugs or agrochemical products necessary to obtain their marketing approval.[182] The Indian government has so far refused to grant exclusive rights over such data, despite the demands by the USA and the EU to do so. A commission was set up by the government to consider what kind of protection should be conferred on such data for pharmaceuticals, taking into account both the obligation to comply with the Agreement on Trade Related Aspects of Intellectual property Rights (TRIPS Agreement) and the Indian national interests. The commission's report concluded that data exclusivity was neither required nor advisable. It noted that:

> [T]here is enough flexibility in the provisions of the TRIPS Agreement for a country to determine the appropriate means of protecting test data. In terms of paragraph 4 of Doha Declaration, the provisions are to be *'interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.*[183]

Another area where clear TRIPS-plus provisions are sought by the EU relates to geographical indications (GIs).The commercialization, particularly in foreign markets, of some products based on conventional biotechnologies may be affected by the regulations on GIs. Not surprisingly, the draft FTA proposed by

177. See, e.g., European Community and its Member States, *Disclosure of origin or source of genetic resources and associated traditional knowledge in patent applications*. Proposal of the European Community and its Member States to WIPO, 16.12.2004, link.
178. Similarly, an FTA signed between Colombia and the European Free Trade Association (EFTA) provides for civil, administrative or criminal sanctions in case of deliberate or unjustifiably false declaration on the origin or source. See D. Vivas-Eugui, "EL TLC entre la AELC y Colombia: un hito hacia la conservación de la biodiversidad", *Puentes*, vol. X, n. 4, September 2009: 8, link (*Accessed October 10, 2009*).
179. The same position would apply to 'plant protection products'.
180. Although there is no explicit text in the EU proposal about the patenting of second pharmaceutical indications (that is, of a known medicine for which a new therapeutic use is found) article 9.3.3 of the draft suggests that India should extend the duration of patents on the 'pediatric use' of pharmaceutical products.
181. This is a central aspect of the *WHO* Global strategy and plan of action on public health, innovation and intellectual property adopted in May 2008 by the Sixty-first World Health Assembly. See link.
182. Article, 2.2 refers to the 'protection of undisclosed information' as separate from 'the protection against unfair competition as referred to in article 10*bis* of the Paris Convention for the Protection of Industrial Property (Stockholm Act 1967). The TRIPS Agreement, however, subjects such information to the discipline of unfair competition (see paragraphs 1 and 3 of article 39).
183. Report on Steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPS Agreement, 1.11, Satwant Reddy (Secretary, Department of Chemicals & Petrochemicals, Ministry of Chemicals & Fertilizers) Gurdial Singh Sandhu (Joint Secretary, Department of Chemicals & Petrochemicals, Ministry of Chemicals & Fertilizers), Government of India, 31st May, 2007. The report refers to the Doha Declaration, World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration], available at *http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm*.

the EU contains detailed provisions on the subject, including for the mutual recognition and protection of a number of listed EU and Indian GIs. The possible enhancement of GIs protection has divided developed and developing countries alike at the WTO, where disagreement persists regarding this issue as well as the legal effects and modalities of an international registry for GIs relating to wines and spirits. India has been one of the supporters of the enhancement of GIs protection, possibly motivated by the extended use of the denomination 'basmati'[184] for rice cultivated outside India. Hence, the interests of India and the EU might converge in this area.

The negotiating texts so far known do indicate that India has not agreed on several aspects of the EU demands for higher IPRs standards. While in some cases, India has apparently rejected particular EU proposals (e.g. extension of the patent term, data exclusivity), in other cases its strategy has apparently been to accept certain obligations but only to the extent admissible under 'existing' or 'applicable' laws (e.g. articles 6.3, 6.4, 12, 13, 16, 17, 18) or where the proposed measures are deemed 'appropriate' by the relevant authorities (e.g. articles 14, 15, 16).

Many provisions proposed by the EU, particularly in the area of trademarks have been simplified in the counterproposals. In the area of enforcement, provisions with mandatory intent ('the Parties shall…') have apparently been redrafted by India as facultative ('the Parties may…') (e.g., article 13, 14, 16, 18, 19, 20, 21, 23) or converted into a best effort obligation ('the Parties shall endeavor…') (e.g. articles 17 and 22).

The EU-India draft FTA obligates the Parties 'to co-operate to promote and reinforce the protection of plant varieties based' on UPOV 1991 (article 11).[185] It makes a specific reference to the possibility (allowed by article 15(2) of UPOV 1991) of introducing an exception for the use, in their own exploitation, of seeds saved by farmers. Given the sensitivity of the issue of plant varieties protection in India, it is unlikely that this clarification would be sufficient to change India's possible preference for a more flexible system of plant variety protection. The Indian Protection of Plant Varieties and Farmers' Rights Act contains elements absent in the UPOV Convention, such as the registration of extant and farmers' varieties and benefit sharing provisions to compensate farmers' for their innovations. In addition , the Act allows farmers to 'to save, use, sow, resow, exchange, share or sell his farm produce including seed of a variety protected under this Act in the same manner as he was entitled before the coming into force of this Act (article 39(iv)). Notwithstanding the divergences between the UPOV Convention and domestic law, India has attempted to join UPOV in the past.[186]

Access to databases may be of particular importance for biotechnological research in India. The EU draft FTA (article 2.2) refers to the protection of 'non original databases', which are regulated within the EU under the Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases.[187] The protection of non-original databases –not required by the TRIPS Agreement- has been critically reviewed[188] and has failed to gain support outside Europe.[189]

184. This is a variety of long grain rice originally grown in India and Pakistan, notable for its fragrance and flavor.
185. The corresponding provision of the EU draft FTA for Central America is more flexible, as it reproduces the wording of TRIPS article 27.3(b) (article 10).
186. See link.
187. An evaluation by the European Commission casts doubts, however, about the necessity of the sui generis protection established by said Directive. The European Commission has noted, for instance, that '[T]he economic impact of the "sui generis" right on database production is unproven. […] Is "sui generis" protection therefore necessary for a thriving database industry? The empirical evidence, at this stage, casts doubts on this necessity' (see DG INTERNAL MARKET AND SERVICES WORKING PAPER, *First evaluation of Directive 96/9/EC on the legal protection of databases*, Brussels, 12 December 2005, available at link. See also 'Program Schedules, Event Data and Telephone Subscriber Listings under the Database Directive. The 'Spin-Off' Doctrine in the Netherlands and elsewhere in Europe', paper presented at Fordham University School of Law, Eleventh Annual Conference on International IP Law & Policy, New York, 14 to 25 April 2003, available at link.
188. An evaluation of the operation of the EU Directive on the subject has recommended to repeal the whole Directive or the "sui generis" right or to amend the "sui generis" provisions. See *Evaluation of the 1996 Database Directive raises questions*, Single Market News Article - Issue No. 40 - January 2006, at link; European Commission, DG Internal Market and Services Working Paper, First evaluation of Directive 96/9/EC on the legal protection of databases (2005), at link.
189. For instance, the USA does not protect such databases.

Finally, with regard to transfer of technology, the EU draft seems to contribute little to address the concerns repeatedly voiced by India in international fora about the need to substantially expand the transfer of technology to developing countries.[190] Article 3.1 of the draft FTA refers to this subject but would impose a very general obligation on the Parties. They only commit themselves to an 'exchange of views and information on their domestic and international policies affecting transfer of technology'. The draft also requires the creation of an 'enabling environment for technology transfer in the host countries, including issues such as the relevant legal framework and development of human capital'. This text puts the burden of taking appropriate action on India, as recipient country, rather than on the European countries as potential suppliers of technologies.

The final outcome of the IPRs negotiations in the EU-India FTA is still uncertain. It is impossible at this stage, in particular, to anticipate possible implications of the adoption of an agreement on the development and transfer of biotechnology. Indian government staff has the expertise and the negotiating capacity to address the IPRs issues in a way consistent with Indian perceptions of the national interests. Civil society organizations, which have been strongly involved since the adoption of the TRIPS Agreement in national debates on developments in IPRs legislation, are closely monitoring the FTA negotiations with the EU and urging the government not to accept TRIPS-plus standards, particularly as they might affect access to medicines and farmers' rights.[191]In this scenario, India is likely to find difficult to make commitments to introduce TRIPS-plus standards of IPRs protection,[192] with the exception perhaps in the area of GIs.

3. INTELLECTUAL PROPERTY POLICIES REGARDING UNIVERSITIES' DISCOVERIES AND THE BAYH-DOLE EXPERIENCE

India devotes significant resources to R&D.[193] The public sector accounts for the largest share of R&D expenditures,[194] despite the growth of in-house R&D by the private sector following the country's economic liberalization since the 1990's.[195] There have been concerns, however, about the extent to which public investment in R&D translates itself into innovations effectively leading to new production processes and products. Some institutions have put in place active policies to increase the transfer of R&D results to industry, including by promoting the patenting of inventions eventually obtained by their researchers. A telling example has been the policy of the Council of Scientific and Industrial Research (CSIR)[196] which, as of 2008, had 1926 patents in force.[197] CSIR has been one of the top ten users

190. For instance, in a submission to the WTO in 1999, the Indian government noted that '[O]ne of the important objectives of the WTO Agreement, as mentioned in its preamble, is the need for positive efforts designed to ensure that developing countries secure a share in the growth in international trade commensurate with the needs of their economic development. However, the TRIPS Agreement in its current form might tempt IPR holders to charge exorbitant and commercially unviable prices for transfer or dissemination of technologies held through such IPRs. It is important, therefore, to build disciplines for effective transfer of technology at fair and reasonable costs to developing countries so as to harmonize the objectives of the WTO Agreement and the TRIPS Agreement' (WT/GC/W/147, 18 February 1999, available at www.commerce.nic.in/D644e.doc) (*Accessed June 2010*).
191. See, e.g link.
192. It is to be noted that, according to article 4 of the TRIPS Agreement, any concessions eventually made to the EU in the field of IPRs should be unconditionally and automatically extended, under the most-favored-nation clause, to all other members of the WTO.
193. R&D investment is around 0,8% of its GNP (see link). India is among the world's top 15 R&D-performing nations (see http://www.nsf.gov/statistics/seind10/c4/c4c.htm).
194. The Central Government funds 71% of civilian R&D activities in India. See, e.g., D. Kumar Abrol, V. Kumar Upadhyay, P. Sikka, 'Financing of S&T in India', *India Science & Technology 2008*, 2008, abstract available at SSRN: link.
195. See, e.g., P. Das, 'Economic liberalisation and R&D and innovation responses of Indian public and private sector industries', *International Journal of Management and Decision Making*, vol. 5, nº 1, 2004, *pp. 76 - 92*.
196. Established in 1942, it has 39 laboratories and 50 field stations or extension centers in India.
197. Additionally, 3245 patents were under prosecution, of which 1.94% had been commercialised or licensed. See S. Basheer and S. Guha (2010), 'Patenting Publicly Funded Research: A Critique of the Indian "*Bayh Dole*" Bill', available at link.

of the Patent Cooperation Treaty (PCT) in terms of individual applicants from developing countries.[198] However, only 5,7% of the patents obtained by CSIR have been commercialized.[199]

Several developing countries (Brazil, South Africa, Malaysia, Jordan) have recently proposed or adopted legislation inspired by the U.S. Bayh-Dole Act with the aim of increasing the utilization of R&D results. The U.S. Bayh-Dole Act, passed in 1980, allowed universities to acquire patents on inventions developed with federal funding. The implementation of the law has raised considerable controversy. While some commentators consider that the Act has promoted innovation through university-industry linkages and contributed to the funding of academic research, others have argued that, given the cost of administration, most US institutions earn little or no gross revenue, and that the aggressive pursuit and defense of patents has hindered the progress of research and the relationship with industry.[200] Further, it has been noted that, in the particular area of biotechnology, the patentability of basic research outcomes and research tools has created, in some cases, 'a veritable tax on commercialization'.[201]

While many questions about the impact of the Bayh-Dole legislation remain,[202] various commentators have recommended caution in adopting the same system in developing countries. For instance, it has been observed that

> "…the present impetus for BD [Bayh-Dole] -type legislation in developing countries is fueled by overstated and misleading claims about the economic impact of the Act in the US, which may lead developing countries to expect far more than they are likely to receive. Moreover, political capital expended on rules of patent ownership may detract from more important policies to support science and technology, especially the need for public funding of research. Given the low level of public funding for research in many developing countries, for example, the focus on royalty returns at the expense of public goods may be misplaced. Furthermore, it is unclear whether any of the positive impacts of BD in the US would arise in developing countries following similar legislation, absent the multiagency federal pluralism, the practically oriented universities, and other features of the US research system discussed above.
>
> In any event, both the patent laws and patterns of scientific collaboration have changed substantially since BD was passed in 1980. To the extent that legislation governing the patenting and licensing of public sector research is needed in developing countries at all, it should reflect this new context rather than blindly importing a US model that is 30 years old."[203]

The "Protection and Utilization of Publicly Funded Intellectual Property Bill" was introduced to the Indian Parliament in 2008, with the goal of encouraging patenting by universities and autonomous research institutions that are government funded.[204] In assessing this Bill, it has been held that '[O]verall, data from the U.S. experience suggest it is unlikely that Indian institutions will earn much money, or even cover costs, from these activities. If income is the goal of the new legislation, the game is probably not worth the candle'. It has also been noted that while CSIR generated 4 crore rupees (approximately $1 million) in licensing revenues, it spends over twice that much on patenting/licensing costs (10 crore

198. See M. Singh Nair (2006), 'India: A Drop in India's PCT applications', available at link.
199. S. Basheer and S. Guha, op. cit.
200. B. Sampat (), *The Bayh-Dole Model in Developing Countries: Reflections on the Indian Bill on Publicly Funded Intellectual Property*, UNCTAD - ICTSD Policy Brief No. 5, 2009.
201. A. D. So, B. N. Sampat, A. K. Rai, R. Cook-Deegan, J. H. Reichman, et al., (2008) "Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience", *PLoS Biol* 6(10): e262. doi:10.1371/journal.pbio.0060262.
202. See, e.g., R. Churchill , D. Lorence , J. Chin, F. Peo and L. Gonzales, *International Journal of Technology Transfer and Commercialisation*, vol. 8, nº 1 / 2009, pp. 98 - 109.
203. A. D. So, B. N. Sampat, A. K. Rai, R. Cook-Deegan, J. H. Reichman, *et al*. (2008) op. cit..
204. See, e.g., M. Saurastri, "The Indian version of the Bayh-Dole Act", *Intellectual Asset Management*, March/April 2009,, available at link.

rupees).[205] Further, the Bill has been questioned, inter alia, on the grounds that under the Indian legal system universities and other research institutions can already obtain patents in their own name, and that the Bill mandates patenting (under threat of heavy sanctions) rather than addressing the obstacles found at the stage of commercialization of inventions.[206] Other commentators, however, have welcomed the initiative as 'a step in the right direction' that may 'encourage and motivate inventors and institutes and provide a legal framework for better interaction between industry, academia and government – which is sorely needed'.[207]

A key policy dilemma faced by India and other developing countries is how to manage public R&D funding in order to obtain the highest social returns and development impact. In particular, public investment in recombinant DNA technology may contribute to address problems that are socially and ecologically relevant, such as research on under-utilized or "orphan crops" like millets, legumes and tuber crops cultivated in dry farming and fragile environments'.[208] A policy that generally penalizes non-patenting (that is, putting knowledge in the public domain) may reduce rather than enhance the potential contribution of publicly funded R&D.[209] At the same time, there are situations in which the appropriation of research results may be justified, for instance, when they would only be further developed or exploited in the country if they are subject to patent protection.

205. S. Basheer,S. Guha, op. cit.
206. *Ibid*.
207. M. Saurastri, op. cit. p. 64.
208. Task Force on Agricultural Biotechnology, op. cit., pp. 29-30.
209. See B. Sampat, op. cit. p. 6.

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