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Intellectual property rights, biotechnology and food security

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Summary

This paper examines the relationship between food security, agricultural biotechnology and intellectual property rights (IPRs), particularly for developing countries and poorer groups within those countries. As a result of industry pressure, harmonised standards of IPRs have been agreed at the global level, chiefly through TRIPs/WTO. Recent empirical work demonstrates that for low income developing countries, the costs of strengthening IPRs may well outweigh the gains. Moreover, potential gains through increased technological inflows resulting from stronger IPRs are likely to be realised over the long term, while costs accrue immediately, suggesting that developing countries should thinking carefully about promoting the expansion of IPRs, particularly in the field of agriculture. This is because although in the long term, IPRs incentivize research and development they also go hand in hand with unsustainable, and possibly unsafe, forms of agriculture, make R&D more expensive, especially in developing countries and tend to reduce national developmental choices. Despite this, pro-IPR industry representatives and trade officials, with privileged access to patent offices, judicial processes and WTO negotiations, continue to push for stronger IPRs at the global and national level. Those negatively impacted, such as small-scale farmers, traditional knowledge holders, environmental groups and developing countries, will need to play a larger role in IPR policy-making, at all levels, if biotechnology is to benefit the poorest and most vulnerable groups in the global economy. Lack of negotiating power and policy expertise of developing countries within the WTO, combined with strategic forum-shifting by more powerful countries, needs to be countered to ensure that the IPR playing field is not skewed further against R&D that would benefit the poor and forms of agriculture that would improve their food security must be positively encouraged.

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Preface

Biotechnology Policy Series

This IDS Working Paper series emerges from a series of three interlinked projects. They involve collaboration between IDS and the Foundation for International Environmental Law and Development (FIELD) in the UK and partners in China (Center for Chinese Agricultural Policy (CCAP)), India (Centre for the Study of Developing Societies, Delhi; Research and Information Systems for the Non-Aligned and Other Developing Countries (RIS), Delhi; National Law School, Bangalore), Kenya (African Centre for Technology Studies, Nairobi) and Zimbabwe.

Three key questions guide the research programme:

- What influences the dynamics of policy-making in different local and national contexts, and with what implications for the rural poor?
- What role can mechanisms of international governance play in supporting the national efforts of developing countries to address food security concerns?
- How can policy processes become more inclusive and responsive to poor people's perspectives? What methods, processes and procedures are required to "democratise" biotechnology?

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This paper is a product of the 'Globalisation and the International Governance of Modern Biotechnology' project. Other papers in the Biotechnology Policy Series are listed inside the back cover.

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'Democratising Biotechnology: Genetically-Modified Crops in Developing Countries' Policy Briefing Series

Issues covered in the series include: food security and biotechnology, trade, IPRs, the role of the corporate sector, science and decision-making, biosafety regulation, biotech in Africa and China, Bt cotton, rights-based approaches to biotech, and the use of citizens juries to expand participation in biotechnology policymaking.

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Introduction

This paper examines the development and enforcement of intellectual property rights (IPRs) at the international and national level and the impacts of IPRs on biotechnology, agricultural practices and food security concerns in the context of globalisation. The paper assesses whether the development and enforcement of IPRs has constrained the ability of regulatory bodies in developing countries and international institutions to promote food security policies. Recommendations to enhance the ability of international institutions and governments to promote food security policies that benefit the poorest countries and groups are suggested. The paper is structured as follows.

Section 1 sets the context of the study and deals with scope and definitional issues. It also examines different approaches to the relationship between IPRs, agricultural biotechnology, food security and globalisation. It highlights the difference in approach of institutions focusing on macroeconomic analysis, used by the WTO and global financial institutions, and the approach of those more concerned with the effects on people at microeconomic level, such as development agencies, NGOs and the family of UN institutions.

Section 2 surveys the key actors promoting IPRs/globalisation and those opposing them and the strategies they have adopted. The section describes the national and international policy-making institutions as well as patent offices and courts as the latter have played an important role promoting IPRs. Pro-IPR industries have strategically targeted key economic policy-making fora, such as the GATT/WTO and patent offices.

Section 3 provides an historical account of significant policy and regulatory developments that have lead to the extension of IPRs. The account examines national and international developments across a range of institutional fora illustrating the complex dynamics between corporate, governmental, NGOs and judicial actions. As is clear from the timeline, IPRs have evolved over centuries. The general trend has been for strengthening IPRs, particularly as higher levels of economic development are reached.

Section 4 examines how IPRs, as embodied in TRIPs, impact the food security of poor and vulnerable groups globally. Given public resistance to genetically modified (GM) foods, the continued grant of IPRs for biotechnological inventions in the agricultural sphere appears to advance the interests of particular corporations rather than consumer interests or the pursuit of sustainable development.

Section 5 focuses on how IPRs are impacting the ability of researchers to engage in research directed to improving the food security of developing countries, particularly poorer groups of farmers within such countries. The focus is on whether the current IPR landscape unduly restricts the freedom to operate of such researchers.

Section 6 looks at the impact of enforcement of IPRs on farming practises, particularly in developed countries. A key question here is whether the freedom of farmers to grow non-GM or organic crops is being restricted by the enforcement of IPRs granted on genetically modified crops and seeds.

Section 7 sets out conclusions and recommendations.

1 Scope, definitions and context

This paper deals with the linkages between food security, biotechnology and intellectual property rights with a view to identifying policy relevant insights and recommendations promoting food security in developing countries. This section addresses the scope and definitional issues and addresses the context of globalisation within which the linkages between IPRs, biotechnology and food security must be examined.

1.1 Biotechnology

The focus of this paper is primarily on agricultural biotechnology because agriculture is overwhelmingly important for the economies and livelihoods of developing countries.[1] It is also a sector in which modern biotechnology has already made a substantial impact and where supporters of biotechnology point to significant future benefits (Scoones 2002).

Recent reports have focused on biotechnology's ability to serve the poor by highlighting biotechnological developments that could be of most use to farmers with smallholdings, with limited access to capital, modern marketing systems and few choices about what they can grow. (Cohen 2001) These developments include biotechnological products providing:

- Pest and virus resistance to reduce use of pesticides;
- Improved yields;
- Tolerance to biotic and abiotic stresses, such as drought/flood tolerance;
- Nutritional benefits, such as enhancing vitamin A/iron levels in staple crops;
- Reduced environmental impacts, such as controlling root disease in reduced tillage areas; and
- New diagnostics and vaccines for livestock diseases, such as for foot and mouth disease. (Cohen 2001)

Developing biotechnological products will require large-scale financial capital: it takes a quarter of a billion US dollars and four to seven years to bring a biotechnology-based product to market. (Nenow 2001) This capital can be lost if a company fails to deliver a marketable end product. (Buckingham 1998) Because of these risks, the biotechnology industry, like the pharmaceutical industry, is heavily dependent on IPR protection as an inducement if private sector actors are to risk financial resources and years of research to develop new products.

1.2 Intellectual Property Rights

Intellectual property refers to the category of intangible rights protecting commercially valuable products of the human intellect. (Black's Law Dictionary) The category comprises primarily trademarks, copyrights, and patent rights but also includes geographical indicators, trade-secret rights, publicity rights, moral rights

[1] In developed countries, 8 per cent of people farm for a living (US = 2 per cent and EU = 4 per cent). For developing countries, those numbers average 50 per cent with some countries as high as 80 per cent. (Murphia 2001: 8)

and rights against unfair competition. Intellectual property also covers plant breeders rights (PBRs) – a *sui generis* form of intellectual property designed to reward commercial plant breeders.

IPRs were designed to encourage innovation, creativity and knowledge dissemination in a commercial, industrial context (Gerster 2001). Their use is widespread in developed countries and heavily supported by economists and those within knowledge intensive industries who argue IPRs are an engine for research and development, particularly for sectors with high research costs, such as the biotechnology sector (Dodds *et al.* 2001).

The recent geographical spread of IPRs, facilitated chiefly by the WTO through TRIPs, coupled with the extension in scope of IPRs to cover plants and life forms, has generated intense controversy about the benefits of IPRs across the globe for a number of reasons.

Firstly, the traditional subject matter of IPRs has not been designed for rewarding informal systems of innovation, creativity and knowledge dissemination such as those practised by collective groups such as farmers or indigenous peoples. The lack of reward systems for past conservation, on-going collective innovation and knowledge disclosure – whether in the form of extension of IPRs, development of sui generis options or through non-IP related policies – is one issue of concern in the linkage between IPRs, food security and biotechnology (WIPO 2001).

Those promoting biotechnology's positive role in promoting food security advocate a range of national and international IPR related policies:

- Clearer definition of what is patentable to clearly demarcate what is claimable as private rights for agricultural biotechnological inventions (Graff and Zilberman 2001);
- Effective enforcement of IPRs;[2]
- An IPR clearinghouse to facilitate technology transfer (Graff and Zilberman 2001);
- Public-private partnerships (Cohen 2001); and
- Finance of public research targeted at pro-poor technologies (CGIAR 2001);

Controversial issues highlighted by those questioning or opposing the extension of IPRs in the field of agricultural biotechnology include the role IPRs play in:

- Promoting unsustainable, and possibly unsafe, forms of agriculture;[3]
- Making agricultural research more expensive especially in developing countries (CGIAR 2001);

2 See e.g. US interventions in WTO/TRIPs.

3 For example, many academics and NGOs have argued that biotechnology promotes agriculture entailing, *inter alia*, monocultures, intensive and unaffordable chemical inputs which in turn damage the environment and/or impact negatively on biodiversity. (See Pardey *et al.* 2001; Chang 2001; Cohen 2001).

- Reducing national developmental choices;[4] and
- Generating concerns that run counter to fundamental moral and ethical principles.[5]

1.3 Food security

The concept of "food security" has been defined in various ways. In the 1970s, food security was used to refer to the availability of foodstuff in sufficient quantity at a global level. (Scoones 2002) During the course of the 1980s and 90s, academics and NGOs pointed out the inadequacy of food security approaches rooted in promoting global production levels and a country's access to world markets for food alone. They emphasised instead that food security approaches should guarantee livelihoods which would generate sufficient food at the household level.

At the 1996 Rome World Food Summit (WFS), the UN Food and Agricultural Organisation (FAO) produced a new definition. The FAO definition of food security is 'food that is available at all times, that all persons have means of access to it, that it is nutritionally adequate in terms of quantity, quality and variety and it is acceptable within the given culture.' Although this definition tried to remedy earlier deficiencies, it is by no means universally accepted. The biotechnology industry, in common with World Bank, WTO and IMF studies, continue to use the term "food security" largely to denote increased global production of food.(Scoones 2002; Cohen 2001) This is in keeping with their focus on the macro-economic level.

Development NGOs, on the other hand, tend to be orientated to the microeconomic – the effects on people, in particular, on food security of vulnerable households.(Murphia 2001: 2) Since 1996, a number of development NGOs have begun to use the term "food sovereignty" as the 1996 FAO definition, in their view, endorses food security approaches that rely on imports paid for by exports – a strategy which in their view involve risks and compromise the ability of agricultural production to be an engine for sustainable development (Murphia 2001: 8).

The different levels of analyses used – macroeconomic versus microeconomics – account, in part, for the different conclusions reached by different actors in assessing whether biotechnology has a positive or negative impact on food security of developing countries.

1.4 Sustainable development

Protecting the world's environment whilst meeting the needs of present generations and safeguarding natural resources for future generations is an enormous challenge at all levels of governance. It is agreed that in terms of access to food, the world is not food secure: over 800 million people, mostly in

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4 For example, impeding the ability of governments to protect infant industries and/or provide affordable access to certain types of seeds or in the case of public health, certain types of medicines. See, e.g. Food rights, TRIPS on Trial: TRIPS and the threat to food security and farmers rights, (ActionAid 2001).

5 For example, many religious, local community and indigenous groups believe that patenting living organisms fundamentally offends deeply held notion about the integrity of life. (CIDSE 2000; Canadian Biotechnology Advisory Committee 2001).

developing countries, are undernourished and over 200 million children under five are underweight.[6] Ensuring adequate global food production to feed a growing world population whilst guaranteeing that all persons will have access to it at the household level will thus be an important component of the transition to sustainable development to which all governments committed themselves at the 1992 Earth Summit.

Although developing countries are gene-rich in terms of plant genetic resources relevant to developing agriculture on a sustainable basis they are widely recognised to be resource poor in terms of technological and institutional capabilities when compared with developed countries. Such imbalances are part of the wider, on-going disparities between developed and developing countries in terms of economic, political and military power. Thus notwithstanding the fact that the World Food Summit Declaration states that the "primary responsibility" for attaining food security rests with individual governments, the ability of developing countries, acting alone, to achieve food security goals unaided is compromised by many factors.[7]

1.5 Globalisation

Globalisation also defines the context in which developing countries can formulate, implement and assess food security policies. Biotechnology and the development and enforcement of IPRs is taking place in the context of globalisation. The forces of globalisation, currently organised under two tracks, are reshaping the basic structures of the world community (Takahashi n.d.). The two tracks are building two sets of alliances and structures that will interact to shape the context in which future actions to promote pro-poor food security policies will have to operate. It is essential therefore to understand the driving forces of globalisation.

The first track has been described as market-based globalisation (Takahashi n.d.). It is shaped by market forces, strengthened by financial market liberalisation, development of financial instruments, trade liberalisation and the information technology revolution. It is most heavily promoted by multi-national enterprises, the United States government and international organisations such as the IMF, WTO and the governments of the OECD. Due to the rapidity of the impacts such forces produce worldwide, it has also been termed "fast-track globalisation."

The second track has developed as a response to the problems brought about by or aggravated by market-based globalisation. These problems include poverty, environmental destruction, and marginalisation of (some) developing countries and local and indigenous communities in decision-making structures. This track is promoted by civil society, NGOs, many United Nations agencies, multilateral environmental agreements (MEA) secretariats, bilateral aid agencies, developing country governments and most recently by the World Bank which orientated its position as one of partnership with civil society and

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6 WFS Rome Declaration and Plan of Action, 1996.

7 Economic factors that can affect food security and over which a government may not have full control include trade liberalisations policies, subsidies and financial policies, the state of the domestic economy, pressures to privatise, need for foreign exchange and poverty and unemployment. Other matters too can have an impact, such as the incidence of HIV/Aids, natural disasters and erratic weather patterns. (CIDSE 2002)

other UN agencies. The main objective of these actors is primarily to strengthen public interventions (through governments, international organisations or other members of civil society) to address poverty, environmental degradation and marginalisation problems. Due to the difficulties involved in delivering tangible results (integration of environment and development concerns, need for institutional coordination and substantive policy coherence) this track has been termed "slow-track globalisation."

> The development and enforcement of IPRs, and whether these can have a positive or negative impact on the contribution biotechnology can make to food security can be best understood if the two processes of globalisation are seen at work. Interactions between the two forces are producing new types of policy responses, such as the need to enact new forms of IPRs (GRAIN 1998) and the need for novel forms of public-private partnerships (Pardey *et al.* 2001). But it remains to be seen whether these will prove politically, legally and administratively feasible, and if so, whether their implementation will promote food security at the household level.

2 Policy-making institutions, actors and strategies

This section describes briefly the institutions involved in policy-making on IPRs as well as the key companies, countries, and NGOs/civil society elements most active on IPR issues. Even this briefest of surveys indicates the complexity of institutional arrangements through which IPR related developments take place.

2.1 IPR policy-making institutions

Like most issues in the context of globalisation and sustainable development, formal decision-making on IPRs takes place at various levels comprising national governments, multilateral channels and through international organisations. The membership of such bodies, their rules on transparency and accessibility and focus of their "core concerns" have played an important role in the debate on biotechnology and food security.

The mandates and competences of the institutions involved are not fixed in stone but subject to negotiation. When IPRs came to be included in the WTO, the role of UNCTAD and WIPO was reduced to a role more focused on the provision of technical assistance and capacity-building for the IPR agenda set within the WTO (Drahos 2002a; Sell 1999). There is evidence that countries strategically "shift forum" if it appears to favour their interest. For example, Drahos cites the example of the US targeting the WTO as the forum of choice once it became apparent that developing countries were using their numerical advantage to press for reforms in WIPO. More recently, the US and the EU have used bilateral trade and investment negotiations as a way of advancing implementation of the TRIPs rather than relying on the multilateral negotiations in hand within the WTO (GRAIN 2001a; Drahos 2002b) . A number of scholars have argued that the complexity of international negotiations on genetic resources issues, coupled with scope of differing viewpoints within even a single country 'is the perfect setting for a breakdown of international consensus on the issue of genetic resources.' (Petit *et al.* 2000)

The following section describes the key IPR institutions and their current activities at the international level. As the following section shows, the role of national patent offices and national courts in interpreting IPRs law to the needs of the emerging biotechnology industry has been critical in the extension of IPRs in developed countries. As developing countries start to enact IPR legislation to implement their TRIPs commitments, it is likely that developing county patent offices and courts will be become increasing active in IPR adjudication.

More recently, international organisations involved in developmental, environmental and human rights aspects, all of which are central to the notion of sustainable development, have also had an important "tempering" effect on the extension of IPRs and food security debate. For example, UNDP and the UN Sub-Commission on the Promotion and Protection of Human Rights have both undertaken analyses of the linkages between IPRs and developmental issues. This reflects and supports the idea of "two track globalisation" – one track being pursued by institutions concerned with economic/trade/finance issues with the other adopting a more holistic, sustainable development approach incorporating developmental, environmental and human rights concerns.

Table 2.1 Institutions and current activities

Institutions	**Current activities**
WTO/TRIPS	TRIPs implementation; Doha issues: IPR/public health and geographical indicators, traditional knowledge IPR interface
WIPO	Technical assistance for TRIPs, managing other IPRs treaties, IPR searches
UPOV	Implementation of treaties dealing with plant breeders rights
FAO/Commission on Genetic Resources for Food and Agriculture	Plant Genetic Resources Treaty; management of ex situ collections
UNCTAD	Technical assistance; policy analysis; educational material on IPR/developmental issues
UNDP	Capacity-building on IPR/developmental issues
UN Sub. Commission on the Promotion and Protection of Human Rights	IPR/human rights linkages
Convention on Biological Diversity CBD	Traditional knowledge; access to genetic resources/IPR linkages
World Bank	Nexus between development and knowledge-based economies
European Patent Office	Assessing patent claims
EU	Implementation of EU Biotechnology Directive; establishment of Community patent system
Organisation for African Unity / African Union	Model law on protection of rights of local communities, farmers, traditional breeders
Council of Europe	Moral, ethical dimension of biotechnology/IPRs
National Patent Offices: e.g. US, Canada, South Africa	Assessment of patent claims

2.2 Countries

Developed countries with strong representation in R&D intensive sectors, such as the US, Japan, Canada and many European countries have promoted IPRs to support their industries (Emmert 1990; Gutowski 1999). Countries which have emerging industry in knowledge intensive sectors, or which otherwise lack the resources/infrastructure to support local manufacturing, have tended to accord less priority to IPRs. Developing countries with predominantly agrarian workforces, those marginalised in the world trading system, such as Africa and other LDCs, as well as those with emerging industries have attempted to resist pressures to extend IPRs. This lack of priority for stringent IPR standards conforms fully to historical experience in developed countries where evolution of IPRs has gone hand in hand with economic development with many developed countries enacting comprehensive IPR systems only from the 1960s onwards.

Although many developing countries objected to inclusion of TRIPS in the Uruguay Round as they considered more stringent IPR regulation inappropriate for their economic circumstances (Patel 1989), it is clear that few developing countries were properly represented at the meetings at which TRIPs was finally agreed, few fully understood the implications of the TRIPS agreement at the time of its signature and fewer actually agreed with its content (Drahos 2002a). Despite attempts to slow the pace and scope of TRIPs obligations post-1994, a recent study of developing countries' influence on international IPR policy-making concluded that they 'have comparatively little influence' (ibid.). The main reason being 'the continued use of webs of coercion by the US and EU, both of which remain united on the need for strong global standards of intellectual property protection' (ibid.).

Notwithstanding this conclusion, it should be borne in mind that in the case of biotechnology, a growing number of developing countries also have capacity to undertake R&D and have emerging national biotechnology industries. These include India, (Visvanathan and Parmar 2002) China (Huang *et al.* 2001), Brazil, Argentina and even smaller countries such as Kenya (Odame *et al.* 2003). In these countries there is a strong legacy of public funded agricultural research. Many researchers working in developing countries acknowledge difficulties in raising research funding without collaboration with the private sector which is likely to require stronger IPR protection. In addition, many policy-makers within developing countries, influenced by development paradigms that stress the importance of the new "knowledge – based" global economy, are strong advocates of biotechnology (Dhar 2003). In India, for example, a number of federal and state level agencies have prioritised biotechnology as an industry of the future, offering significant tax incentives and regulatory sweeteners for investment because they see a direct (positive) link "from IT to Bt." (ibid.) Thus whilst the majority of developing countries remain opposed to negotiating strong(er) IPR standards at the international level, domestic constituencies supporting IPR exist in many developing countries.

These factors could explain, in part, why many developing countries are relatively far advanced in their implementation of the TRIPs agreement and why few of them appeared to have taken advantage of the flexibilities offered to them by TRIPs. (Thorpe 2001) It could explain why the author of a recent study on TRIPs implementation by DCs, concludes that 'developing countries are to a large extent fully aware

of the legislative opportunities provided under TRIPs' (ibid.). It must be noted, however, that this conclusion sits at odds with analysis undertaken by other academics and NGOs suggesting that many DCs are being coerced into implementing TRIPs, particularly through the negotiation of "TRIPs-plus" provisions in investment and bilateral trade treaties with the EU and the US, and that many do not appear to follow in detail the full implications of the particular TRIPs plus provisions (Drahos 2002a; GRAIN 2002).

2.3 Corporate interests

As Annex II demonstrates the overwhelming majority of intellectual property is created in industrialised countries. Accordingly, the corporations based in industrialised countries have been most active in promoting global standards in this area (World Bank 2001). Studies of industry assessing the importance of IPRs as a driver of research and development consistently reach the same conclusion: however little IPRs may matter for other sectors of the economy, for the pharmaceutical, chemical and petroleum sectors, availability of patents is a highly significant factor inducing investment in research and development (Chang 2001). For example, it is estimated that a new drug takes $800m and 10–15 years to develop.[8] This is also true for biotechnology which is an emerging new industry requiring large scale investments in development and production technologies with the potential to provide large, albeit uncertain levels of benefits (EU-US Biotechnology Consultative Forum 2000). It is unsurprising therefore, that companies from research-intensive pharmaceuticals, chemicals, petroleum and biotechnological sectors, as well as their associations, have prioritised the extension of IPRs.

Research examining the role of industry in promoting IPRs nationally and internationally suggests that a small group of corporate executives of US based multinational corporations have played a major role in promoting global harmonisation of IPRs (Sell 1999). This group first ensured that there was a strong commitment to IP domestically within the US, and once that was achieved, lobbied for an equivalent commitment globally (ibid.). European and Japanese industry, by contrast, played a lesser, albeit supportive, role (ibid.). Business from the South has had little involvement in international developments relating to IPRs (ibid.; Braithwaite and Drahos 2000).

Pro-IPR industries have strategically targeted key economic policy-making fora, such as the WTO and patent offices (Sell 1999; Drahos 2002a). Industry representatives have privileged access to these fora, and in the case of many patent offices, actually indirectly finance their operation. In the specific area of biotechnology, there are numerous studies of the role of the corporate sector in sensitising governments officials and patent offices including for example in relation to the 1998 EU Directive on the protection of biotechnological inventions and the US refusal (and subsequent reversal) over signing the 1992 Convention on Biological Diversity which centred on analysis of the perceived implications of the IPR provisions undertaken by a handful of US corporations.

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[8] See Biotech Indsutry's Still Waiting to Break Out 21 May 2002, www.sustain.org/biotech/News/news.cfm?News_ID=3324

In the late 1990s through a complex array of sales and mergers and acquisitions, several huge life-science companies were formed (Corporate Newswatch 2001). The concentration of patents and market share in such few hands reinforces developing country and NGO concerns relating to unfair monopoly practices. These concerns include the pro-active role played by such actors in international policy-making; the lack of availability of patented technologies to those working in the public domain and the ability of these large companies to manipulate markets and prices of basic food stuffs.

The ActionAid "corporate takeover" report shows six giant corporations (Aventis, Dow, Du Pont, Mitsul, Monsanto and Syngenta (formerly Astrazeneca and Novartis) buying up local seed markets in developing countries in their attempts to corner global markets. Together the six control:

- 98 per cent of the global market for patented genetically modified crops
- 70 per cent of the global pesticide market and
- 30 per cent of the global seed market.

In 2002 there is a more subdued atmosphere within the biotechnology industry. The October 2001 acquisition by Bayer of Aventis LifeScience at a very low price was reported to reflect an atmosphere of uncertainty within the crop science industry with a number of companies reported to be selling off their crop protection/seed interests (ibid.). Reasons cited include downturn in global crop and agrochemical markets; continuing public opposition to GM foods, and failure to recoup expected returns. By May 2002, the American Stock Exchange Biotechnology Index was down about 30 per cent from an interim peak of 618 in late November 2001, and down almost 50 per cent from an all time high of 785 in September 2002.[9]

It is unclear what effect, if any, this will have on biotechnology related R&D which has in turn driven the extension of IPRs. And what effect, if any, this will have on the intensity with which IPR related issues will be scrutinised by industry players.

2.4 Public research institutions

Until recently agricultural R&D was supported by public funds and carried out in universities who made their knowledge directly available to farmers around the world. The levels of funding for this type of research are declining (CGIAR 2001). In OECD countries private investment now accounts for about half of R&D with governments increasingly focusing on basic research and expecting the private sector to fund near-market research (Tansey 2002). Growth in the stock of publicly generated knowledge in the North is slowing thereby limiting the pool of science and technologies that can spill over to developing countries (ibid.). Furthermore, the pool has limited relevance for developing countries because much public research in rich countries is focused not on traditional agricultural production but on local

[9] See Biotech Industry Still Waiting to Break out 21 May 2002, www.sustain.org/biotech/News/news.cfm?News_ID=3324

environmental and food safety concerns and on the quality of food stuff preferred by Northern consumers (ibid.).

These trends have underlined the importance of IPRs. Most government laboratories and universities in the developed world now have their own IP offices and use IPRs to protect their knowledge (Dodds *et al.* 2001). Apart from a handful of publicised cases, such as the *Bt.* maize in Kenya or the vitamin A enhanced "golden rice", private proprietary science will only invest in areas where expected returns are high, neglecting research into improving traits in crops of interests to poorer, small-scale or subsistence farmers (GRAIN 2001). Thus the slow-down in public funding for agricultural research, coupled with the extension of IPRs over new technologies, is limiting the potential of developing countries to develop locally relevant technologies and tap into Northern knowledge pools (ibid.).

In view of these trends, an important source of international expertise in agricultural biotechnology occurs through the 16 member research centres of the Consultative Group on International Agricultural Research (CGIAR) (Cohen 2001). In 1998, these centres invested about $25 million on biotechnology. That same year, Monsanto alone invested $1.26 billion in R&D (CGIAR 2001). The scale of private funded research, and the increasing scope of basic research tools covered by IPRs, means public sector researcher's freedom to operate is highly restricted unless they enter into agreements with the private sector. An alternative path is to eschew the trend towards IPRs, as recommended by some radical NGOs. Developing country governments' freedom to deny IPR protection to biotechnology, however, is now fairly restricted as a result of the TRIPs agreement.

2.5 NGOs and civil society

Those opposing the extension of IPRs include small-scale farmers, traditional knowledge holders, and religious and environmental groups. These groups have not, until very recently, been familiar with workings of the IPR related institutions. The lack of transparency and accessibility to these groups of the WTO and national trade and patent offices has meant that until recently such groups played a largely reactive role in the key IPR policy-making bodies, challenging, questioning and trying to overturn decisions after the fact. In the European context, for example, a coalition of sixteen organisations from religious, environmental and development groups launched a high-profile media legal challenge to the 1992 patent granted by the EPO on Harvard University's genetically engineered mouse. In the South, small scale farmer associations, such as the Karnakata State Farmers Association (KSSR), led by Professor Mahanta Nanjundaswamy, have led civil protests involving millions of farmers and thousands of Ghandhian-style arrests in their campaign to "cremate Monsanto." (ILEIA 1999; Corporate Watch 1999). Since then, the KRRS has taken part in the Inter-Continental Caravan (ICC), a group of 400 farmers touring Europe to protest at the way in which genetically modified products and seeds were introduced into India raising issues of permission, information monitoring and control – issues that go to the heart of globalisation – directly with Europe policy-makers (ILIEA 1999).

There is a growing sensitisation of the key IPR related institutions to the perspectives these groups which stands testament to the success of their advocacy. The issue of traditional knowledge, for example,

is being now being studied by WIPO and recent reports by UNDP and the World Bank have focused on the impact of IPRs on developing countries. Finally the Doha Ministerial Declaration on the TRIPs Agreement and public health is evidence that WTO members recognise the public concern generated by the strict enforcement of IPRs in the face of health emergencies.

Getting something on the international agenda is, however, only part of the story. Beyond 2001, the challenge is to turn the insights brought by those currently opposing extension of IPRs into implementable policies creating positive links between IPRs, food security and biotechnology, benefiting especially the poorest and most vulnerable groups in the global economy.

Table 2.2 NGO activities

Organisation	**Aims and activities**
ActionAid	Improving food security for farmers, developing countries, tackling poverty, community based approaches
African Centre for Technology Studies	Policy research and assistance to developing countries, policy-makers on biotechnology, bio-safety, sustainable development issues
Christian Aid	Focus on moral, ethical concerns about patenting life forms as well as negative trade impacts on development
Gene Campaign, New Delhi	Negative effects of biotechnology on farmers' caused by trade, IPRs, global agri-business
GRAIN	Campaigning for rural agricultural issues, farmers' rights, indigenous groups rights, linking food security, TRIPs, trade
Greenpeace International	Direct action, campaigning and legal challenges against GM technology on environmental grounds
Institute for Agriculture and Trade Policy	Policy analysis of trade, aid, agriculture negotiations at WTO
KRRS/Prof. Nanjundaswamy	Network of farmers' group organised against multinational agri-business and WTO
Oxfam	Policy analysis and assistance for communities on food security, WTO, poverty, aid issues
RAFI	Rural and agricultural issues for poorer farmers and indigenous groups, biotechnology and bio safety
Research Foundation of Science and Technology/Vandana Shiva	IPRs, biotechnology, agribusiness, gender concerns
Third World Network	Campaigning for North/South development issues, WTO, agriculture/TRIPs

3 Extension of IPRs: chronology of developments

This section provides a historical account of significant policy and regulatory developments that have lead to the extension of IPRs worldwide. The table contained in Annex I of this report provides a chronology of key national and international developments across a range of institutional fora. The chronology illustrates a number of important points.

First, IPRs have evolved over centuries. Since the initial grant of patents in Venice in the 14th century, policy-makers across many different cultures and stages of economic development have accepted IPRs as a useful policy tool for rewarding innovation. This is despite the absence of empirical evidence

proving a causal relationship between IPR and technological innovation in all except a handful of industries.[10] Although IPR opponents continue to point out that innovation is driven by many other factors such as imitation lags and "natural advantages," today's policy-makers, like their past counter-parts, continue to prefer statutory IPR provisions applicable across the board, rather than an IPR framework confined to particular industries. Predicting the direction of technological change, the needs of particular industries needs as well as devising an institutional and administrative framework subject to continued legislative oversight are no doubt some of the reasons policy-makers continue to prefer IPR protection framed in the most general terms and to eschew specialist (*sui generis*) options.

A second point to note from the chronology is that the progression of events concerning IPRs do not appear inevitable. The gradual expansion in scope and geographical coverage of IPRs has not been linear. In many cases, IPR laws were repealed or restricted in many European countries due to concerns about monopolies and protection of infant industries (Chang 2001). In other cases, there were fierce institutional, political and legal battles to restrict the scope or geographical extension of IPRs. It took nearly ten years, for example, for the United States to achieve its goal of including IPRs in the WTO. It is arguable that had developing country resistance been stronger and their negotiating strategies different, TRIPs inclusion may not have been a foregone conclusion. Likewise the grant of patents in the European context to biotechnological innovations. The restrictive wording of the European Patent Convention, combined with legal challenges from NGOs during the nineties caused considerable legal uncertainty for the biotechnological industry. It took ten years, and many compromises, for the EU to put in place a legislative framework allowing IPR for biotechnological inventions. Thus although the playing field appears at times to be stacked in the biotechnology industry's favour, developing countries, NGOs and civil society have often combined forces to impose reversals, sets backs and restrictions on the expansion of IPRs, and in some cases to challenge the underlying framework for IPRs altogether. For example, since 1992 traditional knowledge, "biopiracy" issues have highlighted the inadequacy of the existing IPR paradigm for encouraging informal, incremental innovation carried out by groups such as farmers and indigenous peoples. As a direct result of such advocacy, the November 2001 Doha Ministerial Declaration provides that in context of review of TRIPs Article 27.3(b), the TRIPS Council should examine, *inter alia*, the relationship between TRIPs, CBD and protection of traditional knowledge and folklore, and other relevant developments raised by Members pursuant to Article 70.1 as well as taking the "development dimension" fully taken into account.

The chronology also illustrates the complexity of institutional and geographic dynamics between corporate, governmental, intergovernmental, NGO and judicial actions concerning IPRs. There are many battles between many agents taking place at multiple levels of governance – as might be expected under

[10] In a survey of 12 US industries when R&D executives were asked which inventions would not have made if they had not been able to obtain patent protection, only 3 industries (pharmaceuticals, chemicals, petroleum) gave a "high" response; the remainder were "none" or "low." These results have confirmed in a number of other studies undertaken elsewhere and more recently. (Chang 2001)

the two tracks of globalisation set out in section 1. As regards standard-setting on IPRs, the following tensions can be discerned:

- National versus international policy-making;
- Legislative versus judicial/regulatory policy-making
- Economic/trade intergovernmental institutions versus social/developmental/environmental IGOs;
- North versus South;
- Corporate versus NGOs/public research institutions; and
- Biotechnology industry versus traditional plant/animal breeding.

Thus, at any one time policy-makers have to make sense of these sometimes opposing dynamics, and given the interconnectivity of decision-making between multiple levels of governance, work out effective strategies to operate within the complex web of international policy-making on IPRs. National positions may often be derived from or informed by international developments rather than the other way round.

A final point to note from the chronology is that patent offices and judicial bodies have played a remarkably active role in the story of IPRs. Yet their role has been little analysed. More often than not legislative and standard-setting bodies are the primary target of corporate/NGO advocacy. This is surprising given that most day to day decisions on IPRs are made by patent offices, and where challenged, by judicial processes. And the role of such bodies to make further decisions of a fundamental nature is likely to increase in the future as governments enact national legislation to implement their TRIPs agreement.

4 Impact of IPRs on food security

This section examines the policy debate concerning the impact of IPRs on the food security of developing countries. A key issue is to what extent have developing country governments' ability to set IPR policy appropriate to their national circumstances been compromised and to what extent have DC governments' ability to pursue food security objectives been compromised by IPR developments elsewhere.

4.1 TRIPs requirements

Developing country governments' ability to set IPR policy appropriate to their national circumstances has been curtailed by the TRIPs agreement because TRIPs requires all WTO members to establish minimum standards of IPRs irrespective of a country's level of economic and technological development. In the future, developing country governments will have to devise food security policies that respect the international commitments incumbent upon them as a result of TRIPs. Furthermore IPR developments set elsewhere, such as IPR legislation enacted by developed countries in response to TRIPs as well as the rules and practises of their patent offices may have a persuasive effect on the direction of TRIPs implementation by developing countries. For these reasons, it is important the section below sets out both the scope of the patenting obligations set by TRIPS for developing countries and then discusses the

exceptions, limitations and flexibilities available to developing countries in their implementation of TRIPs.[11]

TRIPs requires 20 year patents be available for the products and processes of all types of technology and that patent rights be enjoyable without discrimination as to the place of invention and whether products are imported or locally produced.[12] These provisions mean that the ability of DC governments to exclude the biotechnology sector from IPRs, as developed countries once excluded pharmaceutical sector, has now been curtailed. The 20 year term requirement means that developing countries have lost the opportunity to define a shorter term ensuring existing proprietary knowledge holders enjoy a long period of technological advantage. Biotechnological innovations in the agricultural sector are likely to lead to higher input prices for farmers because of IPRs-related royalty payments and also because IPRs facilitate market concentration in the seed sector which could lead to anti-competitive behaviour (ActionAid 2002). It could also lead to reduced levels of biodiversity as a result of increased reliance on monoculture based farming (ibid.).

Weaker IPRs and shorter IP protection periods would have helped local firms to build capabilities by permitting imitation and reverse engineering. Developing countries that want to build up indigenous biotechnology industries will now have to do so by first guaranteeing the IPRs of established industry players who are based predominantly in the North. Licensing, establishment of subsidiaries and joint ventures will thus form the primary vehicle of technology transfer between North and South giving proprietary knowledge holders considerable leverage over the location and substantive direction of future research. Additionally, licensing fees and royalties will flow from developing countries institutions to developed countries.

Recent studies indicate that for low income developing countries, the costs of strengthening IPRs may well outweigh the gains (UNCTAD/ICTSD 2001). There is no clear developmental case that most developing countries below the newly industrialising stage will gain in net terms from TRIPs and the least developed countries are likely to lose. As pointed out by one recent study, 'the gains that might accrue through increased technological inflows are likely to be realised over the long term, while the costs will accrue immediately. In present value terms, therefore, there is likely to be a significant net loss.' (ibid.)

TRIPs requires that a wide range of exclusive rights be conferred on patents covering the making, using, offering for sale, selling and importing. The wide range of the rights conferred by patents means

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11 This section focuses on TRIPS obligation relating to patents of particular relevance to biotechnology, agriculture and food security.

12 Article 27.1 TRIPs provides: 1. Subject to the provisions of paragraphs 2 and 3, 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. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. Article 33 stipulates the 20 year term. TRIPs provides that Members shall require that an applicant for a patent disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application (Article 29.1).

that most acts covering a patented product or process will require prior authorisation by the patent holder. For *process* patents protection must include rights over the use of the process as well as over products obtained directly by the process. [13] If the subject-matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process, where certain conditions indicating a likelihood that the protected process was used are met (Article 34). This reverses the normal burden of proof thus strengthening the hand of proprietary knowledge holders in legal proceedings. Collectively these provisions will mean that research activities will only be possible as a result of licensing agreements with the patent holder. This may make "catching up" in the biotechnology race more difficult as developing country public research institutions are likely to face additional burdens in the process of negotiating and payment of research licenses.

TRIPs requires availability of effective civil judicial legal procedures for IP right holders. TRIPs sets out detailed requirements for WTO Members to ensure that enforcement procedures are available to right holders to permit "effective action" against "any act of infringement of IPRs covered by TRIPs." No equivalent requirements granting standing are stipulated for those who may wish to challenge IPRs such as NGOs. Where a WTO Member intervenes to control anti-competitive practices in contractual licenses, TRIPs ensures that the home state of the right holder is notified and is able to enter into consultations with the Member State trying to correct the anti-competitive behavior of a foreign company.

4.1.1 Limitations on exclusive rights

WTO members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties (Article 30, TRIPs). The limited exemptions authorised by Article 30 TRIPs do not require a government decision in each case, distinguishing it from the compulsory licensing provisions in Article 31 discussed below. The exact circumstances in which a country can make use of Article 30 is currently subject to intense intergovernmental dispute but there is agreement that it was intended to allow exceptions to patent rights for such things as research exemptions, prior use rights and pre-expiration testing. Currently, one of the controversies about Article 30 is whether it can be used to justify export of generic medicines to countries lacking or having insufficient manufacturing capacities in the pharmaceutical sector (Love 2002).

Article 31 TRIPs allows WTO Members to issue compulsory licenses and allow government use without the authorisation of the right holders subject to conditions aimed at protecting the legitimate interests of the right holder on a case by case basis. These include the obligation, as a general rule, to grant such a licence only if an unsuccessful attempt has been made to acquire a voluntary licence on reasonable terms and conditions within a reasonable period of time; strict restrictions on exports; the requirement to

[13] Article 28.

pay adequate remuneration in each case, taking into account the economic value of the licence; and a requirement that decisions be subject to judicial or other independent review by a distinct higher authority. Certain of these conditions, such as the requirement that use be predominantly to supply the domestic market, are relaxed where compulsory licences are employed to remedy practices that have been established as anticompetitive by a legal process although it is not clear what this entails. These conditions should be read in the context of Article 27.1, which requires that patent rights shall be enjoyable without discrimination as to the field of technology.

4.1.2 Flexibilities

Given the vastly different economic development levels of WTO members, TRIPs might have been expected to create differentiated sets of commitments for countries. This is not the case. TRIPs contains instead a common set of commitments for all countries irrespective of their economic and technological circumstances. It does, however, provide for a differentiated timetable. When the TRIPs agreement took effect on 1 January 1995, developed countries were given one year to ensure that their laws and practices conform with the TRIPS agreement. Developing countries and, under certain conditions, transition economies were given five years and least developed countries (LDCs) eleven years to ensure compliance with TRIPs.[14] The Council for TRIPs can provide extensions to this period for LDCs if so requested by an individual LDC.[15]

Apart from these general "grace periods", TRIPs provides that if a developing country did not provide product patent protection in a particular area of technology when the TRIPS Agreement came into force, it has up to 10 years to introduce the protection. Thus in the case of pharmaceuticals, for example, India has until 2005 to provide such protection as it had hitherto excluded these from Indian patent legislation. TRIPs provides that for pharmaceutical and agricultural chemical products, countries such as India must accept the filing of patent applications from the beginning of the transitional period, though the patent need not be granted until the end of this period. The implementation of this provision has already been the subject of WTO dispute settlement.[16]

Article 67 sets out developed countries' commitments on technical cooperation. This Article provides that developed country members must provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country members to facilitate TRIPs implementation. Such assistance can include assistance in drafting laws and regulations to protect IPRs as well as establishment or reinforcement of domestic enforcement agencies.

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14 The WTO recognises as least-developed countries those countries which have been designated as such by the United Nations. There are currently 48 least-developed countries on the UN list, 29 of which to date have become WTO Members. These are: Angola, Bangladesh, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Democratic Republic of the Congo, Djibouti, Gambia, Guinea, Guinea Bissau, Haiti, Lesotho, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Niger, Rwanda, Senegal, Sierra Leone, Solomon Islands, Tanzania, Togo, Uganda, Zambia.

15 Article 66.2.

16 See www.ejil.org/journal/Vol9/No1/sr1f-02.html for background to India Mailbox Dispute.

Developed country members have agreed to present annually to the TRIPS Council a description of their technical cooperation activities in the area of intellectual property. The TRIPs Council is monitoring how developed countries fulfil their obligations under Article 67 to ensure that developing countries can have adequate information on the assistance on offer and to ensure any of their unfulfilled needs are identified and responded to. Independent analysis of the provision of technical assistance suggests that it has tended to be used to facilitate earlier and more stringent TRIPs implementation by developing countries than needed (Drahos 2002a). One recent study has noted that the technical assistance on offer from WIPO in drafting legislation has tended to expedite implementation of TRIPs by developing countries as well as foreclosing some of the options available to developing countries, in some cases actually transposing into national legislation commitments that go beyond the TRIPs known as "TRIPs plus." (ibid.)

Finally, at the November 2001 Doha Ministerial meeting, WTO Members agreed to examine the scope and modalities of complaints under Article XXIII of GATT 1994 in so far as these relate to TRIPS.[17]At Doha, WTO members agreed to not initiate such complaints under the TRIPs Agreement until the review of the scope and modalities is completed.[18]

4.1.3 Exclusions from patentability

As discussed below TRIPs provides for patentability of all technologies. The Agreement does, however, give WTO Members discretion to make three kinds of exclusions:

- inventions contrary to *ordre public* or morality, including inventions dangerous to human, animal or plant life or health or seriously prejudicial to the environment.[19]
- 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, any country excluding plant varieties from patent protection must provide an effective *sui generis* system of protection. [20]
- diagnostic, therapeutic and surgical methods for the treatment of humans or animals.[21]

17 Article XXIII relates to nullification and impairment claims.

18 Paragraph 11.1, Doha Ministerial Declaration on Implementation related issues and concerns. WT/MIN (01)/DEC/17.

19 Article 27.2.

20 Article 27.3.b

21 Article 27.3(a). This limitation will not be examined here in detail as it does not impact as directly on agriculture/food security issues.

Exclusions from Patentability, TRIPs Article 27

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) 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.

Exclusion Provisions of the European Patent Convention Article 53 (a) and (b)

European patents shall not be granted in respect of:
(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

Exclusion Provisions of EU Directive Article 4 :

1. The following shall not be patentable:
(a) plant and animal varieties;
(b) essentially biological processes for the production of plants or animals.
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.
3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

The key issue relating to implementation of these exclusions by developing countries are:

- whether to limit the availability of patents to biotechnology (as is the case in the European Patent Convention (EPC) countries) or whether to give biotechnology the broadest possible patent protection (as with the US);
- if there are to be limits on the availability of patents relating to plants/animals and essentially biological processes, how to define the boundaries between exclusions on the one hand and any *sui*

generis plant variety protection system on the other; and

- how to interpret and apply the *public ordre* and morality exclusions.

Biotechnology challenges the boundaries of nature. Defining corresponding scientific boundaries is difficult, particularly in the face of continuous technological developments. These features make it difficult to draw legal boundaries around patentable subject circumscribing its ambit. None of the key terms in Article 27 limiting the scope of patentability are defined in TRIPs. This is also the case for the European Patent Convention (EPC) as a result of which much of the development of key concepts has come from through interventions by the European Patent Office (EPO) in the context of particular cases.

The way in which the terms of Article 27 TRIPs will be given effect by developing countries will have a significant impact on the scope of patents available to the biotechnology seed industry which in turn will affect agricultural practises in developing countries. Because these exceptions are modelled closely on Article 53 of the European Patent Convention, the section discusses what these provisions have come to mean in the EPC context with reference to the case law of the European Patent Office and the newly enacted EU Directive 98/44/EC on the legal protection of biotechnological inventions.[22] Although this case law is not legally binding on other countries it is influential in setting the parameters of permissible legal leeway in any dispute about the interpretation of these terms. Should disputes arise at the WTO level, the interpretation and practise of the EPC countries, for whom the exceptions in Article 27.3 were included in TRIPs, is likely to form an important background to any TRIPs related disputes about the scope of exclusion to patentability. In June 2000, for example, the US filed a dispute at the WTO accusing Argentina of failing to implement legislation that among other things would allow the patentability of micro-organisms.[23] The EU and Switzerland requested to join in the dispute .[24] Disputes such as this are likely to increase in the future.

4.2 European patent convention

As the chronological table of IPR related developments in Annex I indicates, the grant of patents under the 1973 European Patent Convention to the biotechnology sector has been dogged by controversy. The EPC contains mandatory exclusions from patentability of a range of living matter and stipulates considerations of public policy and morality in the grant of patents, elements that are absent from the US legal context. Furthermore unlike the US, the EPC allows legal standing for NGOs and other interest groups to challenge patents. This has led some writers to comment that 'citizens of the EPC possess the

22 Official Journal L213, 30/07/1998 00013-0021

23 WT/DS/196, Argentina. Certain measures on the protection of patents and Test Data. The US filed a complaint on 6 June 2002 arguing that Argentina's implementation of TRIPs through its new legislation, Decree 260/96, "improperly excludes certain subject matter, including microbiological organisms, from patentability. The case has now been settled by mutual consent."

24 WT/DS/196/2 (EU), WT/DS/196/3 (Switzerland)

power to shape the regulatory agenda respecting biotechnologies through the judicial process, unlike their American counterparts confined to the agonisingly slow bureaucracy of its legislature.' (Scalise and Nugent 1993).

NGOs and the European Parliament have indeed made use of EPC provisions to challenge biotechnology patents on legal, economic, environmental and moral grounds. Notwithstanding citizen challenges, however, decisions taken by the European Patent Office, when evaluated over the course of a decade, have resulted in a gradual expansion of the scope of patentable subject matter under the EPC – echoing legal developments in the US where the scope of legal challenges has been far more limited.[25]

European IPR policy-makers have tried to give the widest possible IPR protection to the biotechnology industry, fearing that the EU biotechnology industry may be put at a competitive disadvantage *vis-à-vis* the US because of the initial legally restrictive EPC approach. The fear that European businesses must not get left behind in the "knowledge-based" global economy has clearly strengthened harmonisation of IPR standards at the EU level (EU Commission). Legal challenges from European citizens' groups have caused lengthy delays in the patent process, introduced a greater element of legal uncertainty and increased transaction costs for the biotechnology industry in Europe. But over the course of a decade, such challenges have not resulted in a significant denial of patents being granted given the overall numbers and scope of biotechnology patents being granted.[26] Thus whilst there remain important differences between the patent rules of the US and the EU, the general trend is towards a substantive convergence of patentable subject matter in the EU and the US.[27]

This is not to underplay the very different IPR regulatory approaches of the US and EPC states nor to overlook the remaining differences (discussed below). It is important to recognise, however, despite citizens' intervention in the regulatory arena, IPR policy-makers, particularly patent offices, have played a significant harmonising role supporting biotechnology by using their legal authority to widen the scope of patentable subject matter. The EPC experience therefore, suggests caution in terms of the extent to which developing countries' legal creativity in interpreting the exceptions and flexibilities contained in TRIPs will lead to IPR regimes very different from those pertaining in Europe and the US.[28] This is particularly because, as with the European countries, biotechnology is perceived by many developing country policy-makers as a technology of the future and one which be given incentives to function in the globalisation context.

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25 This is due in part to the lack of legal standing in the US for NGOs to bring challenges to issues relating to grant of patents. See Animal Legal Defense Fund v. Quigg932 F.2d 920 (Fed. Cir.1991).

26 From the early 1980s to 1998, the EPO received a total of around 15 000 patent applications for biotechnology inventions. Of these 4000 concern genetic engineering: 500 for transgenic animals, 1000 for transgenic plants, and over 2000 for DNA sequences isolated from the human genome. (Gitter 2001).

27 Many of the most controversial patent cases have taken between 5–10 years to resolve.

28 See discussion of the US challenges to Argentina's implementation of TRIPs and also the US challenge to Brazilian patent legislation allowing compulsory licensing. WT/DS/199/3, Brazil – Measures Affecting Patent Protection, filed 9 January 2001.

Table 4.1 Article 27 TRIPs

Excludable from patentability	**Subject to mandatory patentability**
Plants and animals	Micro-organisms
Essentially biological *processes* for production of plants and animals	Non-biological & biological *processes* (and their products)
Plant varieties provided effective sui generic system for protection of plant varieties exists	Plant varieties if no effective *sui generis* system for protection of plant varieties exists
Inventions the commercial exploitation of which is needed to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment	

4.2.1 Micro-organisms

Micro-organisms are subject to mandatory patentability whilst plants and animals may be excluded. This implies a clear distinction can be made between plants/animals on the one hand and micro-organisms on the other and furthermore, that such a distinction is one that will be shared by WTO members. Yet from a scientific point of view, there is no single scientific definition of "micro-organism" (Adock and Llewelyn 2000). The division between plants, animals and micro-organisms is not a strict one and there is significant overlap between the kingdoms (ibid.).

The practise of the US, European and Japanese patent offices has been to not attempt to define the term "micro-organism", focusing instead on including as wide a range of subject matter under micro-organisms as possible. Thus in the developed world context, the term "micro-organism" has been interpreted to include, over time, not only bacteria and fungi but also viruses and animals and plant cells.[29] Although all these are the subject of microbiology, not all these are presently considered to be "micro-organisms" by the scientific community. Thus the inclusion of these as patentable subject matter, coupled with the refusal to define the term "micro-organism" by developed country patent offices supports patent protection for the widest possible range of biotechnology developments as possible. This may or may not have been what the legislators of the EPC intended. An assumption that it was reflects an implicit bias favouring biotechnology. Saying that technological developments in biotechnology would necessitate legislators/policy-makers revisiting the definition of "micro-organisms" is, by implication, allowing technology (and thereby industry which sets the direction of future R&D) to dictate the foundational elements of the regulatory environment.

In the case of "micro-organisms", one significant effect of a broad "on-going" definition is that it considerably narrows the range of excludable subject-matter permissible under TRIPs. Thus although TRIPs allows "animals and plants" to be excluded from patentability, individual cells from plants and

[29] The EPO has defined "micro-organisms" to include 'plasmids, viruses and all generally unicellular organisms with dimensions beneath the limits of visions which can be propagated and manipulated in a laboratory'. The EPO defines the concept of "microbiological processes" under Article 53 (b) to refer to "processes in which micro-organisms (or their parts) are used to make or modify products or in which new micro-organisms are developed for specific uses." EPO Case T/0356/93, Greenpeace v. Plant Genetic Systems, 1995. The EPO defines plant cells as "microbiological products" as they are the results of "microbiological processes."

animals are now patentable as "micro-organisms." As these cells can now be used to propagate whole specimens, the exclusion of plants/animals has far less bite in restricting the kinds of patents granted.

Recognising this problem, the Brazilian legislation implementing TRIPs provides a definition of micro-organism which appears to be designed to give effect to the plant/animal exclusion as well as to stop patenting of naturally occurring micro-organisms. Brazilian legislation excludes from patentability all plants and animals and their parts, except micro-organisms that satisfy the requirements of novelty, inventive step, and industrial application. These micro-organisms must be created by means of human intervention and have a characteristic that is not normally attainable under natural conditions. [30]

Few other developing countries implementing TRIPs appear to have chosen to follow the Brazilian example.[31] Reasons include pressure put on developing countries by the US and EU to follow the US/EU interpretation during bilateral negotiations of "TRIPs-plus" agreements, cautious guidance to developing countries drafting legislation from organisations like WIPO who are providing such countries with technical assistance, (Drahos 2002a) and a genuine uncertainty on the behalf of developing country policy-makers as to what definition, if any, would be in their long term interests (Dutfield 2001).

4.2.2 Plant varieties

Under the EPC, "plant varieties" are subject to mandatory exclusion from patents. Under TRIPs, Members have discretion to exclude "plants and animals." WTO Members must provide protection for "plant varieties" either by means of a patent or an "effective sui generis system" or by any combination thereof. The term "plant varieties" is not defined in TRIPs. There are a number of significant issues at stake in defining "plant varieties" for developing countries:

- Should genetically engineered plant varieties be granted patent protection or should these be protected through a *sui generis* system?
- What kind of IP protection should landraces and farmers' plant varieties be given?

In the European context, the definition of what is a "plant or animal variety" has been developed largely through EPC case law against the backdrop of the UPOV system and the specialised system of plant breeder's rights tailored specifically for the agricultural and horticultural innovations.[32] The term "plant varieties" has been interpreted by the EPO to refer to plants subject to protection under the UPOV

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30 Brazilian legislation allows patentiability of "transgenic micro-organisms" defined as 'organisms, except for all or part of plants or animals that express, by means of direct human intervention in their genetic composition, a characteristic normally not attainable by the species under natural conditions'. *Review of Article 27.3(b): Communication from Brazil*, IP/C/W/228; Minutes of TRIPS Council Meeting of 20–21 October 1999, IP/C/M/25; Minutes of TRIPS Council Meeting of 21 March 2000, IP/C/M/26; BNA Int'l Trade Daily (4 December 2000).

31 See TRIPS / biodiversity related developing country legislation, GRAIN website, www.grain.org/brl/index-en.cfm

32 The term "animal variety" has been examined in detail in the EPC case law concerning Case T19/90 Harvard Oncomouse.

system.[33] The EPO's decisions have been based on an implicit understanding that the exclusions permissible under Article 53(b) EPC relating to plant varieties is that patents should be granted to everything that falls outside the scope of plant variety protection allowed by UPOV.

In its recent decision in the *Novartis* case, the EPO Enlarged Board of Appeal states that 'the purpose of Article 53 (b) EPC [is that] European patents should not be granted for subject-matter for which the grant of patents was excluded under the ban on dual protection in the UPOV Convention 1961.'[34] In the Board's view, Article 53 (b) 'defines the borderline between patent protection and plant variety protection. The extent of exclusion for patents is the obverse of the availability of plant variety rights.'[35] The Board goes on to state that 'inventions ineligible for protection under the plant breeders' rights system were intended to be patentable under the EPC provided they fulfilled the other requirements of patentability.'[36]

This "mutually exclusive" view of the exclusion provisions in Article 53(b) benefits the biotechnology industry because it means that the EPO has clearly stated that it will construe Article 53(b) in such a manner as to ensure grant of patents to all manner of biotechnology inventions not covered by UPOV.[37] On the other hand, the EPO's insistence that there be a strict demarcation between the patent and plant variety system has lead the EPO's to deny *product patents* for transgenic plant varieties as demanded by the biotechnology industry. [38]This is because, in the EPO's view 'the mere fact of being obtained by means of genetic engineering does not give the producers of such plants varieties a privileged position relative to breeders of plant varieties resulting from traditional breeding only.'[39] By interpreting "plant varieties" to refer to UPOV, the EPO has avoided the result that some biotechnological innovations could be excluded both from the patent system and the UPOV system.

Although the biotechnology industry would prefer to have product patents for transgenic plants, the EPO's final decision in Novartis actually provides for very wide patent protection for transgenic plants and their parts. The decision of the Enlarged Board of Appeal makes clear that a product patent claim in which specific plant varieties are not individually claimed is not excluded from patentability under Article 53 (b) even though the claim may "embrace plant varieties". This overrules the view of the Technical Board of Appeal (which had referred the Novartis case to the Enlarged Board of Appeal) as the Technical Board had argued that it would be illogical to hold that a patent should not be granted for a single plant variety but might be granted if its claims were to cover more than one variety. By stating that if the subject-matter of the claimed invention is neither limited to nor directed to a plant variety or varieties then

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33 Under Article 1(vi) of the 1991 UPOV Convention, plant varieties are defined as follows: 'variety means a plant grouping within a single botanical taxon of the lowest rank, which grouping, irrespective of whether the conditions for the grant of a breeders rights can be fully met, can be: defined by the expression of the characteristics resulting from a given genotype or combinations 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'.

34 EPO Case G 1/98, Novartis AG, Decision of the Enlarged Board, 20 December 1999, paragraph 3.6.

35 Id. Paragraph 3.10.

36 Id, paragraph 3.7.

37 Providing, of course, that other criteria for patentability are met.

38 Novartis, note 34.

39 Id. paragraph 5.3.

it does not fall into the Article 53 (b) exclusion, the Enlarged Board of Appeal has given future patent attorneys license to draft transgenic plant patent claims in broad terms to get round the Article 53 (b) exclusion.

Finally, the Enlarged Board's decision in Novartis confirms very wide scope of availability of "product-by-process" patents for transgenic plants. By construing key terms in the EPC in this way, the EPO has tried to minimise the negative effects of the plant variety exclusion embedded in the EPC on the biotechnology industry. The end result may not quite match the patents for "everything under the sun" approach of the US. But the restrictive legal language of the EPC has been stretched to the limit by the EPO to accommodate the IPR needs of European biotechnology industry.

4.2.3 Essentially biological processes, micro-biological and non-biological processes and their products

TRIPs gives Members discretion to exclude from patenting of "essentially biological processes" for the production of plants and animals. Non-biological *processes* and micro-biological *processes* are subject to mandatory patenting under TRIPs. This is also the case with the EPC. These terms are undefined and again, do not correspond to any agreed, internationally recognised scientific definitions.

Non-biological processes have been described as technical in nature. And the EU Biotechnology Directive defines "essentially biological processes" in terms of whether the process 'consists entirely of natural phenomena such as crossing or selection.'[40] There is no clear dividing line between non-biological processes/micro-biological processes and "essentially biological processes" (which are excludable).[41] The demarcation turns on the degree of human intervention and the nature of the claimed invention – matters subject to interpretation rather than a strict scientific demarcation.

Under TRIPs, as with the EPC, products directly obtained by the patented process also enjoy patent protection.[42]The scope of the "product-by-process" provision is an important consideration. This is because it is not clear whether a *product* of a non-biological process or a micro-biological process which is otherwise excluded from patentability (because, e.g. it is a plant or animal variety) become patentable if it can be shown it is a *product* of a process that enjoys mandatory patentability. The biotechnology industry has been arguing "yes", because industry prefers patents to plant breeders' rights as patents provide for stronger IP protection.[43] Traditional plant breeders do not want more extensive patent protection for plant varieties resulting from recombinant gene technology as this would give the biotechnology industry

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40 Article 2(2) Biotechnology Directive.

41 The EPO has stated that 'technical processes involving a microbiological step' (such as a process for producing a plant) may not simply be equated with "microbiological processes" and that the products of such processes cannot be defined as "products of microbiological processes". EPO Case T 0356/93, Greenpeace v. Plant Genetic Systems.

42 Article 28.1 (b) TRIPs. Article 64(2) EPC which provides: 'If the subject matter of a European patent is a process, the protection conferred by the patent shall extend to productions obtained by such process'.

43 For example, patented microbiological techniques will be protected against all types of industrial uses (plant breeders rights allow for research and farmers' exemptions. Furthermore patent protection is not dependent on developing an end product and patents can be obtained without testing.

stronger IPRs than the UPOV style plant variety rights thus undermining plant breeder's place in the market. Allowing plant varieties patentability through "product-of-process" provisions would re-introduce patentability of excluded matter by the "backdoor."

In the *Novartis* case, the EPO stated that the EPC 'legislators could not have intended that plant varieties should be patentable as products of microbiological processes' as at that time it was inconceivable that varieties could be obtained with the help of microbiological techniques.[44] Although modern biotechnology has developed from traditional microbiology and cells are comparable to unicellular organisms under current EPO practise, that does not 'mean that genetically modified plants are to be treated as products of microbiological processes within the meaning of Article 53(b), second half sentence EPC.'[45] To treat them otherwise would mean circumventing the exclusion on plant varieties. Thus for the meantime, genetically modified plants, in the form of patent claims for specific varieties, will not get the strongest forms of IP protection from the EPO.

This could change depending on how the EPO, national patent offices and courts interpret the provisions of the EU Directive 98/44/EC on the legal protection of biotechnological inventions (hereinafter Biotechnology Directive) which EU Member States were required to give effect to by July 2000.[46] The Biotechnology Directive excludes "plant varieties" from patentable subject matter but defines "plant varieties" narrowly so that most transgenic plants would not fall within the definition and thus be subject to patentability.[47] Specifically Article 4(2) of the Directive, coupled with the provisions of Recital 30 and 31[48] of the Biotechnology Directive conflicts with the EPO decision in the *Plant Genetics Systems* case which denied patentability to transgenic plants.[49] This is deliberate because the Biotechnology Directive was intended to provide patent protection to transgenic plants hitherto denied by the EPO (Perdue 1999).

Implementation of the Biotechnology Directive has been under a legal cloud since the *Netherlands* (joined by Italy an Norway) challenged the legal validity of the Directive.[50] The basic thrust of the

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44 Novartis, note 34, paragraph 4.

45 Id. paragraph 5.3.

46 After the adoption of the Biotechnology Directive, the Administrative Council of the EPO amended it Implementing Regulations to the EPC changing its guidelines for examination in the EPO. Rule 23(b) now requires that "EU Directive 98/44/EC is to be used as a supplementary means of interpretation."[46]OJ/7/1999- Decision of the Administrative Council of 16 June 1999 amending the implementing Regulations to the EPC. EPO Press release 5 November 2001, 1 September 1999 new rules 23b–23e entered into force, implementing the requirements of the EU Directive 98/44/EC on the legal protection of biotechnological inventions into European Patent Law.

47 Article 4(1) of the Directive states that plant and animal varieties and essentially biological processes for their production are not patentable but Article 4(2) goes on to limit this exclusion by providing that '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'.

48 Recital 31 states that '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'.

49 Technical Board of Appeal in Plant Genetic Systems.

50 R. v. Legal Protection of Biotechnological |Inventions: The Netherlands (Italy and Norway, intervening) v. European Parliament and EU Council (E.C. Commission, intervening) Case C-377/98), European Court of Justice, 9 October 2001. The ECJ the highest judicial organ of the EU.

Netherlands' objection to the Directive is acceptance of the "notion that plants, animals and parts of the human body may be patentable."[51] The Netherlands considers that the right to a patent in the field of biotechnology should be limited to the biotechnological *process* and not extended to the products deriving therefrom: in other words neither plants and animals as such, including genetically modified plants and animals, nor human biological material should be patentable."[52] This is in keeping with long standing Dutch opposition to grant of life patents *per se*. To support this basic principle, the Netherlands has challenged the Directive on several substantive and procedural grounds. These include, inter alia, that the Directive's provisions unduly overrides Member States' sovereignty with regard to patentable subject matter; that it breaches the provisions of the Convention on Biological Diversity and, furthermore, that it breaches fundamental right to human dignity by allowing patentability of elements isolated from the human body. In addition, the Netherlands argues that a number of legal irregularities mean the adoption of the Directive, which has the effect of harmonising, and at the same time strengthening the patent laws of the Member States, is either unnecessary, inappropriate or unlawful.

The European Court of Justice (ECJ) has rejected each of the grounds put forward by the Netherlands. As a result the Netherlands will now have to provide life patents which it had hitherto not granted. The Directive has curtailed sovereignty on this fundamental ethical principle because it explicitly provides that biological matter must be subject to patentability.

In addition, the Court specifically considered, and rejected, arguments put forward by the Netherlands and Norway suggesting that the Biotechnology Directive would lead to plant and animal varieties being patentable as a result of the Directive's provisions conferring patent protection for the *products* of biotechnological processes. [53] In the ECJ's view, the Dutch objection to the Directive on this ground fails to distinguish the concept of patentability from the concept of protection conferred by a patent.[54] The ECJ has concluded that the Directive does not make plant varieties patentable *per se* as patents and plant variety rights remain mutually exclusive. [55]The ECJ has confirmed that 'an invention – such as the genetic modification of a plant so as to increase its resistance to a herbicide – may be patented if its technical feasibility is not confined to a particular variety, or to put it another away, it will not be excluded from patentability solely because the claim encompasses plant groupings which embrace more than one variety.'[56] The ECJ's decision in the Netherlands' case thus follows the logic of the EPO Enlarged Board of Appeal's decision in *Norvatis*.

The end result of the enactment of the Biotechnology Directive is that patent protection in the EU, and under the EPC, will be available for transgenic plants provided the patent claim can be crafted in such a manner as to encompass more than one plant variety. Thus the exclusion of "plant varieties" mandated

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51 Id.
52 Id. Paragraph, A10.
53 Id. Paragraphs A119–128.
54 Article 8(1) of the Directive provides that the protection conferred by an original patent extends to future generations of biological material derived through propagation or multiplication.
55 Id. A126.
56 Id. Paragraph A139.

by the EPC, and technically duplicated in the Biotechnology Directive, has been considerably narrowed through incorporations of other provisions and judicial reasoning. Thus the arguments of the biotechnology industry have, to a very large extent, swayed the judicial processes of both the ECJ and the EPO in favour of an interpretation favourable to the biotechnology industry. In addition, by explicitly affirming the EPO's December 1999 Novartis decision, the ECJ has reduced the likelihood that a national court or patent office might interpret the provisions of the Directive and the EPC in a manner inimical to the interests of the biotechnology industry. Thus the harmonising effect of the Directive has been to restrict national choices EU Member States to limit patents for biotechnology and/or favour the availability of plant variety rights for biotechnological innovations dealing with plants.

Thus in the European context, as in the US, legislative and judicial processes have, to a large extent, supported the needs of the biotechnology industry rather than the moral, ethical and environmental concerns raised by NGOs and civil society groups. There is some evidence to support the view that European judges have already begun to communicate with one another in an effort to harmonise EU patent law. (Gitter 2001) The IPR rules of the US and the EU may not have aligned themselves completely. But the EU Biotechnology Directive, and its use as an interpretative instrument of clarification by the EPO, demonstrate acceptance by European policy-makers that European laws are a hindrance to the biotechnology industry that need to be changed and "re-interpreted" to fit the technological circumstances of today. This is despite the fact that large segments of European public has challenged the re-alignment of EU IPR law to US standards by intervening in judicial and legislative processes, as well as by rejecting genetically modified foods as consumers.

4.2.4 Ordre public and morality

Both TRIPs and the EPC allow countries to exclude inventions from patentability to protect *ordre public* and morality, including inventions dangerous to human, animal or plant life or health or seriously prejudicial to the environment. An exclusion on these grounds cannot be made merely because the exploitation of the invention is prohibited by law. This means that approval or disapproval of the exploitation of an invention based on national laws or regulation did not constitute *per se* a sufficient criterion for exclusion. In order words, the law or regulation had to be justified.

In the ECP content, the EPO has defined the concept of *ordre public* to refer to public policy considerations such as the protection of public security and the physical integrity of individuals as part of society.[57] The concept of *morality* relates to a belief that some behaviour is right and acceptable whereas as other behaviour is wrong. Judging right and wrong must be done according to the accepted values deeply rooted in the culture inherent in European society and civilisation.

The *ordre public* and morality provisions of the EPC have been litigated intensively over the course of the last 15 years through a series of high profile cases.[58] The enactment of the EU Biotechnology

[57] T 356/93 Plant genetics systems, 1995.
[58] The key cases are T 19/90, T 356/93 and T 356/93.

Directive is a response, in part, to quell the controversy created by this litigation by providing definitive legislative input and guidance to the EPO on *ordre public* and morality issues within the patenting process. It has taken the EU over a decade to enact the Directive.[59] The legal challenge to the Directive's validity launched by the Netherlands demonstrates that some Member States continue to oppose the Biotechnology Directive on fundamental grounds based on morality even though it has passed through the complex EU legislative process. [60] This has led one legal scholar to point out that 'enactment of the Directive is not the culmination of the debate over biotechnology patent law in the EU, but is a starting point for future refinements and enhancements of the morality provisions.' (Gitter 2001)

In the ideal world, EU citizens, acting through their elected legislative institutions, would play an active part in defining how the *ordre public* and morality should be further refined (ibid.). In the real world, it is more likely that case law will determine how these provisions will be further elaborated. Case law and the patents process is driven largely by the biotechnology industry's need for IPRs. Patent applications will be challenged only if NGOs have strategic reasons, and the finances, to mount legal challenges.

It is possible that NGOs/civil society elements opposed to biotechnology may use litigation in a strategic manner to cause delays and uncertainty in the patenting process. For this reason, a number of scholars have argued that the *ordre public* and morality provisions of the EPC and EU Biotechnology Directive could be used in this way and lead to delays in the harmonisation and strengthening of IPRs the Directive was supposed to achieve (ibid.). But this depends on funding and whether NGOs consider it is in their interest to target European patenting processes as a key point of intervention in their fight against biotechnology. Given that in all the major cases considered below, NGOs actually failed in preventing patents being granted on *ordre public* and morality grounds, it is by no means clear that NGOs will either want, or have the finances available to challenge individual patents based on *ordre public* and morality considerations alone.

So far as NGOs/civil society outside Europe are concerned, legal challenges to particular decisions by patent offices and courts on *ordre public* and morality grounds may provide an important avenue for testing the scope of TRIPs implementing legislation. It is also likely that cases will also arise at the WTO level on TRIPs implementation. It is important therefore to consider the European experience with the case law dealing with *ordre public* and morality exclusions.

Thus far, there have been five major cases dealing with these provisions at the EPO. The recent Netherlands challenge before the European Court of Justice, has also shed light on the approach the ECJ may take with regard to future litigation invoking the morality provisions in the EU Biotechnology Directive.

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59 The EU Commission first proposed the Directive in 1988. The delay in its enactment is due in part to its controversial subject matter. It was also due in part to the fact that the Directive was the first major piece of legislation to go through a new "co-decision procedure" which gave the EU Parliament significantly more say in the form of the legislation than had previously been the case.

60 Netherlands case, note 50.

The first case concerned the grant of a patent for a hybrid transgenic plant for *Lubrizol Genetics Inc.*[61] Environmental groups objected on the environmental grounds that the grant of the patent would result in a loss of biodiversity as well lead to restrictions in the free flow of plant germplasm. Religious groups argued that patenting living matter was against fundamental moral principles deeply embedded in European religion and culture.

The EPO examined these objections with reference to then guidelines on examination of patents. These stipulated that in order to determine whether an invention is contrary to *ordre public* or morality, ' a fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of a patent right would be inconceivable.' (Gitter 2001) The Guidelines went onto explain that the morality exclusion provision 'is likely to be invoked only in rare and extreme cases.' Using this "public abhorrence" test, the EPO went on to reject all the grounds of opposition presented by NGOs (ibid.). The EPO pointed out that many European countries, and the US which has Christian tradition, granted patents to living matter so it could not be said that European religious sensibilities would be offended by the grant of the patent. As to loss of biodiversity, the EPO pointed out that biotechnology increased genetic diversity by introducing new plant varieties, and because traditional breeding techniques could also result in loss in biodiversity, biotechnology could not be singled as a special case, and that in any case, there were many other causes of biodiversity loss. Finally, it is interesting to note the EPO also made a pertinent comment about its own role stating that 'patent law is not an appropriate instrument for regulating the development on new technologies and that the legislature should determine whether a certain technology is so dangerous and unacceptable to the public that it should be suppressed (ibid.).

A second case in which the EPO applied the "public abhorrence" test concerned the grant of a patent for a DNA fragment encoding a human protein produced by pregnant women with useful medical applications: the *Hormone Relaxin* case.[62] In 1992, the Green Party launched an opposition to the patent on morality grounds. It is important to bear in mind that around this time, the Biotechnology Directive was going through the EU legislative process and the EU Parliament, with an active green element, supported by many NGOs, was opposing the Directive on moral and ethical grounds. In this case, the EPO stated that the morality exclusion in the EPC must be 'seen as a measure to ensure that patents would not be granted for inventions that would *universally be regarded as outrageous.*'[63] The EPO used the fact the EU Biotechnology Directive was supported by some and opposed by others as evidence that patenting of human gene sequences was not *universally* regarded as outrageous (Gitter 2001). The EPO pointed out that there was no provision in the EPC stating that only inventions which met with public approval should be patentable. Exclusion from patentability should require an "overwhelming consensus" that an invention

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61 T0320/87, 1990, A patent was granted for the product because the hybrid plant and its seeds lacked stability and so did not fall under the "plant variety" exclusion and also for the process which was not "essentially biological" as it could not happen in nature.

62 Hormone Relaxin, 1995, O.J.E.P.O.388.

63 Id. (emphasis added).

was immoral to trigger exclusion on immorality grounds. The EPO also rejected the Green Party's arguments that patenting of material taken from a pregnant women offended against human dignity and amounted to a modern form of enslavement. It pointed out that a sample had been taken with consent of the patient and DNA sequences could not be held to be equivalent to "life" but were to be seen as carriers of information useful for medical research.

The third case, or more accurately, the series of cases involving the *Harvard/Oncomouse* have provided the most detailed consideration of the *ordre public* and morality issues in the EPC. In 1985, Harvard University filed a patent application with the EPO for a genetically modified mouse containing the insertion of an activated oncogene.[64] The application was initially rejected on the grounds that it breached the EPC exclusion of "animal varieties" which the Examining Board interpreted to mean animals *per se.* [65] Harvard appealed this to the Technical Board of Appeal. The Technical Board of Appeal provided guidance to the Examining Division on what the term "animal variety" encompassed stating that it did not excludes animals *per se*. It then asked the Division to re-examine the case to see if the invention in fact constitutes an "animal variety." [66] In view of the opposition to the grant of a patent on a living mammal, the Board ordered the Examining Division to examine whether exploitation of the invention would be contrary to *ordre public* and morality.[67] In doing so, the Board asked the Examining Division to 'carefully weigh up the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other.' This approach to considering ordre public and morality issues, requiring a balancing of different interests, is quite different from the "public abhorrence" test deployed in the *Lubrizol* and Hormone *Relaxin* cases. This approach has been called the "unacceptability test."

In a second decision in 1992, the Examining Division granted the "oncomouse" patent and in view of the intense public interest in the case, issued a statement setting out their reasons for the grant of the patent. [68] It concluded that the usefulness of the oncomouse in the fight against cancer outweighed other considerations relevant to considering *ordre public* and morality. The oncomouse would result in fewer animals being the subject to research. And the benefit of anti-cancer treatments would be a "valuable and highly welcome by everyone." The potential risks to the environment were dealt with in a perfunctory manner with the Examining Division focusing on whether or not there was a risk to the environment if oncomouse were deliberately released into the environment through and accident or blatant ignorance on the part of laboratory personnel. The EPO decided that 'that the mere fact that such uncontrollable acts are conceivable cannot be a major determinant for deciding whether a patent should be granted or not.' And exclusion from patentability cannot be justified merely because a technology is dangerous. In its explanatory note, the EPO is clear that 'the regulation of the handling of dangerous materials is not the

64 The US patent for the oncomouse was applied for in 1984 and granted in 1988.
65 Case V 0004/89, Harvard/Oncomouse, Examining Division Decision of 14 July 1989.
66 Case T0019/90, Decision of 3 October 1990, 1990, E.P.O. R 501.
67 Id.
68 Statement of the Examining Division on Decision in T19/90, in 1991 E.P.O.R. 525.

task of the EPO but is rather the business of specialised governmental authorities.[69] Finally the Examining Division stressed that the balancing test it had undertaken in this case applied solely to the present case and that 'other cases of transgenic animals are conceivable for which a different conclusion might be reached in applying Article 53(a) EPC.'[70]

Following the grant, seventeen organisations, political groups and NGOs filed opposition to the patent. In 1995, the Opposition Division of the EPO held oral proceedings to hear the objections. Because the time allocated proved insufficient to hear all the applicants, written proceedings were instead continued. These lasted until 1999 when it knew Rules 23b-23e entered into force which implemented the EU Biotechnology Directive into European patent law. In addition, the highest appeal body of the EPO, the Enlarged Board of Appeal, had issued a decision in the *Novartis* case which defined "plant varieties" in a way which would also have implications for the way in which the term "animal varieties" should be construed. Some have argued that the opposition to the oncomouse patent was put on hold for five years to allow guidance from the EU and the Enlarged Board to filter through to the Opposition Division of the EPC dealing with the oncomouse case.[71] Given these new legal and political realities, the Opposition Division in September 2000 invited parties to the case to make any further oral interventions. These were held in November 1991 when the EPO opposition division decided to maintain Harvard's patent albeit in an amended form.[72]

It should be noted that the "public abhorrence" test used in *Lubrizol* and *Hormone Relaxin* seemed to relate quite clearly to the concepts of right and wrong which are central to the notion of morality. The "unacceptability test" deployed in the *Oncomouse* case is rooted in a more utilitarian approach which places the emphasis on whether benefits to some would outweigh the negative effects suffered by others. The issue of whether such a trade-off is right or wrong, i.e. moral or immoral, is not considered as the Board has implicitly assumed that it is moral to make such a trade-off in the first place. Thus although the Examining Board comes to the conclusion that patenting the oncomouse is not immoral, it does so by deploying a test which appears to essentially ignore, rather than address, the moral concerns actually presented by opponents.

The unacceptability test was referred to but not actually fully deployed in the *Plant Genetic Systems/Greenpeace* case decided by the Technical Board of Appeal in 1995.[73] The aim of the patented invention was to develop plants and seeds which were resistant to a particular class of herbicide thereby enabling selective protection against weeds and fungal diseases. Modern biotechnological techniques were used to develop such plants and seeds which were integrated into their genome in a stable manner, herterologous DNA encoding a protein capable of inactivating or neutralising such herbicides. The patent

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69 Id.

70 Id.

71 K. Spindler, Current Patent Protection Granted For Genetically Modified Organisms Under The European Patent Convention And The Scandal Of Ep 0695351, 18 Computer & High Tech. L.J. 95

72 The EPO press release of 11 November 2001 announcing this states it is open to Harvard or the other applicants to appeal this decision.

73 T356/93.

claimed the resulting plant variety as well as the method for producing such a plant and reproduction of the plant. Opposition to the patent was entered by Greenpeace on several grounds, including whether the resulting plant variety should be patentable and the implications of the scope of products of micro-biological processes (discussed above) and also on environmental grounds under Article 53 (a).

The Board decided that seeds and plants *per se* do not constitute an exception to patentability under Article 53 (a) merely because they represent living matter. Thus the Board rejected the "patents on life" argument based on fundamental moral beliefs.[74] The Board also stated that plant biotechnology *per se* cannot be regarded as being more contrary to morality than traditional selective breeding, since both involve the introduction of novel genetic material in order to change plant properties. In this particular case, the form of herbicide resistance could also be obtained by traditional selection techniques. Therefore, the subject-matter of the patent did not concern activities which were wrong as such in light of conventionally accepted standards of conduct of European culture. By emphasising the "sameness" of biotechnology with traditional breeding, the Board downplayed the unique feature of biotechnology that has caused the public to have widespread concerns: that genetic material can be incorporated across species boundaries and produce creations beyond the limits of traditional breeding.

In relation to the environmental concerns, the Technical Board of Appeal held that the concept of *ordre public* encompasses environmental protection and that inventions the exploitation of which is not in conformity with the conventionally accepted standards of conduct pertaining to the culture inherent in European society and civilisation are to be excluded from patentability. The Board rejected survey and opinion evidence presented by Greenpeace concerning public attitudes to genetically modified plants. The Board stated that such evidence is "not decisive" when assessing whether an invention is to be regarded as being in conformity with conventionally accepted standards.[75] On the other hand, particular subject-matter should not be automatically regarded as complying with the requirements of Article 53(a) merely because its exploitation is permitted in some or all countries.

Greenpeace had argued that if the EPO was to do the kind of balancing exercise embedded in the "unacceptability test" used in the *Oncomouse* case, the Board should be prepared to balance the benefits of the claimed invention with its potential disadvantages which might include negative environmental consequences. The EPO accepted Greenpeace's submission that 'the EPO, being at the crossroads between science and public policy, was qualified to make value judgements about a given technology."[76] But the Board held that revocation under Article 53(a) on the basis of serious prejudice to the environment requires that the threat to the environment be sufficiently substantiated at the time of the EPO decision. The evidence submitted in the *Plant Genetics* case by Greenpeace (for example, as to transformation of crops into weeds, spreading of the herbicide-resisting gene to other plants, damage to

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74 The Board cited the Oncomouse decision in support and also previous Decision 49/83 where it was stated that "no general exclusion of inventions in the sphere of animate nature can be inferred from the EPC."

75 The Board pointed out the survey of Sweden and opinion poll in Switzerland submitted by Greenpeace did not represent Europe and that the results of such instruments can "fluctuate" and can be "easily influenced and controlled" depending on the question asked, size of poll sample, the representativeness of the sample.

76 Paragraph IX.

ecosystems) did not justify such a conclusion as there was only evidence of possible risk. And it would be 'unjustified to deny a patent…on the basis of possible, not yet conclusively documented hazards.' Such hazards should be looked at by regulatory bodies in charge of determining whether a patented invention could be used. The board also stated that 'in the present case, since no sufficient evidence of actual disadvantages has been adduced, the assessment of patentability with regard to Article 53(a) may not be based on the so-called "balancing exercise" of benefits and disadvantages . . . The Board observes that such a "balancing exercise" is not the only way to assessing patentability with regard to Article 53(a) but just one possible way, perhaps useful in situations in which actual damage and/or disadvantages (for example, suffering of animals as in the case of Decision T19/90) exists.'[77] Without stating the exact nature of approach it was using, the Board decided that none of the claims in the patent contravened the provisions of Article 53(a), based on its observations about the lack of evidence about serious risks to the environment and that, in any case, it was really up to other regulatory bodies, not the EPO, to evaluate whether the risks should result in banning or limiting the use of an invention.

The fifth and most recent case which has been subject to an opposition proceeding at the EPO which has touched on Article 53(a) is the *Novartis* case.[78] The questions referred to the Enlarged Board of Appeal did not raise *ordre public* and morality issues. Because Greenpeace had objected to the grant of the patent for many reasons, including *ordre public* and morality, and given the Board felt these objections raise questions which are of interest to many members of the public, the EPO responded to Greenpeace's objections. [79] The EPO stated that it 'has not been vested with the task of taking into account the economic effects of the grant of patents in specific areas and of restricting the field of patentable subject-matter accordingly.'[80] The EPO admitted that 'the positions adopted in society on genetic engineering are controversial . . . there is no consensus among Contracting States condemning genetic engineering in the development of plants.' But it went on to point out that the Biotechnology Directive explicitly states that promotion of innovation in the biotechnology is considered necessary in Europe and its provisions take into account the interests of plant breeders. In passing comment on the issues raised by Greenpeace, the EPO has indicated a general pro-biotechnology stance even though it has stated, and still accepts, that decisions on Article 53(a) exclusion must be made on a case by case basis.

In 2001, the European Court of Justice (ECJ) has examined the scope of the *ordre public* and morality provisions of the EU Biotechnology Directive and their consistency with article 53(a) EPC in its decision on the Netherland's case. The Dutch argument that the Directive was invalid because it made exclusion on *ordre public*/morality grounds available only when an invention was "commercially exploited" whereas the EPC provided for exclusion on either the "publication or exploitation" of the invention, was rejected by the Court. The ECJ went onto say that 'there is no need to consider that the concept of *ordre public* falls to be interpreted differently in the Convention and in the Directive'. Any risk that national courts will,

77 Paragraph 18.8.
78 See G 1/98.
79 Id. Paragraph 3.9.
80 Id. Paragraph 3.9.

when applying national law implementing the Directive, interpret the concept differently from the European Patent Office when applying the Convention, is now moreover ever further reduced since the entire text of the Directive has . . . been incorporated in the Implementing Regulations to the Convention which state that the Directive 'shall be used as a supplementary means of interpretation.'[81] So far as the difference between the Directive referring solely to commercial exploitation and the Convention to publication and exploitation, the Court emphasised that the 'difference . . . has no practical impact since an invention whose publication but not whose commercialisation would be so contrary seems scarcely conceivable.'[82]

These statements by the Court give a strong indication that in future disputes about *ordre public* and morality, the ECJ will expect national courts interpreting the Biotechnology Directive to look closely at the case law of the EPO and to make decisions that are broadly consistent with previous EPO decisions. Such guidance by the ECJ is likely to limit the extent to which national courts will adopt varied, and contradictory, interpretations of the EPC and EU Biotechnology Directive.

It should be noted that of the five biotechnology-related cases where *ordre public* and morality exclusions have been raised, none has been excluded from patentability, notwithstanding their controversial nature. Indeed, it seems that some regard the EPO as having come under 'pressure to declare such inventions morally acceptable' (Gitter 2001). Given the negative attitudes towards genetic engineering in Europe, in particular, the large scale rejection of genetically modified foods, award of patents on biotechnology innovations in agriculture has obviously conferred some degree of "acceptability" on these new products: that a patent process has decreed an invention to be beneficial for society at large and not immoral must surely count for something in the public relations battle that has been raging between the biotechnology industry and its opponents.

Assessment of the European case law suggests that of all the institutions involved in biotechnology regulation, patent offices have perhaps been the most consistent supporters of biotechnology. Other European institutions, such as the various legislative bodies of the EU, and the regulatory bodies in charge of release of GMOs into the environment, have, over time, tempered their enthusiastic support of biotechnology and given due consideration to the ethical, economic, environmental and moral concerns raised by NGOs and civil society. Through its case law the EPO has, by contrast, defined an approach to considering *ordre public* and morality issues in such a manner as to make it virtually impossible for any of these concerns to actually succeed in deny patents to biotechnological inventions.

Reasons for why this should be so are complex. Perhaps the in-built pro-technology bias of patent offices reflects an instinctive understanding of their role as *promoters* of technology and innovation. Although the EPO has recently agreed with Greenpeace's view that 'patent offices are placed at the crossroads between science and public policy' the case law nevertheless reflects a degree of discomfort about their exact role in the public policy-making process. Additionally, the fact that most patent officials

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81 See Kingdom of the Netherlands v European Parliament and Council of the European Union, European Court of Justice Case number Case C-377/98 paragraph A164.

82 Id. Paragraph 165.

tend to be drawn from natural science or engineering disciplines, and have only had to deal with the industries making patent claims, make them more likely to favour industry arguments than the development, environmental and religious NGOs who have targeted the EPO in more recent years.

Patent offices in developing countries are more likely than not to share some of the cultural background of their European (and US) counterparts which seems to favour, albeit on an implicit basis, the grant of patents to biotechnology. If this is the case, patent officials and courts in developing countries are more likely to interpret TRIPs implementing legislation in a manner broadly favourable to the biotechnology industry, however successful national NGOs may have been in trying to enshrine more restrictive provisions into domestic legislation.

This is important because the foregoing analysis of European case under the EPC has shown the crucial role played by patent offices and courts in the interpretation of patent legislation, which on the face of it, could have been construed in a manner highly restrictive to the needs articulated by the biotechnology industry. Patent offices and courts will be continue to play a significant role in IPR policy with technological developments and the changing economic and financial landscape driving the debate. Developing country patent offices and courts, which have hitherto, not played a major role in interpreting biotechnology related IPR legislation, will now, as a result of TRIPs, become more involved in IPR policy making as developing countries implement TRIPs legislation and as the demand for adjudicating between competing visions of what this legislation should mean in practice increases.

The increasingly important role that patent offices and courts are likely to play in the future has been recognised by the US biotechnology industry. With support from industry sources, a new project – Biojudiciary.org – has been set up with the explicit goal of providing US judges, law clerks, lawyers and legal academics with information about biotechnology.[83] With thousands of new patents for biotechnology issued and pending in the US, Biojudiciary's organisers believe 'we could be poised for an avalanche of new litigation. The outcome of such disputes will be crucial not only to the particular companies but in some cases to the industry as a whole.'

The crucial role of courts in "nurturing our industry" is thus acknowledged and provides the rationale for the industry to target its educational resources at the judiciary.[84] Biojudiciary's website states that the project's aim is to 'provide judges and legal professionals an objective educational resource. Given the expense and inherent risks of scientific enterprise, and the many hurdles to bringing a product to market, the investor-dependent biotechnology industry can thrive only if the legal and regulatory environment remains consistent and predictable.' The kind of information that Biojudiciary hopes to provide will cover 'not only the finer points of each case but also the broader ramifications it may have on the industry, those who use the technology and American society.' Thus although the information

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83 For details of Biojudiciary see www.biojudiciary.org/about/forward/asp, 21/05/2001. Biojudiciary is supported by, inter alia, the Biotechnology Industry Organisation and Ernest and Young.

84 The website states 'When we consider how government policy influences biotechnology, we think first of Congress and the executive branch, and the issues over which they hold sway, such as Food and Drug Administration regulation and reform, investment incentives and the like. But the third branch of government is every bit as vital to the nurturing of our industry' www.biojudiciary.org/about/forward/asp, 21/05/2001.

Biojudiciary will provide is meant to be "objective" and "neutral", it is clear it will focus on explaining the needs of industry and broader interests of the US as a whole.

Earlier sections of this paper explained how the impetus for including IPR in the Uruguay Round which led to TRIPs came from a small group of US chief executives who focused their efforts on creating a linkage between trade and IPR issues, initially on US policy-makers. The Biojudiciary project reflects forward thinking by the biotechnology industry about next steps it sees are necessary to advance its interests. Currently, the Biojudiciary project appears to be focused on US judicial processes. But it is easy to see how such an initiative could in due course, expand to cover "educating" the judiciary and patent offices of other countries, particularly those in the processes on implementing TRIPs legislation.

Judicial and patent offices in developing countries should have access to information about the IPR case law elsewhere. But this must not just be filtered through industry perspectives, but also include the perspectives of others that have been involved in the IPR/biotechnology debate in the US, Europe and elsewhere. This speaks in favour of establishing a project like Biojudiciary but incorporating a much wider range of educational material and perspectives, including moral, ethical, environmental and equity issues of relevance to developing countries implementing TRIPs legislation, not least because such consideration are likely to be underplayed in educational material provided by the biotechnology industry.

4.3 TRIPs implementation by developing countries

In 2000 and 2001, the TRIPS Council began the process of reviewing the legislation of the developing country Members whose transition periods for implementing TRIPs had expired.[85] Many of these countries have put into effect national legislation to implement the TRIPS Agreement before the 1 January 2000 deadline. Thus far, developing countries' implementation of TRIPs is taking the familiar shape of the patent/UPOV type plant varieties legislation developed in the US and EU.

One of the major reasons is the pressure being put on developing countries by the US and the EU in their trade, aid or bilateral investment treaties (BITs). These agreements are generally negotiated by trade ministries without parliamentary or public scrutiny. And this provides one reason why the US and EU have targeted developing countries to include various "TRIPs-plus" provisions or other pro-biotechnology clarifications as part of their bilateral deals with these individual countries (GRAIN 2001a). Rather than developing *sui generis* forms of plant varieties protection on the basis of public debate, Cambodia, Jordan, Morocco, Tunisia and Vietnam have recently joined UPOV as a result of bilateral agreements with the US. (ibid.) Other TRIPs-plus clauses in bilateral investment treaties concluded by the EU and/or US include explicit requirements to allow patenting of plants and animals and provision for

[85] Antigua and Barbuda, Argentina, Bahrain, Barbados, Belize, Bolivia, Botswana, Brazil, Brunei Darussalam, Cameroon, Chile, Colombia, Congo, Costa Rica, Côte d'Ivoire, Cuba, Cyprus, Dominica, Dominican Republic, Egypt, El Salvador, Estonia, Fiji, Gabon, Ghana, Grenada, Guatemala, Guyana, Honduras, Hong Kong, China, India, Indonesia, Israel, Jamaica, Kenya, Korea, Kuwait, Macau, Malaysia, Malta, Mauritius, Mexico, Morocco, Namibia, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Paraguay, Peru, Philippines, Poland (areas which were not reviewed in '96–'98), Qatar, Saint Lucia, Singapore, Sri Lanka, St. Kitts and Nevis, St. Vincent and Grenadines, Suriname, Swaziland, Thailand, Trinidad and Tobago, Tunisia, Turkey, United Arab Emirates, Uruguay, Venezuela, Zimbabwe.

enforcement of IPRs at the "highest international standards." (ibid.) The impact of these treaties will be a gradual convergence of IPR policy between developed and developing countries IPR policies at level much higher than the minimum standards specified in TRIPs. This harmonisation will facilitate life for the biotechnology industries but at the expense of crafting tailor made policy choices more appropriate for developing countries.

India and Kenya have adopted quite different approaches to IPRs and to TRIPs requirements, and in different ways, played leadership roles in the negotiation of the TRIPs agreement at the WTO. Kenya, for example, has spoken on behalf of the African Group.[86] India has had a long standing tradition of limiting IPRs to protect public policy goals of advancing developments in the agriculture and pharmaceutical sector and has been one of the few developing countries where there has been widespread public debate about the benefits of implementing TRIPs.

Kenya is one of the few developing countries to have IPR legislation in place before TRIPs and has needed to do comparatively little by way of TRIPs compliance. At the WTO and other international fora, however, Kenya has taken a strong position on the need for a substantive review of Article 27.3(b) and the need to extend the deadline for TRIPs implementation five years after the substantive review. [87] It has argued that there is lack of clarity on the reasoning used to decide what can and cannot be excluded from patentability in Article 27.3(b). Kenya has opposed compulsory patenting of micro-organisms (which are natural living things) and microbiological processes (which are natural processes), arguing that the provisions of Article 27.3 contravene the basic tenets on which patent laws are based: that substances and processes that exist in nature are a discovery and not an invention and thus are not patentable. Moreover, by giving Members the option whether or not to exclude the patentability of plants and animals, Article 27.3(b) allows for life forms to be patented." Kenya has argued that the substantive review of Article 27.3(b) should clarify: (1) why the option of exclusion of patentability of plants and animals does not extend to micro-organisms as there is no scientific basis for the distinction, (2) why the option of exclusion of patentability of "essentially biological processes" does not extend to "microbiological processes" as the latter are also biological processes, and (3) that plants and animals as well as micro organisms and all other living organisms and their parts cannot be patented, and that natural processes that produce plants, animals and other living organisms should also not be patentable.

Kenya's domestic legislation to implement the patents parts of TRIPs was passed in August 2001. The Act has received Presidential assent but it remains in unpublished form and so has not yet been implemented.[88] The Act appears to adopt the provisions of Article 27.3(b). It excludes plant varieties from patentability but provides that parts of plants varieties and products of biotechnological processes are patentable. By doing so, the Act fails to incorporate clearly the clarifications Kenya is demanding at the international level in relation to Article 27.3(b).[89]

86 Preparations for the 1999 Ministerial Conference. The TRIPS Agreement: Communication from Kenya on Behalf of the African Group, WT/GC/W/302.; Minutes of TRIPS Council Meeting of 20–21 October 1999, IP/C/M/25.

87 Id.

88 Kenya Industrial Property Act 2001.

89 Section 26 (a) Kenyan Industrial Property Bill 2000.

Plant varieties excluded from patent protection will protected in Kenya under the Seeds and Plant Varieties Act.[90] At the WTO, Kenya has argued that any *sui generis* law for plant variety can provide protection under Article 27.3(b). Such a system could provide for: (i) the protection of the innovations of indigenous and local farming communities in developing countries, consistent with the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources; (ii) the continuation of the traditional farming practices including the right to save, exchange and save seeds, and sell their harvest; and (iii) preventing anti-competitive rights or practices which will threaten food sovereignty of people in developing countries, as is permitted by Article 31 of the TRIPS Agreement.

Whilst supportive of farmers' and communities' rights at the international level, Kenya's has not given concrete substance to the concerns it has articulated at the international level in its plant varieties legislation. [91] Kenya is only one of three African countries to have acceded to the 1978 UPOV convention. Although Kenya has argued at the WTO that it believes that implementation of plant variety protection needs to be clarified to allow developing countries to meet other international obligations (i.e., CBD, FAO International Understanding, now ITPGRFA) and should cover protection of traditional knowledge, its own accession to UPOV has meant that its formal system of plant varieties protection does not provide any form of legal protection for farmers' varieties or traditional knowledge.

Perhaps one reason is the rushed nature of Kenya's implementation of TRIPs. It has been argued that the new Industrial Property Act was hastily drafted after the Kenya Medical Research Institute KEMRI discovered, KEMRON, a drug said to have curative value in managing AIDS.[92] Scholars has also expressed surprise at Kenya's decision to implement speedily, and ahead of its own stated preference to be given more time, TRIPs implementing legislating strengthening patents and plant varieties legislation (Cullet 2001). One staff member at Kenya's newly established Plant Breeders' Rights Office is also sceptical about the benefits Kenya's establishment of plant breeders rights and accession to UPOV will bring to Kenya pointing out that 'plant breeders rights will . . . weaken research on crop varieties . . . such as traditional food crops . . . and shift . . . research priorities' toward cash crops/high value crops such as roses and other cut flowers (Dutfield 2001). Out of 136 applications filed and tested since 1997, only one was a stable food crop while most concerned cash crops such flowers and sugarcane and more than half were rose varieties (Cullet 2001). Furthermore, between 1997 and 1999, 91 per cent of the applications came from foreign institutions (ibid.). Thus the Kenyan experience with the introduction of plant varieties legislation shows that that it has not fostered the development of new *food* crops nor led to increased applications from domestic institutions. On the other hand, the cost of running the newly strengthened patent office and the PBR Registry fall on public expenditures although patent applicants make some contribution towards these through pay of patent fees. The Kenyan experience with IPRs suggests that the requirements of international processes and pressure to implement their WTO commitments have left little time for national policy processes to define their own IPR needs and to plan a legislative timeframe which fits in with national priorities. Most of the pressure to have strong IPRs has come from international sources. Kenyan interests engaged in growing cash crops for exports and horticulturalists, who also rely on exports, seemed to have provided an additional rationale for the Kenyan government to develop IPRs.

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90 The Seeds and Plant Varieties (Plant Breeders Rights) Regulations, 1994, gives effect to the 1972 Seeds and Plant Varieties Act which was heavily modelled on UPOV and most of which lay dormant on the statute book until the 1994 Regulations.

91 The Kenyan focus on protection of traditional knowledge has been to develop protection of folklore under copyright and to use "utility model" patent like provisions to protect indigenous inventions, which fall mostly under the category of arts and crafts such as Maasai beadwork rather than plant varieties. Dr Ottiene Odek, University of Nairobi, Towards TRIPs compliance: Kenya's experience and legislative reforms, 31 July 2001. More recently, Kenya has incorporated in section 50 of its 1999 Environmental Management and Coordination Act, a requirement for the new authority established under the Act to protect the indigenous property rights of local communities in respect of biological resources.

India's implementation of TRIPs has been subject to intense scrutiny and public debate at the domestic and international level. India's pre-TRIPs IPR legislation, with its wide range of exemptions for the agriculture, horticulture and pharmaceutical sectors, combined with India's large domestic market and its ability to export products in these areas, made India one of the targets of US global efforts to tighten IPRs. Large-scale civil protests against TRIPs in the early 1990s strengthened the Indian government's hand in international negotiations. As a result, India was one of the few countries that fought actively against inclusion of TRIPs in the Uruguay Rounds. More recently, India has focused its attention on trying to find creative ways of strengthening the scope and enforcement of IPRs as required by TRIPs with its long-standing commitment to balance IPRs against other policy goals, such as public health and food security.

Unlike Kenya, implementation of TRIPs by India has required fundamental changes to its existing IPR legislation. Furthermore, the existence of an active and informed civil society highlighting the linkages between IPRs, food security, farmers' rights, biopiracy and public health issues has sensitised the legislative branch about the implications of IPR policy choices. This environment has created the necessary "political space" for India to think creatively about how to safeguard its fundamental interests whilst at the same time giving effect to TRIPs.

India's approach is embedded in four separate but related Acts of Parliament: the First Patent Amendment Acts;[93] the Second Patent Amendment Act;[94]the Plant Variety Protection and Farmers' Rights Act;[95] and the Biological Diversity Act which is intended, primarily to implement the 1992 Biodiversity convention.[96]

India has established a *sui generis* system for plant varieties, excluding plant varieties and a wide range of related subject-matter, such as seeds, from patentability. The Plant Variety Protection and Farmers' Rights Act ensures that farmers are able to save, use, resow, exchange, share as well as sell farm-saved seeds from protected varieties to neighbours in accordance with traditional practice. The sell of seeds was one of the most controversial aspects of the legislation because multinational companies did not want farmers in India, who currently provide about 87 per cent of the country's annual seed requirements, to be able to sell seeds from protected varieties.[97] Although farmers will not be able to sell such seed in a commercial fashion, the ability to sell informally will ensure that companies will not be able to dominate seed production.

Apart from this significant farmer-friendly provision, the Act allow establishes a system of registration by a wide range of groups of existing (as opposed to new) farmers' varieties thus making it possible for farmers' to gain compensation (through the establishment of a National Gene Fund) when existing farmers varieties are used for making new varieties. Hitherto, formal breeders had been able to make use of farmers' varieties without any formal acknowledgement or financial recompense.

Numerous procedural requirements in the Act give effect to farmers' rights contained in the Act, by for example, requiring full disclosure of the parentage of the new variety and giving farmers access to such documentation free of change. Liability provisions are included to protect farmers from harvest failures caused by supply of defective seeds. Significantly, farmers are given some protection against breeders

92 Statement of Stella Munyi of KIPO, quoted in AllAfrica.news, Experts seek to review legislation on patent system, 23 October 2000.

93 The first Patent Amendment Act was passed in 1999 (amending India's 1970 Patent Act) to implement specific TRIPs requirements relating to "mail box" protection for pharmaceutical and chemical sectors. This amendment was introduced prior to 2000 as a result of cases bought by the US and the EU before the WTO. See WT/DS50/R, India: patent protection for pharmaceutical and agricultural chemical product (US complaint), report of Panel, 5 September 1997, and also WT/DS50/AB/R.

94 This was passed on 14 May 2002 and deals with the substantive changes required by TRIPs, including those dealing with the scope of patents.

95 September 2001. Bill No. 123 of 1999.

96 Bill No. 93 of 2000.

should farmers unwittingly use seeds protected by plant variety rights. Apart from these foregoing modifications to suit the interests of India's farmers, in most other respects, the Act relies on the 1978 UPOV approach.

The recent decision by the India's Union Cabinet to approve the Ministry of Agriculture's proposal for India to join UPOV has, however, generated considerable debate about whether India's approach to plant variety protection as set out in the new Act is consistent with UPOV. Perhaps the most significant deviation concerns the "farmers' exemption." Under UPOV farmers are allowed to re-sow saved seeds from their own holding, not to sell to others, as envisaged in the Indian legislation.[98]

Internationally India has raised concerns about the unduly broad scope of protection potentially mandated by TRIPs given the lack of definitions continued in Article 27.3 TRIPs.[99] India's revised patent legislation tries to give effect to some of the concerns India has raised. India has, for example, exercised the option to exclude plants and animals from patentability. Although it has argued that it would be preferable to exclude all life forms from patentability until there is a substantive review of Article 27.3, its domestic implementation has undercut its international position by allowing for such patents. India has attempted, however, to restrict the ambit of life patents by disallowing patents on cells, cell-lines, mitochondria and genes – all of these are patentable in developed countries (Sahai 2002). The purpose of these exclusions is to keep as much basic research technologies in the public domain (ibid.). Because it is mandatory under TRIPs, India has had to introduce patents for micro-organisms and also for microbiological processes. India believes it should be left to national policy to decide what micro-organisms are patentable. Thus biotechnological processes that make plants resistant to pests, such as *Bt* cotton, will be patentable. A further question that arises is whether the products of such processes will also receive patent protection. As seen from European context, this is an important question for the biotechnology industry which the case law and the EU Biotechnology Directive have resolved in industry's favour.

Indian traditional knowledge has been the subject of NGO and governmental challenges to IPRs; the *Neem Tree* case and *Texmati Rice* cases are good examples. India's new patent laws exclude any invention from patentability which constitutes traditional knowledge or derives from traditional knowledge (ibid.). These provisions give legal substance to India's positions on traditional knowledge at the WTO and the CBD and also back up the provisions introduced in its Biodiversity Act which regulates access to India's genetic resources. The Biodiversity Act provides that inventors making use of Indian biodiversity must seek the prior approval of the National Biodiversity Authority for any applications for IPRs inside or outside India.[100] The Authority can oppose grant of IPRs outside India on any biological resources obtained from India.[101] Although the Act has been criticised by some as being unnecessarily bureaucratic and centralised, (Agarwal DATE) it is one of the few examples where a developing country has tried to create a framework for benefit sharing with linkages with its patent system. The conditionality imposed on grants of patents could be challenged at some future at the WTO and would raise questions about the relationship between the CBD and TRIPs – an issue which the WTO is set to examine in further detail as a result of the Ministerial Agreement reached at Doha.

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97 Dr S. Shari, India: Plant Variety Protection, Farmer's Rights bill Adopted, September 2001, and www.nside.org.sg/title/variety.htm.

98 A Betrayal of Trust: India sets out to join UPOV, Kisanwatch, June 14, 2002, www.kisanwatch.org/eng/analysis/june02/an_UPOV_3.htm.

99 Review of the Provisions of Article 27.3(b): Communication from India, IP/C/W/161; Minutes of TRIPS Council Meeting of 20–21 October 1999, IP/C/M/25; Minutes of TRIPS Council Meeting of 21 March 2000, IP/C/M/26; Business world (Philippines) (6 October 2000); BNA Int'l Trade Daily (4 December 2000); Businessworld (Philippines) (15 December 2000).

100 Section 5.1, Biodiversity Act.

4.4 Conclusions

IPRs facilitate control over seeds and plants by agri-business at the expense of small and subsistence farmers. The payment of forms of IPR royalties combined with restrictions on farmers' ability to save and sell seeds from IPR protected plants could undermine the food security of these already vulnerable groups. The benefits of biotechnological innovation, in the form of staple food crops, or higher incomes for poorer farmers are by no means assured over the long term.[102] And in any case, apart from a few well publicised examples, such as "golden rice" or *Bt* maize, there is no systematic programme of biotechnological research aimed at improving the staple food crops. The introduction of IPRs in developing countries, facilitated by TRIPs, will make research into cash crops or those with high market value, such as horticulture, more attractive *vis-à-vis* staple food crops of the kind produced by smaller, subsistence farmers. The introduction of IPRs by developing countries, in and of itself, is likely to make little difference: recent studies demonstrate that apart from a handful of developing countries that have the knowledge base and export infrastructure to benefit from increased IPR provisions, most developing countries will not gain from TRIPs implementation.

Such studies were unavailable to most developing countries at the time of the TRIPs negotiations, which in any case many were simply excluded from as a result of closed policy-making processes within the GATT. Rather than providing justification for an extension of the time-frame for TRIPs implementation, or relaxing the minimum standards, such studies are being virtually ignored in the WTO policy process. Ironically, there is now increased political and economic pressure for developing countries to accelerate their implementation of TRIPs with both the EU and the US using trade, aid and bilateral investment treaties as a leverage tool.

TRIPs implementation by developing countries is at an early stage. Many developing countries have "imported" the IPR legislation of developed countries. Others, such as India, have taken a more creative approach but it remains to be seen whether their tailor made solutions survive judicial scrutiny – at the domestic and international level. As the study of the case law of Europe and the US shows, patent offices and the judiciary have played a significant role in the expansion of IPRs in advance of, or instead of, legislative processes, and for the most part have not been sympathetic to concerns raised by NGOs and civil society. The post-Doha plan of work requires the TRIPs Council to study the relationship between CBD/TRIPs, traditional knowledge and the "development dimension."[103] Its future work is likely to provide early signals about the political acceptability of the Indian and other approaches.

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101 Section 18.4, Biodiversity Act.

102 Recent studies are beginning to produce evidence that GM crops involve higher than expected costs and that initial yields decline over time. See The Guardian, GM damages environment, but not pests says study, 8 June 2002.

103 Paragraph 19, Doha Ministerial Declaration states: 'We instruct the Council for TRIPs in pursuing its work programme include under the review of Article 27.3 (b), the review of implementation of the TRIPs Agreement under Article 71.1, and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, the relationship between the TRIPs Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking his work, the TRIPS Council shall be guided by the objectives and principles set out in Article 7 & 8 of the TRIPs Agreement and shall take fully into account the development dimension.'

IPR protection for biotechnology innovations in the sphere of agriculture is, however, only part of the suite of policy choices of significance for improvement of food security for developing countries and the poorer groups within those countries. Reforming trade policies that improve the position of developing countries with regards to agriculture (such as through reducing protectionism and subsidies and improving market access for DC agricultural products) is far more likely to improve the food security of developing countries than tinkering with IPR policies. Reform of agricultural subsidies and protectionism in the EU and US is, however, an enormous challenge for developing countries in the forthcoming post-Doha trade liberalisation round. The recent announcement by the US that it plans to increase its subsidies by $180 billion over the next ten years, much of which will go to large-scale "corporate farmers", combined with the EU's historically high levels of agricultural subsidies, mean that developing countries have limited room to improve their gross earnings from agriculture no matter how successfully they innovate with regards to agricultural products. [104] Thus developing countries' ability to pursue food security objectives may be as compromised by the forthcoming WTO agricultural negotiations as by IPR related developments set elsewhere.

5 Food security research by public institutions

This section focuses on how IPRs are impacting the ability of researchers to engage in research directed to improving the food security of developing countries, particularly poorer groups of farmers within such countries. The focus is on whether the current IPR landscape unduly restricts the freedom to operate of such researchers.

Section 2 outlined the declining levels of agricultural R&D supported by public funds in both developed and developing countries (CGIAR 2001). It is clear that private proprietary science will only invest in areas where expected returns are high, neglecting research into improving traits in crops of interests to poorer, small-scale or subsistence farmers (GRAIN 2001b). Yet public institutions in developed and developing countries pursuing basic research, or staple crops, are also running into an additional problem: the increasing scope of basic research tools covered by IPRs, known as the "thicket of patents" problem.

This means that public sector researcher's freedom to operate is becoming more restricted unless they enter into agreements with the private sector which holds a large share of the patents in the field of biotechnology. Such agreements take time to negotiate and are usually dependent on payment of licence fees and royalties. This is particularly problematic in the biotechnology sector because modern methods to develop new crops varieties depend on a wide range of component innovations, the rights to which may be held by many competing parties – be they patent rights or assigned use rights via commercial contracts or licences (Pardey *et al.* 2001).

Evidence is emerging from the field of health that the patenting of gene fragments and gene sequences is stifling new research by making new treatments more expensive; restricting exchange of

104 *The Guardian*, Greed in action: US farming subsidies will hit world's poor, 5 June 2002.

information between researchers and involving parties in extensive and costly legal battles (Genewatch UK & EcoNexus 2001). There are similarities with the agricultural biotechnology sector. In April 2001, Dupont and Monsanto, the two largest seed enterprises in the world, came to an informal arrangement resulting in the two companies agreeing to share their agricultural biotechnology patents and dropping a large number of outstanding patent lawsuits against each other (ETC Group 2002). The new agreement has allowed them to issue cross-licences to each other for patented technologies concerning maize, canola (oilseed rape) and soybean crops without fear of expensive, lengthy licence negotiation and the fear of further lawsuits. Although claimed by the companies as a "win for farmers", the agreement concentrates the seed market further. It does at the same time, however, indicate that the current "thicket of patents" on agricultural biotechnologies is causing multinational companies to re-think their IPR strategies and to favour limited forms of co-operation over litigation.

Smaller companies and public institutions do not have the kind of resources to come to such agreements nor any facilitative channels, such as an IPR clearing-house, for doing so. Thus the slow-down in public funding for agricultural research, coupled with the extension of IPRs over new technologies, is limiting their potential to develop new locally relevant biotechnologies and to tap into Northern knowledge pools (ibid.).

Although the extent to which the "freedom to operate" for researchers in developing countries is hampered due to the "thickets of patents" is subject to dispute, it is clear that there are problems for researchers, particularly in developing countries, many of whom have difficulty in establishing who holds patents over particular technologies (Pardey *et al.* 2001).[105] As a result, those promoting biotechnology's positive role in promoting food security have advocated an IPR clearinghouse to facilitate technology transfer (Graff and Zilberman 2001); patent donation; a greater role for public-private partnerships (Cohen 2001; Krattinger 2002); and increased finance of public research targeted at pro-poor technologies (CGIAR 2001).

The recent agreement reached between the US National Institute of Health (NIH) and Dupont concerning use of the Oncomouse provides a concrete example of the way in which the universities, biotechnology and pharmaceutical companies and government laboratories can cooperate over patented technology. (*Signals Magazine* 2002) Since receiving its patent, the Oncomouse has become an important model system for studying cancer and early stage testing of anti-cancer drugs. But academics wishing to use it in their own basic research were prohibited from doing so under fear of patent infringement (ibid.). The NIH/Dupont agreement means that such scientists will be able to use the Oncomouse for non-commercial purposes without payment of a fee. They will be able to freely publish their results and will not be subject to "reach-through" rights (which give the patent holder royalties on future inventions) –

[105] Pardey *et al.* argue that developing country researchers are not as restricted as developed country researchers simply because in most developing countries, patents over many of the basic technologies have not been registered, thus anyone is free to make use of them. They argue that so long as such countries do not export back to developed countries, there is no infringement of IPRs and in any case this is not a problem given that most stable crops are not intended for exports. They argue that a more fundamental problem for developing country institutions is the lack of human and technological capacity to undertake basic research.

restrictions often found on most technology transfer licences in the biotechnology field (ibid.). The NIH/Dupont agreement took seven years to negotiate and could provide a blue-print for basic biotechnological research tools currently covered by IPRs.

An additional factor affecting public research in agriculture is conservation and access to genetic resources, whether in the field or in national and international gene collections. The international legal framework for conservation and access to plant genetic resources has been subject to considerable negotiations over the last two decades. The 1983 FAO Undertaking on Plant Genetic Resources deemed plant genetic material to be a "common heritage of mankind." This was increasingly seen by many developing countries to be unduly favourable to the needs of the formal breeding sector whilst failing to recognise the contribution made by farmers and local communities to conservation and innovation. The inconsistency of legal approach between the 1983 Undertaking with the framework of benefit-sharing predicated on sovereign control over access to genetic resources established by the 1992 CBD, led to the renegotiation of the 1983 Undertaking. FAO convened negotiations on this issue, which lasted almost 8 years, and resulted in the adoption in November 2001 of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITGRPFA – or International Treaty for short). [106]

The ITGRPFA establishes a "multilateral system" to govern access to plant genetic resources covered by the Treaty. These comprise the major food crops listed in the annex to the Treaty. Governments have agreed to ensure that collections under their direct control will provide access to genetic resources on the basis of the Treaty and to encourage collections not under their direct control, such as those held by the CGIAR, to do likewise. A major progressive provision of the multilateral system is that all such access will be subject to standard terms delineated in a "Material Transfer Agreement" which will include provisions for benefit-sharing, including through commercialisation arising from the material.

From the point of view of IPRs, the Treaty provides that

> Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts of components, in the form received from the multilateral system.[107]

This wording clearly excludes IPRs being granted on the materials as originally received. It is deliberately ambiguous, however, with regards to forms derived from or isolated from the original material. So far as innovations or compounds derived from the original material are concerned, some countries are likely to interpret the ITFPGA provision in a restrictive manner so as to limit the availability of IPRs. The degree to which such innovations will be subject to IPRs will thus depend on the interpretation of a countries' domestic IPR legislation by national IPR offices and courts. Dispute resolution processes at both the

106 Available at ftp://ext-ftp.fao.org/ag/cgrfa/ITPGRe.pdf.
107 Article 12.3(d), ITPGRFA.

national and international levels will be important as will as legal and policy developments elsewhere, including the availability of IPRs to the biotechnology industry world-wide.

6 IPRs and farming choices

This section focuses on recent developments related to the enforcement of IPRs in developed countries and the impact of this on farming practices. A key issue here is whether the freedom of farmers to grow crops of their choice is being restricted by the enforcement of IPRs on genetically modified crops and seeds.

In the US and Canada, where GM crops form a large share of agricultural production, contractual agreements between seed companies and farmers are now standard practice (GRAIN 2001b). The purpose of these agreements is to ensure that the farmers respect the IPRs of the biotechnology companies. The agreements prevent farmers from using saved seed or supplying seed to others. They also specify all the company's production methods and management requirements known as "technology use agreements" (Moeller 2001). From 2001, Monsanto's contract with farmers obliges farmers take on the liability provisions concerning risks from growing genetically modified crops as well as stipulating binding arbitration as the sole means of settling disputes with arbitration being handled by a private company selected by Monsanto (ibid.).

Two recent cases highlight the iniquitous legal position farmers could increasingly face when choosing whether to grow GM or non-GM crops. The first case concerns Monsanto lawsuit against a Canadian farmer for infringement of its patent on a Roundup (herbicide) resistant crop of canola. [108] The case highlights the growing tension between farmers and large agricultural biotechnology companies whose high tech crops are transforming the traditional ways farmers tend their fields. At issue in the case was whether Mr. Schmeiser should pay royalties to Monsanto for growing a canola crop in 1998 from seed he saved from his 1997 canola crop. Mr. Schmeiser denied Monsanto's claim arguing he had never bought seed from Monsanto and that pollen or seed had blown in from a neighbours land, contaminating his crop. His argument that he had inadvertently grown Monsanto's crop was rejected by Judge McKay. In a key part of the judgement, Justice McKay concluded although a farmer generally owns the seeds or plants grown on his land if they are blown in or carried there by pollen, this is not true in the case of genetically modified seed. In the judge's view, in the case of patented seed

> A farmer whose field contains seeds or plants originating from seed spilled into them, or blown as seeds, in swaths from a neighbour's land or van flowing from germination by pollen carried onto his field from elsewhere by insects, birds, or by wind, may own the seed or plants on his land even if he did not set about to plant them. He does not, however, own the right to the use of the patented gene, or of the seed or plant containing the patented gene or cell.

[108] 29 March 2001, Federal Court of Canada, Judgement of Justice McKay, T-1593-98, 2001 FCT 256.

One implication of this is that people who are in the neighbourhood of genetically modified crops will have to pay royalties to companies for products they have never purchased and have been deprived benefit from. Additionally, the farmer's right to use his or her own saved seed has been taken away. The decision in the Schmeiser case has been seen as a major victory for companies that produce genetically modified crops and a significant setback for farmers who fear they will be prosecuted for breach of patent rights if pollen blows onto their fields transmitting patented genes to their crops without their knowledge or consent and without the farmers' engaging in conduct to encourage growing of GM crops on their farms.

In view of its significance for limiting choices to farmers who wish to continue growing non-GM crops without fear of risk of liability for inadvertently growing GM crops, the decision has been appealed by Mr. Schmeiser.[109] Key issues in the Schmeiser case – cross-pollination/contamination of seed and farmers' inadvertently growing patented seeds – will also be raised in another case before the Canadian courts. In 2001, two farmers commenced legal proceedings against Monsanto and Aventis for loss of income resulting from their loss of status as organic canola farmers as they cannot guarantee their crops are 100 per cent GM free.[110]

Complex liability issues surrounding contamination of GM and non-GM grains and foods are also being brought before the US courts in a series of cases dealing with the discovery on GM "Starlink corn" in taco shells and other food products. Because Starlink corn had been approved by the US Environmental Protection Agency (EPA) for animal feed or industrial (non-food) uses, the Starlink cases have raised important safety issues surrounding the regulation of grain handling and food industries (Moeller 2001). At present, at least nine class action lawsuits have been filed on behalf of restaurants against Aventis, holder of the Starlink patent in at least six states (ibid.). Aventis is also being sued by the Attorney General of Missouri on behalf of farmers claiming that Aventis did not adequately teach farmers how to keep corn intended only for animal feed out of the human food supply chain (ibid.).

In developed countries, the availability of patents for GM technologies backed by aggressive enforcement through national courts combined with weakening of farmers rights to use saved seeds has made farmers more dependent on a handful of vertically integrated seed/crop control corporations. If the first instance judgement in the Schmeiser case is upheld on appeal, it will make it difficult and expensive for farmers to continue with or switch to organic farming.[111] Given public resistance to GM foods on grounds of safety, the growing popularity of organic food and its positive environmental impacts, such an outcome would be a retrograde step. The issue of who should bear legal liability in such a case should ideally be made by regulatory bodies on the basis of an assessment of the wider public policy issues raised

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109 Result of appeal expected in mid 2002.

110 By 2000, about 20 000 farmers in Canada, producing some 40 per cent of Canadian canola, were growing GM canola with some provinces such as Saskatchewan accounting for 60 per cent of canola. www.planetark.org/avantgo/dailynewsstory.cfm?

111 See e.g. Canada as evidenced in case of Shmeiser v. Monsanto.

by GM farming rather than on the narrow facts of one case where one judge has given preponderant importance to the enforcement of one company's patent rights.

If enforcement of IPRs in developing countries follows the reasoning of the Schmeiser case, there is a strong likelihood that the immediate livelihood (and hence food security) of farmers in developing countries will be adversely affected. Thus it is important for there to be an advanced understanding of the legal liability issues among developing country policy-makers, including regulators, those involved in judicial processes, farmers and NGOs.

7 Conclusions and recommendations

The role of biotechnology in agriculture has been marked by controversy. This paper has sought to focus on examining the relationship between food security, agricultural biotechnology and IPRs, particularly for developing countries and poorer groups within those countries.

Biotechnology has the potential to promote food security because it could increase crop yields, enhance nutritional content, improve resistance to pests, viruses, pesticides and environmental stresses, and provide new diagnostics and vaccines for livestock diseases. Yet the extent to which public institutions and developing countries are undertaking biotechnological research of relevance to food security concerns is extremely limited. Apart from a limited number of "gift" donations of IPR covered technology, such as sweet-potato and golden rice, there is little incentive for the private sector to devote R&D resources on agriculture products useful to the poor as few are able to afford the more expensive resulting innovations.

IPRs contribute to innovations but also make the resulting products more expensive for consumers. Innovations made in the informal sector, for example, by farmers and local communities, which are often the basis for formal research efforts, go relatively unrewarded. Innovative legal concepts, such as "farmers rights" are subject to national legislation and do not have a strong international enforcement machinery.

Biotechnology companies have been at the forefront of campaigning for stronger IPRs arguing this is necessary to recoup their R&D investments. To date, key institutions such as patent offices, courts and other national and international bodies which are directly concerned with IPR policy and enforcement, such as the WTO, have been receptive to industry arguments. As a result of industry pressure, harmonised standards of IPRs have been agreed at the global level but this has generated intense controversy. The most recent studies indicate that for low income developing countries, the costs of strengthening IPRs may well outweigh the gains. Such studies were unavailable to most developing countries at the time of the international negotiations.

Developing countries' initial resistance to TRIPs appears justified by the lack of clear developmental gains. Rather than providing justification for an extension of the time-frame for TRIPs implementation, or relaxing the minimum standards, such studies are being virtually ignored in the WTO policy process. Ironically, there is now increased political and economic pressure for developing countries to accelerate their implementation of TRIPs. These only serve to highlight the lack of negotiating power and policy

expertise of developing countries within the WTO and the strategic forum-shifting policies of the US and EU on trade/IPR related matters.

Developing countries' ongoing lack of policy expertise and the political pressure bought to bear on them has meant that in many instances NGOs, rather than developing country governments, have been at the forefront of challenging IPRs. NGOs have forged close links with developing country governments in international fora, particularly those dealing with social and developmental issues. Developing country and NGO arguments against IPRs include that they promote unsustainable, and possibly unsafe, forms of agriculture, that they make research more expensive especially in developing countries and that stronger IPRs reduce national developmental choices. Additionally, many civil society groups have raised concerns about patenting of life forms arguing that this runs counter to fundamental moral and ethical principles.

In Europe, where rules on legal standing allow NGOs to oppose patents, legal challenges have been lodged against decisions made by patent offices and courts. Such challenges have served to highlight the crucial role of patent offices and judicial bodies in making IPR policy. The ten year legislative process that resulted in the adoption of the 1998 EU Biotechnology Directive also provided an opportunity for the European public to comment on all aspects of the emerging IPR legislation for biotechnology. By contrast, the patent and legislative process in developed countries such as the US, Japan and the EU, patent offices and courts has not been as controversial and in general their resulting policy is more conducive to industry needs than in the case in the EU.

In general, opportunities for public comment on prospective IPR legislation have not been readily available in developing countries. For many developing countries, bilateral trade or aid related agreements signed with developed countries have foreclosed opportunities for public comment as well as foreclosing options for such countries to develop sui generis IPR policies appropriate to their developmental circumstances.

Although TRIPs implementation by developing countries is at an early stage, many developing countries have "imported" the IPR legislation of developed countries. Others, such as India, have taken a more creative approach but it remains to be seen whether their tailor made solutions survive judicial scrutiny – at the domestic and international level.

As the study of the case law of Europe and the US shows, patent offices and the judiciary have played a significant role in the expansion of IPRs in advance of, or instead of, legislative processes, and for the most part have not been sympathetic to concerns raised by NGOs and civil society. Future IPR policy with relevance to biotechnology, including whether developing countries' implementation of TRIPs accords fully with TRIPs requirements, will also be determined to a large extent by patent offices and judicial bodies.

Those opposing the extension of IPRs, such as small-scale farmers, traditional knowledge holders, environmental groups and developing countries, have not, until very recently, been familiar with workings of the IPR related institutions like patent offices. The next challenge is to turn the insights brought by those currently opposing extension of IPRs into credible policies creating positive links between IPRs,

food security and biotechnology, benefiting especially the poorest and most vulnerable groups in the global economy.

IPRs facilitate control over seeds and plants by agri-business at the expense of small and subsistence farmers. The payment of forms of IPR royalties combined with restrictions on farmers' ability to save and sell seeds from IPR protected plants could undermine the food security of these already vulnerable groups. The benefits of biotechnological innovation, in the form of stable food crops, or higher incomes for poorer farmers are by no means assured over the long term.

Apart from a few well publicised examples, such as "golden rice" or *Bt* maize, there is no systematic programme of biotechnological research aimed at improving staple food crops. The slow-down in public funding for agricultural research in developed countries, coupled with the extension of IPRs over new technologies, is limiting the potential of developing country researchers to develop new locally relevant biotechnologies. Although the extent to which the "freedom to operate" for researchers in developing countries is hampered due to the "thickets of patents" is subject to dispute, it is clear that there are problems for researchers, particularly in developing countries. The IPR provisions in the International Treaty on Plant Genetic Resources remain ambiguous in terms of what restrictions, if any, countries may legitimately impose on materials acquired under the multilateral system established by the Treaty.

In developed countries, aggressive IPR enforcement through national courts combined with weakening of farmer's rights to use saved seeds is making farmers more dependent on a handful of vertically integrated seed/crop control corporations. Complex liability issues surrounding contamination of GM and non-GM grains and foods are being brought before the US and Canadian courts. The issue of who should bear legal liability for contamination of crops caused by cross-pollination or "drift" – seed companies or farmers – could determine how difficult and expensive it is for farmers to continue with or switch to organic farming. Thus it is important for there to be an advanced understanding of the legal liability issues among developing country policy-makers, including regulators, those involved in judicial processes, farmers and NGOs.

IPR protection for biotechnology innovations in the sphere of agriculture is only part of the suite of policy choices of significance for improvement of food security for developing countries and the poorer groups within those countries. Reforming trade policies that improve the position of developing countries with regards to agriculture (such as through reducing protectionism and subsidies and improving market access for DC agricultural products) is far more likely to improve the food security of developing countries than changing IPR policies.

The recent report of Commission on Intellectual Property Rights, established by the UK Government, highlighted many of the issues discussed in this paper and supports many of the key recommendations set out below (Commission on Intellectual Property Rights 2002).

The main policy relevant recommendations for national and international policy-makers are that they should:

- Enhance developing countries' capacity for policy analysis of IPR options in international institutions
- Allow for increased time-frames for TRIPs implementation for all DCs, not just LDCs
- Allow DCs time and resources to craft *sui generis* options for IPRs relating to plant varieties and biotechnological innovations
- Ensure DC patent offices and judicial bodies understand flexibilities available under TRIPs and implications of different interpretation of key terms, including how such terms were interpreted by developed country patent offices and courts
- Ensure research into improving basic food crops is increased through public institutions
- Increase access to basic research biotechnologies e.g. by allowing licensing for research without payments, IPR clearing house.
- Promote greater levels of policy coherence on the food security/IPRs debate at international and national level
- Recognise that IPR protection for biotechnology innovations in the sphere of agriculture is only part of the suite of policy choices of significance for improvement of food security for developing countries and the poorer groups within those countries.
- Recognise that trade policies to improve the position of developing countries' agriculture (such as through reducing protectionism and subsidies and improving market access for DC agricultural products) will also have a big(ger) impact on improving the food security of developing countries.

Annex I: History of the development of IPRs

Date	Forum/ jurisdiction	Policy/regulatory development
13th–14th Century	Europe	Grant of monopolies/privileges (quasi-patents) begin to be awarded to specific artisans.
1474	Italy, Venice	First broadly modern patent law enacted by Venetian Senate
1624	United Kingdom	British Statute of Monopolies aims to control previous awarding of monopolies in trades/inventions
1709	United Kingdom	British law of copyright (Act of Anne) offers similar protection (14 years) to texts (not necessarily authors)
1790–1850	Developed Countries	Introduction of patent, copyright and trademark laws in most European countries and US. In most countries chemicals and pharmaceuticals remain unpatentable until 1960s/70s; discrimination against IPRs of foreign citizens was possible and patents were only valid if "locally worked"; disclosure and inventive step not always a necessity for grant of patent
1883	Paris	First International Treaty on IPRs signed in Paris signed by most European countries. Strengthened in 1911, 1925, 1834, 1958 and 1967. Many countries including Netherlands repeal patent laws after opposition to monopoly aspects of IPRs
1886	Berne	First international treaty on copyright signed in Berne by mostly European countries
1930s–60s	Developed countries	Creation of plant variety protection in most developed countries
1961	Geneva	Signing of Convention for the Protection of New Varieties of Plants, establishment of International Union for the Protection of New Varieties of Plants (UPOV) in Geneva. Strengthened in 1972, 1978, 1991.
1973	Munich	European Patent Convention providing for a single patent to cover Europe. Article 52.3(b) excludes plant/animal varieties except for microbiological processes. 1977 European Patent Office established.
1970s/80	UNCTAD/ WIPO/UN	G-77 push for New International Economic Order (NIEO) and relaxation of IPR regimes to favour DC development particularly regarding Paris Convention (Patel 1989). UNCTAD studies support cautious approach to IPRs as their benefits depend on level of development and other factors
1970s/80s	WIPO/UN	Developed countries, pushed by patentees, go on counter-offensive to G-77 proposing more stringent standards/enforcement of IPRs
1980	US Supreme Court	*Diamond v. Chakrabarty*. Bacterium held to be patentable. Court ruled there is no basis in law for excluding living things as Congress intended patents to cover "anything under the sun made by man."[112]
1983	FAO	Adoption of "common heritage principle" and "free access" in relation to plant genetic resources adopted via International Undertaking on Plant Genetic Resources (IU).[113]
1985	US courts	*Re Hibberd*: plants held patentable notwithstanding availability of plant varieties laws
1980s	US Trade Representative	USTR puts bilateral pressure on industrialising DCs to "improve" their IPRs following wave of resentment against foreign "theft" of US IPRs.[114]
1980s	US courts	US courts, hitherto lax about enforcement of IPRs, start awarding high damages for IPR infringement and continue widening scope of patent protection to cover living matter, mostly plants and micro-organisms (Chang 2001)

112 There appears to have been no significant opposition to this decision which is seen as boosting biotechnology.

113 Supported by DCs and plant breeders, most of which were engaged in public research.

114 Most of the IP "theft" relates to counterfeit goods, cds, tapes etc. Not biotechnology.

1984	US	US Trade Law amendments (i.e. Super 301 Section, amended 1988) allows US to use trade threats to press other countries to "improve" their IPRs[115]
1986	GATT	US first proposes TRIPS be included in Uruguay Round. Although opposed by DCs, IPRs are included. Notwithstanding violent demonstrations in India against the "Dunkel Draft" in 1993, TRIPs continues to be part of the final "package" of WTO agreements. (Correas & Yusuf 1998; Gervais 1998)
1990	European Patent Office	EPO grants patents to *Plant Genetics Systems* on herbicide resistant genetically modified plants, cells and processes to produce these.[116]These are subject to high profile opposition by Greenpeace and others
1990	US Patent Office	*Moore v. Regents of University of California*. Court confirms patentability of cells lines and their products even though no permission was sought or benefits conferred to the patient whose cells had been taken.
1991	UPOV	Amendments strengthen plant breeders' rights making them more "patent-like" and weaken "farmers' privilege" which allowed farmers to use saved seeds without reference to breeder. Despite widespread opposition by farmers' rights group such as GRAIN, and RAFI, developing countries agree new amendments.
1992	European Patent Office	*Oncomouse*: patent granted for genetically modified mouse. The patents raise huge media attention and are challenged by over 16 organisations/individuals from religious, development and green groups. The opposition battles for ten years against this patent but it is upheld. [117]Canadian and US courts also grant patents on oncomouse.
1992	Convention on Biological Diversity	Developing countries reject "common heritage principle" accepting instead sovereignty to determine access to genetic resources and that IPRs should support biodiversity; US rejects treaty agreeing with a small number of biotechnology industry representatives that CBD IPR provisions may undermine IPRs
1993	FAO	Decides to revise International Undertaking on plant genetic resources for consistency with CBD.
1994	European Patent Office	*Franktion der Grunen v Howard Florey Research Institute*: patentability of DNA and proteins from humans confirmed. CBD decides to exclude human genetic resources from consideration by COP.
1994	WTO, Marrakech	Agreement reached to establish the WTO with powerful dispute settlement procedure and TRIPS Council to oversee TRIPS implementation
1994	US, Patent Office	*W.R. Grace* granted patent for use of neem oil in fungicide applications[118]. This is challenged by 200 organisations for lack of "prior art" in the US.
1995	US Patent Office	*University of Mississippi* granted patents for turmeric to be used to heal wounds.[119] Indian Council for Scientific and Industrial Research (CSIR) challenge the patent on "prior art" grounds documenting the qualities of turmeric being patented as publicly known for thousands of years.
1995	US Patent Office	*US Dept. of Health & Human Services* granted patent on a virus found in the blood of Hagahai tribesman from Papua New Guinea[120]
1995	European Patent Office	EPO decides not to grant patents on animal and plant varieties after considering objections by Greenpeace to patents claimed by *Plant Genetic Systems.*[121] After this case, EPO did not grant patents on *animal/plant varieties*.

115 US Omnibus Trade and Competitiveness Act, section 301, and special 301 on IPRs.

116 EPO Patent No 0 242 236.

117 November 2001, EPO finally rejects opposition and allows patent to stand. The EPO judgements on the case over the ten-year define the way in which they will approach assessing objections based on moral, environmental and economic grounds.

118 US Patent 5,124,339.

119 US patent/US 5, 401, 504. March 1995.

120 US patent/US 5, 397, 696. Earlier patents were withdrawn due to public protests.

121 Case T 0356/93.

1995	WTO,	1 January 1995, TRIPs enters into force
1996	CBD	Conference of the Parties (COP) begins examination of impact of IPRs on conservation/sustainable use of biodiversity & benefit sharing. Requests observer status at WTO's Committee on Trade and Environment.
1996	FAO	World Food Summit. Governments affirm commitment to reducing poverty, cutting under nourishment by half by 2015, recognising links between agriculture, trade and food.
1997	WTO	WTO panel upholds US complaints that India's compliance with TRIPs Article 70.8 (a) does not provide sufficient legal certainty for "mailbox" patent applications regarding pharmaceutical patents.[122]
1997	US, Patent Office	Texas-based *Rice Tec Inc*. granted patent on basmati rice lines and grains developed using Indian basmati rice and marketed under the "basmati" name.[123]
1997	US Patent Office	The PTO revokes all six patents on neem tree marking a major victory for traditional knowledge advocacy groups.
1997	CBD	COP mandated workshop on protection of indigenous knowledge, innovations and practices convened to consider Article 8(j) CBD, including linkages with IPRs
1997	European Patent Office	EPO declines Novartis patent application for transgenic plants to EPO appeal but refers key questions for appeal board.
1998	EU	EU adopts Directive 98/44/EC on the legal protection of biotechnological inventions.[124]This explicitly allows for patenting of all manner of life forms except for clearly stated exceptions, such as the human body. The Directive is not fully consistent with the European Patent Convention's exclusion of plant/animal varieties.
1998	WIPO	Establishes fact-finding mission on intellectual property needs of traditional knowledge holders. WIPO agrees with WTO to facilitate DC implementation of TRIPs with the 2000 deadline.
1998	World Bank	WB calls for a fairer deal on patents and knowledge. Points out strong IP could deter research, and that DCs should be assertive in negotiating access to their natural resources. (World Bank 1998)
1998	South Africa	A coalition of pharmaceutical manufacturers obtained interim ruling preventing South African government implementing its 1997 Act which gave it constitutional powers to provide access to medicines. The companies claimed, inter alia, the Act violates South Africa's WTO obligations.
1998–99	WTO, TRIPs	Review of Article 27.3 (b) begins but is stalemated because of highly divergent approaches from developed and developing countries. DCs contend TRIPs provisions run contrary to CBD and that TRIPs be amended to protect traditional knowledge.
1999	European Patent Office	EPO approve *Novartis* patent application for transgenic plants, reviewing exclusions to patentability under ECP very narrowly & taking into account UPOV 1991 & TRIPs.
1999	Council of Europe	Council (which is separate body not related to EU) adopts Resolution 1425 affirming that it "believes that neither plant, animal nor human derived genes, cells, tissues or organs can be considered as invention and nor be subject to monopolies granted by patents."[125]
1999	WTO, Seattle	DC proposals for reviewing TRIPs get mothballed amidst collapse of agreement on new round

122 WT/DS50/RS.
123 US Patent 5, 663, 484
124 Official Journal L213, 30/07/1998 00013-0021
125 Recommendation 1425 (99), 23 September 1999.

1999–2000	US Patent Office	US Patent Office grants patents on "terminator technologies". After widespread condemnation of such technologies as being incompatible with farmers rights, food security (e.g. from COP 5 of CBD, FAO) patent holders Monsanto/Aventis vow not to commercially utilise. Many countries ban their commercial use. [126]
2000	US Patent Office	In June 2000, India, supported by ActionAid, challenge *Rice Tec Inc* patents & also object to use of the term "basmati" claiming only rice grown in the Basmati region of India can use this term. The challenges are pending although Rice Tec withdraws some of the patents and calls its rice "Texmati". The case highlights the expense of challenging patents as Pakistan who had wanted to challenge the case revealed it would have had to pay £300, 000 to US attorneys. (Tripathi 2000)
2000	WTO, TRIPs	US files dispute accusing Argentina of failing to implement legislation that, *inter alia*, would allow the patentability of micro-organisms contrary to its TRIPs obligations. EC and Switzerland join the consultations on the dispute[127]
2000	WTO, TRIPs	US challenges Brazilian legislation authorising use of compulsory licensing/parallel imports to promote local working of patents, particularly in relation to medicines combating HIV/AIDS
2000	European Patent Office	EPO, after a highly publicised NGO led opposition, revokes patents granted to W.R. Grace and US on uses of neem.
2000	UN Sub commission on the Promotion and Protection of Human Rights	Mounting concern in human rights bodies about patenting of living organisms and the social impacts of TRIPs leads Sub commission to pass landmark resolution identifying key human rights as being at threat by TRIPs.[128] Sub-commission begins examining relationship between IPRs, globalisation and human rights.[129]
2000	UNDP	UNDP Report attacks global patent regimes as a threat to human rights and development, particularly TRIPs. (UNDP 2000)
2000	Council of Europe	Unanimously calls on EU Member States not to implement Directive 98/44/EC on biotechnological inventions, to seek its re-negotiation and to support challenges before the ECJ. French President writes to EU Commission demanding re-negotiation, likewise Germany which supports negotiations
2000	EU, European Court of Justice (ECJ)	Netherlands, backed by Italy and Norway, challenge EU Directive 98/44/EC on protection of biotechnological inventions.[130] In October 2001, the ECJ rejects the Dutch legal challenge. The Directive continues to cause many EU Member States problems despite the fact that they are legally obliged to implement it by 2000.
2001	Canadian courts	*Monsanto vs. Percy Schmeiser.*[131] Monsanto sue a farmer for loss of licence fee and punitive damages claiming he grew Roundup Ready canola seeds without their permission. In the March 2001 judgement, the Judge held that Schmeiser must have known, or ought to have known, he was growing Roundup and should respect Monsanto' patent.

126 See RAFI, Terminator Technology, 1998 and 2000 update.

127 WT/DS196. EC=WT/DS/2. Swiss=WT/DS/196/3

128 The resolution "reminds all governments of the primacy of human rights obligations under international law over economic policies and agreements…and to take international human rights obligations and principles fully into account in international policy formulation." E/CN.4/Sub.2/RES/2007

129 See Report by Ms J. Oloka-Onyango and Ms D. Udagama, E/CN/Sub.2/2001/10. See also Resolution in 2001, E/CN/Sub.2/RES/2001/21.

130 The Directive means EU law would sanction patentability of genes, plants, animals and isolated parts of the human body. The Netherlands challenge was based on their view that biotechnological inventions should be limited to processes and not extended to the products derived there from, in order words that plants, animals or human parts should not be patentable as such. The Directive means EU law would sanction patentability of genes, plants, animals and isolated parts of the human body.

131 Monsanto v. Schmeiser, 2001, FCT 56.

2001	Canadian courts	Two farmers sue Monsanto and Aventis for loss of income resulting from their loss of status as organic canola farmers as they cannot guarantee their crops are 100 per cent GM free (in Saskatchewan, 60 per cent of canola is GM). [132]
2001	South Africa	A massive campaign by health, development NGOs prods US Clinton administration and EU to change their position by pledging to not use legal avenues to challenge the right of African governments to protect public health. (Greenpeace International 2001) In April 2001, after massive adverse publicity, industry backs down claiming they have reached "a partnership."
2001	US Patent Office	Terminator patents continue to be granted in US. Syngenta (Zeneca), US Patent 6,228,643, issued May 8, 2001. Dupont (Pioneer Hi-Bred International), US Patent 6,297,426, issued October 2, 2001. Patent for methods of mediating female fertility in plants resulting in functionally female sterility. [133]
2001	Canada	After September 11 attacks in US, Canada announces on October 18 that it would suspend Bayer's patent on anti-anthrax drug, Cipro, and allow generic drug makers to manufacture and sell this drug in the country. Within hours, the Canadian authorities reverse their stand announcing they will honour Bayer's patent on Cipro and buy the drug only from the company. [134]
2001	US	US decides to honour *Bayer*'s Cipro patent, seeking instead a "behind the scenes deal" with Bayer to avoid having to use compulsory licensing.
2001	FAO	Eight years after negotiations commenced, FAO adopts International Treaty on Plant Genetic Resources for Food and Agriculture.
2001	India	Legislature passes Plant Variety Protection and Farmers' Right Bill and its Biological Diversity Bill containing IPR related provisions designed to balance CBD/TRIPs and farmers rights.
2001	WTO, Doha	TRIPs related outcomes include: (i) Declaration on TRIPs Agreement and Public Health which applies broadly to public health (not just HIV/AIDS) [135](ii) In context of review of TRIPs Article 27.3(b), Article 71.1 (review of implementation), TRIPS Council is mandated to examine, inter alia, the relationship between TRIPs, CBD and protection of traditional knowledge and folklore, and other relevant developments raised by Members pursuant to Article 70.1. The "development dimension" is to be fully taken into account as well as Articles 7 & 8 TRIPs and (iii) WTO's Committee on Trade and Environment told to give particular attention to TRIPs in its future work on enhancing mutual supportiveness of trade and environment and examination of relationship between existing WTO rules and trade obligations in MEAs; information exchange between MEAs and WTO and reduction/elimination of barriers to environmental goods and services.[136]

132 www.planetark.org/avantgo/dailynewsstory.cfm?

133 Syngenta (Zeneca), US Patent 6,228,643, issued 8 May 2001. Dupont (Pioneer Hi-Bred International), US Patent 6,297,426, issued October 2, 2001. Patent for methods of mediating female fertility in plants resulting in functionally female sterility.

133 The patent describes a promoter, isolated from rapeseed, and the control of plant traits (including fertility) that can be inactivated and restored by application of a chemical inducer. In one embodiment, the seeds will not germinate unless sprayed with a chemical inducer.

134 www.organicconsumers.org/corp/cipro110801.cfm, posted 11/07/01.

135 The Declaration confirms that 'TRIPS does not and should not prevent Members from taking measures to protect public health' although it should be interpreted/implemented to support member's right to promote public health including access to medicines, including through grant of compulsory licences. Up to each member to decide what is an emergency/urgency. Declaration on TRIPS/Public Health, WT/MIN (O1)/DEC/2 adopted on 14 November 2001.

136 Doha Ministerial Declaration, WT/MIN (O1)DEC/1 adopted on 14 November 2001.

Annex II: Intellectual Property Rights and development

From: Duttfield, Intellectual Property Rights and Development – Policy Discussion Paper UNCTAD/ICTSD, November 2001

Geographical origin of Patent Cooperation Treaty patent applications filed in 1998 and 2000

From figures published on WIPO

Region	**Country of origin**	**No. patents filed 1998**	**No. patents filed 2000**	**% of total 1998**	**% of total 2000**
North America	USA	28,356	38,171	42.3	42.0
	Canada	1,315	1,600	2.0	1.8
Total North *America*		*29,671*	*39,771*	*44.3*	*43.8*
Western Europe / EU	Germany	9,112	12,039	13.6	13.2
	UK	4,383	5,538	6.5	6.1
	France	3,322	3,601	5.0	4.0
	Sweden	2,554	3,071	3.8	3.4
	Netherlands	2,065	2,587	3.1	2.8
	Switzerland	1,293	1,701	1.9	1.9
	Finland	1,092	1,437	1.6	1.6
	Italy	925	1,354	1.4	1.5
	Denmark	624	789	0.9	0.9
	Austria	421	476	0.6	0.5
	Norway	394	470	0.6	0.5
	Others	1,101	1,463	1.6	1.6
Total Western *Europe/EU*		*27,286*	*34,526*	*40.7*	*38.0*
East Asia and China	Japan	6,098	9,402	9.1	10.3

	South Korea China	485 322	1,514 579	0.7 0.5	1.7 0.6
Total East Asia and *China*		*6,905*	*11,495*	*10.3*	*12.6*
Eastern Europe	Russia Others	429 402	590 627	0.6 0.6	0.7 0.7
Total Eastern Europe		*831*	*1,217*	*1.2*	*1.3*
Australasia	Australia New Zealand	1,408 178	1,627 264	1.6 0.3	1.8 0.3
Total Australasia		*1,226*	*1,891*	*1.9*	*2.1*
Total Middle East		*707*	*925*	*1.1*	*1.0*
Total Rest of Asia		*146*	*473*	*0.2*	*0.5*
Total Latin America/ *Caribbean*		*209*	*252*	*0.3*	*0.3*
Total Africa		*26*	*398*	*<0.1*	*0.4*
Total applications		*67,007*	*90,948*	*100.0*	*100.0*

References

ActionAid, 2002, 'TRIPS on trial: TRIPs and the threat to food security and farmers rights'. ActionAid Report

Adock, M. and Llewelyn, M., 2000, 'Micro-organisms, definitions and options under TRIPS', *Occasional Paper No. 2*, Quaker United Nations Office, Geneva

Agarwal, A., 'The Bill of Contentions', www.cseindia.org/html/dte/dte20020115/dte_edit.htm

Black's Law Dictionary. West Group

Braithwaite J. and Drahos, P., 2000, *Global Business Regulation*, Cambridge, Cambridge University Press

Buckingham, L, 1998, 'Shock for shares as treatment fails to yield hoped for dividends', *The Guardian*, April 28 1998

Canadian Biotechnology Advisory Committee, 2001, Biotechnology and Intellectual Property: Patenting of Higher Life Forms and Related Issues

Consultative Group on International Agricultural Research (CGIAR), 2001, *Slow magic: agricultural R&D a century after Mendel*, Document AGM/01/17 October

Chang, H., 2001, 'Intellectual property rights and economic development – historical lessons and emerging issues', *Journal of Human Development* Vol 2 No 2

CIDSE (International Co-operation for Development and Solidarity), 2000, Bio patenting and the Threat to Food Security, Part 1 – Bio patents: A Christian and Development Perspective

—— Impact of trade liberalisation on food security of the South, www.cidse.org/en/tg1/tradelibbgr01.htm

Cohen, J., 2001, 'Harnessing biotechnology for the poor: challenges ahead for capacity, safety and public investment', *Journal of Human Development*, Vol 2 No 2

Commission on Intellectual Property Rights, 2002, *Integrating Intellectual Property Rights and Development Policy*, London

Corporate Newswatch, 2001, 'The underlying rationale to maximise "synergies" in the human health and crops protection/seed interests', *Corporate Newswatch Newsletter,* November-December 2001, Issue 6

Corporate Watch, 1999, 'Karanakata State Farmers Union – an inspiration to us all,' *Corporate Watch*, Issue 9

Correas, C. and Yusuf. A. (eds), 1998, *Intellectual Property and international trade: the TRIPS Agreements*, Kluwer

Cullet, P., 2001, 'Plant variety protection in Africa: toward compliance with the TRIPs Agreement', *Journal of African Law*, Volume 45/1, SOAS/CUP

Dhar, B., 2003, 'Regulating Biotechnology in India', FIELD/IDS project on Globalisation and the International Governance of Modern Biotechnology, at www.ids.ac.uk/IDS\env\PDFs\Dhar India.pdf

Dodds, J.H., Ortiz, R., Crouch, J.H., Mahalasksmi, V. and Sharma, K.K., 2001, 'Biotechnology, the gene revolution and proprietary technology in agriculture', A strategic note for the World Bank, *IP Strategy Today*, No. 2

Drahos, P., 2002, 'Developing countries and international intellectual property standard-setting', *Study Paper 8*, commissioned by the UK Commission on Intellectual Property Rights, available from www.cipr.org.

Drahos, P., 2002, 'Negotiating intellectual property rights: between coercion and dialogue', in P. Drahos and R. Mayne (ed.), *Global Intellectual Property Rights: Knowledge, Access and Development*, Oxfam

Dutfield, G., 2001, Intellectual Property Rights and Development, UNCTAD/ICTSD *Capacity Building Project Paper*

Emmert, F., 1990, 'Intellectual property in the Uruguay round – negotiating strategies of the western industrialized states', *Michigan Journal of Law*, Vol 11

ETC Group, Dupont and Monsanto, 2002, '"Living in Synergy"? The Five Giants are Becoming Four', 9 April

EU Commission, 'Intellectual property, seeds and food security', *Technical Paper*, www.europa.eu.int/comm/europeaid/projects/resal/Download/report/mission/coord/1000stcoordtripsgb.pdf

EU-US Biotechnology Consultative Forum, 2000, *Final Report*

Genewatch UK and EcoNexus, 2001, *Patenting Genes – Stifling Research and Jeopardising Healthcare*, April

Gerster, R., 2001, *Patents and Development, Lessons Learn from the Economic History of Switzerland*, TWN

Gervais, D., 1998, *The TRIPs Agreement: Drafting History and Analysis*, Sweet and Maxwell

Gitter, D., 2001, 'Led astray by the moral compass: incorporating morality into European Union biotechnology patent law', *Berk. J. Int'l. Law*, 1

Graff, G. and Zilberman, D., 2001, 'Toward an intellectual property clearinghouse for agricultural biotechnology', *IP Strategy Today*, No 3

Genetic Resources Action International (GRAIN), 2001a, "TRIPs-Plus through the back door – how bilateral treaties impose much stronger rules on IPRs for life than the WTO." www.grain.org/publications/dsp_publications.cfm?type_id=19&type_type=3

—— 2001b, 'Intellectual property rights: ultimate control of agricultural R&D in Asia'

—— 1998, 'Signposts to sui generis rights'

—— 2002, TRIPs and Agreements available at www.grain.org/brl/trips-plus-brl-en.cfm

Greenpeace International, 2001, 'Agonizing over Patents, A review of policy developments on access to genetic resources, benefit sharing, protection of traditional knowledge and the WTO TRIPs agreement'

Gutowski, R.J., 1999, 'The marriage of intellectual property and international trade in the TRIPs agreement: strange bedfellows or a match made in heaven?', *Buffalo Law Review*, Vol 47

Ha-Joon Chang, *Intellectual property rights and economic development – historical lesions and emerging issues*, TWN, 2001

Huang, J., Wang, Q. and Keeley, J., 2001, 'Agricultural biotechnology policy processes in China', *IDS Mapping Paper* at www.ids.ac.uk/ids/env/PDFs/China.pdf

Centre for Information on Low External Input and Sustainable Agriculture (ILEIA), 1999, 'Green Caravan challenges gene giants', *Newsletter*, December 1999

Kisanwatch, 2002, 'A betrayal of trust: India sets out to join UPOV', www.kisanwatch.org/eng/analysis/june02/an_UPOV_3.htm 14 June

Krattinger, A., 2002, 'Public-private partnerships for efficient biotech management and transfer and increased private sector investment', *IP Strategy Today*, No 4

Love, J., 2002, 'Access to medicines: solving the export problem under TRIPs', *Bridges*, Year 6 No.4. www.ictsd.org

Moeller, R., 2001, GMO Liability Threats for Farmers, Genetically Engineered Food Alert

Murphia, S., 2001, 'Food security and the WTO', *Position Paper,* CIDSE (International Cooperation for Development and Solidarity)

Nenow, L., 2001, 'To patent or not to patent: The EU's new Biotech Directive', *Houston J. Int'l Law* 569

Odame, H., Kameri-Mbote, P. and Wafula, D., forthcoming, 'Globalisation and the International Governance of Modern Biotechnology: the implications for Food Security in Kenya', *Biotechnology Policy Series 20, IDS Working Paper*, Brighton: Institute of Development Studies

Pardey, P., Wright, B. and Nottenburg, C., 2001, 'Are intellectual property rights stifling agricultural biotechnology in developing countries', *IFPRI, 2000–2001 Annual Report*, www.ifpri.org.

Patel, S., 1989, 'Intellectual property rights in the Uruguay round: a disaster for the south?' *Economic and Political Weekly*, 6 May

Perdue, D., 1999, 'The changing landscape for patenting transgenic plants in Europe', www.law.washington.edu/casrip/newsletter/newsv6i1Perdue.html

Petit, M., Fowler, C., Collins, W., Correa, C. and Thornström, C., 2000, *Why Governments Can't Make Policy. The case of plant genetic resources in the international arena,* CGIAR

Porter, G., 1993, 'The United States and the biodiversity convention: the case for participation', *Biopolicy* 12

Sahai, S., 2002, 'Patent issues, A mixed bag', *Frontline*, Issue 11, 25 May– 7 June

Scalise, D. and Nugent, D., 1993, 'Patenting living matter in the European community: diriment of the draft directive', *Fordham Int'l L.J*, 990

Scoones, I., 2002, 'Agricultural biotechnology and food security: exploring the debate', *IDS Working Paper* 145, Brighton: Institute of Development Studies

Sell, S.K, 1999, 'Multinational corporations as agents of change: the globalization of intellectual property rights', in A.C. Cutler, V. Haufler and T. Porter (eds), *Private Authority and International Affairs*, Albany: State University of New York Press

Signals Magazine, 2002, 'NIH, Dupont Sign Landmark Oncomouse Accord', 21 May, www.signalsmag.com

Takahashi, K., *Reversing the Decline of ODA: How Effective is the Current Policy Agenda?*

Tansey, G., 2002, 'Intellectual property rights, food and biodiversity', *Harvard International Review*, Spring

Thorpe, P., 2001, 'Implementation of the TRIPS agreement by developing countries', *Study Paper 7*, commissioned by the UK Commission on Intellectual Property Rights, available at www.cipr.org

Tripathi, R., 2000, *Implications of TRIPs on livelihoods of poor farmers in developing countries*, Institute for Agriculture and Trade Policy (IATP)

United Nations Conference on Trade and Development/International Centre for Trade and Sustainable Development (UNCTAD/ICTSD), 2001, 'Indicators of the relative importance of IPRs in developing countries', draft paper, November

United Nations Development Programme (UNDP), 2000, *Report on Human Development*

Visvanathan, S. and Parmar, C., 2002, 'A biotechnology story: notes from India', *EPW, Review of Science Studies*, 37.27

World Intellectual Property Organization (WIPO), 2001, *Intellectual Property Needs and Expectations of Traditional Knowledge Holders*, Report on Fact-Finding Mission on Intellectual Property and Traditional Knowledge, Geneva

World Bank, 2001, 'Intellectual property: balancing incentives with competitive access', *Global Economic Prospects*, 129–150, Washington, D.C.: World Bank

—— 1998, *Knowledge for Development*, Annual Report