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Impact of the Protection of Confidential Business Information on the Public Interest

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TABLE OF CONTENTS

ABBREVIATIONS

ABS	Access and Benefit Sharing
ACTA	Anti-Counterfeiting Trade Agreement
BCH	Biosafety Clearing-House
CBD	Convention on Biological Diversity
CBI	Confidential Business Information
CESCR	Committee on Economic Social and Cultural Rights
CJEU	Court of Justice of the European Union
DSB	Dispute Settlement Body
EC	European Communities
ECHR	European Convention on Human Rights
EIA	Environmental Impact Assessment
EMA	European Medicines Agency
EU	European Union
FOIA	Freedom of Information Act
GATT	General Agreement on Tariffs and Trade
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Convention on Economic Social and Cultural Rights
IP	Intellectual Property
IPR	Intellectual Property Right
MAT	Mutually Agreed Terms
NAFTA	North American Free Trade Agreement
NCE	New Chemical Entity
OECD	Organisation for Economic Co-operation and Development
PIC	Prior Informed Consent
REBSP	Right to Enjoy the Benefits of Scientific Progress
RIA	Right to Information Act, India
SPS	Sanitary and Phytosanitary (Measures)
TBT	Technical Barriers to Trade
TK	Traditional Knowledge
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
UNECE	United Nations Economic Commission for Europe
UNESCO	United Nations Educational, Scientific and Cultural Organization
VCLT	Vienna Convention on the Law of Treaties
WCT	WIPO Copyright Treaty
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

I. Introduction

The past two decades have seen a movement, primarily in Organisation for Economic Cooperation and Development (OECD) countries, towards greater transparency and more open access to government decision-making and regulatory processes. But with it have come new tensions between a public seeking to better participate in regulatory processes and businesses pursuing to protect confidential information. The aim of this study is to examine how to reconcile the potentially conflicting interests embodied in rules on the protection of confidential business information and those of access to information.

As commercial activities have tended to become more knowledge intensive, the value of that knowledge and information has increased. We have seen in the past 25 years an unprecedented expansion in the nature and scope of protection of intellectual property. At the international level this has been exemplified by the entry into force of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[1]; but it also finds expression in national and regional processes to expand protection to new areas, e.g. sui generis database protection in the European Union[2], and increased enforcement of intellectual property protection as attempted through the Anti-Counterfeiting Trade Agreement (ACTA)[3]. In terms of information disclosure, these systems have not necessarily been problematic as they rest on the basic IP bargain of disclosure for protection. These may nevertheless present problems where the interests of disclosure lie in enabling subsequent use. This is most pertinent in the case of disclosure of clinical test data, which could be used by regulators or competitors to assess the equivalence of generic versions of drugs that have already been approved for marketing.

Examples of the move to open access and greater transparency are open government meetings, comment periods, and impact studies prior to decisions. A push in the environmental arena has led to the involvement of local communities and other stakeholders in planning decisions. The necessity for access to information in order to promote informed debate and allow for prior informed consent has become a core principle of many environmental advocacy frameworks. This access to information principle led to the creation and adoption of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters[4]. Freedom of Information Acts and regulations have also proliferated as mechanisms by which stakeholders can hold government agencies accountable, especially in controversial areas of political and regulatory action.

While open access has always run into difficulties in the national security arena, it has included deliberations of standard-setting bodies in food regulation, medicines safety, and automobile safety. Where the information sought or provided by governments involves information submitted by private individuals or non-governmental legal entities (corporations, institutes, civil organizations), there has been tension between providing sufficient information and the reasonable privacy and economic expectations and interests of individuals and businesses. Such tensions have historically been managed at the domestic level within the constitutional structures balancing access to information, privacy interests, and economic interests. There has been an almost simultaneous advent of international norms and treaties containing obligations to ensure access to information (as embodied in treaties such as the Aarhus Convention), and rules providing

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1 Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement), Annex 1C to the Marrakesh Agreement establishing the World Trade Organization (WTO Agreement), Marrakesh, 15 April 1994, in force 1 January 1995, 1867 United Nations Treaty Series (1995) 4.

2 Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases.

3 Anti-Counterfeting Trade Agreement. Available at: http://www.mofa.go.jp/policy/economy/i_property/acta.html (last visited 3 August 2016). Japan is the depositary state. Participants included Australia, Canada, the European Union (EU), Japan, Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland and the United States of America. Australia, Canada, Japan, South Korea, Morocco, New Zealand, Singapore and the United States signed on 1 Oct 2011. The EU and some EU member states signed it on January 26, 2012, but the EU as a whole did not ratify the treaty at the EU level after it was rejected by the European Parliament. Six instruments of ratification are required for the ACTA to enter into force. (Article 39). After ratification by Japan in October 2012, there have been no further ratifications, and the agreement has yet to enter into force.

4 Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, entry into force 30 October 2001, 2161 UNTS 447; 38 ILM 517 (1999). Available at: http://www.unece.org/env/pp/treatytext.html.

for greater scope and stronger protection of confidential business information (e.g. the TRIPS Agreement). Meanwhile, proposals by the European Commission to harmonize and increase protection of confidential business information[5] have created a problem that is proving difficult for domestic law to solve and caused potential contradictions in international law that may be difficult to reconcile in the absence of a systematic approach to the generation and interpretation of these norms.

New norms and treaties set up processes requiring manufacturers to lay open information about the production processes or content of their products, or adherence to certain rules such as having obtained prior informed consent for the utilization of genetic resources. In many cases, however, businesses have little interest in publishing this information because they fear losing their competitive advantage or because they might face demands for compensation. In response they have sought exceptions within these norms, as well as increased requirements for governments to maintain the confidential nature of such information. In particular, in the arena of pharmaceutical test data submitted for market approval, this has resulted in demands that governments restrict not just access to clinical test results but the use of such information by regulatory authorities as a basis for decision-making in approving generic medicines. Governments implementing their obligations under these treaties have to decide how to reconcile and integrate what may be competing sets of regulation and values.

Focus of this Study

This study will begin with an examination of the underlying rationales for access to information and those for the protection of undisclosed information, which is sometimes known as trade secrets. It will go on to discuss whether the underlying values are competing, in contradiction, or reconcilable. Access to information and protection of undisclosed business information both fall under the same broader regulatory framework governing relations between private actors. This paper will not examine treaties that require access to information as a function of implementing government-to-government relations or obligations such as boundary agreements, water access agreements, or nuclear non-proliferation, unless those provisions are aimed at ensuring and achieving direct public access to the information.. Neither does this study aim for a comprehensive review of provisions in such treaties. Rather, it takes the examination of rationales and justifications and looks at two key areas that present ongoing controversies: the implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity and the protection of pharmaceutical test data.

[5] See Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure. Available at: http://ec.europa.eu/internal_market/iprenforcement/trade_secrets/index_en.htm

In the sections to follow, the study will provide a comparative analysis of the international framework of relevance to how access to information related to the Nagoya Protocol manages the relationship to undisclosed information on the one hand; and how the requirements for protection of undisclosed information relate to the need for access to information on the other hand. The study examines the way in which the conflict is managed in examples of legislation from: The European Union, India, and South Africa.

This paper will take a broader view of access to cover two main modes. The first is access that involves dissemination to the public and stakeholders. The second is access that, even if limited to one or two other actors, allows instrumental use of the information to achieve a public interest outcome. A specific example of the latter is use of pharmaceutical test data.

II. What Are Access to Information Regimes? What Are Trade Secrets? How Do They Interact?

Ensuring access to information has a powerful normative basis. In a democratic society, the ability to access information generated and used by executive and other government bodies is crucial to ensuring an informed citizenry that can participate properly in government decision-making.[6] Rather than simply being embedded in a mistrust of government and government incentives to hide information from citizens that may be politically damaging to the government of the day, a large part of the rationale for creating a 'right to access to information' lies in the sheer amount of material generated by governments which the government is simply not in a position to disseminate, as a matter of time or cost. Underlying this is a presumption that unless otherwise justified, the default position should be that government information should always be available, even if no affirmative obligation is placed on governments to share it.

However, there are other bases on which access to information can be rationalized as a basic principle if we first presume a large and interested civil society or set of non-governmental stakeholders, including individuals, with an interest in government decisions. Where the stakeholders are regulated entities or affected individuals, access to the basis and rationale for government decisions that affect their activities is crucial for determining when and how such government action can be challenged. Where the activities of such regulated entities affect third parties, the action or lack of action by government also creates a need for such parties to have access to such information.

A crucial reflection of these democratic participation and accountability rationales are Freedom of Information Acts and other similar measures (hereinafter referred to generally as FOIAs). In general, these legislative acts create a request mechanism by which citizens can request information in the hands of governments to be disclosed to them. Though quite varied in their specific provisions and scope, they all grapple with the same basic issues:

- Who may request? Interested parties or any person?
- How to address privacy concerns of those the information may concern, if they have a privacy interest?
- How to address the commercial interest of those with such interests at stake?
- Scope of the disclosure.
- Is the disclosure discretionary or required?
- Who can object to the disclosure, if at all?
- How is a conflict between the requester and the objector to be resolved? Administratively? Judicially?
- If there is disclosure, should there be compensation, as is traditional in the case of the government use of private property?

This section will examine the underlying rationales for both access to information and the protection of undisclosed information.

II.1 WHAT ARE TRADE SECRETS AND CBI?

Trade secrets and confidential business information (CBI) can essentially extend to: marketing strategies, contract terms, customer lists, human resources, and the content of products on the market. For example, a chemical solvent, or cleaner, or aerosol spray will contain the trade secret on the identity and quantity of the chemicals used in it. In the absence of any obligation to disclose, such identifying information can be made subject to trade secret or CBI protection.[7] There is clearly a competitive advantage to be gained in being able to prevent others from knowing the exact content or formulation of your product. However, that secrecy prevents the generation of information about that product by any but the holder of the information, preventing studies on toxicity or other potential effects. In terms of environmental and health information, trade secrets may not only impede the disclosure of such information but may actually serve to prevent the generation of such information.[8] Coupled with the fears that liability may accrue if such information is disclosed, firms may actively avoid generating internal knowledge about harms related to their products, and where they do have such information, will actively work to prevent the generation of confirming information. Trade secrecy and protection of CBI place such information in the hands of those with the strongest interest in preventing its generation. Thus, there is little suggestion that trade secret and CBI protection serve the aim of actually generating knowledge generally and environmental and health information specifically.

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6 See Roesler, S., "The nature of the Environmental Right to Know", 39 Ecology L.Q. 989 (2012).

7 See Lyndon, Mary L., Trade Secrets and Information Access in Environmental Law (October 21, 2011), in Rochelle C. Dreyfuss & Katherine J. Strandburg, eds., THE LAW AND THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH, (Edward Elgar, 2011); St. John's Legal Studies Research Paper No. 1947514. Available at SSRN: http://ssrn.com/abstract=1947514.

8 See p467, Lyndon, Mary L., "Secrecy and Access in an Innovation Intensive Economy: Reordering Information Privileges in Environmental, Health, And Safety Law", 78 U. Colo. L. Rev. 465 (2007).

Trade secrets, intellectual property, and public policy?

Trade secret protection has normally been outside traditional IP protection. The lack of legally mandated exclusivity has been a key missing element and most legislation in Europe[9] and the rest of the world has treated trade secrets as lacking core characteristics of intellectual property, which is why it has been protected through other mechanisms such as unfair competition. It is understood that trade secret protection should be retained as a business option for firms. But the public policy rationale for its protection is much thinner – what remains is largely an argument for special interest protection of business interests, especially small and medium enterprises with few resources to engage in patenting for example. One main public policy rationale is, as van Overvalle notes, that it allows for inter partes exchange of information so that information does flow, albeit slowly.[10] Where the claim is to information that a firm has no interest in other than the potential for commercial harm, and that has little exchange value in product or process terms, there is little public policy rationale for such protection from a knowledge generation and dissemination standpoint. [11]

There are legislative attempts to increase the level of protection provided to trade secrets and beyond. The TRIPS Agreement does not address trade secrets very extensively but it does go beyond the Paris Convention by formulating the very specific methodology by which trade secrets should be protected, not just against unfair competition per se.[12]

There is some strong argument that certain kinds of information, though commercially valuable, may not count as trade secrets. As noted below, information held by a firm with regard to a harmful characteristic or quality of its product, while having value, may not fall within the ambit of information that is commercially valuable to competitors because they can unfairly appropriate and benefit from using that information in relation to their products. This has prompted some expansion of the category of information to be protected from that of traditional trade secrets to confidential business information more broadly. Thus where trade secrets seemed largely restricted to technical information on how to make products or use processes, CBI extends to information around these products as well as other competitively useful information.

There remain, however, basic principles from within trade secret law which govern the boundaries of trade secrets. Trade secrets may not be used to justify the prevention of the following activities:

- Restrictions on workers' mobility or ability to compete.
  - In general, absolute restrictions on workers' ability to move to other employment are not permissible except where an employee explicitly signs away such rights. Even in such circumstances, such restrictions must be limited.
- Freedom of expression.
- Public interest relevance to public health or safety.

II.2 WHAT ARE ACCESS TO INFORMATION REGIMES IN THE ENVIRONMENTAL AND HEALTH CONTEXTS

As noted above, access to information has a powerful normative basis in democratic governance. This has been the basis for a whole host of freedom of information act (FOIA)-like measures in many different countries. It has had very specific implementation in the environmental and health risk arena, rooted in two main considerations: 1) the need for regulated entities and their stakeholders to understand what and how

[9] Hogan Lovells International LLP Report on Trade Secrets for the European Commission Study on Trade Secrets and Parasitic Copying (Look-alikes) MARKT/2010/20/D (2010).

[10] VAN OVERWALLE, G., 'Uncorking Trade Secrets: Sparking the Interaction Between Trade Secrecy and Open Biotechnology', in Rochelle Dreyfuss and Katherine Strandberg (eds.), The Law and Theory of Trade Secrecy: A Handbook of Contemporary Research (Edward Elgar, 2011). See also Mark A. Lemley, The Surprising Virtues of Treating Trade Secrets as IP Rights, 61 STAN. L. REV. AT 118 (2008).

[11] See p148, Levine, D., "Trade Secrets in our Public Infrastructure", 59 Fla. L. Rev. 135 (2007).

[12] Article 39.3 TRIPS states: 3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use. https://www.wto.org/english/docs_e/legal_e/27-trips_04d_e.htm.

the government is regulating them; 2) ensuring that negative externalities are disclosed so that third parties may understand the harms that others may be causing them.

This creates a range of different disclosure measures that the government can engage in. The first thing to note is that we can make a distinction between measures that are an expression of an affirmative obligation or action on the part of the government to disclose information; and those that require an affirmative request.

- Affirmative Disclosure measures and obligations
- Motivated and affirmative requests
  - requiring a showing of standing or interest
  - no requirement of a showing of interest

In addition, we need to distinguish between situations where firms or entities are submitting to the government information that is required of them, placing them in a situation where the government is forcing them to disclose as a prerequisite for either participating in the market (certain food and drug rules for example, as well as the whole field of pharmaceutical marketing approval) or health and safety requirements (such as occupational safety and exposure to chemicals), and situations where they are requested to provide such information to the government but are not necessarily required to do so.

In the first situation, the element of coercion means that a strong public policy justification is usually required and the loss of protection for secrets implied in the disclosure of information submitted under such a requirement may implicate commercial and financial losses, if not the viability of the firms so affected. This therefore may lead to a weighing of interest as addressed in the conflict discussion below. The situation where government has requested information that is not required presents a different issue in that incentives will be needed in order to encourage the generation and the willingness to share information. In such situations, regulators may argue a stronger need to bargain for access to such information with promises to keep such information secret.[13] As Rowe discusses, in the absence of assurances that the secrecy of information will be kept, firms may simply refuse to submit such information without a court ordering them to do so. If a requester challenges such a refusal to disclose, then a court will have to determine if there is sufficient public interest that outweighs the interest of the trade secret holder. This threshold will generally be higher than that for mandated information and may involve examination of the legitimate expectations of submitters as well as the urgency of the need for such information on the part of the requester or the public generally.

The categories of information inflow to public authorities therefore constitute:

1. Information required to be submitted to government by a legislative or regulatory act.
2. Information not required to be submitted to government,
   - voluntarily disclosed,
   - involuntarily disclosed due to court order.

The category of information affects the rights of the submitter and the extent to which it can be disclosed to and used by parties other than the government agency. The justifications for disclosure also play out differently where the information is voluntarily disclosed or needs to be voluntarily disclosed. The extent of access to each category of information will be influenced by the kinds of rationales being put forward for systematic disclosure or disclosure in each specific case.

Utilitarian arguments

- Information should be disseminated to those best situated and motivated to generate information about the possible harms of a particular product.[14] While this clearly includes the government, it also implicates the broader scientific community. Users or communities of users are directly implicated, but they are probably least capable to engage in the kind of knowledge generation.

- Consumers should be informed and knowledgeable about the risks that they take when they choose to consume particular products. In this case, disclosure serves an important market function of allowing consumers to make well-informed purchasing decisions, by requiring information of ingredients to be listed on products.[15] This serves to ensure that the market most efficiently serves those products that consumers consider safest and least risky based on the information that is generally known publicly about the ingredients.

[13] Rowe, E., "Striking a Balance: When Should Trade Secret Law Shield Disclosures to the Government?", 96 Iowa Law Review 791 (2011).

[14] See eg. Lyndon, Mary L., Trade Secrets and Information Access in Environmental Law, op.cit., footnote 7.

[15] Lyndon, Mary L., "Information economics and chemical toxicity: Designing laws to produce and use data", 87 Mich. L. Rev. 1795 (1988).

Fairness and justice arguments

- Tort law: These are arguments relating to who should bear the cost of harms of actions.[16] Where a private party engages in behavior that harms others and keeps the information that creates such harms secret, disclosure creates a disincentive for actors to engage in such activities and properly imposes the burden of preventing harm on the private party making the product. This is a basic tort argument in many ways. Disclosure allows the tort system to function and allows for the foreseeability of harm and apportionment of liability appropriately. Requiring parties to disclose the risks of their actions to the public allows for that.

- Fraud prevention: Those against whom a person is committing or may be committing a fraud are justified in seeking information and having it disclosed. Where the fraud is general, such as to a broad community of consumers, the rationale for public disclosure is stronger. In many ways, this underlies the requirement that firms disclose ingredients on their products in order to show that their product contains the ingredients and has the effects claimed. This is part of the protection of consumers not only against harm but against misrepresentation. Thus there is an obligation to ensure the accuracy of representations as to efficacy or other benefits of a product by being able to accurately assess whether the product contains characteristics or is processed in a way that supports such claims.

Public disclosure may be even more necessary where the search cost for the person seeking to vindicate rights is prohibitive because of the secretive nature of the trade secret regime. In contrast to other intellectual property regimes where disclosure at the pre-grant stage is a key part of providing notice to others of possible infringing activity, trade secrecy does not have that same safety valve built into it. In the context of disclosure of origin of genetic resources used in patent applications or other commercial uses, where the rationale is to allow others to protect their rights and prevent misappropriation, the use of others' materials and products is a necessary element of enabling such protection. In that context, providing an exception to disclosure for trade secrets or CBI may run entirely counter to the aim of preventing fraud or misappropriation related to genetic resources.

- Rights-based approaches: Access to information is invoked as a part of the right to freedom of expression. This is framed as a right to receive information to enable participation in public life and democratic governance. An example of this is article 10 of the European Convention on Human Rights, which in a series of interpretations by the European Court of Human Rights has consistently been found to exist, although it must be balanced with other rights in the broader European framework.[17]

The framework for access to information has always been defined in opposition to those interests in not disclosing. So the juxtaposition of justifications for such access and the definitions of the boundaries of the conflict between access to information and other interests has always existed.

II.3 THE NATURE OF THE CONFLICT

From the discussion above, we see that there can be common purposes in protection of trade secrets and that of access to information. Where protection of trade secrets results in the generation and greater availability of information, it aligns itself with the broader aim of ensuring better information on environmental and health risks. But trade secret protection also restricts the flow of such information to those best situated to assess and address environmental and health risks, and thus formulate policy, and therefore remains in fundamental conflict with access to information measures. However, it is not always essential to the assessment of environmental and health risks that information is disseminated to the public as a whole. Thus, where there is an argument that such information is not needed by the general public in order for either the public or the government to engage in risk assessment and policy formulation, there may be no need for public dissemination.

Acknowledging there is a double interest in disclosure both in the generation and dissemination of the information, and in the public disclosure for environmental and other purposes – what is the countervailing interest besides that of the personally harmed firm? The following outlines the various justifications that have been raised:

- What if the public interest is specifically about disclosing a harm or risk of harm, such as harm to the rights of a third party revealing that a firm has indeed been using another party's intellectual property unwillingly. Absent criminal concerns, is there a need to prevent such self-incrimination? Where the goal of the instrument is to prevent such action it cannot be that the very information sought would then be classified as a trade secret or CBI.

- More directly, as noted above, environmental harms and risks imposed by some actors on others present a significant countervailing interest against maintaining a trade secret. It is crucial that where trade secrets are exempted from certain kinds of information disclosure that there is a balancing of harms. However, it is not always the case that such a balancing takes place, especially where such an exemption can be unilaterally claimed and cannot be questioned by the government receiver of the information, or the requester of the information. In particular, if the trade secret is specifically about the harm or the risk being imposed rather than any other commercially advantageous characteristic of the product or process, can there be any justification for maintaining such secrecy other than commercial harm to the company were such information to be released to the public?[18]

In doing such an assessment, the challenges that arise in the FOIA context also arise more broadly in the context of disclosure of information. The conflict arises in many different contexts and legislative acts. In general, each of these has different scope in the legislative act, in the practice and within the constitutional framework in which they operate.

For example, whether compensation is required depends on a country's rules on whether requiring disclosure of a trade secret is tantamount to expropriation that must be compensated. This depends on whether the trade secret or CBI is considered an object of property under the national constitutional framework. If so, it may be capable of being expropriated, but then the question is whether a regulation that requires submission and disclosure of information is tantamount to transferring ownership, or destroying ownership and enjoyment of the trade secret.

The danger here is that a default process is followed where such a balancing takes place on a case by case basis rather than through a systematic broad basis, creating a presumption driven by specific policy outcomes and goals.[19] This then favours those parties with strong personal interests and financial capacity, primarily the parties claiming confidentiality.[20]

The following decision tree outlines a sequence of possible ways in which the determination to disclose can take place:

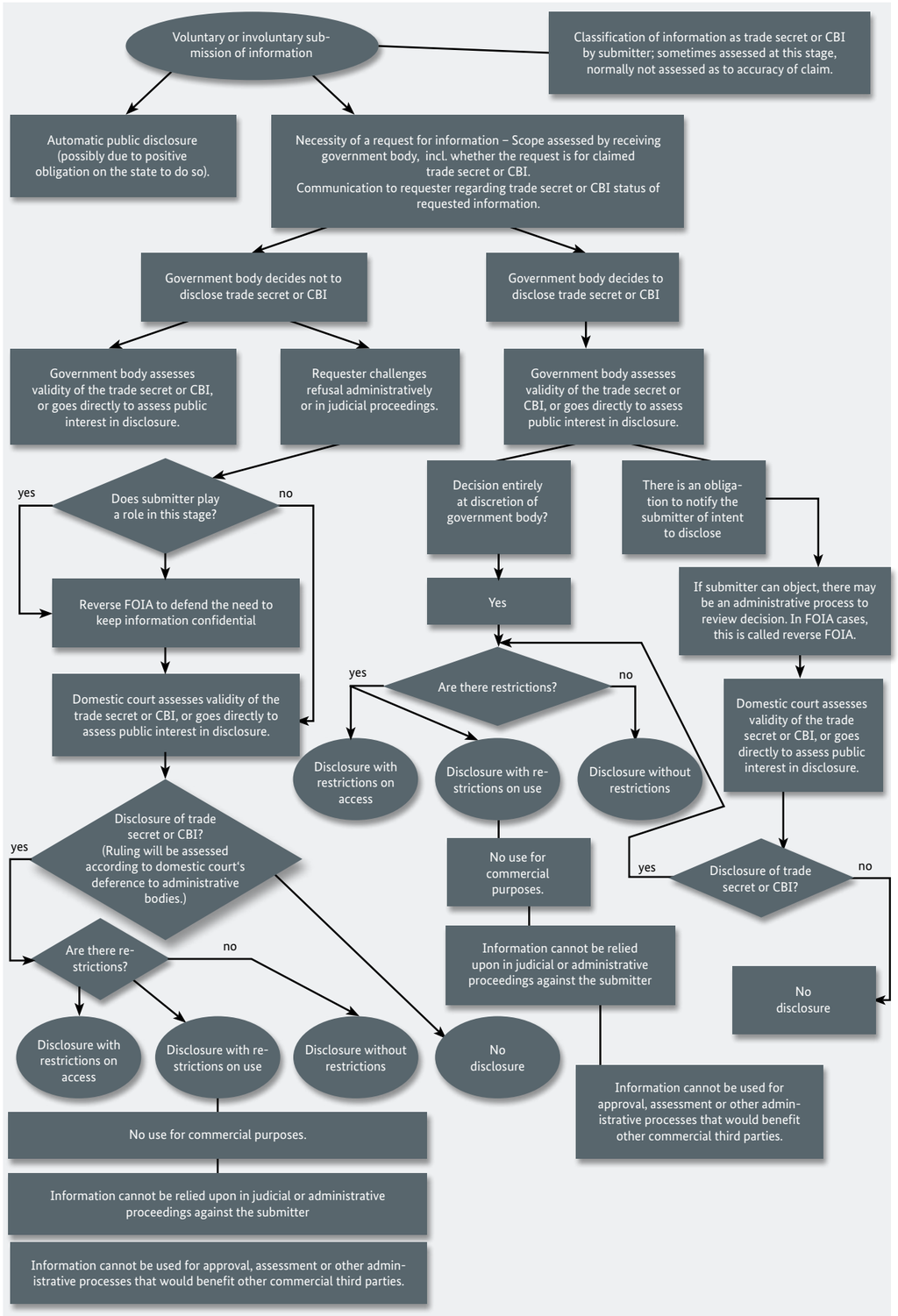
16 See p 456, Lyndon, Mary L., Trade Secrets and Information Access in Environmental Law, op.cit., Footnote 7.

17 See Társaság a Szabadságjogokért v. Hungary, Application no. 37374/05, ECHR, Judgement of 14 April 2009; Kenedi v. Hungary, Application 31475/05, ECHR, Judgement of 26 May 2009. Also General Comment No. 34, on article 19 of the International Covenant on Civil and Political Rights (freedom of expression).

18 The core question posed on p458, Lyndon, Mary L., Trade Secrets and Information Access in Environmental Law, op.cit., footnote 7.

19 See p466, Lyndon, Mary L. "Secrecy and Access in an Innovation Intensive Economy. Op. cit., footnote 8.

20 Ibid., p466.



Looking at examples of general access to information laws and how they manage the conflict with commercial information we can point to three experiences of relevance: the Indian Right to Information Act; the South African promotion of Access to information Act; and the European Union.

India

The Indian Right to Information Act[21] is one of the more extensive FOIA-like structures out there with regional and national information commissions and commissioners independent of the government to whom appeals may be made for refusals. In looking at the grounds for refusal in the Indian RIA, the issue of confidential information is addressed in Article 8(1)(d) of Chapter II. That states that there shall be no obligation to provide:

> *"information including commercial confidence, trade secrets or intellectual property, the disclosure of which would harm the competitive position of a third party, unless the competent authority is satisfied that larger public interest warrants the disclosure of such information".*

Thus under the RIA, publication is still possible based on a weighing of the public interest. There is very little available case law on how this has been interpreted and managed, but at minimum a balancing exercise seems to be mandated. At least one court has dealt with interpreting Article 8(1)(d)[22] in a case that dealt with documents submitted in a tender by private parties to carry out consulting work for the state. The court in that case gave great weight to the object and purpose of the act in ensuring access to public information and scrutiny of public acts. In particular, the court noted the need for special scrutiny of commercially significant public acts[23] as implicating the very dangers that the act was meant to address, i.e. secrecy relating to public funds and possible corruption. The court noted that once a decision was made regarding a tender, the public had a right to know the basis of the decision and thus documents submitted in order to win the tender must of necessity be made available to allow the public to perform its scrutiny function.[24] The court also saw no justifiable countervailing interest on the part of the private actor claiming confidentiality as participating in tenders was a voluntary process. The court ruled that the information did not fall within the exemption of article 8.1(d).

South Africa

The South African Promotion of Information Act[25] in contrast provides little or no discretion to public authorities regarding confidential information. As part of a broader system of mandatory grounds for refusal, Article 36.1 requires refusal to disclose:

(a) Trade secrets of a third party;
(b) financial, commercial, scientific or technical information, other than trade secrets, of a third party, the disclosure of which would be likely to cause to the commercial or financial interests of that third party; or
(c) information supplied in confidence by a third party the disclosure of which could reasonably be expected-
  (i) to put that third party at a disadvantage in contractual or other negotiations; or
  (ii) to prejudice that third party in commercial competition.

These exceptions cannot be breached. Thus, where a claim is made that information is a trade secret and the authority determines that it is as such, then the authority may not disclose it no matter the over-riding public interest. Article 36.2 contains one exception to the limitation in that information "about the results of any product or environmental testing or other investigation supplied by, carried out by or on behalf of a third party and its disclosure would reveal a serious public safety or environmental risk" must be disclosed. Again the disclosure is not optional. Thus at least where serious environmental risks are concerned there is disclosure. In contrast to India, the South African approach appears very narrow.

The European Union

The EU Transparency Regulation handles the conflict similarly to the South African approach by making the refusal to disclose mandatory in the case of confidenti-

21 Right to Information Act (2005) (Act No. 22 of 2005 as modified up to 1st of February 2011). Available at: http://righttoinformation.gov.in/rti-act.pdf.
22 State Of Jharkhand And Anr. vs Navin Kumar Sinhga And Anr. on 8 August, 2007, AIR 2008, Jhar 19, 2007 (3), JCR 668 Jhr.
23 Citing the Indian Supreme Court decision in The State of Uttar Pradesh v. Raj Narain and Ors. AIR 1975, Supreme Court S65.
24 See para. 26, State Of Jharkhand And Anr. vs Navin Kumar Sinhga And Anr. on 8 August, 2007, AIR 2008, Jhar 19, 2007 (3), JCR 668 Jhr.
25 Promotion of Access to Information Act 2 OF 2000. Available at: http://www.dfa.gov.za/department/accessinfo_act.pdf.

al information, subject to an over-riding public interest, and in any case subject to consultation with the private party submitter of the information.[26] Historically, the EU bodies have been deferential to refusals by third parties to allow disclosure.[27]

II.4 CONCLUSION

Generally, FOIA-type rules have been considered insufficient to address environmental and health concerns precisely because they impose few affirmative government obligations to disclose and share information, absent a motivated request.[28] Thus it may not be appropriate for countries implementing disclosure regimes for the Nagoya Protocol or for clinical trial data to rely on FOIA-like structures to achieve the aims of transparency and efficiency and effective citizen and scientific participation in decision-making and monitoring.

In the survey in the next section, the decision tree sequence guides our assessment of the various provisions in international treaties and national legislation. Thus, the provisions on access to information will be assessed according to how they address the conflict with trade secrets and CBI. By contrast, the legislation on protection of trade secrets and CBI will be assessed according to the room and space it provides for disclosure of relevant environmental and public health information. Crucially, we will look at how the Aarhus Convention itself manages the relationship to undisclosed information, and how it may relate to other treaties providing a means for deciding how to place the obligations in each treaty in relation to each other. Our analysis will look at:

1. The internal balancing rules for how to relate to
    1. Access to information treaties and provisions and protection of trade secrets and CBI.
    2. Protection of trade secrets and access to information and public disclosure and use rules.
2. The rule for relating to other international treaties
    1. generally, as embodied in savings clauses;
    2. specifically, as embodied in provisions addressing mutual supportiveness of particular articles with those of other treaties, if any.

[26] Article 4, REGULATION (EC) No 1049/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

[27] Driessen, B., "Access to Member State documents in EC law: a comment." 31(6) E.L. Rev. 906 (2006).

[28] See e.g. Herz, M., "LAW LAGS BEHIND: FOIA AND AFFIRMATIVE DISCLOSURE OF INFORMATION." 7 Cardozo Pub. L. Pol'y & Ethics J., 577 2008-2009.

III. Access to Information in Environmental Treaties

III.1 THE AARHUS CONVENTION[29]

The Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters is the primary international/regional instrument framing the direct right to access information on environmental matters. For our purposes, it is important to understand the triggers for information falling under the Aarhus Convention and then what framework the convention provides for the protection of trade secrets and confidential information if any. As a primarily European instrument to which the EU as an institution is also a signatory, the case law of the Court of Justice of the European Union (CJEU, formerly the ECJ) will also play a role, but will be discussed in more detail in the case study. For the moment we are concerned with just the treaty itself.

The rationale for the treaty remains very clear and is embodied in the preambles and the objective in Article 1:

"In order to contribute to the protection of the right of every person of present and future generations to live in an environment adequate to his or her health and well-being, each Party shall guarantee the rights of access to information, public participation in decision-making, and access to justice in environmental matters in accordance with the provisions of this Convention."

Thus access to information here reflects not just a utilitarian function but is seen as a contribution to the right of each and every person, present and future, to a healthy environment. This is fundamental as it frames access to information as a human right, rather than simply as a means. This is in line with broader human rights jurisprudence on the freedom of expression that notes that access to information is a primary element of the right to engage in free expression and participate in the democratic process.[30]

Regarding the trigger for action, Article 2(3) defines the very broad scope of what constitutes environmental information subject to disclosure:

"'Environmental information' means any information in written, visual, aural, electronic or any other material form on:

(a) The state of elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites, biological diversity and its components, including genetically modified organisms, and the interaction among these elements;

(b) Factors, such as substances, energy, noise and radiation, and activities or measures, including administrative measures, environmental agreements, policies, legislation, plans and programmes, affecting or likely to affect the elements of the environment within the scope of subparagraph (a) above, and cost-benefit and other economic analyses and assumptions used in environmental decision-making;

(c) The state of human health and safety, conditions of human life, cultural sites and built structures, inasmuch as they are or may be affected by the state of the elements of the environment or, through these elements, by the factors, activities or measures referred to in subparagraph (b) above;"

These obligations therefore include any information related to biodiversity or genetic resources about which the government is making decisions relating to the distribution, marketing or use of. In the context of this study, this is generally not read to include information on pharmaceutical products, particularly new chemical entities (NCEs), except where such products may be based on genetic resources. In Article 2(5) a broad definition of what constitutes the public is also used, although there is some notion of those likely to be affected or having an interest in the decision-making.

Article 4 of the Aarhus Convention imposes an obligation to provide information upon request. States may not impose a standing requirement or require an interest to be stated.

Internal rules for resolving conflict with confidential or other undisclosed information

There are circumstances under which a request for disclosure may be refused. These are outlined in Article 4(4).

"A request for environmental information may be refused if the disclosure would adversely affect:

(d) The confidentiality of commercial and industrial information, where such confidentiality is protected by law in order to protect a legitimate economic interest. Within this framework, information on emissions which is relevant for the protection of the environment shall be disclosed;

(e) Intellectual property rights;

(f) The confidentiality of personal data and/or files relating to a natural person where that person has not consented to the disclosure of the information to the public, where such confidentiality is provided for in national law;

(g) The interests of a third party which has supplied the information requested without that party being under or capable of being put under a legal obligation to do so, and where that party does not consent to the release of the material;"

First, generally the exclusions are discretionary and are to be decided by the public authority. They are not mandatory, nor do they require the consent of third parties if the government nevertheless determines either on a case by case basis, or on a broader basis that disclosure is appropriate. In addition, the final paragraph of Article 4 of the Aarhus Convention notes that these exceptions should be construed narrowly, given the strong public interest in access to the information, especially where it may address emissions to the environment:

"The aforementioned grounds for refusal shall be interpreted in a restrictive way, taking into account the public interest served by disclosure and taking into account whether the information requested relates to emissions into the environment."

This more broadly reflects the rationale and conviction that trade secrets should not protect those responsible for engaging in potentially harmful behavior. The Aarhus Convention Implementation Guide also notes that restrictive treatment implies a higher burden of proof in order to exercise the discretion to refuse. This includes showing of actual harm from the release rather than the mere possibility thereof[31], including that the harm cannot be remedied by other compensatory mechanisms. The existence of the harm may still be countenanced as long as the adverse effect is not so severe when balanced against the existence of the right, or against, as the implementation guide notes, the public interest in disclosure. Thus some measure of adverse effect must be allowed when weighed against strong interests in disclosure.[32] The weaker the public interest the easier it may be to invoke the exceptions.

Looking specifically at the exceptions, Article 4(4)(d) expresses the paradigmatic concern over the disclosure of trade secrets or CBI. Such information must however be explicitly stated and protected by law[33] as trade secrets or undisclosed information in some fashion. Where such information is protected under different systems such as unfair competition, it remains unclear whether that would reach the threshold under the convention as 'protected by law'. The implementation guide argues that the protection must be explicitly as commercial or industrial secrets[34], meaning that normal unfair competition law protection may not qualify as such. As stated, it appears quite broad and foresees a relatively deferential approach. That said, the authority will have to assess the legitimacy of the economic interest claimed (thus to some extent the validity of the information as a trade secret or as CBI). As with other international treaties, legitimacy has both an economic and normative framework suggesting already that legitimacy must be examined in the context of legitimate claims by others to that same information. In addition, it makes clear that no such claim can be made regarding undisclosed information related to emissions into the environment. This reflects the absolute barrier to confidentiality claims related to information regarding environmental harms.

Article 4(4)(e) presents a puzzling claim except perhaps to address the lacunae where trade secrets in particular are treated as intellectual property. If so, it seems to impinge on the scope of Article 4(4)(d). If it referred to other intellectual property rights then a category mistake seems to have been made as all other such rights must by definition involve disclosure to the public in order for such a right/grant to exist in the first place. However, the implementation guide points to copyright claims as a possible barrier to disclosure where an author may wish to prevent dissemination of a work, such as a study or report.[35] It also points to a decision by the compliance committee that such claims should not prevent disclosure of documents created specifically for public purposes such as environmental impact assessments.[36]

[29] Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters. Available at: http://www.unece.org/env/pp/treatytext.html.

[30] See e.g. Leander v. Sweden, judgment of 26 March 1987, Series A No. 116. ECHR; Lingens v. Austria, 1986; Sener v. Turkey, 2000; Thoma v. Luxembourg, 2001; Dichand and Others v. Austria, 2002, ECHR.

[31] See p90, UNECE, The Aarhus convention – An Implementation Guide, Second Edition, 2014.

[32] "Thus, in situations where there is a significant public interest in disclosure of certain environmental information and a relatively small amount of harm to the interests involved, the Convention would require disclosure." European Community ACCC/C/2007/21, ECE/MP.PP/C.1/2009/2/Add.1, 11 December 2009, para. 30.

[33] See p88, UNECE, The Aarhus convention – An Implementation Guide, Second Edition, 2014.

[34] See p88, ibid.

[35] See p88, ibid.

[36] See p88, ibid.

Article 4(4)(f) relates to personal information which is protected under privacy and data protection regimes and impinge upon core personal autonomy rights. It is however, limited only to natural persons.

Finally, Article 4(4)(g) reflects one of the other rationales discussed above, that in order for a state to encourage voluntary submission of environmental information for its own regulatory processes, it may limit disclosure. This article is a clear expression of that claim, the utility of which, as I noted above, may not always be as clear, given the structural incentives of market actors.

The discretion to agree to disclose is absolute under the convention and expressly does not allow for third parties to object to the release of information[37], but the discretion to refuse to disclose is restricted by a requirement of justification under Article 4(7) and the obligation to make available a review procedure under Article 9. Such a review must be conducted by a body independent of the public authority and should be judicial or quasi-judicial. Where it is judicial, an intermediate review body should also be available for expedited, cost-effective decisions. The procedure does not require the participation of the affected third parties or submitters of information under Article 4(4).

Importantly, the Aarhus Convention imposes not just a right to access information but imposes several positive obligations for the public authorities to engage in disclosure of specific kinds of information even absent requests to do so in Article 5(7) but still subject to the discretion to refuse to disclose information covered in article 4(4).

The implementation of these rules in national law has varied.[38] The convention itself has also addressed these issues as part of its interpretation of the treaties.

The rule for relating to other international treaties

Article 3(7) notes that parties must promote the aims and goals of the convention in any other negotiations on environmental treaties.

> *"Each Party shall promote the application of the principles of this Convention in international environmental decision-making processes and within the framework of international organizations in matters relating to the environment."*

Thus where environmental matters are addressed or triggered by another treaty, the parties must ensure that they should conform with their obligations under Aarhus. This does not make clear that Article 3.7 applies to obligations under the TRIPS Agreement or other bilateral and regional free trade agreements on protection of trade secrets or protection of undisclosed information submitted to the government although the WTO is included within the ambit of relevant fora.[39] In looking at the Almaty Guidelines on Promoting the Application of the Principles of the Aarhus Convention in International Forums (Almaty Guidelines)[40], the obligation is triggered by "decision-making processes within the framework of other international organizations in matters relating to the environment."[41] However, on public participation, the guidelines encourage states to ensure that these fora enable access to information on the processes and to ensure that refusals to provide information are based on the same rules and principles as in Article 4(3) and 4(4) of the Convention. The guidelines do not address the issue of how states should handle barriers to access to information in the substantive law of those fora. Examples are the rules on the protection of undisclosed information negotiated in TRIPS or bilateral and regional free trade agreements.

Other than the general statement, the Aarhus Convention provides very little guidance to countries on how they are to relate to other treaties. At the national level of course, the directions on how to address trade secrets and undisclosed information above have been very specific. Article 3(1) mandates states to ensure the compatibility of other provisions of law with the convention and to alter those laws that are incompatible. While not creating a hierarchy, this does specify that laws inconsistent with the obligation must be harmonized or justified. It also specifies that the Convention must nevertheless be made effective and incompatibilities removed or adjusted for while engaging in the proper public interest balancing mandated by the Convention.

37 ECE/MP.PP/C.1/2009/2/Add.1 (Findings with regard to communication ACCC/C/2007/21 concerning compliance by the European Community), para. 31 (b).

38 UNECE, The Aarhus convention – An Implementation Guide, Second Edition, 2014.

39 ECE/MP.PP/2005/2/Add.5 (decision II/4), annex.

40 ECE/MP.PP/2005/2/Add.5 (decision II/4), annex.

41 ECE/MP.PP/2005/2/Add.5 (decision II/4), annex, para 4.

The Aarhus Convention has been implemented by the member states of the European Union and has the EU and the European Economic Area countries (including Norway and Switzerland) as parties. The interpretations of the compliance committee and the implementation guide have significantly framed the implementation of the Aarhus Convention. In the EU, implementation took place through the Aarhus Regulation[42] as well as through the Environmental Information Directive.[43] In that context they have also had to deal with claims of confidentiality and when to disclose such information, as well as having to determine how the Aarhus Convention should relate to other access to information legislation in the EU, such as the Transparency Regulation.[44] Most significantly, the Aarhus Regulation applies the Transparency Regulation to environmental information.[45] In addressing the Transparency Regulation's treatment of confidential information, the Aarhus regulation, Article 6(1) shifts the traditionally restrictive approach to one that is more broadly favorable to release of information. Environmental information relating to emissions is defined as subject to the over-riding public interest necessary for the release of confidential information in the Transparency Regulation. In addition, the other grounds for refusal in the Transparency Regulation will be interpreted restrictively according to the Aarhus Convention. The Aarhus Convention does not establish a requirement that the concerned third party be consulted or have a right of review as in reverse FOIA-type frameworks. But the continuing applicability of the Transparency Regulation means that Article 4.4 still applies and consulting with the concerned third party is required even for environmental information. One recent case dealt directly with this issue, regarding a request for access to testing data and production methods submitted by firms seeking market entry of glyphosate into the EU. The Commission had refused to release the documents based on concerns that intellectual property and trade secrets would be disclosed.[46] The case revolved around the mandatory disclosure element that required information relating to emissions to be disclosed in which the Commission argued that part of the information on methods and identity of the impurities and products was not related to emissions and was therefore not an over-riding interest under the Transparency Regulation.[47] The Court ruled against the Commission arguing that the Aarhus regulation overruled and governed any other measures in any directive or regulation if it concerned environmental information related to emissions.[48] In addressing the relationship of the Aarhus Regulation to the EU Fundamental Charter of Rights and the European Convention on Human Rights (ECHR) on property, the Court essentially argues that the Aarhus Regulation is not in contradiction to these, especially given how clearly and unequivocally the Regulation addresses the balance between the public interest and the right to property in its text.[49] The decision has raised concerns that it fundamentally changes the expectations of firms submitting confidential information for marketing approval.[50] However, given the clarity of purpose of the Aarhus Convention, this very outcome was foreseen and intended by the drafters of the treaty and the regulation. Whereas all access to information regulations in the EU had previously been submitted to the Transparency Regulation, the Aarhus Regulation made the Transparency Regulation subsidiary in the specific case of environmental information. Thus much of the debate now in the EU will largely revolve around what is environmental information, and

42 Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies.

43 Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC

44 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents REGULATION (EC) No 1049/2001

45 Article 3, Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies.

46 Judgment of the General Court of the EU on Access to Information under Substance Law; Case T-545/11, Judgment of 08 October 2013.

47 Holleben, H., "Judgment of the General Court of the EU on Access to Information under Substance Law Case T-545/11, Judgment of 08 October 2013.", 4 Eur. J. Risk Reg., 565 (2013).

48 See p566, ibid.

49 Para 44, Judgment of the General Court of the EU on Access to Information under Substance Law; Case T-545/11, Judgment of 08 October 2013.

50 See p569, Holleben, H., "Judgment of the General Court of the EU on Access to Information under Substance Law Case T-545/11", op. cit. footnote 47.

what is information that relates to emissions into the environment with reference to practice in the Aarhus Compliance Committee. This conflict within the EU suggests that any Aarhus-like implementation of information disclosure of the Nagoya Protocol should make sure to define what information would be directly related to the mandatory requirements at a minimum by perhaps using an open list.

III.2 CONVENTION ON BIOLOGICAL DIVERSITY

The Convention on Biological Diversity (CBD) is in many ways an access to information treaty in that it aims to regulate the access to, terms of disclosure and use of information related to genetic resources and the distribution of benefits from such disclosure and use. In that sense it should reflect a balance that allows access, but makes effective the ability of all to trace and assess when and how benefit sharing should occur. To do so, transparency about who the holders of genetic resources are and the terms on which they will provide access is crucial. Also crucial is transparency about who the users of genetic resources are, the uses to which they put genetic resources, and the terms on which they are willing or able to share the benefits from their use of the genetic resources. Given the importance of such transparency, the CBD is not always entirely clear on the second part of that information equation, that is: how to determine who the users of genetic resources are and how and when they are using such resources.

The CBD and its Nagoya Protocol have several provisions where either information is to be shared and submitted to the CBD or its institutions, or parties are mandated to encourage - or require - submission of information to relevant national institutions. These include:

Article 14(1)(a) – "Introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity with a view to avoiding or minimizing such effects and, where appropriate, allow for public participation in such procedures";

This will require the generation and dissemination of such EIAs. The provision encourages states to allow for public participation and seems silent about access to such information but the conduct of EIAs implies submission to the government and broader public disclosure. As addressed below, the CBD makes no provisions for ensuring access to EIA information nor for how to address confidential or undisclosed information contained within it.

Article 15(7) – "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms."

Article 19(2) – "Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms."

Access to information on the source and the user is the core of the issue with respect to the utilization of genetic resources. How are parties to know that they are entitled to the results and benefits arising from biotechnologies unless there is transparency as to whom such resources are transferred to and the uses to which they are being put? While seemingly innocuous, the 'mutually agreed terms' places the onus on contractual behavior between providers and users. This ensures that any information will be dependent on the enforceability of contract terms not just in the provider country but in the user country and any subsequent country. The behavior of third parties not included in the contract will not be covered, nor will the behavior of those who access genetic resources without the consent of provider communities and countries. Thus the effectiveness of article 19(2) in the absence of access to information is problematic. The argument has been, and this is what should underpin the Nagoya Protocol, that access to information and disclosure as to the origin of genetic resources (in patent or other marketing approval or grant-making processes) is a necessary although not sufficient element ensuring proper access and benefit sharing under the Convention on Biological Diversity.

Internal rules for resolving conflict with protection of trade secrets and CBI

The CBD contains no guidance or rule on how access to information that it requires or implies should be balanced against protection of undisclosed information. The only guidance may be that as in many articles, the obligations are limited to those which are 'practicable' or are 'appropriate' seemingly leaving significant room to determine what is practicable or appropriate. From a strictly legal viewpoint, these terms seem to pose no barrier to countries placing limits of access to information based on concerns about confidentiality or protection of trade secrets.

The rule for relating to other international treaties

Article 22 of the CBD addresses the interaction of the CBD with other treaties. The article notes:

"1. The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.

2. Contracting Parties shall implement this Convention with respect to the marine environment consistently with the rights and obligations of States under the law of the sea."

The question is whether an agreement such as the TRIPS Agreement would be considered existing at the time of the signing of the CBD. The CBD was signed in Rio de Janeiro in 1992 and entered into force on 29 December 1993. Under this interaction clause, the TRIPS Agreement is a subsequent agreement under international law and is not subject to this savings clause in Article 22. Thus the TRIPS Agreement, signed in 1995 must be presumed to have been signed with the CBD in mind. Of course where the TRIPS Agreement might be considered a subsequent agreement on the same subject matter, then it may indeed be argued that it has altered the obligations of countries under the CBD. As noted in the later analysis on the TRIPS Agreement, there is no savings clause in the TRIPS Agreement for its relationship to prior international agreements.

This issue and in particular the argument regarding disclosure of origin in patent applications has become a broader element in the context of intellectual property generally and specifically in the relationship between the WTO TRIPS Agreement and the CBD, and the WIPO Patent Cooperation Treaty. This study will not replicate the entirety of that historical debate[51] but it has found expression in the argument that privatization through patents and other forms of intellectual property removes material from the communities where it has evolved and threatens the survival and evolution of the knowledge and the communities. The issue of disclosure of the origin of genetic resources has thus been raised at WIPO in the Standing Committee on the Law of Patents, and also led to the formation of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore. Developing countries and civil society groups have sought recognition of indigenous and other local communities' rights to their traditional knowledge and folklore and have proposed alterations to the international IP system to accommodate the concerns and rights of such groups. In particular they have pursued an amendment to the TRIPS Agreement requiring disclosure of the origin of genetic resources and associated traditional knowledge as a way of generating information relating to the use of genetic resources in the patent system. That amendment (Article 29bis), submitted in April 2011 by Brazil, China, Colombia, Ecuador, India, Indonesia, Kenya (on behalf of the African Group), Mauritius (on behalf of the African-Caribbean-Pacific Group), Peru, and Thailand[52] aims to ensure that all WTO members institute a disclosure of origin requirement in their patent law.

The justification for the Article 29bis amendment comes from the contention that allowing patenting on genetic resources sourced from or provided by communities and countries without their permission or without benefit sharing constitutes a violation of CBD obligations, specifically, Article 19 described above. There remains significant disagreement about what the proper relationship should be between the CBD and the TRIPS Agreement. But the particular stance one takes on this issue has implications for whether TRIPS rules on protection of trade secrets and undisclosed information should be seen as superseding or compatible with obligations on access to information in the CBD and more pertinently the Nagoya Protocol. The Article 22 statement from the CBD seems to make it relatively clear, but the content of its obligations may or may not entirely conflict with rules of protection of trade secrets under the TRIPS Agreement when it comes to information submitted to the government. In order to more closely examine the nature of the access to information obligations we need to look at the Nagoya Protocol's rules on how these issues are addressed.

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51 For more see: http://www.iprsonline.org/resources/biodiversity.htm.

52 Draft Decision to Enhance Mutual Supportiveness between the TRIPS Agreement and the Convention on Biological Diversity" (TN/C/W/59).

III.3 THE NAGOYA PROTOCOL

The Nagoya Protocol aims to more explicitly lay out the content of the provisions of Article 15, 16 and 19 of the CBD. It has several provisions requiring the submission of information.

Article 6.3(e)

"3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:
[...]

(e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit sharing Clearing-House accordingly;"

This implies that the body requiring PIC shall create such information, have possession of the contract outlining mutually agreed terms and communicate these to the ABS Clearing House. The language may allow for certification of the existence of these rather than the actual documents but it already creates a provision that requires submission of such information to a national body with an obligation to communicate it to an international clearing house mechanism. The exact nature and scope of the clearing house mechanism will be discussed below, but where such information is publicly accessible, which it should be, the interaction with undisclosed information then comes into play.

Article 14 establishes the ABS Clearing House as an information sharing mechanism. Under Article 14(2) it will receive mandated information from the national level provided by parties, as including:

"(a) Legislative, administrative and policy measures on access and benefit-sharing;
(b) Information on the national focal point and competent national authority or authorities; and
(c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms."

Crucially, the submission of information to the ABS Clearing House Mechanism is "without prejudice to the protection of confidential information." The content of this broad brush exception remains to be elaborated but one thing to note is that it embodies a similar construction as that under the Aarhus convention. Thus while it appears to suggest that any prejudice can prevent submission of information, it may be that, as under the Aarhus Convention, some harm or prejudice may be contemplated and balanced against the interest in accessing the information. In particular, it may be that where the information specifically concerns the identity of the user, and the uses to which they intend to put the accessed genetic resources, there may be a sufficient concern to over-ride certain kinds of relatively small harms. Of course, to the extent that research firms wish to keep particular research plans or strategies from competitors, such information may be economically valuable and lack of confidentiality may give away research head starts that such research firms have come to rely on. This balancing will need to take place in each market at the national level so it may be left to national focal points and national ABS clearing houses to manage the details of such conflicts. In addition, the international ABS clearing house will have to elaborate principles on which it will operate and it may be appropriate for that body to consider the Aarhus rules on access to information as models for its own operation.

The Nagoya Protocol also requires submission of information in other articles:

Article 17(1)(a)(iii) – "Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate;"

The information here includes information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources. Again, the submission of information is "without prejudice to the protection of confidential information". This therefore seems broader than just trade secrets but any information claimed to be confidential.

In looking at what the future ABS Clearing House may do with respect to the interaction between confidentiality and the need for access to information, the experience of the Biosafety Clearing House under the Cartagena Protocol[53] may be useful.

[53] Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Montreal, done at Cartagena on 29 January 2000.

The Cartagena Protocol in Article 20 (3) addresses Information Sharing and the Biosafety Clearing House. The BCH is open to any person who wishes to register. Article 21 specifically addresses confidentiality and states:

"1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential (author's emphasis). Justification shall be given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favorable than its treatment of confidential information in connection with domestically produced living modified organisms.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

a) The name and address of the notifier;
b) A general description of the living modified organism or organisms;
c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
d) Any methods and plans for emergency response."

In contrast, the Nagoya Protocol does not address the issue of confidentiality beyond the basic references. The Cartagena Protocol, on the other hand, very clearly states the information that may never be considered confidential, and while it allows for claims of confidentiality to be made it makes clear that:

- Submission of required information and disclosure to the biosafety clearing house is required and non-disclosure is an exception. In the absence of a claim of confidentiality, submission of information to the clearing house is automatic. This may be broader than trade secrets and apply far more broadly to cover any information claimed as confidential, even where it is non-commercial.
- The decision on whether to refuse disclosure rests with the national authority and is discretionary, but must be justified based on an assessment that the information is confidential, and any review of its decision need only be internal. Whether this comports with other obligations to protect such information will be examined below, but where such information must be protected under another law, then it is likely that at the very least an independent authority will need to assess the correctness of the authority's decision.
- Where the authority does believe that the information is confidential then, unlike in the Aarhus Convention, Article 21 requires that such information be protected absolutely against disclosure. There appear to be no exceptions to this.
- There are no restrictions on standing and access, according to the regulations of the BCH. Access to the BCH information is open to any person willing to register.[54] There is also no need to request information once it has been submitted: it is always available.
- There is a restriction on use, namely protection against commercial use by the authority. In this context such use by the authority can only be that which benefits other commercial actors. This has some parallels to arguments relating to pharmaceutical test data protection, where firms argue that the protection of data submitted to government authorities for marketing approval may not be used/relied on by the authority to approve other market actors' entry into the market. Whether this is a correct interpretation is in much dispute as the wording of the TRIPS obligation (Article 39.3), does not appear to place the restriction on the authority itself. In the context of the Cartagena Protocol such a restriction appears to be explicitly binding on the authority itself.

[54] See http://bch.cbd.int/database/

Overall, the details of the Cartagena Protocol show greater consideration of problems related to reconciling access to submitted information and claims of confidentiality. It may be that similar provisions may be drawn upon and function in the Nagoya Protocol context but absent a treaty provision, it seems countries will largely be left to their own national devices to determine how to appropriately balance the need for confidentiality with that of access to information. This will then depend on what rules they may have on access to environmental information; rules of access to information held by states generally such as through FOIAs; rules on the protection of undisclosed information and the limitations they may place on information submitted to government.

Looking at a particular implementation of these provisions of the Nagoya Protocol, the EU has adopted a Regulation on ABS.[55] Recital 14 states that the implementation should be mutually supportive with other international treaties and obligations provided that they are compatible with the principles and objectives of the Convention on Biological Diversity and the Protocol. The recitals, however, make no mention of the need to protect confidential information although Recital 26 mentions the importance of the ABS Clearing House mechanism for information exchange. Article 4 discusses the information that must be transferred from a user to subsequent users. It also identifies market approval as one of the checkpoints for determining compliance and the existence of PIC, certificate of origin and/or mutually agreed term provisions.[56] Submitted information is addressed in Article 7 on user compliance where information must be submitted to national authorities and the ABS Clearing House. As in the protocol, Article 7.5 states:

"The competent authorities shall take due account of the respect of confidentiality of commercial or industrial information where such confidentiality is provided for by Union or national law to protect a legitimate economic interest, in particular concerning the designation of the genetic resources and the designation of utilisation."

Interestingly, while adopting this rule, the regulation makes no mention of the EU's own rules on transparency and access to information especially including:

- The Aarhus Regulation 1367/2006[57] which implements the broad-based permissive framework for access to environmental information of the Aarhus Convention.
- The Transparency Regulation[58] (which contains a mandatory exception for confidential information and intellectual property) submitted by private parties.

This failure to mention or apply the Aarhus Regulation to the implementation leaves the information exchange elements at the mercy of developing case law and regulation in Europe on the protection of trade secrets, whether these are to be treated as human rights and subject to compensation for any regulatory interference.

The rule for relating to other international treaties

The Nagoya Protocol, written after many years of debate in other fora, but especially the WTO as to the appropriate relationship between the CBD and the WTO has an extensive chapter 4 on the relationship to other treaties. With that history in mind Article 4(1) reiterates the language of CBD article 22:

"1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments."

This now has a very different effect than the statement in the CBD. The TRIPS Agreement now functions as an existing agreement with respect to the Nagoya Protocol meaning that the savings clause now applies

55 Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union Text with EEA relevance. It entered into force on 9 June 2014. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0511&qid=1470686736899&from=en.

56 Article 4.6 Regulation ((EU) No 511/2014).

57 Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies.

58 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

to it. Thus the operative element for assessing access to information restrictions posed by protection of undisclosed information is whether allowing countries to engage in refusals to provide disclosure or access to information would result in serious damage or threat to the environment. This remains a very high threshold. In addition, this clause is now much more explicit, in that it does not aim to place its principle above those of other international treaties. This thus leaves few measures for imposing the obligations of this treaty on other treaty mechanisms or placing the values of the protocol higher in legal standing in national implementation than those of other treaties. On the other hand, Article 4 does allow for further agreements on the same topic and establishes the agreement as a floor.

Finally, Article 4(3) addresses the nature of implementation which, while not specifically mentioning the WTO or WIPO, adopts the language and terms of those opposing any legal measures to change those agreements to bring them into conformity with the CBD, i.e. 'mutually supportive'. The opponents of a disclosure of origin provision have long argued that there is no inherent conflict between the TRIPS Agreement and the CBD and that these can be implemented in a mutually supportive way. The language in article 4(3) adopts this same basic approach:

"3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol."

Overall, both in generality and in specifics, the Nagoya Protocol makes small gestures regarding confidentiality, but in doing so, it opens the doors to significant claims of confidentiality regarding the identity of users and the uses of genetic resources. This may fatally undermine the ability to keep track of those who engage in activities to which providers may have legitimate rights and benefits. By leaving so much to the national level in terms of determining when and how such claims of confidentiality are to be treated, the access to such information will be left to each country's rules on protection of undisclosed information, and on access to environmental and general information, as well as the existing domestic framework for reconciling clashing claims. By also making it clear that implementers of the Nagoya Protocol cannot appeal to international rules either placing the Nagoya Protocol on a superior footing under international law, or by requiring countries to seek compatibility and instead selecting for 'mutual supportiveness' as a framework, the parties to the Nagoya Protocol provide no further guidance on how to balance and decide conflicting claims regarding access to and disclosure of relevant information under the protocol[59]. This means that any room to maneuver may have to be found in the rules on protection of trade secrets and undisclosed information and how those rules provide for exception for the public interest, if at all, regarding information submitted to the government. Before examining other rules relating to this, the study will examine whether there are rules in human rights approaches that may enable access and or use, especially in the realm of pharmaceutical data.

59 Parties could however address future Meetings of the Parties of the Nagoya Protocol on the issue and give guidance.

IV. The International Human Rights Framework Affecting Access to and Use of Pharmaceutical Test Data

There exist no general international FOIA-like rules, especially in the arena of pharmaceutical test data. However, within the human rights framework there are two main approaches that may have implications for this area.[60] There is some good history on access to information as an integral part of the freedom of expression framework, which requires the ability to receive information in order to meaningfully participate in democratic governance. But this is an area that has been discussed above, though it has been less well developed in the context of the right to health. One area that has, however, significant implications is Article 15 of the International Convention on Economic, Social and Cultural Rights (ICESCR). Article 15(1) as a whole[61], requires states to recognize the right of everyone:

"(a) To take part in cultural life;
(b) To enjoy the benefits of scientific progress and its applications;
(c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."

In particular, we address ourselves to the first two parts of Article 15, which implicate to a significant extent the right to access and receive information. The Committee on Economic, Social and Cultural Rights (CESCR) has addressed this issue in a general comment on the right to take part in cultural life but has also addressed Article 15(1)(c). The scope and full legal meaning of Article 15(1)(b) has yet to be articulated. While conceptually attractive, there is very little literature on the relation of this article to access to information although there have been some attempts to address it in the right to health context. It is in that context that there may be purchase to go beyond simply requiring disclosure of information but to seek actual use of protected data for the purposes of allowing individuals access.

There are of course broader claims also being made out of the right to health framework generally, but it seems important in this study to focus on the information and undisclosed information elements of the discussion. There is ample work on whether the right to health may be able to justify various interventions related to intellectual property and this study will not reiterate that whole debate.[62]
Beginning with Article 15(1)(a), what does the committee have to say about access to information? In General Comment 21[63] the committee focuses on the cultural part of access and participation in knowledge, limited to culture, creative activity and the development of international contacts and cooperation in cultural fields.[64] This means that it should have little to say specifically about technical information or data or related information about the environment. However, the committee provides a sufficiently broad definition of culture to encompass concepts such as the environment in which people live. It notes:

"The Committee considers that culture, for the purpose of implementing article 15 (1) (a), encompasses, inter alia, ways of life, language, oral and written literature, music and song, non-verbal communication, religion or belief systems, rites and ceremonies, sport and games, methods of production or technology, natural and man-made environments (author's emphasis), food ..."[65]

Regarding the right to participate in cultural life, the committee notes therefore that everyone has the "right to seek and develop cultural knowledge and expressions and to share them with others, as well as to act creatively and take part in creative activity." The right also implicates access where everyone has the right to access information necessary to express, develop and influence their cultural environment.[66] The committee also emphasizes that a key element of the right is accessibility which includes the right of everyone "to seek,

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60 An earlier version of some of this material can be found in M. Orellana, D. Shabalala, B. Tuncak, "Technology Transfer in the UNFCCC and other International Legal Regimes: The Challenge of Systemic Integration.", ICHRP Working Paper 2010. Available at: http://www.ichrp.org/files/papers/181/138_technology_transfer_UNFCCC.pdf.

61 The Committee on Economic, Social and Cultural Rights views the provisions as a unitary set, despite the fact that it has chosen to elaborate different sets of General Comments to address each one.

62 See http://www.iprsonline.org/resources/health.htm. Recently the relationship between the right to health and intellectual property rights has been at the centre of the mandate of the United Nations Secretary-General's High-Level Panel on Access to Medicines, http://www.unsgaccessmeds.org/the-process/.

63 United Nations Economic and Social Council, Committee on Economic, Social and Cultural Rights, General comment No. 21, Forty-third session, 2–20 November 2009, E/C.12/GC/21.

64 See p2, ibid.

65 See p3, ibid.

66 See p4, ibid.

receive and share information on all manifestations of culture in the language of the person's choice, and the access of communities to means of expressions and dissemination."[67]

The obligations of the states therefore are to respect the right to access information.[68] The committee does not elaborate whether this is information held by the state but that may be addressed by the state's obligation to fulfill the right of access to information. Access to state-held information may also be required by the obligation to respect the right to "take part freely in an active and informed way, and without discrimination, in any important decision-making process that may have an impact on his or her way of life and on his or her rights under article 15, paragraph 1 (a)."[69]

However, the committee fails to fully elaborate on the obligation on the part of governments to provide and facilitate access to information held by the government. As discussed below, this is elaborated more concretely in the General Comment 23 on freedom of expression as embodied in the International Covenant on Civil and Political Rights (ICCPR).

The right to participate in cultural life does not seem to be able to extend sufficiently to support an obligation or the capacity of the state to allow 'use' of information held by it, that is implicated by the rights of others. That may be more easily found in Article 15(1)(b) as elaborated below.

Noting that the right in Article 15(1)(a) is not unlimited, the committee states that as with all rights elaborated by the ICESCR, there are intrusions into the rights which can be justified provided that:

> *"Such limitations must pursue a legitimate aim, be compatible with the nature of this right and be strictly necessary for the promotion of general welfare in a democratic society, in accordance with article 4 of the Covenant."*[70]

Thus, the protection of others' rights, including in rights to material and moral interests of their creation must be considered as a legitimate aim, as embodied in Article 15(1)(c). How this balance may need to be maintained will be discussed below in the discussion on Article 15(1)(b).

Article 15(b) would appear to establish an individual right for persons to benefit from scientific progress. Legally, this raises two questions: what does it mean to "enjoy the benefits," and what is meant by "scientific progress and its applications"? The history of the article suggests that a deliberate distinction was being made between pure scientific research, which is generally not done for purposes of commercialization and sale, and "the applications" of science, which are more applicable to technologies and more closely linked to patents and trade secrets.[71] Both categories of knowledge are included within the scope of the provision. The definition of benefit has not been elaborated. However, Article 15(1)(c) suggests that benefit should, at the least, mean access to the use of scientific knowledge and applications of which others are the authors. Some work has been carried out at UNESCO[72] on elaborating Article 15(1)(b). The provision has been included in the Universal Declaration on Bioethics and Human Rights (Article 15 (1))[73], which states:

> *"Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:*
> *(a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;*
> *(b) access to quality health care;*
> *(c) provision of new diagnostic and therapeutic modalities or products stemming from research;*
> *(d) support for health services;*
> *(e) access to scientific and technological knowledge;*
> *(f) capacity-building facilities for research purposes;*
> *(g) other forms of benefit consistent with the principles set out in this Declaration."*

67 See p4, ibid.

68 See p12, ibid.

69 See p13, ibid.

70 See p6, ibid.

71 Schabas, William A., "Study of the Right to Enjoy the Benefits of Scientific and Technological Progress and Its Applications," in Donders Y., and Volodin V. (eds) Human Rights in Education, Science and Culture: Legal Developments and Challenges, UNESCO 2007, at p275.

72 UNESCO "Report of Experts Meeting on the Right to Enjoy the Benefits of Scientific Progress and its Applications." Amsterdam, 7-9 June 2007. Available at: http://unesdoc.unesco.org/images/0015/001545/154583e.pdf.

73 Universal Declaration on Bioethics and Human Rights. Available at: http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html.

Thus, at least within the realm of health and bioethics, Article 15(1)(b) ICESCR has interpreted the concept of "benefit" to include access to scientific and technical knowledge, as well as the provision of new scientific products and capacity building. However, this has been in the context of research and what is owed to participants in research. To extend this approach to the use of pharmaceutical test data, a broader approach may be needed. UNESCO considers that the fulfillment of the right to enjoy the benefits of scientific progress and its applications is necessary for the fulfillment of other rights such as: the right to health, the right to education, the right to information and the right to food.[74] Thus, it may be that the power of the provision lies at its junction with the delivery of other rights.

There may be an inherent tension between IPRs and the right to enjoy the benefits of scientific progress (REBSP).[75] In part, this viewpoint has been informed by the experience of access to medicines activists in their attempts to ensure that the TRIPS Agreement was not interpreted in ways that restricted access to medicines for poor and marginalized populations. However, the direct link to the REBSP is relatively new, as the majority of actors have viewed the access to medicines issue through the lens of the right to health.

One could conclude that there is the need for a General Comment addressing the REBSP, especially its relationship to other economic, social and cultural rights.[76] In particular, the extent and nature of the relationship between the REBSP and other rights remains unclear and requires elaboration. Given the complexity of the needs and the different forms of technology implicated by each right, it may be appropriate to elaborate on that relationship on a case-by-case basis. Core to this are issues of balancing and conflicts of rights with Article 15(1)(c). General Comment 17 on Article 15(1)(c) has prompted groups to consider the relevance of Article 15(1)(b) in part because many felt that the committee had gone too far in the direction of privileging patterns of exclusive ownership over knowledge. However, the first thing that should be noted is that the General Comment is quite clear that while there may be parallels between human rights and IPRs, the content of Article 15(1)(c) is not synonymous with IP, by virtue of the different characteristics and the utilitarian nature of IP.[77]

The Committee on Economic, Social and Cultural Rights (CESCR) also recognized an intrinsic link between Article 15(1)(c) and Articles 15(1)(b) and (a).[78] Of particular relevance is the concept that the right in Article 15(1)(c) is not absolute and must be limited by the need to ensure that:

- the "moral' interests of the author are protected, i.e. the connection between the creator and the creation is maintained and that the aims and goals of the creator with respect to the creation are not unjustifiably distorted;[79] and
- the material interests of the author are protected, i.e. some kind of remuneration with respect to the creation is provided and is linked to some extent with the standard required for the author to make an adequate standard of living.[80]

Thus, as long as some form of recognition of creators is established and some form of ensuring earnings from the creation is maintained, states may deliver on Article 15(1)(b) by whatever means they choose. The beneficiaries of Article 15(1)(c) protection are also limited to natural persons or groups of natural persons, not legal entities.[81] Thus, neither transnational corporations nor states have direct claims under this article. States may, however, channel and facilitate the realization of this right. Thus, for the purposes of access to and use of pharmaceutical test data, while the rights to benefits may be exercised by the state on behalf of citizens, when dealing with the kinds of trade secrets and un-

74 See p4, UNESCO "Report of Experts Meeting on the Right to Enjoy the Benefits of Scientific Progress and its Applications." Op. cit., footnote 72.

75 Ibid. at 7.

76 Ibid., p9.

77 United Nations Economic and Social Council, Committee on Economic, Social and Cultural Rights, General comment No. 17, Thirty fifth session, 7 25 November 2005, E/C.12/GC/21. Available at: http://docstore.ohchr.org/SelfServices/FilesHandler.ashx?enc=-4slQ6QSmlBEDzFEovLCuW1a0Szab0oXTdImnsJZZVQcMZjyZlUmZS43h49u0CNAuJIjwgfzCL8JQ1SHYTZH6jsZteqZOpBtECZh96hyNh%2F%2FHW6g3fYyiDXsSgaAmIP%2BP.

78 Ibid., p2.

79 Ibid., p3.

80 Ibid., p4.

81 Ibid., p3.

disclosed information held by legal persons, the state does not need to engage in balancing of rights. States can privilege access to information and even use where the knowledge claimed is held by a legal entity rather than a natural person. Even where it is held by a natural person, it appears sufficient under the human rights framework that use is compensated in some fashion and moral rights are maintained.

A problem of carrying out a balancing exercise does arise much more specifically in those regions where intellectual property is protected as a human right, or as a fundamental right that can be held by legal persons. Intellectual property is established as a fundamental right in the European Fundamental Charter of Rights in Article 17(2), in the same way as property in Article 17(1). The European Convention on Human Rights (ECHR) has also acknowledged that intellectual property is a human right covered under the right to property in Article 1 of the 1st Protocol to the ECHR.[82] What remains under dispute within the European framework is whether undisclosed information, in particular trade secrets, are objects of property and are protected as intellectual property. For the moment, a recent study commissioned by the European Commission has shown that the vast majority of member states do not protect undisclosed information as intellectual property per se[83] but provide contract, unfair competition or criminal law protection. This has not been changed by the Directive on the Protection on Undisclosed Information[84] but the discourse on its adoption may encourage member states to treat undisclosed information as intellectual property, thus triggering the obligations regarding recognition and compensation under the ECHR and the Charter on Fundamental Rights.[85] This would cause greater problems precisely because while most intellectual property rights are aimed at disclosure as a natural consequence, trade secrets are aimed at secrecy. It is important to note that even within this framework of treating intellectual property as property, significant and frequent instances of interference with the right to property are allowed. In the ECHR several concerns have to be addressed, as Helfer[86] notes, including "the owner's reasonable expectations; imposition of an inequitable or excessive burden; the provision of compensation; the uncertainty created by the regulation; and the speed and consistency with which the state acts."[87]

If these concerns are addressed then interference with real property has traditionally been countenanced. Logically this would extend to the treatment of intellectual property and thus states are indeed free to establish interferences for public interest reasons, although the need for compensation may present an insurmountable barrier, which is what lies at the heart of the conflict between protection of undisclosed information and access to information. A rights-based approach to intellectual property makes it very difficult to envision a regulatory action that takes or interferes with a right but that does not provide compensation of some reasonable kind, increasing the costs of transparency to the state considerably. The peculiar nature of undisclosed information is exactly that the need for disclosure directly destroys the undisclosed nature of the information and thus implicates an absolute right so there can rarely be any balancing of harms.

What has been of the most significant concern has been the language of the General Comment on limitations outside the context of Article 15. The committee states that any such limitation must be proportional and "must pursue a legitimate aim, and must be strictly necessary for the promotion of the general welfare in a democratic society, in accordance with Article 4 of the Covenant."[88] The Comment contains very well-articulated sets of restrictions on what States must do to respect, protect and fulfill Article 15(1)(c), in

[82] See Dima v. Romania, App. No. 58472/00; Melnychuk v. Ukraine, App. No. 28743/03; Anheuser-Busch Inc. v. Portugal, App. No. 73049/01, 45 Eur. H.R. Rep. 36 [8301 (Grand Chamber 2007).

[83] Hogan Lovells International LLP Report on Trade Secrets for the European Commission Study on Trade Secrets and Parasitic Copying (Look-alikes) MARKT/2010/20/D (2010).

[84] See Directive 2016/943 of the European Parliament and of the Council of 8 June 2016 on the Protection of Undisclosed Know-how and Business Information (trade secrets) against their unlawful acquisition, use and disclosure, 2016 O.J. (L157) 59.

[85] See Bronckers, M and N McNelis "Is the EU obliged to improve the protection of trade secrets? An inquiry into TRIPS, the European Convention on Human Rights and the EU Charter of Fundamental Rights." 34(10), EIPR 673 (2012).

[86] Helfer, L "The New Innovation Frontier? Intellectual Property and the European Court of Human Rights", 49 Harvard International Law Journal 1-52 (2008)

[87] See p10, Helfer, L "The New Innovation Frontier? Intellectual Property and the European Court of Human Rights", 49, Harvard International Law Journal, 1-52 (2008).

[88] See p7, United Nations Economic and Social Council, Committee on Economic, Social and Cultural Rights, General comment No. 17, op. cit., footnote 77.

language that is virtually indistinguishable from that used in the context of IPRs. Therefore, in the absence of equally compelling language and discussion on Article 15(1)(b), states and private actors may provide greater protection to technology and knowledge holders, and focus less on providing access and benefits to scientific progress and its applications. As noted above, article 15(1)(c) is very clear in that it is not referring to intellectual property rights as the sole or only mode of protection and in fact exclusive rights are not necessary to fulfill the aims of article 15(1)(c). That does, however, mean that unlike in the European Charter on Fundamental Rights and the ECHR, undisclosed information may actually lie within the ambit of what is protected by Article 15(1)(c). Thus the expansive language limiting restrictions on the right are problematic for promoting access to and use of information.

Nevertheless, the General Comment notes that Article 15(1)(c) should not be implemented in a way that systematically impedes the fulfillment of other rights, such as the right to health, the right to education, the right to food, as well as the REBSP. In addition, a strong statement on balancing interests can be found in the discussion of the core obligations that states must comply with immediately to give effect to Article 15(1)(c) which includes:

> *"To strike an adequate balance between the effective protection of the moral and material interests of authors and States Parties' obligations in relation to the rights to food, health and education, as well as the rights to take part in cultural life and to enjoy the benefits of scientific progress and its applications, or any other right recognized in the Covenant."*[89]

Regarding information held by the state, the UN Human Rights Committee has elaborated on Article 19 (freedom of opinion and expression) of the ICCPR (International Convention on Civil and Political Rights) in General comments 10 and 34. General Comment 10 reiterates that the right to free expression must include the right to receive information of all kinds.[90] Regarding limits on the right, the Committee notes that restrictions have to be limited to those "provided by law"; only imposed for one of the purposes set out in sub paragraphs (a) and (b) of paragraph 3[91]; and they must be justified as being "necessary" for that State party for one of those purposes. In that context, the rights related to material and moral interests of creations fall under "protection of the rights of others".

General Comment 34 replaces and elaborates on the issues raised in Comment 10. In looking at limitations on the rights, including those to receive information and addressing in particular the states' obligation to facilitate and fulfill access to information, including that held by the state, the general comment explicitly states that there is indeed a right of access to information held by public bodies.[92] Again, this primarily drives disclosure and does not address itself to use. Nevertheless the comment provides a strong interpretation in favor of such access, even encouraging the adoption of FOIA-type legislation. However, the comment does not address or provide a framework for managing the potential conflict with undisclosed information held by the state.

Thus, generally, international and regional human rights frameworks provide little guidance for balancing the interests in access to publicly held information that is claimed as confidential by private parties.[93] Even where a right to such access is recognized it is limited according to the protection of the rights of others. The CESCR's expansive reading of Article 15(1)(c) also makes it difficult to frame a proper balancing test. More worrisome is that where undisclosed information may be treated as human rights subject matter, then compensation for interference with the right becomes a necessary part of any regulation to ensure access that may limit or destroy that right. While use may remain an option and compensation for use may be envisioned in those circumstances where valuable information is involved (such as that of pharmaceutical test data),

[89] See p7, United Nations Economic and Social Council, Committee on Economic, Social and Cultural Rights, General comment No. 17, op. cit., footnote 77.

[90] See para. 2, General Comment 10, Article 19 (Freedom of opinion and expression), Human Rights Committee, 1983.

[91] (a) For respect of the rights or reputations of others; (b) For the protection of national security or of public order (ordre publique), or of public health or morals.

[92] See para. 18, General Comment 34, Article 19 (Freedom of opinion and expression), Human Rights Committee 2011. See also "Joint Declaration. United Nations Special Rapporteur on Freedom of Opinion and Expression. Organization of Security and Cooperation in Europe (OSCE) Representative on Freedom of the Media. & Organization of American States (OAS) Special Rapporteur on Freedom of Expression. (Dec. 6, 2004).

[93] See in support Kravchenko, S., "Is Access to Environmental Information a Fundamental Human Right?" 11, Or. Rev. Int'l L. 227 (2009).

treating trade secrets as IP subject matter makes any disclosure an interference or destruction of the right and subject to compensation. It is therefore fundamental and crucial that countries implementing the Nagoya Protocol and concerned with ensuring access to clinical trial data do not treat undisclosed information as human rights subject matter. Such an outcome would interfere, for example with the release of clinical trial data by the European Medicines Agency (both in the present and in the proposal for automatic release[94]), which does not consider information submitted to it for the purposes of safety and health testing as a trade secret, or as it refers to it, commercially confidential information. It also states that even if so, where the information is for this particular purpose, the strong public purpose over-rides that of the submitter.[95] In combination with a harmonized standard for the existence of trade secrets under the proposed Directive on undisclosed information[96] this would make the release of such information subject to compensation placing a significant barrier to transparency by the EMA. Use on the other hand is deeply restricted in the European Union due to its data exclusivity regime for that same clinical test data.[97] In that sense, the restrictions on use make the argument for disclosure much stronger as the 'harm' from such disclosure is minimized and limits activity by competitors to enter the market based on that data.

94 See EMA "Policy 70: Publication and access to clinical-trial data", http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/06/WC500144730.pdf.

95 Ibid.

96 Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure . Available at: http://ec.europa.eu/internal_market/iprenforcement/trade_secrets/index_en.htm

97 Article 10 of Directive 2004/27/EC (amending 2001/83/EC)

V. Conclusions on Access to Information Regimes in the Environmental and Health Arena

In looking at the access to information rules in the international treaties with which we are concerned (the CBD and the Nagoya Protocol) it seems that, absent the Aarhus Convention, there is little guidance to national authorities on how to manage and treat access to confidential information. There is an understanding that the relationship needs to be managed but no guidance on the key elements that we have identified in the first section of this study. The human rights framework provides little further guidance on how to address the conflict between access and confidentiality, or use of such information, and may in fact be a negative for access and disclosure. What can be noted is that the Aarhus Convention continues to provide a strong framework for ensuring access and best reflects the public interest framework. Even where countries are not signatories, they may wish to pursue a framework based on the Aarhus Convention in order to ensure the best available information for ABS implementation. In terms of international treaties and examples that may better enable use, the human rights framework provides little purchase for use, except perhaps through the long existing arguments relating to the right to health.

Thus, in implementing the Nagoya Protocol, states are primarily left to their own devices in national law in reconciling access to information and the demands of confidentiality relating to publicly held information.

Without an international treaty or rules enabling stronger access, then the primary limiting factor will be the states' obligations on protection of undisclosed information or trade secrets. Thus each state's access to information regime (e.g. the Right to Information Act in India; the Promotion of Information Act in South Africa; Aarhus implementation in the European Union) may end up being the default process. The Aarhus countries will likely continue to run into some of the problems described above but the non-Aarhus countries will have to apply their existing framework on freedom of information to address the decision points outlined in the flowchart on page 14 above.

Finally, this section clearly outlines the fact that there is little or no international treaty support for use by third parties (or the state itself) of information submitted to government authorities. Thus the scope of use will almost be exclusively determined by the extent to which the requirements for protection of information submitted to governmental bodies must be protected.

VI. International Provisions on Protection of Undisclosed Information

This section seeks to outline the extent to which the TRIPS Agreement may limit the ability of countries to enable access to confidential information. The TRIPS Agreement is the primary international set of rules for the protection of trade secrets and undisclosed information. It incorporates the previous major international treaty on the same subject matter, the Paris Convention for the Protection of Industrial Property. In addition, in the period following the TRIPS Agreement, many countries have signed onto bilateral and regional free trade agreements with more extensive protections for trade secrets and undisclosed information. This study will not examine each and every one of these but will suggest that taking on additional obligations beyond those under the TRIPS Agreement may be inappropriate if access to information is to be properly enabled. In the TRIPS Agreement the rule for protection of undisclosed information can be found in Article 39.

The internal rules for relating to public disclosure and access to information

Article 39(1) states:

"In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3."

Paragraph 3 is what is most relevant to this study and requires governments to protect such information against three core acts: false allegation, confusion, and misleading statements regarding quality, source, processes, and manufacturing based on the Paris Convention. In the final case, the aim may have been to try and prevent the use of statements regarding equivalence, e.g. that generic medicines are equivalent to the branded protected medicines. In all cases, this paragraph restricts itself to use of information rather than disclosure of such information.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
(b) has commercial value because it is secret; and
(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

This is the paragraph that adopts the current framing in most jurisdictions regarding protection of trade secrets. This is the new element that TRIPS introduced that requires all states to provide protection not simply against use but also against disclosure. It also embodies a softer requirement that continues to protect the information even if it is known to some in the field as long as it is not 'generally' known. In addition, a footnote provides even more detail noting that "For the purpose of this provision, 'a manner contrary to honest commercial practices' shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition." This therefore reflects the attempt to extend secondary liability. However, the manner of implementing such protection is not addressed but left up to states, as long as it is at least sourced in unfair competition law as defined by the Paris Convention and Footnote 10 of TRIPS Article 39.2.[98] This reflects the basic viewpoint of the majority of states at the time of signing the TRIPS Agreement that trade secrets were not objects of property in the same way as traditional intellectual property. There is some argument, most notably from Bronckers and McNelis[99], that TRIPS actually requires that trade secrets be protected as intellectual property and not simply through unfair competition law. They argue that to provide protection through unfair competition law would be to negate the meaning of Article 39.2 since Article 10bis of the Paris Convention is not intended to provide protection for trade secrets. A counter to their argument is that Article 39.2 is meant to create precisely that link between unfair competition law and trade secrets that the Paris Convention failed to do and that the aim was to justify being able to place these further rights and restrictions in the TRIPS Agreement. Without reference to the Paris Convention,

98 VAN OVERWALLE, G., 'Uncorking Trade Secrets: Sparking the Interaction Between Trade Secrecy and Open Biotechnology', in Rochelle Dreyfuss and Katherine Strandberg (eds.), The Law and Theory of Trade Secrecy: A Handbook of Contemporary Research.

99 Bronckers, M. and N. McNelis "Is the EU obliged to improve the protection of trade secrets? An inquiry into TRIPS, the European Convention on Human Rights and the EU Charter of Fundamental Rights." 34(10), EIPR 673 (2012).

the Article 39 obligations would have been sui generis for most states, in a similar way that obligations of geographical indications were. As I note above in the section on human rights frameworks, treating trade secrets as intellectual property would then bring them under the protection of the ECHR and the European Charter of Fundamental Rights, which would require compensation for any disclosure or use, a key conclusion of Bronckers' and McNelis' paper.

The possibility to prevent action does not seem to encompass action by the government to use or require submission of trade secret information. Thus the possibility to prevent third parties does not necessarily extend to the possibility to prevent the government from requiring submission of the information, or from disclosing such information to third parties or the public. The fact that there is no exception for disclosure for the public interest is not pertinent here as Article 39.1 and Article 39.3 are meant to cover the obligations of states with respect to information that they require individuals or firms to submit to them. There may however be an argument that the right does extend to the government itself, where the actions of the government can be characterized as acting in a manner contrary to honest commercial practices. As such, if the government were to act as a commercial actor capable of engaging in the four behaviors outlined in footnote 10:

- breach of contract
- breach of confidence
- inducement to breach
- acquisition by third parties who know, or were grossly negligent in failing to know, that such practices were involved in the acquisition,

then a claim could be made that, not only the state was not in compliance with its obligations under the TRIPS Agreement, but that under national law it could be sued as a violator of the rights itself. Thus for information beyond the scope of pharmaceutical and agricultural test and other data necessary for marketing approval, Article 39.2 may still be relevant as a potential limitation. The absence of an exception to Article 39.2, even for the public interest means that we would have to fall back on the broader framework of Article 7 and 8.1, discussed in more detail below. There is little literature on this and no case law at all, but it seems unlikely that a WTO panel would look at Article 39.2 as limiting government action when government action relating to undisclosed information is clearly placed under Article 39.3 by Article 39.1.

Finally, the final part of Article 39, addresses marketing approval for pharmaceutical and agricultural products.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Thus a first look at Article 39.3 notes that it only imposes obligations of governments regarding the protection of such information in very specific circumstances: *only* when they require that such information be submitted for *marketing approval* of agricultural and pharmaceutical products which use *new chemical entities*. Thus when the information is submitted for purposes other than marketing approval, the obligations in Article 39.3 are not triggered. Where the data does not concern new chemical entities, the obligation is not triggered. And where the data is not about agricultural or pharmaceutical products the obligation in Article 39.3 is not triggered.

The first question that arises is the scope of the information to be protected. The same phrase "undisclosed' is used to describe the data or information suggesting that therefore the same definition of undisclosed information is being used for articles 39.2 and 39.3. Article 39.2 uses the term 'information lawfully in their control from being disclosed to' in its chapeau, whereas secrecy is defined in the subprovisions below. Does this actually mean that Article 39.3 protection extends to information that is undisclosed but that does not necessarily meet the standard of secrecy in Article 39.2a, b and c? That seems to be an absurd reading of an article that should be taken to be using similar terms to have similar meaning. This may be borne out by the fact that the only requirements for triggering the obligation in 39.3 is that the information be undisclosed, and that the origination of the data required considerable effort.

Thus the undisclosed information that must be protected under Article 39.3 must conform at least to the requirements of undisclosed information that must be protected under Article 39.2. However, Article 39.3 adds an additional criterion that the origination of the information must have involved considerable effort. A plain reading would suggest that this is an additional requirement for such information to meet, rather than an alternative to the one already described in Article 39.2. There is no compelling reason anywhere else in

the text that requires us to believe that the meaning of undisclosed data or information as used in Article 39.3 is not at least bounded by what is required in Article 39.2.[100]

Article 39.3 then requires states to protect such information from not just unfair competition but from actual disclosure, thus going beyond simply preventing use. Disclosure can thus only be justified in the interests of protecting the public. The last line also suggests that disclosure can be allowed provided that unfair commercial use is prevented, suggesting that as long as disclosure rules prevent use and allow a trade secret holder to nevertheless prevent others from making use of the data under Article 10bis of the Paris Convention and Footnote 10 of Article 39.2. There has been no interpretation of this provision in the WTO Dispute Settlement process.[101] However, several commentaries have outlined what they believe to be the content and extent of this requirement. Gervais addresses the negotiating background. He does not specifically address the issue of what would constitute 'protection of the public' except to note that it should be commensurate with the exceptions in GATT article XX(b). However, given that TRIPS has its own exceptions, in articles 7 and 8, as well as articles 30 and 31, it would seem more appropriate to refer to those rather than the GATT. Given the jurisprudence on the issue in the Canada – Pharmaceuticals case[102], the level of necessity required to justify disclosure may be problematic. This is addressed later in this section. However, Gervais does elaborate on what he believes to be the scope of protection against unfair commercial use.[103]

Looking at "protection of the public" one can at least outline the evolution of this phrase and related concepts in the various drafts preceding the final TRIPS text. The Brussels draft Article 4A, provided for five-year exclusivity against use by the agency (e.g. relying on the data for approval of drugs), and additionally protection against disclosure with the same exact wording of "except where necessary to protect the public".[104] However, almost all of the article was bracketed meaning that it was a proposal but not an agreed part of the text per se. In the Draft of July 23, 1990; the conditions under which disclosure is allowed could take place were elaborated in articles 3Ab.1 – 3Ac.2. In 3A.b.2 allowed disclosure only to the extent "required to carry out necessary government functions".[105] This seems somewhat broader than the language restricting it to those conditions necessary to protect the public. On the other hand, a governmental interest may be construed somewhat more narrowly than a public interest, thus affecting the standing of those who seek information. Thus under that formulation, individuals, especially under FOIA frameworks, would likely not have standing to seek disclosure. In any case, the proposed text would provide for confidentiality obligations or agreements to be imposed or negotiated with the person to whom the information was disclosed. Thus broad public dissemination is clearly not envisioned as part of what would be allowed. This is especially clear in Article 3Ab.3, which allows disclosure to protect human health or safety or to protect the environment, but also allows limits to be placed on the person to whom the information is disclosed.[106] On the other hand, proposed text in Article 3Ac.1 offered an alternative that general disclosure is allowed but only to the degree indispensable to inform the public of the actual or potential danger of a product. This at least seemed to envision release to the public as a whole, without any compensation. Finally, Article 3Ab.1 at least envisioned that the use of the information by a third party under a government permission or license would be appropriately compensated, suggesting at least that it was understood that trade secrets could indeed be made available under a compulsory license as long as confidentiality obligations were imposed.[107]

The question now is whether the final text is narrower or broader than the original drafts. The lack of a requirement to allow for confidentiality obligations or the opportunity to negotiate such obligations suggests that the limits on receivers of such information have been removed from the final text. The rationales for such release may however be narrowed where

100 See p427, Gervais, Daniel, The TRIPS Agreement: Drafting History and Analysis: Third Edition, (London: Sweet & Maxwell, 2008).

101 WTO Analytical Index. Available at: http://www.wto.org/english/res_e/booksp_e/analytic_index_e/trips_03_e.htm#article39B

102 Panel Report, Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R, adopted 7 April 2000, DSR 2000:V, 2289 (Canada – Pharmaceutical Patents).

103 See p424, Gervais, Daniel, The TRIPS Agreement: Drafting History and Analysis. Op. cit., footnote 100.

104 See p421, ibid.

105 See p423, ibid.

106 See p423, ibid.

107 See p423, ibid.

protection of the public is not framed in particular as action necessary to protect human health and safety of the environment. However, what is finally clear is that disclosure for the needs of protection of the public was the final text that won out, likely encompassing protection of human health and safety and protection of the environment. Broader disclosure to the general public is also envisioned as part of this article as the proposals to limit such disclosure did not survive the negotiating process. The article even provides a dual framework for disclosure: where steps are taken to ensure protection against unfair commercial use, there may be no necessity to actually show a need to protect the public.

Now, while it is clear that the article contains its own exception that allows disclosure, the question does arise as to whether it should be consistent with the other exceptions in the TRIPS Agreement. The TRIPS Agreement contains no General Exceptions article such as that embodied by GATT Article XX, but for each specific category of rights, it establishes a standard exception (for copyright in Article 13, for trademarks in Article 17, for patents in Article 30). So while there is no specific exception for undisclosed information under Article 39, the article contains its own allowances. One phrase that it uses which is not found in the other provisions is the use of "necessary' to protect the public. This makes it important to then look at Article 8.1 of the TRIPS Agreement which uses the same concept of necessity and embodies the same concern for balancing.

The 'necessity' requirement in Article 8.1 of the TRIPS Agreement, states that:

> *"Members may, in formulating or amending their laws and regulations, 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." (Emphasis added)*

The only panel that has addressed the interpretation of Article 8.1 appears to have simply treated Article 8.1 as synonymous with the limitations and exceptions enumerated in TRIPS articles 30, 31 and 40.[108] The issue is complicated by the fact that, unlike GATT Article XX, exceptions which are premised on the idea that the measures in question are not in conformity with the other requirements of the GATT, in the case of TRIPS Article 8.1, the text already states that such provisions must be in conformity with the TRIPS Agreement before they are tested. The key part of the provision that enables this is the final element of the sentence: 'provided that such measures are consistent with the provisions of this agreement.' The task for any person seeking to give content to an exception in TRIPS is to determine the exact effect of that last sentence of Article 8.1.

As an initial premise, we must establish that Article 8 has to be given full effect and cannot simply be left as a statement devoid of any specific legal content. It cannot be that Article 8 is entirely subsumed by articles 30 and 31 and other limitations and exceptions.[109] The first part of Article 8.1 must be given content separate from that of other articles on limitations and exceptions and on balancing rights and obligations. Whereas the public interest exception to protection of undisclosed information in Article 39.3 can be considered a specific subset of situations under Article 8, the article itself recognizes a broad right that itself constitutes an additional scope beyond those of the 'exceptions' in the TRIPS Agreement. In this case, the Article 39.3 exception for disclosure to protect the public is not only subsumed by Article 8.1 but uses the same language to further specify the ways in which the public may be protected.

In addition, Article 8 has to be seen as a reiteration of the basic principle of state sovereignty and rights to make policy in these crucial areas. As such, restrictions on that broad right must function as exceptions and should be construed narrowly, even where those rights are restricted by being submitted to regulation under an international treaty. The burden for non-compliance with Article 8 should be on those claiming that the discretion under the broad right established by Article 8.1 has been abused.

However, that burden may be shifted by the last sentence of Article 8.1. We are therefore tasked with answering the question of what is meant by "consistent

108 Panel Report, Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R, adopted 7 April 2000, DSR 2000:V, 2289 (Canada – Pharmaceutical Patents). Earlier versions of the following analysis appeared in D. Shabalala "TRIPS and Technology Transfer for Emissions Reduction." In D. Prevost and G. van Calster, Research Handbook on Environment, Health and the WTO. Edward Elgar, 2013.

109 For a slightly contrary view, see p121, Gervais, Daniel The TRIPS Agreement: Drafting History and Analysis, op. cit., footnote 100, who views article 8 as primarily a statement of the policy embodied on Articles 30, 31 and 40.

with the provisions of this agreement". By definition this must of course include all the TRIPS articles. Thus Article 7[110] is one of the measures of consistency with the agreement, just as much as articles 27, 30, 31 or 39.3. The phrase may also have the consequence of shifting the burden of proof that would normally be the case in a positive obligation such as this one. In this case, we understand that the burden of showing that a measure is not in compliance with the provisions of the TRIPS Agreement lies with the defendant. The question is whether such a finding is final and dispositive regarding the TRIPS Agreement. Is it the case that where a measure is found to be in violation of one of the rights established by Article 39.3 that Article 8 cannot be used as an independent defence? That appears to be the case if the language is taken literally. This appears to be the same outcome even where a violation of Article 39.3 is found, and it is not excused under the public protection exception or any other exception.[111] Given the literal content of the last part of Article 8.1, it does not appear possible to access or give content to the first part of Article 8.1 where a measure is already found to be inconsistent with any of the provisions of the TRIPS Agreement. Does that mean that the first part of Article 8.1 has no content? This would clearly be an absurd outcome and thus requires some recourse to supplementary materials under Article 32 of the Vienna Convention on the Law of Treaties.[112]

The formulation in Article 8.1 is unique and not found in any of the other WTO agreements. For there to be an article that appears to allow flexibility to address key issues but conditions that flexibility on compliance is an unusual but, it appears, deliberate approach. Some sense of the meaning of the provision can be found in looking at the legislative history of the two related provisions, Article 7 and Article 8, of the TRIPS Agreement in the Uruguay Round negotiations which led to the agreement.

The main body of the Anell text[113] included a draft on 'Principles':[114]

8 Principles

8B.1 PARTIES recognize that intellectual property rights are granted not only in acknowledgement of the contributions of inventors and creators, but also to assist in the diffusion of technological knowledge and its dissemination to those who could benefit from it in a manner conducive to social and economic welfare and agree that this balance of rights and obligations inherent in all systems of intellectual property rights should be observed.

8B.2 In formulating or amending their national laws and regulations on IPRs, PARTIES have the right to adopt appropriate measures to protect public morality, national security, public health and nutrition, or to promote public interest in sectors of vital importance to their socio-economic and technological development.

8B.3 PARTIES agree that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and enhance the international transfer of technology to the mutual advantage of producers and users of technological knowledge.

With respect to Article 8.1, the later Brussels Draft[115] stated:

1. Provided that PARTIES do not derogate from the obligations arising under this Agreement, they may, in formulating or amending their national laws and regulations, 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.

110 This requires that 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."

111 Article 30 states: Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

112 As argued by Frankel, S., "WTO Application of 'the Customary Rules,'" 46 Va. J. Int'l L. 390 (2006), noting that the WTO panels and Appellate body have spent too little time looking at the object and purpose of the agreement as required by the interpretive approach of Articles 30 and 31 of the Vienna Convention on the Law of Treaties.

113 This was a draft titled "Chair's Draft", produced by the Chair of the TRIPS Negotiating Group, Mr Lars Anell in June 1990, on his own responsibility and then later adopted as a formal negotiating document. The text was "Chairman's report to the Group of Negotiation on Goods, document MTN.GNG/NG11/W/76, dated July 23, 199 cited by Daniel Gervais "The TRIPS Agreement: Interpretation and Implementation" E.I.P.R. 1999, 21(3), 156-162, p157.

114 See p 122, ICTSD/UNCTAD Resource Book on TRIPS and Development. UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights, June 2005, available at: http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm and Cambridge University Press, 2005.

The constraint in Article 8.1, as it was finally adopted, is that the measures they adopt should not violate the terms of the agreement. The ICTSD/UNCTAD Resource Book on TRIPS and Development suggests that 'measures adopted by Members to address public health, nutrition and matters of vital socio-economic importance should be presumed to be consistent with TRIPS, and that any Member seeking to challenge the exercise of discretion should bear the burden of proving inconsistency'.[116] This approach presumes that the sequence of examination begins with whether the measures are of the kind envisioned, and if they are, then it goes on to address the issue of whether they are inconsistent. Under such an approach, there therefore exists a difference in scope between exceptions, and Article 8. Thus, where a measure is aimed specifically to "protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development" then Article 8 would create a presumption that the measure is consistent that must be rebutted by the complainant. Article 8 would thus shift the burden for public interest measures. This would require that a claim be structured in the following way: the complainant would assert that a measure either does not fall under those contemplated by Article 8.1, and even if they did, the measure was not consistent with the provisions of the TRIPS Agreement. The burden of showing inconsistency would then lie with the complainant which can be crucial in the weighing of evidence. This approach however only allows Article 8.1 to have a burden shifting role in certain situations. But this does not negate the fact that compliance with Article 8.1 would remain dependent on either not violating a right granted by a provision or by coming within the boundaries of an exception or limitation enumerated elsewhere in the TRIPS Agreement. There would still be no substantive effect to the first half of Article 8.1

An alternative approach to that advocated by the authors of the Resource Book on TRIPS and Development would be to take the approach that measures must be consistent with the rest of the TRIPS Agreement before they will be covered by the terms of Article 8.1. In that case, an examination of consistency takes place first and if the measures are found to be inconsistent, Article 8.1 plays the role of a thumb on the scale to move measures that fall under its coverage back into consistency. This would not necessarily be in literal line with the wording of the article but not doing so leaves the first part of Article 8 devoid of content. The negotiating history, as well as the broader context in which the TRIPS Agreement stands suggests that literal consistency with the TRIPS Agreement cannot be the limit of the effect of the provision. Why is the 'necessity' language in there if the consistency requirement has to be met? Article 8.1 cannot simply be co-terminous with the sum of the exceptions and limitations in the agreement. If that is the case why have Article 8.1 in the first place? Thus there must already be a sense in which the measures contemplated by Article 8 go beyond the strict limits of consistency. Necessity therefore could be seen as controlling how far outside the limits of consistency they may go and that it may not allow the provisions of the agreement to be entirely null and void. However, the use of almost exactly the same language in Article 39.3, "necessary to protect the public", suggests that there is no distinction between the scope of the examination in the first half of Article 8.1 and that in Article 39.3. A finding that disclosure was necessary to protect the public under Article 39.3 would by definition be consistent with the Article 8.1 requirement that the measures be consistent with provisions in the TRIPS Agreement. Thus either Article 8.1 shifts the burden of the examination of necessity under Article 39.3, or it is at the very least co-extensive with any finding in Article 39.3 exceptions for public protection.

In addition, Article 8.1 is supported by Article 7, with which the states must also comply in their implementation of the TRIPS Agreement.[117] Authors such as Derclaye[118] and Correa[119] argue that Article

116 See p 127, ICTSD/UNCTAD, Resource Book on TRIPS and Development. Op. cit., footnote 114.

117 Article 7 states: 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

118 p270, Derclaye, Estelle, 'Intellectual Property Rights and Global Warming', 12 J. MARSHALL REV. INTELL. PROP. L. 263 (2008). Available at SSRN: http://ssrn.com/abstract=1016864.

119 Correa, Carlos M., Trade Related Aspects of Intellectual Property Rights: A Commentary to The TRIPS Agreement, 99-101 , Oxford University Press (2007).

7 establishes that intellectual property rights clearly must be in service of broader social values. Where the provision of rights contradicts or conflicts with broader public welfare goals, the article provides a means by which IPR protection can be modified, diminished or removed. Correa also argues that while Article 8.1 contains the limitations on 'consistency', Article 7 does not, and so one of the provisions with which Article 8 must be consistent is Article 7, as well as the preambles.[120] Thus, as an overriding principle, interpreters are bound to ensure that Article 7 is given as much effect as any other provisions of the agreement and cannot be considered only hortatory.

Article 7 provides guidance for the interpreter of the TRIPS Agreement, emphasizing that it is designed to strike a balance among desirable objectives. As Article 7 makes clear, TRIPS negotiators did not mean to abandon a balanced perspective on the role of intellectual property in society. However, given the structure of Article 8.1 the approach that seems to have won out over others is that any attempt to justify measures to protect health and nutrition and to promote the public interest in sectors of vital importance to socio-economic and technological development cannot rely solely on articles 7 and 8 but must enter first through other provisions in the TRIPS Agreement and then, in the course of applying these articles use the weight of articles 7 and 8.1 to tip the scales in favor of justifiable policy actions. This has ostensibly been the approach taken in the context of the interpretation of TRIPS provisions relating to exceptions and limitations.[121] The interpretation of articles 7 and 8 remains unclear, however, as the Appellate Body itself has found that Article 7 and 8 have yet to be interpreted in a way that provides guidance to their applicability in future cases.[122]

It is not clear that Article 8.1 has truly been given content, such that members are actually able to take measures to protect human health and nutrition and to promote the public interest in sectors of vital importance to socio-economic and technological development. To the extent that a necessity test is not applied in the evaluation of TRIPS measures to address public health and nutrition and promote the public interest, the more difficult it may be to escape narrow interpretations of TRIPS flexibilities.

Despite the difficulties above, the inclusion of the necessity element in Article 39.3 means that the full weight of Article 8.1 can probably be brought to bear on disclosure actions taken to protect the public. In addition, the language is clear that remuneration for disclosure is not required where it takes place in order to protect the public.

Such necessity may also suffice to remove the protection against unfair competition for use when combined with disclosure, although Article 39.3 itself provides no exception for the protection against unfair commercial use when disclosure has not taken place. Again, there is little precedent or rationale for this in the text or jurisprudence, and there is little evidence that Article 8.1 can act as an independent defense to an infringement on rights.

Looking at "sufficient protection against unfair commercial use", a key question is whether the unfair commercial use described in 39.3 has the same meaning as "a manner contrary to honest commercial practices" as used in 39.2. This is key as the definition of the latter is provided by a minimum level in Footnote 10. The definition thus includes at a minimum:

- breach of contract
- breach of confidence
- inducement to breach
- acquisition by third parties who know, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

The protection must be against:

- disclosure,
- acquisition and
- use

through any of the methods above.

There is little guidance as to whether unfair commercial practices and dishonest practices are indeed the same concept, i.e. that unfair commercial practices amount to the same thing as contrary to honest practices. This wording is drawn directly from the Paris Convention Article 10bis 2, and to which many countries responded

120 See p107, ibid.

121 para 7.26, Panel Report, Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R, adopted 7 April 2000, DSR 2000:V, 2289 (Canada – Pharmaceutical Patents).

122 Para 101, Appellate Body Report, Canada – Term of Patent Protection, WT/DS170/AB/R, adopted 12 October 2000, DSR 2000:X, 5093 (Canada- Patent Term).

by applying their law on unfair competition. However, at the very least it is clear that while unfair commercial 'use' is limited to use of the information by third parties, as is logically implicated by the text, paragraph 2 of Article 39 provides broader protection including both acquisition and disclosure of the information. More interesting is that the obligation in 39.3 does not simply directly refer to the scope of protection in 39.2, thus suggesting that a different scope of protection was truly meant. Some clue may however be gleaned from the phrasing in 39.1, that the obligation to protect under paragraph 2 and 3 is done so in pursuance of the obligation to protect against unfair competition from Article 10bis of the Paris Convention. Thus, it may be that the specific obligations of Article 39.2 are subsets of the general protection afforded by unfair competition law or that they are specific implementations of the unfair competition obligation in Article 10bis of the Paris Convention. It is not clear that we should apply the definition in Article 39.2 rather than the standard in Article 10bis which extends at a minimum to:

(i) all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor; (
(ii) false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;
(iii) indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods.

The minimum standard in Article 10bis remains very different from that articulated in Article 39.2 which identifies and focuses on the manner of acquisition, disclosure and use. It may be that the basic Article 39.2 is additional rather than alternative to Article 10bis(3), but they clearly set different thresholds and since Article 39.3 very explicitly does not refer to Article 39.2, a plain reading suggests that the applicable threshold is more likely to be Article 10bis.

Under 39.2 the disclosure, acquisition and use must be a) without consent and b) contrary to honest practices. This is in contrast to 39.3 which only requires that if the data meets the requirements of:

- being mandatorily submitted data for approval of marketing pharmaceutical and agricultural new chemical entities;
- is undisclosed
- its origination requires investment and effort
- then protection is afforded against
- unfair commercial use
- disclosure (with the exception discussed above)

Where unfair commercial use is a subset rather than an alternative to the broader protection of dishonest practices as defined in 39.2 and Article 10bis of the Paris Convention, then such data must be protected against use that represents at a minimum;

- breach of contract
- breach of confidence
- inducement to breach
- use of information acquired by third parties who know, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

This suggests that the minimum level of protection required is relatively narrow and that use by the government, e.g. relying on the data to approve generic pharmaceuticals or biosimilars, without disclosing the data to third parties, would not be in violation of Article 39.3. This is because the information would not have been acquired by the government through any breach and does not entail disclosure or use by the third party whose new chemical entity the government is evaluating for marketing approval.

However, there remains significant disagreement as to what the provision actually requires and extends to. This is in part driven by an intuition, if not always the legal argument, that the unfair competition referred to in Article 39.3 is much broader than that referred to in Article 39.2. The claim is that Article 39.3 actually requires that governments provide not just protection against unfair commercial use, but that any such use would per se, be unfair, including reliance on the data by the government. Thus the argument is that governments are required to provide exclusivity for a specific period during which disclosure and/or use is not allowed, and reliance by the government on the data is not allowed.[123] Gervais seems to agree with this framing in suggesting that use by a competitor of such data in trying to prove the bio-equivalence of their product to one already registered may fall under unfair

123 See p213, Sellin, J., Access to Medicines: the Interface between patents and human rights. Does one size fit all? School of Human Rights Research, Series Volume, 64 (Intersentia 2014).

competition, where the competitor has not himself generated the information.[124] This approach is evident in various provisions such as Article 1711(6) of the North American Free Trade Agreement (NAFTA) as well as subsequent provision of bilateral free trade agreements pursued by the US and the European Union. However, it is also clear that earlier drafts contained provisions that proposed exclusivity periods and were not included in the final text.[125] This argues against interpreting Article 39.3 as requiring exclusivity or a specific term of exclusivity. That exclusivity may not be appropriate does not necessarily mean that use by the public authority itself, without compensation, would still be appropriate. The definition of unfair commercial use above, whether it be the Article 39.2 formulation or the Paris Convention formulation does not implicate behavior by the government.[126] It only implicates behavior by the third party and such behavior must be a breach of some kind as noted in Footnote 10. Thus it is difficult to find such a restriction based on that reading.

There is of course significant debate on this issue as well, as some authors argue that the concept of unfair competition in Article 39.3 must include benefits accrued by a competitor through use of the information without compensation. Basheer argues for this exact position in his evaluation of whether India's legal regime for test data was TRIPS-compliant.[127] It is not clear that such a position can be supported by a close reading of the text of Article 39 and the inter-relationship between Article 39.1, noting that the protection is based on Article 10bis of the Paris Convention, and Article 39.2 that defines dishonest practices as part of unfair competition. It seems necessary to read Article 39.3 together with the definitions of unfair competition outlined in the first two. Importing a concept of unfair competition which is found in common law and other jurisdictions may seem obvious but where there is a special meaning alluded to in the text, such an approach is probably mistaken. This is crucial and the term unfair competition or unfair commercial use is a term of art with special meaning under the Paris Convention and Article 39.2. It is inappropriate to ignore such meanings in favor of dictionary plain meanings. This is not to say that countries may not choose to make the unfair competition protection referred to in Article 39.3 and 39.2 co-extensive with that of broader unfair competition law in the domestic arena, but there is no requirement to do so, given the narrow approach in Article 39 itself to that definition.[128] That definition must be limited only to acquisition through breach or dishonest practices. Importantly, the unfair commercial use element of Article 39.3 has to be read in conjunction with the disclosure element. The article clearly contemplates that the government may engage in disclosure of information but then places an obligation on the government to prevent parties from using such information in ways that meet the unfair commercial use definition in the Paris Convention or Article 39.2. To do more is to suggest that the protection against use for government-disclosed data is greater than that for information held privately and never submitted, which seems beyond what was contemplated by the signatories to the agreement. However, in relation to information that the government has in its hands, the requirement to protect against unfair commercial use probably requires the government to at least stand in the place of the holder of the undisclosed information in relation to the breaches referred to in Article 39.2. Thus the government should act against third parties or allow the holder of the information to pursue claims against those who acquire the information from the government in ways that are dishonest, and prevent them from acquiring, disclosing or using the information.

Very clearly however, no such apparent limitation applies to the protection against disclosure in Article 39.3, which does not rely on a finding or assertion of the disclosure being carried out in an unfair way or in a manner that would be dishonest commercial practices. The only way in which such information may be disclosed is through the exception: to protect the public; or, more interestingly, where steps have been taken to ensure the data are protected against unfair commercial use. The clearest understanding from this is that, to the extent that 'use' is prevented, Article 39 does not present a barrier to government disclosure of information submitted to it. The article clearly contemplates that disclosure could occur and to the extent that the government essentially imposed conditions on those

124 See p428, Gervais, Daniel, The TRIPS Agreement: Drafting History and Analysis. Op. cit., footnote 100.

125 See p421-422, ibid.

126 Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary to The TRIPS Agreement, op.cit., footnote 119.

127 Basheer, Shamnad, "Protection of Regulatory Data Under Article 39.3 of Trips: The Indian Context". Intellectual Property Institute (IPI), Available at SSRN: http://ssrn.com/abstract=934269.

128 See page iv, Reddy, S., "Report on Steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPS Agreement." 2007

who receive the information, or the public at large not to use the information in ways that violate domestic unfair competition law, including acts covered under the Paris Convention Article 10bis, and Article 39.2 of TRIPS, then disclosure is allowed.

This also means that outside the realm of new chemical entities, Article 39 of TRIPS does not present a barrier to government disclosure, provided that the information is not used, acquired or disclosed by third parties in violation of Article 39.2. In any case, as long as the government provides a remedy in civil or other law against third parties, there is no limit on the government's disclosure of information submitted to it, except in the specific subject area of information submitted for marketing approval of new chemical entities (NCEs) for pharmaceutical and agricultural products. Thus in the area of toxic chemicals that are not new chemical entities relating to pharmaceutical or agricultural products Article 39 of TRIPS does not pose a barrier to government disclosure of submitted information. Even for pharmaceutical and agricultural products information not being submitted for marketing approval but for other purposes such as safety and health management and vigilance, government disclosure is not limited by Article 39.3. Other information, such as processes or marketing strategies and other strategic information are not covered by Article 39.3.

Rules on the relationship to other regimes[129]

The TRIPS Agreement contains no specific savings clause regarding prior obligations, except that it provides for the incorporation of all the substantive provisions from the Paris Convention. There are no rules for how to relate to other international treaties and regimes. However, there is broader WTO case law on how the WTO agreements should relate to other treaties.

There is an enormous body of literature on the relationship between trade and environment and several analytical frameworks have been developed to deal with the interaction.[130] These frameworks are generally addressed at three potential access points: jurisdiction, in which a WTO panel decides whether the dispute or claimed violation falls within the scope of rights and obligations of the covered agreements; applicable law, which is the sources of law which determine the scope and nature of the rights and obligations over which the panel has jurisdiction; and interpretive weight, addressing the evidentiary weight to be given to various sources in determining the meaning of specific terms and provisions of a covered agreement. In practice, where environmental issues are concerned this has meant that a panel has to determine whether an environmental measure is within its jurisdiction to address; whether the environmental treaty or regime which governs that environmental measure should be applicable law in a WTO dispute; and failing that, whether the meaning ascribed to a term or provision in an environmental treaty/regime should inform (either by expanding or narrowing) or have the same meaning as a similar or identical term in a WTO-covered agreement.

These questions have been addressed with respect to trade in goods and in the context of the SPS Agreement[131] and the TBT Agreement[132]. It is not the intent of this study to go over discussions that are much more effectively covered by other writers but the aim is to explore how these principles would apply in the context of a TRIPS dispute that addressed the unilateral implementation of measures that might create a dispute about whether they met the standard of necessary to protect the public in Article 39.3. Are there ways in which the objectives and goals of the Aarhus Convention, the Convention on Biological Diversity, and the human rights framework might be taken into account and given substance and even deference by a WTO panel? Drawing from the WTO jurisprudence we find that:

- Jurisdiction over WTO matters is compulsory and that, because the Appellate Body uses an 'effects' test to determine jurisdiction, this requires the WTO dispute settlement system to be involved in

129 An earlier version of this section can be found in D. Shabalala, "TRIPS and Technology Transfer for Emissions Reduction." In D. Prevost and G. van Calster, Research Handbook on Environment, Health and the WTO. Edward Elgar, 2013.

130 See e.g. Pauwelyn, Joost, Conflict of Norms in Public International Law - How WTO Law Relates to Other Rules of International Law. Cambridge: Cambridge University Press, 2003.

131 Agreement on the Application of Sanitary and Phytosanitary Measures, Annex 1A to the Marrakesh Agreement establishing the World Trade Organization (WTO Agreement), Marrakesh, 15 April 1994, in force 1 January 1995, 1867 United Nations Treaty Series (1995) 4.

132 Agreement on Technical Barriers to Trade, Annex 1A to the Marrakesh Agreement establishing the World Trade Organization (WTO Agreement), Marrakesh, 15 April 1994, in force 1 January 1995, 1867 United Nations Treaty Series (1995) 4.

ALL disputes that affect the rights and obligations of members under WTO-covered agreements.[133] Thus, it is not how a measure is characterized or justified but whether it has an impact on trade that triggers the compulsory jurisdiction of the dispute settlement system.

- In applying Article 31(3)(c) of the Vienna Convention on the Law of Treaties, all sources of law can be considered as applicable law including customary law, principles of international law as well as treaties. However, as applicable law in the context of a dispute between WTO members, only those rules that are applicable between the parties to the WTO can be considered, meaning that only treaties to which all WTO members are party can be considered applicable law in a WTO dispute.[134]
- Other rules of international law may nevertheless play a role in providing evidence of the ordinary meaning of a term or provision in a WTO-covered agreement, but a panel is not required to use such evidence where it does not consider it necessary or relevant.[135] Whatever the outcome, decisions by the DSB cannot add to or diminish the rights and obligations of members.[136] This suggests that no other law can function as applicable law within the context of WTO disputes.

Significant controversy has attended the panel approach in EC – Approval and Marketing of Biotech Products which interpreted the 'applicable law' referred to by Article 31(3)(c) VCLT as being limited only to those treaties to which all WTO members were parties at the time of the dispute.[137] The International Law Commission's report on the Fragmentation of International Law went so far as to suggest that the panel made a fundamental error, arguing that this would make it impossible for any treaty to have the role of applicable law in a WTO dispute as none could have the exact same scope of membership as the WTO[138], or even be one to which the membership of the WTO is a subset. The effect of this approach in the TRIPS and environmental agreements discussion is clear. If one presumes that the approach in EC-Biotech remains applicable, then, absent any other statement from within the institutions of the WTO, the CBD, the Nagoya Protocol or the Aarhus Convention cannot be used as applicable law between the parties to a dispute at the WTO that challenges a unilateral measure that has an effect of a TRIPS-related right or obligation. However, this does not preclude the use of similar terms and provisions in those treaties informing the meaning and scope of similar or identical terms in the TRIPS Agreement. Since these could not be used to actually alter or justify a measure that is TRIPS-inconsistent, this would have to enter through the traditional interpretive route of exceptions and limitations.

This pattern is evident in at least one IP-related panel decision. In the context of the US – Section 110(5) Copyright Act[139] copyright case, we do have an example of a panel using a provision from the WIPO Copyright Treaty to inform the meaning of the copyright exception in TRIPS Article 13.[140] In particular, the panel in that case stated:

> In paragraph 6.66 we discussed the need to interpret the Berne Convention and the TRIPS Agreement in a way that reconciles the texts of these two treaties and avoids a conflict between them, given that they form the overall framework for multilateral copyright protection. The same principle should also apply to the relationship between the TRIPS Agreement and the WCT. The WCT is designed to be compatible with this framework, incorporating or using much of the language of the Berne Convention and the TRIPS Agreement. (footnote omitted) The WCT was unanimously concluded at a diplomatic conference organized under the auspices of WIPO in December 1996, one year after the WTO Agreement entered into force, in which 127 countries participated. Most of these countries were also participants in the TRIPS negotiations and are Members of the WTO. (footnote omitted) For these reasons, it is relevant to seek contextual guidance also in the WCT when developing interpretations that avoid conflicts within this overall framework, except where these treaties explicitly contain different obligations.
>
> The panel thus argued that where a treaty forms part of a general framework and has similar provisions and wording, it should be interpreted in a manner that avoids conflicts with the broader framework. The overall framework of treaties that they consider relevant are those that cover intellectual property and are developed within related institutions, and that are concluded by a significant number of WTO members even if they are not in force. While not extending to making these treaties part of the applicable laws, the panel clearly stated that similar provisions using similar wording and reflecting specific understanding should be interpreted to mean the same thing so as to avoid conflict. While this discussion was in reference to Article 13 on exceptions and limitations and the similarity to the same terms in Article 10 of the WIPO Copyright Treaty and to Article 9(2) of the Berne Convention, this also opens the door to the interpretation of the terms in articles 7 and 8, as well as to the provisions on unfair competition in the Paris Convention. In principle, it could be argued that protection of undisclosed information, and exceptions to such protection, use similar language about the very same subject matter as covered by Article 39.3. At the very least, such an approach would require that the meaning of the terms should be read to be consistent across the international framework of treaties addressing the same issue. Nevertheless, the panel in this case appeared to limit its approach to the network of intellectual property treaties negotiated at WIPO, some of which are incorporated by reference in the TRIPS Agreement. It remains unclear the extent to which the panel's decision approach will be carried forward. As a general matter therefore, there appears to be a very limited set of ways in which WTO panels must or can take into account other international treaties. Nevertheless, some specific developments on intellectual property, subsequent to the panel decisions have provided some clarity on what the WTO access points for these other treaties may be, although not necessarily enabling those treaties to function as applicable law in a dispute. The most current and salient are the public health issue and the issue of how TRIPS relates to the Convention on Biological Diversity.

The Doha Declaration on TRIPS and Public Health[141] serves as the most authoritative statement of the WTO rule-making process' views on how the WTO relates to public health interests. There is an explicit interpretive direction in this Declaration with regard to how to interpret the TRIPS Agreement as regards other regimes related to health. Paragraph 5(a) therefore states: "In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles." This means that, in particular, articles 7 and 8 must be given due weight in interpreting other provisions of the treaty. This statement is a direct instruction to panels and the Appellate Body and a rebuke to the approach taken by the panel in Canada – Pharmaceuticals which did not appear to actually apply articles 7 and 8.

Most relevant to this study is paragraph 4 of the declaration which states:

> *"We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."*

The legal effect of the Declaration is unclear. As an authoritative instruction by the WTO General Council, it must clearly place an obligation on WTO institutions to comply with its provisions. Thus the Dispute Settlement Body is obliged to follow the instruction contained in the Declaration. It may also function as a subsequent agreement regarding the interpretation of the treaty, in the sense of Article 31(3)(a) of the Vienna Convention of the Law of Treaties.[142] Its content does not suggest that it is altering or adding to the obligations or rights of members, but it nevertheless clearly creates a preference for specific interpretive outcomes. However, the declaration provides no clear instruction to make other treaties function as applicable law in a TRIPS dispute by interpreting VCLT Article 31(3)(c) more broadly. In the case of Article 39.3 TRIPS it requires a more expansive and liberal interpretation of disclosure as 'necessary to protect the public'.

133 Article 3.2, Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), Annex 2 to the Marrakesh Agreement establishing the World Trade Organization (WTO Agreement), Marrakesh, 15 April 1994, in force 1 January 1995, 1867 United Nations Treaty Series (1995) 4.

134 See p334, Panel Reports, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R/ WT/DS292/R / WT/DS293/R, Add.1 to Add.9, and Corr.1, adopted 21 November 2006, DSR 2006:III-VIII, 847 (EC – Approval and Marketing of Biotech Products).

135 See p341, ibid.

136 Article 3.2, Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), op. cit., footnote 133.

137 See para. 7.70 – 7.71, Panel Reports, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R / WT/DS292/R / WT/DS293/R, Add.1 to Add.9, and Corr.1, adopted 21 November 2006, DSR 2006:III-VIII, 847 (EC – Approval and Marketing of Biotech Products)

138 See p227, 237, Martti Koskenniemi et al., "Fragmentation of International Law: Difficulties arising from the Diversification and Expansion of International Law." Report of the Study Group of the International Law Commission. International Law Commission, 13 April 2006, UN Doc. A/CN.4/L.682 p. 1-256 and 18 July 2006, UN Doc. A/CN.4/L.702.

139 Panel Report, United States – Section 110(5) of the US Copyright Act, WT/DS160/R, adopted 27 July 2000, DSR 2000:VIII, 3769 (US – Section 110(5) Copyright Act).

140 Para. 6.66 – 6.70, US – Section 110(5) Copyright Act.

141 Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2. Adopted 14 November 2001.

142 See Peter K. Yu, "Objectives and Principles of TRIPS." 46, Houston Law Review 4, p979 in support of this approach.

VII. General Conclusions and Recommendations

The analysis in this study focused on the ways governments can implement the access to information provisions in international treaties such as the Nagoya Protocol, while avoiding restrictions in the TRIPS Agreement. This study found that while there are no absolute restrictions on domestic regimes, or in the way international treaties can be implemented, countries have to carefully construct how they ensure full and effective access to information. The following sections provide conclusions and guidance on this core implementation issue.

VII.1 GENERAL CONCLUSIONS ON PROTECTION OF UNDISCLOSED INFORMATION SUBMITTED TO THE STATE

1. The TRIPS Agreement does not require states to provide trade secret protection as exclusive intellectual property. Countries remain free to use their systems of unfair competition to provide protection against the practice identified in Article 39.2. This is crucial as including the protection of undisclosed information under traditional intellectual property may serve to trigger obligations for compensation relating to fundamental rights and human rights to property, or more directly for the protection of intellectual property as a human right.
2. The obligations in Article 39.3 are limited only to information submitted for marketing approval. ABS agreements are concluded at the first stage of the value chain, so they do not relate to market approval. Thus, submission for patent granting or information provided in the context of ABS PIC and MAT, is not covered by Article 39.3.
3. The obligations in Article 39.3 only extend to submission of data on new chemical entities. Therefore, any information outside of that is exempt from the requirements of Article 39.3. This means that Article 39.3 would not be applicable to most environmental information except that related to toxicity and other data related to chemicals, but only if the chemical is new. Marketing approval for new uses of existing chemicals, as is the case with most industrial chemicals, would not be included.
4. The TRIPS Agreement requires protection of undisclosed information in Article 39.3 that is somewhat narrower than that entailed by Article 39.2. It provides an additional criterion that the origination of the information must have entailed considerable effort.
5. Article 39.3 does not limit governmental use of the data, but it does at a minimum require the government to stand in the place of the holder of undisclosed information in preventing the unfair practices defined in the Paris Convention and in Article 39.2.

VII.2 GENERAL RECOMMENDATIONS ON THE PROTECTION OF UNDISCLOSED INFORMATION

States remain free to choose their particular method of implementation of their obligations to protect undisclosed information under Article 39.2 of TRIPS. However, states should be cognizant of the fact that where the constitutional or human rights framework in which they operate treats intellectual property as a fundamental or human right available to both legal and natural persons, then treating undisclosed information as exclusive property within the framework of intellectual property has a specific effect in the realm of undisclosed information. The act of disclosure interferes directly with the existence and the exercise of any right to undisclosed information and will trigger obligations to compensate the holder of such information for any interference. The only counter will be if the domestic regime also treats access to information as a fundamental or human right of at least equal, if not greater, public interest, requiring a balancing of one right versus another. Given that the right of access is not well developed in many domestic human rights frameworks, it may be appropriate to avoid that issue for the moment by explicitly excluding protection of undisclosed information from the ambit of intellectual property protection in the constitutional or human rights framework.

VII.3 RECOMMENDATIONS FOR IMPLEMENTATION OF THE NAGOYA PROTOCOL.

The Aarhus model remains the best available model for national implementation of the information exchange and disclosure under the Nagoya Protocol. There are three options:

Option 1 – Adoption of the Aarhus Convention but with several additions

- A statement that all information submitted and exchanged under the Nagoya Protocol is to be considered environmental information subject to the Aarhus Convention.
- A statement that all information necessary for providers under the Convention on Biological Diversity to determine the identity of genetic resources and associated TK, the users of such resources, as well as the uses to which such resources are being put, shall be treated as equivalent to information related to emissions into the environment and may never be refused to be disclosed.

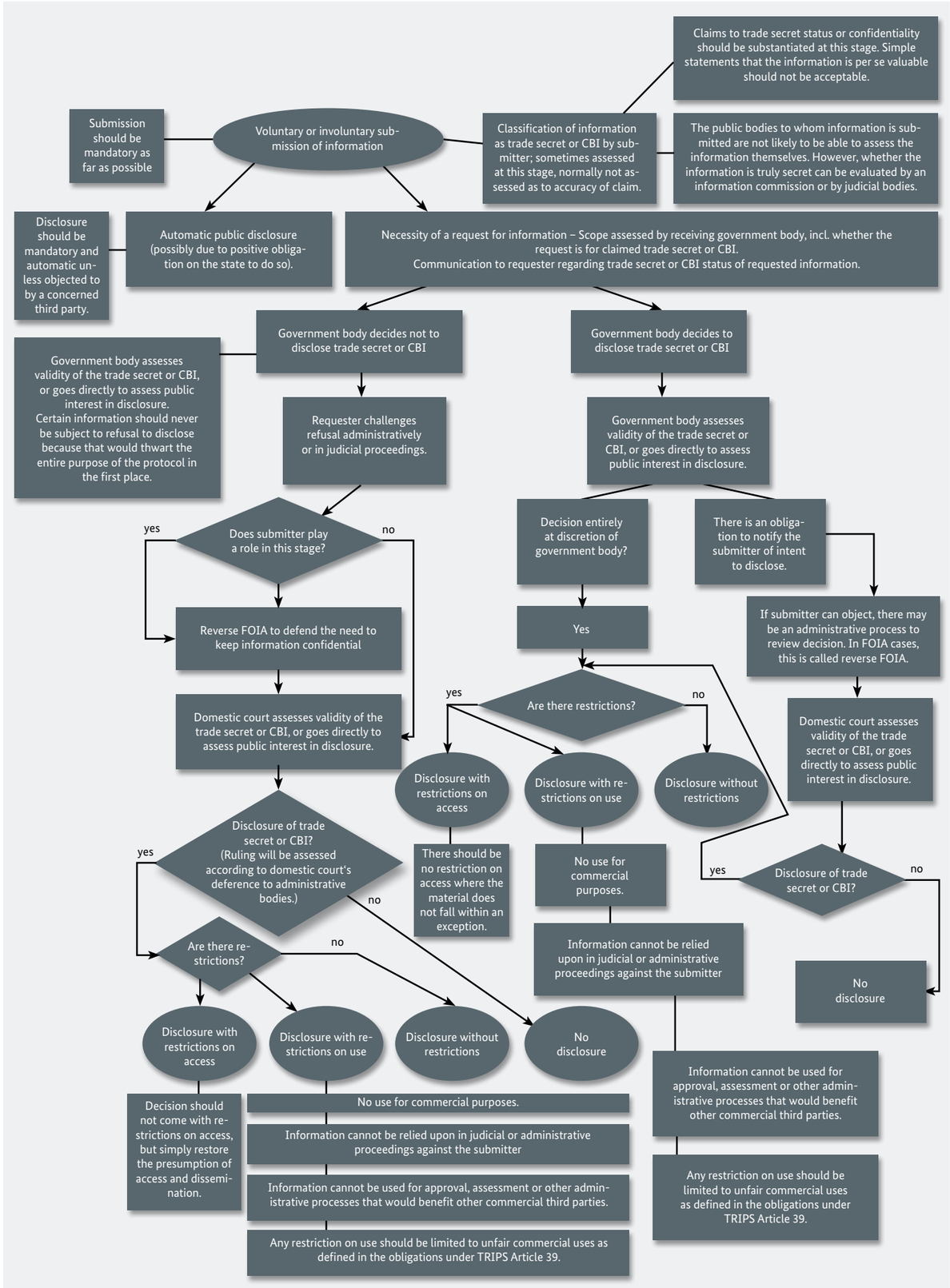
- Commit to making information disclosure mandatory and automatic, subject to the traditional exceptions within the Aarhus Convention. It may be appropriate to have confidential information or other information subject to an exception, covered by a request procedure.

Option 2 – Creation of a sui generis Aarhus-like model of access to information

- This would embody the basic substantive framework envisioned in option 1 but specific to access and dissemination of ABS information.

Option 3 – Implementing the information access provisions under the Nagoya Protocol within the broader FOIA-type frameworks

- This would require that, in considering exceptions to disclosure, all information necessary for providers under the Convention on Biological Diversity to determine the identity of genetic resources and associated TK, the users of such resources, as well as the uses to which such resources are being put shall be presumed to be of over-riding public interest in relation to the interest in the exceptions. Ideally this would treat confidential information as equivalent to information related to emissions into the environment and would never be refused to be disclosed. However, it may be that some balancing exercise would be envisioned in which case a consistent methodology may need to be formulated as shown below.



The ABS Clearing House should adopt the Aarhus Model described in option 1, but looking especially to the Almaty Guidelines on Promoting the Application of the Principles of the Aarhus Convention in International Forums (Almaty Guidelines)[143] as guidance for information sharing and disclosure and the relationship with undisclosed information.

VII.4 RECOMMENDATION ON DISCLOSURE AND USE OF PHARMACEUTICAL TEST DATA

Pharmaceutical test data falls squarely within the Article 39.3 obligations. States should set up a process to ensure that:

- The submitted information is indeed undisclosed and did involve considerable effort and investment in its origination. If it did not, then there are no obligations to protect it against disclosure or unfair competition.
- Even where disclosure of such data is aimed at and is desirable, Article 39.3 does seem to require that as holder of the information the governmental body stands in the place of the submitter and places restrictions on use on all who receive the information. Thus disclosure must be accompanied by restrictions on use by third parties of the information even if it has stopped being secret. One way to get around the obligation to protect the information against unfair commercial use is to declare, as a principle rule, that disclosure is necessary to "protect the public". Thus the argument could be that access to clinical trial data assists consumers, doctors and scientists to determine and assess themselves the safety and risk of a medicine. In particular, marketing approval only sets a floor but transparency allows for broad-based pharmacovigilance of side effects and other risks. This would then allow use of the information by others but probably only for the public interest reasons listed above. It is not likely that allowing the information to be used to develop new products would be acceptable.
- Governmental use and reliance on the data to carry out its own statutory safety assessments does not appear to be restricted by Article 39.3, thus the government remains free to rely on an originator's test data to assess and decide whether to approve identical products brought by other market actors, as long as the government does not allow such actors to use the data themselves. There is no public interest exception to the obligation to prevent unfair commercial use where the government has not itself disclosed the information.
- Countries should refrain from agreeing to TRIPS-plus measures in regional and bilateral free trade agreements that provide greater exclusivity or protection against disclosure for pharmaceutical and agricultural test data. They should also resist any attempts to expand the subject matter of Article 39.3 beyond that already agreed to in TRIPS.

[143] ECE/MP.PP/2005/2/Add.5 (decision II/4), Annex. Available at: http://www.unece.org/fileadmin/DAM/env/documents/2005/pp/ece/ece.mp.pp.2005.2.add.5.e.pdf

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GIZ Sector Project Development-oriented Trade Policy,
Trade and Investment Promotion
Friedrich-Ebert-Allee 36 + 40
53113 Bonn
Germany
Tel. +49 (0) 228 44 60 - 0
Fax +49 (0) 228 44 60 - 1766

Dag-Hammarskjöld-Weg 1-5
65760 Eschborn
Germany
Tel. +49 (0) 6196 79 - 0
Fax +49 (0) 6196 79 - 1115

trade@giz.de
www.giz.de/trade

Author
Prof. Dr. Dalindyebo Bafana Shabalala, Department of International and European Law, Maastricht University

Edited by
William New (Intellectual Property Watch), Corinna Heineke (GIZ Sector Project Development-oriented Trade Policy, Trade and Investment Promotion), Dr. Hartmut Meyer (GIZ Global Project Implementing the Nagoya-Protocol of the Convention on Biological Diversity – ABS Initiative)

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Adresses of the BMZ offices
BMZ Bonn
Dahlmannstraße 4
53113 Bonn
Germany
Tel. +49 (0) 228 99 535 - 0
Fax +49 (0) 228 99 535 - 3500

BMZ Berlin
Stresemannstraße 94
10963 Berlin
Germany
Tel. +49 (0) 30 18 535 - 0
Fax +49 (0) 30 18 535 - 2501

poststelle@bmz.bund.de
www.bmz.de

www.giz.de/trade