Intellectual Property in Free Trade Agreements

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Note

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Chapter 1

Introduction

COUNTRIES may increase their level of IP protection through bilateral influence, acceding to the World Trade Organization (WTO) or the intellectual property chapter of a bilateral or regional trade agreement (FTA)[1]. This book focuses on FTAs, but the same provisions may enter developing countries via the other routes mentioned above.

Investment agreements such as bilateral investment treaties (BITs) and the investment chapter of FTAs can increase effective levels of intellectual property protection either explicitly (when 'investment' is defined to include IP), or possibly even implicitly (for example via an expropriation provision).[2]

How Much Intellectual Property Protection Must Countries Provide?

Countries that are members of the WTO are required to abide by the minimum intellectual property protection standards set by the Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS). For example, TRIPS requires:

- patents to last for 20 years in all fields of technology
- copyright to last for at least 50 years from the date of publication for most copyrightable materials

However, least-developed countries (LDCs) that are Members of the WTO do not have to implement any of the substantive obligations

of TRIPS until at least 1 July 2013 (although there is a standstill provision whose legality has been criticized). Least-developed country Members of the WTO are also not obliged to implement patents on or data protection of medicines until at least 1 January 2016.

Currently, 151 countries are Members of the WTO.[3] Developing countries which are not yet Members of the WTO are not obliged to provide TRIPS-level of intellectual property protection until they become WTO Members, unless they are bound to by some other treaty. Although many developing countries are in the process of joining the WTO,[4] some may never join as they have few exports facing significant tariff barriers.

Some developing countries may be required to provide stronger intellectual property protection than TRIPS requires (because for example they have signed a North-South trade agreement). This is known as 'TRIPS-plus' protection.

TRIPS

The introduction of IP as an issue with binding rules within a trade agreement was very controversial, and remains so, after TRIPS was incorporated within the WTO. Since then, many economists ranging from Joseph Stiglitz to Jagdish Bhagwati have decried the inclusion of IP and TRIPS in the WTO.

There is a growing realisation that high IP standards, promoted by TRIPS to developing countries, are inappropriate to the development needs of developing countries. In particular, the former head of the World Bank's trade research department, Michael Finger, estimated that the cost to developing countries of implementing their TRIPS obligations amounts to US$60 billion annually, and that this more than offsets the gains they may expect to benefit from expanded market access in agriculture and textiles in the Uruguay Round. (Khor 2005).

There is now a movement by developing countries to clarify some aspects of TRIPS or to amend them, to reduce the more developmentally-negative aspects. For instance the Doha Declaration on TRIPS and Public Health has clarified that developing countries can make use

of 'flexibilities' such as compulsory licences to offset the monopoly privileges of patent holders.

Developing countries are also trying to have TRIPS amended to deal with the problem of 'biopiracy', by requiring that patent applications involving biological resources be accompanied by disclosure of the countries of origin and evidence of benefit-sharing arrangements with these countries. Moreover, TRIPS requires some life forms to be patented (micro-organisms and micro-biological processes) but allows the prohibition on patenting of other lifeforms (plants and animals), and gives countries the leeway to define what is an invention and thus what is patentable.

IP Negotiations Shift to FTAs

As WTO negotiators have become more aware of the development dimensions of IP, the developed countries have tried to introduce even higher standards of IP globally through the World Intellectual Property Organization (WIPO). However, many developing countries have now established a 'development agenda' within WIPO. They have also resisted attempts at harmonizing patent and copyright laws at even higher standards.

Thus, there is now an attempt by the developed countries to seek the forum of FTAs to: (a) remove or reduce the flexibilities in TRIPS and (b) establish even higher standards of IP protection in developing countries. IP is thus a major item in bilateral or regional trade agreements involving developed countries, and countries like the US, Japan, the European Union (EU) and European Free Trade Association (Iceland, Liechtenstein, Norway and Switzerland) are keen to have their interests furthered, beyond what is in TRIPS.

These FTAs threaten the use of TRIPS flexibilities in relation to (a) patents and access to medicines; (b) IP protection of plant varieties with respect to the sui generis system, and the rights of farmers; biodiversity; (c) affordable agricultural inputs; (d) moving up the value chain; (e) access to information.

Prior to TRIPS, countries were able to tailor their level of

IP protection to suit their level of development. Many of today's industrialised countries such as the USA, Europe,[5] Japan, South Korea and Taiwan did not have high levels of IP protection until it suited them. For example Switzerland did not allow patents on chemicals until 1978; Italy, Sweden and Switzerland did not allow patents on medicines until 1978[6] and Spain did not allow patents on chemicals or medicines until 1992 because it said it could not afford the higher medicine prices as a result of patents.

According to the Commission on Intellectual Property Rights, 'development objectives need to be integrated into the making of policy on intellectual property rights'[7] and there should be wide-ranging consultations before any changes to IP laws are made to ensure they are in line with development objectives in agriculture, health and industry.[8] In addition, it emphasizes that 'developing countries will incur significant costs if they rush to establish an IP regime that is inappropriate to their level of development.'[9]

'Almost without exception, developing countries are net importers of technology.'[10] 97% of all patents are held by rich countries.[11] Even in an industrialized country like Australia 90% of patents are granted to foreigners according to government statistics.[12] Most countries in the world are net intellectual property importers, except those such as the USA[13] and European Union. If net IP exporters can obtain broader and longer periods of IP protection, the profits of their companies will increase

Switzerland earns more per capita from exporting inventions than any other country. Nevertheless, in 1990 the Swiss government still said that further extension of patent protection in developing countries could be contrary to the interests of developing countries as they are primarily importers of technology.[14]

If developing countries broaden and lengthen their intellectual property protection beyond their current treaty obligations while they still have reduced capacity to generate their own intellectual property, they can expect to see their royalty outflow increase. For example, according to the Malaysian Government's 9th Malaysia Plan, in 2005 there was already estimated to be a net outflow of royalties of US$1.7billion.[15]

Apart from the costs to users of IP listed below, implementing and enforcing an IP regime is 'costly'.[16] 'In developing countries, where human and financial resources are scarce, and legal systems not well developed, the opportunity costs of operating the system effectively are high. Those costs include the costs of scrutinising the validity of claims to patent rights (both at the application stage and in the courts) and adjudicating upon actions for infringement. Considerable costs are generated by the inherent uncertainties of litigation.'[17]

Industry Influence in the USA

The Office of the United States Trade Representative (USTR) has long promoted the interests of its industries that have heavy IP protection such as pharmaceuticals, software and films and television. The USTR is advised by these private sector industries via committees whose role according to the USTR is 'to ensure that U.S. trade policy and trade negotiation objectives adequately reflect U.S. commercial and economic interests.'[18]

These committees include the pharmaceutical companies, chemical companies, Biotechnology Industry Organization, copyright owners such as Time Warner, International Intellectual Property Alliance, Recording Industry Association of America, Intellectual Property Owners Association, Motion Picture Association of America.[19]

The pharmaceutical industry spent US$91.4million on 675 lobbyists to engage members of the US Congress and Administration.[20] This is seven lobbyists per US Senator.[21] It also makes contributions to US election campaigns. For example the top 25 pharmaceutical firms donated US$48.6million from 1997-2002.[22]

By contrast, the Commission on Intellectual Property Rights states that the imperative 'is for developed countries to ensure that their policy objectives for IP standards in regional/bilateral trade agreements are demonstrably consistent with their broader objectives for promoting international development and poverty reduction… Negotiators for developed countries need to take account of the costs to developing countries of higher IP standards, as well as the benefits to their own industries.'[23] Given development objectives, it goes on to say that 'it

would be unwise to let IP policy be influenced by domestic industrial and commercial interest groups in developed countries.'[24]

WIPO Treaties

One of the key aspects of the IP chapter in some North-South FTAs is that the parties have to sign up to many international intellectual property treaties, not required by TRIPS. These treaties benefit IP exporting countries such as the USA, but may not benefit developing countries. For example, the Commission on Intellectual Property Rights in its report stated: 'Developing countries should think very carefully before joining the WIPO Copyright Treaty.'[25]

WIPO is 'a firm advocate of stronger IP protection in developing countries. Indeed, the analyses in WIPO's various published policy documents pay little attention to the possible adverse consequences of such protection.'[26] Furthermore, depending on the year, about 90% of its funding comes from patent applicants.[27] According to the Commission on Intellectual Property Rights, 'WIPO has always been responsive to the needs of the industrial sectors which make intensive use of IP. We are less persuaded that it is as responsive to the interests of consumers or users of IP-protected products.'[28]

Due to a perceived bias in WIPO towards stronger intellectual property protection, developing country governments are trying to reform WIPO to make it more development oriented via a 'Development Agenda'. This has been echoed by the Commission on Intellectual Property Rights established by the British Government.

Given the concerns above about the impact of stronger IP protection on development, including access to knowledge, developing countries should be very cautious about entering any treaties that require stronger IP protection and cross-sectoral consultations and detailed cost-benefit analyses should be conducted before any decision is made.

Analysis of the nature and effects of some of the WIPO treaties are made in this report in various sections below.

Chapter 2

Effects of TRIPS-plus Provisions on Health (Access to Medicine and Tobacco)

Access to Health: Impact of IP on Access to Affordable Essential Medicines

i. Introduction

GENERIC medicines are chemically the same as branded medicines. For example the branded version of paracetamol is called 'Panadol' and is made by GlaxoSmithKline (who once had a patent on it) but the generic version of paracetamol could be made by an Indian generic medicine company such as Cipla. In most countries, generic medicines have been tested by governments to ensure they are just as safe and effective as the branded version.

A patent is a monopoly that is usually national[29]. TRIPS specifies that the patent only has to last for 20 years from the date it is applied for. During the patent period, only the patent owner or holder can make, use or sell the patented product.[30]

Before TRIPS, countries were allowed to exempt medicines from being granted patents. This made it easier for these countries to make or import generic medicines that are usually much cheaper. After TRIPS, it was compulsory to allow patents on medicines (although LDC WTO Members have a transition period, see above). But there are many 'flexibilities' in TRIPS which countries can use (such as compulsory licences) to maximize their access to generic medicines. However, North-South FTAs can erode or remove many of these flexibilities.

Generic versions of medicines are usually much cheaper than

the patented equivalent. For example, the patented version of medicines to treat Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) cost US$15,000 per patient per year, but the generic version only cost US$99 per patient per year.[31] Malaysian academics found that patented medicines can be 1,044% more expensive than their generic equivalents in Malaysia.[32] Fluconazole was marketed under patent in Thailand by Pfizer until 1997. When the patent expired generic competitors entered the market, and within one year prices fell to 3% of its original level.[33] Costa Rican officials have estimated, for example, that without generic options the Social Security system, which offers universal health coverage, would have to increase its pharmaceutical budget from $70 million to $390 million to offer the same coverage. If the budget was fixed, coverage would be reduced to 18%.[34]

In the WTO Doha Ministerial, developing countries had their rights under TRIPS reconfirmed that they are able to offset patents through compulsory licences, government use and parallel importing, including for medicines. The flexibilities available for policy measures to promote access to cheap medicines were spelt out.

However, TRIPS-plus provisions found in North-South FTAs may require patents on more medicines, the patents to last for longer, reduced access to cheaper sources of the patented medicine (via limits on parallel importation), monopolies for a number of years even when there are no patents via 'data exclusivity' and reduced ability to access generics during the patented period (via limits on compulsory licensing). These TRIPS-plus provisions undermine or negate the TRIPS flexibilities that can be used to safeguard access to affordable essential medicines.

Explanations of the main relevant TRIPS-plus provisions are below.

ii. More medicines may be patented

More patent applications

A given medicine may not be patented in a developing country with a small population who can afford to buy it because the market is too small for the multinational company to spend the time and

money applying for a patent in that country. If there is no patent on that medicine in that country, then the country is free to import or manufacture the cheaper generic version of that medicine.

One of the key aspects of the IP chapter in some North-South FTAs is that the parties have to sign up to many international intellectual property treaties, not required by TRIPS. These treaties benefit IP exporting countries such as the USA, but may not benefit developing countries. These treaties include the Patent Cooperation Treaty (PCT) and Patent Law Treaty (PLT). The PCT and PLT make it easier for companies to apply for a patent in multiple countries by reducing the procedural barriers. Based on the experience of other countries according to WIPO statistics, joining the PCT is likely to result in more patents being applied for in a given developing country. If patents continue to be granted at the same rate, this will mean a greater proportion of medicines are patented in that developing country.

More medicines are eligible for patents

TRIPS allows countries to refuse to give patents on plants, animals, new uses of existing medicines and diagnostic and surgical methods.[35] There can be ethical and cultural objections to patenting life.[36]

Some medicines are plants or plant-based, such as artemisinin to treat malaria. If plants can be patented, this may reduce access to affordable versions of these medicines.

Many medicines are in fact new uses of an old medicine. For example zidovudine (AZT) was first developed to treat cancer, then it was found to be effective in treating AIDS.[37] If patents for new uses were allowed, zidovudine would enjoy a 40 year monopoly (20 years + 20 years).

North-South FTAs may require countries signing them to allow patents on: plants; animals; new uses of existing medicines and diagnostic, therapeutic and surgical methods which would reduce access affordable versions of these medicines. The UK Commission on Intellectual Property Rights has advised against any of these being patentable.[38]

The US has introduced patents for surgical procedures. When the introduction was made, ‘a blizzard of lawsuits followed. This unhealthy

circumstance was halted in 1996 by the American Medical Association and Congress, which decided that doctors couldn't sue other doctors for using patented surgical procedures.'[39]

More patents may be granted

Under TRIPS, countries can permit oppositions to a patent application ('pre-grant opposition') and actions to revoke a patent once it has been issued. This pre-grant opposition can allow anyone (for example a generic company or patient) to oppose a patent application for a variety of reasons, such as they may know that it is actually a traditional medicine in another country and so should not be considered new enough to get a patent. Pre-grant opposition is usually cheaper, simpler and faster than opposing a patent after it has been granted, so it can be an effective way to ensure that only high quality patents are granted for medicines that are really new, inventive and industrially applicable.

TRIPS-plus provisions in North-South FTAs may prevent (or restrict) pre-grant opposition. This means patents can only be opposed after they are issued, via the typically more expensive and slower court route and in the meantime the patent is usually in force and no generic versions of the medicine are available in the country.

iii. Extending patent life span

For WTO Members, TRIPS requires patents on medicines to last for 20 years from date of filing.[40] Prior to TRIPS, many of the countries that did allow patents on medicines only allowed them for fewer years Through FTAs, developed countries may seek to extend the life of the patent beyond the 20 year period. This is usually to 'compensate' for any 'unreasonable' time a national drug regulatory authority (DRA) or patent office takes to examine or approve an application. If a DRA feels under pressure to quickly approve medicines (or risk the monopoly period being extended), it may hurry through the data submitted and inadvertently approve unsafe medicines which then reach patients. If a patent office feels it has to quickly issue patents (or risk the monopoly period being extended), it may not have time to check all the existing

inventions in other countries (whether in written or oral records) which could result in patents being granted for medicines that are not really new or inventive and so should not have been given a patent.

iv. Data exclusivity

Before medicines can be sold, in most countries they need 'marketing approval' from the Health Ministry's DRA to confirm that the medicine is safe and beneficial. The DRA requires the first person to apply for marketing approval for a medicine to submit data (such as from clinical trials) to prove that the medicine is effective (treats the disease) and safe (does not cause undue side effects).[41]

The WTO does not require 'data exclusivity', i.e. that data submitted by the originator company to the DRA cannot be used by generic companies to get marketing approval for their equivalent medicines. Thus, under TRIPS, a generic producer can make use of the originator's clinical trial and other data proving the safety and efficacy of the compound when it seeks marketing approval for the same compound from the DRA. However, in North-South FTAs, developed countries often seek to establish or expand 'exclusive rights' over test data provided by the originator companies in order to prevent generic companies from registering an equivalent generic version of the medicine. It should be noted that this 'data exclusivity' applies even to generic versions of medicines that are **not** patented. If a medicine is patented, data exclusivity also prevents or makes it difficult for a compulsory licence to take effect, because any generic medicine imported or manufactured under the compulsory licence cannot be registered for the duration of the data exclusivity (which can be five or more years).

v. 'Linkage' or making the drug regulatory authority play the role of 'patent police'

The DRA does not normally have deal with patents or the patent status of the medicine. However, North-South FTAs such as those with the USA have changed the role of the DRA by making them

part of the 'patent police.' Some FTAs require that the DRA 'shall not grant marketing approval to any third party prior to the expiration of the patent term unless by consent of the patent owner'. This is not required by TRIPS.

This effectively prevents generic products from being available through the whole patent term. This means any compulsory licence or government use order would be ineffective for the whole patent term as any generic medicine produced or imported under such a licence/order could not be registered and so could not reach patients. This drastically curtails the ability of governments to ensure the health of their citizens, particularly in emergencies such as avian influenza or severe acute respiratory syndrome (SARS).

Furthermore, these provisions significantly alter the role of the DRA by requiring the DRA on receiving a registration application for a generic version, to enquire: (1) whether there is a patent claimed in the developing country for that generic product, (2) whether that the developing country patent is in force (ie the fees have been paid on time), (3) whether the patent actually covers the generic medicine as generic manufacturers usually change their version enough to avoid infringing the patent. Ascertaining this can take the courts up to 10 years, expert witnesses, thousands of documents and millions of dollars. It is not an easy question which the DRA with no patent expertise can determine; and (4) whether consent has been granted by the patent owner if all of the above occur.

Historically, the duty of the DRA has been to ensure that a medicine is safe, effective and of sufficient quality before it registers the medicine. It is the patent office's task to ensure that patents meet the criteria of patentability and ultimately the courts are the only authority that can determine if a patent is valid and has been infringed by a generic product.

This linkage of marketing approval to the patent term has been so controversial that countries such as the Philippines,[42] the European Union and Australia have explicitly refused to do it. Australia was eventually pressured to do it in the FTA it signed with the USA. The European Union's DRA argues that it does not have the training, skills, expertise or capacity to determine such questions of patent status. In fact

the US Food and Drug Administration, which is required by law to do linkage, has also admitted that it does not have the capacity to do it.[43]

vi. Limitation on situations in which compulsory licences can be used

TRIPS allows countries to issue compulsory licences (to companies or government agencies to produce or import generic versions of a medicine that has been patented) and does not restrict the situations in which they can be used. The Doha Declaration on TRIPS and Public Health confirms that countries have 'the freedom to determine the ground upon which such licences are granted.' However, North-South FTAs may seek to limit the circumstances under which compulsory licences on medicines are issued. For example, the US-Singapore FTA allows compulsory licences only for remedying anti-competitive practice by the patent holder; for public non-commercial use; and in the case of national emergency or circumstances of extreme urgency. Such limitations erode the 'policy space' available to the government to issue compulsory licences.

The effectiveness of compulsory licences can also be limited by data exclusivity and linkage, see above.

vii. Effective prevention of parallel importation

Parallel importation is one of the key methods of keeping medicines affordable. It involves legitimately importing the patented product from another country where it is sold more cheaply (for example because of price controls in that other country). TRIPS allows parallel importation as developing countries fought to retain that right.

Some North-South FTAs have effectively prevented parallel importation by requiring countries to prevent it if the patent holder has not consented to it. Since patent holders in practice will never consent, parallel importation will be made impossible.

However, the US Congress has recently refused to fund the inclusion in any new FTAs of the provisions restricting parallel importation that are found in some existing US FTAs.[44] This decision by Congress

should allow developing countries to reject any proposed restrictions on parallel importation in US FTA negotiations.

viii. The effects

The above TRIPS-plus FTA provisions result in the government taking on IP obligations beyond what the WTO requires. The World Health Organization (WHO) has an economic model of the impact of these TRIPS-plus provisions on medicine consumption and a country's generic medicine manufacturers. The model predicts that the full impact of medicine price rises will not be felt until about 15 years after the USFTA begins because the stronger IP protection only applies to each new medicine after the FTA starts so it will not affect all medicines in a country and the overall medicine price until about 15 years has passed.

When the WHO model was applied to Colombia, it found that the effect of most of these TRIPS-plus provisions is that Colombia would require an extra US$1.5billion to be spent on medicines every year by 2030.[45] If this were not spent, Colombians will have to reduce their medicine consumption by 44% by 2030.[46]

A study of the impact thus far of the TRIPS-plus provisions of the Jordan-USFTA found that: one hospital alone has increased its medicine spending six-fold, medicine prices in Jordan have already increased 20% since 2001 when the FTA began, over 25% of the Ministry of Health's budget is now spent on buying medicines, data exclusivity has delayed the introduction of cheaper generic versions of 79% of medicines launched by 21 multinational companies between 2002 and mid-2006 and ultimately the higher medicine prices are threatening the financial sustainability of government public health programs.[47] However, other countries could expect worse outcomes because recent USFTAs can have twice as many provisions that are likely to delay the introduction of cheaper generic versions of medicines as the Jordanian one and the Jordan-USFTA has not yet been in force for the approximately 15 years the WHO's model predicts it will take for the full effects to be felt of these provisions on medicine prices.

The extension of patent terms alone has been calculated by the

Korean National Health Insurance Corporation to cost 504.5 billion won (US$529 million) for having to extend medicine patents for 3 years and 722.5 billion won (US$757 million) if it has to agree to a four year extension in its USFTA negotiations.[48]

It was recently estimated that eight years of data exclusivity alone in Canada would have added $600 million to prescription medicine costs alone in the last five years.[49]

Research at the Australia Institute in Canberra has estimated that if provisions in the Australia-US FTA succeed in delaying by 24 months market entry of generic versions of just the top five Pharmaceutical Benefits Scheme (the 'PBS' is the Australian Government medicine reimbursement scheme) expenditure medicines due to come off patent, this could increase the cost of the PBS by $1.5 billion over 2006-2009. The budgetary cost could easily swamp the $53 million a year in economic gains from the agreement estimated by modelling work commissioned by a Senate Committee investigating the FTA.[50]

Malaysia issued a type of compulsory licence to import the cheaper generic version of patented medicines for people with HIV/AIDS. It reduced the average cost of treatment per patient per month by 81% and more than doubled the number of patients who could be treated.[51] The Thai Government recently issued compulsory licences for three types of medicines and estimates that it could save it up to US$24million each year.[52] The World Bank has estimated that if Thailand uses compulsory licensing to reduce the cost of second-line antiretroviral therapy to treat people living with HIV/AIDS by 90%, the government would reduce its future budgetary obligations by US$3.2 billion discounted to 2025.[53]

North-South FTAs could significantly restrict the ability to effectively issue compulsory licences in future.

Many have expressed their concerns about the way the intellectual property provisions found in USFTAs make medicines more expensive, including the United Nations Special Rapporteur on the Right to Health,[54] the World Health Assembly,[55] the WHO's Commission on Intellectual Property Rights, Innovation and Public Health,[56] Ministers of Health from ten Latin American countries,[57] the Ministers of Health[58] of the African Union, the African Union's Ministers of Trade[59], the UK Government's Commission on Intellectual Property Rights[60] and Nobel

Peace Prize winning Doctors Without Borders[61].

The government of the state of Western Australia was concerned about the impact of the Australia-USFTA on medicine prices in Australia. They noted that 'PBS data indicates that the prices of brand name (patented) medicines fall by an average of more than 30 per cent after patent expiration and the entry of generic medicines. Delays to the availability of generic pharmaceuticals will therefore significantly increase pharmaceutical expenditures in Australia over time particularly in hospitals where generic brands are used extensively… A rise in medicine costs through the PBS and any delays in the availability of generic equivalent medicines will have a direct impact upon the cost of medicines purchased by the public sector. Medicines are the second most expensive item after salaries in the health budget and a small increase in costs in addition to the implementation of new medicines in the market will have a significant impact upon the health budget.'[62]

In conclusion, the following can be expected to be the results of these TRIPS-plus provisions on access to medicines:

1. There will be severe curtailment on the supply and availability of cheaper generic medicines. The biggest victims will be patients suffering from a wide range of ailments, who will have to pay much more. If the prices are too high, this has a tremendous effect on access to medicine and to the people's health.

2. The Ministries of Health in countries which subsidise medicines will have to pay for the higher costs of medicines as a result of these provisions.

ix. Trademarks

The provisions relating to common names not being able to impair the effectiveness of trademarks in some FTAs may reduce the ability of countries to require the international non-proprietary name of a medicine (e.g. paracetamol) to be placed in large letters on all medicine packaging so consumers can more readily see that the different brands are all the same chemical and so they can choose on the basis of price (i.e. the generic) more easily.

FTAs' Effects on Tobacco Control

In many developing countries, smoking is a significant public health issue. For example, in Malaysia, nearly half of all Malaysian adults smoke, and according to the Malaysian government, nearly half of the health ministry's budget is spent on treating tobacco-related disease.[63] It estimates 10,000 Malaysians die a year from smoking-related disease.[64] Developing countries may currently or in the future wish to reduce smoking rates to decrease the number of deaths from tobacco-related disease and its burden on the health system.

However, IP and other[65] provisions in North-South FTAs can reduce the ability of governments to take tobacco control measures. Some examples are listed below.

i. Plain packaging requirements

Tobacco companies claim that a USFTA provision that requires 'adequate and effective protection' of IP prevents the use of plain packaging for cigarette packets as this would diminish the integrity of the trademark.[66]

ii. Bans on the use of 'mild'/'light' terminology

There is a consensus amongst public health experts that descriptions of cigarettes as 'mild' and 'light' are misleading because they are just as hazardous to smokers' health (partly because smokers compensate for reduced tar and nicotine by inhaling more deeply, covering the 'vents' on filters and by other means). A survey showed that more than a third of smokers of 'light' or 'mild' cigarettes choose these products for health reasons.[67] In 2001 when Canada was planning to ban the use of the word 'mild' or 'light' on tobacco packaging, tobacco companies claimed this may infringe their trademark rights under the North American Free Trade Agreement (NAFTA).[68] (Canada has been part of NAFTA which has some of TRIPS-plus provisions since 1994).

As of February 2005, Canada had not implemented its ban on 'mild' and 'light' on tobacco packaging.[69]

iii. Disclosure of cigarette ingredients

The trade secret protection in FTAs has also been cited by tobacco companies to prevent them from having to disclose the ingredients of cigarettes.[70]

Chapter 3

Effects on Agriculture and Biodiversity

Agriculture

THE IP provisions of North-South FTAs can reduce the income of farmers through a number of mechanisms.

There are different types of IP protection possible for plants. The strongest type of IP protection on plants would be a patent on the plant (including on the genes, cells, plant phenotypic characteristics) and/or plant variety. The second strongest form of IP protection for plant varieties is via the 1991 version of a treaty on plant variety protection called the International Convention for the Protection of New Varieties of Plants (UPOV).

i. Patents on plants and animals

As noted above, TRIPS allows countries to exclude the patenting of plants and animals. However some North-South FTAs oblige countries to make available '**patent protection for plants** that are new, involve an inventive step and are capable of industrial application.' If a developing country agreed to allow patents on plants, this would extend monopoly rights and monopoly prices to more of the inputs that farmers need. Patents on plants would stop or restrict the farmer from being able to save seed from one crop to re-plant or exchange it with another farmer, as well as prevent or restrict the use of the patented materials for further research by others. For example, 97% of Iraqi farmers in 2002 saved seeds to replant.[71]

It is interesting to note that there were 600 patents relating to rice issued in the US in 2000 and the rate of patenting is rapidly rising.[72] There were about 11,000 patents on plants registered in the USA between 1985–1999 according to ActionAid.[73]

Patents over plants and/or its components and phenotypic characteristics can also impede research by other parties, especially public research targeted at providing seeds to poor farmers in developing countries.

ii. Plant variety protection under UPOV 1991

TRIPS allows WTO Members the choice of patenting plant varieties or establishing a 'sui generis' system of intellectual protection for plant varieties.[74] This gives WTO Member countries the freedom to choose their own system, and some countries have stressed the right of farmers to save and re-use their seed. However some North-South FTAs oblige countries to be members of UPOV 1991. TRIPS does not require countries to join UPOV 1991.

UPOV was 'designed with the commercialised farming systems of the developed countries in mind.'[75] Adopted in 1961, and revised in 1972, 1978, and 1991 each revision of UPOV has led to more benefits for institutional/commercial plant breeders by according them higher and higher IP protection. UPOV 1991 creates breeders' rights over plant varieties, including discovered and developed varieties, harvested material and products made directly from harvested material.

UPOV 1991 favours formal plant breeders (in laboratories) and does not sufficiently safeguard the right of small farmers to save and re-use seeds and breed and develop new plant varieties. The balance between farmers and formal plant breeders is more in favour of farmers in UPOV 1978.

The majority of developing countries have chosen not to be a party to UPOV and so of the current 63 UPOV Members, only a few are from developing countries and most of these are members of UPOV 1978. New members can only adopt UPOV 1991 (except for India which can still join UPOV 1978) which would disadvantage small farmers who constitute the vast majority of farmers in developing countries. All the

US FTAs since NAFTA (including the one with Singapore) oblige the parties to be members of UPOV 1991.

Plant varieties are types of the same plant, for example D24 is a *durian* variety in Malaysia. Plant varieties are often developed by private companies and multinational agriculture companies such as Monsanto. These 'plant breeders' in laboratories want to maximize their profits by restricting what farmers can do with the plant varieties they develop so that they can have exclusive market shares. This means that like any other IP legislation, plant variety protection has to find the appropriate balance between the user (in this case the farmer) and the 'creator' (plant breeder) of the IP. Even among plant breeders, there is a need to balance between public researchers in developing countries and foreign researchers in order to ensure that the fruits of research and the use of materials from those developing countries will primarily benefit the countries concerned.

At the current stage of research and development in agriculture in most developing countries, in practice UPOV 1991 would allow breeders' rights to be claimed much more by foreign researchers rather than local farmers or researchers.

Joining UPOV 1991 would restrict the policy space of developing countries, for example by:

a) **removing the protection which can be given to farmers and indigenous peoples who have developed varieties themselves over the millennia in the field, to prevent biopiracy (where others take their plant resources and make profits without their prior informed consent or providing them with a fair and equitable share of the benefits). UPOV 1991 essentially only gives legal protection to the varieties arising from formal laboratory techniques.**
b) **preventing protection against biopiracy (for example requirements that applications for plant variety protection include the source of the genetic resource, prior written consent of the indigenous people or local community if they developed it from traditional varieties and evidence that the applicant has complied with any law regulating genetically modified**

organisms if the plant variety was developed via genetic engineering).

c) preventing small farmers from exchanging seeds amongst themselves and selling the farmer's farm-saved seeds if the farmer cannot make use of them because of natural disaster, emergency or other factors beyond the farmer's control. UPOV 1991 would instead require a compulsory licence to be applied for if farmers wanted to sell their farm-saved seed in this situation. This is more difficult, time consuming and not an automatic right the way TRIPS allows.

d) reducing the situations in which a compulsory licence can be issued (to overcome plant variety protection).

e) preventing a country from prohibiting the registration of plant varieties that may cause a negative impact on the environment.

f) preventing safeguards that ensure that plant varieties developed from samples from the developing country are available in that developing country for example for local researchers to work on.

iii. Data exclusivity and farmers

The 'data exclusivity' requirements in North-South FTAs can also apply to agricultural chemicals. This prevents suppliers of generic versions of these chemicals from being able to make use of the test data of the companies that first received registration of the chemicals in order to get the safety approval to market their generic products. Data exclusivity is not required by TRIPS.[76]

Based on USFTAs, this would mean that no generic version of a herbicide or pesticide can be registered and therefore used in countries that agree to these provisions for ten years.

For example, generic versions of agricultural chemicals are two to three times cheaper than their counterparts that are patented or have data exclusivity and the agricultural chemicals make up 10%-14% of total input costs for Australian farmers.[77]

Therefore the Australian farmers concluded that 'Australian farmers

have no subsidies to aid payment for input costs like chemicals, they survive in a distorted world market by keeping their input costs minimal. The competitive generic chemical market has evolved to meet the Australian farmers requirements and needs to remain for Australian farmers to stay internationally competitive… these laws if implemented in Australia, they have the potential to destroy the generic companies that exist in Australia and the beneficial competition that goes along with their presence in the market.'[79]

The farmers asked that 'data protection be taken out of the Intellectual Property Chapter or the entire Chapter be set aside for re-negotiation.'[80]

Some pertinent questions arise. Have developing countries contemplating introducing data exclusivity for agricultural chemicals calculated whether this will also lead to a rise in input costs for their farmers of 10%-20% from data exclusivity alone? If so, will the farmers be compensated for the duration of the North-South FTA that requires data exclusivity on agricultural chemicals? Any such increase in costs will add to the other problems facing the farmers as a result of the North-South FTA, such as higher competition from (often subsidized) imports as tariffs are reduced or eliminated, and higher costs of seeds due to the strict IP to be introduced for plants and plant varieties.

iv. Does stronger IP lead to increased agricultural productivity?[80]

Increasing agricultural productivity can reduce poverty which enables families to spend more on health and education etc.[81]Looking at agriculture in particular, Boldrin and Levine found that total factor productivity in US agriculture overall did not accelerate after the introduction of patents on plants.[82] Furthermore, a case study of US corn showed that yields did not increase faster after patents on plant varieties were allowed.[83] According to Alston and Venner, the results of introducing Plant Variety Protection Act (PVPA) in USA were that 'The PVPA appears to have contributed to increases in public expenditures on wheat variety improvement, but private-sector investment in wheat breeding does not appear to have increased. Moreover, econometric

analyses indicate that the PVPA has not caused any increase in experimental or commercial wheat yields. However, the share of U.S. wheat acreage sown to private varieties has increased – from 3 percent in 1970 to 30 percent in the 1990s. These findings indicate that the PVPA has served primarily as a marketing tool ...'[84]

Protection of Biodiversity

Communities in many developing countries rely on biodiversity as a direct source of income (such as indigenous peoples who live off forest products) or indirectly (such as alternative crop varieties being an important alternative when crops fail due to weather, pests or weeds).

The policy space of developing countries to protect this biodiversity may be reduced by a variety of North-South FTA provisions (such as prohibitions on export taxes/licences/quotas and investment protection such as expropriation provisions which will be covered by other reports).

The ability of developing country governments to reduce and prevent biopiracy and ensure enforceable fair and equitable benefit sharing of the proceeds made from any biological resource may also be reduced through a side letter of North-South FTAs.[85] The side letter may require the developing country to agree that mere contracts are sufficient to stop biopiracy (even though they have not been successful to date), rather than an international legally enforceable framework such as the international access and benefit sharing regime being negotiated under the Convention on Biological Diversity or amendment to TRIPS as a large number of developing countries have suggested to require that applications for patents involving biological resources show proof of source/country of origin, prior informed consent and fair and equitable benefit sharing.

Chapter 4

Effects on Manufacturing

i. Moving up the value chain

IP protection can reduce the ability of companies in developing countries to move into higher technology industries as historical cases show. For example, in 1864 La Fuchsine, a French dye company was given broad patents on dyes and so dominated the French market. No other French dye companies could manufacture because of the patents so they moved to Switzerland where chemical products were unpatentable until 1978. La Fuchsine innovated little and when its patents expired, it could not compete and disappeared. Meanwhile, the formerly French companies carried out significant innovation in Switzerland where there were no chemical product patents. By World War I, there was no chemical production in France.

By contrast, after patents on medicines were removed in India in 1970, Indian pharmaceutical manufacturers flourished. When India had high levels of intellectual property protection prior to 1970, Indian medicine manufacturers only supplied 32% of the Indian market. After India's intellectual property protection was lowered, the share of the Indian pharmaceutical market supplied by domestic companies has increased to 77%.[86] India has also changed from being a net importer of medicines to a net exporter with exports worth US$3177 million in 2003-4 and exports are growing at an annual rate of 20.8%.[87] It exports to 65 countries including developed countries such as the USA and Europe and developing countries.[88] India has the most US Food and

Drug Administration-approved manufacturing facilities outside the US which indicates the high technology and quality standards achieved by Indian manufacturers when intellectual property protection was lowered.[89]

Similarly, because the Netherlands abolished its 1817 patent law in 1869, Philips was able to start its production of light bulbs in 1891 in the Netherlands without having to worry about infringing Edison's patents.[90]

Likewise, in Switzerland in the 1880s two of Switzerland's most important industries, chemicals and textiles, were strongly opposed to the introduction of patents as it would restrict their use of processes developed abroad. Steiger (a textile manufacturer) commented that 'Swiss industrial development was fostered by the absence of patent protection. If patent protection had been in effect, neither the textile industry nor the machine-building industry could have laid the foundations for subsequent development, nor would they have flourished as they did'.[91] Benziger (a manufacturer) noted that 'Our industries owe their current state of development to what we have borrowed from foreign countries. If this constitutes theft, then all our manufacturers are thieves.' In 1907, Switzerland had to allow patents on chemical processes or Germany would impose trade sanctions. In the debate: Federal Councillor Brenner told the Parliament 'In our deliberations on this law, we would do well to bear in mind that it should be framed in such a way that it is adapted to the needs of our own industries and conditions in our own country. These considerations, rather than the demands and claims of foreign industries, must be our primary concern in shaping the law.'[92]

ii. Technology transfer

'Technology is a motor for human development.'[93] Increasing manufacturing productivity can reduce poverty which can enable families to spend more on health and education etc.[94] Increased productivity can occur through technology transfer. According to Chang, technology transfer has been key in industrialisation and as a determinant of a country's prosperity.[95] For example, Britain's transition

from a backward raw material producer to a leading manufacturing nation via technology transfer from the then more advanced economies of continental Europe in the 16th and 17th-century (methods included: industrial espionage, enticing skilled migrants and importing machinery).

Does lower IP protection reduce technology transfer? Abolishing patents does not seem to slow technological development according to the history of the Netherlands.[96]

In fact, IP was not a factor when pharmaceutical multi-national companies explained their considerations when deciding whether to transfer technology: 'the major factors that attract foreign companies to embark on such projects with local companies are: volume of business, ie large market; good manufacturing practices; tax incentives; low production costs; fast production response and turnaround; low product customization; restrictions on equity ownership.'[97]

iii. Patent Cooperation Treaty

TRIPS does not require countries to join the Patent Cooperation Treaty (PCT). However, all recent US Free Trade Agreements have required the countries signing them to join the PCT.[98]

Patents are national. It is not possible to apply for a worldwide patent. The PCT is designed to enable people to apply for a patent in multiple countries more easily. It does this by standardizing the application procedures and requiring Parties to the PCT to accept the standardised procedure. Applications can then be sent to multiple countries by basically 'ticking a box'.

The PCT is more beneficial for countries with inventors who wish to apply for patents in other countries. In a developing country such as Malaysia, 98% of patents granted are to foreigners and this has been constant for the last five years according to Malaysian Government statistics.[99] 1.1% of patents granted in Indonesia from 1993-2006 were to Indonesians.[100] From 1998-2005, 0.6-1.4% of patents granted in the Philippines were to Filipinos.[101] In sub-Saharan Africa 0.01% of patent applications in 1997 were by residents.[102] Even in Australia, approximately 90% of patents granted each year are to foreigners.[103]

As the PCT makes it easier for foreigners to apply for patents in developing countries by lowering the procedural hurdles, the developing country can expect more patent applications after joining the PCT. This was the experience of all other countries joining the PCT except one according to WIPO's data. For example China's patent applications increased five-fold, Iceland's increased 12-fold and Vietnam's increased 15-fold.[104]

If it turns out that the PCT causes a flood of patent applications causing the patent office to fall behind in its examinations, or causing more medicines to be under patent monopolies, it is possible for countries to unilaterally withdraw from the PCT,[105] without penalty, if joining the PCT has not been locked in by an FTA. Countries have reversed their levels of intellectual property protection in the past, e.g. the Netherlands used to grant patents, then it abolished its patent law (before later reinstating it).[106]

The rapid increase in patents in the developing country could have several effects on access to the resources needed for a decent standard of living from manufacturing. A few examples are given below.

Moving up the value chain

If the developing country wishes to move up the value chain, joining the PCT could make this more difficult because in higher technology industries, the inputs are also technology. If a greater proportion of machinery etc is patented in the developing country because it joins the PCT, this will increase the cost of inputs (as more royalties will have to be paid) and make it harder for the developing country to move up the value chain. (This would be exacerbated under a North-South FTA which may require all of the developing country's tariffs to be bound at 0% making it very difficult to start new industries higher up the value chain as they are exposed to competition from day 1).

Biotechnology

If the developing country wishes to encourage a biotechnology industry, the developing country actually needs to grant as few patents as possible so that its inputs (such as machinery, consumables for example enzymes etc) are not patented. See also 'Impact of stronger copyright

protection' for the impact of longer copyright periods on access to scientific journal articles needed by the biotechnology industry. The main thing is that patents continue to be granted in the main markets for the products of the developing country biotechnology industry, i.e. the USA and European Union.

iv. Micro-organisms: Budapest Treaty

TRIPS makes it mandatory for WTO members to allow **patents for micro-organisms** and certain microbiological processes.[107] However it is left to members to determine what types of micro-organisms to allow for patenting. For example, some countries do not allow patenting of naturally-occurring micro-organisms.

The Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure ('Budapest Treaty') is about micro-organisms. TRIPS does not require countries to join the Budapest Treaty. Almost all USFTAs have required the countries signing them to join the Budapest Treaty.

The Budapest Treaty aims to make it easier for people to get patents in multiple countries, in this case for micro-organisms. Countries may want to require applicants for patents on micro-organisms to deposit a sample of the micro-organism with them. This is because micro-organisms can be difficult to adequately describe on a paper patent application.[108] Part of the quid pro quo underlying the patent system is that a monopoly is granted (for 20 years for WTO members) to the inventor in return for the inventor disclosing how to make the invention so that at the end of 20 years, anyone can make the invention.[109] This disclosure occurs in the patent application. To ensure there is adequate disclosure to justify getting a patent, countries can require the patent applicant to deposit a sample of the micro-organism at a storage facility in the country.

Patent applicants say the cost and effort of posting micro-organism samples to each country they want a patent in makes it procedurally more difficult for them to get patents in multiple countries. If countries have signed the Budapest Treaty, people seeking to get a patent in those countries only have to give a micro-organism sample to an

'international depositary authority'. As of March 2006 there were 37 such authorities: seven in the United Kingdom, three in the Russian Federation and in the Republic of Korea, two each in China, Italy, Japan, Poland, Spain and the United States of America, and one each in Australia, Belgium, Bulgaria, Canada, the Czech Republic, France, Germany, Hungary, Latvia, India, the Netherlands and Slovakia. The majority of the depositories are in developed countries and these hold the bulk of the deposits.

Implications for developing countries

If a developing country signs the Budapest Treaty, as most USFTAs have required, it is likely to receive more micro-organism patent applications due to the easier application procedure and if these are granted at the same rate, more micro-organisms will be patented in that developing country. This is likely to raise the cost of inputs for the food, medical and agricultural industries[110] in the developing country, including the biotechnology industry.

For example Thai industries rely on imported micro-organisms costing an average of US$1.6billion-US$1.9billion per year.[111] In the context of the Japan-Thailand Economic Partnership Agreement 'Khao-Kwan Foundation chairman Day-cha Siripatra said the country would lose several hundred billion baht a year if the government allowed Japan to patent micro-organisms, because Thailand relied on Effective Micro-organism (EM) imports from Japan to support many industries and solve the environment problem.'[112]

As 93.5% of biotechnology patents between 1990 and 1995 originated in the USA, Japan or European Patent Office countries,[113] more patents on micro-organisms are likely to increase the outflow of royalties from the developing country, contributing to greater foreign exchange losses.

There are also concerns that international depositary authorities may not be properly managed so it would be difficult for the country of origin or providing country to safeguard its interests and rights over the samples. Developing countries have significant biodiversity, including in micro-organisms and this may lead to biopiracy. Furthermore, the international depositary authority may deal with the sample in a way

the country does not desire. For example Indonesia freely gave samples of its avian influenza virus to the World Health Organization who then passed it onto an Australian company who developed a vaccine and would not give it free to Indonesia but insisted on Indonesia paying commercially for it.[114]

v. Impact of stronger copyright protection

Stronger copyright protection can hamper the growth and development of knowledge-based industries. According to a UNESCO report: 'Copyright has emerged as one of the most important means of regulating the international flow of ideas and knowledge-based products, and will be a central instrument for the knowledge industries of the twenty-first century.

Those who control copyright have a significant advantage in the emerging, knowledge-based global economy. The fact is that copyright ownership is largely in the hands of the major industrialized nations and of the major multimedia corporations placing low per capita income countries as well as smaller economies at a significant disadvantage.'[115]

Copyright-based industries including publishing, film, television, radio, music and computer software 'have helped bring about dramatic increases in productivity through aiding the creation of information-based products like desk-top publishing software, electronic mail or sophisticated scientific computer databases.'[116]

Access to computer software is a 'pre-requisite for access to information and for competitiveness in the global economy. . . In the knowledge-based global economy, computer technologies are an essential requirement for accessing and using information, accelerating technology transfer and boosting the growth of productivity' according to the Commission.[117]

If the developing country is seeking to encourage the growth of copyright-based industries, it should be noted that countries such as Benin and Chad which joined the Berne Convention many years ago 'have not seen significant increases in their national copyright-based industries or in the level of copyright-protected works being created

by their people.'[118] So increasing copyright protection alone does not seem to be sufficient to stimulate these industries as they may also be affected by other factors.

Copyright can also increase the cost of creative industries, for example, Cannes Film Festival hit movie 'Tarnation' cost US$218 to make, but to add copyrighted music and video clips will cost US$400,000 in royalties.[119]

The Queensland Government commented in the context of the Australia-US FTA's (AUSFTA) extension of copyright duration from the TRIPS 50 year requirement to 70 years that 'There are also significant concerns from industry that the extension of copyright protection represents a barrier to innovation by restricting access to intellectual property for longer periods.'[120]

'In the recent challenge posed to the U.S. *Copyright Term Extension Act 1998* (CTEA) in *Eldred v Ashcroft*, the strong arguments made to the court for repealing the CTEA, such as the added costs to users, the minimal long term awards to owners and the speculative nature of predictions on creative incentives arising from extended monopoly were not disputed…

The available reports on the topic such as the Allens report, *Copyright Term Extension: Australian Benefits and Costs* (July 2003) provides no clear evidence of any short or long term economic benefits of extension. No claims have been made that the economic benefits of harmonisation with the U.S. is any more than marginal and no data has been presented to substantiate even this weak assertion. Although the benefits of harmonisation are theoretically plausible, the reality is that the beneficiaries of harmonisation will be multinational companies, who are based mostly in the U.S. and European Union… No proponent of term extension has relied on an argument that an extra 20 years of protection *after* the death of the author will have any impact on the incentive of authors to produce more work.' [121]

See also 'access to information' below.

vi. Trademarks

The AUSFTA chapter requires the countries to allow trademarks

on sounds and scents.[122] The human development implications of this (for example on the ability of developing country industries to grow freely) need to be studied further.

vii. Generic medicine manufacturing industry

The combined effect of most of the TRIPS-plus provisions outlined in the access to medicines section is predicted by the WHO/PAHO model to cause Colombian medicine manufacturers to lose 64% of their market share by 2030.[123]

South Korean Health and Welfare Minister Yoo Si-min said, 'Under free trade talks, the damage to the South Korean pharmaceutical industry may total between 600 billion won to 1 trillion won (US$629 million-1.05 billion) if the U.S. proposal is accepted.'[124]

viii. Generic agricultural chemical manufacturing industry

When ten years of data exclusivity for agricultural chemicals was introduced in Australia as part of the Australia-USFTA, a submission to a Parliamentary inquiry said 'These changes will have a devastating effect on the independent generic chemical companies which provide competitively priced chemicals to farmers… In the context of this submission we ask that the Senate Committee to consider taking the important issue of data protection out of the FTA agreement or set aside Chapter 17 [on intellectual property] of the FTA from the broader agreement. This will allow Australia to set our own laws which best serve our market and stakeholders.'[125] The Submission also noted that if the TRIPS-plus provisions were implemented, 'they have the potential destroy the generic companies that exist in Australia'.[126]

ix. Software patents

TRIPS does not require patents on software either[127] and many countries do not allow patents on software. However the USA allows patents on software and some information technology lawyers are concerned that certain provisions in USFTAs could eventually lead to

software patents.[128] For a table that details the many provisions in the Australia-USFTA that affect software, see http://linux.org.au/projects/fta/fta_comparison_table_040322.pdf.

In many developing countries there is a strong open source software industry which could be adversely affected by software patents as can be seen by how it is playing out in the USA. 'A single patent can ruin an Open Source project… With the USPTO granting an estimated 45,000 software patents in 2003 and rising, it is not possible to audit software against the hundreds of thousands of patents.'[129]Alleged infringement of one software patent alone resulted in the US court awarding damages of US$521million.[130]

Even Bill Gates, Chairman of Microsoft, commented that 'If people had understood how patents would be granted when most of today's ideas were invented, and had taken out patents, the industry would be at a standstill today.'[131]

Similarly, Jerry Baker, Senior Vice President of Oracle Corporation, said that 'Our engineers and patent counsel have advised me that it may be virtually impossible to develop a complicated software product today without infringing numerous broad existing patents. … As a defensive strategy, Oracle has expended substantial money and effort to protect itself by selectively applying for patents which will present the best opportunities for cross-licensing between Oracle and other companies who may allege patent infringement. If such a claimant is also a software developer and marketer, we would hope to be able to use our pending patent applications to cross-license and leave our business unchanged.' [132]

Chapter 5

Internet Service Provider Liability

INTERNET service providers (ISPs) do various things. Some ISPs merely provide access to the internet. Others provide people with space online to host their webpages. One ISP (such as Malaysia's TM Net[133]) could host millions of webpages. People put things on these webpages without getting permission from the ISP. So the webpages may contain things that infringe copyright such as copyrighted books, articles, music or movies. In many countries, ISPs are not liable for the copyright infringing material that people have posted on the websites they host.

However, in the USA, there were conflicting court decisions about whether ISPs were liable for copyright infringing behaviour by their end-users, including having copyright-infringing items on the websites they host.[134] For this reason, ISPs wanted legislation to give them 'safe harbours' so that they could carry out their normal business activities with only limited liability, if they complied with certain conditions.[135] These safe harbours have been criticized as being too narrow and procedurally burdensome to use.[136]

TRIPS does not require internet service providers to be liable for copyright infringing material put on websites they host by others.[137]

USFTAs contain these ISP safe harbours. USFTAs may create ISP liability in countries where none previously existed because:

- Recent USFTAs require temporary reproductions (for example in the memory of the computer while accessing a webpage), to be a copyright infringement.[138] Since digital communication

involves serial reproduction and distribution of temporary reproductions of digital works, ISPs may face increased liability if temporary reproductions are considered infringing and there is no corresponding limitation on copyright.

- In addition, the existence of safe harbours may imply the existence of liability where none previously existed in domestic law, and has been used to create a de facto liability standard in the USA, where copyright owners have sued ISPs for failure to comply with safe harbour conditions as evidence in itself of copyright infringement (even though under US law failure to comply with safe harbour conditions only means that infringement still has to be proven on general principles).
- The non-violation provision in the dispute settlement chapter of all USFTAs[139] applies to the intellectual property chapter and so may mean that even if the USFTA does not require ISP liability to be created, if the USA reasonably expected it to be and the developing country (G) which signed the USFTA does not make ISPs liable, G may be sued at the international tribunal by the US Government. If the USA wins the case and G does not change its law to make ISPs liable, the US can raise tariffs on G's exports to the USA.

How ISP liability works in USFTAs

To benefit from the safe harbour, in the Australia-USFTA, the person or company must fall within the definition of 'internet service provider', must be involved in one of the four activities listed below and the ISP has to comply with the conditions attached to each activity.

If the ISP meets all of these requirements, courts cannot fine them for authorizing copyright infringements on their networks in that category of activity. Courts can still do things like order the ISP to remove or disable access to the copyright infringing material or terminate the user's account.

For Category A activities, courts can only order the ISP to terminate specified accounts or take reasonable steps to block access to a specific online location that is not in the ISP's country.

For activities in other Categories, the court can only order: access to the copyright infringing material to be removed or disabled, specified

accounts to be terminated and other remedies the court finds necessary as long as they are the least burdensome to the ISP compared to other forms of relief. Courts can basically only order these things if the ISP has received notice and a chance to appear before the court.

Definition of ISP

The definition of ISP in the Australia-USFTA is broad enough[140] to cause even universities to be concerned that they will be considered to be ISPs, see below.

Activities[141]

Category A activities are known as 'conduits' where the ISP transmits, routes or provides connections: i.e. a transitory communication.

Category B activities, automatic 'caching', i.e. where ISPs store material automatically, for example to make it faster to retrieve rather than the user having to connect to the overseas site again.

Category C activities, 'hosting/storing', is where material is stored on the ISP network/system at the user's direction.

Category D activities, 'directing', is where users are directed to copyrighted material, for example via links.

Conditions ISPs must comply with to get safe harbour protection

As Category A and B activities are seen as more passive, they gain almost automatic safe harbour status with minimal conditions attached.[142] However for Categories C and D where ISPs exercise greater control, there are more rigorous conditions to qualify for safe harbour protection such as 'take-down notice' procedures.[143]

The main conditions to qualify for the safe harbour protection are:

- All Categories must have adopted and reasonably implemented a termination policy for accounts of repeat infringers

- Category A:
  - ISPs must not have initiated transmission of copyrighted material and
  - ISPs cannot have made substantive modifications to the content

of the transmitted material (it is ok to make technical modifications such as format shifting)

- Category B:
  – ISPs must not have initiated transmission of copyrighted material and
  – ISPs cannot have modified the original user access conditions for significant parts of the cached material and
  – ISPs must have expeditiously removed or disabled cached copyright material when it has been removed or disabled at the originating site and a notice of claimed infringement has been received
  – ISPs cannot have made substantive modifications to the content of the transmitted material (it is ok to make technical modifications such as format shifting)

- Category C:
  – ISPs must not have initiated transmission of copyrighted material and
  – The ISP cannot have received any directly attributable financial benefit from the copyright infringing activity
  – The ISP must have expeditiously removed/disabled material if it gets actual knowledge of the infringement or becomes aware of circumstances which make the infringement apparent such as a take-down notice claiming infringement.
  – The ISP must publicly designate a representative to receive take-down notices.

- Category D:
  – The ISP cannot have received any directly attributable financial benefit from the copyright infringing activity
  – The ISP must have expeditiously removed/disabled material if it gets actual knowledge of the infringement or becomes aware of circumstances which make the infringement apparent such as a take-down notice claiming infringement.

– The ISP must publicly designate a representative to receive take-down notices.

Steps in a take-down procedure

1. Copyright owner (C) notifies the ISP that C thinks there is infringing material on one of the websites the ISP hosts
2. ISP 'takes down' the allegedly infringing material
3. ISP sends notice to person whose material was removed (D) (otherwise the ISP could be sued by D)
4. D sends ISP counter-notification that not infringing
5. ISP promptly sends counter-notification to C and tells C will restore the material unless C starts court case within 10 days to get injunction
6. ISP restores the material unless C gets injunction
7. ISP also has to provide identification of D to C

C usually does not have to have waited for the court to decide that D's material is infringing C's copyright.

Problems with take-down procedure

If this procedure is required, then to minimize the burden on the ISP, the copyright owner's notice should identify all the copyright work(s) alleged to have been infringed so the ISP can more easily find them and remove them. Furthermore, to prevent abuse of the system by copyright owners, the notice should be accompanied by a statutory declaration – that is, a statement made on oath by someone with direct knowledge of the facts of the matter [that it believes the material is infringing]. Otherwise many notices can be sent when the material is not infringing.

However the combination of the side letter and non-violation complaint in the AUSFTA may mean these safeguards are not allowed.

The cost of ISP liability

According to the lawyer who is the Associate Director of the Intellectual Property Research Institute of Australia, the ISP liability

provisions in the AUSFTA 'will impose significant costs on Australian ISPs.'[144]

The impact on developing country ISPs of a standard USFTA can be seen from the effect of this system in the USA. The enforcement agent of one copyright industry association sent one ISP over 16,700 arguably invalid takedown notices.[145] One small US ISP had received over 20,000 notices in 2003 and all were invalid.[146] Another US ISP received over 30,000 notices from January to April 2004 alone, only two of which were legitimate takedown notices.[147] In the previous 12 months, the same ISP received over 90,000 invalid peer-to-peer notices.[148] As the Vice President and Associate General Counsel of Verizon Communications, Inc., Sarah Deutsch noted, copyright owners can use automated programs to send out notices with no due diligence, but each notice received requires human intervention by the ISP to see if they are valid or not.[149]

More detailed information including about the subpoena system in the US and its cost to ISPs can be found at http://www.eff.org/IP/FTAA/ISP_june05.pdf and more examples of invalid takedown notices at http://www.eff.org/IP/P2P/20030926_unsafe_harbors.php.

This abuse of the take-down notices in the USA led a US Congressman to call for a Congressional investigation into the practice.[150]

Given the concerns of all of the Vice-Chancellors of the universities in Australia about the effect of the internet service provider provisions on them as they may be considered to be ISPs,[151] have developing country governments consulted all their universities as to their ability to comply with any internet service provider provisions in a North-South FTA they may sign?

Australia's obligations under the AUSFTA with respect to internet service providers closely parallel those in the USA's Digital Millennium Copyright Act[152] which has been widely criticized and challenged. Submissions to the Australian Senate Inquiry into the Australia-USFTA reiterated that 'recognition must be given to the realities of resource limitations in managing networks.'[153]

Chapter 6

Does Stronger IP Lead to Increased Foreign Direct Investment?

IF developing countries wish to increase foreign direct investment (FDI), for example to reduce unemployment or increase technology transfer, it is not clear that stronger IP protection will generate this.

i. Main study claiming stronger IP protection leads to more FDI has been thoroughly criticized

The ubiquitously cited study[154] claiming that stronger intellectual property protection will cause increased foreign direct investment (FDI) has been criticized by Heald[155] for a number of reasons. The main ones are outlined below.

Usually developing countries want foreign direct investment that stays for the long term and involves establishing factories in their country which employ local staff and produce goods which can also be exported to earn valuable foreign exchange. Ideally such a foreign investment would also transfer technology and knowhow to the local staff. Foreign 'investment' in the form of short term capital flows or a one person office which imports finished products for consumption in the developing country does not bring as much benefit.

According to Heald, when a company is considering 'establishing a factory' in a developing country, one of its greatest fears is that the local staff will learn its production methods and then resign and set up their own competing factory. This can be prevented by strong trade

secret law which prevents employees from telling others the secret production methods they learnt while being employed by the foreign company. Strong employment law which enforces contracts where locally employed staff promise not to use the trade secrets they learn to set up a competing enterprise also reassures companies considering establishing a factory in the developing country.

By contrast, if a foreign company is weighing up whether to set up a small office to import its finished products into the developing country, they will be most concerned about trade mark and copyright law. This is to ensure that local competitors cannot copy the investor's trade mark or packaging of the finished product and encroach on their market share.

It should be noted that in neither of these scenarios is the period or scope of patent protection of the protection of clinical trial data relevant to companies considering investing in the developing country. This is reinforced by quotes from the companies that Mansfield himself surveyed such as 'Our concern still resides in being able to procure a quick injunction [a court order stopping someone doing something] against a confidant who is in a position to disclose confidential information'; or 'we have not implemented manufacturing operations there that use our highest level of technology due to uncertainty over trade secret protection'.[156]

Furthermore, the only way in which patent protection is relevant is that countries with shorter patent periods and where less is patented should be favoured by foreign investors choosing countries to manufacture in because fewer of their inputs will be patented so they will have to pay less in licence and royalty fees and can lower their production costs.

ii. Other factors have been found to be more important in FDI decisions

The United Nations' study on intellectual property rights and foreign direct investment found that there is insufficient linkage between patents and foreign direct investment.[157] The study found that cost, market size, levels of human capital and infrastructure development and broad

macro-economic conditions were more important.[158] For example China[159] and India[160] had very large FDI inflows when they had low levels of intellectual property protection. In contrast, African countries which have the highest standards of intellectual property protection have very low levels of FDI.

India is an interesting case study because prior to 1970 it had strong patent protection because of the colonial laws it inherited from the British. During that period there was very little FDI.[161]

Multinational companies did not set up factories in India during that period because, in the words of Pfizer, the Indian market (those who could afford medicines) was too small.[162] In 1970, India passed a patent act to suit its level of development and which weakened patent protection (relative to the pre-1970 Act).

Between 1970 and 1995 India received significant amounts of FDI.[163]

Since 1995 when India has had to strengthen its intellectual property protection in accordance with World Trade Organization requirements, levels of FDI have not considerably increased.[164]

Similarly, when patents on chemicals were too broad in France, French chemical and dye companies moved to Switzerland because it did not allow patents on chemicals, see 'Moving up the value chain'.

Likewise, despite Canada's and Italy's lack of patent protection they had no trouble attracting FDI according to the United Nations Development Programme (UNDP).[165]

In fact, in the Malaysian case, 41% of total foreign direct investment in the years 1988-1998 was from Taiwan or Singapore alone[166] and much of this was used to produce generic medicines.[167] Foreign direct investment for generic medicine manufacturing would be discouraged by stronger intellectual property protection (see for example 'IP: Summary on effects of FTAs ').

Malaysian evidence

A study by Malaysian academics found that 'Although Malaysia has relatively strong patent laws which are of world standard, foreign investment into the pharmaceutical industry has been negligible.'[168] Even when Malaysia had to increase its intellectual property protection

to comply with World Trade Organization requirements in 2000 there was no increase in the number of foreign pharmaceutical companies setting up factories in Malaysia. In fact, a number of foreign companies closed their factories in Malaysia, presumably because of other reasons such as rising wages and increasing competition from domestic generic manufacturers.

The same study asked multinationals why they did not invest in Malaysia (presumably in the manufacturing sense).[169] The reasons given were because the Malaysian market is relatively small so it is not profitable nor economically viable to have large scale foreign direct investment here.[170] Furthermore, according to the multinationals, there was a lack of other forms of fiscal incentives such as tax incentives and the imposition of 'equity' ownership also discouraged them.[171]

The study therefore concluded that 'patent laws are relatively unimportant to foreigners in determining whether to invest in Malaysia or not. Patent law should not be seen as the sole attraction for foreign direct investment. Other factors must also be taken into account.'[172]

Even the Pharmaceutical Association of Malaysia which represents multinational branded pharmaceutical companies in Malaysia has admitted at a meeting with the Malaysian Ministry of Health that if intellectual property protection was strengthened in Malaysia they could not guarantee that more multinationals would invest here.[173]

Therefore comparisons between countries with different levels of intellectual property protection and comparisons within one country as it changes its levels of intellectual property protection show that stronger intellectual property protection does not lead to increased FDI.

Chapter 7

IP and Economic Growth and Productivity

ECONOMIC growth can decrease poverty and increase government revenue which enables government to spend more on health, education, infrastructure etc.[174] As the Human Development Report notes 'Many economist now argue that the free flow of knowledge can facilitate growth for all'.[175]

For example, economic growth can be hampered by stronger IP protection. This is because if medicines are more expensive in the developing country because of stronger IP protection, patients who pay for medicines themselves or governments that subsidise medicines may not be able to afford to buy all the medicines needed. More people are likely to be sick for longer and life expectancies will be shorter if they cannot afford the medicines they need. A healthier population can work harder and increase economic productivity,[176] so the World Health Organization's Commission on Macroeconomics and Health found that a 10% increase in life expectancy at birth is associated with a rise in economic growth of at least 0.3-0.4% of economic growth per year (all else being held constant).[177] Conversely, a high malaria prevalence is associated with a reduction in economic growth of more than 1% per year.[178]

An increased number of patents in the USA was not accompanied by or followed by an equally visible increase in total factor productivity or innovation.[179]

Chapter 8

IP and Environmental Technology

IP can restrict the ability of developing countries to acquire and use environmentally-friendly technologies to ensure their development is as sustainable as possible. For example, India was required under the Montreal Protocol to phase out its use of chlorofluorocarbons (CFCs).[180] Indian air conditioner and refrigerator manufacturers wanted to shift from using CFCs to a more environmentally friendly substitute, HFC134a.[181] However the patent holder was a developed country company that said the Indian company could only use their patented HFC134a if they paid US$25million.[182] It was estimated that the licence fee should have been US$2-8million.[183] The patent holder offered the Indian company the alternative that it would get a majority share in a joint venture with the Indian company, or the Indian firm would agree to restrict its exports of products it made with HFC134a.[184]

It remains to be seen whether access to technologies to slow global warming will be similarly restricted.

Chapter 9

Impact of FTA on Copyright and Access to Information

i. Background

NORTH-SOUTH FTAs may require stronger copyright protection than TRIPS in several ways and because most developing countries are net importers of copyrighted material (and technology)[185] (75% of global book exports were from the US (20%), UK (17%), other European countries, Canada and Singapore)[186] the benefits of the stronger copyright protection largely flow to developed countries.

When the USA was a net importer of copyright materials, it did not recognise copyright on materials printed outside the USA.[187] This is no longer possible for WTO Members.

The text of several insightful remarks on copyright and North-South FTAs are given below.

Copyright-based industries including publishing, film, television, radio, music and computer software 'supply the intellectual 'raw material' for science and innovation, as well as for education and instruction in general.'[188]

'Software, textbooks, and academic journals are key items where copyright is a determining factor in pricing and access, and which are also essential ingredients in education and other spheres crucial to the development process. For instance, a reasonable selection of academic journals is far beyond the purchasing budgets of university libraries in most developing countries, and increasingly in developed countries as well.'[189]

In the context of the Australia-US FTA (AUSFTA) a submission

noted that as a result of the successful lobbying of powerful US copyright markets, 'the U.S. copyright regime sets one of the highest standards of copyright protection in the world but one which is not recognised as providing a balance between the interests of users and copyright owners… It is apparent however that many of the FTA provisions closely mirror those provisions already in the U.S. *Digital Millennium Copyright Act 1998* (DMCA) so that harmonisation equates to unilateral action to amend Australian copyright legislation to U.S. legislation.'[190]

The IP chapter (Chapter 17) of the AUSFTA 'creates obligations to amend the Australian copyright regime in ways that will reduce access to materials, increase costs for institutions which provide public access to knowledge, and ultimately curb innovation. This neglect is disturbing and unsatisfactory given that a balanced intellectual property regime forms the research and resource base upon which our knowledge and creative industries depend. Overall, the provisions in Chapter 17 fail to provide a satisfactory level of balance. The ADA does not believe that the provisions pertaining to copyright serve the interests of Australians and does not support the ratification of the FTA on that basis.'[191]

An Australian legal academic K. Weatherall found that the IP provisions of the AUSFTA would mean that

- Increased costs to users
- As a net IP importer, more royalties will flow overseas.
- Some new works not created because of the increased costs to Australian creators and researchers of using older material.
- Transaction costs of searching for the author to ask permission to use the material
- Lost opportunities to create archives or digital collections of older works such as Project Gutenberg.
- Orphaned works where the author cannot be found to get permission and so it is not available.[192]

The Australian Libraries' Copyright Committee (ALCC) is the cross-sectoral body acting on behalf of Australian libraries and archives on copyright and related matters. It seeks to have the interests of users of libraries and archives recognised and reflected in copyright legislation, and in so doing, help build and sustain a copyright regime

which promotes learning, culture and the free flow of information and ideas in the interests of all Australians.[193] In their Submission on the Australian-US FTA, they state that:

> The ALCC does not support the ratification of the FTA on the basis that the provisions of Chapter 17 [intellectual property] will result in substantial damage to our creative and innovative potential by restricting access to and increasing the costs of access to knowledge.
>
> It is ALCC's submission that overall, the obligations created by the FTA will require change to Australia's copyright regime that will fundamentally alter the current balance in Australian law with detrimental impacts on our cultural, educational and information environments… The extension of copyright term will place a significant burden on libraries which will ultimately be borne by users and the Australian public…
>
> The ALCC is disappointed to note that the importance of maintaining a balanced copyright regime is not properly reflected in the draft text of Chapter 17 of the FTA. Chapter 17 creates obligations to amend the Australian copyright regime in ways that will reduce access to materials, increase costs for libraries and archives which provide public access to knowledge and ultimately impede the flow of information.
>
> This neglect is disturbing given that a balanced copyright law forms the necessary foundation for fulfilling Australian government policy goals in building a 'clever country'. Overall, the provisions in Chapter 17 fail to provide a satisfactory level of balance. The ALCC does not believe that the provisions pertaining to copyright serve the interests of Australians and does not support the ratification of the FTA on that basis…
>
> As stated repeatedly by negotiators from Australia and the U.S., the overall effect of Chapter 17 is the 'harmonisation' of

> our respective copyright regimes. It is apparent however that many of the FTA provisions closely mirror those provisions already in the U.S. *Digital Millennium Copyright Act 1998* (DMCA) so that harmonisation equates to unilateral action to amend Australian copyright legislation to match U.S. legislation.
>
> The alignment of our copyright legislation to meet obligations created by the FTA has dangerous potential to create severe distortions within our domestic regime. Although Australia and United States share a common law tradition, some divergence has developed in recent years, marked by the emergence of powerful U.S. copyright markets which have been extremely successful at legislative lobbying. As a result, the U.S. copyright regime sets one of the highest standards of copyright protection in the world but one which has not been recognised as providing a balance between the interests of users and copyright owners. This consequently leads to a great deal of expensive litigation.'[194]

ii. Copyright term extensions

TRIPS requires copyright protection for a period of at least 50 years from publication or making (when it is not calculated on the basis of the life of a natural person).[196]

By contrast, US free trade agreements (USFTAs) require copyright to last for 70, 95 or 120 years.[196]

Former Assistant Commissioner at the Australian Productivity Commission and trade expert, now at the Australian National University in a report that was commissioned by the Senate Committee, looking at the AUSFTA found that 'Australia's net royalty payments could be up to $88 million higher per year as a result of extending the term of copyright' [from 50 years to 70 years].[197]

In addition to the increased royalty payments, much of which flows overseas, there are economic costs of seeking permission to reproduce a work when it is still copyrighted. For example the Carnegie-Mellon

study by US universities found that the cost of seeking permission to copy an out-of-print or commercially unavailable work is US$150-200, without guarantee of a response.[198]

In the context of the USA's decision to extend copyright from 50 to 70 years, US Justice Breyer said 'the costs of obtaining permission, now perhaps ranging in the millions of dollars, will multiply'.[199] To get clearance for one work, 'consumed approximately a dozen man-hours per work. The College Art Association says that the costs of obtaining permission for use of single images, short excerpts, and other short works can become prohibitively high.' [200] Justice Breyer went on to state that the 'economic effect of the Copyright Term Extension Act 1998 (US) is to make the copyright term 'virtually perpetual.' He observes that the legislation creates a copyright term worth 99.8% of the value of a perpetual copyright: The economic effect of this 20-year extension – the longest blanket extension since the Nation's founding – is to make the copyright term not limited, but virtually perpetual. Its primary legal effect is to grant the extended term not to authors, but to their heirs, estates, or corporate successors. And most importantly, its practical effect is not to promote, but to inhibit, the progress of 'Science' – by which word the Framers meant learning or knowledge.'[201]

Universities were also concerned about the impact of extending copyright term in Australia. For example, the executive director of the Australian Vice-Chancellors Committee, John Mullarvey, said that 'Australian universities now paid $20 million a year in copyright fees and adding 20 years to the period of copyright protection would add to that sum. How much I couldn't even guess'.

For people in remote areas who would have been able to rely on electronic versions of books via the internet such as via the free Project Gutenberg which uploads them once they are out of copyright, this means waiting another 20 years before they can access them.

Furthermore, copyright term extensions are unlikely to promote creativity, the basic objective of copyright law because 'Milton Friedman and 17 other economists (including 5 Nobel Prize winners) found that the economic benefit of 20 extra years to copyright owners was less than US$0.01 per year per work and so was unsustainable as an economic argument for extension.'[202]

Expressions of concern in Australia about the extension of copyright duration to 70 years due to the AUSFTA

Australian Federal Government concerns

The Australian Federal Government negotiated and signed the Australia-USFTA which contained an extension of the copyright period to 70 years, despite earlier having concluded that such an extension would not be advisable, for example in the reports below.

'The Minister for Communications, Information Technology and the Arts, The Hon Darryl Williams, [informed the Media Entertainment and Arts Alliance] that the Government would make no concessions to the US regarding extension of copyright term. The Minister explained it was Government policy that copyright term not be extended because of the negative financial impact doing so would have on Australia. The Minister advised that his department, DCITA, had undertaken work on extension of term and had concluded the cost to Australia would be so considerable that reviewing Government policy could not be contemplated.'[203]

Similarly, the Office of Regulation Review which is part of the Productivity Commission which is the 'Australian Government's principal review and advisory body on microeconomic policy and regulation'[204] made a submission to a Committee's review of the Copyright Act and recommended against an extension of copyright term saying that 'The ORR considers that a general extension of copyright protection' would have few (if any) tangible benefits and holds the risk of substantial costs:

- it represents an unjustifiable redirection of funds (i.e. economic rents) from Australian consumers and secondary producers without commensurate benefits;
- it would be likely to cause an increase in net royalty flows to overseas authors and publishers;
- there is no evidence that it would provide a significant incentive to produce works not already being produced'[205]

State Government concerns

'The NSW Government is concerned… that the proposed extension of the period of copyright protection from 50 to 70 years from the death of the author, will have a significant financial impact on libraries, universities and schools… The extension of the copyright term would delay the entry of works into the public domain and restrict the flow of creativity and knowledge into the public domain. It will impose greater limits on access to information, which is a fundamental principle of library services.'[206]

Similarly, the 'The Queensland Government is concerned that this change would have serious implications for large scale users of copyright material who will have to pay significantly more in copyright fees, particularly government, libraries, universities TAFEs and other education institutions. There are also significant concerns from industry that the extension of copyright protection represents a barrier to innovation by restricting access to intellectual property for longer periods.'[207] The Queensland Government thought consideration should be given to a 'funding mechanism to allow educational and research institutions to accommodate the extra 20 years of copyright protection.'[208]

Librarians' concerns

'Librarians warn a free trade deal with the US may result in a massive transfer of wealth from the Australian public and performers to US monopoly copyright holders. Negotiations for the US Free Trade Agreement…may result in a tenfold increase in licence fees for Australians performing original works by US artists, if overseas experience is a guide.

Australian Library and Information Association copyright adviser Colette Ormonde says in a recent case an Australian performer touring the US was denied the chance to perform the works of Hungarian composer Bela Bartok because an extension to the US copyright term had clawed Bartok's work back from the public domain. Bartok died in 1945 and his works entered the public domain – where they could be performed without paying licence royalties – in 1995. But under new US laws, the Bartok estate retains control over his works until 2015.

'Extension of the copyright term in the US benefited the publishing conglomerates and film and record producers but disadvantaged copyright users. Amateur musicians, for example, found that the licensed cost of a music score for a one-night performance increased from $100 to $1000. The worst result for copyright users was that authors and composers whose work was out of copyright became protected again… Ormonde says the cost to Australia – a net importer of copyrighted works [209] such as films, music and books – will continue to grow as copyright terms are extended and won't be compensated by the greater returns to Australian publishers of original works.

'The rewards to Australian copyright owners in extending the term of protection are minimal because they don't have the huge product of major European and US publishers and never will have.'…

Project Gutenberg Australia, an online repository of works in the public domain, will be among the first to feel the impact of any extension to copyright terms. Named after the famous bible first printed by Johannes Gutenberg in 1454 with the then newly invented printing press, Project Gutenberg was started by volunteers in the US 32 years ago to make available to the public works of cultural significance that are in the public domain. Downloads are free.

Project Gutenberg Australia's maintainer, Col Choate, says if a new deal was to extend the term of copyright it would 'just about wipe us out'. He says works by authors such as Virginia Wolfe, D.H. Lawrence and George Orwell now in the public domain would be taken back into the hands of private copyright holders.

Copyright term extension undermines the foundation for creation of copyright. The legal and economic basis for copyright is that creators should be protected and rewarded for a set period in order to stimulate further creativity and innovation. Apart from financial reward, the stimulation of creativity and further works depends on the eventual entry of works into the public domain so that others can freely learn from and draw from a collective pool of knowledge and creativity. The extension of copyright term prejudices a generation of creators and users by denying access to a rich public domain.

Term extension has generated fierce debate within the U.S. where numerous successive extensions of copyright have effectively locked

works out of the public domain and displaced the intended cycle of creation and contribution upon which copyright was originally justified. In the recent challenge posed to the U.S. *Copyright Term Extension Act 1998* (CTEA) in *Eldred v Ashcroft*, the strong arguments made to the court for repealing the CTEA, such as the added costs to users, the minimal long term awards to owners and the speculative nature of predictions on creative incentives arising from extended monopoly were not disputed…

The available reports on the topic such as the Allens report, *Copyright Term Extension: Australian Benefits and Costs* (July 2003) provides no clear evidence of any short or long term economic benefits of extension. No claims have been made that the economic benefits of harmonisation with the U.S. is any more than marginal and no data has been presented to substantiate even this weak assertion. Although the benefits of harmonisation are theoretically plausible, the reality is that the beneficiaries of harmonisation will be multinational companies, who are based mostly in the U.S. and European Union… No proponent of term extension has relied on an argument that an extra 20 years of protection *after* the death of the author will have any impact on the incentive of authors to produce more work.

In addition, Australia is a net importer of copyright materials from the U.S. by a substantial margin; an extension of copyright term will, other things being equal, lead to a reallocation of resources and adversely affect our balance of trade. An extension of copyright term has serious consequences for libraries, cultural and educational institutions in relation to raised costs of maintaining access to information and increased costs associated with the already formidable and resource-intensive task of tracing copyright owners and requesting permissions. The groups of people who will be ultimately affected by the added burden of term extension include historians, scholars, teachers, writers, artists and researchers of all kinds.

… Overall the copyright provisions in Chapter 17 create obligations that will erode public access to works and diminish the power of libraries and archives to carry out their mandate to preserve and provide access to cultural, intellectual and creative works. The obligations imposed by the FTA unilaterally raises the standard of protection of copyright

owners in Australia by adopting DMCA-like measures which would fundamentally alter the balance struck in the *Copyright Act*.'[210]

And again, 'This submission, expresses the serious concern of those responsible for Australia's research and academic information services at the copyright changes identified in Chapter 17 of the Free Trade Agreement with the USA… CAUL is cognisant of the fact that Australia has developed a Copyright Act which, while meeting Australia's obligations to the WIPO treaties, also balances the needs of the copyright creators and the users. The Act has received worldwide recognition as a model of best practice.

US copyright legislation is significantly different to that in Australia. These differences are due to a very different history and the fact that in the US copyright is driven by sustained lobbying from large corporations and powerful industry associations, especially the entertainment and media industries.

The 'balance' of the Digital Millennium Copyright Act (DMCA) is tipped firmly in favour of copyright owners, as demonstrated by the extension yet again of the term of copyright, and continues to attract criticism as it is considered to be cumbersome, punitive and highly supportive of big corporations in opposition to individual creators, researchers, students and the general public.

In proposing to 'harmonise' the well respected Australian copyright legislation with that of the problematic US legislation under Chapter 17 of the FTA, the carefully developed balance between the interest of copyright owners and users apparent in the Australian legislation, will be destroyed and tipped firmly in favour of the owners. This outcome will be to the disadvantage of writers, artists and filmmakers, as well as the general public, who all depend on using copyright materials to create, to learn and to participate in community life.

Specifically, the impact on higher education in Australia will be to raise the cost of compliance on an annual basis. In addition, researchers, who – in Newton's words – stand on the shoulders of giants, will be required to pay for information which would under current Australian law have come into the public domain.'[211]

The Australian Library and Information Association (ALIA) in its submissions to Senate Committees pointed out that the 'ALIA

represents 900 library and information organizations and the interests of 10.7million users of library and information services. It is opposed to the copyright extension in the AUSFTA… Australia is and will be for the foreseeable future a net consumer of information… Extensions of the copyright term benefit producers and publishers of massive amounts of content. They do not benefit the estates of individual creators or promote further creativity, the basic objective of copyright law…' According to them, 'The extension of copyright terms is an extension of corporate monopoly. It has no place in a free trade agreement, is anti-competitive and burdens information consumers with escalating and unpredictable costs and legal obligations.'

Australia's largest reference library, the National Library of Australia stated that moves to increase the copyright term to 70 years 'would not be supported by the National Library. We submit that this would have adverse consequences for the public interest. The purpose of copyright is dual: to advance learning as well as to recompense creators. The public domain is an integral part of the creative process and allows the public access to the fruits of an artist's labours after the expiry of the copyright term. This is particularly true for creators of works such as reference books, CD-ROMs, multimedia material, and documentary and educational films, all of which draw heavily on public domain material. Because the copyright regime exists to serve everyone, not just specialist interest groups, the National Library would regard any extension of the copyright term, and the consequent reduced access to a large portion of our common heritage, as detrimental to creativity and against the public benefit.'

Application of Agreement to existing subject matter

The AUSFTA specifically requires the copyright extensions to apply to material that is currently under copyright.[212]

iii. Anti-circumvention provisions

A technological protection measure (TPM) is a digital lock on digital material to stop access or copying. This can prevent even legal copying, for example if the copyright has already expired on a movie

or book, a TPM could stop a digital copy of the book from being able to be copied.[213] This is therefore an extra, potentially infinite, monopoly in addition to copyright. Other examples of legal copying could include a blind person using the software to read aloud a computer file,[214] making a back-up copy of legitimate software in case the computer breaks down and the software has to be re-loaded, 'region coding for DVDs, anti-copying music CDs that will not play in a PC, encrypted software requiring entry of a registration code before being installable, passwords and encryption used to prevent unauthorised access to online databases'[215]

TPMs can significantly restrict access to knowledge. 'For developing countries, where Internet connectivity is limited and subscriptions to on-line resources unaffordable, it may exclude access to these materials altogether and impose a heavy burden that will delay the participation of those countries in the global knowledge-based society [and] could be very harmful to the interests of developing countries in accessing information and knowledge they require for their development. . . [therefore] it is premature at the present time for developing countries to be required to go beyond TRIPS standards in this area.'[216]

A concrete example is that some scientific databases protected by TPMs can only be accessed from one dedicated terminal in the library. This prevents students and researchers who live long distances away and could otherwise use it online from being able to access the information in that database. Similarly, if a developing country government department bought a CD with a database on it that was not protected by copyright, a TPM could nevertheless stop the department from making legal copies to educate its staff.

Circumvention devices can get around TPMs. Circumvention devices are allowed under TRIPS. The WIPO Copyright Treaty (see above) has an anti-circumvention provision[217] but it allows room for national copyright exceptions, but some North-South FTAs such as USFTAs go further than the WIPO Copyright Treaty.[218]

All USFTAs since NAFTA have required countries to ban the act of circumventing a TPM (i.e. penalizing the user, see below) and the manufacture, importation and distribution of circumvention devices, even if they would be legal under national copyright law

for non-copyright-infringing uses, like the examples given above.

Because USFTAs require a ban on circumvention by consumers, the end users of a circumvention device may be liable even when s/he did not know they were circumventing a TPM, for example when playing a DVD on a DVD player that can play DVDs from multiple parts of the world.[219] This is because if the person had reasonable grounds to know that they were circumventing a TPM, they can be liable.[220] The AUSFTA also makes distributors of circumvention devices liable even if they did not know it was a circumvention device. Since circumvention devices can be physical or computer programs, this was stated as being inappropriate for Australians who do not understand the technology so cannot be expected to know when they are circumventing a TPM.[221] If this is the case for Australian consumers, it should be even more true for a developing country.

Although there is a provision which says that additional exceptions to the ban on the act of circumvention may be allowed for users if they can credibly demonstrate in an administrative/parliamentary review at least every four years that there is an adverse impact on their non-infringing use,[222] a similar system in the USA has been problematic.[223] The problems include:

- The process only exempts the act of circumventing a technological measure, but does not legalize the circumvention tools necessary to do so, so it only applies to the limited number of technologically-savvy users who can make their own circumvention tools. This means the blind would each have to write their own computer programs to read things aloud as no one else can make or distribute them, nor can anyone (including the blind person) import them or share them to their blind colleagues or associations.[224]
- Consumers without lawyers to represent them find they cannot use the process because it is so complex
- It is a costly and time consuming process, so it makes it particularly difficult for the non-profit sector who are most likely to need such exceptions
- It is very difficult to credibly prove harm from copyright. For example of the 392 comments in one batch and 5 days of hearings

in the 2003 inquiry, only two exemptions were granted.

See http://www.eff.org/IP/DMCA/copyrightoffice/DMCA_rulemaking_broken.pdf for more details of the very difficult things which are requested to prove to obtain one of these exceptions.

If these provisions were in an FTA involving a developing country and the developing country's Ministry of Education distributed software to schools for the blind so it could read aloud technologically protected electronic books, the Ministry of Education may be liable under the laws implementing the FTA. Similarly, if the schools or libraries bought electronic books, these books may have technological protection measures which limit the number of times it can be viewed (unlike a normal book which can be borrowed from the library many times until it falls apart). This limitation on the number of times it can be viewed is not required by copyright law. If the library disabled the limitation on the number of times it can be viewed so that it could be 'borrowed' like an ordinary book by all the library members, this could be a violation of the anti-circumvention laws required under the FTA because it is not allowed by one of the seven exceptions in the AUSFTA.[225]

One of the seven exceptions is for reverse-engineering a computer program to make it interoperable with another one. Unfortunately this does not necessarily cover situations where data needs to be compatible with a program. For example for the open source Open Office program's word processor to be able to read a Microsoft Word file, it has to be able to interact with the data file, not with the computer program Microsoft Word. Furthermore, the interoperability exception does not cover device-program interoperability where the machine and the program need to be able to work together.

The narrowness of the seven exceptions can be seen from their operation in the USA where no one has ever successfully defended themselves because they used one of the equivalent seven exceptions in a case where they have been sued for circumventing a TPM.

These seven exceptions are further limited by Article 17.4.10 of the AUSFTA which says that a) the exceptions have to be confined to special cases that do not conflict with the normal exploitation of the

copyrighted product and do not prejudice the legitimate interests of the copyright owner; b) the exceptions cannot allow the retransmission of TV on the internet for any reason; c) the rights under the TRIPS+ WIPO Treaties still apply.

When circumvention is needed

Those seeking to prohibit circumvention devices want a monopoly beyond copyright.

Circumvention is needed to:

- Make lawful uses under existing exceptions and limitations in the developing country's copyright law
- Ensure that different computer programs can operate together[226]
- Overcome artificial geographic market segmentation, for example to allow material such as DVDs that is bought in one geographical region of the world to be played in another. [Companies segregate the markets via region coding of DVDs to allow differential pricing]. The Australian Government had a policy to allow the parallel importation of some copyrighted items (i.e. buying a legal copyrighted version in another country where it is cheaper and bringing it to Australia) to avoid the price-inflating effects of market segmentation.[227] This was done to ensure that Australian consumers could access copyrighted material more cheaply and was strongly supported by the Australian Competition and Consumer Commission (the independent statutory authority which protects consumers).[228] The AUSFTA makes this type of parallel importation impossible.[229]
- To allow material to be made accessible for the blind
- American rights holders have argued that 'circumvention device' can include someone pointing out a security flaw in software in an academic paper
- To avoid being locked into buying the consumable parts, such as printer cartridges from the maker of the machine (the printer).

Because of its potentially severe impact on the blind in developing countries,[230] the effect of the anti-circumvention provisions

in any North-South FTA should be carefully studied including via detailed consultations with the blind community, before anything is agreed to.

The possible impact on developing countries can be seen from the cases that have occurred under the US provision.

Threats to ability to make flaws public

An industry group (SDMI) in the US issued a public challenge for experts to try and defeat certain digital watermarking technologies. Professor Felten from Princeton was one of those who participated in the challenge and when he succeeded he tried to present his results at an academic conference. SDMI threatened to sue Professor Felten claiming that presenting an academic paper could be a circumvention device.

Sony-BMG: Sony had put software on its CDs that installed itself on computers and left computers vulnerable to malicious third parties. When a student discovered this, he consulted lawyers for two weeks about whether publicly revealing the security flaw would be illegal circumvention.

Similarly, a Russian programmer who visited the US to speak at a conference was jailed and kept in the USA for five months for working on a program that others *might* use to illegally copy products. Skylarov was ultimately acquitted.

Impeding innovation and competition

When RealNetworks developed technology designed to allow interoperability of their music on Apple iPods, the threats of legal action from Apple made Real give up.

A company that reverse engineered a way to allow refilled ink cartridges to run in Lexmark Printers was sued by Lexmark. Lexmark eventually lost but not because it was an allowed circumvention.

iv. North-South FTAs may require developing countries to join WIPO 1996 Internet Treaties

North-South FTAs may require the ratification of the WIPO

Internet Treaties (i.e. the WIPO Copyright Treaty (WCT) and the WIPO Performers and Phonograms Treaty (WPPT)) that came about as a result of a Diplomatic Conference on Certain Copyright and Neighbouring Rights Questions, proposed by the US and held in December 1996. [A Diplomatic Conference launches negotiations.]

The treaties that entered into force in 1996 draw their texts upon studies submitted by national governments, in particular the US, European Community and Japan, thus reflecting the lobbies in those countries.

It has been suggested by some critics that the treaties came about as a way to overcome domestic opposition in the US against strengthening the copyright law domestically. With the existence of the internet treaties, there was then justification for the US government to implement standards as part of their multilateral obligations. It would also in addition ensure the worldwide implementation of strong IP standards preferred by certain individuals and organizations in the US. The US, in response to the WCT, legislated the Digital Millennium Copyright Act, which goes beyond the WCT.[231]

The US-based digital civil rights organisation, Electronic Frontier Foundation, documents how the anti-circumvention provisions of the DMCA have been used to stifle a wide array of legitimate activities, rather than to stop copyright infringements. It illustrates how they are being invoked against consumers, scientists, and legitimate competitors, rather than pirates.[232]

Of these two treaties, WCT has been very strongly criticised as it goes beyond what is required under TRIPS and the Berne Convention for the Protection of Literary and Artistic Works. It provides copyright holders exclusive rights over material in the on-line environment and specifically calls for countries to provide effective legal remedies against the circumvention of the technological protection measures (TPMs).

Some of the concerns raised by the Electronic Information for Libraries (eIFL) are as follows:

i) TPMs cannot distinguish between legitimate and infringing uses. The same copy-control mechanism which prevents a person from making infringing copies of a copyright work, may also prevent

a student or a visually impaired person from making legitimate copies under fair use/fair dealing or a legal copyright exception.

ii) Long-term preservation and archiving, essential to preserving cultural identities and maintaining diversity of peoples, languages and cultures, must not be jeopardised by TPMs/DRMs. The average life of a DRM is said to be between three and five years. Obsolescent DRMs will distort the public record of the future, unless the library has a circumvention right.

iii) The public domain must be protected. TPMs do not cease to exist upon expiry of the copyright term, so content will remain locked away even when no rights subsist, thereby shrinking the public domain.

The UK Commission Report on IP and Development, in its report states that 'more analysis needs to be undertaken about the best means of protecting digital content and the interests of right holders whilst at the same time honouring the principles that ensure adequate access and 'fair use' for consumers. More specifically policy makers need to gain a better understanding of the impacts of the trend towards on-line distribution and technological protection of content on developing countries'.

The report adds that it is 'not clear how reasonable requirements of 'fair use' will be guaranteed in such an environment'. It goes on to caution 'Developing countries should think carefully before joining the WIPO Copyright Treaty and should not follow the lead of US and the EU by implementing legislation on the lines of the DMCA'.

More analysis needs to be done with the engagement of the various stakeholders, such as libraries, open source initiatives, industry, internet service providers and other relevant NGOs to have a discussion to understand better the costs and benefits of signing on to the WIPO internet treaties.

v. Some implications of copyright section for society in developing countries

Enhancing human capital and human resource development are heavily dependent on access to information and North-South FTAs

may restrict access to knowledge in the ways outlined above.

Furthermore, developing countries that are party to the United Nations Convention on the Rights of the Child (CRC) are legally bound to implement its provisions. North-South FTAs could impact the rights of the child in a number of ways. The CRC contains a right to education.[233] Textbooks are key to students and a copyright term extension may extend the monopoly on textbooks and other educational materials to 70 or 95 years before they can be copied. This makes them expensive for longer and potentially reduces the access of children to the materials necessary for their education because parents (or a developing country government that subsidises them) can no longer afford to provide them.

Chapter 10

Effects of Stronger IP on Research and Development/Innovation

i. IP can block innovation

IP can block innovation because innovators must: do costly patent searches to make sure they do not infringe existing patents, pay royalties for IP-protected inputs or pay legal and court fees if found to infringe.

For example, a US court fined Eli Lilly because its drugs infringed Ariad's patent which covers any drug that works by influencing a particular protein. This patent stops all drug development aimed at that biological pathway and Lilly has to pay US$65.2 million in back royalties and a 2.3% royalty in future on sales of its two medicines that use that pathway. [234]

Multi-national companies have said: [235]

- Bristol-Myers Squibb chief scientific officer: There were 'more than 50 proteins possibly involved in cancer that the company was not working on because the patent holders either would not allow it or were demanding unreasonable royalties.'
- Kodak former general counsel: 'If the uncertainties are such that you cannot be confident that your products are free and clear of others' patents you will not commercialize them, or a higher return will be demanded if you do to compensate for the additional risk. And this probably means you will not do the R&D that might lead to low return (or no return) products.'
- Hewlett-Packard general counsel and director: 'pervasive uncertainty about legal rights, both in terms of ability to enforce

one's own patents and ability to avoid rapidly escalating exposures to infringement claims by others. And that uncertainty heightens risks surrounding innovation investment decisions.'

Bessen and Hunt has estimated that innovative activity in the software industry would have been approximately 15% higher **without** patents.[236] See also 'software patents' in 'manufacturing'.

Furthermore, most inventions, particularly in science, 'stand on the shoulders of those who have gone before', that is they are built on and adapted from previous inventions in an incremental process. This process is obstructed by intellectual property rights because although later innovators could seek a voluntary licence from the patent holder, the patent holder is unlikely to want to grant it as the improved invention will be competition.[237] Korea's ability to do adaptive innovations was helped by its intellectual property rights policy.[238]

Patents have been such a blockage to further innovation in some industries that companies involved have had to agree to 'pool' their patents to overcome this problem. For example, sewing machines (1856),[239] Bessemer steel (1870s),[240] movie projectors (1908),[241] folding beds (1916),[242] aircraft (1917),[243] semi-conductors (mid 20th century),[244]video (MPEG-2, 1997; DVD, 1998, 1999)[245].

ii. Innovation can occur without IP

Innovation has occurred in a number of sectors without IP protection for example: Switzerland made most of its famous discoveries during a period when it offered no intellectual property protection,[246] traditional medicine, iron and coal industry innovations,[247] Taiwanese machine tool industry[248] and open source software (OSS).

Traditional medicines in developing countries were developed over thousands of years when there was no intellectual property protection. Such medicines include the last remaining effective treatment for malaria in many places, artemisin. These traditional medicines can be very effective, use available resources and appropriate technologies and were developed by communities for diseases that affected them without the problem of market failure[249] and without the need for an intellectual property based rewards system.

OSS is developed without IP protection. OSS such as Linux has an estimated 30% market share and is used to run Google and other well known applications.[250] Two out of six major databases are OSS and open source webserver Apache has 68% of the market (compared to Microsoft's 21%).[251]

There are alternative ways to stimulate research and development (R&D), for example prize funds as The Economist magazine has championed, and Eli Lilly and others have implemented via the www.innocentive.com website which has been solving a number of scientific problems. Companies using this to stimulate inventions they need include: Boeing, Ciba, Dow, DuPont, Eli Lilly and Company, Novartis Pharma AG, and Procter & Gamble.[252] There are more than 125,000 people involved in solving problems in 175 countries.[253] A number of problems have already been solved and awarded prizes.[254]

According to a Carnegie Survey carried out in 2000 research directors replied that the following methods are effective in appropriating gains from innovation: [255]

- Secrecy: 51%
- Lead time: 53%
- Complementary manufacturing: 46%
- Complementary sales/service: 43%
- Patents: 35%
- Other legal: 21%

This Carnegie Survey supports the Yale Survey findings of 1987.[256]

These findings are also supported by a survey of 650 high-level R&D managers of companies listed in the US which reported that patents are considered much less important in preserving an innovator's advantage than the temporary technology monopoly that occurs from innovation, even in the absence of a patent law.[257] This temporary technology monopoly is due to natural advantages the innovator enjoys such as: imitation lag (the time it takes for competitors to absorb new knowledge), reputational advantage (being the first and so best-known producer) and the head start in improving productivity through longer experience.

iii. Empirical evidence re whether stronger IP protection leads to more innovation/R & D

Historical evidence

Boldrin and Levine identified 23 empirical studies which examined whether stronger patent protection had in fact increased innovation. These studies found weak or no evidence that strengthening patent protection increase innovation. Stronger patent regimes merely increase patenting.[258]

For example, in Italy prior to 1978, there was a thriving pharmaceutical industry (500 firms) for more than 100 years. In 1978 Italy allowed patents on medicines. Post 1978 the generic industry largely disappeared, the proportion of new active chemical compounds developed in Italy fell, there was no significant increase in invention of medicines from 1978-1988 and the size, innovative input and economic performances of the pharmaceutical industry have not improved according to all experts.[259]

Similarly, the European Union significantly increased its IP protection of pharmaceuticals between 1990 and 2005. However, between 1990 and 2005 the European Union became less innovative than other regions.[260]

Likewise, Switzerland only allowed patents on pharmaceutical products from 1977, however its originator pharmaceutical industry was still strong prior to 1977.

Issuing a compulsory licence can be characterized as a reduction in intellectual property protection because it decreases the patent holder's monopoly. However academics have found that issuing compulsory licences does not lead to a reduction of investment in research and development.[261] Scherer studied 70 companies and found those whose patents had been compulsorily licensed actually significantly increased their research and development compared to companies of comparable size who had not been subject to compulsory licences.[262]

Survey findings

Malaysian academics carried out a study which involved interviewing pharmaceutical multinationals in Malaysia which found

that none of the European or USA multinationals did any major research and development in Malaysia.[263] The main reasons given by these multinationals were that Malaysia was a relatively small market and their business in Malaysia only required marketing and distribution.[264] Both the multinationals and the foreign generic manufacturers also said they did not do research and development in Malaysia because: there was a lack of skilled workers, Malaysia imposed equity ownership conditions, there were insufficient incentives for it in Malaysia and Malaysian research facilities were inferior to Singapore's.[265]

None of the branded multinationals said Malaysian patent law being too weak was a reason for failure to do research and development in Malaysia when they were asked whether this was a factor in their research and development location decisions.[266]

iv. There may be other reasons for low levels of innovation

To make scientific discoveries, a country must have sufficient human capital. This includes sufficient science and engineering graduates that some can be spared to do doctoral degrees and academic research. 'Most developing countries do not have the capabilities to conduct research.'[267] For example, East Asia and the Pacific have 722 R&D researchers per million people, South Asia has 119 R&D researchers per million people, whereas high income OECD countries have 3807 R&D researchers per million people.[268]

Furthermore, any brain drain developing country are experiencing may make it harder to retain sufficient numbers of scientists to do research at developing country's current level of development.

Merely increasing intellectual property protection will not increase the number of pharmacists per capita graduating in Malaysia. There are other more direct measures with less 'side-effects' that can be taken to increase the number of science graduates.

v. Rewarding developing country inventors

If innovators in developing countries wish to profit from their

inventions, they can always patent them in major markets such as the USA, European Union and Japan where patentability standards are low. This is what industrialised countries did when they were developing.

For example, Germany did not introduce patents on chemicals until 1967. However, German companies innovated and patented their innovations in the USA.[269](Most US chemical patents before World War I were held by large German companies).[270] German chemical companies such as Bayer, BASF, Hoechst and IG Farben thrived even though they could not patent at home.[271]

Likewise, Switzerland did not introduce patents on pharmaceuticals until 1977. However, prior to 1977, Swiss pharmaceutical companies patented their products in larger markets with great success.[272]

Chapter 11

Enforcement

THE enforcement part of TRIPS very clearly states that 'It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.'[273] This was added to TRIPS to address the concerns of developing countries.[274]

However, the enforcement chapter of North-South FTAs such as USFTAs may specify that a decision that a USFTA country makes on the distribution of enforcement resources shall not excuse that Party from complying with the IP chapter.[275]

For example, USFTAs can have 11 pages of detailed enforcement prescriptions.[276] Some of these specify how a TRIPS level of enforcement should be carried out, others involve much stronger levels of enforcement than TRIPS. The enforcement part of USFTA IP chapters are particularly detailed about internet service provider liability, see 'Internet service provider liability' above.

Chapter 12

Implementation of the FTA

IF countries think that they can sign a North-South FTA and then use loopholes during implementation to mitigate the FTA's effects, they should be aware that in the case of USFTAs, the USTR continues to press for stronger IP protection than the USFTA requires during implementation, including during the drafting of implementing legislation.[277]

For example after Guatemala finalized its USFTA, the USTR gave it four pages of detailed comments and demands which can be seen here http://www.cptech.org/ip/health/trade/cafta/ustr11162005.pdf.

Research and Development

93.5% of biotechnology patents between 1990 and 1995 originated in the USA, Japan or European Patent Office countries.[278] Five US companies or institutions hold 44% of plant patents between 1992-5.[279]

A workshop sponsored by the US Department of Agriculture in 1993 concluded that patents on plant materials may interfere with the exchange of materials among researchers, government, university and private laboratories.[280] Four years later, the working group of a follow-up seminar recommended 'full and open access to genetic materials' and that 'the appropriate standards for utility patents be reconsidered . . . in light of the potential for serious impediments to effective research and genetic resource use, especially in the public sector in countries with limited economic resources'.[281]

Chapter 13

IP: Summary on Effects of FTAs

THE TRIPS-plus provisions outlined above in North-South FTAs may have far-reaching consequences for a wide range of areas: culture; farmers; government-linked companies; students; the blind; businesses; actors, directors, producers and all those involved in the developing country's audiovisual industry and any of their citizens who get sick and needs medicine.

TRIPS has already been widely criticised as obliging developing counties to adopt standards of IP higher than appropriate for their level of development. There are negative effects such as higher medicine prices, obstacles to industries to upgrade their technology, compulsory patenting of some life forms, introducing IP to farm seeds (which in many countries were exempted before), and facilitating bio-piracy (misappropriation by multinational companies of genetic resources and traditional knowledge belonging to developing countries).

The developing countries increasingly realise that higher standards of IP can be detrimental to development in many ways. There must be a balance between the IP monopoly given to private individuals and companies, and the public interest. They have thus initiated a movement inside WIPO to institute a Development Agenda, to orientate IP policies towards development needs and the public interest.

North-South FTAs may impose even stricter standards of IP than even the TRIPS and thus makes the present imbalance even worse.

The developing country's farmers will be affected by making their inputs (such as seeds and agricultural chemicals) more expensive, and as they lose significant control over the saving of their seeds.

The developing country's businesses may also face higher input costs from the IP chapter of a North-South FTA. In specific sectors such as generic medicine manufacturing, one of Malaysia's largest generic companies, Hovid Berhad is already setting up manufacturing in India because 'Once the FTA takes effect, many local pharmaceutical companies such as Hovid would stand to lose out to US-based multinational pharmaceutical companies.'[282]

Another sector that may be significantly affected is internet service providers.

In some developing countries, state enterprises or government-linked companies may be involved in the sectors affected (for example, there are Malaysian government-linked companies that make generic medicines (e.g. Pharmaniaga) and provide internet services (e.g. TM Net)).

The prospect of stronger intellectual property protection under some North-South FTAs has also caused many to fear increases in medicine prices in developing countries signing them. Developing countries agreeing to such provisions are likely to have to change their laws to potentially include: having a data exclusivity clause; extending the term of medicine patents; linkage between patents and marketing approval by the drug regulatory authority; restricting the ground for compulsory licensing; and a possible restriction on parallel importation.

Access to information and knowledge will be another major area to be affected, as copyright laws may tighten, for example via extensions of copyright term and with the 'locking in' of technological protection measures. Not only academics, students, and scientists but also the blind may also be particularly disadvantaged by the stronger copyright provisions.

The possible negative impacts due to the intellectual property chapter can be exacerbated by other chapters in North-South FTAs such as the preamble and the investment and dispute settlement chapters.

As the eminent Commission on Intellectual Property Rights states 'there are no circumstances in which the most fundamental human rights should be subordinated to the requirements of IP protection. IP rights are granted by states for limited times (at least in the case of patents and copyrights) whereas human rights are inalienable and

universal… Developing countries should not have to accept IP rights imposed by the developed world, outside their existing commitments to international agreements.'

Developing country governments could try to use North-South free trade agreements to further their development objectives, such as ensuring access to affordable medicines and reducing biopiracy, however attempts made to date have not appeared to be very successful. For example, when Andean negotiators tried to include language referring to the 2001 Declaration on the TRIPS Agreement and Public Health ('Doha Declaration') in the Andean-U.S. FTA, U.S. negotiators refused because they said the point of the FTA was to obtain TRIPS-plus protection and including references to the Doha Declaration might contradict this.[283]

Endnotes

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101 http://www.ipophil.gov.ph/statreport/statistics.htm
102 World Bank, World Development Indicators 2000
103 Australian Government statistics from www.ipaustralia.gov.au
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105 Art 66.
106 Schiff, E. (1971) 'Industrialisation Without National Patents: The Netherlands 1869-1919, Switzerland, 1850– 1907', Princeton University Press, Princeton.
107 LDC WTO Members have a transition period, see above.
108 UNCTAD-ICTSD Resource Book (2005), available online at http://www.iprsonline.org/unctadictsd/ResourceBookIndex_update.htm
109 UNCTAD-ICTSD Resource Book (2005), available online at http://www.iprsonline.org/unctadictsd/ResourceBookIndex_update.htm

110 http://nationmultimedia.com/2007/02/17/business/business_30027112.php
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113 'Intellectual Property Rights, the WTO and Developing Countries', Carlos M Correa, Zed Books, Third World Network, 2002.
114 For example http://www.thejakartapost.com/detailheadlines.asp?fileid=20070212.A07&irec=6
115 UNESCO (1998) 'World Information Report 1997/98', UNESCO, Paris, p.320. Source: http://www.unesco.org/webworld/com_inf_reports/wirenglish/chap23.pdf
116 'Integrating Intellectual Property Rights and Development Policy', report of the Commission on Intellectual Property Rights established by the British Government, http://www.iprcommission.org/graphic/documents/final_report.htm, page 95.
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118 'Integrating Intellectual Property Rights and Development Policy', report of the Commission on Intellectual Property Rights established by the British Government, http://www.iprcommission.org/graphic/documents/final_report.htm, page 98
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123 'Intellectual property in the FTA: impacts on pharmaceutical spending and access to medicines in Colombia', Mision Salud and Fundacion IFARMA, Miguel Ernesto Cortes Gamba, Bogota, 2006
124 http://english.hani.co.kr/arti/english_edition/e_business/165065.html

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126 Submission to the Senate Select Committee on the Free Trade Agreement between Australia and the United States of America by the Pastoralists and Graziers Association of W.A. (Inc) And Generic Agricultural Chemical Association.

127 UNCTAD-ICTSD Resource Book (2005), available online at http://www.iprsonline.org/unctadictsd/ResourceBookIndex_update.htm

128 http://www.ilaw.com.au/public/softwarepatents.html citing Art 17.9.14 of the Australia-USFTA 'Each Party shall endeavour to reduce differences in law and practice between their respective systems, including in respect of differences in determining the rights to an invention, the prior art effect of applications for patents, and the division of an application containing multiple inventions. In addition, each Party shall endeavour to participate in international patent harmonisation efforts, including the WIPO fora addressing reform and development of the international patent system' as something that could lead to harmonization with the US and therefore allowing software patents in Australia.

129 Submission to Senate Select Committee on the Free Trade Agreement between Australia and the United States of America from http://www.aph.gov.au/Senate/committee/freetrade_ctte/submissions/sub164.pdf

130 http://www.imakenews.com/bakerbotts/index000036038.cfm

131 'Against Intellectual Monopoly', Boldrin & Levine, 2007, http://www.dklevine.com/general/intellectual/againstnew.htm.

132 'Against Intellectual Monopoly', Boldrin & Levine, 2007, http://www.dklevine.com/general/intellectual/againstnew.htm.

133 According to http://www.tm.com.my/business/small_medium/internet/smi_net_CASP.htm, TM Net offers web hosting, domain hosting, server hosting, online storage service, media hosting and tmnet e-browse.

134 Via two doctrines only used in the USA: vicarious copyright liability and contributory copyright liability. In addition, a US report found that the temporary reproductions made by a computer in its memory also infringed copyright and so ISPs could be liable for caching material.

135 http://www.eff.org/IP/FTAA/ISP_june05.pdf

136 For example http://www.eff.org/IP/FTAA/ISP_june05.pdf

137 This is because TRIPS does not require secondary liability or temporary reproductions to be copyrightable. The only provision of TRIPS that could possibly be used to require secondary liability is Art 41.1 'effective action against any act of infringement'. However this does not require secondary liability laws and major WTO members do not allow secondary liability (http://www.eff.org/IP/P2P/MGM_v_Grokster/20050301_sharman.pdf) and yet have not been sued by the USA for failure to comply with TRIPS as you would expect the US to do if it really were required by TRIPS (http://www.wto.org/english/res_e/booksp_e/analytic_index_e/trips_03_e.htm#article41). That TRIPS does not require temporary reproductions can also be seen in the fact that many countries fail to allow temporary reproductions to be copyrightable and yet are not sued by the USA for non-compliance with TRIPS.

138 For example Art 16.4.1 of the Singapore-USFTA which says 'Each Party shall provide that authors, performers, and producers of phonograms and their successors in interest have the right to authorize or prohibit all reproductions, in any manner or form, permanent or temporary (including temporary storage in electronic form).'

139 Except South Korea's which has a moratorium on it for as long as the TRIPS moratorium lasts.

140 Art 17.11.29(b)(xii).

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143 Lawyer Leaellyn Rich writing in the March 2005 New South Wales Society For Computers and the Law Journal, Issue 59, http://www.nswscl.org.au/journal/59/Rich.html

144 Kimberlee Weatherall's submission to the Senate Select Committee on the Free Trade Agreement between Australia and the United States of America.

145 *Pacific Bell Internet Services v. Recording Industry Association of America, Inc et al,* (U.S. District Court, Northern District of California, San Francisco Division, Case No. C 03-3560 SI).

146 http://www.eff.org/IP/FTAA/ISP_june05.pdf

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149 http://www.eff.org/IP/FTAA/ISP_june05.pdf
150 http://www.eff.org/IP/FTAA/ISP_june05.pdf.
151 Australian Vice-Chancellors' Committee Submission to the Senate Select Committee on the Free Trade Agreement between Australia and the United States of America
152 'Protecting the messenger: carriage service providers' liability for third party copyright infringement', Jan Charbonneau, https://elaw.murdoch.edu.au/issues/2006/2/elaw_Protecting%20the%20Messenger%20for%20Carriage%20Service%20Providers.pdf
153 Australian Digital Alliance (a coalition of IT companies, scientific and research organizations, schools, universities, consumer groups, cultural institutions, libraries and individuals) submission from http://www.aph.gov.au/Senate/committee/freetrade_ctte/submissions/sublist.htm.
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156 PJ Heald, Information Economics and Policy 16 (2004) 57-65.
157 'Intellectual Property Rights and Foreign Direct Investment', United Nations, New York, 1993.
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160 http://www.oup.com/isbn/0-19-567482-0?view=in
161 http://www.oup.com/isbn/0-19-567482-0?view=in
162 The WTO and India's Pharmaceutical Industry, Professor Sudip Chaudhuri, Oxford University Press India, 2005, p128.
163 http://www.oup.com/isbn/0-19-567482-0?view=in
164 http://www.oup.com/isbn/0-19-567482-0?view=in
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166 Cited in 'TRIPS, Patents, Technology Transfer, Foreign Direct Investment and the Pharmaceutical Industry in Malaysia', Ida Madieha Azmi and Rokiah Alavi, Journal of World Intellectual Property, Vol 4 No. 6, November 2001 citing the Malaysian Industrial Development Authority.

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168 'TRIPS, Patents, Technology Transfer, Foreign Direct Investment and the Pharmaceutical Industry in Malaysia', Ida Madieha Azmi and Rokiah Alavi, Journal of World Intellectual Property, Vol 4 No. 6, November 2001.
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194 Australian Libraries Copyright Committee submission to Senate Select Committee on the Free Trade Agreement between Australia and the United States of America
195 Article 12 TRIPS.
196 The North American Free Trade Agreement was signed before TRIPS and it has a copyright term of 50 years. Jordan's USFTA does not specify a copyright period as it is a different style of FTA. The other USFTAs all have 70 years except for Oman's which requires 70, 95 or 120 years of copyright protection depending on which measurement system is used.
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208 Queensland Government Submission to the Senate Select Committee on the Free Trade Agreement between Australia and the United States of America.

209 The Victorian Government agrees with this in its submission to the Senate Select Committee.

210 Australian Libraries Copyright Committee submission to Senate Select Committee on the Free Trade Agreement between Australia and the United States of America

211 Council of Australian University Librarians (CAUL) submission to Senate Select Committee on the Free Trade Agreement between Australia and the United States of America. According to their Submission, 'The Council of Australian University Librarians **(CAUL)** represents all Australian university libraries… CAUL members operate in an educational environment which produces a significant amount of copyright material, while their core business is the provision of access to information. Consequently, copyright is integral to the work of university libraries and CAUL has an abiding interest in the development of balanced and effective copyright legislation.'

212 Article 17.1.9. There is an exception for things whose copyright have already expired (Article 17.1.10), for example if a book's copyright expired in 2000 and the AUSFTA came into force on 1/1/2005, that book would not go back into copyright until 2020 because of the copyright extension to 70 years.

213 Although the US Government says that TPMs are only supposed to protect copyrighted material, things have not worked out this way in practice. For example, in 2003 when an exception was sought to circumvent movies that were already out of copyright protection on a DVD, the exception was not granted because it was joined to something that could be copyrighted such as a new introduction to the old movie.

214 In the US, the publishing industry considers providing such software to be a violation of the anti-circumvention provisions.

215 Australian Parliamentary Library Current Issues Brief No. 3 2004-5, http://www.aph.gov.au/library/pubs/CIB/2004-05/05cib03.pdf

216 'Integrating Intellectual Property Rights and Development Policy', report of the Commission on Intellectual Property Rights established by the British Government, http://www.iprcommission.org/graphic/documents/final_report.htm, page 106 and 108

217 Art 11 for copyright and Art 18 of the WIPO Performances and Phonograms Treaty for related rights.

218 Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, Bruce A. Lehman, Electronic Frontier Foundation Briefing Paper On Technological Protection Measures Prepared For The WIPO Inter-Sessional Intergovernmental Meeting On The Development Agenda Proposal & Fourth Session Of The Permanent Committee On Cooperation Related To Intellectual Property Development, April 2005. This is because the WIPO Treaty would still allow fair use exceptions.

219 http://www.eff.org/IP/FTAA/?f=tpm_implementation.html. Most films released on DVD now can only be played in one region of the world, http://www.eff.org/IP/DMCA/copyrightoffice/DMCA_rulemaking_broken.pdf

220 The Chile-USFTA at least limits the liability to when the user actually knew that s/he was circumventing a TPM.

221 Kimberlee Weatherall's submission to the Senate Select Committee on the Free Trade Agreement between Australia and the United States of America.

222 For example Article 17.4.7(e)(viii) of the AUSFTA.

223 Kimberlee Weatherall's submission to the Senate Select Committee on the Free Trade Agreement between Australia and the United States of America and http://www.eff.org/IP/DMCA/copyrightoffice/DMCA_rulemaking_broken.pdf.

224 The American Foundation for the Blind's request for an exemption can be found at http://www.copyright.gov/1201/2006/comments/discipio_afb.pdf and the testimony transcript at http://www.copyright.gov/1201/2006/hearings/transcript-mar29.pdf and the limited exception for blind users that was obtained in 2003: http://www.copyright.gov/1201/2003/index.html

225 The exception for libraries is merely so they can choose whether to buy the e-book, not to allow its members to read it once they have bought it, Art 17.4.7(e)(vii) AUSFTA.

226 There is an exception in the AUSFTA for this, but this exception mirrors that in the USA's Digital Millennium Copyright Act which has still stopped the development of interoperable products, Kimberlee Weatherall's submission to the Senate Select Committee on the Free Trade Agreement between Australia and the United States of America.

227 Kimberlee Weatherall's submission to the Senate Select Committee on the Free Trade Agreement between Australia and the United States of America.

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230 For example, there are 54,000 blind and 464,000 people with low vision in Malaysia. Prevalence of blindness and low vision in Malaysian population: results from the National Eye Survey 1996, British Journal of Ophthalmology 2002; 86: 951-956, conducted by the Malaysian Ministry of Health et al.

231 Musungu, S, Dutfield, G., 'TRIPS plus Multilateral agreements and a TRIPS-plus world: The World Intellectual Property Organisation (WIPO) available at http://www.quno.org/geneva/pdf/economic/Issues/Multilateral-Agreements-in-TRIPS-plus-English.pdf

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243 http://www.cptech.org/cm/patentpool.html#examples
244 The firms concerned could not reach a compromise so the US government intervened and impose a patent pool. Page 138-139, 'Bad Samaritans: Rich Nations, Poor Policies and the Threat to the Developing World', Ha-Joon Chang, Random House Business Books, 2007.
245 http://www.cptech.org/cm/patentpool.html#examples
246 'Patents and Development: Lessons Learnt from the Economic History of Switzerland', Richard Gerster, Intellectual Property Rights Series 4. Available from Third World Network: www.twnside.org.sg.
247 'Against Intellectual Monopoly', Boldrin & Levine, 2007, http://www.dklevine.com/general/intellectual/againstnew.htm.
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249 Market failure occurs when diseases are only experienced by developing countries which are too poor to pay for the medicines and so there is no market incentive to develop medicines to treat these diseases, no matter how long a patent period is offered. This is the case for many tropical diseases.
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Developing countries are signing free trade agreements (FTAs) with developed countries. These FTAs often include intellectual property protection that is stronger than the World Trade Organisation requires (known as 'TRIPS-plus' protection). This book highlights the likely effects on developing countries of agreeing to these TRIPS-plus provisions, particularly those in US FTAs.

In the area of health, it explains the provisions that can increase the price of medicines, summarises some of the recent quantitative studies that show that medicine prices will increase due to these provisions and notes the concern about this issue by bodies including United Nations agencies. It also draws attention to fears that these provisions can make tobacco control more difficult.

In agriculture, the book clarifies the way in which these provisions can increase the price of inputs for farmers (without raising their yields or productivity) and reduce the ability to protect biodiversity from biopiracy.

For the manufacturing sector, the book notes examples of successful industrialisation in the absence of intellectual property protection and explains the way in which these provisions can prevent developing countries from moving up the value chain.

The book also draws together evidence that stronger intellectual property protection can harm innovation, decrease access to information and environmental technology and does not lead to increased foreign direct investment.

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