BEYOND FTA NEGOTIATIONS – IMPLEMENTING THE NEW GENERATION OF INTELLECTUAL PROPERTY OBLIGATIONS

I. Introduction

In the coming years, challenges for developing countries in implementing new obligations in the field of intellectual property (IP) are likely to increase. Indeed, policy and law-makers in developing countries face a formidable agenda in intellectual property reform. This agenda includes finalising implementation of the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), completing accession processes for new members of the WTO, increasing ratification of WIPO treaties, as well as negotiating and subsequently ratifying a new generation of bilateral and regional free trade agreements (FTAs) with comprehensive IP chapters. In the latter case, one should bear in mind that negotiations do not end with signatures on an agreement. They carry on with the incorporation of new obligations at the national level, talks among negotiating parties on implementation, and finally through the post implementation review process.

FTAs that include provisions on IP are mushrooming at the regional and bilateral levels. According to the World Bank, the number of agreements in force now surpasses 250, and has increased six fold in just two decades. These treaties are often one component of a larger political effort to deepen economic relations between selected countries. FTAs might offer important market access and political opportunities with leading economies such as the United States, the European Union and more recently, Japan. Nevertheless a growing number of experts have expressed concerns over the increasingly broad intellectual property (IP) chapters in the FTAs, which promote higher standards of protection that go far beyond what is covered by the TRIPS Agreement and could generate many underestimated costs and limit development prospects.

The latest generation of FTAs tends to incorporate new forms of IP, raise existing levels of protection and reduce opportunities for using flexibilities and exceptions in the implementation of intellectual property policies. A substantial amount of literature today explains in great detail most of the so-called “TRIPS-plus” obligations in FTAs. The objective of this paper, however, is not to restate those obligations and their possible impact on development, but to identify in a preliminary manner a set of options that policy makers could take into account in pro-development implementation of new IP obligations arising from the new generation of FTAs with IP provisions.

It is the view of the authors that the implementation of international IP obligations of all kinds should be adapted, as far as possible, to suit domestic development objectives, including those relating to economic, social and scientific policies. Yet, finding the

balance between domestic policy objectives and satisfying international obligations in the field of IP is an increasingly complex challenge that demands, apart from legal and regulatory infrastructure, sophisticated approaches towards implementation and above all political will.

III. What does implementation imply?

Implementation refers to an act to “put into practice or to give effect to” some aim, such as an order or in this case, a policy. Depending on the area of policy, it could require that a set of political, legal and administrative reforms be undertaken by national authorities once a particular international arrangement has been signed and ratified. These political and legal steps include: translating new obligations into national legislation; drafting and adopting complementary legislation as needed; making new legislative acts and administrative regulations fully transparent; reforming the judicial system to enforce new international commitments and/or national legislation; building internal capacity for the administration; launching the modernization of registration and enforcement systems; and raising awareness among stakeholders and the public in general on the new IP culture.

The TRIPS Agreement in Article 1.1 indicates that “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.” This provision provides the much needed space for WTO Members to adapt international commitments to their respective national legislative frameworks and reform administrative and judicial systems in light of their own legal systems and practices. In terms of actual costs, legal, administrative and judicial reform may generate varying levels of expenses. According to some studies, in the particular case of the TRIPS Agreements, costs could range from less than one million US Dollars to a two digit million number depending on the size of the country in question.

Regardless of general legal, administrative and judicial aspects of the implementation of international IP obligations, the manner in which new substantive obligations are implemented can have a profound effect on the overall development perspectives of developing countries. There are relatively consistent views amongst economists studying intellectual property rights that the interests of countries with respect to standards of protection varies depending on the level of development and other characteristics of the country adopting such protection, thus making a case for a sophisticated and balanced implementation of such substantive obligations.

IV. A road map to implement FTAs commitments in a pro-development manner

A pro-development implementation of FTAs will require the design of a sophisticated process to assist in the transfer of new commitments into the local context. This process could take various forms depending on the political and legal culture in each country. A “road map for implementation” could include a set of minimum steps to ensure that new standards respond to local needs.
Those steps could include the following:

1) as a first step, analyse the FTA commitments in light of national policy goals and TRIPS objectives;
2) clarify terms and expand understanding about new forms of protection;
3) identify policy space left in FTAs;
4) use flanking policies that work in parallel to the intellectual property system in order to promote a competitive and innovative environment; and
5) manage the implementation process from a development perspective, based on domestic interests.

1) Analyse FTA commitments in light of national policy goals and the flexibilities and objectives of the TRIPS Agreement

National policy goals can vary according to the interest of each country and its level of development. Ideally, in any country IP-related policy should be designed taking into consideration its broader impact over society both in the short and long term. It has frequently been argued that only after countries have accumulated a certain level of domestic R&D capacity and the technological infrastructure to undertake creative imitation that IP protection becomes an important element in technology transfer and industrial activities. There is no universal model for the design and implementation of IP policy that suits all countries. Different industrial structures, modes of agricultural production, availability of natural and human resources, and domestic development strategies, call for different types and scope of IP protection. Therefore, each country’s IP policy should be designed so that it is consistent with domestic development policies including economic, scientific and innovative policies and is adapted to country’s economic and social structure and respective level of development.

However, defining domestic policy objectives with respect to IP is not an easy task. It demands a detailed understanding of a country’s current and future industrial profile, its national innovation system, and consumer needs, such as access to medicines or education material. This kind of understanding demands time, experience, coordinated research and resources – all of which are scarce when countries come under pressure to implement international IP obligations – often because IP is not priority in many developing countries when compared to more immediate concerns, such as market access in agriculture or the attraction of foreign direct investment.

Domestic policy objectives are usually established by general governmental/state plans. In addition to setting public policy objectives these plans tend to reflect a complex, consultative process among public and private institutions. They might be set for the short, medium or long term depending upon the country. IP is usually included in such plans, as part of industrial, competitiveness, science and technology and judicial policies. While the guidance provided in the governmental/state plans is in most cases general, the policy objectives they cover can embody a useful framework for the implementation of FTA obligations and promotion of policy coherence.
Governmental/state plans include the following types of general development policy objectives:

- Promote and protect foreign direct investment and other intangible assets;
- Make intellectual property and technology transfer part of the national competitiveness strategy;
- Foster investment in R&D activities;
- Provide incentives for technology transfer;
- Induce local capacities (manufacturing, services, research);
- Encourage and protect creative and cultural activities;
- Enhance and preserve traditional knowledge and creation;
- Facilitate enforcement of IP rights by administrative and judicial authorities.

The objectives and principles of the TRIPS Agreement also provide direction in implementing obligations derived from FTAs. According to Article 7 of the TRIPS Agreement “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.” This article recalls that IP protection is not an end in itself but a means to promote technological innovation and the transfer of technology. It also underlines the need for a system that serves both the producers and the users of technological knowledge.

The principles of TRIPS also offer guidance on how Members may formulate or amend their laws and regulations. According to Article 8(1), Members may “adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement”. These principles recognize that IP does not work in isolation and complementary measures could be needed to protect certain areas where the public interest is essential, such as health and nutrition.

2) Clarify terms and expand understanding about of new forms of protection

Various authors have identified the lack of clarity and understanding of terms and new forms of IP protection as gaps in the implementation of international IP obligations. For many developing countries, some IP provisions in FTAs include concepts that have been “imported” from more technologically advanced countries and devised to solve problems in those societies. In the cases of Europe and the United States experience on the creation and use of IP goes back more than two centuries and has resulted in the development of a vast body of knowledge that helps policy-makers in identifying the optimal level of protection vis-à-vis public and private interests. In contrast, in the case of many developing countries, and especially LDCs, there was limited knowledge and experience on many of the international standards contained in the TRIPS Agreement before it was signed in 1994.
Given the current wave of increased IP obligations in FTAs, many developing countries may choose to simply adopt developed countries’ interpretation of such obligations. By doing so, however, developing countries could bypass an important process of domestic policy formulation, which supposedly allows for adapting those concepts to needs of domestic producers and users of technology. Also, the definition and understanding of terms and new forms of protection may vary according to the legal system (i.e. common law vs. continental law) or in light of the national/regional laws and jurisprudence. The full understanding of the respective IP provisions and their underlying nature is therefore necessary before engaging in the implementation of standards arising from FTAs.

In the case of most FTAs that contain IP provisions, there are many terms that are not defined, leaving this task to national legislative and judicial authorities. In the case of FTA’s sections on patents, regulated products, trademarks, and geographical indications only a few terms tend to be defined. A notable exception is the case of copyrights, where more and precise definitions are provided or are linked to existing WIPO Treaties, generating further harmonisation in that area. Some examples of undefined terms include: invention, patentability criteria, therapeutical, chirurgical and diagnosis methods, national emergency, public use, test data, marketing approval, new use, collective trademark, and certification trademark. Hence, policy makers have the opportunity to define these and other undefined terms in light of their own national interest and priorities by choosing the breadth of actual protection and therefore determining to a certain extent the scope of the obligations applicable to those terms. Defining terms in implementing legislation could serve as a regulating device to restrict or widen the scope and content of certain obligations.

The definition of the term ‘invention’ is one case that illustrates the strategic use of definitions for limiting the scope of patent protection. In many cases, countries have considered that discoveries, scientific theories, and certain methods are not inventions and have explicitly excluded them from the definition. Another relevant example, as mentioned above, is the lack of a definition of patentability criteria. The TRIPS Agreement and some FTAs have in principle allowed parties the freedom to define the criteria of patentability in a strict or liberal manner depending on national policy objectives. Active use of this definition has been considered an important tool in preserving a large public domain for follow-on research and the promotion of competing products to help maintain prices at modest levels. Nevertheless, in some recent versions of FTAs negotiated by the USA certain IP provisions have incorporated new definitions in particular areas, leaving countries with less choice on how to implement them domestically.

Another option available to policy makers in the implementation phase is to avoid any definition of terms and therefore leave some vagueness in the interpretation. This will allow some “flexibility” in setting the scope of obligations by national authorities through practice. The terms will be defined only in the case of conflict between private parties by the judiciary. When employing option, active definitions or vague interpretations, a
danger exists that unilateral pressures that could translate into stricter and narrower
definitions of terms and therefore reducing the scope of interpretation.

Some new forms of IP protection have been directly incorporated in recent FTAs. Many of these new of forms of protection respond to demands and needs of sophisticated markets and do not necessarily respond to the developing country realities. A typical example is the incorporation new measures to protect copyrights, related rights and electronic addresses in the digital environment. While such measures are very relevant in countries with high density of internet use, it would not make sense to invest time and effort in enforcing such protection in countries with low internet penetration. The simple transfer of such protection does not necessarily yield benefits for developing countries and in some cases the cost might be higher that any potential benefit.

When incorporating new forms of protection that did not previously exist in national legislation, it will be essential to promote understanding among users and consumers of the rationale of such protection and the implications for normal commercial and private activities. Many users and consumers might not understand what is subject to protection and what is not, and the economic and social implications of the new protection granted. Cooperation programmes to raise awareness and generate understanding could facilitate implementation by national authorities and adjustment of business and consumer practices when needed.

Selected forms of protection covered by the TRIPS Agreement and recent FTAs can be found in the table below.

<table>
<thead>
<tr>
<th>Table I</th>
<th>Forms of IP protection covered by the TRIPS Agreement and recent FTAs</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>TRIPS Agreement</td>
</tr>
<tr>
<td>Copyright and related rights</td>
<td>X</td>
</tr>
<tr>
<td><strong>Satellite signals</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Internet domain names</strong></td>
<td>N/A</td>
</tr>
<tr>
<td>Geographical indications</td>
<td>X</td>
</tr>
<tr>
<td>Trademarks</td>
<td>X</td>
</tr>
<tr>
<td>Industrial designs</td>
<td>X</td>
</tr>
<tr>
<td>Patents</td>
<td>X</td>
</tr>
<tr>
<td>Integrated circuits</td>
<td>X</td>
</tr>
<tr>
<td><strong>Breeders’ rights</strong></td>
<td>Partially protected</td>
</tr>
<tr>
<td>Protection against undisclosed data</td>
<td>X</td>
</tr>
<tr>
<td><strong>Test data protection</strong></td>
<td>Partially protected</td>
</tr>
<tr>
<td>Enforcement</td>
<td>X</td>
</tr>
<tr>
<td><strong>Measures against technological circumvention</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Non violation complaints</strong></td>
<td>Moratorium on its application</td>
</tr>
</tbody>
</table>

Note: this table is a generalization. The coverage of issues can vary depending of the particular FTA. In this table “X” means that this type of protection is available. Source, Vivas 2004.

3) Identify policy space left in FTAs
When implementing FTAs, national authorities need to consider all of the rights and obligations of the Parties to the agreements including those outside the FTA. Emphasis should not only be placed on fulfilling obligations but also on the rights conferred by the FTA and other international instruments, such as the TRIPS Agreement. In some FTAs, negotiating developing country Parties have avoided, to the extent possible, the waiver of their rights and obligations under the TRIPS Agreement. In fact, in the case of certain FTAs, such as the US–Chile FTA and the US-CAFTA-DR FTA, a non-derogation clause has been inserted indicating that the Parties to the agreements reaffirm their existing rights and obligations under the TRIPS Agreement as well as WIPO treaties. By doing so, they do not only carry on the obligations included in the respective treaties but also the maintenance of existing flexibilities to those obligations unless they are explicitly narrowed or waived in the text of the particular FTAs.

FTAs with IP provisions do not regulate all aspects on intellectual property. There are various policy spaces that still are subject to the sovereign rights of States or are only partially regulated by the FTA and other international agreements including the TRIPS Agreement and WIPO Treaties. The amount of available policy space varies among FTAs and the individual chapters within them. The outcome of the negotiation processes vary widely. It is likely to depend on the bargaining power of the Parties and the nature of political decisions taken during the negotiations.

The following section will provide some analysis on potentially available policy spaces when it comes to FTA implementation. However, further research is needed on a case-by-case basis. Different FTAs often entail different wording – which can lead to very great disparities among the FTAs once implemented. The following section aims to provide a broad overview over the level of discretion left for the design of national laws with respect to certain horizontal rights, such as the exhaustion of rights, exceptions to titleholder rights and compulsory licensing.

3.1. Exhaustion of rights: According to the TRIPS Agreement Members are able to determine their own system of IPR exhaustion (national, regional, or international). The concept of exhaustion may be explained as a legal assumption that title holders have over the particular invention or work, which they exhaust when they or a legitimate licensee places the patented or copyrighted product in the market. In such cases, the exclusive right has been exhausted after the first sale of the product and the titleholder cannot control successive sales. Exhaustion can occur depending of the national law or particular international commitments at the national, regional and international level. Through an international exhaustion regime, developing countries may facilitate parallel imports of legitimate products sold at a lower price from third markets anywhere in the world.

In the area of exhaustion of rights, FTAs have brought different outcomes. In some FTAs signed by the United States, an express authorization exists that prevents parallel imports through contractual arrangements and therefore limiting the flexibility contained in the TRIPS Agreement. In more recent US-FTAs, such as the US-Peru FTA, however, this limitation on parallel import has been avoided due to concerns expressed among
Members of the United States Congress on the need to keep flexibilities to import drugs from third countries in case of pandemics that could affect the United States.

The table below shows the difference in treatment of the issue of exhaustion of rights in recent US FTAs:

<table>
<thead>
<tr>
<th>Table II</th>
<th>The treatment on exhaustion of rights in recent FTAs by the United States</th>
</tr>
</thead>
<tbody>
<tr>
<td>US-Singapore (2003)</td>
<td>A Party may limit parallel imports to cases where the patent owner has placed restrictions on importation by contract or other means</td>
</tr>
<tr>
<td>US-Chile (2003)</td>
<td>Members free to determine their own regime of exhaustion of rights</td>
</tr>
<tr>
<td>US-CAFTA (2004)</td>
<td>Members free to determine their own regime of exhaustion of rights</td>
</tr>
<tr>
<td>US-Morocco (2004)</td>
<td>A Party may limit parallel imports to cases where the patent owner has placed restrictions on importation by contract or other means</td>
</tr>
<tr>
<td>US-Peru (2005)</td>
<td>Members free to determine their own regime of exhaustion of rights</td>
</tr>
</tbody>
</table>


3.2. Exceptions to titleholder’s rights. The international IP system allows for the use of limited exceptions to titleholder’s rights in both the fields of patents and copyrights. Exceptions to title holder’s rights usually refer to a kind of “safe harbor” area of activity to which the rights of a patent or copyright holder do not extend. The reasons for excluding certain areas of activity from the scope of the title holders’ rights are diverse. In the case of patents the main reasons include the defence of the public interest, private and non-commercial use, promotion of scientific and technological development, public health, and facilitation of international travel and international trade. In the case of copyrights, the main reasons put forward for incorporating limited exceptions include the affirmation of freedom of speech, right to be informed, right of education, public welfare, access to knowledge and creativity, and privacy.

International rules on exceptions to title holder’s rights in the patent and copyright fields can be found in the TRIPS Agreement and in WIPO Treaties, such as Paris, Berne, Rome and new WIPO internet treaties. Some exceptions are also included in non-IP international treaties such as the case of the Chicago Convention. In the particular case of the TRIPS Agreement and WIPO treaties, two formats for incorporating exceptions to titleholders’ rights have been adopted: explicit and non explicit. The explicit format consists of the direct incorporation or listing of exceptions in an international treaty. The non-explicit format applies to exceptions established at the national level that fulfil a three-step test contained in the TRIPS Agreement and WIPO treaties (certain special cases, which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder). In the first case the simple incorporation of the exception in the treaty is enough to ensure its validity and international acceptance. While the literature in not consensual, most consider that explicit exceptions are just good examples of exceptions that have fulfilled the three-step...
test. There are several exceptions that are commonly found in comparative law that have never been tested in a WTO dispute. These exceptions could be presumed to fulfil the tree-step test and in many cases are backed by a continuous “state practice”. Some examples of this type of exceptions are the experimental use for scientific purposes in the case of patents and facilitated access of copyrighted works for the blind and visually impaired in the case of copyright. In the case of non-explicit exceptions, they are considered valid unless a legal action is brought for incompatibility within the national context or at the international level.

In order to have a clearer idea of explicit and non-explicit exceptions, table 1 below shows some examples in patent and copyright law.

<table>
<thead>
<tr>
<th>Explicit exceptions in international agreements</th>
<th>Patent</th>
<th>Copyright</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compulsory licensing including abuses and failure to work\textsuperscript{33}</td>
<td>Case of mechanisms, parts, accessories, or operation of aircrafts engaged in international transit\textsuperscript{34}</td>
<td>Use of copyrighted material for review, criticism or commentary\textsuperscript{36}</td>
</tr>
<tr>
<td>Compulsory License\textsuperscript{35}</td>
<td></td>
<td>Use of copyrighted works by way of illustration in publications broadcasts and sounds or visual recording for teaching purposes\textsuperscript{37}</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reproduction of press, broadcasting or communication to the public of articles published in newspapers or periodicals on current economic, political or religious works\textsuperscript{38}</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ephemeral recordings\textsuperscript{39}</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Compulsory license\textsuperscript{40}</td>
</tr>
<tr>
<td>Non explicit (subject to the three step test)</td>
<td>Private non commercial use</td>
<td>Personal use</td>
</tr>
<tr>
<td>Experimental use for scientific purposes</td>
<td></td>
<td>Right of libraries to reproduce works for collecting, preserving and disseminating knowledge</td>
</tr>
<tr>
<td>Prior use</td>
<td></td>
<td>Facilitation access of copyrighted works for disable persons</td>
</tr>
<tr>
<td>Certain preparations in pharmacy immediate therapeutical /chirurgical interventions</td>
<td></td>
<td>Use of computer programmes for the purposes of Interoperability</td>
</tr>
<tr>
<td>Regulatory review (bolar exception)</td>
<td>Forewing vessels, aircrafts and</td>
<td></td>
</tr>
</tbody>
</table>
Today there is a reaction to ever-increasing IP protection trends by an important number of actors, including government officials, parliamentarians, academia and civil society organizations. These actors have called for making use of rights and flexibilities deriving from the TRIPS Agreement and WIPO treaties, and more precisely on exceptions and limitations. These calls have centred primarily on discussions surrounding the Doha Declaration on TRIPS and Public Health and the potential impact of FTAs. Indeed, most developed countries tend to carefully craft their public interest exceptions through law and jurisprudence and have well established institutions that provide avenues for access by consumers. The incorporation and development of exceptions in national legislation by developing countries, however, is still insufficient for addressing public interest concerns. Reasons for the lack of national incorporation and development of exceptions are several. They could include lack of understanding of how to craft such exceptions; the “chilling effect” of the three-step process; the absence of a public interest vision and coordination by certain national authorities; and the weakness or inexistence of civil society actors seeking to advance public interest goals in the intellectual property field.

Exceptions to titleholder’s rights may be a policy area in the field of intellectual property where more work needs to be done by national legislators. This policy space is not only underutilized by policy makers but also sometimes ignored or forgotten in national policy design due to their preoccupation with fulfilling international commitments rather than adapting them to the local context.

In an increasingly globalize IP system there is a significant need for a more balanced system that could incorporate relevant and useful exceptions to address public interest goals. Some countries are starting to advance the idea of creating a minimum list of exceptions and limitations. A recent proposal by Chile, in the WIPO Standing Committee on Copyright and related Rights, has proposed that the issue of exceptions and limitations become a permanent agenda item of such Committee. More precisely, Chile and Brazil are proposing the incorporation of a list of public interest exceptions be entrenched in discussion on a future treaty on the rights of broadcasting organizations in WIPO. These proposals show how countries are increasingly interested in maintaining existing policy space that allows for addressing public interest concerns in all relevant fields of intellectual property.

3.3. Non-voluntary licensing. Only certain FTAs have covered non-voluntary licenses (compulsory licenses). They refer to the use of the subject matter of the patent (invention) without the consent of the titleholders by the government or third parties authorized by the government. They are also a governmental instrument that seeks to restrain the exercise of private rights derived from a patent for the public interest. They are not automatic and therefore subject to the fulfilment of certain conditions as spelled out in...
Article 31 of the TRIPS Agreement. Non-voluntary licenses are usually targeted to one or to a set of particular inventions and titleholders.

The TRIPS Agreement does not limit the grounds for issuing non-voluntary licenses\(^48\). In some FTAs\(^49\), it is only possible to issue non-voluntary licenses in cases of national emergencies, public non-commercial use and as a consequence of antitrust remedies. This specific enumeration of potential grounds for issuing compulsory licenses could exclude certain grounds for issuing compulsory licensing such as the lack or insufficient working of the patent, dependency of patents/inventions and unreasonable pricing depending on their interpretation of national competition law in a particular jurisdiction.

As consequence of the Doha Declaration on TRIPS and Public Health and the related domestic and international debate on access to medicines, the United States has avoided limiting the possibility of issuing non-voluntary licenses through more recent FTAs with developing countries.

Some experts have also pointed out that the fact that FTAs are providing exclusive rights to test data needed for obtaining marketing approval of pharmaceutical and agrochemicals products and might become a barrier to the commercialization of generic versions under compulsory license\(^50\). This could, for example, be the case in a scenario in which through a compulsory license patent protection is waived in a given country; however, due to the protection of clinical test data the domestic regulatory authority does not allow for the marketing approval needed that will ultimately allow for the entry of generic products into the market. While such a limitation is not explicitly mentioned in recent FTAs, it will depend on the national legislation to define whether compulsory licenses also apply to the test data needed to obtain the marketing approval of generic versions of pharmaceutical or agrochemical products.

Non-voluntary licensing is not only available in the patent field. It also exists in the copyright field. A special form of non-voluntary licensing is allowed in the Appendix to the Berne Convention. The appendix allows acceding Parties the possibility of substituting the exclusive right of: a) translation of derived works published or printed in analogous forms of reproduction; and b) the right of reproduction by providing for a non-exclusive and non-transferable system of licenses, granted by the competent authority and subject to various conditions\(^51\).

This Appendix has been underutilized by developing countries (only a few parties to Berne have declared its accession) due to its complicated scheme and burdensome requirements\(^52\). Some consider that the Appendix to the Berne Convention could serve as a potential tool for providing bulk access to copyrighted works for educational purposes through an automatic compulsory license system that requires compensation\(^53\). The Appendix could therefore, after certain reform, become a useful tool to address public interest in the copyright field. The exploration of options for reform of the Berne Appendix and ways to rescue its value in new copyright norm setting could be a possible course of action in WIPO that could facilitate a friendly implementation of new obligations in FTAs aimed at addressing education and other public interest concerns.
The policy spaces identified above are just examples of the most important ones that still are available under certain conditions in particular FTAs. It is important to underline that an important amount of policy space has been affected in one way or another in recent FTAs. The table below compiles some of the policy spaces that still are available under certain FTAs and the degree in which they have been limited.

<table>
<thead>
<tr>
<th>Policy Space</th>
<th>TRIPS Agreement</th>
<th>FTAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom to define patentability criteria, such as ‘novelty’ or ‘inventive step’ and ‘industrial application’.</td>
<td>X</td>
<td>Limited in certain cases, i.e. industrial application has been defined as specific, substantial and credible utility.</td>
</tr>
<tr>
<td>Authorization to exclude certain subject matters from patentability.</td>
<td>X</td>
<td>Limited in certain cases, such as “best efforts clauses” or direct obligations to make available patents to plants or animals.</td>
</tr>
<tr>
<td>Choice to protect ‘new use’ patents.</td>
<td>X</td>
<td>Limited – patents available to ‘new uses’ or “methods” in certain cases.</td>
</tr>
<tr>
<td>The determination of the substantive grounds for the issuance of a compulsory license.</td>
<td>X</td>
<td>Limited to certain grounds (only in cases of national emergencies, anti-trust remedies, and public non-commercial use). Links made with test data protection.</td>
</tr>
<tr>
<td>The determination of an IPR exhaustion regime that best suits domestic conditions (national, regional, international).</td>
<td>X</td>
<td>Limited in certain cases by the obligation to request authorization of the title holder.</td>
</tr>
<tr>
<td>The possibility to define the nature of protection of pharmaceutical and agrochemical test data submitted for regulatory authorities for marketing approval.</td>
<td>X</td>
<td>Limited, countries are obliged to provide for test data protection.</td>
</tr>
<tr>
<td>The authorization to control IPR abuses through competition laws.</td>
<td>X</td>
<td>Available.</td>
</tr>
</tbody>
</table>

Note: X refers to the availability of the particular policy space in the respective agreement.
4) Use of flanking policies that work in parallel to the intellectual property system in order to promote a competitive and innovative environment

4.1. A pro-competitive environment:

While IP in many cases serves as an incentive for innovation, over-restrictive IPRs may have adverse impacts on competitive markets. IPRs grant exclusive marketing rights (monopolistic rights) for a limited period of time. Due to this exclusive nature, these rights may, if abused, limit competition. Abuses of IPRs may give rise to problems of cartels, including price fixing; restrictions on supply, market and customer divisions; and limits to the use of licensed technology for innovation or reengineering processes. In the international economy, this tendency has been exacerbated by the practice in some countries of granting over-broad patent claims, the acquisition and strategic use of patent portfolios to prevent competition by similar but non-infringing products, the continued blurring of the lines between invention and discovery and new mergers and acquisitions in the technological field.

The TRIPS Agreement includes two general provisions on the relationship between competition policy and intellectual property. Article 8(2) of the TRIPS Agreement recognizes that Members may adopt measures to address potential abuses of intellectual property rights. Also, article 40 of the TRIPS Agreement provides that Member states may specify in their domestic legislation licensing practices or conditions that constitute abuses of intellectual property rights having an adverse effect on competition in the relevant market. In recent FTAs, these principles have been reaffirmed in some cases in the general obligation section of FTAs, by indicating that nothing in the IP chapters shall be construed to prevent a Party from adopting any measures necessary to prevent anticompetitive practices that may result from abuses of intellectual property.

According to the UK Commission for Intellectual Property Rights, the regulation of IPRs to control anti-competitive practices by rights holders should be given a high priority in the design of public policy and institutional frameworks. In most developing countries mechanisms aimed at controlling restrictive business practices or the misuse of IPRs are weak or non-existent. According to UNCTAD, only less than half of developing countries have competition policy and only a few have the institutional capacity to apply effectively such policy and enforce it.

The incorporation of competition policy and creation and/or strengthening of regulatory institutions will be a key part of implementing new FTAs and improving market reforms in developing countries. This will not only be important with respect to intellectual property but also to other areas such as investment and services liberalization.

4.2. An innovative environment:

There is important amount of innovative and creative activities in developing countries in areas such as textile designs, plant cultivation, medicines, software, and music.
Nevertheless, much of this innovation ends in informal markets and does not get translated into formal and marketable products and process.

The role of IP protection in fostering innovative activities in developing countries is relative. Various studies have found that the effects of IPRs on technology transfer to and local innovation in developing countries will vary according to countries’ levels of economic development and to the technological nature of economic activities. Such studies also indicate that these countries can reap long-term benefits from stronger IPRs only after they reach a certain threshold level in their industrialisation. Therefore, depending on the level of development the capacities of developing countries to benefit of IP protection can vary.

Through FTAs, IP regimes become stricter and policy space for using the IP system as a tool for industrial and social policy gets reduced. In this context, governments should carefully look at the design of innovative flanking policies that could complement potential effects of the IP regime over innovation. While IP protection has been key in consolidating and expanding innovative activities and investment in knowledge intensive production areas in developed countries, in developing countries other type of polices might have a higher impact on fostering innovation that IP protection. These policies could include:

- prioritize research based on national policy goals;
- redesign the national innovation system to better respond to sectors where comparative advantages exist;
- expand lines of research from basic science to applied science and product/process development;
- use investment incentives and performance requirements (i.e. tax breaks for innovative activities and requirements for training and technology transfer);
- explore the reduction tariffs on imports of capital goods essential to advance in the value added chains of competitive sectors;
- explore the liberalization of structural services sectors (R&D, insurance, information and communication technologies);
- develop national Traditional Knowledge programmes that could turn existing innovation and creativity in more marketable products;
- promote scientific cooperation among states and research centers;
- use new innovation models as public private partnerships, open source and creative and technological commons;
- make effective use of technical assistance/capacity building in research institutions.

This list is just an exemplary selection of possible innovation policies that could be implemented in parallel with new FTAs. They are fully compatible with WTO Agreement and seek to address the lack of scientific and innovative capacities in developing countries. The overall idea of presenting such a list is that countries engaged in the implementation of new IP commitments under FTAs, start exploring options for
redefining their innovation policies and systems. As technologies become more protected and less accessible, the need to generate local technological capacities becomes even more relevant. Development of such technology will be fundamental to maintaining competitiveness, improving the value of corporate assets and using it as currency at international technology markets.

5) Manage the implementation process from a development perspective based on domestic interests

5.1. The need for stakeholder participation

IPRs are unique in the sense that they touch on, and influence to a certain degree, many different public policy spheres. IPRs have an impact on technology transfer, health, education, agriculture, industrial development, let alone science and technology. Their cross-cutting and potentially conflicting nature renders IP policy making particularly complex and demands sophisticated policy coherence. The ability of countries to coordinate their policies and implementation across various governmental agencies and other relevant stakeholders is thus crucial.

The implementation of IP commitments is not an issue of exclusive competence and responsibility of IP offices alone. The only way to address wide ranging concerns such as health, environment, education, and innovation and industrial policy in the national implementation process is by ensuring the involvement of all relevant ministries and other national stakeholders. Wide participation will ensure that governments explore the best possible options for implementing obligations reflecting national development goals. Table V below identifies some of the relevant policy makers and stakeholders that could be involved in the implementation processes on IP commitments as to effectively reflect national policy goals in the implementation process.

Table V
Map of stakeholders relevant for domestic IP policy-making

<table>
<thead>
<tr>
<th>STAKEHOLDER GROUPS</th>
<th>RELEVANT INSTITUTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. The Judiciary</td>
<td>Members of judiciary; courts</td>
</tr>
<tr>
<td>3. The Legislature</td>
<td>National parliaments and parliamentarian commissions</td>
</tr>
<tr>
<td>4. Academic/Research Organisations</td>
<td>Universities, think tanks, research networks, law, business and engineering schools</td>
</tr>
<tr>
<td>5. Civil Society Organisations (CSOs)</td>
<td>Northern and Southern umbrella groups, consumer organizations, development CSOs, environment CSOs, health CSOs, community-based organizations, local CSOs, indigenous peoples</td>
</tr>
<tr>
<td>6. Industry and Industry</td>
<td>Farmers organizations, all relevant industry, including</td>
</tr>
</tbody>
</table>
In many countries, however, it is only a selected group of stakeholders that actually participate and influence in both, the negotiation as well as implementation process of IP obligations through FTAs. Usually in charge is the Ministry that oversees international trade negotiations in collaboration with the national intellectual property office. While selective consultations often take place, the level of participation and influence of diverse stakeholder groups varies greatly. In many cases, final decisions rest in the hands of the Heads of State itself or in the hands of more powerful ministries.

5.2. Strengthen check and balances

One of the main problems found primarily in developing countries is the scarcity of effective check and balances outside the IP system that could allow for improved coordination and implementation of international obligations in accordance with domestic policy objectives.

Indeed many countries, such as the US, possess regulatory mechanisms when it comes to the actual implementation of certain international obligations. Specifically with respect to IPRs the US government has historically developed a system that carefully balances the interests of national consumers and producers when it comes to domestic implementation. This process provides the government with the possibility to intervene or reinterpret certain agreements found on the international level when it comes to their implementation. Precisely, in most FTAs Congress has included the ‘self denying’ effect of its implementing legislation. The so called “self denying” effect implies that in case of a conflict between US Law and any provision in these agreements, that conflict will have no effect on US law. In contrast, in many developing countries, these ‘safety mechanisms’ do not exist. Many FTAs once ratified, tend to be translated directly into domestic law and in many cases may end up with more restrictive interpretations than those existing in developed country counterparts. Setting them up, however, involves sophisticated legal and regulatory infrastructure that cannot be built in the short time frame often provided for implementing new obligations in the field of IP, such as those put forward through FTAs.

Ideally, for achieving a balanced implementation the process should go through institutional review mechanisms. While this process inevitably has to be adapted to the respective domestic legal and regulatory system, certain overall functions could be targeted. Some of these functions could include:

a. General implementation and policy coherence review:

Once the draft laws have been formulated they could be required to pass through a review process that would examine the law critically with respect to tangent policy sectors, such as health, education and environment, for internal policy coherence. This review could be
formed by relevant ministries, parliamentarians and expert groups working in the fields of health, education, environment, science and technology etc. The result of the review could be a set of recommendations for implementation that could take into consideration diverse policy goals. These recommendations could be of assistance for the clarification of terms, for expanding the understanding about the new forms of protection, for assessing domestic implications and for identifying policy space and flexibilities and flanking policies that are needed to keep internal balances in the legal system\textsuperscript{68}.

b. Financial review:

Once the potential road map for implementation and policy coherence issues have been reviewed, the financial and budgetary implications of the overall package of the draft laws and additional implementation measures should evaluated and inserted into the nations budgets. While public budget allocation is usually part of Parliamentarian competences, in the case of some developing countries, financial and budgetary of the implementation is not always considered.

c. Post-implementation monitoring and judicial review:

Once the laws and additional measures are transferred domestically a country should possess the capacity to engage in a process of post implementation monitoring and review in order to get a practical understanding over its domestic impact through time, as well as to ensure that the law maintains to be consistent with current development\textsuperscript{69}. The respective process to engage in monitoring and post implementation review may function differently in distinct regulatory environments. Key to both, however, is the availability by public institutions of independent expertise that examines the application of the new law in practice. This expertise could exist in form of academic institutions or civil society organisations that could monitor the law with an eye on its impact on the wider public interest.

At the national level independent judicial review should ensure the application of the law in particular cases, solve conflicts of interpretation and fill legal gaps. Most countries already have judicial systems providing such services. Nevertheless, their experience in dealing with IP is limited and sometimes independence is not assured. Therefore facilitating training, capacity building, and ensuring independence will be crucial for long term implementation and keeping the balance among title holder and consumers of intellectual property.

Setting up mechanisms and institutions that can engage in the above mentioned activities requires time, and financial and human resources. While many of the larger developing countries possess the needed regulatory machinery as well as the domestic expertise, many smaller ones do not. This may result in scenarios in which the FTA is directly translated into domestic legal text, which could end up as a much stricter interpretation than the one implemented by the larger negotiating party\textsuperscript{70}. Bearing in mind the financial restraints of many developing countries, appropriate mechanisms that could provide some
‘checks and balances’ should be taken into consideration. If appropriate technical assistance in this matter could even be required from outside institutions.

5.2. Dealing with Power Disparities

Having pointed out the complex infrastructure needed for implementing new commitments in the field of IP a further challenge is posed to developing countries that relates to the overall bargaining power between unequal negotiations parties, as one can find often in contemporary FTAs.

It is commonly thought that once a FTA is signed and passed through parliament negotiations are over. However, in practice some of the most important negotiations of the FTA actually continue beyond parliamentary approval, as it is the implementation process and the respective review mechanisms that will eventually determine how the FTA will be implemented at the national level.

Most recently agreed FTAs include a chapter that describes the “administration” of the FTA, which also sets the framework of how the FTA process will be managed.

In the case of the US-CAFTA-DR, for example, Chapter 19, establishes a so called “Free Trade Commission” that is put together by high level representation of all negotiating parties, and, among other, oversees the implementation of the agreements. The Chapter foresees that the Commission should meet at least once each year. All the Committee’s decisions have to be taken by consensus.

On top of that for certain FTAs the US has integrated in its domestic implementation act a section that requires the US President to approve the implementation of the FTA by the other negotiating parties before the US will implement the agreement in its own territory. This is stated in Section 101 of the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act 2005:

(b) CONDITIONS FOR ENTRY INTO FORCE OF THE AGREEMENT- At such time as the President determines that countries listed in subsection (a)(1) have taken measures necessary to comply with the provisions of the Agreement that are to take effect on the date on which the Agreement enters into force, the President is authorized to provide for the Agreement to enter into force with respect to those countries that provide for the Agreement to enter into force for them.

The need for the US “authorization” of successful implementation before the US in turn will act on, for example, market entry concessions, inevitably functions as an incentive for developing countries to implement the FTA swiftly and without too much domestic reinterpretation. Therefore, the use of flanking policies or existing flexibilities will require substantial political strength as they may result in prolonging the actual implementation of market concessions. The political cost of this could be a challenge particularly for smaller countries that depend on the good standing with the US or other powerful trading partners such as the EU.
Many authors have indicated the difference of bargaining power of negotiating parties in recent FTAs, and how this inevitably leads to a biased outcome of the negotiations. Often it is the smaller countries that have to make more concessions in this process, either through legislative change or stronger socio-economic impact.

Similarly, the difference in bargaining power has a strong impact on the actual implementation process. Potential commissions in charge of implementation will also be affected by these power disparities, particularly with respect to questions that demand for a consensus. In this process the US has faced criticism for putting forward expectations for domestic reforms from their negotiating partners that go beyond the actual FTA text, and for using the implementation process as a vehicle to continue the negotiation of the final agreement. Indeed, Members of Congress criticised the USTR in the case of the US-CAFTA-DR for:

- expanding the scope of what is defined as a new product that is subject to data protection rules;
- increasing the regulatory requirements for generic entry into the market; and
- allowing for patent or data protection of a new application of an existing product\textsuperscript{74,75}

Further work is needed to examine the nature of the actual implementation process, its impartiality and how this affects a ‘development friendly’ implementation in developing countries.

V. Conclusions

During the last 10 years policy makers and other relevant stakeholders have placed substantial emphasis on the actual negotiations phase of a new generation of FTAs. The same level of attention will now be needed for the implementation process of the same agreements. The potential impact of the implementation process should not be underestimated. In many cases implementation is as important as the actual negotiations. Badly designed implementation processes may lead to the adoption of standards that are higher than those negotiated and ultimately affect national developmental prospects and access to technology intensive goods.

In order to achieve an interpretation of the FTA obligations on IP in national law that is based on domestic policy objectives, policy makers and stakeholders should consider designing a road map for implementation. The participation of a wide range of stakeholders in the implementation process could assist in achieving the formulation of a more balanced outcome. Transparency, inclusiveness and participatory processes in policy-making and legal standard setting are a fundamental basis for assuring acceptable results and legitimacy among relevant stakeholders.

When implementing new obligations generated by FTAs, the transfer of those obligations into national legislation should be carefully crafted. There is still some policy space left for a development friendly implementation of FTAs but it needs to be carefully
developed and made explicit in many cases. Furthermore, the transfer of international commitments arising from FTAs implies a review of existing “check and balances” at the national level during and after the implementation phase as to ensure an ongoing defence of the public interest in the intellectual property field.

4 See for example the free trade agreements negotiated by the USA with Morocco, Chile, CAFTA-DR, Peru, Colombia, Jordan, Singapore, Bahrain, the UAE, Oman and the proposed IP chapters in the negotiations by USA with SACU and Thailand and Ecuador. Exploratory talks are also being held with Malaysia, Korea and Egypt.
5 Various works by Roffe, Drahas, Correa, Fink, and Vivas 2002-2006.
7 In some countries the ratification or adoption of international commitments (usually through the adoption of a special law) has automatic legal effects in the national jurisdiction without further formalities.
12 Ob cit, Correa, 2002.
14 An example at the international level of an effort to promote deeper understanding of the terms, issues, rights and obligations, and development implications in relation to the TRIPS Agreement is the Resource Book on IP and Development prepared by UNCTAD ICTSD, 2004.
15 An example of a legal provision that negatively defines invention is Article 15 of the Andean Decision 486. According to this article: “The following shall not be considered inventions:
   a) discoveries, scientific theories, and mathematical methods;
   b) Any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing;
   c) literary and artistic works or any other aesthetic creation protected by copyright;
   d) plans, rules, and methods for the pursuit of intellectual activities, playing of games, or economic and business activities;
   e) computer programs and software, as such; and,
   f) methods for presenting information.”
17 An example of this is the definition of “industrial application” criteria as “specific substantial and credible utility” and therefore widening the scope of what is patentable and shifting from the continental law tradition to the common law approach under U.S. Law.
18 See Roffe Pedro, “Bilateral agreements and a TRIPS-plus world: the Chile-USA Free Trade Agreement”, QUNO 2004. This document can be found at http://geneva.quno.info/pdf/Chile(US)final.pdf
19 See US-Chile Article 17.1.5 and US-DR/CAFTA, 15.1.6 but not in US-Jordan, US-Singapore, US- Australia. For a better understanding on the origin and effect of the non derogation clause, also see Roffe Ob Cit.
20 The enumeration of policy spaces is only illustrative. It basically include areas that apply to both patents and copyrights as to provide a horizontal vision when identifying policy space.
In this context, see the CIPR Report 2002, recommending that: "Developing countries should not eliminate potential sources of low cost imports, from other developing or developed countries. In order to be an effective pro-competitive measure in a scenario of full compliance with TRIPS, parallel imports should be allowed whenever the patentee’s rights have been exhausted in the foreign country. Since TRIPS allows countries to design their own exhaustion of rights regimes, developing countries should aim to facilitate parallel imports in their legislation."


Anonymous, interview with trade source.


Idem.

See the TRIPS Agreement, Article 30 in relation to Patents and in article 13 in the case of copyright.

Convention of Industrial Property of 1883, as revised in 1967.


WIPO Copyright Treaty and WIPO Performance and Phonogram Treaty, 1996.

See Chicago Convention on International Civil Aviation, 1944.

See articles 13 and 30 of the TRIPS Agreement. The scope and interpretation of the three step test in both patents and copyrights has been address by two WTO cases: 1) Canada – Patent term protection, WT/DS/170/AB/R of 2000 and 2) US – Section 110 (5) of US Copyright Act, WT/DS/160/R of 2000.

See Article 5.2 of the Paris Convention.

See Article 27 of the Chicago Convention.

See Article 31 of the TRIPS Agreement.

See Article 10(1) of the Berne Convention.

See Article 10 (2) of The Berne Convention.

See Article 10(2) of the Berne Convention.

See Article 11 bis of the Berne Convention.

See for example the Annex to the Bern Convention.

See Vivas, "Regional and Bilateral Agreements and a TRIPS plus world: the case of the FTAA”, CIDA, QUIAP, QUNO, ICTSD, 2003.


In the patent field the use of exceptions in developing countries is low. The only exception that widely use is the so called “research exception”. See Musungu and Oh. “The use of TRIPS Flexibilities by developing countries. Can they promote access to medicines?”. CIPRH, 2005.


See WIPO document, SCCR/13/3, 4 and 5 of 2005.

See Article 31 of the TRIPS Agreement.


Idem.


See article II, III and IV of the Appendix to the Berne Convention.


Okediji, Ruth, Ob Citi, 2006.

For example see article 15.10 of US-CAFTA-DR.
55 Best endeavor clauses to make available patents for plants can be found in the US FTAs with Chile, Peru, Colombia and CAFTA-DR. A direct obligation to make patents available to plants and animals can be found in the FTA between the US and Morocco.

56 Such as in the case of the Article 15.9.2 of the US FTA with Morocco.

57 This has occurred in the case of the US FTAs with Jordan, Singapore, Vietnam and Australia.

58 Included in almost all recent US FTAs, with the exception of the US-Vietnam.

59 This has occurred in the case of the US FTAs with Singapore, Morocco and Australia.

60 All of the US FTAs since NAFTA, with the exception of the US-Israel FTA, include provisions that demand for a minimum standard of data exclusivity on pharmaceutical and agrochemical products. However, the exact level and scope of protection vary among the different FTAs. Some of the EU FTAs and EFTA-FTAs also include provisions on data exclusivity.

61 An example is Article 15.15 of The US-CAFTA. There are cases where this clause has not been included in the text as the case of the US-Morocco. Nevertheless, this not mean that TRIPS principles and competition policy is available in cases of abuses of intellectual property rights.


63 Various UNCTAD presentations since 2002.

64 Ob cit, UNCTAD/ICTSD, 2003.

65 Ob cit, Sanjaya Lall and Manuel Albaladejo., 2003.

66 An example of a potential conflict could be the interest between high levels of IP that may encourage an increase in foreign direct investment, but in the same time raise the price of technology intensive goods, such as pharmaceutical products.


68 The need for such mechanism has also been highlighted, for example, in the final report of the WHO CHPI (2006). See: http://www.who.int/intellectualproperty/documents/thereport/en/index.html

69 For example, a country may go through unexpected developments, such as being struck by an epidemic of large proportions or the introduction of new technologies, and as a result the government may want to adapt its law to the new scenario.


71 One should note that the Commission also will set up a Committee that provides technical advice and capacity building for implementation. This technical assistance is put into place by the negotiating parties, therefore likely to lead to a transfer of knowledge and technical guidance provided by the stronger negotiating party. The impartiality of this technical assistance has to be called into question, as inevitably it will be biased if it stems from a source that is also Party to the same agreement.

72 Similar provisions can be found in the case of the US FTAs Chile, Oman, Singapore, and Bahrain.

73 Very few countries have actually halted or terminated FTA negotiations with the US or the EU on the basis of not finding a common ground, as it is politically a very challenging move. The few more recent exceptions to this are the cases of Switzerland that has terminated talks with the US before the official negotiations had started and the SACU countries that have, at the time of writing this paper, halted negotiations with the US. However, in the case of the US-Jordan FTA, critics have felt that the Jordanian government actually chose not to make use of TRIPS flexibilities when negotiating and implementing the FTA, for the fear of losing the good standing with the US.

74 See Letter to Congress by Six US Representatives:

75 Similar allegations have been made in the case of the US-Jordan FTA. Jordan which is in the process of implementing the FTA at the time of the writing of this article has set up jointly with the US a committee that oversees implementation. Similar to the US-CAFTA-DR some Jordanians feel that the level of protection put forward by the USA during the implementation process goes beyond what has been agreed during the actual negotiations. Particular concerns have been expressed with respect to the interpretation of ‘new use’ for qualifying for data exclusivity protection and the pressure on implementing a ‘linkage’ system rather than ‘notification’.