Chilling Productivity in Australian Agriculture, Biotechnology and Pharmaceutical Industries

The impact of Disclosure and Prior Consent provisions in the CBD and TRIPS Agreement

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Acronyms

ABS	Access and Benefit Sharing
ABARE	Australian Bureau of Agriculture and Resource Economics
AHOEWG	Ad Hoc Open Ended Working Group
BIO	Biotechnology Industry Organization
CAEPR	Centre for Aboriginal Economic Policy Research
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CIMMYT	International Maize and Wheat Research Centre
COP	Conference of the Parties
CSIRO	Commonwealth Scientific and Industrial Research Organization
DAFF	Department of Agriculture, Fisheries and Forestry
DFAT	Department of Foreign Affairs and Trade
FAO	Food and Agriculture Organization
NFF	National Farmers' Federation
PhRMA	Pharmaceutical Research and Manufacturers of America
RIRDC	Rural Industries Research and Development Corporation
SMTA	Standard Material Transfer Agreement
TRIPS	Trade Related Aspects of Intellectual Property
UPOV	International Union for the Protection of New Varieties of Plants
WIPO	World Intellectual Property Organization
WTO	World Trade Organization
UN	United Nations

Executive Summary

Proposals by Brazil, India and the Africans for a new and legally binding Protocol to the Convention on Biological Diversity (CBD) governing access and benefit sharing arrangements to genetic material would impose major costs on Australia's agricultural, biotechnology and pharmaceutical industries. These costs would be even greater if Brazil and India were to succeed in attempts to negotiate a disclosure obligation for new patents in the World Trade Organization's Trade Related Aspects of Intellectual Property Rights (TRIPS).

If adopted these proposals would undermine the capacity of patent law to reward innovation and constrain the capacity of Australian agricultural, biotechnology and pharmaceutical industries to continue to deliver benefits to the Australian economy from new and improved patents and technologies.

A decision in the CBD is scheduled in October 2010. Draft negotiating text refers to revocation of existing patents; criminal penalties; new border restrictions; payments to developing countries; a trust fund where origin is unclear; and inclusion of NGOs in dispute resolution procedures.

What would the likely impact be on key Australian industries? This report demonstrates that the costs are likely to be substantial for Australia's agriculture, biotechnology and pharmaceutical industries. Grains and horticulture would likely incur the highest costs of all agricultural industries. Dairy and beef would also suffer, primarily via higher grain input prices but also from long term slowing in the rate of improvement in herd quality. The pharmaceutical industry would be hit hard, especially from outcomes which slowed the process of sharing information on new virus strains.

Detailed assessments of the nature and extent of the costs for key Australian industries have not been undertaken. Such analyses should be done urgently. Australia is about to engage in end game negotiations without knowing the cost implications for key agricultural and other industries.

The case for a legally binding instrument rests on allegations of biopiracy of developing countries' genetic material. The incidence of biopiracy is however low or non-existent. Existing intellectual property arrangements have overturned patents cited as examples of biopiracy. The system is working. There is no case to overturn it.

The case masks a mistaken assessment by officials in some countries that this is an effective way of ensuring the full benefits from bio invention derived from natural materials are delivered to national rather than foreign entities. Brazil, India and the Africans, which are seeking economic rent, are supported by groups who oppose intellectual property and consider natural materials should be owned communally rather than privately.

The rights of indigenous peoples, in Australia and elsewhere, to secure benefits from developments derived from traditional knowledge or resources over which there is

traditional ownership can easily be secured. Revision of the basic concepts of patent law is neither necessary nor justified. The Queensland model, where rights to explore and develop traditional resources are formally licensed, is a model arrangement. In most developing countries where complaints are made that indigenous knowledge is exploited no system to allocate rights and regulate commercialization of them exists. A CBD instrument would not change that.

Alternative options such as strengthening existing CBD guidelines and national regimes, market-based instruments, voluntary industry codes of conduct and national certificates of compliance would involve lower economic impacts on Australian industries than what is proposed in the draft negotiating text. Australia should develop and seek support for such options in the CBD. It must ensure that all the details are agreed before signing, let alone ratifying, a new legally binding instrument.

Introduction

Proposals to alter intellectual property law with far reaching implications for agricultural, biotechnology and pharmaceutical industries are on the table in international fora.

The goal of settling a new global regime to manage access and benefit sharing of genetic resources by October 2010 has been set by parties to the UN Convention on Biological Diversity (CBD). There are proposals to adopt a legally binding Protocol to the Convention which would alter significantly international law governing granting of patents on inventions utilizing genetic resources of derivatives of them.

In the Doha Round of negotiations in the World Trade Organization, there are proposals to insert change which would have similar effect to the provisions of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

This report examines the implications for Australian industry. It also proposes strategies that would meet the commitment to create a global regime for Access and Benefit Sharing of Genetic Resources, but without undermining the benefits existing intellectual property law generates for Australian industry and the Australian economy.

This research is part of a program on research on intellectual property by the Australian APEC Study Centre at RMIT University, Melbourne. The work has been part funded by a grant from the Pharmaceutical Research and Manufacturers of America (PhRMA).

Chapter 1: The Issues

1. General proposition

There is general proposition that biopiracy of the genetic resources of developing countries is widespread and needs to be addressed. New legal rights are being proposed in international instruments to redress this so-called problem.

A Protocol to the CBD on Access and Benefit Sharing of Genetic Resources is sought, amendments have been proposed to the WTO Agreement on TRIPS and the matter is on the agenda of the World Intellectual Property Organization (WIPO).

The case that biopiracy is a problem is so weak, it would be more accurate to say there is no systemic problem. Yet the remedies proposed are so far-reaching they would seriously undermine the capacity of society to secure the benefits of innovation and to protect intellectual property. Development and growth of agricultural, biotechnology and pharmaceutical industries would be jeopardized.

A review of the general question of biopiracy is set out in Annex A.

1.1 Proposal in WTO

The mandate for the Doha Round negotiations requires WTO members to review the relationship between the Convention on Biodiversity and the protection of traditional knowledge and folklore. Reference is made to several articles. There is also an obligation to review Article 27.3(b) of TRIPS, which gives members the right to exclude from patentability plants, animals and essentially biological processes for the production of plants and animals. No specific objective is stated for the review.

A group of developing countries represented by Brazil and India wants to amend the TRIPS Agreement so that patent applicants are required to disclose the country of origin, to show evidence that they received “prior informed consent”, and evidence of “fair and equitable” benefit sharing.

Discussions in TRIPS have revealed very substantial differences between developed and developing countries on a disclosure obligation for patents. It is unclear how, let alone when, such differences might be resolved. Nor is it clear whether Brazil and India might be prepared to trade off what they are seeking on a disclosure obligation in TRIPS in exchange for their other objectives in the Doha Development Round.

1.2 Proposal in CBD

Parties to the CBD have agreed there should be an international regime on access and benefit sharing of genetic resources.

The supporting contention is that developing countries which "own" genetic material are not receiving sufficient compensation because of biopiracy of their genetic resources.[1] It is asserted that multinational pharmaceutical companies are not paying developing countries sufficient compensation for utilization of their genetic resources or derivatives of them, – especially for "blockbuster" drugs which allegedly generate super normal profits.

The proposal is informed not by interest in protecting biological diversity, but rather to address biopiracy and ensure rents are secured by national entities. They are also advanced by some non-governmental organizations which exhibit long-term antipathy to the basic precepts of intellectual property, particularly the granting of patents and similar rights, such as to plant varieties.[2]

The formal debate is about how to ensure there is appropriate access to genetic resources and how benefits should be shared from that access.

There is no consensus among parties to the CBD about the nature of an ABS regime. Most developing countries (led by Brazil, India and the African group) favor a legally binding Protocol to the CBD. They seek arrangements that would restrict access to genetic resources and weaken intellectual property rights that govern use of inventions on food, agriculture and forestry.[3] Most developed countries are opposed.

The same group of developing countries also proposes in the World Trade Organization that it commence negotiations on a disclosure obligation in TRIPS to enable "holders" of the genetic material from which patents are developed to receive payment for using it. They also propose that the CBD should endorse this position.

Draft negotiating text is on the table.[4] A decision is scheduled at the tenth Conference of the Parties (COP 10), to be held in Japan in October 2010. This will be preceded by two

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[1] There is no agreed definition of biopiracy and no evidence it exists or is a substantial problem. Detail is in Appendix A.

[2] Soplin and Muller claim that "The CBD principles and rules on ABS were conceived on the basis of a "classic" paradigm *which is becoming in a way, outdated and illusory* (our italics). Soplin, S and Muller, M, *The Development of an International Regime on Access to Genetic Resources and Fair and Equitable Benefit Sharing in a Context of New Technological Developments,* Initiative for the Prevention of Biopiracy, Year IV No. 10, April 2008, p.3. Link at http://www.cbd.int/abs/doc/serie-iniciativa-2009-04-en.pdf

[3] Gollin notes that "to implement DOO (disclosure of origin obligations) a country would need to pass national legislation amending patent laws, and promulgate regulations for the national patent office to follow". Gollin, M, *Feasibility of national disclosure of origin requirements,* WTO Public Symposium, April 2005, p.1, at http://www.iprsonline.org/ictsd/docs/DOO3_Gollin.pdf

[4] UNEP/CBD/WG-ABS/7/8, 5 May 2009. Report of the Seventh Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, at *http://www.cbd.int/doc/?meeting=ABSWG-07*

meetings of the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing : in Montreal from 9-15 November 2009 and in March 2010 at an unspecified venue.[5]

The draft negotiating text is heavily bracketed.[6] Securing consensus will be difficult. It may be impossible. The draft text contains objectionable proposals such as retrospective revocation of patents; new border restrictions; payments to developing countries; a trust fund when origin is unclear; criminal penalties for non-disclosure; and inclusion of non government organisations (NGOs) in dispute resolution procedures.

These measures appear wholly disproportionate to the condition which the measures are supposed to ameliorate: evidence that biopiracy is a major problem, or even exists, is scant. A legally binding ABS instrument would radically change established procedures for awarding patents and undermine long established and effective multilateral systems for awarding and protecting intellectual property rights.

If a legally binding ABS instrument is agreed for plants, the precedent would be established for extending it to animals, increasing the chilling effect of this regime more widely across agricultural industries.

1.3 Proposal in WIPO

The Committee on the Protection of Traditional Knowledge and Genetic Resources of the World Intellectual Property Organization (WIPO)has been considering for some time "technical matters concerning (a) defensive protection of genetic resources; (b) disclosure requirements in patent applications for information related to genetic resources used in the claimed invention; and (c) intellectual property issues in mutually agreed terms for the fair and equitable sharing of benefits arising from the use of genetic resources".[7]

Little progress has been made. There are substantial differences between developing and developed countries over how to approach these issues, mirroring differences over the same issues in the WTO and the CBD.[8] No formal recommendation on the future of the committee's work was submitted to the meeting of the WIPO General Assemblies in

5 This meeting was to have been also held in Montreal.

6 Square brackets are used in multilateral negotiations when there is no agreement on particular issues.

7 WIPO, March 2006, Brief Summary of Working Documents, WIPO/GRTKF/IC/9/INF/3, paragraph 15.

8 The African Group has proposed talks on a legally binding international instrument on protection of genetic resources, traditional knowledge and folklore. Developed countries argued that deciding on a goal prior to beginning negotiations was unwise. Australia said it wanted the committee's mandate renewed, but it could not support the text proposed by the African Group. Brazil made it clear that it wants an internationally legally binding instrument. See WIPO, Draft Report of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, WIPO/GRTKF/IC/14/12 Prov,2, August 26, 2009, paragraph 245.

September 2009.[9] It is unclear how WIPO's work on this issue might progress, what the outcome might be and when a decision might be reached.

[9] Intellectual Property Watch, 22 September 2009, *Fate Of Traditional Knowledge A Key Decision At WIPO Assemblies,* at http://www.ip-watch.org/weblog/2009/09/22/fate-of-traditional-knowledge-a-key-decision-at-wipo-assemblies

Chapter 2: Economic Implications of Disclosure Obligations

This chapter identifies the key economic implications and the broad nature of the likely impacts. The general impacts of policy change are first reviewed, and then the economic implications are reviewed. Attitudes of Australian farm and groups and biotechnology and pharmaceutical groups are also reported.

No research could be located on the impact on Australian agriculture of the proposed changes.

2.1 The administrative impact – high compliance costs and legal uncertainty.

The obligation to disclose the source of a genetic resource will increase the cost and time taken to secure a patent. That is assuming there will be agreement on what constitutes a "genetic resource". In none of the fora where the matter is under debate is there agreement on a definition; in some cases there is not even concurrence that a definition is required. It is evident that the looser the definition the broader is, the more uncertain and prospectively wider is the impact of the obligation.

Discussions in the CBD indicate that in the minds of the advocates of compulsory disclosure is the creation of related rights for the owners of genetic resources to approve or disapprove of the use of the genetic resource and even to seek financial compensation for the use of the resource.

There is a clearly expressed belief in official circles in Brazil that by this means, a proper return for the utilization by some one of a Brazilian natural resource will be secured.

2.1.1 High compliance costs

A requirement to disclose the origin of genetic material, with a view to demonstrating that appropriate payments had been made to the original owners of it, would involve substantial compliance costs.[10]

Brazil argues in the CBD that "Compliance must be secured in user countries with national laws and requirements, including the previous informed consent and mutually agreed terms

[10] Fowler suggests these costs would be significant. Fowler, G, 2000, Implementing access and benefit-sharing procedures under the Convention on Biological Diversity: The dilemma of crop genetic resources and their origin, paper prepared for the Global Forum on Agricultural Research, Document GFAR/00/17-04-5-07, p.7

of the country providing such resources".[11] There are fundamental differences between developed and developing countries over compliance arrangements.[12]

2.1.2 Legal uncertainty

Intellectual property law and the TRIPS agreement have provided legal certainty. That has in turn enabled intellectual property rights to maximize its contribution to economic growth. Australia's Department of Foreign Affairs and Trade (DFAT) notes that "Intellectual property is an integral part of international trade, and its importance is increasing as the effective use of knowledge contributes even more to national economic prosperity. The current value of intellectual property in Australia is over $30 billion. As a trading nation with a strong research tradition and a need for access to new technologies, Australia has interests in the agreed international standards on the protection and exploitation of intellectual property rights."[13]

Legal certainty is central to maximizing the benefits for all those with an interest in patents and R&D. This includes patent holders, R&D entities that helped obtain the patent, research laboratories, users of the patents in production – in both developed and developing countries – as well as consumers. To undermine legal certainty is to reduce the benefits these groups have secured via TRIPS.

The changes proposed would create legal uncertainty. This would be exacerbated significantly if a Protocol were adopted where disclosure obligations and derivative rights were not clear. Such an outcome would undermine the nature of intellectual property rights of invention which included or was derived from a genetic resource.

Unfortunately there is precedent for this in some other environmental agreements negotiated in the UN where legal rights and obligations were created, but the definition of them was left to the Parties to settle after the Agreement came into effect.[14]

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[11] UNEP/CBD/WG-ABS/7/8, paragraph 19

[12] A co-chair of the contact group on compliance reported to the April 2009 meeting of the Open Ended Ad Hoc Working Group that work on compliance "had come to a halt owing to entrenched positions and, having failed to resolve an issue over placement of texts, was suspended until a closed meeting between the co-chairs and the spokespersons of the regional groups had arrived at a solution". UNEP/CBD/WG-ABS/7/8, paragraph 77

[13] DFAT, *Intellectual Property and International Trade,* at http://www.dfat.gov.au/ip

[14] This has been the practice with the Basle Convention limiting Transboundary Movement of Hazardous Waste and the Biosafety Protocol to the CBD.

2.2 Diminution of the value of intellectual property rights

The integrity and value of property rights is clearly diminished if another party has a claim to it or to part of it, or has a lien over it, or has a right to secure some of the proceeds earned from the sale of products based on the invention. This would be the effects of the sort of right to some stream of proceeds from the sale of a patented product envisaged by some parties to the CBD.

This would chill innovation in any country that enacted such a measure, in particular in areas where patents and breeder rights were important. This would include agricultural, biotechnology and pharmaceutical industries and resources. These impacts would manifest themselves in various ways.[15],[16]

2.3 Economic impacts

A legally binding ABS instrument would reduce incentives for innovation. The result would be reduced spending on the development and approval of new patents. There would be **an initial, or static, reduction in the flow of new patents and technologies**. Costs for users of new patents and technologies, including germplasm, would be higher than they would otherwise have been. Value added would be lower, which would in turn reduce the value of output, exports, profits and jobs - especially in regional and rural Australia.

There will be further, dynamic, impacts.[17] Less innovation will result in fewer patent applications, approvals and deployment. A self-reinforcing cycle of lower economic benefits

[15] Fowler concludes that "Efforts to apply the CBD's definition (of country of origin) to agro-biodiversity will likely lead to reductions in access and use, and high transaction costs, without significant additional "benefits". Fowler, op cit, p.7.

[16] Oldham notes that while the 1990s witnessed the emergence of major demand for patent protection, "limited attention has so far been paid to economic analysis of the relationship between biotechnology and patent protection in developing countries". Oldham concludes that analysis of the contribution of patents to economic effects of patent protection "is severely lacking and is linked to the need to develop indicators of national, regional and international activity to inform analysis and decision-making for patent activity in relation to biological diversity and traditional knowledge". Oldham, P, *Biodiversity and the Patent System: An Introduction to Research Methods,* Economic Centre for Economics and Social Aspects of Genomics, Year 11, No. 6, March 2006, p.5, p.28

[17] See for example Hirshhorn, R and Langford, J, 2001, *Intellectual Property Rights and Biotechnology: The Economic Argument,* paper prepared for The Canadian Biotechnology Advisory Committee Project Steering Committee on Intellectual Property Rights and the Patenting of Higher Life Forms, p.15 and footnotes 3 and 4. Their third and fourth footnotes, on p.23, are as follows: "Dynamic efficiency gains result from innovation and investment that increase productivity growth and help raise real income per capita over time"; and "Static efficiency requires that the economy's resources are allocated to generate maximum social welfare. For static efficiency, product prices should be set

from the development and deployment of new innovations would set in. The chill winds of less incentive and therefore lower investment will reduce output and jobs in industries that rely on access to continued improvements in technologies and germplasm. Skilled technicians would leave Australia for countries such as the US where they could achieve better pay and conditions. A "CBD decelerator", a self-reinforcing downward spiral, would set in.[18]

2.4 Economic consequences

The primary economic effect of these changes would be to reduce the economic benefits from innovation in those countries where the measures were adopted.

2.4.1 Less collaborative research

Incentives for governments and the private sector to invest in and undertake collaborative research in Australia would be reduced – especially vis a vis the US, which would not be affected by measurers set out in an ABS Protocol because it has not ratified the CBD. Lowering the growth rate and profits of a vibrant collaborative research industry would impose costs up and down the collaborative research pipeline in Australia.

2.4.2 Diminished effectiveness of multilateral gene banks and related bodies

The multilateral gene banks established under the auspices of the Consultative Group on International Agricultural Research (CGIAR) have been central to delivering improved agricultural productivity worldwide. A 2008 World Bank report concluded that "investments in R&D have turned much of developing world agriculture into a dynamic sector, with rapid technological innovation accelerating growth and reducing poverty".[19]

A legally binding ABS instrument in the CBD would impede access to the multilateral gene banks because of the need to consult owners of genetic resources about providing access to

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to allow purchases to be made by all who place value on units of a good or service that exceeds its cost of production (i.e., marginal cost)".

[18] A CBD decelerator would be the reverse of the well-known accelerator principle in economics. The accelerator principle describes the growth in output that induces continuing net investment. Net investment is a function of the **change** in output, not its level. A legally binding ABS instrument and/or a disclosure obligation in TRIPs would work in reverse. Output from agricultural, pharmaceutical and biotechnological industries in Australia would decline. Lower output would in turn lead to lower levels of investment – which would further reduce output via what could best be described as "the CBD decelerator".

[19] World Bank, 2008, World Development Report, *Agriculture for Development,* p.158. Link at http://siteresources.worldbank.org/INTWDR2008/Research/WDR_00_book.pdf

their contents. This would reduce the effectiveness of the CGIAR centers, which specialize in particular crops. It would likely also undermine their funding.

Fowler concludes that for all countries to have the same access to the world's largest collection of rice samples at the International Rice Research Institute through bilateral agreements would require 12,210 such agreements. Because of rapid genetic development of rice strains, the number of bilateral agreements would never stop growing.[20]

The effectiveness of the International Union for the Protection of New Varieties of Plants (UPOV) would also be diminished. An analysis of the benefits delivered by UPOV concluded that the non-EU older members of the Union, including Australia, "has also seen an increase in the number of applications received, particularly from non-residents, and also shows that the number of applications made by their breeders in other territories has also increased".[21] That report also concluded that "membership of UPOV provides important technical assistance and maximizes opportunities for cooperation, which enables PVP (plant variety protection) to be extended to the widest range of plant genera and species in an efficient way thereby enabling the benefits to be maximized".[22]

Access to genetic resources as provided for by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (FAO Treaty) would be impeded. The Convention was established precisely to improve access of agricultural producers to genetic resources. Soplin and Muller, for example, conclude that "although it (UPOV) has (only) been in force since 2004, its implementation has been affective, in terms of the *number* of Standard Material Transfer Agreements (SMTA) which have been used to transfer plant genetic resource samples for food and agriculture (and the subsequent exchange of these resources)".[23]

It is notable that officials from FAO and UPOV have consistently expressed their concerns at CBD meetings about the adverse impacts on their relevant activities of formal requirements for disclosure and approval.

2.4.3 Reduced growth of global food output and slower poverty alleviation

There would be serious impacts on grain production in, and exports by, the key grain exporting countries (Australia, Canada, US and Argentina) from actions that result in slowing the development and deployment of new and improved germplasm for grains and other

[20] Fowler, op cit, pp.5-6.

[21] International Union for the Protection of New Varieties of Plants (UPOV), 2005, *UPOV Report on the Impact of Plant Variety Protection*, p.87

[22] UPOV, op cit, p.90

[23] Soplin and Muller, op cit, footnote 25, p.8

food. Yield growth in the major food exporting countries and developing countries would be lower. Prices will be higher than they would otherwise have been.[24] Higher prices will impose welfare losses on developing country food importers – particularly the poorest of the poor.[25]

2.4.4 Reduce innovation globally

Given the significant correlation between protection of rights and economic growth,[26] reduced incentives for innovation would reduce the level of innovation in many countries. These industries, which are not making super normal profits, undertake substantial and risky long term investments in R&D and product development. They require patent protection. Burrill reports that total shareholder returns to biotechnology companies declined by 25 per cent since 1998.[27] Colombia University has concluded that "the odds of finding a new drug from botanical samples are very low (from 1 in 80,000 to 1 in 250,000 plant samples)".[28] These reports suggest that even a modest increase in costs via a legally

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[24] This is a key conclusion by Brennan, J and Quade, K, *Analysis of the Impact of CIMMYT Research on the Australian Wheat Industry,* Economic Research Report No.25, October 2005, NSW Department of Primary Industries, p.25, at http://www.google.com.au/search?hl=en&source=hp&q=Brennan%2C+J+and+Quade%2C+K%2C+Analysis+of+the+Impact+of+CIMMYT+Research+on+the+Australian+Wheat+Industry%2C+Economic+Research+Report+No.+25%2C+October+2005%2C+NSW+Department+of+Primary+Industries&meta=&aq=null&oq. Encouraging biofuel production via subsidies in developed countries has had the unintended consequence of reducing the proportion of arable land used for food production and increasing global food prices. A similar unintended consequence from an adverse ABS instrument would be to reduce the growth in productivity in food production.

[25] Crop Life International reports that in 2008 R&D "expenditure for the fifteen leading companies in plant science reached an estimated $5 billion. It is equivalent to over 8.5% of sales. $2.4 billion was spent on seed and traits R&D, and $2.7 billion was spent on agrochemicals". This report also notes that the annual benefits from better yield stability in maize and wheat alone are estimated at about $300 million". Crop Life International, 2009, *Facts and figures – The status of global agriculture,* p.8. The same report (p.9) argues that improved plant varieties in the 1980s and 1990s accounted for as much as 50 per cent of yield growth.

[26] Fernandez, J, *Intellectual Property Is Driving Agricultural Innovation, Says Crop Life,* Intellectual Property Watch, at http://www.ip_watch.org/weblog/?p=6331. Fernandez concludes that "Protection of regulatory data is a tool that welcomes industry's commitment to … social goals by providing the framework to enable and encourage innovation and investment, and countries should not refrain from its implementation".

[27] Burrill, S, *State of the Biotechnology Industry: A Global Perspective,* p.63, at http://www.burrilldatacenter.com/pdf/BioTechIsrael.pdf.

[28] Colombia University School of International and Public Affairs, Environmental Policy Studies, Working Paper Number 4, *Access to Genetic Resources: An Evaluation of the Development and Implementation of Recent Regulation and Access Agreements,* p.87, at http://wwwdiodiv.org/doc/case-studies/abs/cs-abs-rpt.pdf

binding ABS instrument leading to a disclosure obligation in TRIPS would reduce profit margins and therefore innovation.

Chapter 3: Impacts on Australian Agriculture, Biotechnology and Pharmaceutical Industries

3.1 General impacts

Most of the general impacts would be felt in Australia.

Less collaborative research would be undertaken and there would be less R and D investment than there would have been otherwise.[29] Given likely high multiplier effects from collaborative research in Australia, the costs from such outcomes are likely to be substantial.

Weakening the effectiveness of global gene banks, plant breeder rights and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture carries a cost for Australian agriculture and weakens the agricultural sectors and thereby markets for Australian food exports. Brennan and Quade for example recommend that to maximize economic benefits from research by the International Maize and Wheat Research Centre (CIMMYT), Australia should "continue to fund research at CIMMYT, particularly research that can develop and enhance spillovers to Australia".[30]

A worst case outcome would be **high compliance costs undermining profitability** of developing or importing new technologies.

Loss of competitive advantage. Unlike Australia,[31] agricultural, pharmaceutical and biotechnology industries in some developed and many developing countries would not comply with all or some of their CBD obligations.[32] The US would be exempt. Australia's competitors would have an incentive to import technologies and germplasm that did not

[29] More detailed analysis of the costs facing specific industries consulted is in Annex A

[30] Brennan and Quade, op cit, p.36

[31] Australia has a well deserved reputation for abiding by its multilateral commitments. If it ratifies a multilateral agreement it meets its obligations. That is reflected in the seriousness with which Australia has engaged in multilateral negotiations (which, apparently unlike this case, are usually informed by detailed cost/benefit analyses undertaken or financed by the Australian Government) and the requirement to submit treaties to the Parliamentary Joint Standing Committee on Treaties.

[32] It is unclear how compliance with an ABS instrument would be assessed and enforced. There is likely to be an incentive to cheat on CBD commitments. This would enable competitors in countries which are either lax in their enforcement of the new requirements or ignore them to secure a competitive advantage over Australian industries. If commercial advantage can be achieved by ignoring commitments that are difficult or impossible to monitor or enforce, it will be taken.

comply with their ABS commitments. Their costs would be lower than costs facing Australian entities.[33]

3.2 Impacts on grains, horticulture, livestock and dairy

There would be very serious adverse economic impacts on the Australian grains, horticulture, livestock and dairy industries from what is proposed in the CBD and TRIPS. Further detail is at Annex B.

Australia's **grains** industry is likely to be the biggest loser among agricultural industries. Brennan and Quade have examined the impact of research undertaken by the International Maize and Wheat Improvement Centre (CYMMYT) on the Australian wheat industry. They estimated the potential impact on the Australian wheat industry from spillover benefits from research and deployment of new varieties developed from genetic material by CIMMYT. They conclude that "spillover benefits to Australia lead to welfare benefits totaling $1,425 million over the period 1965 to 2020".[34] They also conclude that CIMMYT's research increased Australia's wheat yields by an average of 4.6 per cent in 2001.[35]

The World Bank reports that "In the 1980s and 1990s, improved varieties are estimated to have accounted for as much as 50 per cent of yield growth, compared with 21 per cent in the preceding two decades."[36] But global yield growth is declining - from around 3 per cent per year in 1970 to just over 1 per cent per year by 2007. Howden attributes this to a lack of investment in boosting genetics and management.[37]

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[33] See Rogge, K, from the World Bank Institute, 2003, *Bioprospecting Values.* Rogge notes (slide 20) that the incentive to cheat would be determined by the perceived payoff from undetected violations, rates of detection, the extent of penalties and the costs of participation in an ABS instrument. Link at http://info.worldbank.org/etools/docs/library/107771/SD_Communication/epublish/zip_files/biodiversity_russia2003/pdf/BioprospectinRogge.pdf.

[34] Brennan and Quade, op cit, p.31. They also concluded (p.34) that CIMMYT maize research had "led to large supply shifts and a lower price for wheat globally than would have occurred without CIMMYT research".

[35] Ibid.

[36] World Bank, 2008, World Development Report, *Agriculture for Development,* p.160, at http://siteresources.worldbank.org/INTWDR2008/Research/WDR 00 book.pdf.

[37] Howden, M, CSIRO, *Climate change: Crop yields and distribution,* power point presentation to the 2008 Crawford Fund Annual Conference. Howden uses IPPC data and research by Raupach and Canadell. Link to this report is on the website of the Crawford Fund, at http://www.crawfordfund.org/events/conference08.htm. Similar conclusions have been reached by Dixon et al, who conclude that "Following widespread adoption of semi-dwarf varieties, the annual yield growth rate peaked at 2.75% p.a in the 1980s. Since then, yield growth has slowed in part because varietal replacement is now more widespread than initial adoption, and also because of

Blakeney concludes that "It is estimated that about 6.5% of all genetic research undertaken in agriculture is focussed upon germplasm derived from wild species and land races".[38] He observes that "The development of gene technologies for modern agricultural research, and the proprietization of those technologies, is an explanation of the growth of private agricultural research in the OECD at an annual rate of 5.1%, compared with the 1.7% growth rate for public agricultural research".[39]

Yield growth in Australia's grains industry depends on access to and development of new varieties – which in turn depends on an enabling set of global intellectual property arrangements and institutions.

Given that new plant varieties and patents are key to generating value added and that many patents in place for 10-20 years expire shortly, the **horticulture** industry believes it would be very seriously affected by what is under negotiation - including via the "CBD decelerator". Collaborative research with NZ would be lost to the US. An outcome in the CBD that compromised the funding and effectiveness of the multilateral gene banks and other institutions would deliver adverse biodiversity outcomes for horticulture in Australia.

Beef and dairy would also be adversely affected – primarily via higher grain input prices as well as possible impacts on herd quality from less genetic research being undertaken.[40] There are no direct estimates of the costs on beef and dairy. Analysis by the Australian Bureau of Agriculture and Resource Economics (ABARE), reported in Annex B, suggests they would likely be substantial.

A leading Australian veterinary academic has observed to ITS Global that Australia's livestock industries are reliant on rapid, market-based movement of genetic resources. Without such movement, this expert believes that the productivity enhancements that have been secured in merino sheep; enabling cattle to survive and thrive in tropical Australia; the

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environmental factors". Dixon, J, Hellin, J, Erenstein, and Kosina, P, *U-impact pathway for diagnosis and impact assessment of crop improvement,* Journal of Agricultural Science, 2007, 134, p.196.

[38] Blakeney, M, *Intellectual property, biological diversity, and agricultural research in Australia,* Australian Journal of Agricultural Research, Volume 53, 2002, CSIRO, 2002, p.139. Blakeney's emphasis on the key role of private sector research is markedly at odds with apparent bias in Chapter 7 of the World Bank's World Development Report against private sector research. His article contains a background to Australia's ratification of the CBD and the importance of the CGIAR for Australia.

[39] Blakeney, op cit, p.127.

[40] Impacts on herd quality are complex. ITS Global consulted three veterinary scientists and an industry representative on this issue. There is disquiet at the prospect of value adding via improved herd quality being compromised by restrictions on the use of semen and improved genetic stock - but uncertainty as to how the transmission mechanism from the CBD to Australia might work in practice. There is a view in some quarters that if Brazil and India succeed on plant varieties they will seek to negotiate similar arrangements for animals.

deployment of Holstein/Friesian genes in the dairy industry; and the development of rust-resistant wheat would not have occurred. There are therefore solid grounds for concluding that the potential costs from a slowing in herd quality improvements for beef and dairy would be significant.

3.3 Impact on biotechnology and pharmaceutical industries

The Australian pharmaceutical industry employs around 34,000 people, has a yearly turnover of around $18 billion, invests more than $750 million in R and D and exports nearly $4 billion per year.[41]

An essential foundation for any pharmaceutical industry is first class intellectual property laws that both encourage investment in innovation and protect intellectual property of others. Diminishing the strength of Australia intellectual property law would jeopardize key aspect of Australia's pharmaceutical industry.[42]

The industry is also concerned about the potential impacts from Brazil's proposal to include sharing of new virus strains in a legally binding ABS instrument in the CBD. The recent difficulties Australia experienced in persuading Indonesia to share new influenza virus strains would be repeated in other countries if Brazil's proposal on virus strains is included in a legally binding instrument in the CBD. Such an outcome would have potentially serious implications for the ability of Australia's pharmaceutical industry to develop and sell new vaccines. The costs were described by one pharmaceutical expert as being "huge". The World Health Organization (WHO) is finding it difficult to secure progress on this issue.

Faunce has argued that "The importance of a thriving Australian domestic generic pharmaceutical and bio/nano tech industry in terms of biosecurity, similarly appears to have been given insufficient policy attention."[43] Whether those responsible for biosecurity in Australia have assessed the implications from what is proposed in the CBD or TRIPS is unclear.

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[41] Speech by Innovation Minister Carr to AusPharma 2008 Medicines Australia Conference, 8 April 2008, at http://minister.innovation.gov.au/Carr/Pages/Auspharma2008.aspx.

[42] Minister Carr emphasised in his speech that Australia's pharmaceutical industry should increase its share of global R and D and improve its niche manufacturing production capabilities to offset low cost countries such as India and China. Achieving these objectives will be more difficult than would otherwise have been the case if a legally binding ABS instrument in the CBD makes it more difficult to obtain new virus strains for the development of new drugs. Australia would likely lose competitiveness to US manufacturers as they would be exempt as the US has not ratified the CBD.

[43] Faunce, T, College of Law and Medical School, Australian National University, Canberra, Australia, *Challenges for Australia's Bio/Nanopharma Policies: trade deals, public goods and reference pricing in sustainable industrial renewal,* Australia New Zealand Health Policy, 2007, Abstract.

3. 4 Impact on traditional knowledge and rights

The impact on Aboriginal people in Australia using their traditional knowledge and rights to encourage bioprospecting and thereby secure economic benefits was analyzed by Oxley and Bowen. They quote Professor Jon Altman from the Centre for Aboriginal Economic Policy Research (CAEPR) at the Australian National University, as saying that "no significant payments have been made to an Aboriginal group from bioprospecting, although activities are undertaken for floral species such as Morinda Citrifolia in Arnhem Land (Northern Territory) and Sandalwood in Western Australia. CAEPR further advises that securing a balance between regulation and equity is required and that an important issue is widespread "ownership" of species owing to religious or shared indigenous knowledge".[44]

CAEPR has advised for this report that indigenous people have strong property rights in botanical and faunal species. There is also interest are the development of sustainable wildlife harvest industries, including the potential extraction of venom on a commercial basis from a recently discovered species of tarantula, as well as from various snake species.

An ABS instrument in the CBD is not required to enable bioprospecting and development of patents and benefit sharing with Aboriginal people. Australia already has its own national legislation in place governing bioprospecting on Commonwealth land. Some states have such laws in place. Others do not.

Access to and benefit sharing from bioprospecting on Aboriginal-owned land, with a view to generating jobs and income from bioprospecting, was a key issue at a conference on the CBD negotiations, held in Canberra on 14 September 2009. An ABS instrument along the lines sought by Brazil and India would be contrary to the interests of Aboriginal people as it would discourage bioprospecting on their land – thereby depriving them of potential jobs and income from payments to engage in bioprospecting.

[44] Oxley, A and Bowen, B, Australian APEC Study Centre, 2005, Developing an effective international regime for access and benefit sharing for genetic resources using market-based instruments, footnote 54.

Chapter 4: Strategies to Protect Australian Interests

4.1 General approach

Key Australian economic interests are at stake in the CBD and TRIPS.

No economic assessment of the impact of the measures under consideration in the CBD has ever been undertaken by the Secretariat nor requested by Parties.
Australia should as a matter of urgency undertake a national economic impact assessment of the options under consideration.

The precedent of agreeing to open to signature incomplete agreements should be avoided.

The limited participation of the United States (it is not party to the CBD as it has not ratified it) needs to be taken into account. Normally it resists consideration of poorly conceived proposals in UN meetings. Australia needs to be more pro-active to defend its interests than otherwise might be the case. It cannot rely on the US to block consensus.

Australia should seek to collaborate with other agricultural exporting nations to advance and defend common interest in the negotiations.

Australia should exert leadership to avoid the more objectionable, and costly, proposals in the draft CBD negotiating text being adopted.

A legally-binding regime is unnecessary. There are other more effective, less damaging approaches for creating a regime for access and benefit sharing of genetic resources.

It should identify, develop and secure the support of like-minded countries for less costly alternative options.[45]

The following options should be considered.

Strengthening the Bonn Guidelines

The Bonn Guidelines, adopted by CBD parties in 2002, are voluntary and intended to help countries draw up national access and benefit-sharing strategies and measures. They outline the roles and responsibilities of various players at the national and local levels in governing

[45] A range of members of the G77/China is concerned about what is under negotiation and the impact on their agricultural, biotechnology and pharmaceutical industries. ITS Global was advised at the Grenada ABS meeting in 2005 and at the Curitiba Conference of the Parties in 2006 that Australian leadership would be welcomed in identifying the potential costs from what is proposed and in identifying less costly alternatives.

the use and transfer of genetic resources. They include suggestions for ways to put into practice principles like prior informed consent to ensure no genetic resources are developed without the consent of those who manage or control them. The Guidelines could be strengthened as an alternative to a legally binding ABS instrument – while retaining their voluntary intent.

Strengthening national regimes

There are no obvious limitations on the use of national regimes to underpin and encourage bioprospecting and hence access and benefit sharing. Proponents of a legally binding ABS instrument claim that in some instances national regimes could and should be improved. If there are areas where national regimes governing ABS need to be strengthened, and the country agrees, there is no reason why technical assistance could not be provided to that end. The Biotechnology Organization and PhRMA, for example, have proposed that such capacity building be "implemented through activities coordinated through appropriate intergovernmental organizations and other forms of voluntary assistance" and "be done on a voluntary, case by case, basis".[46]

Use of market-based mechanisms

Market-based instruments to address ABS would be more effective. An approach is set out in an earlier paper by the APEC Study Centre. It envisaged creating "property rights to bioprospecting by legislation or regulation specifying that the holder of such rights could engage in bioprospecting under specific conditions" and identified how such a system could be designed and operate.[47]

This proposal received support from a range of developed and developing countries at ABS meetings in Grenada and Curitiba. Use of market-based instruments should be developed in more detail, including how to make them tradeable. Such proposals should be discussed with like-minded countries and proposed by Australia as a more viable option than a legally binding instrument.

National certificates of compliance

Countries could issue their own certificates of compliance, certifying that the holder complies with national laws governing bioprospecting and ABS. Such national certificates

[46] Biotechnology Industry Association and PhRMA, July 2009, Views And Proposals of the Biotechnology Organization and the Pharmaceutical Research and Manufacturers of America (PhRMA) for the Eight Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing, p.13. Link at http://www.bio.org/letters/20090731.pdf.

[47] Oxley and Bowen, op cit, pp.26-35

could be tradeable.[48] There would be no need to tie such certificates into a legally binding ABS instrument. Nor should they be tied to other laws, especially intellectual property laws. Australia is arguably at world's best practice with its ABS legislation, including for traditional knowledge. It would be well placed to design a model certificate of compliance – and exert leadership to get this model certificate endorsed.

The Biotechnology Industry Association and PhRMA argue that "private international law mechanisms including alternative dispute settlement resolution mechanisms and civil law regarding enforcement of foreign judgments, can ensure effective compliance. In respect of foreign enforcement of judgments, however, it should be noted that CBD Parties have been generally reluctant to recognize judgments from other jurisdictions".[49]

Development of voluntary industry codes of conduct

Voluntary industry codes of conduct could be developed. The Biotechnology Industry Association and PhRMA have proposed "Codes of conduct for important groups and identification of best practice codes of conduct". They propose voluntary industry codes be established "by an industry association or group of non-commercial entities representing users of genetic resources with participation by industry and/or other relevant actors."[50]

Voluntary industry codes of conduct are a well established component of international agreements.[51] As it already has its own bioprospecting legislation in place, the Australian Government would be well placed to consult with key agricultural, biotechnology and pharmaceutical industries and, if they support it, to develop a draft voluntary industry code of conduct. It should be consistent with what industry has proposed.

4.2 Specific strategies in the CBD, TRIPS and WIPO

Australia needs to develop specific strategies in the CBD, TRIPS and WIPO to advance and protect its interests.

[48] Oxley and Bowen, op cit, pp.36-47

[49] BIO and PhRMA, op cit, p.6

[50] Bio and PhRMA, op cit, p.7

[51] Gollin, for example, concludes that direct disclosure of origin obligations "may be more problematic than indirect or voluntary approaches". Gollin, M, *Feasibility of national disclosure of origin requirements,* WTO Public Symposium, April 2005, p.1, at http://www.iprsonline.org/ictsd/docs/DOO3_Gollin.pdf

In the **CBD** Australia should:

- Undertake or commission detailed analyses of the potential costs facing Australia's agricultural, pharmaceutical and biotechnology industries from adverse outcomes in the CBD and TRIPS. Australia should make such analyses available to both developed and developing countries and use its diplomatic network to secure support for them. This work should be undertaken quickly;
- Assess likely compliance costs before COP 10. Australia needs to ensure compliance costs are kept as low as possible;[52]
- Work with like-minded countries in insisting that all of the detail in a proposed ABS instrument in the CBD is identified and agreed before it signs, let alone ratifies, a new instrument;
- Consider the alternative options suggested in Chapter 6.1, and develop and seek support for those it considers most prospective;
- Resist any suggestion that the CBD must deliver a result on ABS;
- Resist strongly attempts at COP 10 to get the CBD to request TRIPS to negotiate a disclosure obligation in TRIPS;
- Emphasize that TRIPS must not be made subordinate to the CBD;
- Be wary of any suggestions that the ABS can somehow "ring fence" the FAO Treaty and prevent a legally binding ABS instrument undermining it. Any such "ring fencing" is highly unlikely to work. If proposed it should be rejected; and
- Argue that the FAO Treaty, UPOV and the CGIAR not be undermined by the CBD.

In **TRIPS** Australia should:

- Continue to insist on securing greater clarity of what is proposed and what the impacts would be;
- Insist that TRIPS not be subordinate to the CBD;
- Continue to work closely with the US and other like-minded countries in opposing what Brazil and India are seeking; and
- If the CBD requests TRIPS to negotiate a disclosure obligation, argue that TRIPS not do so.

[52] Facilitative compliance arrangements are almost always more effective and efficient than punitive compliance in multilateral environment agreements.

In **WIPO** Australia should:

- Continue to seek clarity of what is proposed; and
- Resist attempts to reach a compromise between developed and developing countries that is not in Australia's interests.

Annex A: The Biopiracy Debate

2.1 What is it? A bogus issue?

There is no agreed definition of biopiracy – in the CBD, TRIPS or the academic literature.[53] Measuring it is therefore impossible. The contention is exploitation. The lack of evidence for biopiracy suggests that it is a bogus issue being used to cloak the real objective: economic rent. What is the evidence?

2.2 Overview of biopiracy

An analysis of and evidence for biopiracy undertaken by Oxley and Bowen in 2006 concluded that "There is no empirical evidence for the claim there is a problem. The research behind this report did not reveal substantial cases of biopiracy or any instance of highly profitable returns from a product developed via the acquisition of genetic resources from developing countries. Substantial royalty payments from bioprospecting have not materialized."[54]

That report also examined the extent of bioprospecting and whether any so-called blockbuster new drugs had been developed and marketed from biopiracy of developing countries' genetic material. It quoted Colombia University as having concluded that "no active compound had been developed into the commercialization phase: as of yet, no royalty or commercialization-driven monetary benefits have resulted from any of the (bioprospecting) agreements".[55] In other words, there was no evidence that blockbuster drugs had been developed from bioprospecting – whether via biopiracy or payment to engage in bioprospecting.

A 2008 bibliography on access and benefit sharing identifies only one substantive new article on biopiracy since the 2006 report.[56] Chen concludes that "Most allegations of biopiracy are so thoroughly riddled with inconsistencies and outright lies that the entire genre, pending further clarification, must be consigned to the realm of "rural" legend."[57]

Bastuck reached the same conclusion. "In sum one must come to the conclusion that the fear of 'biopiracy' patents and the criticisms related to them are exaggerated and with

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[53] Williams, China, *Access and Benefit-Sharing Bibliography, July 2008,* Royal Botanic Gardens, Kew, UK, at http://www.kew.org/conservation/access-benefit.pdf

[54] Oxley, A and Bowen, B, 2006, op cit, p.6, at http://www.apec.org.au

[55] Colombia University, op cit, p.87

[56] Williams op cit.

[57] Chen, J, 2006, There's no such thing as biopiracy …. And it's a good thing too, McGeorge Law Review 37, p.5

respect to the impacts not justified. … Moreover, developing countries themselves are able to prevent internationally 'bad' as well as 'good' patents from being granted. Thus they themselves are able to avoid the alleged negative impacts by enacting appropriate national legislation. Moreover, they are also able to profit from their genetic resources and traditional knowledge by enacting appropriate IPR (intellectual property rights) and accompanying legislation."[58]

Chen observes, moreover, that patents cited as evidence of biopiracy have been overturned. He recalls that "the European Patent Office revoked W.R.Grace's patent on "Neemex", a pesticide and insect repellant derived from … neem".[59] He argues that "The fear that the Grace patent would deprive Indian villagers of the right to continue traditional uses of neem … is purely scurrilous. Neem in its natural state is unpatentable."[60] Bastuck reports that a US patent awarded in 1996 for the healing properties of turmeric was overturned in its entirety in 1998 on the grounds of prior art when the Indian Council for Scientific and Industrial Research appealed successfully against the patent.[61]

The practical difficulties associated with operationalizing biopiracy were demonstrated in a document submitted in 2006 by Peru to the World Intellectual Property Organization (WIPO).[62] The same document was submitted to TRIPS. It notes that for the particular species under examination, camu camu, there was insufficient information; documented background information could not be obtained; it was not possible to find a document of a proven date to demonstrate camu camu was used in "certain applications"; camu camu is also found in Brazil, Colombia and Venezuela; and "it was not possible to find documents that reliably substantiated certain information because it is commonly the custom in the communities to transmit traditional knowledge orally from generation to generation".[63] In other words, proving the existence of biopiracy is in practice next to impossible.

Fowler concludes that "while most genebanks maintain databases including information on source countries of their material, few if any maintain information on the Country of Origin as defined by the CBD. Certainly, none would contain information on where the separate properties of each accession first arose".[64]

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[58] Bastuck, C, 2006, *'Biopiracy' and Patents – Developing Countries' Fears are Exaggerated,* p.59, at http://lawspace.law.uct.ac.za:8080/dspace/bitstream/2165/275/1/BastuckC_2006.pdf

[59] Chen, op cit, p.29

[60] Chen, op cit, p.5

[61] Bastuck, op cit, pp.22-23

[62] Government of Peru, 2006, World Intellectual Property Organization, *Analysis of Potential Cases of Biopiracy,* WIPO/GRTKF/IC/10

[63] Government of Peru, op cit, Annex, p.3, p.6

[64] Fowler, op cit, p.5

Two conclusions are warranted. First, claims about the nature and extent of biopiracy are not substantiated. There is neither an agreed definition of nor convincing evidence for biopiracy. Second, patents have been revoked on appeal if there is evidence they have been awarded incorrectly. Existing intellectual property arrangements governing patents are working well. There is no case for overturning them by a legally binding instrument in the CBD.

2.3 The anti-free market philosophy of those pushing the changes

The Governments and NGOs pushing for changes in the CBD and in TRIPS exhibit a clear anti-free market philosophy and bias. Brazil, India and the Africans argue that free markets will not deliver benefits on access and benefits sharing to developing countries. They are supported by a range of anti-globalization NGOs and others. Third World Network claims that "since the CBD came into force in 1993, benefit sharing has not been implemented.

There is nothing going from the user countries – from the pharmaceutical companies and so on – to the providers of genetic resources who are in most cases in the Global South".[65] Munoz Tellez supports a disclosure obligation in TRIPS as she argues free markets are not working. Global regulation is therefore required. She concedes that "The disclosure of origin requirement is a defence mechanism aimed at asserting (developing countries') offensive interest in the area".[66] Vandana Shiva exhibits similar anti-globalization bias. "The problem of biopiracy is a result of Western style IPR systems, not the absence of such IPR systems in India. Therefore, the implementation of TRIPs, which is based on the U.S. style patent regimes, should be immediately stopped and its review started."[67]

2.4 No case to weaken important international law

There is no case to weaken important international law. TRIPS is a key part of the international legal intellectual property system. It promotes economic growth by supporting the global intellectual property system. By conferring patent certainty and thereby underpinning investment, it has helped lift millions of people out of poverty. Attempts to negotiate a legally binding ABS instrument in the CBD, and for the CBD to recommend TRIPS commence negotiations on a disclosure obligation for new patents, must be resisted strongly.

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[65] Third World Network, 25 January 2008, at http://www.twnside.org.sg/title2/intellectual_property/info.service/2008/twn.ipr.info.080201.htm.

[66] Munoz Tellez, V, *The campaign against "biopiracy""introducing a disclosure of origin requirement,* at http://www.ipngos.org/NGO%20Briefings/Disclosure%20of%20Origin%20rev.pdf.

[6767] Shiva, V, 1999, Biopiracy: need to change Western IPR systems, at *http://www.sedos.org/english/shiva.htm*.

Annex B: Attitudes of Australian Industries

The Consultant sought responses from representatives of the Australian industries likely to be most seriously affected about the impacts of prospective outcomes in the CBD and TRIPS. A brief background paper including a set of questions was circulated in advance of consultations then direct discussions were undertaken with respondents. For reasons of confidentiality, the institutions and individuals consulted are not named in this report.

There are four key conclusions. First, respondent were not aware of the potential costs. Some were aware of the broad nature of what is under negotiation in the CBD and discussions in TRIPS and WIPO, but not the detail or the likely impacts. Second, this was the first time the potential costs had been identified in such detail. Third, the dynamic costs would be much greater than the static impacts.

Finally there was a common view that a detailed assessment of the likely impacts was needed as a matter of urgency, to inform Australia's negotiating position in the lead up to and at COP 10 of the CBD.

Grains

- Likely to face substantial costs.

Horticulture

- Horticulture would be very seriously affected. The static costs would be progressively outweighed by dynamic costs;

- New plant varieties and patents that are key to generating **value added and securing and retaining competitiveness**, which are issued under US and Australian patent law, would be less than would otherwise have been the case;

- Imported technologies and germplasm is very important, especially for apples and pears. The new Trans Tasman research body, PREVAR, is particularly important for apples;

- Annual output is around $8 billion per annum, which funds research of $80 million per annum. Reducing the value of output would reduce the research on which Australian horticulture depends;

- A disclosure obligation in TRIPS would be worse than a legally binding ABS instrument in the CBD;

- A CBD outcome that compromises plant breeders rights would be a disaster – particularly in regional and rural Australia;

- Many patents in place for 10-20 years expire shortly. That presents major challenges to the industry, which would be exacerbated by adverse CBD or TRIPS outcomes;

- Undermining the **multilateral gene banks** would compromise and undermine the **management and preservation of Australia's biodiversity;**

- **Collaborative research**, especially with NZ, would suffer. Australia would lose ground to the US.

- There are no obvious impacts on **biosecurity.**

Dairy

- The primary impact on the dairy industry from an adverse outcome in the CBD and in TRIPS would be via **higher grain and feed** prices;

- Semen and other technological improvements are imported without restrictions. There could be potential impacts on herd quality and therefore on the value of output and value added, but the nature, extent and transmission mechanism are unclear; and

- The dynamic costs would be much higher than the static costs.

Beef

Table 1 presents ABARE's estimates of the annual output and Total Factor Productivity growth on Australian broad acre and dairy industries between 1977-78 and 2006-07.[68]

Table 1
Annual output and total factor productivity growth, Australian broad acre and dairy industries, 1977-78 to 2006-07

	TFP Growth %	Output Growth %
Beef	1.5	1.7
Dairy	1.2	5.1

Source: Adapted by ITS Global from ABARE.

[68] ABARE, *Australian beef, June 2009. Financial Performance of beef farms, 2006-07 to 2008-09,* Table 6, at http://www.abareeconomics.com/interactive/09-SeriesPapers/

Output growth in dairy has been stronger than beef. Total factor productivity growth in beef has been marginally stronger than in dairy. An adverse outcome in the CBD or TRIPS that reduced the growth of total factor productivity and output growth in the beef and dairy industries (for example via higher grain input prices and slowing the rate of herd improvements) would reduce growth in total factor productivity as well as slow the growth of output. Such outcomes would impose potentially serious costs on both industries.

There are no analyses of the impacts on beef and dairy from adverse outcomes in the CBD or TRIPS on ABARE's website.

Pharmaceuticals and biotechnology

- The pharmaceutical industry is concerned about the potential impacts from adverse outcomes in the CBD and TRIPS – particularly Brazil's proposal to have an ABS instrument cover the sharing of influenza viruses. The recent difficulties with Indonesia in securing quick access to new and damaging influenza virus strains demonstrated the wider problems that a highly intrusive ABS instrument in the CBD might generate. The World Health Organization is experiencing difficulties in ensuring the fastest possible exchange of new virus strains.

- The potential costs from a worst case ABS instrument in the CBD, let alone a disclosure obligation in TRIPS, would be "huge". The long term, dynamic, costs for the industry in Australia would be much greater than the static impacts.

Questions put to industry

- How important are new and improved agricultural and biotechnological patents and technologies for your industry?

- What is the approximate share of new technologies imported versus domestically produced?

- What is the approximate value of output (and, if possible, value added, exports and jobs) dependent on continued access to new and improved technologies in your industry?

- What impact would a legally binding ABS instrument in the CBD, leading to a disclosure obligation in TRIPS, have on output, value added, productivity, exports and jobs in your industry?

1. Static and dynamic costs

- Can you provide an assessment of the likely static, or short term, and dynamic, or longer term, impacts on your industry?

2. Undermining the multilateral gene banks

- What impact would a legally binding ABS instrument leading to a disclosure obligation in TRIPS that undermined the multilateral gene banks have on your industry?

3. Impact on collaborative research in Australia

- What would the likely impacts be on your industry from a reduction in collaborative research based in Australia caused by a legally binding ABS instrument leading to a disclosure obligation in TRIPS?

4. Impact on biosecurity in Australia

- What would the potential impacts be on biosecurity in your industry

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