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EXPLORING THE FLEXIBILITIES OF TRIPS TO PROMOTE BIOTECHNOLOGY CAPACITY BUILDING AND APPROPRIATE TECHNOLOGY TRANSFER

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SUMMARY

The objective of this work is to assist developing countries in designing their patent systems in order to promote biotechnology-based development. Many countries are unclear about how to tailor their patent regulations to promote their interests in the acquisition, development and application of biotechnology, and therefore how best to exploit the flexibilities of international law, especially the TRIPS Agreement. Two types of flexibility exist in Article 27.3(b) of TRIPS, which are a key focus of the present study: (i) the optional subject matter exceptions, specifically plants, animals and essential biological processes for the production of plants and animals; and (ii) the possibility to define these terms and others such as micro-organism in a variety of ways.

Existing studies are very useful in linking the importance of IPRs, especially patents, to levels of development, and answering the question of what conditions in a specific country or industrial sector are necessary to ensure that IPRs foster, rather than inhibit, domestic innovation including 'creative imitation' and technology transfer. One inference is that it is only after countries have accumulated indigenous capabilities with extensive science and technology infrastructure to undertake creative imitation that IPR protection becomes an important element in innovation and technology transfer.

However, few studies have focused specifically on biotechnology, and even fewer have linked biotechnological capabilities to implementation of TRIPS. This report seeks to fill this gap by focusing on relative biotechnology capabilities in different countries and linking such capability levels to a 'menu' of interpretative options arising from a close examination of the flexibilities of the relevant section of the TRIPS Agreement in order to achieve optimal outcomes.

We started this project with great ambition. We wanted to lay out the full range of patent subject matter options available to developing countries and give some general impressions as to the policy-related implications of selecting one particular option over another (e.g. a broad or narrow interpretation of 'micro-organism'). We hoped also to be able to develop a reliable ranking of developing countries according to their relative capacities in biotechnology. Having fulfilled these two tasks we intended to link these relative capacities to the interpretive options so as to generate optimal biotech patent regimes for each country.

In practice this proved to be extremely difficult. The biggest challenge we faced was to find a way to objectively assess the biotechnological capacities of individual countries and then to use such an assessment to rank countries from lowest capacity at the bottom to highest capacity at the top. Unfortunately, we discovered that all of the indices devised and used so far are flawed. Therefore we adopted a more qualitative approach which sought to identify and draw inferences from general indicators of current capacity and future potential. We selected three countries which are considered to be relatively advanced, and one that is perhaps the most advanced of all developing countries in terms of biotech capacity and growth potential (India). We reckoned that if these countries have very limited capacity to innovate at the present time, then most of the developing world has minimal if any capacity at all. And this in turn suggests that they will gain little from a biotech-friendly patent regime and may

lose out overall in terms, for example, of having to pay out royalties and licensing fees that may be unaffordable. Consequently, the policy options for most developing countries as far as implementing Article 27.3(b) goes are quite simple: keep your subject matter inclusions narrow as possible and your exclusions as wide as possible. But for the most advanced developing countries, this may not be the most sensible option. While it is highly unlikely for these countries too that a US-style include everything and exclude nothing model would be at all helpful, a more nuanced calculation of where the lines should be drawn between patentable and unpatentable subject matters ought to be made. Again, this study should provide some guidance on how to do this.

National policymakers in developing countries reading this report should ask themselves if their country's biotech capacity is on the level of South Africa or Kenya, or below these countries. In such case, the TRIPS de minimis approach (what we call the "all exceptions option") should probably be followed. Countries which have a capacity similar to that of India should study the "some exceptions option" and then figure out how best to put that option into effect.

After a brief introduction, the report explains what we mean by biotechnology, discusses some of its commercial applications and explains why the relationship between patents and technological development, especially biotechnology, is very complex, very controversial and extremely important (Chapter 2). The following section (Chapter 3) explores and critiques the effectiveness of current methodologies available to form the basis for a ranking scheme for developing countries on relative biotechnological capacities that could offer pointers to the design of an optimal biotech patent regime. These are all highly limited if not flawed and so we present some plausible "rules of thumb" to be used as assumptions to make up for the deficiencies of these indices. We then continue with the three national case studies, which together reveal the severe lack of capacity of even the more advanced of the developing countries (Chapters 4-6). Chapter 7 comprises a detailed analysis of the language of Article 27.3(b) of TRIPS. On the basis of this analysis, Chapter 8 first casts doubt upon two matters: (i) that we yet have the tools to rank developing countries accurately; and (ii) that any more than a handful of developing countries has the ability to take advantage of patents to build up their biotech industries. More positively, though, it goes on to present the interpretative menu and discuss its applicability. We also offer some reflections on how patent policy making is conducted and ought to be conducted.

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1. INTRODUCTION

The overall aim of this study is to provide reliable guidance on how to design patent rules that are optimal in terms of enabling developing countries to participate in the 'biotechnology revolution' and to thereby benefit their economies and populaces. Since most countries of the world are members of the World Trade Organization, the starting point of the study is the WTO's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), which all members must comply with. According to Article 27.1, 'patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.'

Since biotechnology is obviously a field of technology, it is not possible to keep biotechnology out of the patent system altogether, whether or not to do so would be deemed as desirable. Nonetheless, it is important to understand that biotechnology is covered in the context of *exclusions* from patentability. Thus, Article 27.3(b) permits WTO Members to exclude from patentability:

> plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

The problem is that many countries are unclear about how to tailor their patent regulations to promote their interests in the acquisition, development and application of biotechnology, and therefore how best to exploit these flexibilities.

In essence, two types of flexibility exist in Article 27.3(b). These are (i) the optional subject matter exceptions, and (ii) the possibility to define the terms in a variety of ways. Clearly, the language of this provision is complicated. But it is also subject to a wide range of interpretations, a situation that allows policymakers to implement TRIPS in a very large number of possible ways.

The challenges that subsequently arise are threefold. The first challenge is to identify all possible ways that Article 27.3(b) can be interpreted. The second is to identify the goals that governments wish to use their biotech-related patent rules to further. This must surely be based upon assessments of present biotech capacity of the country in question and of its future potential. The third is for government policymakers on the basis of such an assessment, and a decision on the goals it wishes to pursue, to select from our 'interpretational menu', as presented in our final chapter, the optimal patent rules available under Article 27.3(b).

There is little doubt that countries will meet these challenges in a variety of ways. This should not surprise us. Developing countries, least developing countries and the former socialist nations together represent an enormous diversity in terms of socio-economic conditions, levels of development, and potential. Consequently, accommodation of such diversity had to be built into the study.

A few clarifications and disclaimers are in order. First, patents are one among several legal and policy measures to promote local innovation and technology transfer and may not be the most important.

Second, patent subject matter scope decision are not the only way to balance interests of all stakeholders and secure the best interests of the public. Patent systems should strike a balance so that the economic rights of inventors are sufficient to encourage invention, innovation and the dissemination of useful technical information, but not so excessive as to unduly hinder competition, stifle follow-on invention, or harm the public. Various measures are available to ensure that this balance is struck as optimally as possible. These may include:

1) Subject matter exceptions, such as those that may be applied to drugs, software programs, business methods, plants and animals, whether or not the standard patentability criteria can be met
2) Limitations to rights, such as compulsory licensing, government use provisions, research exemption and the 'bolar' (regulatory review) exemption
3) The patent examination, which is supposed to ensure that what is disclosed is enabling, and what is claimed does not extend beyond what is disclosed
4) Local working requirements
5) Pre- and post-grant opposition procedures
6) Morality/ ordre public objections
7) Competition law

This study only deals with the first of these. This might seem to make the study rather limited in terms of what it can achieve. However, biotech patenting subject matter flexibility is extremely broad in TRIPS and since implementation of this part of TRIPS continues to be under review at the TRIPS Council, producing evidence based policy guidance as to how developing countries may take advantage of the flexibilities is both necessary and timely, if not long overdue.

One might add here that the existence, quality and size of the wider legal infrastructure, including patent practitioners, trained examiners, and well functioning courts is essential to make any patent system work. A balanced patent system in theory cannot become an optimal patent system in practice without these. But dealing with this issue falls beyond the scope of the study.

Third, this study takes no position on specific biotechnological applications that some might endorse while others would deem them to be dangerous, immoral or otherwise inappropriate. Neither does it insist that countries should prioritise biotechnology-related research and development over other fields of technology or industrial sectors. But we do accept that biotechnology has lots of potential and ought to be promoted, and that in any case WTO members are required to make patents available for at least some biotechnological inventions. Nonetheless, we do not take it as axiomatic that what is good for the biotechnology industry is good for the public.

This study provides some useful guidelines on how to design optimal patent regimes for biotechnology within the confines of what TRIPS allows. That is about as far as we are able to go. But at the very least, our research shows how complicated it is to achieve efficient patent regimes especially in new fields of technology, and highlights

the failure of policymaking generally to take into account the complexities. Another inference of the present study is that technical assistance providers and others claiming to be authorities on how to design biotech patent regimes sensitive to the specificities of individual countries should be urged to provide convincing objective evidence for their prescriptions.

2. BIOTECHNOLOGY, THE LIFE SCIENCE INDUSTRIES AND INTELLECTUAL PROPERTY

What is biotechnology?

Biotechnologies are not only new and cutting-edge but also very old. This becomes evident if, as some experts do, one divides biotechnologies into three generations. The first generation includes traditional technologies like beer brewing and bread making, which goes back thousands of years, and the second begins with the microbiological applications developed by Louis Pasteur 'based on the germ theory of disease' culminating in the mass production by fermentation of the antibiotics. Tissue culture and modern plant and animal breeding also fall within this 'generation'. The third generation biotechnologies, or 'the new biotechnologies', includes the various genetic engineering techniques for transferring DNA from one life form to another to make transgenic organisms expressing new and useful traits. The first such technique, known as recombinant DNA ('rDNA'), was invented in 1973 by Stanley Cohen at Stanford University and Herbert Boyer at University of California at San Francisco (UCSF), and patented by the former university. The technique enabled foreign genes to be inserted into microorganisms and passed on to others through cell division. Since then other genetic engineering techniques have been invented. This latest generation also includes hybridoma technology,[1] polymerase chain reaction (PCR)[2] and cloning. The present studies deal mainly with the second and third generations, especially the latter.

The 1980 US Supreme Court decision in Diamond versus Chakrabarty, famous as a landmark decision for the patenting of life forms, claimed an engineered bacteria that was capable of breaking down oil products, and thereby clear up oil spills.

The first commercial breakthroughs in biotechnology were seen in the pharmaceutical industry with products such as human insulin, growth hormone (GH) and erythropoietin (EPO). These were synthesised by bacteria that included human genes. These products avoided problems encountered with the previous forms of the drugs, such as incompatibility in the case of insulin because of impurities that resulted from the method of extraction as it was gathered from pigs, viral infection in the case of GH, or the extremely low amount of production for EPO.

From its beginnings in the use of micro-organisms as a factory for the production of compounds of interest, modern biotechnology evolved toward the use of life forms as such with enhanced capabilities. Breakthroughs such as the discovery of *Bacterium tumefasciens* allowed biotechnology to affect much bigger organisms, plants in that case.

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[1] Hybridoma cells result from the fusion of a type of cancer cell known as a myeloma with another antibody-producing cell. Hybridomas produce multiple antibodies of a highly specific type, which are called monoclonal antibodies. The technology, which was developed in 1975 by Georges Köhler and Cesar Milstein, working in Cambridge at the Medical Research Council's Laboratory of Molecular Biology, has considerable potential in both diagnostics and therapeutics.

[2] PCR technology provides a means rapidly to replicate potentially vast quantities of a selected DNA section in a test tube. PCR is an extremely valuable research tool with many applications including genome sequencing and diagnostics.

In the biomedical industry, the use of biotechnology can be seen at various levels. Apart from insulin, GH and EPO, engineered bacteria are being used for the synthesis of safer compounds, later used as drugs. Animals are currently especially valuable in the creation of models for the analysis of disease.

Based on the current definition of biotechnology, which is genetic engineering, there are two main distinctions: the resource or gene construct of interest to be inserted and the technology capable of inserting such gene or set of genes toward the realization of the objectives.

The identification of genes of interest requires prospecting and access to resources; how extensive this has to be is dependant on the objective of the activity. The identification as such of the source of the trait of interest, the gene, will require a certain know-how and technological capacity. Once one is in possession of the gene, then the mechanisms of insertion will also de different depending on the subject matter.

While it is a common practice nowadays to insert genes into bacteria toward the realisation of one's objective, the complexity of macro-organisms makes the feasibility of attaining the predicted effect more complicated. Hence it might necessitate an even higher level of expertise and know-how, again associated with further technological capacities. Finally, once the objectives are realised, the specificities of the output will be at stake, opposing processes with products. In the case of insulin, GH, cheese, soy sauce, it is the product that holds value, but its enhanced features cannot be reproduced as such from the product. It is the process that constitutes the limiting factor. Hence the control or property will generally be enjoyed at the level of the process.

In the case of genetically modified organisms such as the oncomouse, Bt cotton, golden rice, while the process is itself complex but capable of being reproduced, it is the product that becomes problematic. The final outcome, being a living organism, is capable of duplication. Also, the duplication can be achieved at very low costs and without any specific technological advances. Indeed, general farming practice for the reproduction of plants or animals could be sufficient. It has to be noted that the enhanced features of those organisms might not be passed toward the offspring with the same efficiency; this will be dependant on the organism in question. Wheat, soy, green beans, tomatoes, for example, are considered as fixed varieties with pure lineage with the consequence that they tend to reproduce identically to themselves, and are therefore easy to reproduce identically within normal farming capacities. While the control will still occur at the stage of the process, which is already limiting because of the technological requirements, it will also be at stake at the finality of the product, being more easily reproduced. A response from the industry against the latter problem was the development of the infamous terminator gene that provided a technological restriction against the plant duplication in traditional farming methods.

Overall, most government funding and commercial activity relating to the new biotechnologies has been in the area of health. Health biotechnology is not only used to develop new types of drug but also in diagnostics and to enhance the efficiency of the drug discovery process. In fact, the latter has become the main objective of health biotechnology research. The types of product being developed include so-called

'biopharmaceuticals' such as genetically-engineered therapeutic proteins and vaccines. Other common types of product are diagnostic kits for diseases linked to genetic defects.

Comparatively speaking, agricultural biotechnology is a much smaller field in the United States and Europe though it is a high priority for some developing countries, such as India and Kenya, which are heavily dependent on the viability of agricultural sectors for food security and employment, and in many cases, foreign exchange and political stability. Much of the research done so far has been geared towards the development of new seed products with introduced traits providing mainly agronomic benefits such as disease resistance, pest resistance and herbicide tolerance, and also to extend shelf-life of harvested produce. Little of the research has been directed so far at improving output quality for the benefit of consumers, although this situation is beginning to change. Unlike the healthcare case, there are relatively few agricultural dedicated biotechnology firms, even in the USA.

In the livestock industry, the development of transgenic animals is occurring as well. But the applications are still very limited. While the technology should be sufficient, it is mostly a matter of consumer perception. Where the development and commercialization of transgenic plants induced fierce public debate and actions against such crop and practice at large, it follows that the issue will be even more problematic if addressed over livestock, which are viewed as closer to mankind.

The food processing industry is also quite acquainted with biotechnology. A great part of the processed food results from the interaction of raw material with micro-organisms (cheese, yoghurt, soy sauce, beer, and so on…). Hence, innovation occurs nowadays by improving the characteristics of those micro-organisms towards certain industrial objective such as the optimization of production or increase in quality of the processed product.

Healthcare products tend to be most commercially attractive. This is because they have potentially much higher returns, and because demand tends to be much less cyclical. Most of the remaining biotechnology companies provide industrial or environmental products and services such as industrial enzymes and pollution diagnostics.

In terms of future trends and opportunities, it is likely that sequencing and analysing human, animal, plant and microbial genomes and proteomes will take less and less time and money, suggesting ever-lowering barriers to entry. This increases the possibility that a few developing countries like India, China and Brazil will become major sources of innovations in this field in the coming years.

What is the biotechnology industry, and what does it do?

The 'biotechnology industry' is not a discrete industrial sector. Rather, there are firms that do nothing but biotechnology, and other companies, universities and public research institutes that conduct biotechnological work but do not specialize in it. The new biotechnology and genomics revolutions have created completely new commercial opportunities, and spawned four types of business. These are (i) the technology providers who manufacture the DNA sequencing machines and other

equipment; (ii) the information providers that collect and organize sequencing information; (iii) the research firms, consisting mainly of the firms that generally do the upstream research but lack the resources or the ambition to do the downstream product development and marketing; and (iv) the health, agricultural and industrial biotechnology firms. These include the larger vertically integrated firms, and much longer established businesses, which are mostly pharmaceutical, chemical and life science corporations. These business types are not necessarily discrete. For example, Millennium Pharmaceuticals and Human Genome Sciences are also involved in drug discovery and development.

To date much if not most of the basic research in biotechnology and genomics has been financed and conducted by governments, universities and private foundations. But private sector investment has increased in recent years, especially in the United States where commercial biotechnology really began. There are various reasons why the US has dominated from the start. Two important ones are the considerable amount of related state-funded basic research that had already been conducted by the universities and government agencies, and the large quantities of venture capital funds that are available to start up companies with a promising business plan.

While the US system has been relatively effective at turning new discoveries made by public sector and university researchers into commercial products, Europe and Japan have been less successful in putting together the downstream linkages from fundraising for basic research all the way to commercialisation. However, since the 1980s the European Community countries and Japan have been preoccupied with catching up with the US. Both the European Commission and the EU member governments have sought to stimulate biotechnology R&D through industrial policy and more business-friendly product and IPR regulation. So far they have been only partly successful, raising the question of whether developing countries can succeed no matter how carefully their IPR systems are designed.

As for developing countries, quite of lot of our observations concerning innovation, investment motivations, business strategy and the role of intellectual property may not apply much if at all to them. All the more reason to conduct research on how best they should promote innovation taking into account these countries' intellectual property obligations under international law.

Patents, biotechnology and development: a crucial debate

Article 27.3(b) has become an enduring subject for trade negotiations and NGO activism on TRIPS. Undoubtedly, this part of TRIPS is extremely important for developing countries. What is less clear is how they can take advantage of its provisions to further their sustainable development objectives. The situation is not helped by disagreement on what the paragraph actually means. In addition, many developing countries find themselves in circumstances that make it difficult to plan for the future and therefore to tailor their policies to specific development goals. So it is hardly surprising that they are unsure about where their national interests lie with respect to the paragraph's provisions.

While TRIPS does not allow WTO members to exclude biotechnological inventions from their patent systems in any explicit sense, Article 27.3(b) allows them to use

their discretion in determining the extent to which inventions in this technological field can be protected. The problem facing developing countries is that if they lack a clear idea of how biotechnology can benefit their economies and improve the lives of their citizens, they are in no position to design an IPR system to promote welfare-enhancing biotechnological innovation. Moreover, many of these countries have no biotechnology industries to speak of, and there is every reason to be highly sceptical that such businesses will spring up just because life-forms and micro- and non-biological processes can be patented.

Another reason why it is difficult for developing countries to come up with a common position on the review of Article 27.3(b) is that they vary so much in their national capacities to generate or apply biotechnological inventions. Policy makers in the more technologically-advanced developing countries who believe that the new biotechnologies can be beneficial should design their IPR system with the goal of encouraging domestic innovation and technology transfer, and attracting funds for start-up firms. The experience of developed countries suggests that a carefully-designed IPR system could indeed stimulate innovation, although there is a real danger of a carelessly-designed one turning out to be worse than not having one at all, for example, by over-protecting upstream research and thereby inhibiting more applied downstream research, or by allowing large companies to control markets, raise prices, and distort research priorities. But for many, if not most other, developing and least-developed countries, it is difficult to see how strong IPR protection will encourage innovation if the capacity to do the necessary research is barely existent anyway. But how much empirical evidence do policymakers have on which to base their decisions? Not enough.

Previous studies have linked the importance of IPRs, especially patents, to levels of development, and addressed the question of what conditions in a specific country or industrial sector are necessary to ensure that IPRs foster, rather than inhibit, domestic innovation (including 'creative imitation') and technology transfer. One inference is that it is only after countries have accumulated indigenous capabilities with extensive science and technology infrastructure to undertake creative imitation that IPR protection becomes an important element in innovation and technology transfer. However, few studies have focused specifically on biotechnology, and even fewer have linked biotechnological capabilities to implementation of TRIPS. This study fills this gap by focusing on biotechnology capabilities in different countries.

Debate concerning implementation of Article 27.3(b) is part of a much wider controversy concerning biotechnology patenting. Critical literature has focused on a number of aspects. Perhaps the following five are the most significant. The first is the moral significance of assigning property rights over life forms and their parts. The second is the way that such patents are considered to challenge the basic criteria for patents. The third is the concern that basic research may be discouraged by the patenting of molecular biology research tools. The fourth is the concern that such patents promote 'biopiracy'. The fifth is that patents on plants and plant breeders' rights can or at least may infringe the basic right of farmers to save and exchange harvested seed. These are all important issues that need to be taken very seriously,

though they have been reviewed at some length already.[3] Instead, this part of the report reviews the debate on the relationship between patents, both generally and in the specific field of biotechnology, and innovation, technology transfer and development, while taking into account the specific characteristics of the biotechnology business.

Patents are supposed to enable creativity and innovation to develop in an optimum manner. By providing an incentive to invent and to disclose invention, patents help to make R&D and the marketing of research outputs into commercially viable activities. Arguably, this function is workable at any stage of economic development. Hence, it is sometimes claimed that patents will promote innovation in developing countries, first by ensuring that there is a proper system in those countries to nurture their own innovative development, but also, by securing foreign investment as well as transfer of technology from other countries.[4]

On the other hand, even if we accept that patents help ensure a sustainable stream of innovation, in addressing the interest of developing countries with respect to foreign technology it could also be argued that the development of an innovative system starts with copying. Freedom to imitate in a non wealthy environment, it is argued, should ensure the rapid diffusion and uptake of foreign technology or information. Under that assumption, strong patents may be counter effective. Then large scale creativity as such might first be experienced under creative imitation that soon will turn to proper innovation, which supposedly is sustained thanks to patents. The proper growth of a country in term of its technology might require patent regimes to adapt consequently.

Plausible as that may seem, copying may not always result in full access to the technology. Indeed, according to the nature of the technology, transfer often requires the active participation of its owner. To protect the accessed information might then be a prerequisite for effective transfer of technology. In addition, the specificities of each technology make the association between patents and innovation even less predictable. Biotechnology includes a complex set of industries and implications, and both arguments could hold. Because of the complexity of the technology, its transfer will frequently require the cooperation of the holder of the technology, at least if one is considering capacity building and technology transfer. On the contrary, its output might be easily copied, as an example transgenic seeds can be reproduced through basic agricultural methods. Hence, copying might ensure that the agriculture of those countries takes advantage of the advance of developed countries without bearing the costs. Also, it will avoid control from developed country on the agriculture of developing country, which can be seen as a matter of food security. On the opposite, the development of plants of interest that suits the country natural conditions might need the developer to specifically invest for such country; cost that he will not bear if his investment is not protected within the recipient country.

As with other science-based sectors, the road leading from basic research to product development is long, winding, and has many branches, some of which may be short cuts but are mostly dead ends. It is also very expensive to use, especially as journey's

[3] See Dutfield, G. (2004) *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, London: Earthscan.

[4] Park, W.G. & D. Lippoldt (2005) *International Licensing and the Strengthening of Intellectual Property Rights in Developing Countries during the 1990s*, OECD.

end approaches. And the companies best equipped to carry a product to the end of the road are not necessarily the most competent to start the journey, just as the front runners are often ill-equipped to complete the course.

This situation provides both obstacles and opportunities for business. For new start-up firms it is hugely difficult to transform themselves into biopharmaceutical corporations. The opportunities lie in the fact that as the big firms concentrate on their core competences they outsource more and more tasks that may be essential elements of the research and development (R&D) process. Therefore niches are created that new small and medium-sized science-based firms can occupy profitably.

Arguably, biotechnology patents encourage such a diversification of business activity by stimulating the foundation of small but highly-innovative firms and then by helping them to survive and remain independent. It has always been crucial to have access to large amounts of investment capital just to stay in business. Patent portfolios are the main magnet for outside investors – which also include larger science-based firms – and the larger the portfolio, the greater the interest from investors. In common with other industries, patents also become a form of currency in inter-firm transactions. It is sometimes claimed that research decisions in many companies can depend as much, if not more, on the advice of patent lawyers as the opinions of the scientists. Naturally, companies have a strong interest in securing patents that encompass the broadest possible scope and whose claims are drawn in ways that seek to anticipate future scientific developments.

But there is a danger in the increasing dis-integration of the genomics innovation chain. For new firms that provide genetic information to the drug development firms, what they sell are to them final products but to their customers further down the chain are mere research tools. In order to protect these 'products' – and to secure funding to produce further ones – the firms have a strong incentive to privatize their information through IPRs. But since the development of future commercial products such as therapeutic proteins or genetic diagnostic tests often requires the use of multiple research tools such as gene fragments, an increasing number of which are being patented, companies intending to develop such products will need to acquire licences from other patent holders. In doing so, they will incur large (and possibly prohibitive) transaction costs. To return to the road metaphor, the danger is that more and more tollgates will be installed making the journey ever more expensive and excluding more and more potential travellers. So not only is the product development race becoming a relay race with more and more runners, but each runner is being forced to pay for the privilege of receiving the baton from the previous runner. The question is, will this slow down innovation and lead to fewer products on the market than would otherwise be available? And if so, how should the regulation of innovation through intellectual property protection be re-contoured in response? And what about developing countries?

It is often observed that developing countries tend to be rich in biodiversity but poor in biotechnology. That is a gross simplification though in many cases it contains more than just a grain of truth. In that light, it can be argued that for many developing countries, the challenge facing them is to improve their life-science R&D and production capacities so as to take better advantage of the resources at their disposal.

The second is to identify, develop and mark high-value primary and semi-processed products.

A static understanding of the principle of comparative advantage might lead us to suppose that while option 2 is feasible, biodiversity-rich developing countries need not consider attempting option 1, and have little alternative other than to export raw biological material. This generalisation is quite sweeping, and is unlikely to be true for those developing countries that are relatively advanced in science, technology and industrial development. Nonetheless, one must be cognisant of the very real obstacles to following option 1, especially the huge investments in training, education, and advanced R&D facilities that would be required.

Encouraging the three 'bios': biotrade, bioinnovation and biotechnology transfer

Enhancing the scientific and technological bases of developing countries requires appropriate regulatory and legal frameworks providing rewards and incentives for innovation and investment. The task for developing countries is, one can argue, to follow successful former developing countries like Japan and South Korea by transforming their comparative advantage from producing low-value commodities to high-value goods and services while increasing employment possibilities for the poor and not just for the well educated.

While science-based research-intensive industries and technologies like pharmaceuticals and the new biotechnologies are extremely important, competitive high value-added products can of course be developed without cutting-edge scientific knowledge and equipment. High-value products may succeed in the market based on knowledge acquired from such sources as traditional communities. Products will command high prices in international markets only if they are knowledge-intensive, but this does not by definition require them to be science-based, high-tech, R&D intensive. In fact, various kinds of knowledge must be acquired and used for *any* product to succeed in the increasingly competitive global economy. According to Mytelka and Tesfachew, these kinds of knowledge include: (i) product design; (ii) process engineering; (iii) quality control; (iv) management and maintenance routines; (v) knowledge about markets and investment opportunities; and (vi) skills and capabilities needed to undertake changes in products and processes, create networks, and sustain partnering activity.[5]

Innovation as understood in this broad sense is essential for countries seeking to produce high value-added manufactured goods and commodities rather than low-value raw materials. Innovation connotes newness but it is possible to argue that an innovation for one company or national economy may not necessarily be innovative to another. Indeed, promoting innovation in developing countries also means facilitating the acquisition, dissemination, and (where necessary) adaptation of knowledge and technologies from elsewhere. Local innovation and technology transfer, thus, are inextricably linked.

[5] Mytelka, L K and Tesfachew, T (1998) *The Role of Policy in Promoting Enterprise Learning During Early Industrialization: Lessons for African Countries*, UNCTAD, Geneva, 2.

Although innovation takes place in all parts of the world, developing countries tend to be net importers of modern technologies. Consequently, for several decades, technology transfer has been a major priority for these countries. Industrial technologies are conventionally transferred through such formalised means as foreign direct investment (FDI), joint ventures and licensing, of which FDI is the main channel.[6]

According to Roffe, formal private-sector[7] technology transfer 'is a commercial operation that takes place through firm-to-firm arrangements and involves flows of knowledge, be they embodied in goods (as in the sale of machinery and equipment) or in the form of ideas, technical information and skills (through licensing, franchising or distribution agreements). Technology transfer can take place at arm's length, as in the case of the export of capital equipment or of licensing agreements between unaffiliated firms, or it can be internalized through the transfer of new production techniques within a transnational corporation, between affiliate firms'.[8] In fact, a great deal of formal international 'technology transfer' takes place within the same companies.

Informal technology transfers can also take place on a large scale and in those countries in the early stages of industrialisation these may be far greater in number than formal ones. By definition, informal transfers are not based on any monetary transactions or legal agreements.

The relationship between levels of IPR protection and the volume and direction of inward technology flows is highly complex. According to Maskus,[9] in countries with strong IPR protection and enforcement, transnational corporations are likely to favour technology licensing agreements and joint ventures. In countries with weak IPRs, FDI would be the favoured business strategy in overseas markets.[10] But technology flows are nonetheless likely to involve a great many factors whose relative importance will vary widely from one country to another.

What is the empirical evidence concerning the links between stronger IPRs, investment flows, R&D and technology transfers? In fact, the data produced so far are hardly conclusive and suggests that FDI decisions may depend on a host of factors including the general investment climate. A study by Maskus[11] claimed some evidence of a positive correlation, while conceding that IPRs are one of several

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[6] Radosevic, S. (1999) *International Technology Transfer and Catch-up in Economic Development*, Edward Elgar, Cheltenham, at 28.

[7] Governments are also involved in technology transfer. Informal and free-of-charge technology transfers are also possible.

[8] Roffe, P. (1999) 'Transfer of technology and competition policy in the context of a possible'. In: Picciotto, S. and Mayne, R. (eds), *Regulating International Business: Beyond Liberalization*, Macmillan Press, Basingstoke, pp 142-160, at 151.

[9] Maskus, K. (2000) *Intellectual Property Rights in the Global Economy*, Institute for International Economics, Washington DC, at 123.

[10] Similarly, Vishwarao suggests the possibility that gains for a developing country from lack of IPR protection would be 'offset by strategic behavior by Northern firms who opt for technology transfer via subsidiary or monopoly production'. Vishwarao, S. (1994) 'Intellectual property rights and the mode of technology transfer'. *Journal of Development Economics*, 44, pp 381-402, at 381.

[11] Maskus, K.E. (1998) 'The role of intellectual property rights in encouraging foreign direct investment and technology transfer'. *Duke Journal of Comparative and International Law*, 9(1), pp 109-161.

factors that may facilitate technology transfers, and also that strengthening IPRs will involve unavoidable costs (in terms of legislation, administration and enforcement) as well as benefits for developing countries.[12] A World Bank study was even more cautious and recommended further research before firm conclusions could be made.[13]

Research by Kim on the experience of South Korea suggests that 'strong IPR protection will hinder rather than facilitate technology transfer to and indigenous learning activities in the early stage of industrialisation when learning takes place through reverse engineering and duplicative imitation of mature foreign products'.[14] He also concludes that 'only after countries have accumulated sufficient indigenous capabilities with extensive science and technology infrastructure to undertake creative imitation in the later stage that IPR protection becomes an important element in technology transfer and industrial activities'.

Finally, while it is the private sector that will be most involved in external trade, governments have a vital role to play in capacity building and in creating a conducive institutional-regulatory environment to promote innovation from basic research to commercialisation, of which the patent regime is an important part.

[12] Finger, J.M. & P. Schuler (1999) 'Implementation of Uruguay Round commitments: the development challenge'. Presented at the WTO/World Bank Conference on Developing Countries in a Millennium Round, WTO Secretariat, 20-21 September, Geneva; United Nations Conference on Trade and Development (1996) *The TRIPS Agreement and Developing Countries*, United Nations, New York and Geneva.

[13] Primo Braga, C.A. & C. Fink (1999) 'International transactions in intellectual property and developing countries'. Mimeo.

[14] Kim, L. (2002) 'The protection of intellectual property rights and technology transfer: a developing country view'. Case Study for the ICTSD-UNCTAD Capacity Building Project on IPRs and Sustainable Development, Geneva, at 5.

3. DETERMINING THE BIOTECHNOLOGICAL CAPACITIES AND PATENT INTERESTS OF COUNTRIES: SOME METHODS AND ASSUMPTIONS

Undoubtedly, developing countries vary considerably according to the capacity of their research institutions and businesses to put the new biotechnologies to work and generate innovations of their own. Bhagavan[15] divides developing countries according to their science and technology (S&T) capacities. Thus, these countries are members either of the 'strong', 'medium' or 'weak' South. The Strong South includes such countries as Brazil, China, India and Mexico, which are moving into high-technology fields such as the third-generation biotechnologies. The Medium South includes Indonesia, Malaysia and Argentina, while the Weak South consists of most other countries which are as technologically dependent on the developed countries as they were before decolonization. Several developing countries, including India, China, Brazil and Cuba, have the capacity to use third generation biotechnologies. However, the overwhelming bulk of biotechnology applications even in these countries is of the earlier generations such as fermentation and tissue culture.

Measuring biotechnology capabilities is important for a variety of reasons; for the purposes of the present study, two of these stand out: first, it is undisputed that if developing countries are to prosper they must build the capacity to take advantage of new technologies such as biotechnology. Secondly, understanding what biotech capabilities exist in a given country will be instructive in designing appropriate systems and institutions that bolster domestic innovation and encourage technology transfer. These twin reasons form the foundation for this enquiry. Of course, to determine the biotechnological capacities, one needs to select workable criteria and indicators.

One can envisage a potentially useful schema for different developing countries which builds on the work of economists Sanjaya Lall and Linsu Kim. Such a schema could be based on (i) indicators of biotechnological activity derived inter alia from levels of research and development financed by productive enterprises and patenting activity, (ii) industrial performance, (iii) absorptive and innovation capacities, (iv) and biotechnology product, service and royalty and license fee trade balances. But this section of the report casts a sceptical light on the quantitative methods that such a schema would largely be based upon.

Defining terms

Innovation systems literature is at pains to distinguish innovation from inventiveness. According to Hall[16], the efficient application of knowledge is the departure point. Innovation is the application of knowledge to achieve a desired outcome whereas innovativeness is the ability to create novel things, irrespective of whether they are used or not. Bell and Pavitt[17] distinguish research capacity from technological

[15] Bhagavan, M.R. (1997) 'Introduction'. In: Bhagavan, M.R. (ed) *New Generic Technologies in Developing Countries*, Basingstoke: Macmillan Press, Basingstoke, pp 1-21, at 3-4.

[16] Hall, A. (2005) 'Capacity development for agricultural biotechnology in developing countries: an innovation systems view of what it is and how to develop it', *Journal of International Development,* 17, 611-630

[17] Bell, M. and K. Pavitt (1993) 'Technological accumulation and industrial growth: contrasts between developed and developing countries'. *Industrial and Corporate Change,* 2/1, 157-210.

capacity in that the former concerns the resources needed to conduct scientific research while the latter concerns those needed to manage technical change. This includes skills, knowledge and experience, institutional structures and linkages between various disciplines, organisations, enterprises and policy and regulatory bodies.

Being concerned with factors that encourage domestic innovation, this WP necessarily enquires into the larger technological capacity rather than research capacity.

Quantitative methods of measuring biotech capabilities

Scholars and economists alike have over time proposed various methods of measuring technological capacity in countries. This section examines some of the proffered methods primarily to explore if any of the methods suit the purposes of the present study. This exercise is by no means meant to be exhaustive but rather indicative of the various perspectives technological capacity can be viewed from and the inherent difficulties in adopting particular methods.

Patents

Perhaps the most often cited method of measuring technological capacity in both developing and developed countries is the use of patents. In virtually all the composite indices discussed below, patenting forms an integral part in developing each index. Although patents may seem like the most straightforward and obvious indicators of technological capacity, their use is rife with complexity and difficulty. A study conducted in 2000 by Thompson on rankings of the most innovative companies by patent filings highlighted the difficulties in using patents as a measure of technological capacity. Foremost, is the question of what patent database to use. The study accentuated that different results are obtainable depending on the patenting authority used.[18] The difficulty in applying patent statistics to rank companies is indicative of the more arduous task when the subject sample shifts from relatively straightforward organisations such as companies to countries; the problem is further compounded when comparing countries especially if they happen to be in different stages of development.

Although the temptation to use domestic statistics when comparing patenting activity in countries may exist, the caution is that lack of homogeneity among different national patent legislation, procedures and practice will render results inaccurate. Use of an international patent system is generally considered more consistent over time and location.[19] Some studies have used both national and international patent systems in comparative innovative capacity studies.[20] The choice of international patent

[18] See Thomson (2000) 'Rankings of the most innovative companies by patent filings'. IBM was the top company when statistics from USPTO were used, while it did not feature when PCT and JPO were used where Siemens and Toshiba were top respectively. Siemens was top company according to EPO statistics while IBM was 9th and Toshiba did not feature in the top ten.

[19] Earlier work comparing inventive activity using international systems include Dosi, G., K. Pavitt & L. Soete (1990) *The Economics of Technical Change and International Trade*. New York: New York University. See also Eaton, J. & S. Kortum (1996) 'Trade in ideas: patenting and productivity in the OECD'. *Journal of International Economics,* 40(3-4) 251-278

[20] See for example, Porter, M. & S. Stern (2000) 'National innovative capacity'.

system brings us back to the initial problem. The use of a single international patent system assumes that firstly, the system is equally accessible to all the target study countries; secondly, that fees and procedures affect everyone equally and thirdly that the target countries are equally keen to use the selected international patent system.

The USPTO's patent statistics have been used in many studies to measure foreign countries' technological capacity.[21] For Porter and Stern, the justification is that the use of USPTO is a sign of innovations' potential economic value given the high costs of patenting as well as providing a high standard of technical excellence. The downside of using the USPTO (especially for this WP whose target nations are developing countries) is that foreign individual investors and small firms are less likely to patent abroad especially in the US.

The WIPO administered Patent Cooperation Treaty (PCT) system is more suitable when comparing developing countries' technological capacity. The EPO is also a candidate but given that many applications passing through the latter are initially made through the former, using the PCT system seems easier to use for comparisons among developing countries. The assumption is that of all the international patent systems, individuals, small firms and companies in developing countries are most likely to apply for patents through the PCT system not in the least because it is accessible in terms of both costs and procedure. The downside is that the system is only available to PCT members. In our case, all the study countries are PCT members therefore this does not present a problem as such. It has also been said of the PCT system that it is biased towards high technology industries; being concerned with biotechnology, this is not a problem for the purpose of this study. Another drawback of the PCT system is that many applications may not be new as the assessment of novelty is only made at the grant stage (although you have since 2004 the IPER, International Preliminary Examination Report). This presents the related problem of whether the statistics to use are the number of patent applications or the number of patents granted in which case using the PCT system would be irrelevant given that the PCT system does not grant patents as such. Related to this and to the use of patent statistics generally is that not all inventions are patented and some forms of creativity particularly in developing countries are not patented.[22] Further, some patents are considered more valuable and important than others leading studies such as Bosworth, Filiou and Longland[23] into developing weightings to rank inventions.

Another approach is that of the triadic patent family. This entails the counting of those groups of patents on the same invention that are granted by three patent-granting offices, usually the US PTO, the European Patent Office and the Japan Patent Office which are of course the most important ones. According to Chow et al: 'the triadic family concept aims to provide for an ever-increasing need for reliable patent statistics and high quality indicators in measuring the performance of the various

[21] See Pouris A. (1991) 'Identifying areas of strength in South African Technology'. *Scientometrics* 21(1) 23-35 for a study on South Africa; Bergeron, S. et al (1998) 'Location of innovating activities, industrial structure and techno-industrial clusters in the French economy, 1985-1990'. *Research Policy* April 1998 on France and more recently, Porter & Sern *supra.*

[22] See Jewkes, J. (1969) *The Sources of Invention*, 2 ed. Macmillan who gives various reasons why patent statistics are difficult to use. (p. 89-90)

[23] Bosworth, D. Filiou, and M. Longland (2003) 'Measuring the "Quality" of Patents', London: UK Patent Office.

nations on a comparable basis. The triadic family patent measurement is proposed on the basis that counting patents filed at different offices eliminates the problem of home bias and of ensuring that only high value added innovation should be the basis for comparison'.[24] After all, for businesses to go to the effort and expense of filing patent applications in all three offices on the same inventions, these must presumably be deemed as non-trivial inventions (to say the least).

It is clear from the foregoing discussion that relying on patent statistics alone as a measure of countries' technological capabilities is dangerous and would not yield any meaningful or accurate results. Primarily because of this, various complementary or alternative indices have been developed. Some of these are discussed below.

Composite indices[25]

Oslo Manual

The 1992 OSLO Manual was the first attempt by the OECD to harmonise methodologies for collecting standardised information on innovation activities in firms. The manual served as a basis for the first 'Community Innovation Surveys' (CIS) conducted in thirteen EU states in 1994 and has since been revised. The Oslo Manual measures R&D and patenting activities as well as non-R&D inputs and has been influential even in developing countries. However, discussions have been underway on how to adapt the Oslo Manual to the peculiar situation of developing country in order to take into account the largely informal setting for conducting innovation, the importance of incremental and organisational change and other features characterising innovation in developing countries.[26]

ArCo (Archibugi and Coco)

The ArCo Technology Index[27] takes into account three main dimensions of technological capabilities which are weighted evenly: the creation of technology (with the subsets of patents and scientific articles); diffusion of technology (subsets are internet penetration, telephone penetration and electricity consumption); and human skill (subsets are tertiary science and engineering enrolment, mean years of schooling and literacy rate). Besides the already covered problem of using USPTO statistics, ArCo uses Science Citation Index for an alternative source of codified knowledge. Article counts are based on the country authors are from. It is not clear if this is their nationality or country of residence. This distinction is important given the ease with which scholars and academics change their residence. It is especially paramount where nationals of developing countries work outside the continent and vice versa. ArCo does not use resources on R&D 'because the data in many developing countries are unsatisfactory' and does not fit within the definitions developed under the OECD

[24] Chow, K.B., K.M. Leo and S. Leong (2007) Singapore. In U. Suthersanen, G. Dutfield & K.B. Boey (2007) *Innovation without Patents: Harnessing the Creative Spirit in a Diverse World.* Cheltenham: Edward Elgar.

[25] The following brief analysis focuses on the choice of the components or sub indexes rather than the statistic analytical methods and formulas used. The latter is beyond the competence of the author and the scope of this paper.

[26] UNU-INTECH (2005) 'Measuring innovation: making innovation surveys work for developing countries'. *Technology Policy Briefs*, vol. 4/1

[27] See Archibugi, D. and A. Coco (2004) 'A New Indicator of Technological Capabilities for Developed and Developing Countries (Arco)', *Centre for International Studies on Economic Growth Research Paper Series,* 15/44 (January).

Frascati Manual.[28] There is no attempt to place this data in another subset; this information falls through the cracks.

The UNDP Technology Achievement Index
The main focus of UNDP TAI[29] is to capture how well a country is creating and diffusing technology. The study uses data relating to 72 countries although it stresses that it is not a ranking of 'technological might' of a country. The index is made up of four main components: (i) the creation of technology is measured by patents granted per capita[30] and receipts of royalty and licence fees from abroad per capita;[31] (ii) diffusion of recent innovations which comprises of internet hosts per capita and exports of high and medium technology products as a share of all exports; (iii) diffusion of old innovations which is made up of electricity consumption per capita and telephones per capita; and finally (iv) human skills assessed by mean years of schooling and gross enrolment ratio of tertiary students in science, mathematics and engineering. All the components have equal weighting.

The study acknowledges the lack of sufficient data but assumes that the lack of data on patents indicates that little innovation is occurring and consequently assigns a value of zero for missing indicators. In its formulation, TAI does not make provision for technologies and innovations occurring in the informal sector and in indigenous knowledge systems; it does however caution that this must be borne in mind when interpreting the values and rankings.

Others
The UNCTAD Innovation Capability Index focuses mainly on inputs – education and R&D. It has two main components: human capital index and technological activity index. The former is assessed by looking at (i) the literacy rate as a percentage of the population, (ii) secondary school enrolment as a percentage of age group and (iii) tertiary enrolment as a percentage of the age group. The technological activity index consists of (i) R&D personnel per million population (ii) US patents granted per million population and (iii) scientific publications per million population.

The UNIDO Competitive Industrial Performance Index focuses on manufacturing competitiveness. The index is made up of four main components: manufacturing value added (MVA) per capita, manufactured exports per capita, share of medium and high- tech activities in MVA and share of medium and high-tech products in manufactured exports. This index's main concern is technological capacity in industry and does not include other fields of technology.

The World Economic Forum's National Innovative Capacity Index focuses on the institutional and policy environment for innovation. It consists of five components: (i) share of scientists and engineers per capita (ii) innovation policy (iii) cluster innovation environment (iv) innovation linkages and (v) operations and strategy.

[28] Ibid., at 8.
[29] UNDP (2001) *Human Development Report*.
[30] The Patent Cooperation Treaty (PCT) is used.
[31] To reflect the stock of successful innovations of the past that are still useful and therefore with market value.

The World Bank Knowledge Economy Index has four main components: (i) the economic incentive and institutional regime which is assessed by tariff and non-tariff barriers, regulatory quality and rule of law; (ii) education and human resources which comprises of adult literacy rate, secondary enrolment rate and tertiary enrolment rate; (iii) innovation system made up of number of researchers in R&D, patent applications granted by USPTO and S&T journal articles and finally (iv) ICT infrastructure consisting of telephones, computers and internet users per 1000 population.

The Francisco Sagasti – S&T Capacity Index index consists of three main components: science, technology and production whose components are classified into internal capacity and external linkages. The science component has two sub indices: R&D expenditure as percentage of GDP and number of scientific publications. The technology component is made up of number of scientists and engineers per million people and number of patent applications by residents and non-residents while the production component consists of high tech exports as a percentage of total exports and infrastructure, communications, and technology index.

Less of an index and more of a list of factors to consider, UNU-INTECH[32] lists measurement priorities with specific reference to developing countries: knowledge accumulated through human resources, procedures and routines; linkages, quality assurance systems and the incorporation of ICT; more complex issues for example types of decision-making support systems and firms' actual potential for knowledge absorption.

What the foregoing shows is that the choice of index is determined by the task and focus at hand. And even then, the most careful selection of indicators cannot yield absolutely accurate results.

Soubbotina[33] cautions on the use of composite indices and suggests considerations in selecting capacity indicators some of which are summarised thus:

- Input and output indicators are selected depending on whether the aim is to measure technological effort or technological achievement
- economies of scale and critical mass effect render absolute size of inputs as important as input intensity
- Some indicators reflect current capacity while others reflect expected but uncertain future capacity
- Indicators of knowledge sales reflect quality of knowledge rather than just its quantity

Commentary

The foregoing discussion reveals, first, that a country's technological capability is composed of a variety of sources of knowledge and innovation and is larger and more complex than any index can encapsulate. Many aspects of innovation are difficult to quantify and even if quantifiable, there is always the problem of lack of reliable data particularly in developing countries. Important technology innovations in the informal

[32] UNU-INTECH (2005) *supra.*
[33] T. Soubbotina (2005) 'Grouping Countries by National Models of Technological Learning', *STI Thematic Group.*

sector may not be recorded and therefore difficult to take into account in the formulation of an index the components of which are in their nature, definite values.

There has been significant change in biotech R&D in the past two decades. Private sector involvement in agriculture and health, both in R&D and in product and service delivery, has become more entrenched. The role of the state has similarly changed with implications on research and delivery of research products. Above all, globalisation of knowledge, markets, regulatory and trade regimes has had pervasive implications on agriculture and health.

Hall writes that the emergence of biotechnology is evidence of the change in the broader framework conditions under which S&T takes place. He identifies the critical features of biotechnology to include technological paradigm shifts, institutional changes including a greater degree of ownership of knowledge and new patterns of partnerships and science and society controversies surrounding ethical, environmental and health risks.[34]

An effort to measure biotechnology capabilities would have to take into account these defining features. Biotechnology often has high R&D content and therefore traditional input and output indicators will be our starting point. An assessment of governance issues - laws and policies - will be crucial in understanding the environment under which innovation in biotechnology flourishes. An attempt will be made at exploring the synergy between organisations.

Unlike most of the composite indices discussed above, this study's approach is primarily qualitative rather than quantitative. Given the range and complexity of the data to be collected, we found it best to opt for a case study approach. We chose three developing countries: South Africa, Kenya and India. We use secondary data from reports, surveys and reviews to supplement information obtained from the interviews.

Estimating the development-related patent interests of countries on the basis of levels of development

According to Lall, there is evidence that 'the need for IPRs varies with the level of development'. He then goes on to say that:

> Many rich countries used weak IPR protection in their early stages of industrialisation to develop local technological bases, increasing protection as they approached the leaders. Econometric cross-section evidence suggests that there is an inverted-U shaped relationship between the strength of IPRs and income levels. The intensity of IPRs first falls with rising incomes, as countries move to slack IPRs to build local capabilities by copying, then rises as they engage in more innovative effort. The turning point is $7,750 per capita in 1985 prices …, a fairly high level of income for the developing world.[35]

[34] Hall, A. (2005) 'Capacity development for agricultural biotechnology in developing countries: an innovation systems view of what it is and how to develop it'. *Journal of International Development,* 17, 611-630.

[35] Lall, S. with M. Albaladejo (2003) 'Indicators of the relative importance of IPRs in developing countries'. Issues Paper no. 3, UNCTAD-ICTSD Project on Intellectual Property Rights and

Of course, it is one thing to say that relatively advanced developing countries have preferred to weaken their IP rights in order to advance their capacities to innovate through imitation-derived technological learning. It is quite another thing to assume that such a policy works just because many governments have favoured it. Nonetheless, intuitively it makes a lot of sense.

Let us then make four working assumptions to be tested in this study. But before doing so we introduce a caveat. This is that we do not accept that the optimal patent scope[36] in terms of subject matter relates directly to indicators of income and output, such as gross national product (GNP). Optimal patent scope is more likely to be related to the capacities to absorb technological knowledge, to learn and to innovate.

The first assumption is that least-developed countries that are inactive in the field of biotechnology would benefit most from keeping as much biotechnological invention out of the patent system, assuming conveniently that the fees acquired through the processing of biotechnology patent applications are insufficient to cover the costs of examining patents and making them enforceable through the court system. Second, low-middle income developing countries may find it beneficial to expand the extent to which biotechnology inventions are patentable so as to encourage investment and technology transfer. Such inventions might in many cases be difficult to copy anyway. However, they may wish to introduce certain limitations to the rights such as a fairly broad research exemption so that emerging local firms may be able to do some imitation without fear of litigation. Third, high income and technologically advanced developing countries with a much higher capacity to imitate would benefit from reducing the extent to which biotech inventions are patentable since the advantages of such imitation would compensate for any losses in terms of reduced investment and technology transfer. Fourth as developing countries join the ranks of developed countries, they become sufficiently innovative that they will find it advantageous to again extend the scope of biotech patenting in line with developed world standards.

Sustainable Development, Geneva. (Citing K.E. Maskus, *Intellectual Property Rights in the Global Economy*, Washington DC: Institute for International Economics (2000), at 95-96.)

[36] To clarify patent scope in this context does not relate to the breadth of individual patents, but to the extent of subject matter limitations.

4. SOUTH AFRICA

Introduction

South Africa has a well-developed economic and commercial sector which has been largely based on natural resources. The resources available for biotech in South Africa are limited with the proportion of the national budget directed towards biotech much lower than in developed countries. South Africa has firmly-established national priorities for utilisation of available resources resulting in strong government influence on research direction. The government has adopted biotech as one of the areas in which to focus its research support.

Biotech in South Africa has until recently focused mainly on first-generation applications such as those in the food industry. There are well-developed industries involved in brewing and food production including a successful wine industry. More recently, activities around developing biotech industries focusing on chemical, pharmaceutical, industrial and environmental biotech have progressed rapidly particularly because of government prioritisation of biotech.

Institutional framework

Institutional actors in biotechnology R&D in South Africa include academic institutions, public research institutions, and industry. Academic institutions constitute the largest group of participants in biotechnology. They are engaged in both basic and applied research.

The institutions charged with the development and regulation of biotech include the Department of Science and Technology (DST) which is the lead department in biotech. It coordinates biotech related research of all other departments and is a vital link to the Treasury. Medical research falls under the Department of Health which coordinates the National Bioethics Committee and advises the Biotechnology Advisory Committee. The Department of Trade and Industry supports innovation in industry and provides funding through incentive schemes. It also plays a crucial role in commercialisation of biotechnology. The Department of Agriculture implements the GMO Act and the Plant Breeders Act. It has a lead role in biosafety issues and advises the Biotechnology Advisory Committee. Other government departments with operations related to biotech include Department of Environmental Affairs and Tourism, the Department of Labour and the Department of Education.

Research activity

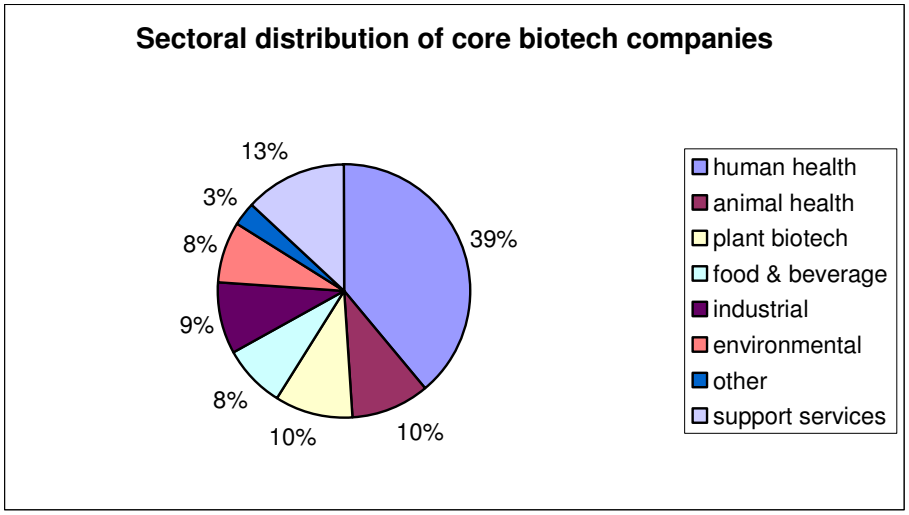
The 2003 National Biotech Survey[37] identified 106 companies engaging in biotech related activities; of these, 47 were core and 59 non-core.[38] Majority of the core biotech companies engage in human health. The rest are evenly distributed across the

[37] Mulder, M and Henschel, T. (2003) *National Biotech Survey 2003*, available at https://www.oecd.org/dataoecd/7/37/36036991.pdf

[38] Id.The study focussed on modern biotech companies, therefore leaving out those that engage in more traditional forms of biotechnology.

other sectors with the exception of the 'other' category which attracts only 3% of the core biotech companies.

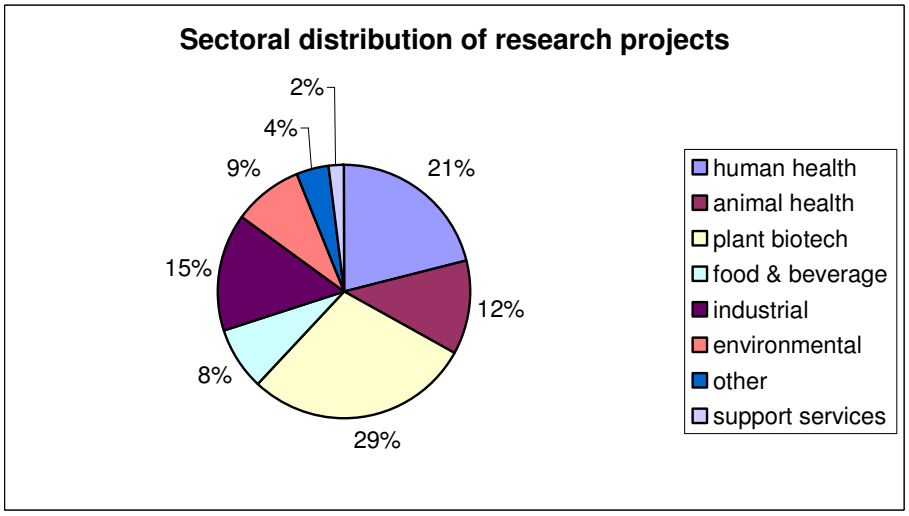
Figure 1: Sectoral distribution of core biotech companies



Source: *National Biotech Survey, 2003*

In total, there are about 1000 projects relevant to biotechnology; these are spread over seven sectors and includes projects undertaken by both public and private sector. The National Biotech Survey classified the projects as biotech, potential biotech, fundamental research and biotech services according to their relevance to biotech. The sectoral distribution of research projects is represented below.

Figure 2: Sectoral distribution of biotech research projects



Adapted from National Biotech Survey, 2003

The largest sector is plant biotechnology where most of the biotechnology carried out in the sector is on crop improvement i.e. insect, fungal, viral resistance and herbicide and drought tolerance. Others involve indigenous plant utilization, fruit improvement,

forest tree improvement and micro-propagation, horticultural propagation, improvement of storage properties, weed control and yield and quality enhancement.

In plant biotechnology, over 590 applications involving the commercial release, importation, exportation, contained use, trials and clearance of GM crops have been received and granted by the registrar of the GMO Act as shown below.

Table 1: GMO permits issued by the Registrar under the SA GMO Act Dec'99 - June'03

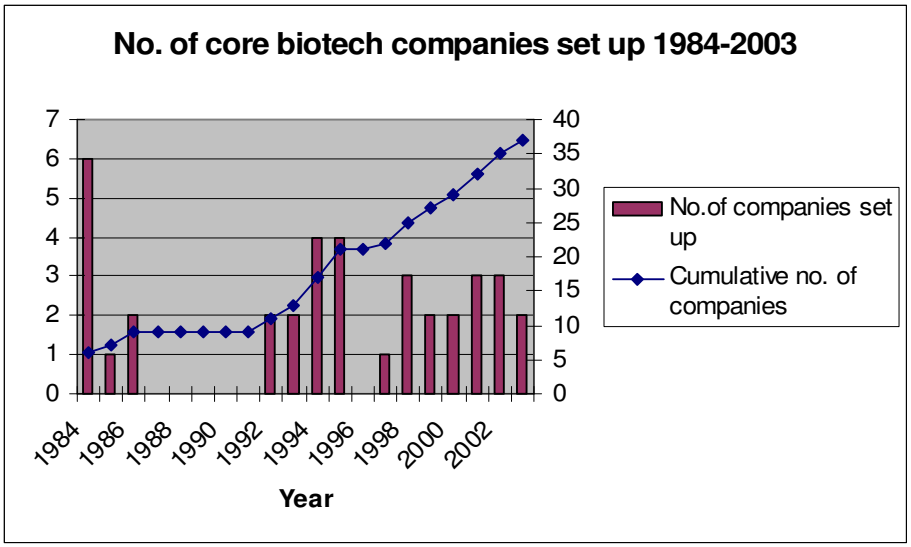
Applications	**1999**	**2000**	**2001**	**2002**	**2003**
Commodity import	1	6	3	37	4
Import	0	50	64	58	19
Field trials	2	45	61	50	1
Export	0	3	22	36	34
Transit	0	0	0	2	1
Animal Feed/ Food	0	1	3	1	1
General Release	0	1	3	1	1
Commodity clearance	0	0	6	4	0
Contained use	0	11	1	2	1
Greenhouse trials	0	0	2	1	0
Commercial planting	0	0	9	11	8
TOTAL	**3**	**122**	**172**	**219**	**73**

Source: SA Dept of Agriculture, 1999, 2000, 2001, 2002 and 2003

According to a survey conducted by Webster and Koch,[39] there is a limited number of new companies established that are solely biotechnology based. Most are small and medium sized enterprises (SMEs). There are also a few multinational companies especially in the seed sector. The majority of the 47 companies identified as 'core' in the 2003 survey comprise of either new start-ups or spin-offs from other enterprises.

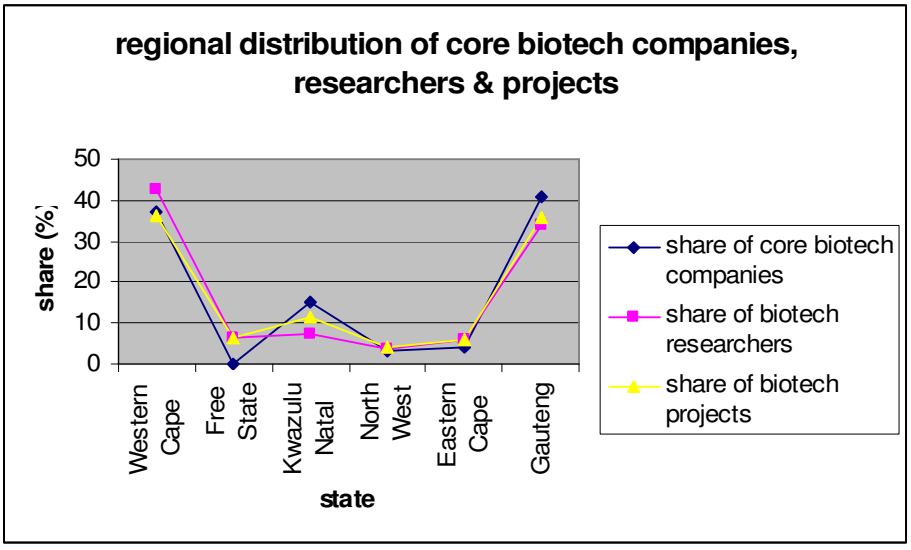
[39] Webster and Koch (1998) *Biotechnology Survey: A Statistical Analysis of South Africa and Sub-Saharan Africa*. CSIR Internal Report.

Figure 3: Number of core biotech companies set up 1984 to 2003 against cumulative number of core biotech companies



With regard to geographic distribution, various studies[40] show that the majority of research stakeholders are found in the Western Cape, Gauteng, KwaZulu Natal and Free State. The regional distribution of biotech research projects and core biotech companies mirrors this.

Figure 4: Regional distribution of core biotech companies, biotech researchers and biotech projects



Adapted from National Biotech Survey, 2003

[40] Bioventures, Catalyst Innovation Incubator, Acorn Technologies, and eGoli BIO studies conducted as of 2003.

Funding

The total funding on biotechnology R&D has been raising steadily since 1997 when it was R100million; R200million in 2002 and in excess of R290 million in 2003.[41] The 2001 National Biotechnology Strategy proposed the set up of Regional Innovation Centres (RICs) under the Department of Science and Technology. DST committed an initial R450 million from 2004 to 2007 for biotech development.[42] The Biotechnology Partnership for Africa's Development (Biopad) was established in 2003 as a collective response by stakeholders in biotechnology to the biotech needs of the region and continent.[43] In 2003, the government committed R250 over two years in an effort to boost Biopad led commercialisation of biotechnology. It pledged to increase R&D spending from 0.27% to 1% of national GDP.[44] The biotechnology policy launched in 2004 looks towards forming strategic partnerships as the way forward in attracting investment.

Funding from the private sector is limited. The impact of RICs and other technology incubators established under the national strategy on private sector investment is yet to be seen. It is hoped that there will be more incentive for increased private sector investment. Consolidation of the international seed industry has led to technology being held by a small number of multinational companies.

Institutional linkages exist between South African institutions on one hand and local and international universities on the other. These linkages are characterized by information and material exchange. There are other limited collaborations between national research institutes, international organizations, government departments, NGOs and the private sector. The need for improved institutional linkages was expressed by those interviewed.

Venture capital has not taken much root in South Africa. There are however some public and private sources of venture capital funding for start-up companies wishing to engage in biotechnology. These include HBD Venture Capital, Bioventures, Brait Private Equity, Support Programme for Industrial Innovation, Technology and Human Resources for Industry Innovation, Industrial Development Corporation, Synexa Life Sciences, and Catalyst Innovations. Biotech firms are yet to be listed on the AltX or JSE Securities Exchange.[45]

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[41] Webster & Koch (1998) *supra*; Webster & Koch (2002) *Biotechnology Sector Report. Implications of the Information Revolution for Economic Development in South Africa*. DTI Policy Support Programme; National Biotech Survey (2003) *supra*.

[42] SouthAfrica info (2003) *Developing South Africa's Biotech Industry.*

[43] See biopad website http://www.biopad.org.za/

[44] Maistry, P. (2003) 'Modern biotechnology and genetic modification: bridging the gap between business and practice'.

[45] SouthAfrica info (2004) *SA's Budding Biotech Industry*, 5 January 2004 available at http://www.southafrica.info/ess_info/sa_glance/scitech/biotech-audit.htm. Companies need to have profits greater than R8 million before they can be listed on the stock exchange. Only 20% of biotech firms have revenue in excess of R10 million.

Human resource development

There are a significant number of scientists with postgraduate qualifications. In 1998, the figure was estimated at 1200, 20% of which had PhD qualifications and 20% with MSc degrees.[46] The highest concentration of the qualified individuals is found in academic institutions. Loss of graduates and staff from the system has however lately been of concern as qualified personnel seek greener pastures in the private sector and abroad.

The 2003 Survey identified approximately 1020 staff in biotech related activities with biotechnology companies showing a relatively even distribution of employees by qualification. This is probably a function of the averaging out of R&D personnel and technical/production staff in a sample that includes R&D intensive as well as production-orientated companies. As is to be expected, research groups are dominated by employees with at least a degree qualification, and frequently a post-graduate degree.

The Survey reports that approximately 50% of companies and 81% of research stakeholders that participated in the survey indicated that they had experienced shortages in human resources. The majority of research stakeholders listed skilled scientists at various levels, particularly MSc's and PhD's, as being in short supply. It is expected that capacity for commercialization of biotechnology will improve with the implementation of the national strategy through the establishment of the RICs.

Administration and regulation

Until 2004, South Africa did not have a national biotech policy. National policies on areas that are related to biotechnology and biosafety such as the environment and agriculture, do not focus much attention on biotechnology and biosafety save for perhaps the National Policy on the Conservation and Sustainable Use of Biodiversity. This expresses the need to adopt measures to regulate the use, handling, transfer and release of GMOs. The 1996 White paper on Science and Technology underscores the role of science and technology in promoting South Africa's economy and recognizes the benefits that science and technology offers in the improvement of the livelihoods of South Africans. It however only identifies biotechnology as an area of collaboration both nationally and internationally and across various partners.

After numerous national pronouncements indicative of the political recognition of the opportunities offered by biotechnology, a national biotechnology policy was launched in September 2004. The policy[47] identifies health, agriculture, industry, mining and the environment as priority areas. The policy also identifies need related to research infrastructure for the design, testing and manufacture of drugs and vaccines. It adds that human resource development must be promoted and greater capacity and awareness of the need and potential of bioinformatics is crucial.

[46] Wolson, R. (2001) *Agricultural Biotechnology Assessment in Sub-Saharan Africa, Country Study: South Africa*. Report prepared for the African Centre for Technology Studies
[47] DST (2004) *Biotechnology Platforms: Strategic Review and Forecast*, 9 September 2004.

The National Biotechnology Strategy

In spite of South Africa's long history in use of biotechnology and the large number of biotechnology-embracing projects, various stakeholder meetings determined that the potential of third generation biotechnology had not been maximized and that very few products and processes were under commercialization. The limiting factors were identified as including the lack of infrastructure for R&D, institutional capacity, business support and management for start-up technology companies, lack of technology platforms in science and technology, coordination of policies and programmes, lack of collaboration and funding for innovative ideas. In response to this, the Department of Science and Technology embarked on a study which resulted in the drafting and gazettement of the National Biotechnology Strategy for South Africa in November 2001.[48]

The Strategy identifies gaps and suggests new institutional arrangements and specific actions to be taken by government departments. Key interventions currently being implemented as a result of the strategy include the creation of three Regional Innovation Centres (RICs), creation of a National Bioinformatics Network to develop capacity and support services in bioinformatics, development of Biological Resource Centres to ensure the adequate protection and optimal use of biodiversity, establishment of the Biotechnology Advisory Committee to implement the strategy, coordinate R&D and address ethical issues, the establishment of a Bioethics Committee, promoting the public understanding of biotechnology and the development of a Biobank.

Working groups of experts in human health, plant improvement, animal health, industrial processes and new biotechnology platforms are currently analysing information on opportunities, key technologies and market trends under the DST Biotechnology Roadmapping Project. The emphasis is on R&D, human resource development and infrastructure needs in the named areas. The working groups consist of experts from government, industry and academic institutions.

Legal framework

There is no specific Act of parliament regulating biotechnology in SA; rather, there are various Acts regulating biotech related activities. These include the GMO Act of 1997 which covers biosafety issues relating to GM products. Agricultural products are regulated by the Agriculture Act of 1947 while the Biodiversity and Protected Areas Acts regulate the use of biodiversity for biotechnology. In the health sector, the Medicines Control Act of 1965 governs the registration and use of medical substances, while the Human Tissue Act of 1983 regulates the use of human tissue for research.[49] Legal Guidelines for Research in Biotechnology, 2006 exist in draft form are intended to guide applicants from the initial considerations in respect of what research is permissible and how to obtain authorisation to conduct research to the final stage of commercialisation of the research by way of patent protection. The

[48] South Africa National Biotechnology Strategy (2001). www.dst.gov.za/publications/reports/dst_biotechnology_strategy.PDF

[49] The National Health Act of 2003 is set to replace the Human Tissue Act. A major departure is that the former will allow therapeutic cloning which is impermissible under the latter.

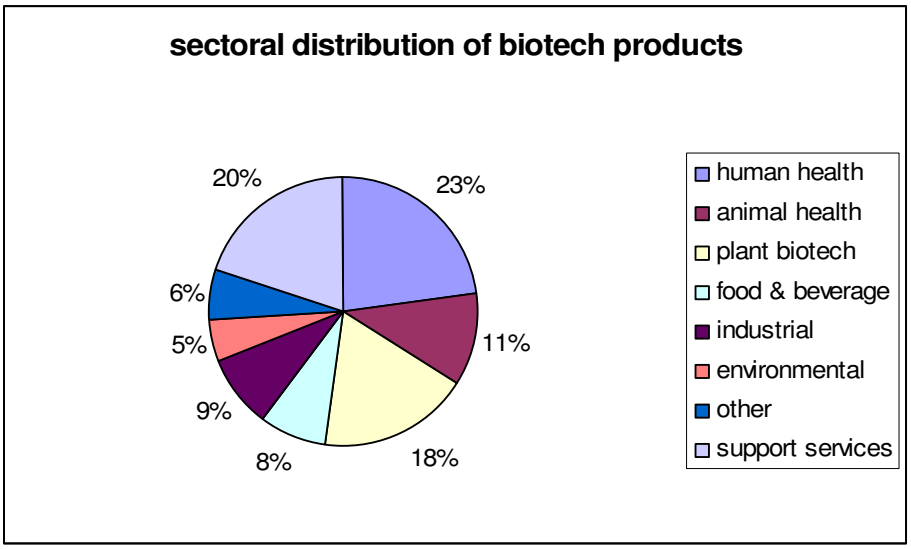
corresponding Ethical Guidelines for Research in Biotechnology deal with ethical considerations.

South Africa has five Acts of parliament addressing intellectual property. These are the Patent, Trademark, Copyright, Registered Designs and Plant Breeders' Rights Acts. All are administered by the Department of Trade and Industry with the exception of the Plant Breeders' Rights Act which is under the Department of Agriculture. The Patent Office is a non-examining office. For a country as advanced in innovation, at least by African standards, the intellectual property infrastructure is basic.[50] The National Biotechnology Strategy highlights the requirements for a review of the patent legislation.

Outputs and outcomes

In spite of biotechnology being in use for 25 years, few local products have been developed. The 47 companies classified as 'core' biotech companies produced about 155 products and/or services which were applied predominantly in human health, support services and plant biotech.

Figure 5: Sectoral distribution of biotech products



Source: National Biotech Survey, 2003

The creation of biotechnology RICs is intended to address this gap between research and innovation. There are currently three BRICs which specialize in different areas. The Biopad RIC of the Gauteng region focuses on animal health and industry and environmental related biotechnology. A reported 25 projects are currently being funded by the Gauteng Centre.[51] The Cape Biotech Initiative (CBI) represents the Western Cape region and focuses on human health bioprocessing. The East Coast Biotech (Ecobio) serves the Kwa Zulu Natal and the East Coast. This too focuses on human health and bioprocessing. Initially, no emphasis was placed on plant

[50] Wolson, P. (2001) *supra.*
[51] SouthAfrica info (2003) *Developing SA's Biotech Industry*, 10 March 2003 available at http://www.southafrica.info/doing_business/trends/newbusiness/biotech.htm

biotechnology as can be seen from the allocation of focal areas. It was decided that all BRICs will contribute to plant biotechnology although Ecobio will coordinate and receive funds for plant biotech. Eventually, this will be phased out over time and as funding increases, the other BRICs will also be involved in plant biotechnology.

The formation of the National Bioinformatics Network (NBN) is also central to the innovation, commercialization and advancement of biotechnology in South Africa. This is based at the University of Western Cape and the University of Pretoria. The NBN provides computational power, genome interpretation facilities and networking links between the BRICs and other research institutes. The NBN also enhances the creation and development of bioinformatics skills and capacities in South Africa.

Other actors in the South Africa biotechnology landscape with activities likely to influence commercialization and innovation include the GODISA programme which aims at increasing economic growth and employment creation through the enhancement of technological innovation, improvement in productivity and accelerated international competitiveness of South African small, medium and micro Enterprises (SMMEs). The programme supports an Innovation Support Centre, a Technology Demonstration Centre, and six Technology Incubators. Plans are underway for further funding of more technology incubators. Most of these initiatives are in the implementation stages and only a handful have operations spanning three years. As such, their impact on commercialisation of biotech remains to be seen. Data on this was not available. The initiatives however present a positive outlook for commercialisation of biotech in South Africa.

Patenting activity

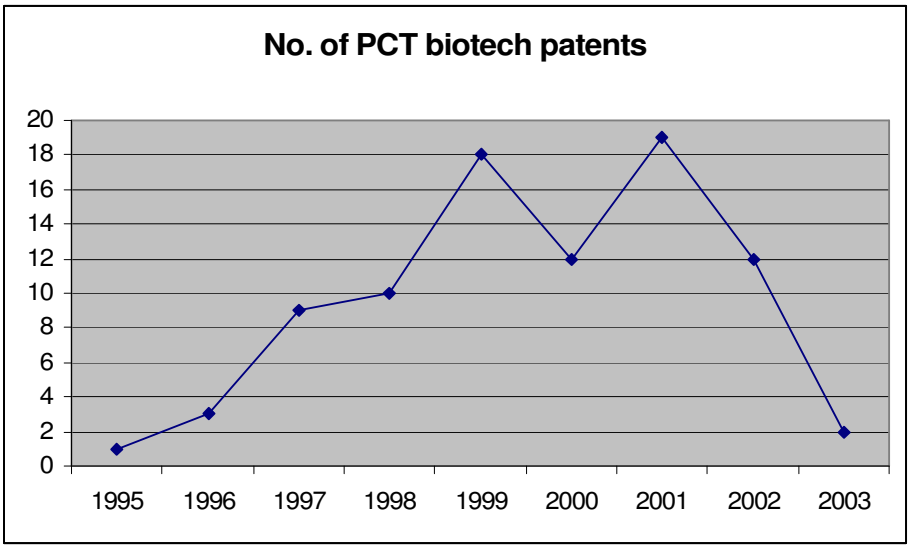
Generally, scientists in South Africa have favoured publication rather than the commercial value of their work; consequently, the level of patent output is low compared to other developing and developed countries.[52]

There were at least 200 biotechnology-related patents filed in the South African Patents Office by South African inventors between 1979 and 2002[53] while 86 biotech patent applications by South African inventors were received by the Patent Co-operation Treaty (PCT) between 1985 and 2003. It is possible that the patent numbers reflected do not reflect full complement of IP in South Africa given that ongoing research is yet to yield products which can be protected by IP. The substantial filing fees may be a deterrent for South African biotech companies, most of which are SMEs, from seeking patents abroad.

[52] Generally, Cloete, E., L. Nel & J. Theron (2006) 'Biotechnology in South Africa'. *TRENDS in Biotechnology* 24/12 557-562; Quach, U. et al (2006)' Biotechnology patenting takes off in developing countries'. *International Journal of Biotechnology* 8, 43-59; and Katnelson, A. (2004) 'South Africa fights low patent rate'. *Bioentrepreneur* available at http://www.nature.com/bioent last accessed 28 November 2006

[53] National Biotech Survey (2003) *supra*. This notes that the figure is an estimate given that the SA patent office does not use International Patent Classification. The estimate figure represents those patents which the researchers presumed to be biotech patents from the titles in individual patent applications.

Figure 6: Number of PCT biotech patents



Conclusion

Commercial biotechnology in South Africa is mainly led by Small and Medium sized private firms. The government has targeted biotechnology development as a priority research area and has increased funding to the sector. However, in spite of over two decades of research, there are few local biotech products, and the local biotech sector is largely dependent on imported technology. This is reflected in relatively low levels of local biotech innovation.

In spite of increased government funding and private investment, the sector suffers from insufficient public and private funding for research and commercialisation. The newly created regional innovation centres have potential to attract funding although their impact remains to be seen. There is a shortage of suitably skilled technical personnel and entrepreneurial and technology transfer skills.

Recent government emphasis on biotech has led to an increase in the number of biotech related policy documents, strategies, road maps and plans which define the framework under which biotech can develop. It is expected that the new framework will rectify the general lack of cohesion in research programmes and address the gap between research and commercialisation.

5. KENYA

Overview of biotechnology

In most literature, reports and surveys on biotechnology in Kenya, there is virtually no mention of biotechnology in other sectors other than in agriculture. There is however anecdotal evidence of biotechnology in the health and industrial chemical sectors. As such, this report is constrained in its unintentional leanings towards agricultural biotechnology rather than biotechnology as a whole.

Plant biotechnology has been in use in Kenya since the 1960s. During the colonial period, European farmers through the then Kenya Farmers Association were employing biological nitrogen fixation biotechnology for the production of fodder legumes and soybean.[54] The early 1980s saw a rise in the use of tissue culture in the production of citrus plants and pyrethrum under a joint initiative by Kenya Agricultural Research Institute (KARI) and the University of Nairobi. In 1990, the government established the National Advisory Committee on Biotechnology Advances and their Applications which advised that the use of modern biotech in Kenya would remain uncertain in the face of inadequate technical and regulatory capacity. By 1995, the application of tissue culture in crop improvement was commonplace in various public and private sector institutions. However, it was not until 2000 that modern biotechnology in crop production was used in Kenya. Currently, five transgenic crops are in various stages of the approval process by the National Biosafety Committee.

The policy and regulatory framework

Kenya lacks a specific policy on biotechnology. Issues relating to biotechnology and biosafety have generally been addressed in the national science and technology policy. Biotechnology R&D is therefore evolving in a policy vacuum.

Policy makers have in the past made ad-hoc policy related statements on biotechnology. This has led to fragmentation and poor communication of the biotechnology R&D agenda among various stakeholders. For example, most of the biotech initiatives reflect interests of concerned individuals and particular institutions. There is little inter-organizational interactions and modern biotechnology activities are influenced by institutional preferences and donor funding and are not necessarily guided by or aligned to national priorities.[55]

There is lack of national priority setting and political will to implement biosafety. This reflects a lack of awareness of biotechnology and its impact at all levels of society beginning with policy makers.[56] The National Council for Science and Technology (NCST) is charged with the regulation of biotech and has drafted a national biotechnology policy which awaits adoption. The draft policy arises out of

[54] Odame, H., P. Kameri-Mbote & D. Wafula (2003) 'Governing modern agricultural biotechnology in Kenya: implications for food security', IDS Paper

[55] Anyango, B. and P. Shiundu (1999) 'Institutional arrangements towards biotechnology policy making in Kenya'. Paper presented for Biotechnology and Public Policy Training Course, ACTS, Nairobi, Kenya.

[56] This was the resounding view of most of the people interviewed.

the recognition that there is need for a national biotechnology policy and framework to address all aspects of biotechnology.

The policy has a wide scope which extends to public awareness, legal framework, intellectual property issues, capacity for biotech R&D, institutional framework to coordinate biotech efforts, funding, safety issues and protection of indigenous resources and knowledge.

In 1998, the National Council for Science and Technology (NCST) developed guidelines for biosafety in biotechnology. The NCST through the National Biosafety Committee (NBC) is the coordinating office on all issues related to biosafety. The 1998 Regulations and Guidelines lack an enabling statute. While non-legislative means such as a ministerial decree are faster and simpler to issue and are more readily amended or replaced, there are enforcement constraints. Without an enabling statute, the guidelines may lack substance. It is for example legally difficult to prosecute one who contravenes the guidelines as they lack the weight and enforcement power of government regulatory authorities. A draft Biotechnology Development and Biosafety Bill is currently in parliament awaiting debate. The bill establishes the National Biosafety Board whose functions include formulating and implementing policies, plans and programmes for the development of biosafety in Kenya; overseeing the formulation of standard provisions governing rights and obligations of biosafety institutions; promoting efficiency in the development of biosafety through the establishment of appropriate institutional linkages and promoting and encouraging the use of environmentally friendly technologies.

The current Regulations and Guidelines cover research on recombinant DNA, categorized experiments, plant biosafety, quarantine procedures, containment and field experimentation. Other areas such as the deliberate release of GMOs, the importation of biotechnology products and sanctions to ensure compliance with biosafety measures are also addressed.

The regulations describe the steps to be followed to develop a national biosafety system. The NCST was designated by the government as the authority to oversee the coordination and implementation of biosafety Regulations and Guidelines. Its secretariat, the inter-agency NBC, draws up policies and procedures and vets research applications to ensure responsible application of biotechnology in Kenya. The NBC has been operational since 1998.

Research activity

Although Kenya seems to have a comparative advantage in biotechnology due to great genetic diversity and a significant scientific base borne out of institutions that have a long tradition in research, there does not seem to be much emphasis placed on actual investment in new and innovative ways of tapping benefits from biotechnology or in biotechnology research and development.

Kenya has a well established system of national research in agriculture as well as in health. This is characterized by public goods research, use of conventional technology, and centralized and hierarchical organization. The institutions in this national system include national research institutes, academic institutions, NGOs,

producer associations and other community based organizations. The Kenya Medical Research Institute (KEMRI) is the lead institute in health biotech while in plant biotechnology, the actors include the national agricultural research institute i.e. the Kenya Agricultural Research Institute (KARI), universities and international agricultural research institutes (IARCs). Private sector engagement in agricultural biotechnology is taking root in Kenya. However, it is mainly multinational companies that are involved. Although there is some level of collaboration between these groups, there has not been full exploitation of organizational synergies.

In the health centre, the Centre for Biotechnology and Research Development within KEMRI is mandated to develop biotech innovations especially diagnostic tools, vaccines and biological materials. Current areas of research include HIV/AIDs and malaria among others.[57] Anecdotal data shows that medical biotech is also conducted in the department of medicine in Moi University and at the University of Nairobi. Data showing the extent of experimentation is however not available.

Human resource development

Kenya has built capacity over the years in traditional biotechnology. In plant biotech, there are numerous projects involving tissue culture and marker assisted technology most of which are being conducted under KARI and institutions such as universities.[58]

Capacity for molecular biotechnology and risk assessment is however lacking in Kenya as in most African countries. Although the majority of scientists in Kenya have basic scientific knowledge in genetics and molecular biology, they lack practical experience to effectively apply their existing knowledge to modern biotechnology.[59] KEMRI has contributed to health research capacity through various initiatives. These are however not solely targeted to biotech but to health in general. Data on approximate number of researchers working in biotechnology is not available.

The capacity of scientists is underutilized where there is lack of or low funding to provide for research grants and staff salaries. Retaining of qualified personnel is also at risk as the few highly trained scientists leave the country for better career prospects.[60]

The government and research institutions in Kenya do not have specific training strategies for building national capacity in biotechnology. There are however biotech related degree programmes at three universities. The Jomo Kenyatta University of Agriculture and Technology offers various programmes on agriculture while medical biotech courses are available at Moi University and University of Nairobi. Further

[57] KEMRI website www.kemri.org

[58] Traynor, P. and H. Macharia (2003) *Analysis of the Biosafety System for Biotechnology in Kenya: Application of a Conceptual Framework*. ISNAR Country Report 65. The Hague, The Netherlands: International Service for National agricultural Research.

[59] Odame H., P. Mbote P. & D. Wafula (2000) 'Globalisation and the international governance of modern biotechnology: the implications for food security in Kenya'. Paper prepared for a project on Globalisation and the International Governance of Modern Biotechnology under the Globalisation and Poverty Programme

[60] BIO-EARN (2001) 'Safety in biotechnology of foods and feeds, proceedings of a BIO-EARN workshop', NCST, No. 43/2002, Nairobi, Kenya.

data on the breakdown of the biotech related courses and the number of enrolled students is not available.

Research institutions have incorporated their training needs within the framework of individual research programmes.[61] There are insufficient knowledgeable and trained policy makers. Think tanks such as the African Centre for Technology Studies (ACTS) and other policy international and national NGOs have been instrumental in organising training and workshops to raise awareness in biotech among policy makers and researchers. Capacity is lacking in biotech R&D and in auxiliary fields such as intellectual property rights.

Funding

There is limited and contradicting data on level of funding in biotechnology. What is apparent is that research in biotechnology - mainly agriculture and health - is public sector led with the few private sector companies involved being multinationals. A significant proportion of funding comes from bilateral donors and is of a short-term nature. Government funding for biotechnology has remained minimal; research institutions recognise the need to explore alternative long-term financing for biotech. There is lack of appropriate policies, laws and institutional arrangements to support innovative alternatives such as venture capital.

It is worth noting that virtually all experimentation in agriculture and health biotechnology involving private companies occurs in partnership with government institutions. There is therefore an emerging pattern of public private partnerships.

Resources such as appropriate facilities and equipment to conduct biotechnology need upgrading in Kenya. This requires financial resources at a time when public research is faced with dwindling funds. It appears that lack of funding in addition to relevant trained personnel are acute and serious constraints for laboratory capacity in Kenya.

In additional to these implementation drawbacks, other constraints include poor linkages and networks. There is lack of adequate collaborative arrangements amongst researchers and research institutions. Biotechnology requires a multi-disciplinary collaboration between researchers, lawyers, engineers, information technology experts, market researchers, business experts and other professionals. Poor infrastructure poses another problem; biotechnology heavily relies on knowledge flows. Poor information technology - manifested in underdeveloped modern communication systems, access to email and internet- impedes the acquisition and exchange of necessary and relevant information vital in biotechnology.

Research output: patents

The Kenya Industrial Property Institute (KIPI) is charged with the administration of patents. KIPI does not use the International Patent Classification and therefore it is difficult to know what share of the total patents belongs to biotech. Since its inception in 1991, KIPI has received about 450 patent applications from local and foreign

[61] Odame et al (2000) *supra*.

applicants. There have been about 330 PCT applications and over 3000 applications through the African Regional Intellectual Property Organisation (ARIPO).[62]

Conclusion

Kenya is far from being a hotbed of biotechnological invention. Government commitment to biotechnology has not been clearly expressed: there has been no budgetary commitment to biotech R&D and the draft Biotechnology bill and biotechnology policy have been in and out of parliament since 2003. There is virtually no commercialisation of biotech products. Insect resistant maize developed by KARI, the International Research Centre for Maize and Wheat (CIMMYT) and Syngenta Foundation will be the first product of modern plant biotech to be commercialised in Kenya.[63]

Although skilled scientists exist in traditional forms of biotechnology, modern biotech suffers from limited capacity in research scientists. So while there is limited capacity to use second generation biotechnologies, Kenya depends heavily on foreign organisations such as corporations and development agencies for technology transfer, technical support and funding. The private sector in Kenya spends virtually nothing on agro-biotechnology research, and is not a user of genetic engineering techniques except for tissue culture, a situation that has not changed at all since the passage of the Industrial Property Act. Public sector research institutes and continues to contribute almost all of total research expenditure. And much of the total research funding is provided by foreign aid donors. Lack of funds has resulted in limited infrastructure with facilities like testing equipment, laboratories, machinery, etc in dire need of an upgrade.

While the ability of Kenyan firms to copy biotech inventions by reading foreign patent specifications may be quite limited, even this possibility is precluded when the same inventions are patented in Kenya. Therefore, allowing foreign corporations to acquire patents in Kenya arguably only increases dependency without any apparent mitigating benefits.

[62] KIPI (2005) personal communication.
[63] Wachai, J. (2006) 'Kenya inches closer to food sustainability', *Africabiotech* 11 November, available at http://www.africabiotech.com/news2/article.php?uid=151

6. INDIA

Institutional framework

The Indian biotech institutional framework can be traced back to the 1940s with the establishment of the Council for Scientific and Industrial Research (CSIR). This is a government institute with a network of about 40 laboratories, 80 field stations and which employs over 22,000 personnel.[64] Of the 40 laboratories, at least seven engage in biotech research. These are the Centre for Biochemical Technology (CBT) in Delhi, the Centre for Cellular and Molecular Biology (CCMB) in Hyderabad,[65] the Indian Institute of Chemical Technology (IICT) in Hyderabad, the Central Drug Research Institute (CDRI) in Lucknow, the Institute of Microbial Technology (IMT) in Chandigarh, the Indian Institute of Chemical Biology (IICB) in Calcutta and the Central Food Technological Research Institute (CFTRI) in Mysore.[66]

The institutional framework was further bolstered in the 1980s: the Sixth five-year Plan (1980-1985) was India's first policy document covering biotechnology development.[67] CSIR was mandated to ensure co-ordination on an inter-agency, inter-institutional basis. One of the most important boosts to biotechnology development was the establishment of the National Biotechnology Board (NBTB) in 1982 to spearhead the development of biotech. Its primary objective was to identify priority areas in biotech development and to devise a long term plan for biotech in India. In 1983, NBTB issued the 'Long Term Plan in Biotechnology in India' which identified as priority areas self sufficiency in food, clothing and housing, adequate health and hygiene, provision of adequate energy and transportation, protection of the environment, employment, industrial growth and balance in international trade. The NBTB graduated to the Department of Biotechnology (DBT) in 1986. Its mandate is to promote biotechnology throughout India.

At present there are seven major agencies concerned with financing and supporting research in biotechnology. These are the Department of Science and Technology (DST), the Department of Biotechnology (DBT), the Council of Scientific and Industrial Research (CSIR), the Indian Council of Medical Research (ICMR), the Indian Council of Agriculture Research (ICAR), the University Grants Commission (UGC) and the Department of Scientific and Industrial Research (DSIR). These agencies are spread over four different government departments.[68]

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[64] Ernst & Young (2002) *Biotechnology in India.*

[65] This was established in 1977 solely for the advancement of biotechnology.

[66] Maria, A., J. Ruet, J. & M.-H. Zerah (2002) *Biotechnology in India.* A study commissioned by the French Embassy in India (hereafter French Embassy Report).

[67] Bhargava, P. (1995) 'Biotechnology's decade of stagnation'. *Economic and Political Weekly*, vol. 30/48

[68] DST, DBT and DSIR are under the Ministry of Science and Technology; ICMR is under the Ministry of Health, ICAR is under the Ministry of Agriculture, UGC under the Ministry of Human Resource Development. DSIR is the funding agency for CSIR and both fund biotech related research projects.

Table 1: Budget allocations of major biotechnology funding agencies (millions of US$)

	1990/91	2000/01	2002/03	2003/04	2004/05
Indian Council of Agriculture Research (ICAR)	667	1647	1667	1615	1934
University Grants Commission (UGC)	720	1656	1774	1749	1832
Dept of Scientific and Industrial Research (DSIR)	511	1142	1180	1219	1439
Dept of Science and Technology (DST)	533	918	1150	1262	1420
Council of Scientific and Industrial Research (CSIR)	484	1073	1145	1184	1399
Dept of Biotechnology (DBT)	135	160	267	293	358
Indian Council of Medical Research (ICMR)	82	173	185	179	197
TOTAL	**3133**	**6768**	**7368**	**7501**	**8579**

Source: Chaturvedi, 2005

Research activity

In the 1980s, programmes on biotechnology included tissue culture application for medicinal and economic plants, fermentation technology, enzyme engineering for chemicals, antibiotics and other medical product development, agricultural and forest residues and slaughterhouse wastes utilisation.[69] In addition to these first and second generation biotech activities, India's engagement in third generation biotech activities such as pharmaceuticals, plant and animal biotech, aquaculture and marine biotech, and environmental biotech has grown strongly over the past two decades. With India's growing global prominence in information and communications technology, bioinformatics as a sector in biotech is growing rapidly. DBT reports that it received 1325 project proposals in 2005-2006 period 805 of which were recommended for funding.[70]

A study conducted by Ernst and Young in 2000 found that there were 800 biotech companies.[71] 15 percent of these engaged in third generation biotechnology. The study found that the biotech industry at the time employed about 10,000 technical staff and generated about USD 500million in revenue per annum.

Similar studies conducted by the Biotech Consortium India Limited (BCIL) in 2001 and 2003 however display more conservative figures highlighting the problem of discrepancies in the biotech data available. The 2001 survey lists 176 biotech firms while the 2003 survey lists 401 firms.[72] With 85 firms, agriculture was the largest

[69] Planning Commission (1981) *India, Sixth Five Year Plan Document, 1980-1985*, Government of India, New Delhi.
[70] DBT Report, 2006. Available at http://dbtindia.nic.in/publication/publicmain.html
[71] This includes companies engaging in first generation biotech.
[72] Only about 25% of firms are common to both surveys. While this indicates that there is a high number of new firms, there is however no explanation on missing firms. See Chaturvedi, S. (2005) 'Dynamics of biotechnology research and industry in India: Statistics, perspectives and key policy issues', DSTI/DOC(2005)6 for an analysis of the problem of contrasting data.

biotech sector in 2001 representing 48% of the total. Healthcare came second with about 24% of the total. With its 43 firms increasing to 142 firms in 2003, healthcare was the largest sector in 2003 having a share of 35% compared to agriculture's 33%. Firms engaging in environmental biotech increased from 4 to 16 while 2003 figures indicate a sector not present in 2001: industrial biotechnology. These are mostly firms engaging in extraction related activities and at 42 firms represented 10% of the total biotech firms in 2003.

Table 2: Sectoral breakdown of biotech firms in India, 2001 and 2003

	2001		2003	
	Number	Share of total (%)	Number	Share of total (%)
Agriculture	85	48.3	132	32.9
Healthcare	43	24.4	142	35.4
Environment	4	2.3	16	4
Industrial Biotech	-	-	42	10.5
Others	44	25	69	17.2
TOTAL	**176**		**401**	

Source: BCIL 2001, BCIL 2003

Most biotech firms in India are private and are predominantly small. Only about 12 biotech firms are listed on the capital market. BCIL data shows that the share of small firms remained constant at about 60% in 2001 and 2003. The number of large firms decreased from a share of 25% to 40% in 2003 while that of medium sized firms increased from 13% to about 20%. There is a significant number of US and European multinationals with a manufacturing presence in India.[73]

Contract Research Organisations[74] have largely been responsible for the rise in the absolute number of small firms in the healthcare sector from 10 in 2001 to 74 in 2003 representing the largest percentage increase across the sectors over the period. In agriculture and healthcare, medium sized firms have increased at the same pace. In the healthcare sector, large firms have increased by about 80% suggesting a rapid entry of multinational companies.

Table 3: Number of biotech firms by size and sector 2001 and 2003

	Agriculture		**Environment**		**Healthcare**		**Industrial**		**Others**		**Total**	
	2001	2003	2001	2003	2001	2003	2001	2003	2001	2003	2001	2003
Small firms (<51 employees)	63	87	4	9	10	74	-	39	30	31	107	240
Medium firms (51-150 employees)	10	26	-	1	8	21	-	15	6	15	24	78
Large firms (>150 employees)	12	14	-	4	25	45	-	10	8	10	45	83
Total no. of firms	85	132	4	16	43	142	-	42	44	69	176	401

Source: BCIL 2001, 2003 and Chaturvedi, 2005

[73] For example GlaxoSmithKline, Eli Lily in health and Monsanto and US Agriseeds in agriculture.
[74] Chaturvedi, S. (2005) *supra*.

Bioinformatics as a biotech sector is growing rapidly on the back of India's strong IT sector. The government has had a large part to play in the growth of this sector partly by enhancing the equity of foreign companies and institutions in government funded research centres to 51%.[75] In addition, a network of at least 57 research centres linked to a high speed computer network Biotechnology Information Systems Network (BTISnet) has been established.[76] Some state governments have also initiated efforts at strengthening bio-nanotechnology and plant genomics.

A significant proposition of biotech firms is concentrated in Central and Southern India. The 2002 French Embassy survey identified 18 main public research institutions 10 of which are in Central and Southern India. Hyderabad in Andra Pradesh in the south stands out with about 40 research institutes solely dedicated to biotech. Other prominent states include Karnataka, Tamil Nadu and Kerala. The western state of Maharashtra has large biotech centre whose base expands to other states such as Gujarat and Chandigarh.

Funding

Biotechnology is highly dependent of the availability of funds at initial stages of R&D. Access to capital for biotech firms is through government funding or private venture capital. Government support is typically targeted at government institutions and research agencies. There is little government support for private sector R&D outside of that available from the Technology Development Fund which finances CSIR-approved projects. However, some state governments have set up biotech development funds to assist private companies engaging in biotech.

In the 2005-2006 period, the biotech industry registered a revenue of USD 1.07billion recording a growth of 36.55%.[77] Leading public agencies supporting biotechnology programmes include the Indian Council of Agriculture Research (ICAR), the University Grants Commission (UGC), the Department of Scientific and Industrial Research (DSIR), the Department of Science and Technology (DST), Council of Scientific and Industrial Research (CSIR), Department of Biotechnology (DBT) and the Indian Council of Medical Research (ICMR). It should however be noted that apart from DBT which deals solely in biotech, it is difficult to establish the share of funding allocated to biotech in the agencies as allocations are not separately marked for biotech.

The national budget Table 1 above is a broad overview of the total allocations in the above mentioned agencies. Apart from ICMR, DBT has registered modest growth relative to the other agencies. This may perhaps be indicative of its role of coordination of nationwide biotech research rather than direct R&D.

The national budget for the 2001-2002 fiscal year gave biotech firms a 150% tax deduction for R&D in a move aimed at encouraging private sector investment in biotech. The government also promotes the establishment of biotech centres within industrial parks. The Andhra Pradesh state in collaboration with the private sector has

[75] Suresh, N. (2003) 'Bioinformatics policy calls for 51% FDI in government labs', 17 March 2003. Available at http://www.ciol.com/content/news/repts/103031701.asp
[76] Chaturvedi *supra*.
[77] DBT Report 2006 *supra.*

built a state-of-the-art biotech park in Hyderabad. This is intended to be replicated in other states. Some of these projects are partly funded by the central and state governments as well as private investors.

Other measures to promote private sector investment and innovation include the establishment of the Small Business Innovation Research Initiative (SBIRI), a scheme launched for funding early stage pre-proof of concept research. Plans to expand this to fund projects which have established proof of concept and have the ability to get venture capital are underway.[78]

Private sector investment in 2002 amounted to USD10.6billion up from 3.1 in 1999.[79] The health and medical sector accounted for 47% of the total while agriculture received 32%.

Table 4: Private sector investment in biotech 1999 and 2002 (US$ m)

	1999	2002
Health	2118	5024
Agriculture	900	3350
Industrial biotech	-	635
Environment	3	253
Others	101	1354
TOTAL	**3122**	**10616**

Source: BCIL 2001, 2003 and Chaturvedi 2005

Venture capital

The number of venture capital firms in India has increased greatly since 1988 when the government announced the guidelines for setting up venture capital funds. The restriction that venture capital funds could only be set up by banks and financial institutions was removed in 1995 allowing for tax exemption therefore encouraging capital investments from overseas.. The Venture Capital Funds Regulations were promulgated in 1996; at the time, only 8 domestic venture capital funds were registered. In 2004, the number of funds had increased to at least 70 with USD29 billion in assets under management.

There are limitations in data collection with regard to the share of funds available to biotech. However, the data available seems to suggest that venture capital currently plays only a marginal role in funding biotech. In the French Embassy study, only 4 companies of the 41 interviewed received support through venture capital funds.

Interestingly, venture capital in India is dominated by public sector financial institutions the largest of which are Industrial Credit and Investment Corporation of India (ICICI) and Small Industries Development Bank of India (SIDBI). ICICI and the Andra Pradesh Industrial Development Corporation are the leading biotech funds. Other funds include IL&FS Venture Corporation Ltd., Industrial Development Bank of India (IDBI), and the Industrial Finance Corporation of India (IFCI). There are

[78] This will be in the form of soft loan for up to Rs. 10 Crores. DBT Report (2006).
[79] Meaning the total sum of investments made by companies in the biotech industry.

several other financial agencies with limited funds earmarked for biotech. Morgan Stanley is a private venture capital fund that has been active in funding biotech. However, most venture capital funds have been unwilling to invest in biotech R&D opting rather to fund commercialisation of research already developed.[80]

Human resource development

There have been various efforts by the government to build capacity in biotech. In 1984, NBTB launched short term training programmes to address rising demand for trained personnel in biotech. DBT promotes the development of specialised degrees at various universities at both MSc and PhD level. There are about 50 approved training programmes in various institutions.[81] In addition, there are over 60 institutions set up by the private sector offering degrees and diplomas in biotech.[82] Technician training courses, fellowships for students to go abroad, overseas associateships for qualified scientists, lecture series, awards and incentives form an integral part of human resource development in biotech in India.[83]

Table 5: Training in biotech 2003-2004

	No. of institutions	6mnths – 1yr programmes	2 - 3yr programmes	PhD
Msc. Gen Biotech	30		413	
MSc. Agriculture	7		80	
Master in Medical biotech	1		10	
MSc. Marine	2		30	
MSc. Neurosciences	3		25	
MSc. Industrial biotech	1		10	
MSc. Biochemical engineering & biotech	6			110
MSc. Pharmaceutical	1		10	
Post MD./ MSc. Cert in medical biotech	2	9		
PGD genetic engineering & bioprocess development	1	12		
PGD molecular biotech	1	20		
Postdoc course from DBT	3			

Source: DBT report, 2004

In 2003, there was about 160,000 people employed in biotech 39,000 of whom were technical staff.[84] Healthcare had the largest share of employees in 2001 (47%) and in 2003 (53.2%). The share of technical staff in agriculture remained constant at 30.8%

[80] E&Y Report (2002) *supra*.
[81] DBT report (2006) *supra.*
[82] Chaturvedi, S. (2005) *supra,* but no data available.
[83] Awards include the competitive National Bioscience Career Development Awards. There are also special programmes to increase participation of women in science such as the Biotechnology Golden Jubilee Park for Women encouraging women entrepreneurs to take up biotech enterprises.
[84] BCIL (2003) *Directory of Biotechnology Industries and Institutions in India*, BCIL, New Delhi. More recent figures are not available.

in 2001 and 31.3% in 2003. Although this greatly increased from 18.1% to 30.6% in healthcare, agriculture had a greater share of technical staff in both years. Industrial biotech and environmental biotech each accounted for about 9% of technical staff in 2003.

Table 6: Number of employees in biotech 2001, 2003

	2001				2003			
	Total	%	Technical	%	Total	%	Technical	%
Agriculture	15029	24.8	5217	30.8	32623	20.3	12206	31.3
Healthcare	28520	47.1	3066	18.1	85600	53.2	11948	30.6
Environment	66	0.1	30	0.2	6136	3.8	3295	8.5
Industrial	-*	-*	-*	-*	14514	9.0	3335	8.6
Others	16905	27.9	8619	50.9	22026	13.7	8228	21.1
TOTAL	**60520**		**16932**		**160899**		**39012**	

* data unavailable
Source: BCIL 2001, 2003

Synergies and partnerships

The BCIL was set up in 1990 with the aim of providing linkages among research institutions. Its budget comes from various Indian financial institutions as well as private firms. There have been various initiatives aimed at promoting collaboration between various institutions and agencies in the private and public sector some of which are promoted by state governments such as the establishment of biotech parks in Andhra Pradesh,[85] Uttar Pradesh and Karnataka. BT parks offer the infrastructure to facilitate experimentation as well as placing biotech firms in one location thereby creating opportunity to share not only resources but also knowledge culminating in partnerships and collaborations.

Some outstanding examples include CCMB's work with the private sector to develop India's first recombinant DNA vaccine for Hepatitis B.[86] Typically, private firms partner with CCMB by funding a particular project; CCMB does the R&D and the private sector partner handles commercialisation. Other collaborations are between multinational subsidiaries and local companies such as an agreement between Eli Lily and Ranbaxy to market Monsanto's recombinant bovine growth hormone. Of 50 Indian private companies interviewed, there were 53 interactions involving 19 private companies and 27 public institutes. 13 companies had interactions with more than one public institute.[87]

In bioinformatics, the US accounts for about 65% of India's IT exports.[88] Indian companies are looking to leverage data mining and data warehousing with some

[85] The SP Biotech Park is a joint venture between Shapoorji Pallonji & Co. Ltd. and the Andhra Pradesh government. The latter contributed 140 acres of land and owns 11% of the shares. There is also a Knowledge Park in Hyderabad, a joint venture between the state government and ICICI. It sits on 200 acres of land and its primary focus is life sciences. The BT Park and the Knowledge Park form part of a larger blue print of the Genome Valley Project
[86] With Shantha Biotechnics Ltd in Hyderabad, E&Y Report
[87] French Embassy Study, *supra.*
[88] Ernst & Young (2002) *supra.*

considering establishing subsidiaries abroad and using these to nurture business relationships.[89]

Administration and legislative policy

Diversity of agencies characterise regulation of biotech in India; regulation is spread through four ministries - Health, Agriculture, Science and Technology and Human Resource and Development – and over eight agencies within the ministries.

The Indian Patent Act of 1970 as amended does not define 'micro-organism' and does not allow for patenting of plant or animal varieties; it however allows for the patenting of biotech processes. India established biosafety guidelines in 1989 and has Biosafety and Recombinant DNA Guidelines (1990) which fall under the Environment (Protection) Act of 1986. The Guidelines for Biomedical Research were drawn up in 2000.

India does not have a national biotechnology policy but some state governments such as Maharashtra, Andra Pradesh, Karnataka, Tamil Nadu and Gujarat have developed biotech policies at state level and established specific institutions to oversee biotech within the respective states.[90] The central government is in the process of developing a national 10year strategy and action plan which is currently in draft form. The draft biotech strategy broadly reflects that in the IT industry

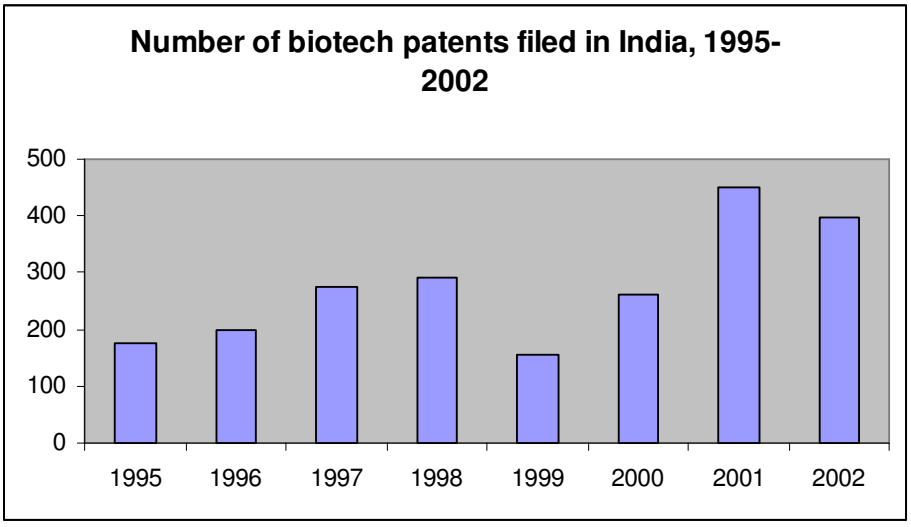
Output

The biotech industry generated USD 1.07 billion in the 2005-2006 fiscal year recording a growth of 36.55%.[91] The number of scientific articles by Indian scientists rose significantly in the same period.[92]

The Technology Information Forecasting and Assessment Council (TIFAC), the National Research Development Corporation and the various patent offices are charged with the responsibility of managing patent data. None of these uses International Patent Classification therefore, while there is data available on overall number of patents applied for and granted, it is difficult to establish which of those relate to biotech. This notwithstanding, Figures from TIFAC estimate that there were about 2300 biotech patent applications filed in India.

[89] Perhaps following the example set by Dr. Reddy's Lab which is listed on the New York Stock Exchange.
[90] Some state governments have gone further to encourage innovation in biotech. In Andhra Pradesh, companies enjoy a sales tax of only 1% on biotech products produced within the state.
[91] DBT Report 2006 *supra.*
[92] Ibid. There was also an increase in the number of publications by DBT's autonomous institutions.

Figure 1: No. of biotech patents filed in India 1995 – 2002



Source: TIFAC, 2003

Conclusion

Framework and strategy for regulating biotech in India borrows heavily from that in the IT sector. The biotech sector faces difficulty owing to the complex nature of administration. State efforts are not coordinated as states compete with each other to become the most attractive location for biotech investment. Nevertheless, there are efforts aimed at streamlining the institutional environment. There is considerable investment in academic and industry infrastructure as well as human resource development resulting in an impressive national network of research institutions with immense potential for growth.

Innovation in biotech in India ranges from highly intensive R&D such as the *Relicord*, a product of human stem cell research developed by Reliance Life Sciences[93] to creative imitation which forms the basis of the Indian pharmaceutical industry. India is both one of the largest market for generic drugs and its pharmaceutical industry is the world's largest exporter of generic drugs, a role soon to change given recent amendments of the Indian Patent Act to conform to TRIPS requirements.

The difficulty in biotech data collection and the disparity in the data available make comprehensive analysis of the biotech environment difficult. Various studies have attempted to address this with limited success. There is no common definition of biotechnology which means that the scope of companies from which biotech data is obtained differs across various studies.

[93] Reliance Life Sciences (2006) *Stem Cell Enriched Cord Blood Repository*. Available at http://www.relbio.com/html/sc_bloodrepository.html

7. ANALYTICAL PRESENTATION OF THE FLEXIBILITIES OF TRIPS ARTICLE 27.3(b)

As indicated earlier, two types of flexibility exist in Article 27.3(b). These are (i) the optional subject matter exceptions, and (ii) the possibility to define the terms in a variety of ways. This part of the report discusses the potential interpretations of Article 27.3(b) of the TRIPS Agreement and their implications for the development of biotechnology. In order to do so the following approach is adopted. An overview of the TRIPS Agreement and Article 27.3(b) addresses the possible interpretations by identifying flexibilities or ambiguities based on the architecture of the article as such, an analysis of the terms under the scientific language, the various legal interpretations and their practical industrial or technological implications. It lays out the various stakes of such article, the reasoning behind the wording, and the precise and practical understanding of the terms.

To illustrate the flexibilities empirically, we also review the way WTO Member States have implemented and applied the wording of Article 27.3(b) in their national law, repeating how terms are interpreted in those implementations. But we start with Article 27.1.

Article 27 of TRIPS

Under Article 27.1 of TRIPS, a list of requirements is set that clarifies what type of innovation ought to be eligible for patent protection:

> […] patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

The implications of Article 27.1 are that, in the context of the application of the TRIPS, Member States shall ensure that a patent regime is available to protect any inventions that fulfil those requirements irrespective of the technology. Thus, under TRIPS, Member States shall not discriminate as to the nature of the technology when assessing patentability.

Whereas any inventions that meet the requirements set under Article 27.1 of TRIPS must be capable of being protected under a patent regime, Article 27 also distinguishes exceptions where this may not be compulsory. Articles 27.2 and 27.3 of TRIPS identify restrictions that, even when the requirements for patentable inventions are met, allow the State to exclude certain subject matter by integrating other stakes. Again, the implementations of those exemptions are not compulsory but left to the discretion of each Member State. There are two types of potential exclusions; the first one characterizes an unwanted effect of applying exclusive commercial rights over certain subject matter, without qualifying which subject matter is susceptible of being excluded.

> […] the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality. Art. 27.2

The second ones specifically exclude certain subject matter:

> […] diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Art. 27.3(a)

Or, and precisely at stake within that report:

> […] plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. Art. 27.3(b)

Article 27.3(b)

Article 27.3(b) starts with the following wording: 'Members may also exclude from patentability'. Again, the TRIPS Agreement does not require or exclude *de facto* the protection of those subject matters, an issue left at the discretion of each Member State. The construction of article 27.3(b) can be divided into two parts:

First, the provision '[…] plants and animals other than micro-organisms' specifies that plants and animals can be excluded as product patents, but such exclusion cannot be extended to microorganisms. Following Article 27.1 TRIPS, it is then required that micro-organisms and any macro-organisms other than plants or animals be patentable subject matter. In addition, at the end of the article is specified that: 'Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof'. Hence, even though Member States do not have to protect plants under their patent regime, plant varieties have to be protected. This can be achieved either under a separate regime held as 'effective' or within the patent law, or by a combination of both.

The second part of the provision addresses issues of process patents, 'essentially biological processes for the production of plants or animals other than non-biological and microbiological processes'. The construction there is more ambiguous. What are potentially excludable from patent protection are essentially biological processes, the definition of which could be understood by the end of the provision, 'other than non-biological and microbiological processes' that leads to the production of plants or animals, and only. Therefore, it can first be understood that non-biological and microbiological processes that lead to the production of plants and animals ought to be capable of being protected. Moreover, it is only when the purpose is for the production of plants and animals, that essentially biological processes can be excluded. Therefore an essentially biological process for the production of anything else than plants or animals is required to be capable of patent protection.

Furthermore, the restriction on 'plants and animals other than micro-organisms' is not being reproduced as the term micro-organism is not being repeated. So, the Member States should have discretion whether patent rights could be provided to essentially biological processes for the production of plants' and animals' micro-organisms, should there be any.

So it appears that the architecture of Article 27(3)(b) provides a certain level of flexibility as to the optional subject matter that is not so explicit and may requires further clarification. Mainly, the lack of clarity of Article 27.3(b) is generated by the terms and associations used that are open to possible different interpretations, thus creating a second level of flexibility of Article 27.3(b), as previously held.

Interpreting the terms of TRIPS

Articles 31 and 32 of the Vienna Convention on the Law of Treaties provide that the terms should be interpreted 'in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose'.

What should be understood as the ordinary meaning could be an accepted definition, as generally found in dictionary. Meanwhile, such definitions might lack precision and create some grey areas. When those areas become positioned over issues of importance then the interpretation of the terms will need further investigation.

A further means of interpretation lies in the intention of the parties to the agreement. Again, the TRIPS Agreement was enacted in order to increase trade harmonization by focusing on standardising IPR amongst its signatory States. Substantive variations in the way the terms are being interpreted could have the consequence of compartmenting the global market, hence would run counter to the intentions of the TRIPS.

As identified by the Vienna Convention, the interpretation should also be made in the light of the object and purpose of the Treaty, which identify a third level of interpretation. The object and purpose of the TRIPS Agreement are to set minimum standards of IPR. In that sense, it is not required that Members include within their laws level of protection above the minimum. The effort of harmonization is only required to the level of those standards, more extensive protection being left at the discretion of the Member.[94] Hence, the extent to which interpretation should be made by confronting other Members' law should be restricted within the minimum standard identified by the TRIPS. Meanwhile, it is obliged that Members incorporate within their laws those minimum standards. In that sense, Article 27.3(b), which is an exception, should be construed narrowly.

Finally, it is under the competence of the WTO Dispute Settlement Body to interpret TRIPS.[95]

Interpretations of the terms of Article 27.3(b) of TRIPS

Article 27.3(b) defines boundaries in disclosing subject matter that might be excluded while providing restrictions on the interpretation made of such subject matter. Thus, whereas the terms might be interpreted alone, their real meaning has to be in conjunction with the other terms they are associated with.

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[94] Leskien, D. and M. Flitner (1997) *Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System,* Issues in Genetic Resources No 6, IPGRI, June 1997.
[95] Art. 64(1) of TRIPS.

Table 1: Biotech patenting in TRIPS: what must be provided and what may not be

MUST PROVIDE	MAY EXCLUDE	UNMENTIONED
1. Microorganisms 3. Microbiological processes 4. Non-biological processes 6. Plant varieties (either by patents or by an effective *sui generis* system or by any combination thereof)	2. Animals and plants (including plant varieties) 5. Essentially biological processes for the production of plants or animals	7. Genes

1. Microorganisms

Microorganism refers to organisms that are not visible by the naked eye, which should be in the range or 10^{-5} m maximum size.[96] The term organism means a complex adaptive system of organs that influence each other in such a way that they function as a more or less stable whole and have properties of life. Generally, plant cells are in the range of 10^{-4}m, 10^{-5} m for animal cells, 10^{-6} m for bacteria or archaebacteria, and even less for viruses. Thus microorganisms are single cell organisms, which are most commonly bacteria or archaebacteria. Viruses are not normally classed as organisms.

As emphasised by the US[97] in a communication to the WTO, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms does not provide a definition for microorganisms; nor does TRIPS or the WIPO Committee of Experts on Biotechnological Inventions and Industrial Property. The reason could be found in a document prepared jointly by the European Patent Office, the Japanese Patent Office and the US Patent and Trademark Office[98] that held:

> None of the laws administered by any of the Offices contains a formal definition of the term 'micro-organism'. Where definitions are used in either classification, definitions or administrative guidelines, the term is defined as a non-exclusive list of organisms which are included within the scope of that term. As noted by the EPO, it does not seem expedient to introduce such a definition as the rapid evolution in the field of microbiology would necessitate its frequent updating.

The USA communication then based their definition of microorganisms, if any, as 'an organism not visible to the naked eye, e.g. bacterium or virus'[99], which should be sufficient in their view to distinguish them from plants and animals.

[96] a doubt is generally 10^{-4} m.
[97] IP/C/W/209 WTO
[98] Comparative Study of Patent Practices in the Field of Biotechnology Related Mainly to Microbiological Inventions, 1988.
[99] Oxford Dictionary of Current English.

Brazil[100] also disputed the necessity to clarify the definition of microorganisms. This was motivated by concerns about broad patents on microorganisms, where issues of novelty, inventive step and industrial applicability were at stake, as well as potential conflict with the Convention on Biological Diversity (CBD). While those two issues have real existence and practical implications, they are not as such related to the implication of Article 27.3(b). Those are matters of basic requirements for patentability and procedures, but not issues of subject matter exclusion as such. In addition, Article 27.3(b) is articulated in such a way that it provides the possibility for Member States to integrate in their patent regime certain exclusions, rather than actually requiring them. Hence, it seems inappropriate for it to serve as a lever against those practices. Consequently it appears that the lack of a more specific definition of microorganisms under Article 27.3(b) is not problematic as to the identification of the subject matter, but as to the consequence of protecting certain type of microorganisms.

Brazil's patent legislation excludes from patentability all or parts of plants and animals, except transgenic micro-organisms that satisfy the three requirements of patentability. For the purpose of this law, transgenic micro-organisms, except for all or part of plants and animals, that express, by means of direct human intervention in their genetic composition, a characteristic normally not attainable by the species under natural conditions.[101]

An African Group communication to the WTO[102] was divergent. It argued that the distinction made did not have any scientific reasoning and its interpretation focused on the exclusion of life forms in general.

In Europe and Japan, the term is understood extremely broadly. According to the European Patent Office microorganism 'includes not only bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plant cells, i.e. all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory. Plasmids and viruses are also considered to fall under this definition.' Similarly, for the Japan Patent Office microorganism includes 'yeasts, moulds, mushrooms, bacteria, actinomycetes, unicellular algae, viruses, protozoa, etc.' and also 'undifferentiated animal or plant cells as well as animal or plant tissue cultures'.

2. Animals and plants (including plant varieties)

The science of taxonomy has evolved over the ages offering an understanding of the linkages within the natural world. While it started with general morphology approach, where appearance was the main factor of distinction, more invasive methods based on cellular biology and genetics provided a more comprehensive and precise picture of the organization of life and its variation.

Until the 1960s, only two kingdoms were usually referred to, namely animals and plants. Protozoa[103] and bacteria,[104] being known at that time, were respectively

[100] IP/C/W/228 WTO
[101] Law No 9,279, 1996, article 18, II.
[102] IP/C/W/163 WTO

included in the animal and plant kingdoms. While this distinction mainly opposed what is called primary and secondary producers[105] and could easily be distinctive of plants and animals at macroscopic level, it was too limiting at the microscopic level. Indeed, more in depth research on the microscopic world revealed life forms that were more differentiated between them than any possible differentiation between plants and animals. In 1959, R. H. Whittaker replaced the two kingdoms with five: Animalia, Plantae, Fungi, Protista and Monera.

The progress of modern genetics affected further our perception of nature's organization. Instead of five kingdoms, it is now three domains that are being differentiated, within which over a dozen kingdoms have been recognized. The main distinction then is not really a matter of size, but is held within the microscopic world. The three domains known as Eukarya,[106] Eubacteria[107] and Archaea,[108] are mainly distinct by their biochemical capabilities, cell structure, and obviously gene sequences. The plant and animal kingdoms are part of the Eukarya.

Two main issues arise from those distinctions; first, plants and animals are only a tiny fraction of the living world in term of diversity. Second, the visual distinction between micro-organism and macro-organism is not representative of fundamental differences or capabilities, i.e. most of the characteristics of life are held within the microscopic world.

A general definition of the plant and animal kingdoms would be:

- *Plant Kingdom*: Members of this kingdom grow out of inorganic material by photosynthesis. They lack ability to move around their environment except by growing or being transported by wind, water, or external forces. They comprise mosses, ferns, woody and non-woody flowering plants.
- *Animal Kingdom*: Organisms that ingest food instead of absorbing or photosynthesizing it. They also have their own means of locomotion in at least one phase of their life cycle. They comprise sponges, worms, insects, fish, amphibians, reptiles, birds and mammals.

In a strict scientific interpretation, 'plants and animals other than micro-organisms' means that only specimens within the plant and animal kingdoms that are visible to the eye are potentially excludable from patent protection. Based on the definitions of plants and animals provided above and repeating the fact that plant cells are in the range of 10^{-4} m and 10^{-5} m for animal cells, they can thus not be classed as microorganisms. Hence, the restriction within the plants and animals exclusion of

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[103] Micro-organisms with a cellular nucleus

[104] Micro-organisms originally identified by the lack of cellular nucleus

[105] This distinction refers to the capacity of plant in creating organic matter from inorganic matter, hence positioned at the beginning of the food chain, compared to animal that require organic matter to develop, thus occupying the second position in the food chain.

[106] An organism consisting of a cell or cells in which the genetic material is DNA in the form of chromosomes contained within a distinct nucleus (that is, all living organisms other than the bacteria and archaea). Concise Oxford English Dictionary

[107] A large group of bacteria with simple cells and rigid cell walls, comprising the 'true' bacteria and cyanobacteria as distinct from archaea. Concise Oxford English Dictionary

[108] Microorganisms which are similar to bacteria in size and simplicity of structure but constitute an ancient group intermediate between the bacteria and eukaryotes. Concise Oxford English Dictionary

microorganisms does not seem to have any scientific relevance, unless one is considering a different approach.

If we have to give a meaning to the opposition between plant and animals, and microorganisms, apart from the requirement that microorganisms be patentable subject matter, such distinction may call for an older interpretation of the meaning of those terms. The USPTO includes in their definition of plants other organisms such as algae and macro fungi.[109] Under a strict definition, such macro-organisms are not part of the plant or animal kingdoms.

Another approach to distinguishing between plants and animals, and microorganisms may also be considered under the term 'organism'. Thus, the use of the term 'microorganism' in opposition to plants and animals could induce the requirement that only plant and animal organisms are susceptible of being excluded. While this interpretation makes no sense scientifically, it might have some practical consequences. The term organism means a complex adaptive system of organs that influence each other in such a way that they function as a more or less stable whole and have properties of life. Plants and animals are organisms when taken as a whole. Should part of a plant or an animal be considered as plant or animal in the sense of the exclusion? Following the definition of an organism, it should be assumed that only part of a plant or an animal that is capable of propagation or development could be excluded. Hence, a gene originating from an animal or a plant cannot be considered as plants and animals, and should be capable of being patented. Whether a plant's or animal's cell including such gene must be patentable is then unclear. In addition, the question could be raised in the case of cell cultures. While they might have the capabilities to a certain extent of propagation and development, are they plants or animals within the meaning of Article 27.3(b)? What would be the situation with stem cells? Those cultures grow identical cells that tend to be independent from each other, hence might fall within the definition of a microorganism. While those distinctions are not important for agricultural activities, they could be much more sensitive in the research aspect of biotechnology as such.

The exclusion of plants and animals seems to derive from the EPO approach. The Strasbourg Convention, 1963, which originated the Munich Convention (EPC), was concerned with the potential consequences of patent rights over certain breeding and farming activities, hence the exclusion of plant and animal variety as such under the EPC. The recent development in breeding activities is advocating the limited efficiency of the EPO approach. Indeed, it is of concern now that biotechnology allows circumventing the exclusion of plants and animals under the EPC, while their development is illustrating the current trend in breeding development. TRIPS provides a broader potential exclusion as it is not limited to varieties, hence it appears to be more integrative of new technologies toward the purpose of potentially excluding a patent regime that would affect breeding activities at large. While the distinction between microorganisms and plants or animals seems rather straightforward as to the purpose of the exclusion in the light of the final outcome, its implications becomes more problematic as to the technology behind breeding activities, as held above with biotechnology activity at the level of cells.

[109] USPTO guidelines

3. Microbiological processes

Microbiological processes in a literal translation should stand for any processes that are being carried out by microorganisms. It does not make much sense scientifically to differentiate between macroorganism and microorganism in their biological activity as most of the complexity is held within the micro realm and is usually not categorized based on such considerations. To put it another way, the most fundamental biological processes are already achieved by microorganisms. Therefore, biological processes other than microbiological processes, in that context, should be understood as processes that could only occur in plants and animals, which should be highly dependant to matter relating to the size. Thus it identifies a subset of biological processes that are macro-biological processes.

On the contrary, in the industry, the interpretation of the terms microbiological processes is focused on microorganisms in opposition to organisms at large. Thus, under such approach, microbiological processes are restricted to those that are specific to microorganisms and not to be found in other organisms. Hence, processes that are shared by all life forms, such as the synthesis of proteins, should then be included as biological processes. This approach adopts a different logic. In fact micro and macro biological processes are a subset of biological processes, thus one can oppose that the distinction between biological and microbiological processes ensures that only processes that exclusively occur in microorganisms shall be considered as patentable subject matter, the rest being left at the discretion of the Member State.

The African Group in a communication to the WTO[110] went even further. It opposed that microbiological processes should be potentially excludable as they were in essence biological processes. While this is scientifically true, again microbiological process are a subset of biological process, the way Article 27.3(b) is worded does not lead to such an interpretation. Hence, it is not held that biological processes at large should be potentially excluded, but those that are not microbiological, thus a distinction is created within the wording.

Thus it appears that a very different approach might be taken depending on which aspect of the definition we are focusing on. If microbiological is opposed to biological, then only processes exclusive to microorganisms will be at stake. On the contrary if the definition assumes a large interpretation of the term microbiological process, then only biological processes that are not found in microorganisms are potentially excludable, thus processes that are exclusive to macro-organisms.

It has to be noted that the purpose of the TRIPS Agreement is to promote the protection of intellectual property rights, patents in the present context. Consequently, such objective may enforce the fact that restriction may have to be interpreted in a narrow manner. This approach would favour the first interpretation that we made, which is that only processes that occur in macro-organisms may be excluded. In addition, such exclusion seems to derive from the EPC approach. The Strasbourg Convention, 1963, which originated the Munich Convention (EPC), was concerned with the potential consequences of patent rights over certain breeding and farming activities, thus focusing on processes that related to such practices.

[110] IP/C/W/163 WTO

4. Non-biological processes for the production of plants and animals

Biological processes are defined as any processes that occur within and by the activity of living organisms. Non-biological processes are thus any processes that are not biological processes, being those that are not accomplished as such under natural conditions. In other terms, non-biological process will include any processes that require the action of man at a certain stage to create their occurrence. It may encompass propagation by cutting, hybridization, genetic engineering and so on.

5. Essentially biological processes for the production of plants or animals

What are potentially excludable from patent protection are essentially biological processes, the definition of which could be understood by the end of the provision, 'other than non-biological and microbiological processes' that leads to the production of plants or animals.

Therefore, it can first be appreciated that non-biological and microbiological processes shall be patentable subject matter, which includes those that lead to the production of plants and animals. Thus, whereas the wording under Article 27.3(b) may permit plants and animals to be excluded as patentable subject matter, certain processes for the production of plants and animals, especially those employed in biotechnology, shall be considered as patentable subject matter. Moreover, it is only when the purpose is for the production of plants and animals, that essentially biological processes can be excluded. Therefore an essentially biological process for the production of anything else than plants or animals is required to be capable of patent protection, as long as the requirement for patentability are met.

Again, biological processes are defined as any processes that are occurring within and by the activity of living organisms. The opposition with non-biological processes and microbiological processes seems confusing scientifically, as explicated above, but the purpose of the TRIPS Agreement as well as some of the basis for such provision seems to restrict the nature of those processes to those that can only be witnessed in macro-organisms or strictly plants and animals.

The use of the term 'essentially' holds no specific scientific meaning in that context and is only a matter of legal interpretation. It is used so as to include a legal qualitative criterion on how the exclusion should be operated. Thus, it introduces a qualitative degree on the interpretation of the exclusion. Instead of an absolute excludable subject matter, this should be understood under a substantive and qualitative approach. In other terms, if a set of processes, or a single multi-step process, which leads to the production of a plant includes a step that is biological, the exclusion should only be effective if the step is viewed as substantively essential. What makes a step substantially essential is undefined.

The possible exclusion of essentially biological processes is restricted under 'the production of plants and animals' in general. Therefore, the processes are being potentially excludable where they are in relation to the genesis of plants or animals, those should include means of selection, breeding, reproduction, propagation, regeneration and so on. Hence, it is mainly processes of propagation at large and

selection from existing material that are excluded. It is the mechanistic processes that are at stake, while the acquired traits of the organism are not. While plants and animals might be excluded, a process that is not included in the definition provided above cannot. In practical terms, this means that a process to insert a gene of interest in a plant, for example, can be patented. But if the exclusion under patent protection for plants and animals is held, the product of such process, the new plant, cannot be enforced under a patent regime. IPR will then regulate the breeding activity rather than the agricultural practice, unless one utilizes a technological lock, such as the terminator gene.

But it could be interpreted differently. Indeed, the point of view could be from the outcome in addition to the mechanistic approach to the development. The production of plants and animals would then embrace the organism at its final stage. Under that interpretation, every process that permitted such outcome will be potentially excludable. The focus there will be as to how the acquired traits are biological processes without being a microbiological process. In that case, the inclusion of a gene that originates from another macroorganism, being a feature not present in microorganism, could be excludable. An example could be the case of basmati rice. The identification of the gene that leads to the specific fragrance of basmati rice and its inclusion within another macroorganism could be excludable. Indeed, it is a macro-biological process that leads to the production of another macroorganism by being inserted within the latter. On the contrary, the exclusion of a trait that originated in microorganism would not be permissible. A practical example would be the Bt technology that transmits in plants the capacity of generating a pesticide compound which originated in a microorganisms.

The most general interpretation of the wording would read as: any processes, which are only occurring in macroorganisms, to the genesis of plants and animals in general (both macro and micro[111]), are potentially excludable from patent protection; the restriction being limited under a legal qualitative criterion. In other terms, what is being restricted are breeding methods, in a broader sense, that occur naturally in plants and animals.

Under the EPC, 'a process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection'.[112] It has to be opposed with what is not 'biological' in that legal definition, which are microbiological and non-biological processes. Microbiological processes are 'any process involving or performed upon or resulting in microbiological material'.[113] Non-biological processes are generally not specified as such, but seem to relate to those that are not occurring in nature. Hence, it appears that the EPC interpretation is specifically in line with the literal interpretation made previously.

The key question arises in the interpretation of the term 'essentially'. For a process to be essentially biological in the sense of the exclusion it requires that the substantial part of the claimed process is not within that exclusion. Hence, the fact that a process, which generally includes different steps, has one of its steps included in the restriction

[111] In that case, the problem encountered before with cell cultures will not occur, as no distinction is made as to the resulting plant and animal size.
[112] Rule 23(b)(5) EPC
[113] Rule 23(b)(6) EPC

must not in itself be a sufficient ground for exclusion. Meanwhile, the fact that one of the steps is either a microbiological process or a non-biological process will not make *de facto* the whole process capable of being patented. Under the EPC, one should take into account the totality of human intervention. For a process not to be an essentially biological process it will necessitate human intervention as to its capability of occurrence and the intervention should be viewed as non-trivial.[114] In a famous landmark decision of the EPO,[115] the Board analyzed each technical step to assess the level of human intervention as to the outcome. Hence, the term 'essentially' should address certain discretion as to the patentability of the process, which will balance the various aspects of the process under the assessment of what appears substantial as to the outcome.

It appears that the distinction made under Article 27.3(b) is again to provide means to exclude, as patent subject matter, processes that are being used traditionally in breeding activities rather than non-traditional biotechnological processes as increasingly used in technologically advanced countries. All legal systems so far reviewed in this study seem to be concerned with basic breeding activities and appear to interpret those terms as restricting the potentially excludable subject matter to those that relate to means of reproduction or selection. Nevertheless, the distinction made previously under the scientific interpretation[116] of the terms could hold under the TRIPS and address substantial effect as to the patentability of biotechnology breeding activities.

7. Plant and animal varieties

The scientific approach is not very conclusive in providing a straight definition as to what a plant variety is. In botany, the following distinctions have been identified: species, subspecies, varieties, subvarieties, forms, groups and cultivars.

A species is constituted of members that are capable of interbreeding (the offspring is not sterile). A subspecies is the taxon immediately subordinate to species, which therefore has the same quality amongst its members as the one identified by a species plus another level of distinction. Its members differ morphologically and genetically from members of other subspecies. Varieties are normally mistaken with subspecies; they are used for lower degrees of distinction, if needed. A form is used to designate a minor variation within a population or region. For instance, white-flowered forms of species that usually have coloured flowers. Finally, a cultivar is a cultivated selection of a plant species that is vegetatively propagated, i.e. a clone, which means that its genetic pool is not affected by sexual reproduction. A good example would be a hybrid.

So it appears from the basic scientific approach that a plant variety is something between a subspecies, which is a group having a certain extent of distinctive morphological and genetic characteristics that are being reproduced within the group, which is theoretically capable of interbreeding with other subspecies, and a form,

[114] EPO, Technical Board of Appeal, T 320/87
[115] Plant Transgenic Systems, EPO, Technical Board of Appeal, T 356/93
[116] Distinction made between the mechanistic approach to the production of plants and animals, and the process involved in the obtaining of certain traits of interest in the outcome

which holds all those features, but where the distinctive aspect is limited to one characteristic.

While varieties can be differentiated based on the occurrence in nature and the various levels of distinction, the term has also evolved responding to the practice of the breeding activity. Hence, based on the mode of reproduction, the means of selection and the stability of the created variety, a necessity in that field, more functional definitions were made.[117] A*utogamous fixed varieties in pure lineage* (wheat, green beans, soy, tomatoes…) are highly homogenous and easy to reproduce identically. *Autogamous fixed varieties* (eggplant, courgette, chilli…) are slightly less stable over reproduction cycles, but still acceptable. *Allogamous homogenized fixed varieties* (carrots, onions, cabbage…) originate from more heterogeneous populations and are generally selected for a specific trait. *Hybrid varieties of first generation* (wheat, colza, melon…) where the parents are fixed or pure lineage; hence have an inherent stability. *Hybrid varieties of second generation* are those where the first generation is not stable enough and requires another crossing to gain in stability. *Clone varieties* (tulip, iris, rosemary, apple and peer trees, wine, potatoes…) are reproduced asexually, therefore are extremely homogenous unless mutations occur. The list is non-exhaustive but is mentioned to illustrate the complexity of the term.

So, depending on the purpose for differentiating living specimens, the term can be used differently and lead to various interpretations. While considering occurring varieties, naturalists will focus on an inherent cluster of biodiversity, distinguishing factions that present certain characteristics in common. Dissimilarly, a breeder will be concerned with the creation of new stable specimens. Whereas the acquired features of the new variety are obviously the purpose of such activity, the distinction is based on the stability of the creation rather than on a comparative analysis amongst the diverse variability and clusters that could be found in the species in question.

Missing a clear cut definition of variety, two potential interpretations can be made for the requirement under Article 27.3(b) for a *sui generis* protection for plant varieties. On the one hand, because of the position of variety in the taxonomy, the general scientific definition, one could argue that TRIPS does not require the protection of anything that is above or below the variety, i.e. subspecies, form and cultivar for example. On the other hand, under the breeder's definition, a variety is an entity that is below the taxon of species, presents certain different features and can be reproduced in a more or less stable manner. Hence, everything that corresponds to those criteria should be capable of being protected either under a patent regime or an effective *sui generis* system.

The International Convention for the Protection of New Varieties of Plants, which is administered by the UPOV,[118] defines the term variety as follows:[119]

[117] Group on Study and Control Variety, www.geves.fr
[118] Union pour la Protection des Obtentions Végétales
[119] International Convention for the Protection of New Varieties of Plants of December 2, 1961, as revised in Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991, (commonly referenced as the UPOV 1991), Chapter I, Article 1(vi)

> *'Plant variety' means any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:*
> - *defined by the expression of the characteristics that results from a given genotype or combination of genotypes,*
> - *distinguished from any other plant grouping by the expression of at least one of the said characteristics, and*
> - *considered as a unit with regard to its suitability for being propagated unchanged.*

This definition is reproduced literally in the Council Regulation (EC) No 2100/94 of 27 July 1994 on Community Plant Variety Rights, Chapter I article 5.2, as well as under the Implementing Regulations to the Convention on the Grant of European Patents, Chapter VI Rule 23b.

An 'effective' *sui generis* protection for plant varieties was defined in the following terms by the USA communication to the WTO:[120]

> Any law establishing rights in property, whether of real, tangible or intangible property, including the various forms of intellectual property, must have certain characteristics if it is to be effective. Nature of the subject matter must be identified in the law clearly enough to enable those concerned to distinguish what falls within the scope of the law from what is beyond that scope. Must defines the characteristics or qualities that particular subject-matter must possess to qualify for protection. Must also establish who is entitled to obtain property rights in particular subject matter, if particular procedures must be followed to obtain rights in particular subject matter and fees, if any limitations are to apply to these legal rights, and the period during which the rights are in force and the circumstances. Finally the legal actions available to the right holder to enforce its rights and the circumstances in which those actions may be taken must also be spelled out and so on….

The UPOV standard seems to provide a sufficient system in that sense. It is not an ambit of this paper to address the way different Member States have implemented such requirement, thus we shall not consider this issue further.

Animal varieties are generally defined in science as a subgroup of species. Therefore they are theoretically capable of reproduction with other subgroup, but are differentiated with a set of characteristics that appears somehow reproduced within the same subgroup. A good example would be a dog pedigree. The distinction between animal and animal varieties is not required under TRIPS but is being provided as it is a matter of exclusion for patentability in certain Member States such as the States signatory to the European Patent Convention.

7. Genes

Genes are obviously of central importance to the development and value of biotechnology. The core aspect of biotechnology is to engineer new organisms that

[120] IP/C/W/209 WTO

incorporate certain traits of interest, traits that are the function of gene expression or non expression. Article 27.3(b) of TRIPS does not mention as such the term gene in the possible exclusions. Thus under a first appreciation, genes must be capable of being patented, reflecting the implications of Article 27.1 of TRIPS. Following the development made above, it seems that under certain interpretations, the term gene might be implied or capable of being incorporated in some of the exclusions.

They can be simply defined as 'unit of heredity which is transferred from a parent to offspring and is held to determine some characteristic of the offspring; in particular, a distinct sequence of DNA forming part of a chromosome'.[121] Thus, by definition, they are parts of any organisms and are involved in determining the characteristics of an organisms, thus their expression have a biological role.

Under Article 27.3(b), plants and animals may be excluded from being patentable subject matter. The question may be raised as to the implications of the terms plants and animals. Are they to be conceived as whole organisms, or can the exclusion apply to parts of them? Under the later approach, genes could then potentially be excluded under Article 27.3(b) TRIPS. On the issue whether a plant or an animal has to be considered as a whole to be excluded, it seems that more restrictive legislations will be specific in the wording of their exclusion rather than including those concerns within a definition.[122] Genes, under the EPO, JPO, USPTO are not considered as life forms but rather as chemical compounds, however even if they were, those patent regime are not excluding life forms as such. It is also interesting to note that under Article 5.3 of the same Council Regulation (EC) No 2100/94 is held that

> A plant grouping consists of entire plants or parts of plants as far as such parts are capable of producing entire plants, both referred to hereinafter as 'variety constituents'

Thus, it seems that under such regulation, the distinction as such between whole or parts is irrelevant; what matters is whether the subject matter is capable of producing an entire plant. This would be in line with the original reasoning behind such exception, which is to free certain breeding activity from patent protection. In the meantime, it is to be noted that breeding activity has evolved and is now deeply involved with technology based on the use of specific genes, thus it might still be implied in the purpose of the exclusion while adapting to modern technology.

In addition, also considered above, genes are the informational bases that define the characteristics of an organism. The information encoded is generally translated to proteins, which have a biological role. Thus a gene as such is what governs most biological processes. So, whereas a gene as such, being a product, may not be excluded as an essentially biological process, the use made of the gene could; especially when such traits is being selected from another plant or animal.

Review of the terms

[121] Concise Oxford English Dictionary
[122] Andean Community Decision 486, Brazilian Patent Act, Indian Patent Act.

Plant: Organisms that grow out of inorganic material by photosynthesis. They lack ability to move around their environment except by growing or being transported by wind, water, or external forces. They comprise: mosses, ferns, woody and non-woody flowering plants.

Animal: Organisms that ingest food instead of absorbing or photosynthesizing it. They also have their own means of locomotion in at least one phase of their life cycle. They comprise: Sponges, worms, insects, fish, amphibians, reptiles, birds and mammals.

Organism: a complex adaptive system of organs that influence each other in such a way that they function as a more or less stable whole and have properties of life.

Microorganism: Any organism that cannot be seen by the naked eye, generally in the range of 10^{-5} m.

Variety: Any of various groups of plants or animals within a species that is distinguished from other groups by characteristics not constant enough or too trivial to distinguish species.[123]

Essentially: To be defined legally

Biological process: Any process that results from the activity of a life form.

Micro-biological process: Any process that results from the activity of a life form when said life form is a micro-organism.

Non-biological processes: Any process that requires the intervention of man.

[123] Britannica Webster. Encyclopaedia Britannica

8. TOWARDS OPTIMAL PRO-BIOTECH PATENT REGIMES

So can we rank developing countries according to their biotechnological capacities?

Are we capable of measuring and thereby ranking the biotechnological capacities of different developing countries so as to determine the most efficient way countries should take advantage of the flexibilities of Article 27.3(b) of TRIPS? Earlier discussion particularly in Chapter 3 would suggest that this is a difficult thing to do since no 100% reliable schemas or indices have yet been devised, certainly not the ones we reviewed earlier which comprise all of the well-known ones. Needless to say perhaps, such a task is possible but requires further research.

The three developing countries that we looked at are widely acknowledged to be among the more advanced developing countries in terms of biotech capacity and potential, especially India. Indeed, India's biotech sector stands apart from almost every other developing country in its size and potential. Yet even here, the ability of India's commercial biotechnology sector to take advantage of the patent system is still quite limited at this time.

As for attracting FDI, India is becoming more successful with life science corporations setting up research and development facilities in the country. Since India's patent system is still considered by many transnational corporations to be inadequate, the existence of a large number of well-qualified and inexpensive-to-hire Indians able to do the research and the enormous growth potential of such a high-population market are likely to be far more significant factors than the patent regime how ever it may be designed. That is not to say that a more expansive patent regime would not necessarily spur accelerated biotech research-oriented FDI. We have no evidence to counter such a scenario, and therefore cannot rule it out. Nonetheless the growth of such investment has so far not been directly influenced by changes to the patent regime and has more to do with the relative cheapness of doing high quality research in India compared to Europe and North America.

The implementation menu

Regulating biotechnology, a new, complex, expensive, research-intensive and rapidly advancing field presents particular challenges for developing country policymakers. If they lack a clear idea of how – and even whether – biotechnology can benefit their economies and improve the lives of their citizens, they are in no position to design a patent system to promote welfare-enhancing biotechnological innovation. Moreover, many of these countries have no biotechnology industries to speak of, and there is every reason to be highly sceptical that such businesses will spring up just because life-forms and micro- and non-biological processes can be patented. And yet, they have obligations under international IP law to provide patent protection for at least some types of biotechnological invention. What is a developing country government to do?

On the basis of what we have covered so far, we present three different ways to implement Article 27.3(b). Option 1 (Table 1) we call the 'no exceptions option'. This

more or less reflects US practice and is unlikely to be optimal for any developing country.

Table 1: Biotech patenting in TRIPS: the 'no exceptions option'

PROVIDE
Microorganisms (broadly defined) Animals and plants (including plant varieties by patents and an effective *sui generis* system) and their parts including seeds, somatic cells, gametes, cells, genes Non-biological processes Essentially micro- and macro biological processes Plant varieties also (either by patents or by or by any combination thereof)

Option 2 (Table 2) is the 'all exceptions option' which incorporates all of the exceptions while construing the terminology widely or narrowly so that what must be provided is the absolute minimum that is legally acceptable and scientifically reasonable, while as much subject matter as possible is kept outside the patent system.

Table 2: Biotech patenting in TRIPS: the 'all exceptions option'

PROVIDE	EXCLUDE
Microorganisms (narrowly defined, e.g. unicellular organisms in the range of 10^{-5} m maximum size.)	Whole animals and plants (including plant varieties) and their parts including seeds, somatic cells, gametes, genes and gene products
Microbiological processes that are specific to microorganisms	Essentially biological processes for the production of plants or animals (even with substantial human intervention)
Non-biological processes	
Plant varieties (only by an effective *sui generis* system, e.g. modelled on UPOV 1988)	

Option 3 (Table 3) is the 'some exceptions option'. It is not really a single option and the table below aims merely to provide some examples of exclusions and interpretations. Between Options 1 and Options 2 lie a whole range of possibilities between the two extremes, and the table provides just a few of these.

Table 3: Biotech patenting in TRIPS: the 'some exceptions option'

PROVIDE	EXCLUDE
Microorganisms (narrowly defined)	Whole animals and plants
Microbiological processes found in microorganisms that are found in larger organisms too.	Essentially biological processes for the production of plants or animals
Non-biological processes	
Plant varieties (only by an effective *sui generis* system, e.g. modelled on UPOV 1988 or 1991)	
Genes (as chemicals with specified function)	

In this study we have been sceptical about the methods available for assessing the biotechnological capacities of developing countries, and explained why calling for more research in this area and, one hopes, making the case this is vitally important. However our survey of three relatively advanced developing countries highlighted that in this recent and rapidly advancing field of technology most if not all of the developing world lags far behind countries like the United States, Japan and such European countries as the UK, Germany and France. Therefore, and taking into account the work of researchers like Lall and Kim, for the overwhelming majority of developing countries the all exceptions option is for the time being the most rational basis for biotech related patent rulemaking. However for the most advanced of the developing countries which are beginning to innovate and seek to develop their inventions either alone or in collaboration with foreign corporations, some elements of option 2 may now be desirable.

From policytaking to policymaking

Historical evidence shows that well designed IPR systems can benefit national economies just as poorly designed ones can harm them. But how does one go about designing and negotiating an appropriate IPR system or fine-tuning an existing one? The economic and social impact of IPR reform is very hard to predict reliably, especially in the long-term. This is particularly the case for developing countries. This is a real handicap in the present situation where countries are pressured to negotiate and implement new multilateral trade rules, bilateral or regional free trade or investment agreements, and to respond to powerful stakeholder groups – often foreign ones – demanding changes to national regimes that may not serve the interests of their citizens and other domestic stakeholders. Such difficulties in measuring impacts make it difficult for governments and their representatives to know what negotiating position to adopt on IP, how best to handle complex trade issue-linkage bargains, and how far they should accommodate the demands of international business interests clamouring for change to domestic IP rules.

As with other areas of business regulation, IP policymaking and negotiation position formation is, or at least should be, a matter for *national* decision making involving the collaboration of all *national* stakeholders including owners, users and the public. Foreign interests should not be ignored but government business regulation is about what is good for the national economy and the country's citizens. Good policymaking cannot be based solely on the implementation of obligations accepted in multilateral treaties or regional or bilateral trade agreements. Unfortunately, policymaking often seems to be done in this way, which is to say that policy*taking* is the norm rather than policy*making*. What we have here are political and technical challenges. So as to better overcome the challenges, and as Workpackage 4 of the IPDEV project on technical assistance provision concludes, technical assistance providers themselves have much to learn. In the present context, they and others claiming to be authorities on how to design biotech patent regimes sensitive to the specificities of individual countries must provide convincing objective evidence for their prescriptions. And recipient countries must of course demand such evidence.

ANNEX 1
PROTECTION OF ANIMALS UNDER A PATENT REGIME

Countries or Regional Agreements	Patentability of the Subject Matter	Other relevant provisions
EPC Member States	EPC - Art. 53 (b) EPC Exclusion of… plant or animal varieties […] - Rule 23c(b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety; EPC	EPC - Rule 23d(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.
European Union	Directive 98/44/EC - Art 4. 1. The following shall not be patentable: (a) plant and animal varieties; 2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.	Directive 98/44/EC - Preamble (27) Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents; - Preamble (45) Whereas processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit in terms of research, prevention, diagnosis or therapy to man or animal, and also animals resulting from such processes, must be excluded from patentability; - Art 8 1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.
Japan	Patentable, no restrictions	
ARIPO	Patentable, no restrictions	
OAPI	BA – Section 1 - Art 6(c) inventions having as their subject matter plant varieties, animal species and essentially biological processes for the breeding of plants or animals other than microbiological processes and the products of such processes;	No specific exclusions under Utility Model protection
Andean Community	ACD - Art 15. The following shall not be considered inventions: b) Any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germplasm of any living thing; - Art 20 The following shall not be patentable: c) plants, animals, and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes;	ACD - Art 3 The Member Countries shall ensure that the protection granted to intellectual property elements shall be accorded while safeguarding and respecting their biological and genetic heritage, together with the traditional knowledge of their indigenous, African American, or local communities. As a result, the granting of patents on inventions that have been developed on the basis of material obtained from that heritage or that knowledge shall be subordinated to the acquisition of that material in accordance with international, Andean Community, and national law. - Art 53 A patent owner may not exercise the right referred to in the previous article with respect to the following acts: e) where the patent protects biological material that is capable of being reproduced, except for plants, using that material as a basis for obtaining a viable new material, except where the patented material must be used repeatedly to obtain the new material. - Art 54 Where the patent protects biological material that is capable of being reproduced, the patent coverage shall not extend to the biological material that is obtained by means of the reproduction, multiplication, or propagation of the material that was introduced into the commerce as described in the first paragraph, provided that it was necessary to reproduce, multiply, or propagate the material in order to fulfill the purposes for which it was introduced into commerce and that the material so obtained is not used for multiplication or propagation purposes. - Art 82 Processes and materials excluded from patent protection may not be the subject matter of utility model patents.
United States of America	USC Sec 100 Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.	

Canada	No specific restrictions	
Australia	APA- -Patentable, no restrictions for standard patents	APA - Innovation patents: Part 3 Art 18 (1A) (3) For the purposes of an innovation patent, plants and animals, […] are not patentable invention (4) Subsection (3) does not apply if the invention is a microbiological process or a product of such process
Singapore	Patentable, no restrictions	
Brazil	BPA Art 10 The following are not considered to be invention (IX) – natural living beings, in whole or in part. Art. 18 The following are not patentable: (III) living beings, in whole or in part, except transgenic micro-organisms meeting the three patentability requirements […]	
Russian Federation	PLRF Art 4(3) The Following shall not be deemed patentable: plant varieties and animal breeds	PLFR Art 5(1) A technical solution relating to a device shall be protected as utility model. (no further restrictions)
India	IPA Chp II 3 (h) a method of agriculture or horticulture (i)any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products. (j) . plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.	
China	PLC Art 25(4) No patent shall be granted: (4) animals and plant varieties.	
Thailand	PAT Art 9 The following inventions are not protected under this Act (1) naturally occurring organisms and their components, animals, plants or extracts from animals or plants	
Malaysia	MPA Sec 13 (1) the following shall not be patentable (a) Plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organisms, micro-biological processes and the products of such micro-organism processes;	
Indonesia	Patentable, no restrictions	
Philippines	IPCP Sec.22 – Non Patentable inventions: (4) Plant varieties or animal breeds or essentially biological process for the production of plants or animals. This provision shall not apply to micro-organisms and non-biological and microbiological processes.	
Tunisia	TPL Art. 3 Les variétés végétales, les races animales ou les procédés essentiellement biologiques d'obtention de végétaux ou d'animaux. Toutefois, cette disposition ne s'applique pas aux procédés biologiques médicaux et aux produits obtenus par ces procédés;	

ANNEX 2
PROTECTION OF PLANTS UNDER A PATENT REGIME

Countries or Regional Agreements	Extent of patentability	Other relevant provisions	Definitions
EPC Member States	EPC -Art. 53 (b) Exclusion of… plant or animal varieties […] this provision does not apply to microbiological processes or the products thereof. -Rule 23c(b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;		EPC Rule 23b (4) 'Plant variety' means any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be: (a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes, (b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and (c) considered as a unit with regard to its suitability for being propagated unchanged.
European Union	Directive 44/98/EC Art 4 1. The following shall not be patentable: (a) plant and animal varieties; 2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.	Directive 44/98/EC Art 2(2) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection. Art 8 1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics. Preamble(27) Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents; Art 11 1. By way of derogation from Articles 8 and 9, the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94. Preamble(29) Whereas this Directive is without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety;	Directive 44/98/EC (30) Whereas the concept 'plant variety' is defined by the legislation protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore possesses individuality and is clearly distinguishable from other varieties; (31) Whereas a plant grouping which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants; (32) Whereas, however, if an invention consists only in genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability even if the genetic modification is the result not of an essentially biological process but of a biotechnological process;
Japan	Patentable, no restrictions		
ARIPO	Patentable, no restrictions		
OAPI	BA Section 1	No specific exclusion under Utility Models	

	Art. 6(c) inventions having as their subject matter plant varieties, animal species and essentially biological processes for the breeding of plants or animals other than microbiological processes and the products of such processes;	
Andean Community	ACD Art 15 The following shall not be considered inventions: b) Any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing; Art. 20 The following shall not be patentable: c) plants, animals, and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes;	ACD Art 3 The Member Countries shall ensure that the protection granted to intellectual property elements shall be accorded while safeguarding and respecting their biological and genetic heritage, together with the traditional knowledge of their indigenous, African American, or local communities. As a result, the granting of patents on inventions that have been developed on the basis of material obtained from that heritage or that knowledge shall be subordinated to the acquisition of that material in accordance with international, Andean Community, and national law. Art 54 Where the patent protects biological material that is capable of being reproduced, the patent coverage shall not extend to the biological material that is obtained by means of the reproduction, multiplication, or propagation of the material that was introduced into the commerce as described in the first paragraph, provided that it was necessary to reproduce, multiply, or propagate the material in order to fulfill the purposes for which it was introduced into commerce and that the material so obtained is not used for multiplication or propagation purposes. Art. 82 Processes and materials excluded from patent protection may not be the subject matter of utility model patents.
United States of America	No specific restrictions	Plant Patent only relevant to the means of reproduction
Canada	No specific restrictions	
Australia	APA- -Patentable, no restrictions for standard patents - Innovation patents: Part 3 Art. 18 (1A) (3) For the purposes of an innovation patent, plants and animals, […] are not patentable invention (4) Subsection (3) does not apply if the invention is a microbiological process or a product of such process	
Singapore	Patentable, no restrictions	
Brazil	BPA Art. 10 The following are not considered to be invention (IX) – natural living beings, in whole or in part.	BPA Art. 18 The following are not patentable: (III) living beings, in whole or in part, except transgenic micro-organisms meeting the three patentability requirements […]
Costa Rica		
Russian Federation	PLRF Art 4(3) The Following shall not be deemed patentable: plant varieties and animal breeds	PLFR Art. 5 (1) A technical solution relating to a device shall be protected as utility model. (no further restrictions)
India	IPA Chp II 3 (h) a method of agriculture or horticulture (i)any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a	

	similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products. (j) . plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.
China	PLC Art. 25(4) No patent shall be granted: (4) animals and plant varieties.
Thailand	PAT- Art. 9 The following inventions are not protected under this Act (1) naturally occurring organisms and their components, animals, plants or extracts from animals or plants
Malaysia	MPA – Sec. 13 (1) the following shall not be patentable (a) Plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organisms, micro-biological processes and the products of such micro-organism processes;
Indonesia	Patentable, no restrictions
Philippines	IPCP – Sec.22 - Non Patentable inventions: (4) Plant varieties or animal breeds or essentially biological process for the production of plants or animals. This provision shall not apply to micro-organisms and non-biological and microbiological processes.
Tunisia	TPL Art. 3 Les variétés végétales, les races animales ou les procédés essentiellement biologiques d'obtention de végétaux ou d'animaux. Toutefois, cette disposition ne s'applique pas aux procédés biologiques médicaux et aux produits obtenus par ces procédés;

ANNEX 3
ESSENTIALLY BIOLOGICAL PROCESSES FOR THE PRODUCTION OF PLANTS AND ANIMAL

Countries or Regional Agreements	Extent of Patentability	Other relevant provisions	Product originating directly from process	Definitions
EPC Member States	EPC Rule 23b(5) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.	EPC Rule 23d(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.		EPC Rule 23b (5) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection. (6) 'Microbiological process' means any process involving or performed upon or resulting in microbiological material.
European Union	Directive 44/98/EC Art 4. 1. The following shall not be patentable: (b) essentially biological processes for the production of plants or animals.	Directive 44/98/EC Preamble(29) Whereas this Directive is without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety;	Directive 44/98/EC Art. 8(2). The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.	Directive 44/98/EC Art. 2. A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.
Japan	Patentable, no restrictions			
ARIPO	Patentable, no restrictions			
OAPI	BA Section 1 Art. 6(c) inventions having as their subject matter plant varieties, animal species and essentially biological processes for the breeding of plants or animals other than microbiological processes and the products of such processes;	BA Section 2 Utility models are not excluding anything specifically	BA Section 1 Art. 7(3)(b)(ii) engaging in the acts mentioned in subparagraph *(a)* above in relation to a product resulting directly from the use of the process.	
Andean Community	ACD Art. 15.- The following shall not be considered inventions: b) Any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing; Art. 20 The following shall not be patentable:	ACD Art 54 Where the patent protects biological material that is capable of being reproduced, the patent coverage shall not extend to the biological material that is obtained by means of the reproduction, multiplication, or propagation of the material that was introduced into the commerce as described in the first paragraph, provided that it was necessary to reproduce, multiply, or propagate the material in order to fulfill the purposes for which it was introduced into		

	c) plants, animals, and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes;	commerce and that the material so obtained is not used for multiplication or propagation purposes. Art. 82 Processes and materials excluded from patent protection may not be the subject matter of utility model patents.		
United States of America	No specific restrictions			USC 103 (b) (3) For purposes of paragraph (1), the term 'biotechnological process' means-(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to-(i) express an exogenous nucleotide sequence, (ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or (iii) express a specific physiological characteristic not naturally associated with said organism; (B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and (C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).
Canada	CPA Sect. 2 'invention' means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter; (No specific restrictions)			
Australia	APA -Patentable, no restrictions for standard patents - Innovation patents: Part 3 Art. 18 (1A) (3) […] the biological processes for the generation of plants and animals are not patentable invention (4) Subsection (3) does not apply if the invention is a microbiological process or a product of such process			
Singapore	Patentable, no restrictions			
Brazil	BPA Art. 10 The following are not considered to be invention (IX) natural biological processes.		BPA Art 43 A patent confers on its proprietor the right to prevent third parties from […] (II) – a process, or product directly obtained by a patented process	
Russian Federation	No specific restrictions	PLFR Art. 5 (1) A technical solution relating	PLFR Art. 10	

		to a device shall be protected as utility model. (no further restrictions) (no processes)	[…] performance of acts, stated in subparagraph two hereunder, in respect to a product obtained directly derived by a patented process.
India	IPA Chp II 3 (h) a method of agriculture or horticulture (i)any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products. (j) plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.		
China	PLC Art.25 For processes used in producing products referred to items (4) of the preceding paragraph patent right may be granted in accordance with the provisions of this Law.		
Thailand	PTA Art. 36(2) where the subject matter of a patent is a process… have in possession ofr sale offer for sale or import the product produced by the patented process		
Malaysia	MPA Sec. 13 (1) the following shall not be patentable (a) Plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organisms, micro-biological processes and the products of such micro-organism processes;		MPA Sec. 36(3)(b)(ii) Doing any of the acts referred […] in respect of a product obtained directly by means of the process.
Indonesia	Patentable, no restrictions		
Philippines	IPCP Sec.22 - Non Patentable inventions: (4) Plant varieties or animal breeds or essentially biological process for the production of plants or animals. This provision shall not apply to micro-organisms and non-biological and microbiological processes.		IPCP Sec.71(1)(b) Where the subject matter of a patent is a process, to restrain, prevent or prohibit any unauthorized person or entity from using the process, and from manufacturing, dealing in, using, selling or offering for sale or importing any products obtained directly or indirectly from such process.
Tunisia	TPL Art. 3 Les variétés végétales, les races animales ou les procédés essentiellement biologiques d'obtention de végétaux ou d'animaux. Toutefois, cette disposition ne s'applique pas aux procédés biologiques médicaux et aux produits obtenus par ces procédés;		TPL Art. 46 (c) Protection on the product directly obtained by means of the process.

ANNEX 4
LIST OF LAWS

Andean Community – ACD - Decision 486: Common Regime on Industrial Property

Australia – APA - Patents Act 1990 (including amendments up to Act No. 120 of 2004)

ARIPO - Protocol on Patents and Industrial Designs within the framework of the African Regional Industrial Property Organization (including amendments 2001)

Brazil – BPL - Law No 9,279 of May 14, 1996

Canada – Canadian Patent Act – R.S. 1985, c. P-4

China – PLC - Patent Law of the People's Republic of China (including amendments of 2000)

EPC Member States- EPC – European Patent Convention (text of the Convention and implementing regulations)

European Union – Council Regulation No 2100/94 on Community Plant Variety Rights - CPVR

European Union – Directive 98/44/EC on the legal protection of biotechnological inventions

India – IPA - Indian Patent Act (including amendments of 2005)

Indonesia – PLI - Law 6/1989 on Patents

Japan – JPL - Japan Patent Law

Malaysia – MPA - Patent Act 1983 (Incorporating amendment Act A1137/2002)

OAPI- BA - African Intellectual Property Organization – Agreement Revising the Bangui Agreement of March 1997

Philippines – IPCP - Intellectual Property Code of the Philippines – Republic Act No.8293

Russian Federation – PLFR - Patent Law of the Russian Federation 1992, 3517 (including amendments 22-FZ)

Singapore – SPA –Statutes of the Republic of Singapore - Patent Act 21 of 1994 (including amendments of 2004)

South Korea – SKPA - Patent Act (Act No. 950, last amended by Act No. 6768, 2002)

Thailand – PAT - Patent Act B.E. 2542 (As Amended by the Patent Act (No. 2) B.E 2535 (1992) and the Patent Act (No. 3) B.E. 2542 (1999))

Tunisia – TPL - Law No 2000-84 on Patents

United States of America – USC - U.S. Code, Title 35, Patents