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# Elements for Legislation in User Countries to Meet the Fair and Equitable Benefit-Sharing Commitment

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## ABSTRACT

The third objective of the Convention on the Biological Diversity, the fair and equitable benefit sharing of the use of genetic resources, is lagging behind at the implementation phase. Very few countries have taken effective measures to promote sharing of benefits arising from the use of genetic resources. This article offers some suggestions as to why this is the case and poses a number of questions that need to be dealt with before such a system can be in place. It develops the concept of *genetic resources* and suggests that the focus need to be at the successful end uses of genetic material rather than at the point in time when genetic material is found in the nature.

**Keywords:** Genetic resources; user-country legislation; benefit sharing

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## INTRODUCTION

Implementation of the third objective of the Convention on Biological Diversity (CBD) the “the fair and equitable sharing of the benefits arising out of the utilization of genetic resources” lags behind in the implementation phase<sup>1</sup> This became clearly apparent at the World Summit on Sustainable Development (WSSD) in Johannesburg, which emphasised that the CBD is “...the key instrument for the conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising from use of genetic resources.”<sup>2</sup> All of the countries present agreed and recognised that:

“A more efficient and coherent implementation of the three objectives of the Convention and the achievement by 2010 of a significant reduction in the current rate of loss of biological diversity will require the provision of new and additional financial and technical resources to developing countries, and includes actions at all levels ...”<sup>3</sup>

Therefore, the World Summit agreed by consensus to:

“(o) Negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources;”<sup>4</sup>

The seventh Conference of the Parties of the Convention on Biological Diversity mandated the so-called *Ad Hoc* Working Group on Access and Benefit Sharing (the Working Group) to:

“... elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention on Biological Diversity and the three objectives of the Convention;”<sup>5</sup>

The Working Group met in Bangkok in February 2005.<sup>6</sup> It emphasised a gap-analysis as one step forward towards the fair and equitable benefit-sharing. In September 2005 the governments of South Africa and Norway hosted an international expert meeting in Cape Town with the aim of creating a better understanding of key issues in the CBD negotiations on an international regime on ABS and to identify relevant gaps that must be solved. The Co-chairs’ summary and the record of the discussions from the workshop will be submitted to the CBD Secretariat for distribution as information documents in advance of the 4<sup>th</sup> meeting in the Ad Hoc Working Group.<sup>7</sup> At this useful meeting important gaps were already identified. This article uses some of the gaps identified and concerns regarding genetic resources raised in the discussions at the Cape Town meeting as a point of departure for technical legal analysis of obstacles and possibilities relevant to the future work of the Working Group<sup>8</sup>.

## **THE GOAL OF THE WORK IN THE WORKING GROUP**

The Mandate of the Working Group opens for “... adopting an instrument/instruments to effectively implement the provisions in Article 15 ... and the three objectives of the Convention”. The emphasis is on the effective implementation of the already existing obligations according to CBD Article 15. Equally important according to the Mandate is the effective implementation of the three objectives of the CBD.

The terms “instrument/instruments” are broad. They include, but are not restricted to, the negotiation of an annex to the CBD,<sup>9</sup> a protocol to the CBD,<sup>10</sup> a guideline undertaken by a regular decision (as the Bonn Guidelines) or could consist of any other legal form that emphasises the effective implementation of Article 15 and the objectives of the CBD. The outcome could for example be a model law for user countries or an international mechanism for benefit-sharing. Each of these instruments will entail different procedures for adoption. The Working Group might also adopt more than one instrument. The Mandate uses the term “regime”, but this does not give much guidance. “Regimes” are often defined as “implicit or explicit principles, norms, rules and decision-making procedures around which actors’ expectations converge in a given issue-area”.<sup>11</sup> According to this definition, the CBD is clearly a regime. When the mandate uses the term “regime” it must clearly also encompass an element or single standalone instruments.

The content of the expected outcome is also specified in the wording of the Mandate. It shall: “... effectively implement the provisions in Article 15 ... and the three objectives of the

Convention". The objectives of the outcome are clearly defined, and thus indicate the direction for the negotiations. The Mandate leaves considerable manoeuvring room for the Working Group to choose the most relevant manners to implement Article 15 and the objectives of the CBD.

Even though the objectives are so clearly defined, e.g. Finston confuses the debate by stating that there is no consensus among members to the CBD on where this process shall lead.<sup>12</sup> Unfortunately, she emphasises problems rather than solutions by concluding: "Now more than ever, it is important for the developing country Members of the CBD to identify their destination in terms of their strategic commercial interests, and to map out a strategy for reaching their goals."<sup>13</sup> First, the interest of developing countries is probably broader than "strategic commercial interests". Second, the aim of the process is the effective implementation of the objectives of the CBD including "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources".<sup>14</sup> This was agreed by all countries at the World Summit on Sustainable Development, follows clearly from the Mandate from CBD-COP-7 and is not altered later in the process.<sup>15</sup> How this can be done most effectively is the topic up for discussion.<sup>16</sup> The Cape Town-meeting organised by the governments of South Africa and Norway gave a number of interesting leads for how this can be done.

## **IDENTIFYING TWO MAJOR GAPS FOR FAIR AND EQUITABLE BENEFIT SHARING**

### **The Problem of Access Legislation**

To find adequate solutions, there is a need to analyse the reasons for the present problems. Until the COP-7, focus has been foremost on access legislation. The Bonn Guidelines illustrate this by almost exclusively addressing measures to be taken in the provider country.<sup>17</sup> There is an emerging common understanding that perhaps access legislation is not the only accurate approach needed to achieve fair and equitable benefit sharing. States are parties to the CBD. Value in biotechnology is created foremost by private parties under the jurisdiction of another country or under the jurisdiction of a number of countries. A general principle of law is that if private persons or companies shall be legally obliged, the obligation must be implemented in the relevant jurisdiction. The principle of legality applies if the state or anyone other than a contractual partner seeks to establish a burden upon a private person. In most countries the parliament must have implemented such an obligation in the national legal system before a private party shall be obliged to share a part of the benefits. A major obstacle for access legislation is that the law of one country is to be enforced upon private parties under the jurisdiction of another country.<sup>18</sup> This is a general problem faced by international law for most cross-boundary activities and global interaction. This obstacle can probably not be solved generally, but needs to be particularly addressed regarding access and benefit-sharing under the CBD. The specific manner to solve this problem is to implement legislation in the countries where genetic resources are being used.

Access legislation is also under pressure from industry representatives identifying it as a major cause for creating legal uncertainty.<sup>19</sup> Often this uncertainty is argued to have led to a declined interest in biological and genetic material. The warning from industry regarding the problems created by access legislation should be taken into account in future works. Perhaps one important virtue of the new instruments is to establish a predictable and clear situation for industry and research.

## **Problems Stemming from a Contractual Approach**

Private law contracts are often promoted as the solution instead of and in combination with access legislation.<sup>20</sup> The concept “mutually agreed terms” indicates some kind of agreement. The “prior informed consent” indicates more of a one-sided approval by the providing country. These two legal concepts have been addressed extensively. An obvious advantage to using contracts is that industry is accustomed to this legal tool. Effective contract law including systems for enforcement are also in place in the majority of countries, increasing the chance for achieving the content of the agreement. There are, however, some serious gaps before the contractual approach is likely to fulfil the objectives of the CBD.

Contracts are legal arrangements between two (or more) private parties. The system rests upon the basic assumption that these two private parties have partly overlapping interests that they negotiate and enter into a more or less balanced agreement. For access to genetic resources, this is seldom the situation. On one side of the negotiations there is one clearly defined private party: the company or researching institution seeking access. On the other side of the negotiations there is a less clearly defined or totally undefined party. The lack of the evident counterpart entails an obstacle for industry willing to enter into an access contract. There are some experiences of this problem applying to industry that tried to enter into a contract, but ended up being accused of biopiracy due to failure to find a coherent and representative counterpart for the access agreement. From the perspective of developing countries, there are a couple of major obstacles: The private party could easily obtain the same or similar genetic material from other sources or without entering into negotiation. There is also often a gap in negotiating capacity between the private corporation and the government of a developing country, placing the latter in a difficult negotiating position.

A contract applies between the two parties signing the contract. Biological material is often transferred from one user to another. Therefore, a contractual strategy leaves a gap of legal uncertainty for users of genetic material. One strategy could be to include a clause which limits the right to transfer the genetic material to third parties to the contract; or only allowing such transfer if the next person or company agrees to the same conditions as the primary user. The possibility for enforcement with respect to these third parties and later successors will be limited as they are not obliged by the first contract. Another problem for this strategy is that this type of contractual restriction upon transfer might have a chilling effect on exchange of genetic resources.

At the Cape Town meeting Clive Stannard raised the issue of whether it is at all possible to create public goods by using private contracts. This is a relevant question for a number of reasons. First, the basic assumption of contracts that there is a legal arrangement between two private parties does not necessarily take into account the *plurality* of needs. Second, on many occasions the ones most in need of a share of the benefits arising from biotechnology are those with the least capacity to fulfil their needs by using contracts. One typical example is sick people in poor countries. Their capacity to achieve their needs by the use of contracts is very limited. Depending only upon a bilateral private law contractual approach will hardly ever have a potential to fulfil *their* needs. Third, several actors using genetic material do not have specialised knowledge about law, contract law or the international legal system. This also exposes them to the risk of not succeeding by the use of contracts.

## **Possible Solution to These Problems – Implementation of Legislation in User Countries**

The experience from 12 years with the CBD is that to rely only upon the twofold approach:

Access legislation in provider countries and private contracts, has not been sufficient to reach the third objective of the CBD. The challenge rests in creating an international and national legal situation being more efficient in respect of providing benefit-sharing. At the Cape Town-meeting, several of the speakers identified the lack of implementation rather than the lack of international obligations, as the major obstacle for the fair and equitable benefits sharing. For example: “Many of the perceived “gaps” that have created a demand for development of an [International Regime] are, arguable, actually gaps in the development of national policies, laws and regulations.”<sup>21</sup> To implement national measures targeting private parties (person or company) in the jurisdiction where the value of genetic resources is being captured will overcome these two main obstacles. Perhaps, the Working Group should therefore single out one topic to deal with first: How to create a legal situation in the user countries that will ensure the fair and equitable benefit-sharing.<sup>22</sup>

The remainder of this article explores options and obstacles for such *user-country legislation*. Section IV explores *genetic resources* as a particular type of natural resources. Section V looks at principles for valuation of genetic resources. Section VI discusses various options and elements that could form a part of an International Regime for ABS. Section VII provides a look at the negotiation in WIPO most relevant for having an effect upon the conditions for benefit sharing under the CBD.

## **THE SUBJECT MATTER FOR THE USER-COUNTRY LEGISLATION – GENETIC RESOURCES**

### **The Point of Departure – the Wording of the CBD**

A basic question that needs to be clarified before implementing user country legislation is the scope of its obligations. Thus the legal concept “genetic resources” must be clarified, as it presently is used with a number of different meanings, which raise distinct challenges. The term “genetic resources” builds upon the definition of genetic material which is: “any material of plant, animal, microbial or other origin containing functional units”.<sup>23</sup> “Genetic material” includes all biological material where there are functional units of heredity.

Perhaps some samples of genetic material could be traced and followed by certificates, disclosure requirements or private law agreements, for example genetic material of cattle. Generally, these legal tools, however, presuppose a complex web of legislation to be enforceable. There are considerable obstacles related to following genetic material from the time it is accessed until it is successfully used commercially. In the majority of situations tracing the origin of the genetic material used in the end product will involve substantial problems.<sup>24</sup> Functional units of heredity (i.e. genes) are present in all biological material, also when used for bulk purposes. For example, a flower exported for horticulture purposes will typically contain seeds and thus genetic material; grains exported as food contains genes and could potentially be used in breeding. Biological material contains genes and thus may potentially be used for its genetic material. Small quanta of biological samples can be sufficient to capture the interesting genetic material. A necessary precondition for effective access legislation to create benefit-sharing would require prevention of unauthorised access or use. As there are major obstacles related to controlling export of genetic material, such exclusive control will not be effective to achieve benefit sharing.

The qualifying term “actual or potential value” establishes an important distinction between genetic material and genetic resources. The focus is on certain types of value arising from use

of biological or genetic material. The difficult issue is to determine the types of value the CBD seeks to capture by this definition of genetic resources. The term “actual or potential value” can be understood as the value of the biological material when it is used to take advantage of the *functional units of heredity*. If this understanding of the legal concept is applied, the concept “genetic resources” will be geared towards uses of biological material for certain purposes or categories of uses.

### **Could the Purpose of the Access Be the Relevant Criterion?**

One theoretically clear understanding of “genetic resources” could be the intentions or purpose of the person or company having access to the biological material. This, however, implies a challenge for access legislation: As functional units of heredity are present in all biological material also when sold for the purpose of commodities, the scope of access legislation would solely have been depending upon the purpose or intention of the one seeking to move biological resources across a boarder. It is hardly possible to survey the intention of any individual transfer of biological material containing functional units of heredity. The intention is not manifest in any objective manner at the point of time of access. To base enforcement mechanism or a court case upon a criterion as subjective as the original *intention* of the exporter is close to impossible. Both researchers and industry need to be faced with a clear legal situation for the genetic material brought to laboratory for doing research. Choosing *intention* as criterion will also not create the predictable situation for research and industry receiving biological. The primary intention for the access to biological material also changes over time after the genetic material has left the country. Access legislation targeting the primary intention will therefore not be robust enough to capture the value created later. To link the obligation to the intention of the user is probably not a successful strategy to achieve benefit sharing. Thus the definition cannot be linked to such a subjective criterion.

### **Drawing Benefits from Utilisation of Genetic Material**

The qualifying term “of actual or potential value” and thus concept *genetic resources* must be understood in the context used in the CBD. The benefit-sharing obligation is focused on sharing “the benefits arising out of the *utilization* of genetic resources”<sup>25</sup> and “the results of *research and development* and the benefits arising from the *commercial and other utilization* of genetic resources”<sup>26</sup>. Common for these formulations is that they are geared towards the utilisation rather than the access to or export of biological material. They cover the value of biological material when used for capturing the actual or potential value of genetic material. A practical application of the definition of *genetic resources* should strive towards capturing the *actual or potential value* of the use of *functional units of heredity*. Presently, the scope of existing legislation and the international discussions are seldom focused at the value created by the utilisation of genetic material, but rather on an unpredictable definition of “genetic resources”. This is an important gap that needs to be bridged by the Working Group to reach the objectives of its work.

The legal concept “genetic resources” could be understood as all activities that *result in capture* of the “actual or potential value” of genetic material by taking advantage of the “functional units of heredity”. The terms *utilization*, *results of research and development* and *commercial and other utilization* indicate a comprehensive scope. The solution for implementation of access legislation rests in an interpretation of the CBD, and could be found by linking the concept genetic resources to specific uses of biological material. Linking the definition to the end-use rather than the intention will clearly will prepare the ground for

legislation in user country.

This, however, does not solve all challenges. The scope of CBD Article 15 targets the cross-boundary situation when genetic resources are used in another country. The gap of enforcement under the jurisdiction of another country will not automatically be bridged. Implementation in user countries is still required. To focus the definition of genetic resources on a number of uses prepares the ground for implementing legislation in user countries.

### **Which Uses of Genetic Material Should Be Included?**

The concepts *utilization*, *results of research and development* and *commercial and other utilization* are also somewhat broad and needs to be developed more specifically. The lack of physical control over genetic material by possession emphasises that the benefit sharing obligation should be triggered by specific uses of genetic resources or for certain forms of drawing benefits from them rather than access to the genetic material.<sup>27</sup>

Innovation and development in biotechnology are dynamic by nature. For a legal system to be able to keep up with development in such a dynamic area, there is a need for robust definitions that are able adapt to all relevant changes. A lesson can be learned from patent law where all the main criteria (e.g. invention, novelty and inventiveness) are dynamic and evolutionary by nature, making the patent system perfectly robust to adapt to changes in technological research and development. Changes are done by altering the interpretation and practice of the terms rather than amending the wording of the acts. If the CBD-related law is to learn from the patent system, there is a need to include a dynamic scope of the legislation. The definition of genetic resources is well-suited for including such a dynamic element.

The most comprehensive approach would be to specify that all results of biotechnology based upon biological and genetic material are covered. Such a broad approach would lead to a wide and unspecific scope of the obligation, and would disregard the differences among users of genetic resources. Therefore, the Working Group might want to specify the uses included in more detail.

#### *Catalogue of Uses or Manners to Draw Benefits*

A related approach could be that clearly defined uses of biological and genetic material count as “genetic resources”. This could be called a **catalogue approach**. Biological material is, however, used in numerous manners. It is a difficult task to list all kinds of use of biological material when the benefits have been drawn from the direct use of the genetic resources. A great deal of flexibility might be lost by such an approach. This is perhaps an obstacle for approaching the confinement of the term genetic resources by listing a catalogue of uses. If establishing a clear list, one should have the need for flexibility in mind and develop categories that are formulated in a dynamic manner.

#### *Confining Use of Genetic Material by Criteria*

An alternative or perhaps supplemental approach could be a **criteria approach**. If the plurality of uses shall be taken sufficiently into account, perhaps the definition of genetic resources could be based on certain criteria. The challenge would be to formulate the relevant criteria taking the need for a dynamic situation and predictability equally into account.

Perhaps, one relevant trigger criterion could be that the genetic material used would no longer be open for being used by others.<sup>28</sup> This could be formulated as if the use of others is reduced

or delimited. To establish exclusivity over a shared resource is in economic theory a successful manner to create or increase value of the open resource. Thus, it would probably be an effective tool to capture the value added by the genetic resources to link the benefit sharing obligation to the capture of such a value. One manner to establish a time-limited exclusive right to use genes is to be granted a patent. Perhaps therefore, the issuing of a patent could trigger benefit-sharing. One advantage by this criterion is that it is a well-defined point of time that is fairly transparent. Being granted a patent is, however, not identical with creating any economic or other benefits from the use of genetic material. Also, to link the benefit-sharing obligation to patenting would leave the user country legislation dependent upon the practice of another legal system, which might turn out to become a challenge.

If academic use of genetic material is not included as one benefit sharing activity, the system will probably create a flexible situation for research. If the outcome of the academic research is formulated as one relevant category of uses of genetic resources that trigger benefit sharing, perhaps also the need of the provider country to capture a part of the subsequent commercial success of academic use may be met.

The Working Group should discuss and define the relevant uses of genetic material that are covered by the scope of the benefit-sharing obligation. These defining criteria must be concrete and specific if they shall serve as a model for how user countries can implement it in their legislation. The Working Group should address relevant criteria or a catalogue of uses that would be relevant for confining the user obligation.

### **Derivatives from Genetic Resources – Unknitting a Gordian Knot**

A contiguous or tense issue for the negotiations in the CBD is that of “derivatives” from the use of genetic resources.<sup>29</sup> The whole problem of derivatives arises from looking at genetic resources as a static type of natural resources that could be regulated at point of time of access. The difficult question is what degree of similarity between the accessed material and the end product that is under the scope of access legislation and benefit sharing obligation.<sup>30</sup>

The solution to this problem can be found directly in the interpretation of the term “genetic resources” presented above. If benefit-sharing legislation is linked to the end uses and the value created by the use of genetic material, the problem of derivatives will automatically be solved. The definition of genetic resources understood as the *utilization, results of research and development* or *commercial and other utilization*, already encompasses what is often referred to as “derivatives” since they refer to the point in time when the value of the genetic material is captured. Thus, the problem of derivatives will be avoided by the definition of the relevant activities drawing benefits from the functional units of heredity (acts of *utilization*) that will be required to meet the benefit-sharing obligation.

In a situation where there is either a catalogue of uses or well-defined criteria for uses that trigger the benefit-sharing obligation according to the CBD, the next topic to address is the level of benefits that should be shared.

## **PRINCIPLES FOR CALCULATING BENEFIT SHARING**

### **Benefit Sharing Shall Be “Fair and Equitable”**

The CBD uses the term “fair and equitable benefit sharing” both as the main objective and an

operational obligation. Member countries to the CBD are legally obliged to ensure a certain level of benefit sharing. The concept *fair and equitable benefit-sharing* is the most neglected term in the CBD. Not all forms of benefit sharing comply with the obligation *fair and equitable*. The difficult question which must be dealt with is: What is the content of the legally binding obligation? When is benefit-sharing fair and equitable?

Despite the fact that this obligation follows directly from the wording, it is among the topics in the CBD that has received least attention. For example, in one of the more recent publications on the subject “benefit-sharing”, it is dealt with as follows:

“The adjectives “fair” and “equitable” remain unclear. This is probably due to the fact that the adequacy of the benefits depends on the circumstances of the individual case. Generally, conditions shall be fair and practical for both the provider and the user.”<sup>31</sup>

This formulation expresses that the content of the term remains unclear. One reason for this legal concept remaining unclear is perhaps that it is seldom addressed. The book *Beyond Access* will deal with this concept of law, both at the level of international law (the obligation according to the CBD) and in national legislation (in the user countries).<sup>32</sup>

### **Recognising the Value of Genetic Resources**

One step on the path to achieving the fair and equitable benefit sharing is to rethink the value added by genetic resources. The value created by agriculture and other application of genetic resources is substantial. Biotechnology contributes to added value to society.<sup>33</sup> It is dependent upon genes, cells, proteins, biological material, related knowledge and various forms of technology. The term “biotechnology” covers a twofold dependency relationship constructed by the two terms “bio” and “technology”, emphasising two equally important components: technology and biology. Imagine genes removed from the picture; then gene- and biotechnology would not have been possible. Knowledge is the other necessary factor. Both of these essential pillars are preconditions for one of the most rapidly growing parts of society.

The emphasis on access rather than end use has also lead to a gap with respect to the valuation of genetic resources. The estimates of the value of genetic resources are repeatedly claimed to be insignificant.<sup>34</sup> These low estimates are then used as an argument against regulating rights to genetic material and benefit-sharing.<sup>35</sup> Interestingly enough, this argument is often claimed by the biotech industry,<sup>36</sup> which inherently depends upon the use of biological material (in addition to synthetic products). Correspondently, the value creation from sectors of industry using genetic resources is substantial and increasing.<sup>37</sup> This is a paradox which turns into an obstacle for the fair and equitable benefit-sharing.

Some attempts have been made to articulate the value of genetic resources. One common approach is to repeat that the value of genetic resources is determined by negotiation between two private parties. The CBD is, however, not primarily a tool for creating a well-functioning international market for the negotiation and sale of resources. If that had been the intention, the ABS legislation could have formed a part of the international trade regime in the WTO. The obligation and the objective of *fair and equitable* benefit sharing emphasises that the scope for the CBD is not primarily to create such a market. Benefit sharing is phrased as a goal in itself according to the objectives of the CBD. In addition, it is a tool and a mechanism to achieve the other two main objectives: the conservation and sustainable use.

Due to a number of reasons, including e.g. unequal negotiating power and market failures, such a contractual approach to valuation does not necessarily lead to a fair and equitable result and value of genetic resources. In Cape Town this was phrased as “[c]urrent form of contractual approach is leading to low value of individual transactions and not to full valuation of environmental services provided by biodiversity.”<sup>38</sup>

The private contract approach fails to include the value of the historical contribution and value-adding efforts put into genetic resources. Genetic material is not only pre-existing in nature, but is partly dependent upon efforts by man. Genetic material is exposed to being regarded as yet another commodity or natural resource open for being conquered. The political choice of not harvesting the benefits of natural resources in bulk as e.g. timber, oil or minerals, can easily be altered. Thus one can argue that there is a need for building an alternative value of biological diversity. As the economic alternative value of biodiversity, as bulk natural resources, often is high, the valuation of the genetic material must be established adequately high in order to be a counterweight in balanced decision making for the future. From this perspective, the manner for determining value of genetic material is an important element of the political choice about whether or not to reduce biodiversity in order to exploit other natural resources.

Unpredictability is often used as an argument to support a low estimate of the value of genetic resources. In bioprospecting the chance of a hit in random screening may be low. Industry needs to do research on a number of samples in order to get one hit. This low probability is often used as a main argument for concluding that genetic material is valueless or of very low value. At the time of access to genetic material, it is impossible to predict the value of the future outcome from its use. This unpredictability is an important argument in favour of approaching benefit sharing at the point in time of success rather than at the uncertain time of access. When the product is developed and sold in a market the value of the total end product becomes more evident. The gross sales income will give guidance to the value of the outcome from the use of genetic resources.

Much of the value of genetic resources rests in the *diversity per se*: Only a very small amount of biological material is required to explore and exploit genetic material. Therefore, it has been argued that the value of genetic material is very low. This rests on the misassumption that the value of the genetic material is equal to the cost of buying or acquiring the biological material. For example, the assumption that the buyer of a sack of beans on the market in a developing country pays the price and thereby determines the value of the genetic material in the beans by the same transaction. Sales of biological material are, however, geared towards its value as a commodity. The buyer expects primarily to have a right to the bulk value of the physical natural or biological resource. The valuation mechanisms in the commodity markets do not reflect the potential and actual value of the genetic material. To include these aspects in the value estimates of transactions involving bulk biological material, would put a burden of transaction costs on trade in commodities that these markets could hardly be prepared for. Therefore, buying commodities can hardly include the appropriation of a legitimate or legal right to the genetic material that is inherently a part of the organisms sold for gross/bulk purposes. One consequence is that the value of the single specimen of biological samples as commodities is not a well-suited principle of valuation of genetic resources.

There is also a tendency of disregarding *diversity* as a resource. Each single payment for acquisition is not primarily a compensation for one sample of a flower or a micro-organism. It

is not the one flower which is the resource that has been used. The resource that has been used is the diversity *per se*. The resource for biotechnology is not single specimens, not even the single one species, but the fact that there is a *diversity* of species and genes being kept and maintained available, often through access to nature or collections in other countries. To maintain this possibility to search for and find the one useful specimen or genetic sequence, entire ecosystems must be preserved so that species can continue to flourish and be of potential interest and value in research and development.

The question of value could be phrased as: What would the value of the product have been without the genetic resources, rather than asking how much it cost to buy one sample of a specimen. It would be impossible to give an exact estimate of this value to answer this question at the point in time of access or exchange of genetic resources. When the genetic resources are being accessed the value they contribute is completely uncertain and undetermined. This emphasises the need for linking the benefit-sharing to the use of genetic resources rather than to the access to such. This solution to the benefit sharing requirement is consistent with the wording of the CBD as it emphasises "... 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...". The focus is at the *results* from the utilisation that will be evident when the genetic resources already have been used.

To link the calculation of the amount of benefit sharing to the outcome from the end use, would reduce uncertainty for business compared to imposing a benefit sharing obligation at the point of time of access. The methodology for stipulating the benefits that are to be shared must be developed so business can include it as a cost in the total budget of each project as a dependent variable linked to the success of sales (perhaps weighed towards the relative contribution to the total income). The more specific methods for calculating such a level of benefits sharing needs to be developed more in detail.

### **Developing a Methodology for evaluating the Contribution from Genetic Resources**

The recognition of value of genetic resources needs to be turned into principles for assessing the contribution made by this resource. A manner/approach/methodology for *valuation* of genetic resources which is internationally recognised must be developed.<sup>39</sup> Hardly any work has been done to develop these principles in the time after the CBD entered into force.<sup>40</sup> Thus, one important (or basic) issue to be dealt with by the Ad Hoc Working Group is how to award the value of the genetic resources.

This is more of a technical question than a political question. Thus, there is a pressing need for a profound technical assistance and analysis with the aim of presenting a methodology or concept for valuation of genetic resources.<sup>41</sup> One core issue is to have a method for calculating share of the value added to the final product from the genetic resources that have been used to reach the said product or process. The interesting question is how the relative contribution of all the necessary elements can be done.

A Norwegian–International group cooperating with Nordic and European universities and research institutes is working on developing a distributed and decentralized "open-source" system including a pool of knowledge. This system includes a system for calculating the relative contribution from each contribution being in the pool of knowledge, to each end product developed drawing upon this pool. The system is called AORTA and will cover not only biotechnology and gene technology but also nanotechnology. The main thought is to

develop a system that, based on semantic analysis, is able to track dependencies between formalized reports on development within a defined field. The dependencies will create estimates of part of the revenue generated from commercialization of mature products that depends upon each contribution to the pool of knowledge. Monetary benefits will flow back from the commercialised end product to each relative contributor. The challenge which is yet not solved is how to calculate the relative contribution from genetic resources (and traditional knowledge) to the commercialised end product. This is however probably a matter of a technical question. It is particularly important from a benefit sharing perspective that the value of genetic resources to the technologies of the future as nanotechnology is recognised and made possible to enforce. In the future, genetic materials may be analyzed and replicated in synthetic mechanical nanoscale systems, and not used directly as genetic resource, it will be essential that they are included in a common platform for calculating dependency and relative contribution of value from genetic resources to such advanced systems to achieve benefit sharing in the future.

Products in gene- and biotechnology draw upon and are heavily depending upon the past work of a number of contributors. In agriculture, development is much more of a continuum than of the idea of one genius. A general idea for benefit sharing, that also the AORTA system builds upon, is to create a system where not only the last entity bringing a product to a market is rewarded. The relevant contributors to each commercial product need to be recognised and receive their fair share of the value according to their contribution. If a situation is created where the relative contribution of genetic resources to products can be determined, there is still a question of how to identify with whom the benefits shall be shared.

### **With Whom Should Such Benefits Be Shared?**

The question of with whom benefits shall be shared is a difficult and perhaps therefore a seldom discussed question. Analytically, it covers two different questions: 1) How shall benefits be distributed internationally among countries and 2) How should they be distributed within each country, for example with private or public entities. The second question perhaps needs differentiated solutions within different countries.

For the first question, one fundamental distinction may perhaps be drawn between cases where it is not possible to identify the provider or origin of the genetic resources and those cases where credible information exists about the provider. In the latter situation it will be possible for the creator of benefits to identify the receiver of benefits. A well-functioning system for certificates of origin or provider could be a helpful tool in this respect. When it is not possible to identify the provider for any reason the provider, the question of who should be the receiver arises. This is a practical situation, since it is often difficult to determine the source for genetic material if information is not already there.<sup>42</sup>

In cases where information does not exist, the obligation in the CBD applies just as strongly in favour of requiring benefit sharing. Where no specific information exists, benefits might be shared to an international fund for conservation of biological diversity that could distribute benefits back to such efforts.<sup>43</sup> This might also have a long-term effect that users of genetic resources will provide better information about from where the genetic material is found.

## **CHOOSING RELEVANT INSTRUMENTS FOR IMPLEMENTATION**

### **Implementation of a Benefit-Sharing Obligation in User Countries**

The Mandate of the Ad Hoc Working Group is geared towards the implementation of both access and benefit sharing. As this article does not cover all topics relevant for the future work, it is confined to focus mainly on benefit sharing aspects. To build a system for benefit sharing will affect the potential for ensuring access. The challenge dealt with here is which legislative tools that can be used to meet the benefit sharing commitments according to the CBD.

### **Incentives and Enforcement Mechanisms**

One gap is the lack of clear incentives for researchers and industry to comply with the benefits sharing obligation. As the primary goal of private enterprises is to earn money, benefit sharing might easily become an extra cost that there are no economic reasons to spend. The success of patent law partly rests in the fact that the patentee has a very clear interest in enforcing the patent upon all other commercial users of the invention. It is in the interest of the private party that others comply with it. The incentive structure in the patent system brings economic benefits to the patentee. One challenge for the Working Group is how to establish a sufficient level of incentives for industry to share a fair and equitable part of the benefits arising from the use of genetic resources.

In a situation where there are few or weak incentives to comply with an obligation, there is a stronger need for enforcement mechanisms. The mere presence of effective enforcement mechanisms will often in itself have the effect of creating incentives to comply. This is a reason for including enforcement mechanisms in the legislation in user countries. Due to the problem of enforcing access legislation of another country, it will probably not be sufficient to depend only upon legislation in provider countries if the goal is to create an enforceable system. Certificates of origin/legal provenance and disclosure of information are two tools often being mentioned as mechanisms to implement ABS legislation.

### **International Tools**

Important work has been done to clarify how these legal tools could be developed.<sup>44</sup> The difficult question is however these tools shall function in the larger picture.

#### *Certificates*

Several interesting analysis and suggestions have been developed regarding certificates suggesting different types of information to be certified, for example origin of the genetic resources or the legal provenance of the access. There are some obstacles that must be dealt with before a certificate system is going to create sharing of benefits. One gap is the special characteristics of genetic resources as a natural resource. Genetic material can easily be transferred across borders and be used whether or not they are followed by a certificate. Certificates are often used as documentation of legality of activities. For example you are only allowed to drive a car with a permit, a certificate of your driving skills. However, the reason why the lack of a driving license will hinder you from driving is not the mere absence of the certificate, but the legislation saying you will be severely fined or punished *if driving without* a certificate. Applied to certificates on genetic resources, there is a need for norms including sanctions if using genetic resources are used without proper certificates. If the lack of a

certificate does not have any legal consequences, the likeliness for a certificate system to alter the behaviour of bio- and gene-technology users when it comes to benefit sharing, is quite low. Therefore, the Ad Hoc Working Group needs to discuss how certificates can be included as a tool in the ABS legislation. A system for certificates can be a relevant tool for identifying “with whom” benefits shall be shared.

### *Disclosure Requirement*

An often quoted solution is to require disclosure of information about the sources, the provider or the legal provenance of the genetic resources in the patent application. There are proposals to include disclosure requirement in the patent system in several fora.<sup>45</sup> The proposal includes various types and levels of information.<sup>46</sup> The patent system has been very reluctant to include such a requirement. The reluctance has been especially strong towards including this as a criterion for being granted a patent. A lot of political effort has been invested in these proposals. Less attention has been given to how this information is supposed to be used in order to achieve the objective (and obligation) of fair and equitable benefit sharing.

The primary outcome from requiring information about the origin of the genetic material is a large amount of information. This information will not necessarily convert into any distribution of benefits. One gap that will need to be bridged is how to take use of this information for the purpose of meeting the benefit sharing commitment. Therefore, disclosure requirements of any kind must be paired with enforcement mechanisms to be a successful strategy. To avoid the problem of extra-territoriality, the legal obligation must be geared towards the user and the one capturing the benefits. An obligation to give information can probably function as an element of a system for distributing benefits. Therefore, the high level of political attention and pressure for an obligation to give information must be discussed in a broader context addressing how this information is going to be used.

### **Obligations in User Countries**

These observations on certificates and disclosure of origin lead to the need for institutions that can take use of such information and the need for interlinked **legislation in the user country**. Before any of these tools are likely to create any benefit sharing they must be enforceable in the jurisdiction where the benefits from genetic resources are generated.

### *Default Contracts*

One manner to implement legislation in user countries that came up at the Cape Town meeting, introduced by José Carlos Fernandez, was to implement “Default Contracts/Clauses”. He described this as a legal tool applying to the use or capture of benefits from the use of genetic resources (*ex post* to access to genetic material). The more details in this suggestion need to be further developed. Perhaps one manner to implement this could be requirements that have to be met in the contract with the provider. Such general obligation could be coupled with a requirement to provide such contracts when the trigger-uses of genetic material happen. Such a minimum condition for contracts could probably avoid some of the problems with private law contracts discussed above. Perhaps this can create sufficient incentives for the users of genetic material to comply with the benefit sharing commitments.

Such a solution would also provide stability for industry and research. A default approach can create a clear and certain legal situation for biotechnology and industry. Industry can for example calculate the percentage of their gross-sales that they must stipulate as benefit sharing costs. If such minimum solution is chosen this would provide flexibility for countries

and companies as they still may enter into contracts supplementing the minimum standard.

#### *Developing a Standard User-Country Legislation*

One instrument that might prove to be effective for the implementation could be for the Ad Hoc Working Group to develop a Standard User Country Legislation.<sup>47</sup> The experience from the Bonn guidelines is that offering a too broad scope of measures and thus a numerous alternative possibilities, reduces the rate for successful implementation. Therefore, perhaps a concrete Standard User Country Legislation could be developed in a manner ready to be implemented directly into the legislation of each country after translating them to the official language or languages of that country. From the perspective of industry, to have a similar legal system in all countries will create a clear and predictable legal situation. The various harmonisation treaties in the patent system contain clear treaty texts that are to be translated into the legal language of each country. The result from this is a higher degree of harmonisation between countries. This emphasises that also for the benefit sharing legislation it is a need for creating close to identical obligations in all user countries, so perhaps the same strategy should be sought. The content of such a Standard User Country Legislation must contain all the elements described and discussed above.

### **A LOOK TO THE IMPORTANT DRAFT SUBSTANTIVE PATENT LAW TREATY IN WIPO**

There are a number of parallel ongoing processes in other international fora relevant to the work of the Ad Hoc Working Group.<sup>48</sup> The most important and most neglected process is the negotiation of a Substantive Patent Law Treaty in WIPO. In CBD fora there is a surprisingly low degree of attention given to the Standing Committee on Patent Law.<sup>49</sup>

The draft SPLT suggests standards governing the patent criteria (novelty, inventive step and industrial application), issues relevant for the patent applications and the patent claims.<sup>50</sup> The draft Treaty also includes a codification of a severe doctrine of equivalence that will give a legal basis for an expansive interpretation of each patent that has been granted. This will affect patenting living organisms and genes, especially since the draft SPLT is unclear whether it will maintain or close the flexibility provided in TRIPS Article 27.3. The negotiations of the SPLT have a holistic view covering all fields of innovation, even though special fields of technology raise distinct challenges.<sup>51</sup> This leads to a situation where it is quite challenging to predict the consequences from the draft SPLT for each specific field of technology.

The SPLT negotiation includes three separate legal documents: the draft Treaty (Substantive Patent Law Treaty, SPLT), the draft Regulations under the Substantive Patent Law Treaty, and the draft Practical Guidelines. Probably only the draft Treaty will be legally binding in the classic sense of international law, while the Regulations and Practical Guidelines will not have treaty status and will not be subject to ratification by the parliaments of the contracting parties. Even though these instruments are not treaties, they will have a normative effect when the SPLT enters into force. Understanding the total effect of these three legal documents read in conjunction is a complex issue.<sup>52</sup> This exposes the negotiations to being biased in favour of the countries pushing for the highest degree of harmonisation.

The on-going negotiations are sailing under the flag of technical negotiations of patent law. The negotiations are undeniably technical. Several of the articles in the draft Treaty and the draft Rules in the draft Regulation will influence the possibilities for achieving benefit

sharing.<sup>53</sup> Little has been written about the negotiations, and they are barely in the scope of public attention. The Working Group should probably analyse the effects that this treaty will have for future ABS regulations.

## CONCLUSION

One important lesson learnt in this article is that one major gap for achieving fair and equitable benefit sharing rests in the lack of implementation of clear obligations upon the beneficiaries from genetic material. Therefore, the Working Group could start on discussing how this gap could be bridged and start the talk on elements in a Standard User Country Legislation. If there also is a need for looking for other gaps, the Working Group could conduct such a gap analysis in a parallel process.

This article has focused upon the need for clarifying the scope for a benefit sharing obligation. One important step to bridge the benefit-sharing gap is therefore to define which uses of genetic material that shall be under the scope of the term genetic resources and thus required to distribute a part of the benefits arising from their use. It is important to develop an understanding of genetic material as a resource and not only any other raw material. These needs for conceptualising user country-measures and mechanisms for benefit-sharing were also the main findings from the Cape Town meeting.

Since benefits arising from the use of genetic resources are diverse, there is a need for including dynamic and flexibility into the legal system regulating them as well. Such flexibility can, however, not include a possibility for industry not at all to comply with the norms embedded in the CBD. This emphasises the need for a minimum-obligation applying to all as a supplement to the contractual approach.

A dangerous strategy for developing countries is to put a too high stake in the disclosure requirements or in the certificates systems if they are not been developed as a part of a total package of implementation of enforceable benefit-sharing commitments upon the beneficiaries. The discussions in the WIPO and the CBD indicate that there is too much of a focus on these tools, and too little focus upon other more legally binding mechanisms. Countries must be aware of the limits embedded in these strategies regarding the potential to create any benefit sharing.

The Ad Hoc Working Group has a broad mandate. Its work could follow a number of paths. Perhaps several instruments should be adopted to serve specific purposes. The less discussed and most unclear concept, namely the fair and equitable benefit sharing, needs to be discussed. The complexity of these topics underscores the need for the Working Group to take one step at the time. Perhaps the most urgent issue to address is the implementation of benefit sharing obligations upon the private party beneficiaries of genetic resources. Therefore, the first step of the Working Group should be to focus on developing a *Standard User Country Legislation* for user countries.

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## NOTES

- <sup>1</sup> The objectives of the CBD: “[...] to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.”, CBD Article 1.
- <sup>2</sup> Johannesburg Plan of Implementation Article 42.
- <sup>3</sup> Johannesburg Plan of Implementation Article 42.
- <sup>4</sup> Johannesburg Plan of Implementation Article 42 (o).
- <sup>5</sup> Decision by the COP-7, UNEP/CBD/COP/7/21, VII/19 D p. 299.
- <sup>6</sup> The documents from the meeting are available at [www.biodiv.org](http://www.biodiv.org).
- <sup>7</sup> See also [www.norsafworkshop.com](http://www.norsafworkshop.com).
- <sup>8</sup> The Mandate for the Working Group also covers implementation of the CBD Article 8(j), and thereby regulation of Traditional Knowledge (TK). Genetic resources and TK are rather different kinds of resources and thus this article cannot cover them both. Canada has announced that there will probably be an expert meeting on this topic probably before the next meeting in the Ad Hoc Working Group on CBD Article 8j. Traditional Knowledge is also dealt with in the work of the Intergovernmental Committee under WIPO, [www.wipo.org](http://www.wipo.org).
- <sup>9</sup> CBD Article 30.
- <sup>10</sup> CBD Article 28, 29 and 32.
- <sup>11</sup> Krasner, 1982, p. 185–205.
- <sup>12</sup> Finston 2005, pp. 141–155.
- <sup>13</sup> Finston 2005, p. 155.
- <sup>14</sup> CBD Article 1.
- <sup>15</sup> Several speakers at the Cape Town meeting took this for granted, for example da Rocha Vianna 2005.
- <sup>16</sup> Scott (2005) emphasises that “It seems that one of the greatest contributions that an ABS/IR could make towards more widespread implementation of the ABS provisions of the CBD would be

through development of an equitable, efficient, transparent, and enforceable instrument that would facilitate access to genetic resources, encourage research involving the use of those resources in ways that can generate added value through new and useful discoveries and inventions, and provide for the sharing of benefits (as in any healthy cooperative joint venture).”

<sup>17</sup> Bonn Guidelines Article 7, 16 and 42 c.

<sup>18</sup> Barber (2005) describes implementation as one of the main obstacles for benefit-sharing.

<sup>19</sup> E.g. Finston 2005 pp. 141–155.

<sup>20</sup> Scott 2005.

<sup>21</sup> Barber 2005.

<sup>22</sup> For an early discussion of the need for implementing user country legislation see Hendrickx, Koester and Prip 1993, pp. 254–255.

<sup>23</sup> CBD Article 2 tenth section read in conjunction with ninth section.

<sup>24</sup> See for example Fowler et alia 2001 and 2004.

<sup>25</sup> CBD Article 1 (emphasised here).

<sup>26</sup> CBD Article 15.7 (emphasised here).

<sup>27</sup> Pythoud (2005) raises a question if “... there [is] a specific type of use of genetic resources that might require additional international instruments to support implementation of CBD Art. 15?”

<sup>28</sup> See for example the benefit-sharing of the International Treaty on Plant Genetic Resources for Food and Agriculture Article 13.2 d ii.

<sup>29</sup> Fowler et alia 2004 and Chambers, 2003, p. 318–320.

<sup>30</sup> Casas-Castañeda (2005) argues that derivatives should be included in the calculation of the fair and equitable benefit sharing.

<sup>31</sup> Dross and Wolff 2005, pp. 56–59 (with further references).

<sup>32</sup> Tvedt and Young 2006, a forthcoming analysis called *Beyond Access*, part of the Access Project at the IUCN.

<sup>33</sup> Hodges 2005, Osman 2005.

<sup>34</sup> Hirsch (2005) for example argues that: “We need to get past the green gold expectation.” One of his points is that “Perhaps there will be a few blockbuster drugs created that will make fortunes for the lucky country of origin of the original substance, but most new products are not the results of a single gene expression.”

<sup>35</sup> Hirsch 2005. Wolfe and Zycher (2005) present figures illustrating that value created from biotechnology being high; and uses that as an argument for developed countries to refrain from regulating benefit sharing.

<sup>36</sup> See for example Finston 2005 (with further references).

<sup>37</sup> Hodges (2005) refers to sales of only marine biotech products to be estimated to some US\$100 million in 2000 (with further references).

<sup>38</sup> José Carlos Fernandez in his presentation in Cape Town.

<sup>39</sup> da Rocha Vianna 2005.

<sup>40</sup> A Norwegian study by Romstad and Stokstad (2005), *Valuation of Genetic Resources*, discusses valuation of genetic resources but focuses only on the genetic resources as an input to biotechnology rather than looking at the contribution made by genetic resources. Their literature review concludes that due to the lack of alternate scenarios, “...the value estimates of most applied studies to date are questionable.” at page 24.

<sup>41</sup> See for example Casas-Castañeda 2005.

<sup>42</sup> Fowler et alia, 2001.

<sup>43</sup> Casas-Castañeda (2005) suggests: “An international fund to reward efforts of indigenous and local

communities regarding the conservation and sustainable use of biological resources, particularly of endemic resources in situ conditions.”

<sup>44</sup> Dutfield, 2002, pp. 899–932, UNU/IAS 2003, Girsberger 2004, pp. 451–490, Biswajit, Dahr and Anuradha, R.V. 2004, pp. 610 sig and WIPO Study No. 3.

<sup>45</sup> Fora including the TRIPS Council of the WTO (see the proposal from the EU WTO document IP/C/W/383); the Patent Co-Operation Treaty under the WIPO (see the Swiss proposal, WIPO document PCT/R/WG/4/13); the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC). It is, however, not suggested in the Standing Committee on Law of the Patents for the draft Substantive Patent Law Treaty (draft SPLT).

<sup>46</sup> See for example the implementation in the Norwegian Patent Act § 8 b:

“For inventions including or having used biological material, the patent application shall include information of the country from where the inventor received or collected the material (providing country). If the national law of the providing country requires a prior informed consent for use of biological material, the application shall include information regarding whether such prior informed consent is received.

In the case where the providing country is another than the country of origin for the biological material, information about the country of origin shall be included. Country of origin shall in this context be understood the country where the material was brought out of its natural environment. If the national law of the country of origin requires a prior informed consent for use of biological material, the application shall include information regarding whether such prior informed consent is received. If information described in this section is not known or available, the applicant shall include stating this.” (Translation from Norwegian for this purpose.) Such a solution to the benefit sharing challenge was suggested by Hendrickx, Koester and Prip already in 1993.

<sup>47</sup> For a discussion of a mediation mechanisms under the CBD, see Chaytor, Gerster and Herzog, 2002.

<sup>48</sup> For example the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (WIPO), The Development Agenda in the WIPO, the ongoing work in the TRIPS-Council of the WTO, and the negotiations of the Standard MTA for the Multilateral System under the ITPGRFA in FAO.

<sup>49</sup> It was mentioned in the paper presented by the WIPO representative at the Cape Town meeting, but the presentation did not analyse the interrelation between the SPLT process and the work of the Working Group.

<sup>50</sup> These are the main topics regulated in the draft treaty.

<sup>51</sup> For example Westerlund 2001 discusses profoundly the concepts of *invention or discovery*, *enabling disclosure* and *the doctrines of equivalence* for biotech patents; and Bostyn 2002 who discusses the requirement for *enabling disclosure* in depth. See also the report from the Nuffield Council which expresses several concerns.

<sup>52</sup> See Tvedt 2005.

<sup>53</sup> For an analysis of the effect of the draft SPLT on the public domain to genetic resources see, Tvedt 2005 (in this Journal). Correa (2004) has, on behalf of the South Centre prepared a position paper analysing the text from a developing country perspective. This article does not take a pure developing country perspective, but a wider look at the relationship between the new WIPO treaty and the public interest.

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