Chapter 6
BRIDGING THE GAP: ADEQUACY OF TRIPS BASED SOLUTIONS

The inconsistency between the TRIPS and the CBD is found to be the legal vacuum in the TRIPS to promote the CBD goals of PIC and benefit sharing through MAT. It is also evident that the CBD’s bilateral contractual framework alone cannot prevent misappropriation of GRs and associated TK through patenting. Basically being an environmental framework, efforts purely from the part of the CBD could not produce much progress in this regard. The complete silence of the Nagoya Protocol on IP provisions is exemplifying this. In bridging the gap between the TRIPS and the CBD framework, different proposals have been put forward in the TRIPS Council. Due to lack of consensus, these proposals are in stalemate and some of the developing countries are trying to keep the deliberations going on by calling for text-based negotiations on the issue. Efforts are going on in the WIPO also to provide adequate protection, inter alia to GRs and associated TK. The present chapter outlines these various proposals and analyses their effectiveness to solve the issue of misappropriation facilitated through IPRs.

The remedial measures suggested are in the form of certain disclosure requirements in different regulatory planes. Three types of disclosure requirements have been suggested. The group of countries headed by Brazil and India known as the disclosure group suggested addition of a requirement in the TRIPS mandating disclosure of the source and country of origin of the GRs and associated TK used in the invention together with the evidence of PIC and fair and equitable benefit sharing. This proposal is known as TRIPS disclosure requirement or triple disclosure requirement. The next proposal by EC relates to the disclosure of the source and country of origin of the GRs
and associated TK used in the invention at the time of filing the patent application and has no reference to PIC and benefit sharing. This too relates to an amendment in the TRIPS. A third suggestion made by Swiss delegation was to bring in changes in the PCT Regulations of the WIPO so as to enable the national legislations to incorporate a disclosure requirement in relation to the source of the GRs and TK used in the invention. Each of these proposals is having varying scope and dimensions which will be discussed in the present chapter.

6.1 TRIPS Disclosure Proposal

A proposal put forward by many of the developing countries to bridge the gap between the TRIPS and the CBD is an amendment in the TRIPS so that Members are bound to require a patent application involving GRs or TK to provide information regarding (a) the source and country of origin of the BR and/or the TK used in the invention, (b) evidence of PIC obtained from competent national authorities under the relevant national regime and (c) evidence of fair and equitable benefit sharing under the relevant national regime. This proposal makes it obligatory on the members to incorporate required changes in domestic patent legislations requiring the patent applicants to mandatorily disclose the three aspects whenever the invention contains GRs or associated TK together with a reporting obligation in the event of patenting or commercialization. A declaration in the patent application accompanied by a certificate issued by the relevant national authority or a duly certified contract between the applicant and the national authority of the country of origin would serve as the evidence of PIC. The

1 Secretariat, "The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity: Summary of Issues Raised and Points Made," IP/C/W/368/Rev.1 dated 8 February 2006, para. 71
2 Id. para. 72; Also see the Disclosure Group, "The Relationship Between the TRIPS Agreement and the CBD and the Protection of Traditional Knowledge," IP/C/W/356 dated 24 June 2002, para. 10
3 Id. para. 73
obligation to provide evidence of benefit sharing would be discharged by providing evidence, at the time of patent application, of a future or existing benefit sharing agreement premised upon MAT which are fair and equitable in the given circumstances\textsuperscript{4}. The terms of benefit sharing would cover elements relating to the conditions, obligations, procedures, types, timing, distribution and mechanism of the benefits to be shared\textsuperscript{5}. There should be an indication in the application as to how the arrangement would be enforced and the burden of proof is limited to providing information and evidence known to the applicant or should have been known to him\textsuperscript{6}. Considering the weak status of the traditional communities in the negotiating process, it is recommended that the benefit sharing agreement primarily entered into with them should be subsequently supplemented and confirmed by the national regulatory authority\textsuperscript{7}. Even in countries where there is no national regime to ensure the CBD goals of PIC and benefit sharing, the applicant has to mention the same \textsuperscript{8} and also provide evidence to the effect that consent has been obtained at least from the authority or community in charge of the GRs or TK accessed or that there is a benefit sharing agreement or a future one is envisaged with the concerned authorities or that access is obtained in full compliance with the other applicable laws, regulation and practices of the country of origin\textsuperscript{9}. When it is found that there is inadequate, wrongful or non-disclosure by the applicant, it is proposed that at the stage of processing of the patent application, processing will be denied until the necessary declaration and evidence of PIC and ABS reaches the patent office and this would be accompanied by penalties and time limits within which the applicant is required to produce the relevant evidence failing to do which will result in the application deemed to have been withdrawn; at the post

\textsuperscript{4} Ibid.  
\textsuperscript{5} Ibid.  
\textsuperscript{6} Ibid.  
\textsuperscript{7} Ibid.  
\textsuperscript{8} Ibid.  
\textsuperscript{9} Id. para. 74
grant stage, on establishing the fraudulent intent, the patent would be revoked; criminal or administrative sanctions must be invoked to ensure punitive damages or adequate compensation outside the IP structure; full or partial transfer of the right to the invention would also follow when full disclosure would have shown that any other person, community or governmental agency is the inventor or part inventor; and narrowing down of the scope of the claims when the claims are affected due to lack of novelty or fraudulent intention or where full disclosure would have resulted in rejection of those parts of the claims and all the above remedies are proposed to be subject to judicial review⁹. Members should be having an obligation to ensure that the effect of insufficient, wrongful or non-disclosure is having adequate deterrent, compensatory and equity value and the countries could define in their domestic legislations, the penalties applicable in case of failure to comply with the requirements and the legal effects mentioned in the proposal are different options available¹⁰. The remedies are proposed to have retrospective effect so as to cover past uses¹¹. The triple disclosure obligation would be triggered by any use including the incidental use of a GR or TK in an invention the disclosure of which is necessary to determine the existence of prior art, inventorship or entitlement to the claimed invention and the scope of the claim and/or is necessary for understanding or carrying it out¹². Such uses could include those that result in forming part of the invention, use during the process of developing the claimed invention, use that is a necessary pre-requisite for the development of the claimed invention, or use to facilitate the development of the claimed invention where it forms part of the necessary background material for the development of the invention¹³. Regarding the burden of proof in case of

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⁹ Id. para. 75  
¹⁰ Id. para. 76  
¹¹ Ibid.  
¹² Id. para. 77  
¹³ Ibid.
non-compliance, it is limited to prove that the resource and/or the knowledge
have been legally and legitimately accessed and that benefit sharing had
taken place or would take place on the grant of the patent. Applicants are
expected to employ all reasonable measures to find out the country of origin
and the source of the material used, but the onus is limited to the disclosure
of evidence that is known or should have been known to him. Regarding
the legal form of the proposed amendment in the TRIPS agreement, three
suggestions have been made; (a) an amendment in Article 27 of the TRIPS
Agreement, (b) amendment to Article 29 or (c) introduction of a new
article in the TRIPS. The advantages of the proposed system are
summarised as: increasing transparency in the ABS system and helping the
source countries to monitor and keep track of compliance with ABS rules in
a cost effective way within the patent system, facilitating and simplifying the
enforcement of CBD obligations through the provision of incentives on

14 Id. para. 78
15 Peru, Article 27.3(b), The Relationship between TRIPS Agreement and the Convention
on Biological Diversity and Protection of Traditional Knowledge and Folklore,
IP/C/W/447 dated 8 June 2005 proposes an amendment to Article 27 in the form of a
further exception to patentability with the wording that
Members may also exclude from patentability:
(c) products or processes which directly or indirectly include genetic resources or
traditional knowledge obtained in the absence of compliance with international and
national legislation on the subject, including failure to obtain prior informed consent of the
country of origin or the community concerned and failure to reach agreements on
conditions for the fair and equitable share of benefits arising from their use.
Nothing in TRIPS shall prevent Members from adopting enforcement measures in their
domestic legislation, in accordance with the principles and obligations enshrined in the
Convention on Biological Diversity.
16 Consisting of the addition of a paragraph as set out in the following alternative sets
proposed.
Members shall require an applicant for a patent to disclose the country and area of origin
of any biological resources and traditional knowledge used in the invention, and to provide
confirmation of compliance with all access regulations in the country of origin. (African
Group, Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement,
IP/C/W/404 dated 26 June 2003)
or
Where appropriate, Members shall require the disclosure of origin and legal provenance in
the patent applications to be submitted. (Peru, Supra n.15)
17 Disclosure Group, The Relationship between the TRIPS Agreement and the Convention
on Biological Diversity and the Protection of Traditional Knowledge, IP/C/W 403 dated
24 June 2003
patent applicants for the conclusion of contracts such as MTAs and ITAs; resulting in the grant of better patents through more focused search in the patent office and lessening the burdensome challenges regarding patent validity, contributing to additional information on prior art regarding TK enabling search that might be outside the scope of established databases; building more confidence in the patent system restoring the trust of all stakeholders and inspiring resource rich countries to provide less complex national ABS regimes; developing a predictable environment for government, investors, traditional communities and researchers that could lead to more biotechnological research and development in developing countries, thus creating a win-win situation for both providers and accessors and finally creating respect for the rights and beliefs of indigenous people and safeguarding the sovereign interest in GRs\textsuperscript{18}.

One of the major disagreements with the disclosure approach was that this would not achieve its purported objective of ensuring PIC and benefit sharing and nor will it prevent the grant of erroneous patents\textsuperscript{19}. It was also argued that the disclosure requirements would introduce many negative consequences, uncertainties in the patent system, impose additional administrative burdens and hinder the role of the patent system in promoting innovation and would also undermine potential benefit sharing\textsuperscript{20}. The counter argument is that the new disclosure requirements would help the source countries to monitor and keep track of compliance with ABS rules in a cost-effective way\textsuperscript{21}. It would also facilitate and simplify the enforcement of obligations under the CBD through incentive measures for patent

\textsuperscript{18} Supra n.1, para. 93
\textsuperscript{19} US on Article 27.3(b), "Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge and Folklore\textsuperscript{2}, IP/C/W/434 dated 26 November 2004; Also see US, Article 27.3(b), "Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge and Folklore, IP/C/W/449 dated 10 June 2005
\textsuperscript{20} Ibid.
\textsuperscript{21} Supra n.1, para. 112
applicant for conclusion of contracts, especially where the legal effects include revocation of patents\textsuperscript{22}. As regards the disclosure of evidence of PIC and benefit sharing it was counter stated that it would not be feasible to require evidence of PIC and ABS in addition to the information regarding source of the genetic material since the patent office is not capable of verifying the same\textsuperscript{23}. The terms and conditions of a contract that is confidential may not be accessible to the patent office and the terms may vary with regard to the benefits to be shared and what is fair and equitable differs on case-by-case basis and the patent offices have no way of judging fairness and equity\textsuperscript{24}. It is also argued that determinations by patent office and other authorities may affect contractual autonomy\textsuperscript{25}. Another point made against the evidence of PIC and benefit sharing was that if the country of origin has no benefit sharing infrastructure in place, there would not be any compensation to the custodians of the resource or knowledge even if a patent relating to these materials is identified\textsuperscript{26}. It was also submitted that it is premature to consider introducing a requirement on PIC and benefit sharing since many countries do not possess fully operational and effective national regimes capable of providing certificates of evidence\textsuperscript{27}. Another argument was that the requirement of PIC and benefit sharing would bring in incoherence with the ITPGRFA since the latter does not foresee any PIC or benefit sharing making the requirement operational only for resources acquired as per CBD and not for ITPGRFA and the patent offices would be

\textsuperscript{22} Ibid.
\textsuperscript{23} Id. para. 118
\textsuperscript{24} Ibid.
\textsuperscript{25} Ibid., also see Switzerland, \textit{The Relationship Between the TRIPS Agreement and Convention on Biological Diversity and the Protection of Traditional Knowledge and Folklore and the Review of Implementation of the TRIPS Agreement under Article 71.1 of IP/C/W/446} dated 30 May 2005
\textsuperscript{26} Ibid. Also see \textit{Supra} n.19
\textsuperscript{27} Ibid.
burdened with distinguishing the applications\textsuperscript{28}. Yet another argument made was that there is some incoherence in the proposal between requiring as a condition for acquiring patent rights that applicants furnish evidence of PIC\textsuperscript{28} and requiring applicants to provide information known to them or which they should reasonably know\textsuperscript{29}. In response to the above concerns, the disclosure group submitted that what is fair and equitable will be decided by the national authorities of the country of origin according to the CBD and not by the patent offices\textsuperscript{30}. It was also reinstated that the burden on the patent offices would be reasonable as the burden would be on the country providing access to prove that the evidence submitted in relation to PIC is false or the benefit sharing is not fair and equitable. If there is any allegation as to the fairness or equity in benefit sharing, the alleger has to take relevant action as per the domestic ABS regime and produce the result before the patent office. The patent office would have to accept the same and is not required to interpret foreign laws on ABS\textsuperscript{31}. As regards the issue of fairness and equity in benefit sharing, it is submitted that there would be a reporting obligation casted upon the person seeking access to the resources or communities in the instance of patenting and commercialization and if this obligation is not carried out, it would be deemed that there is no fair and equitable benefit sharing, and any dispute regarding the same would be dealt by the appropriate national authorities under the domestic ABS regime and not by the patent office\textsuperscript{32}. As regards the contractual autonomy, India submitted that contractual autonomy is subject to the provisions of PIC and benefit sharing and it cannot be used as a tool to prevent implementation of the CBD

\textsuperscript{28} Ibid. ; Also see, Switzerland, fnArticle 27.3(b): The Relationship Between TRIPS Agreement and Convention on Biological Diversity and the Protection of Traditional Knowledge, IP/C/W/400/ Rev.1 dated 18 June 2003.

\textsuperscript{29} Ibid.

\textsuperscript{30} Id. para. 119

\textsuperscript{31} Ibid. ; Also see, Brazil and India, fnThe Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge, IP/C/W/443 dated 18 March 2005

\textsuperscript{32} Ibid.
provisions. Regarding the issue of absence of benefit sharing infrastructure, it is submitted that inclusion of TK within the scope of access as well as mandatory requirement of PIC from the TK holders is a matter of national policy. If the knowledge over the resources vests with the communities and the domestic law requires PIC from them, the person seeking access would be obliged to ensure PIC from them. The anomaly suggested regarding the need to distinguish between the patent applications on the access resulting from CBD and those from ITPGRFA is also not correct since the ITPGRFA has an inbuilt mechanism to ensure benefit sharing and PIC. So a reference to the effect that the source of the resource is the MLS of the ITPGRFA will completely relive the applicant.

Another point that came up for discussion during the negotiation on the triple disclosure requirement relates to the remedies for non-compliance including revocation of granted patents. As regards its implications on the effective functioning of the patent system, one concern expressed was that instead of singling out patent applications and trying to deal them with the new disclosure requirements that may negatively affect technological development, an appropriate solution would be strengthening of national regimes outside the patent system so as to address all instances of commercialization of the misappropriated resources or TK and needs to be addressed outside the patent system in any event. Another submission was that there is no adequate data to the effect that sanctions outside the patent system would have no deterrent effect on the defaulters. Another issue raised was that there is no clarity as to the circumstances that would justify

33 Ibid.
34 Ibid.
35 US, ÚArticle 27.3(b): Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge and FolkloreÚ, IP/C/W/449 dated 10June 2005 para 121
36 Ibid.; Also see, EC, ÚReview of Article 27.3(b) of the TRIPS Agreement and the Relationship Between the TRIPS Agreement and CBD and the Protection of Traditional Knowledge and FolkloreÚ, IP/C/W/383 dated 17 October 2002
revocation of the granted patent and full or partial transfer of the rights over
the claimed invention and also the question who would be the recipient of
such transferred rights. In response to these concerns, the disclosure group
submitted that failure to comply with the disclosure requirement should be
dealt with in the patent system lest it should nullify the requirement and
transform it into a mere formality. This is because of the fact that there is
no effective remedy to deal with the deliberate omission from the part of the
patent applicant to comply with the CBD requirements. Also fines or other
penalties outside the patent system would not substantially affect the validity
of the patent lessening the deterrent effect of the action against
misappropriation. Revocation or invalidation will be applicable only when
nondisclosure is accompanied by fraudulent intention and is similar to
existing procedures in the patent system with respect to cases of revocation
when fraudulent intention is found for insufficient, wrongful or lack of
disclosure and where a proper disclosure would have lead to the refusal of
the grant of patent for reasons of lack of novelty, ordre public or morality.
The disclosure group also argued that the instances of commercialization
other than patents could be effectively taken care of by the national ABS
regimes and it should not be taken that since the disclosure requirements
does not cover all instances of commercialization, such a requirement is not
necessary.

An interesting point of discussion was that such sanctions themselves
would reduce the benefits available to be shared because (i) invalidation of a

37 Ibid. Also see Supra n.25,
38 ld. para. 122; Also see, Disclosure Group, The Relationship Between the TRIPS
Agreement and the Convention on Biological Diversity and the Protection of Traditional
Knowledge. IP/C/W/403 dated 24 June 2003
39 Ibid.
40 Minutes of the TRIPS Council on Brazil, IP/C/M/48 dated 15 September 2005 para. 41
41 Brazil et.al, “The Relationship Between the TRIPS Agreement and the Convention on
Biological Diversity and the Protection of Traditional Knowledge, Technical Observations
on the US Submission IP/C/W/449â, IP/C/W/459 dated 18 November 2005
42 Ibid.
granted patent or non-issuance of patent to an application will render the invention to be freely used and commercialised by third parties without the obligation to share the profits\(^4^3\); (ii) the requirement may prevent a person from applying for patent protection, but still he would be able to commercialise the same without sharing the benefits\(^4^4\). This would destroy benefit sharing and is neither in the interest of innovation nor in the interest of securing benefit sharing. In response, it was contented by the disclosure group that such instances are not different from situations involving any invention or patent and is not limited to patents involving disclosure of source and country of origin. Such situations could be dealt by other remedies outside the patent system within the national regimes in conjunction with other international rules including trade secret laws and competition laws\(^4^5\).

As regards the consistency of the requirement within the TRIPS, it was argued that bringing in such a requirement under Article 27 would result in discrimination among some fields of technology in the context of patent availability\(^4^6\) and this was countered on the ground that there is inherent difference in patent applications for inventions involving GRs and associated TK demanding additional conditions so as to enable better assessment of such applications\(^4^7\).

Yet another point of departure was the necessity of furnishing evidence of PIC and benefit sharing to ensure the goals of ensuring PIC and benefit sharing. Against this requirement, it was contented that the patent disclosure requirements *per se* cannot ensure PIC and benefit sharing as they

\(^{43}\) TRIPS Council Minutes on US, IP/C/M/40 dated 22 August 2003 para. 122

\(^{44}\) Supra n.1 Similar concern is expressed by Canada, EC, Japan, Korea and US

\(^{45}\) Supra n.31

\(^{46}\) TRIPS Council Minutes on Japan, IP/C/M/29 dated 6 March 2001 para. 155

\(^{47}\) Disclosure Group, “The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge” IP/C/W/403 dated 24 June 2003
convey only the required information and do not serve any benefit sharing mechanism\(^{48}\). Another line of argument was that when there is no patenting, the disclosure requirements would be of no use\(^{49}\). Since the sanctions like revocation would negatively affect the incentives to go for patent protection, it may negatively affect the benefit sharing objective of the CBD. In response the disclosure group submitted that all the three elements are necessary in ensuring mutual supportiveness between the TRIPS and CBD. The requirements to furnish evidence of PIC and benefit sharing are essential in ensuring that domestic ABS regimes are respected and implemented effectively through remedial action at the global level through the TRIPS\(^{50}\). Disclosure requirements are not intended as a stand-alone requirement, instead, they have to complement the domestic ABS regimes\(^{51}\).

As regards the usefulness of the disclosure requirements in preventing erroneous patents, one view was that the requirement would be ineffective since (i) information regarding source and country of origin is not information material to patentability without which the examiners can understand the invention properly and examine the application as to judge patentability\(^{52}\); (ii) determination of inventorship is generally based on a country\(^{\circ}\)'s patent law and on acts of invention, and information regarding source or country of origin have little relevance in these considerations\(^{53}\) and (iii) lowering the standards of the requirement to information that is known or should have known to the applicant will render such disclosure

\(^{48}\) IP/C/M/40 Para 122 US
\(^{49}\) Supra n.19
\(^{50}\) Supra n.41
\(^{51}\) Brazil and India, "The Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge\(^{\circ}\) IP/C/W/443 dated 18 March 2005.
\(^{52}\) US, Article 27.3(b), "Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge and Folklore\(^{\circ}\) IP/C/W/449 dated 10June 2005
\(^{53}\) Ibid.
irrelevant. This was strongly countered by the disclosure group emphasising that a reason for questionable patent is insufficient disclosure of existing knowledge and the inadequacy of the existing patent system to check the relevant details. The disclosure requirements would give the patent office useful hints to enquire into the novelty and inventiveness claimed in the invention in the form of information regarding the source and country of origin of the material or the knowledge. If the requirements are made mandatory, the examiners can require more information from the applicants to ensure that the invention is eligible for patent protection. The disclosure group also argued that though mere information on source and country of origin may not help in ascertaining inventorship or patentability, it would be helpful in determining whether the resource or knowledge used is forming part of the claimed invention; during the process of developing the claimed invention; as a necessary prerequisite for the development of the claimed invention; to facilitate the development of the invention; and/or as a necessary background material/information for the development of the invention. Such information would be relevant in determining the existence of prior art and non-obviousness of the claimed invention, inventorship or entitlement to the patent, scope of the claim and for understanding or carrying out the invention. It was also contended that when an invention is based on GRs or associated knowledge, information on source and country of origin would be useful in ascertaining whether the applicant has invented what he is claiming or just found the invention in nature or obtained from traditional cultures.

54 TRIPS Council Minutes on Japan, IP/C/M/48 dated 15 September 2005 para. 75
55 Supra n.19
56 Supra n.54 on India in para. 55
57 Supra n.41
58 Ibid.
59 Supra n. 54 on Brazil in para. 37
The implications of the disclosure requirements on the patent system were also subject to discussion. As regards the burden on the patent offices, one view was that they would have both legal and administrative difficulties in determining the geographical origin of the GRs and the TK. It was also argued that the patent offices would be unable to verify compliance with PIC and benefit sharing for (i) they may not have the technical and legal competence to verify the evidences provided, (ii) the terms and conditions of a contract would remain confidential and may not be available to the patent granting authority and (iii) even if the terms are made available, the verification task would overburden the patent offices, creating problems of legal interpretation in relation to compliance with foreign laws. The requirements were also alleged to cause additional administrative costs for training and system development in patent offices. Against these propositions, the disclosure group submitted that the role of the patent offices would be to ensure that the applications are complete, confirming that the patent application contains a declaration in the prescribed form indicating that PIC has been obtained and that benefits have been shared or/and that there exists an arrangement for future benefit sharing as per the domestic law. It is routine for the patent offices to ascertain necessary evidence in cases of allegation of fraud and the disclosure requirement does not impose any additional burden on them. The disclosure evidences need to be ascertained only when the validity of a patent is challenged in the pre or post grant opposition or revocation stage where the patent office would have evidence from both the parties facilitating it to do the usual assessment at the

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60 US, Review of the Provisions of Article 27.3(b) - Further Views of the US, IP/C/W/209 dated 3 October 2000
61 Supra n.36; Also see Supra n.28; Supra n.25
62 Supra n.26
63 India, Protection of Biodiversity and Traditional Knowledge - The Indian Experience, IP/C/W/198 dated 14 July 2000
64 Supra n.41
stage of opposition or revocation\textsuperscript{65}. The proposed requirements are argued to increase the capacity of the patent offices in examining applications dealing with GRs and associated TK\textsuperscript{66} and the costs and burdens in implementing the requirements should be considered in the light of the high costs of collecting evidence in revocation proceedings in the absence of such requirements\textsuperscript{67}. As regards the burden on the patent applicants, it was contended that the requirements may discourage applicants from seeking patent protection and may prompt them to keep their inventions secret\textsuperscript{68}. Against this, the disclosure group argued that the onus of the applicant is limited to providing information and evidence that is known to him or should have been known to him imposing minimal administrative and cost burden and that the recording and collection of information relating to meet the disclosure obligation fall squarely within the efforts undertaken in the process of developing a patent application for an invention\textsuperscript{69}. It was also argued that in most of the countries, evidence of PIC is a pre-requisite for the grant of access to GRs and associated TK, thus not creating any additional burden\textsuperscript{70}.

As regards the consequence of the disclosure approach on the operation of the patent system and its ability to fulfil its public policy objectives, one argument was that the information from the new disclosure requirements regarding source and country of origin is not relevant to considerations of novelty and inventive step, thereby of little help to patent examiners in making such decisions\textsuperscript{71}. It was also argued that the disclosure requirements together with sanctions like revocation would cause additional avenues of litigation, cause uncertainties and would undermine the role of

\textsuperscript{65} Supra n.19
\textsuperscript{66} Supra n.54 on Brazil in para. 36
\textsuperscript{67} Supra n.19
\textsuperscript{68} Supra n.26
\textsuperscript{69} Supra n.41, India \textit{et.al}, \textit{Elements of the Obligation to Disclose the Source and Country of Origin of the Biological Resources and/or Traditional Knowledge Used in an Invention} IP/C/W/429/Rev.1 dated 27 September 2004
\textsuperscript{70} TRIPS Council Minutes on India, IP/C/M/49 dated 31 January 2006 para. 143
\textsuperscript{71} Supra n.19
the patent system in promoting innovation and technological development\textsuperscript{72}. Another contention was that patent law is not designed to regulate misconduct issues such as misappropriation of TK or GRs and that a contract based ABS system can effectively and adequately achieve domestic policy goals of conservation and sustainable use of GRs\textsuperscript{73}. In contra, the disclosure group submitted that the requirements would facilitate the process of examination by adding information on prior art regarding TK and also enable searches outside the scope of existing databases, resulting in the grant of better patents\textsuperscript{74}.

\textbf{6.2 Appraisal}

The TRIPS disclosure proposal poses a very interesting situation. At the very outset, it argues for disclosure of three elements, viz., source and country of origin of the GRs and associated TK, evidence of PIC and benefit sharing. But as regards the legal form of amendment to be carried out in the TRIPS, Peru suggests that Article 27 could be amended as to

\begin{quote}
\textit{\textbf{\textcircled{c} Members may also exclude from patentability:\textsuperscript{(c)} products or processes which directly or indirectly include genetic resources or traditional knowledge obtained in the absence of compliance with international and national legislation on the subject, including failure to obtain prior informed consent of the country of origin or the community concerned and failure to reach agreements on conditions for the fair and equitable share of benefits arising from their use. Nothing in TRIPS shall prevent Members from adopting enforcement measures in their domestic legislation, in accordance with the principles and obligations enshrined in the Convention on Biological Diversity.}}
\end{quote}

\textsuperscript{72}\textit{Ibid.}

\textsuperscript{73} TRIPS Council Minutes, IP/C/M/47 dated 3 June 2005 para. 48

\textsuperscript{74} \textit{Supra} n.1
Ironically, the proposal is silent on the disclosure of source and country of origin of the resources or associated TK. With respect to amendment in Article 29, the disclosure group suggest insertion of Article 29 bis as

“Disclosure of Origin of Biological Resources and/or Associated Traditional Knowledge

1. For the purposes of establishing a mutually supportive relationship between this Agreement and the Convention on Biological Diversity, in implementing their obligations, Members shall have regard to the objectives and principles of this Agreement and the objectives of the Convention on Biological Diversity.

2. Where the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge, Members shall require applicants to disclose the country providing the resources and/or associated traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin. Members shall also require that applicants provide information including evidence of compliance with the applicable legal requirements in the providing country for prior informed consent for access and fair and equitable benefit-sharing arising from the commercial or other utilization of such resources and/or associated traditional knowledge.

3. Members shall require applicants or patentees to supplement and to correct the information including evidence provided under

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75 Disclosure Group, Doha Work Programme: The Outstanding Implementation Issue on the Relationship Between the TRIPS Agreement and CBD, IP/C/W/474 dated 5 July 2006
paragraph 2 of this Article in light of new information of which they become aware.

4. Members shall publish the information disclosed in accordance with paragraphs 2 and 3 of this Article jointly with the application or grant, whichever is made first. Where an applicant or patentee provides further information required under paragraph 3 after publication, the additional information shall also be published without undue delay.

5. Members shall put in place effective enforcement procedures so as to ensure compliance with the obligations set out in paragraphs 2 and 3 of this Article. In particular, Members shall ensure that administrative and/or judicial authorities have the authority to prevent the further processing of an application or the grant of a patent and to revoke, subject to the provisions of Article 32 of this Agreement, or render unenforceable a patent when the applicant has, knowingly or with reasonable grounds to know, failed to comply with the obligations in paragraphs 2 and 3 of this Article or provided false or fraudulent information.

Even though this recommendation has been put in place by the disclosure group, since there was no progress in the work of the TRIPS Council, in furtherance to carry on the discussions, the disclosure group now calls for text based negotiations on this issue and the draft modality text as submitted by them in this regard reads:

Members agree to amend the TRIPS Agreement to include a mandatory requirement for the disclosure of the country providing/source of genetic resources, and/or associated traditional knowledge for which a definition will be agreed, in patent
applications. Patent applications will not be processed without completion of the disclosure requirement.

Members agree to define the nature and extent of a reference to Prior Informed Consent and Access and Benefit Sharing.

Text based negotiations shall be undertaken, in Special Sessions of the TRIPS Council, and as an integral part of the Single Undertaking, to implement the above. Additional elements contained in Members' proposals, such as PIC and ABS as an integral part of the disclosure requirement and post-grant sanctions, may also be raised and shall be considered in these negotiations. 76

So the implication is that the proposed mandate under the Draft Modality Text relates to disclosure of country providing/source of GR and associated TK and the requirement on PIC and benefit sharing are not yet developed. This has deteriorated the ownership concept under the CBD as the obligation does not expressly confer rights on the country of origin. From the point of view of ABS, recognition of the CBD goal of benefit sharing pursuant to access is again belated.

The triple disclosure obligation is proposed to be initiated by any use of the resources in the invention and this proposition is further explained providing that such disclosure must be essential for determining the prior art, inventorship, entitlement to the claimed invention or the scope of the claims. Use of the resources and knowledge so as to form part of the invention, during the process of developing the claimed invention, use that is a necessary pre-requisite for the development of the claimed invention, or to facilitate the development of the claimed invention where it forms part of the necessary background material for the development of the invention are also

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76 Albania et.al, Draft Modalities for TRIPS Related Issues, TN/C/W/52 dated 19 July 2008
recommended to trigger the obligation. But it leaves the fact that the CBD regime provides for claims in respect of any use of the resources and the knowledge even if its contribution to the alleged invention is very minimal. Though the disclosure requirements seem very effective, there is no consensus among the international community to insert evidences in relation to PIC and benefit sharing and to invoke sanctions within the patent system to deter acts of non-compliance. These requirements should also be weighed in light of the report that the examination policy of some countries is that the patent office is not the best forum to deal with issues of novelty and inventiveness and that the best way to deal with such issues is to grant patents which will be later contested in the courts. If this is the case, there is a need to develop specific examination guidelines in this regard. From an assessment of the triple disclosure requirement, what is made clear is that such a requirement can be included in the TRIPS only if it has a relationship with the substantive patentability criteria of novelty, inventive step and utility. Only if the developing countries can establish that relationship, then only they represent a valid case for amending the TRIPS whether it is in Article 27 or Article 29. Even though some relationship could be established with reference to the disclosure of source and country of origin, the other two disclosures in relation to the PIC and ABS stand protracted. The present section does not go into the details of possibility of the three requirements being linked with the patentability criteria, instead, it further analyses the other proposals suggested and tries to find out their efficacy.

6.3 Mandatory Disclosure Proposal

77 CBD, "Measures, Including Consideration of their Feasibility, Practicality and Costs, to Support Compliance with Prior Informed Consent of the Contracting Party Providing Genetic Resources and Mutually Agreed Terms on Which Access was Granted in Contracting Parties with Users of such Resources under their Jurisdiction", UNEP/CBD/WG-ABS/2/INF/2 dated 29 September 2002 p.38
Another approach suggested is that each country would accept an obligation to require all patent applicants to disclose information on the country of origin or source of the genetic material used in the invention which the patent applicants know or have reason to know and this proposal is referred to as mandatory disclosure proposal\textsuperscript{78}. It is also proposed that the applicant could be required to declare the specific source of the TK associated with the GRs if he is aware that such invention is directly based on such TK and this requirement is proposed to have necessitated an in-depth understanding of the definition of GR\textsuperscript{79}. The requirement would be legally binding and universal and would apply to all national, regional and international patent applications at the earliest stage possible\textsuperscript{80}. This requirement will be only a formal requirement and will not constitute any additional formal or substantial patentability criterion\textsuperscript{81}. In case of failure or refusal to give the specific information, the patent application will not be further processed, and once the patent is granted, the legal effects of non-compliance on finding that the information was incorrect or incomplete, would fall outside the ambit of patent system through civil or administrative sanctions\textsuperscript{82}. The obligation to disclose would be triggered when the TK or the resource forms part of the claimed invention or has been necessary for the development in the claimed invention or to put in, the invention must be directly based on the GRs in question\textsuperscript{83}. The burden of proof in relation to non-compliance would lie on the alleger\textsuperscript{84}. With respect to PIC and benefit sharing, a simple notification procedure to a centralised body could be followed by the patent office every time it receives a declaration\textsuperscript{85}. A list of governmental agencies competent to receive information about patent

\textsuperscript{78} Supra n.1, para 87. \\
\textsuperscript{79} Ibid. \\
\textsuperscript{80} Ibid. \\
\textsuperscript{81} Id. para 88 \\
\textsuperscript{82} Ibid. \\
\textsuperscript{83} Ibid. \\
\textsuperscript{84} Ibid. \\
\textsuperscript{85} Id. para 89
applications containing declaration of the source of the GRs could be established and the list could be maintained by WIPO in close cooperation with the CBD\textsuperscript{86}. Or the Clearing House Mechanism of the CBD could act as the central body to which the patent offices could send the information that would then be available to all parties of the CBD as well as the public\textsuperscript{87}. Regarding the legal form of this proposal, it is submitted that it is too early to discuss on this aspect since it would depend on what substance it would be agreed upon\textsuperscript{88}. The possible options would be to insert a new article on the TRIPS or a new obligation in an existing Article\textsuperscript{89}. Some argue for a mandatory provision in the TRIPS with a possibility to bring it under Article 29 of TRIPS\textsuperscript{90}. It is also submitted that the proposal is facilitating the implementation of the objectives of the CBD without affecting the balance of rights and obligations set out in the TRIPS while creating a favourable environment for research and development in the field of biotechnology in the WTO Member States\textsuperscript{91}.

The proponents further elaborated that the applicant should disclose the country of origin, i.e. the country possessing the GRs \textit{in-situ} and if it is not known, the applicants obligation would be to disclose the source of the specific GR to which the inventor has had physical access and which is known to him\textsuperscript{92}. This could be the research centre, gene bank or the entity from which the inventor acquired the resource\textsuperscript{93}. It is further clarified that if the country of origin is not known to the applicant, he can indicate the source which could, sometimes, be the country providing the GRs\textsuperscript{94}. The proponents also clarify that the term \textit{disclosure of source} is preferred to \textit{disclosure of source}.

\begin{table}
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\textsuperscript{86} & Ibid. \\
\textsuperscript{87} & Ibid. \\
\textsuperscript{88} & \textit{Ibid.} para. 90 \\
\textsuperscript{89} & Ibid. \\
\textsuperscript{90} & Ibid. \\
\textsuperscript{91} & \textit{Id.} Para. 95 \\
\textsuperscript{92} & TRIPS Council Minutes on EC, IP/C/M/47 dated 3 June 2005 para.58 \\
\textsuperscript{93} & \textit{Id.} on EC, IP/C/M/46 dated 11 January 2005 para.42 \\
\textsuperscript{94} & \textit{Id.} para. 14 \\
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\end{tabular}
\end{table}

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geographic origin as all applicants know the source of the GRs or TK; and in certain circumstances, it would be impossible or unduly burdensome for the patent applicant to investigate the entire chain backward to the origin. No additional research would be needed to ascertain the country of origin and it is the inventor who has to decide whether he knows the country of origin.\textsuperscript{95} As regards the problem of genetic material originating from more than one country should be resolved through arrangements with the source countries and in the context of the CBD\textsuperscript{96}. The other discussions on the TRIPS disclosure proposal other than those relating to the sanctions like revocation and on evidence relating to PIC and ABS are also applicable in the context of mandatory disclosure proposal.

6.4 Appraisal

Though the proposal resembles the TRIPS disclosure requirement detailed in the previous section, it varies from the same being proposed as a formal requirement with no implications on the validity of the patents granted. It beautifully develops the coordination needed for the proper functioning of the system, but does not envisage recognition of PIC and benefit sharing within its purview. Emphasis on the declaration of source rather than the country of origin and geographical origin is a clear dilution of the rights of the country of origin. Moreover, when it is emphasised that for TK associated with GR, the disclosure obligation will be triggered only when the invention is directly based on the TK in question, the proposal accepts the link between novelty, inventive step and TK. It ignores the fact that even though the invention is not directly based on the TK, such disclosure can lead to redefining and narrowing down of broad claims. Following such a strict construction will also reduce the chances of the TK holder to be benefitted by providing access to his knowledge which could

\textsuperscript{95} TRIPS Council Minutes on EC, IP/C/M/48 dated 15 September 2005 para. 66
\textsuperscript{96} Supra n.36
become a part of the invention though the invention need not be directly based on the TK. The object of this proposal is not to bring in harmony with the goals of the CBD as to PIC and benefit sharing, but only to prevent the grant of bad patents that do not conform to the patentability standards. So from an ABS perspective, the proposal is only an eye wash. This proposal could be seen only as a partial acceptance of the triple disclosure requirement, politically accepting that there is a relationship between the source and country of origin of a GRs/associated TK without clearly defining the relationship. It is accepting the relationship which the triple disclosure requirement had unsuccessfully tried to convey. More interestingly, it does not address the issue of creating a mechanism to ensure the CBD goal of benefit sharing.

6.5 The PCT Disclosure Proposal

Another proposal envisaged is that the regulations under the Patent Cooperation Treaty (PCT) of WIPO must be amended so as to explicitly enable the national patent legislation of the CPs to the PCT to require the declaration of the source of GRs or TK in the patent application if an invention is directly based on such resource or the knowledge97. There is sufficient freedom for the applicant to fulfil the requirement either at the time of filing the international application or later during the international phase98. This declaration of the source is to be included in the international publication of the application99. Incorporation of the requirement is optional but once incorporated in the national patent legislation, it would be obligatory for the patent applicants applying for patent within those territorial limits of such Member States if the invention is directly based on GRs or associated TK100. In the requirement to disclose the source, the term

97 Supra n.1 para. 81
98 Ibid.
99 Ibid.
100 Id. para. 82
source is to be interpreted in the broadest sense possible since a multitude of entities under the CBD and FAO might be involved in ABS\textsuperscript{101}. The entity competent to be declared as the source should be the one to grant access to the resources and/or the knowledge or the one to participate in the sharing of benefits arising out of their utilization\textsuperscript{102}. Regarding the legal effects, it is proposed that the requirement should be a formal one and not substantive\textsuperscript{103}. The legal effects for wrongful disclosure or non-disclosure currently existing under the PCT and Patent Law Treaty (PLT) should apply in case of wrongful disclosure and non-disclosure of the source of the GRs and associated TK\textsuperscript{104}. If the applicant fails to comply with the requirement within the set time limit of two months, the national law may foresee that in the national phase the PCT application is not processed any further until the applicant has furnished the required declaration or consider it withdrawn on grounds of non-compliance\textsuperscript{105}. On duly complying with the requirement, i.e. the proposed declaration containing standardised wording relating to the declaration of the source, the designated office must accept this declaration and may not require any further document or evidence relating to the source declared unless it reasonably doubts the veracity of the declaration concerned\textsuperscript{106}. Based on Article 10 of the PLT of WIPO that is also affected by the proposed amendment, if it is discovered after the granting of a patent that the applicant failed to disclose the source or submitted false information, national law may envisage the validity of the granted patent being affected by a lack of or an incorrect disclosure of the source only if this is due to fraudulent intention\textsuperscript{107}. The possibility for judicial review and sanctions under national law including criminal sanctions such as fines etc are other

\textsuperscript{101} Id. para. 83
\textsuperscript{102} Ibid.
\textsuperscript{103} Id. para. 84
\textsuperscript{104} Ibid.
\textsuperscript{105} Ibid.
\textsuperscript{106} Ibid.
\textsuperscript{107} Ibid.
suggestions\textsuperscript{108}. For GRs, the obligation would be triggered only when the invention is directly based on a specific GR to which the inventor has had access\textsuperscript{109}. This implies that the invention must make immediate use of the GR, i.e. depend on the specific properties of the concerned resource and that the inventor must have had physical access to the resource, i.e. its possession or at least contact that is sufficient to identify the specific properties of the resource that are relevant for the invention\textsuperscript{110}. In relation to TK, the inventor must know that the invention is directly based on the knowledge, i.e., the inventor must consciously derive the invention from this knowledge and such knowledge in question must be related to the GR in question\textsuperscript{111}. For the proper functioning of the disclosure requirement, a list of governmental agencies competent to obtain information about patent applications containing the required declaration is to be established so that patent offices receiving such applications could inform the competent government agency in another country that it had been declared as the source\textsuperscript{112}. By making the list available on the internet, patent offices would have easy access to it and could provide the requisite information to such authority without much administrative burden or cost, thereby evading the need to verify patent applications worldwide to verify whether a country is declared as the source and its domestic access law concerns are duly met with\textsuperscript{113}. The obligatory disclosure requirement at the national level coupled with the information system could enable the parties to verify compliance with contractual obligations and would also simplify enforcement of such obligations\textsuperscript{114}. The particular advantages of the disclosure proposal are claimed to be: explicitly enabling the CPs to introduce a disclosure requirement in their national laws;

\textsuperscript{108} Ibid.
\textsuperscript{109} Id. para. 85
\textsuperscript{110} Ibid.
\textsuperscript{111} Ibid.
\textsuperscript{112} Id. para. 86
\textsuperscript{113} Ibid.
\textsuperscript{114} Ibid.
providing adequate freedom to Members to make tailored legislations as per their needs; not creating a deterrent effect on filing of patent applications and encourages maintenance of secrecy over inventions; enabling the patent applicant to declare the source most appropriate with regard to the invention in question thereby reducing the risk of lack of knowledge about the source; enabling mutually supportive implementation of international instruments; and representing a specific measure in implementing the Bonn Guidelines by ensuring participation of stakeholders in the process of benefit sharing.\textsuperscript{115}

The proponents also clarify that if the patent applicant has information at hand about the primary source, this must be disclosed; if he has information on the primary source and several secondary sources, the primary source should be disclosed whereas disclosure of the secondary ones are optional. If he has information about a secondary source and not the primary source, this secondary source must be disclosed. If he has information about several secondary sources and not the primary source, the secondary source with the closest relationship to the primary source should be disclosed and the others would be optional\textsuperscript{116}. The proponents also make clear that the term "source" should be broadly understood to cover terms like "CPs providing GRs", "origin", "geographical origin", "country of origin of GRs", the MLS established by the ITPGRFA and any other sources that may be relevant\textsuperscript{117}. It is further explained that primary sources are the CPs providing GRs, ILCs and the MLS established by the ITPGRFA; and secondary sources are ex-situ collection centres such as gene banks, botanical gardens, scientific literature and databases on GRs and TK\textsuperscript{118}. The

\textsuperscript{115} Id. para. 94
\textsuperscript{116} Switzerland, \textit{Further Observations by Switzerland on its Proposals Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications\textcopyright \textregistered IP/C/W/433 dated 25 November 2004}
\textsuperscript{117} Switzerland, \textit{Additional Comments by Switzerland on its Proposals Submitted to WIPO Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications\textcopyright \textregistered IP/C/W/423 dated 14 June 2004}
\textsuperscript{118} Supra n.116
proponents further elucidate that the source/s to be declared must be the most appropriate one/s where an entity is competent to grant access to GRs and/or TK or to participate in benefit sharing. If such a source is not known, a declaration would be made to this effect as a multitude of entities may be involved in the process of ABS and the objective of disclosure must be to increase transparency\textsuperscript{119}. The proposal does not use the term \textit{country of origin} and the proponents reason the same on the ground that the CBD refers to \textit{country providing GRs} in the context of ABS and also on the ground that it excludes the MLS established by the ITPGRFA\textsuperscript{120}.

As regards the immediate use of the GRs in the invention, it was explained that the invention should have made the immediate use of the resources and the inventor must have had physical access to the resource i.e. he must have possessed or at least have had contact which is sufficient to identify the properties of the GRs that were relevant for the invention\textsuperscript{121}. With regard to TK, the proposal would require that the inventor knows that the invention is \textit{directly based on} the knowledge, i.e. he had consciously derived the invention from this knowledge. Since TK is of intangible nature, physical access is not possible and would not constitute a pre-requisite. The term directly is not intended to have any time dimension\textsuperscript{122}.

6.6 Appraisal

It is quite worthy of note that the PCT disclosure proposal emphasizes for disclosing only the source of the GRs used instead of the country of origin. The proposal is not taking into account of the fact that the CBD has categorically indicated that for the purpose of Article 15, 16 and 19, the GRs provided by a country means those provided by the country of origin or

\textsuperscript{119} Supra n.117
\textsuperscript{120} Supra n.92 on Swiss para. 76
\textsuperscript{121} Supra n.117
\textsuperscript{122} Ibid.
acquired according to the provisions of CBD\textsuperscript{123}. The ownership over the resources rests with the country of origin and only it has the right to provide access to the resources. So it is submitted that the PCT disclosure proposal is basically a faulty one, not understanding the spirit of CBD. This argument is not negating the fact that the proposal seeks to expand the ambit of source by including within its meaning terms like CP providing GRs, origin, geographical origin, country of origin, MLS under the FAO and other relevant sources, considering the multitude of entities involved in the process\textsuperscript{124}. But when the CBD makes it clear that for the purpose of access, country providing GRs means the country of origin, there is no need to make confusions like this. The proposal tends to be very soft on the patent applicants on the one hand and negating actual benefits to the real stakeholders on the other by taking such an approach. True that there is a possibility to get access from a multitude of entities considering the enormous transactions that have already taken place in this field. But in such cases, under the CBD, an obligation is cast upon the applicant to employ a reasonable amount of research in tracing the country of origin and to designate the country which is more in proximity as the country of origin.

Another shortcoming of the proposal is in relation to the trigger of the disclosure obligation where it recommends that the obligation sets in motion only when the invention is directly based on the GR to which the inventor has had access. This is also one limiting the scope of property rights envisaged under the CBD which could cover any use including incidental use of the resources. What CBD envisions is a system where the country of origin and the stakeholders of the GRs can retain a right over the resource in its raw, natural, purified, refined, extracted and derived forms. So whenever an invention uses GRs irrespective of its importance to the claimed invention, as per the CBD, the country of origin and the custodians can have

\textsuperscript{123} The Convention on Biological Diversity, 1992, Article 15.3
\textsuperscript{124} Supra n.1 para. 115
a claim for sharing of benefits. A further remarkable contention is that in case of TK, the obligation would be triggered only when the inventor consciously derives the invention from such knowledge. It is true that to fall under the scope of CBD, the knowledge must be associated with the GRs and when the inventor consciously uses the knowledge for developing his invention, he has an obligation to share the benefits. What if the invention is developed independently by the inventor, but it is typically an embodiment or application of an already prevailing TK over the resource? He has of course no obligation to share the benefits. But is his invention eligible for patent protection provided such knowledge is not in secret use? If the invention is granted patent monopoly, it will definitely dilute the patentability standards. Just like the mandatory disclosure proposal, the PCT proposal is also aimed at the prevention of the grant of erroneous patents and not intended to bring in synergy with the CBD goals through recognition of PIC and benefit sharing.

Over and above all, the PCT disclosure proposal is highly inadequate to solve the incoherence between the TRIPS and the CBD as it cannot act as a TRIPS level mandate for the WTO members cannot be made bound by non-WTO instruments.

6.7 Effectiveness of the Disclosure Requirements to Deal with Misappropriation and Erroneous Patents

A perusal of the solutions suggested to ensure the CBD goals and to prevent the grant of bad patents, the inference is that there is no consensus in incorporating the PIC and benefit sharing goals of the CBD within the TRIPS system. TRIPS Council, being a forum to discuss matters related to IP, is more focussed only on the IP related issues during the process of ABS and their strategy is to devise a system that can effectively deal with the issue of erroneously granted patents without upsetting the present patent
policies. It is disappointing to note that despite the constant push from the developing countries to insert the disclosure requirements including PIC and benefit sharing within the TRIPS regime, the developed countries are managing to limit the demand to declaration of source and country of origin only, that too with so many dilutions on the concept of the country of origin. It appears that the developed nations who benefit from the present system do not want to disturb the conventional private property regime that forms the edifice of the TRIPS, for incorporation of PIC and benefit sharing principles expressly recognise the rights of the country of origin and/or the ILCs concerned. As far as the requirement in relation to source and country of origin of the GRs and associated TK is concerned, it seems that there is a general willingness to accept this in principle, but many of them do not want to mention the country of origin. They also want this requirement not to affect the validity of the patent granted. The reason to confine the requirement to disclosure of only the source is pointed out as the difficulty in tracing the country of origin. But if this is allowed, the misappropriation will continue to persist. It is because, in the CBD context, taking of GRs from any source other than the country of origin will constitute misappropriation unless there is a reasonable effort from the part of the person taking it to find the actual country of origin. Even after reasonable enquiry, if the country of origin cannot be ascertained, then he can make a declaration to that effect and obtain the resources as per the domestic law of the source country from where he had obtained the resource. As per the proposed dilutions in the disclosure requirement, there is no possibility for the country of origin to assert its rights. It is because if the source is declared, the inventor would fulfil the legal requirements in relation to his invention. If at a later point of time, it is proved that the country of origin is not the source country, then the former will not have any say and there will be no forum available to listen to it. And no action in this regard will affect the validity of the patent also. The most important point is that if the disclosure requirement is confined only to
disclosure of the source, insisting the evidence of PIC and benefit sharing from the patent applicant would not have any substantial effect in providing any *locus standi* to the country of origin. Thus, the diluted disclosure of source of GRs proves to cause disastrous effects on the very purpose of the CBD itself.

It is to be noted that there is wide disapproval in bringing in requirements relating to the evidence of PIC and benefit sharing. The main reason cited is that they are not information having relevance to the patentability of an invention and that an examiner can judge the patent eligibility without any reference to them. PIC and benefit sharing relate to the legal acquisition of the materials used for the invention. It is true that the requirements of PIC and benefit sharing have nothing directly to do with patentability. But viewing patent as the exclusive monopoly right, is it philosophically wrong to consider the legal acquisition as an eligibility criteria at least in the context of GRs and associated TK? It should be noted that the TRIPS Council deliberations were also a response to the Doha mandate to enquire the relationship between the TRIPS and the CBD and if the triple disclosure requirement proves the sole way to link the two, the countries should accept the reality. Now the question is whether the triple disclosure requirement is compatible with the TRIPS. Some scholars opine that since the patentability criteria spelled out in Article 27.1 ie novelty, inventive step and industrial application are substantive conditions that result from the invention *per se* or that they result from the technical characteristics of the invention.¹²⁵ It is argued that

The requirement quite obviously is not compatible with Article 27.1. The manner of obtaining genetic resources used in the

development of inventions is an external condition. The outcome of inventive activity is indeed independent of the ways and means employed to reach it. The situation that arises from an invention derived from use of genetic resources that have been illegally extracted from their in-situ environment is similar to the situation of an invention that has been developed with the assistance of a stolen microscope. This event would infringe the Common Law, but not patent law under Article 27.1 of the TRIPS Agreement. In both situations inventor would still be entitled to the patent, provided the conditions of patent eligibility were met. Nonetheless they would be subject to criminal and civil liability for stealing (both the genetic resources, depending on the existence of appropriate legislation, and the microscope) in the country from which the resources had been taken.\textsuperscript{126}

As regards Article 29, it is opined that

Article 29 of the TRIPS Agreement contains disclosure conditions. Disclosure of the invention must be in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. As a matter of course, the present language of article 29 is not an appropriate framework for the Requirement. The indication of the origin of the genetic resources and of other circumstances related to their acquisition is not generally necessary for the invention to be carried out by a person skilled in the art. Where the biotechnological invention does require the use of the natural resource to be carried out, the knowledge of where to obtain the resource may be relevant for the practical exploitation of the invention. In this context, the United States statement at the November 24-25, 1997 meeting of the WTO

\textsuperscript{126} Ibid.
Committee on Trade and Environment applies: where the source of the resource is unique, it must be disclosed under article 29. There is no need for additional language to be included in the Agreement. However, sometimes the source of the material may be relevant, even though it may not be of essence. In that case the information may even constitute a trade secret. For instance, a natural extract obtained in some particular geographical area may be more effective than a similar extract obtained somewhere else. However, the scope of Article 29 does not reach beyond the obligation to explain how the invention works. Therefore, the Agreement does not require disclosure of the material’s source where knowledge of that source is not essential to reduce the invention into practice.127

In relation to Article 62 of the TRIPS, it is provided that

Article 62 authorizes Members to require compliance with reasonable procedures as a condition of the acquisition or maintenance of patents. Article 62.1 establishes that such procedures and formalities shall be consistent with the provisions of the Agreement. In other words, they shall comply not only with the basic principles of the Agreement, including the national treatment and the most-favoured-nation treatment principles but also with specific relevant provisions. This means that a link exists between the reasonable procedures admitted by article 62 and the conditions of patentability established in section 5 of part II, namely Article 27.1 and Article 29. Second, Article 62.2 clarifies that the procedures, subject to compliance with the substantive conditions for acquisition of the right established by Article 27.1, should permit the granting of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.

127 Ibid.
Therefore, it appears that reasonable procedures are those that assist patent administrations to assess whether the substantive conditions, such as novelty, inventive step, and industrial applicability have been met by the invention the patentability of which is under examination. In addition, moderate fees are admitted. This understanding results not only from the reading of the text of the TRIPS Agreement, but also from the history of the negotiations. During the negotiations members never proposed that conditions that did not relate to the characteristics of the invention or the fees to be charged by patent offices would be admitted.128

Now, the major issue to be ascertained is whether there are any inconsistencies between the proposed disclosure requirements and the TRIPS. The above argument is an outright denial of any possible effort to link the two agreements. Carlos M. Correa is of the opinion that the obligation to disclose the origin of the biological material is not a patentability criterion, but a component of the disclosure requirement under Article 29 of the TRIPS and that inclusion of the proposal via an amendment is in no way violating any provision in the TRIPS129. He also argues that such an amendment will not discriminate the field of technology as prohibited by Article 27.1 based on the reasoning of the WTO Panel that Article 27 does not prohibit bonafide exceptions to deal with problems that may exist only in certain product areas.130 Adopting the reasoning of Correa, we can come to the conclusion that there is nothing wrong in incorporating the triple disclosure requirement that it is not creating any compatibility problems with the TRIPS. The reason behind emphasising triple disclosure requirement instead of confining it to source and country of origin is clear

128 Ibid.
130 Ibid.
from the interpretation of the WTO Panel. This is because what the Panel has asserted is Article 27 of the TRIPS as a whole and not to Article 27.1 only. From this, we can read that bonafide exceptions can be adopted even in the context of patentability criteria to deal with extreme cases in relation to certain product areas. Even if this reasoning is not adopted, it is possible to establish link between the patentability criteria vis-à-vis the associated TK over the GRs involved in the invention. It is an accepted fact that TK associated with GRs could constitute prior art when they are considered the known uses prevalent regarding the resource\textsuperscript{131}. It can have a relationship with the question of inventive step when a resource holder is considered as the person skilled in the art in relation to the uses of a GR. But its application is limited in the context of CBD because even though a reference to the community/ knowledge holder is given and the benefits are shared with him/them, it cannot cover the whole range of misappropriation taking place through patenting. Such a linking will only help in cases where the TK is involved, and cannot ensure benefit sharing by providing access to the resources only. Now, considering the question of inclusion of requirements in relation to PIC and benefit sharing into the TRIPS, the main bottleneck is the argument that they are not related to the substantive patentability criteria. Based on the present proposals, the only possible way is to accept Correa’s reasoning together with the WTO Panel decision as discussed above and accept the proposal as a political agenda. To keep the TRIPS as a vibrant document responding to the needs of the society at large, such a compromise seems inevitable.

From the CBD point of view, the ultimate aim is to secure benefit sharing from the use of GRs and associated TK. The purpose of integrating CBD goals within the TRIPS is to reap maximum benefits from patenting and subsequent commercialization of the inventions using GRs and TK. But,

\textsuperscript{131} This could be understood from the consideration of novelty in \textit{Neem} and \textit{Turmeric} patent cases.
finally the TRIPS deliberations do not seem to be in line with this objective and are mostly concentrated on the issue of prevention of bad patents. So it is assumed that the outcome of the present negotiations is not going to satisfy the benefit sharing objective of the CBD. This reveals the need of some mechanism within the TRIPS itself which could generate benefits to the countries of origin and the local and indigenous communities concerned and the strategy should not be to confine the same to the IP aspects of ABS, instead should take a holistic approach treating the GR and associated TK as a potent category for IP protection.

6.8 Initiatives in WIPO: A Brief Overview

WIPO is an UN agency for promotion of IPRs among the Member States. WIPO started its work on the interrelationship between GRs, TK and folklore and IP, leading to the creation of an Inter Governmental Committee (IGC) to act as a separate forum to deal with issues related to interfaces between IP and GRs, TK and folklore\(^{132}\). IGC is the negotiating and decision-making body of WIPO. In the initial stages, WIPO envisioned a system of positive protection to TK, comprising the major elements such as PIC and benefit sharing, and prevention of misappropriation\(^{133}\). For GRs, WIPO wanted to devise a defensive protection model with three clusters of options\(^{134}\). Cluster A relates to providing defensive protection for GRs through (i) inventory of databases and information resources on GR; (ii) information systems on GR for defensive protection\(^{135}\) and (iii) guidelines or

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\(^{132}\) WIPO IGC, "Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore: An Overview\(^{\text{a}}\), WIPO/GRTKF/IC/1/3 dated 16 March 2001 para. 1 & 2

\(^{133}\) Secretariat, "The Protection of Traditional Knowledge: Revised Objectives and Principles\(^{\text{a}}\), WIPO/GRTKF/IC/16/5 dated 22 March 2010

\(^{134}\) Secretariat , "Genetic Resources: Revised List of Options\(^{\text{a}}\), WIPO/GRTKF/IC/16/6 dated 22 March 2010

\(^{135}\) This envisages creation of online portal of registries and databases as a one-stop shop for genetic resources.
recommendations on defensive protection¹³⁶. Cluster B relates to disclosure requirements in patent applications for information related to GR used in the claimed invention and the options in this regard include (i) mandatory disclosure requirement on source and country of origin of GRs in patent applications; (ii) further examination of issues relating to disclosure requirements; (iii) development of guidelines and recommendations on disclosure and (iv) alternative mechanisms to bring in consistency between ABS measures for GR and national and international patent law practices. Cluster C relates to IP issues in MATs for fair and equitable sharing of benefits from the use of GR and the options include (i) online database of IP clauses in MATs on ABS; (ii) draft guidelines on contractual practices and (iii) study on licensing practices on GR. Since the negotiations on these items reached nowhere, WIPO, in its sixteenth session of the IGC held during May 2010, called for the creation of three Inter-sessional Working Groups (IWG) to deal with Traditional Cultural Expressions (TCEs), GRs and TK¹³⁷. The IWGs have to provide legal and technical advice and analyses for the consideration of the IGC. The IWGs are mandated to devote equal time to the three items under the consideration of the IGC and to report the outcome of their work to the IGC and to submit recommendations and texts relating to the discussion in the IGC¹³⁸. On GRs and TK, WIPO/GRTKF/IC/16/6¹³⁹ and 16/5¹⁴⁰ constituted the working documents respectively for the IWGs. The third IWG developed objectives and principles for GRs and requested the 18th Session of IGC to consider the same. The 18th session adopted the recommendations of third IWG and narrowed down the options in the objectives and principles and forwarded

¹³⁶ Guidelines or recommendations for search and examination procedures for patent applications to ensure that they better take into account disclosed genetic resources.
¹³⁷ Decisions of the Sixteenth Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, 3-7 May 2010
¹³⁸ Ibid.
¹³⁹ Supra n.134
¹⁴⁰ Supra n.133
the same to 19th IGC as working document WIPO/GRTKF/IC/19/6141. The 19th IGC further reduced the options and recommended for the development of appropriate international legal text for the protection of IP associated with GRs. It also suggested two other documents namely, ‘Options for Future Work on Intellectual property and Genetic Resources’142 and ‘Like-Minded Countries Contribution to the Objectives and Principles on the Protection of Genetic Resources and Preliminary Draft Articles on the Protection of Genetic Resources’143 to be transmitted as working documents along with other existing working documents for the next session of the Committee144.

A glimpse of the Draft Objectives and Principles as contained in IC/19/6 comprises of five different objectives in relation to IP and GRs. The document provides different options for the five objectives and also tries to fix the principles behind such objectives through different options. The first objective is to require compliance with national laws of the country of origin requiring PIC, MAT and disclosure of origin by persons accessing the resources including those who apply for IPR 145. It is based on the principle of recognising ownership rights over GRs and associated TK, including the sovereign rights, rights of ILCs and other private property rights146. The second objective is to prevent the grant of IPRs over GRs and in this area, the language of the different options show two clearly divergent views147. One option is to prevent the grant of IPR over GRs and associated TK when they are obtained in violation of national laws requiring PIC, MAT, benefit

142 Secretariat, ‘Options for Future Work on Intellectual Property and Genetic Resources”, WIPO/GRTKF/IC/19/7 dated 20 May 2011
143 Indonesia, ‘Like-Minded Countries Contribution to the Objectives and Principles on the Protection of Genetic Resources and Preliminary Draft Articles on the Protection of Genetic Resources’ WIPO/GRTKF/IC/19/11 dated 18 July 2011
145 Secretariat, ‘Draft Objectives and Principles Relating to Intellectual Property and Genetic Resources” WIPO/GRTKF/IC/19/6 dated 20 May 2011, Objective 1
146 Id. Principle of Objective 1
147 Id. Objective 2
sharing and disclosure of origin. The other options give emphasis to prevent grant of IPR when the invention do not satisfy the eligibility conditions of novelty and inventive step. Two problems could be identified with the second option. One is that the grant of IPR will not become conditional to benefit sharing obligation. Second is that as of now, there is no universally accepted standards for novelty and inventiveness, which could still lead to potential cases of biopiracy. So the first option seems to be the best considering the interrelationship between GRs, associated TK and patentability standards. As regards the principle behind the objectives, the same divergence could be perceived\textsuperscript{148}. One option talks only about prevention of the grant when patentability criteria are not satisfied and emphasises that the patent system should provide certainty of rights for legitimate users of GRs. On the other hand, the other options talk also about the rights of the legitimate providers of GRs insisting that there should be mandatory disclosure requirements in the IP system, ensuring compliance with the domestic ABS laws. It further adds that patent office should be key check points to ensure disclosure. This could be viewed as an aim which was not achieved at the Nagoya Protocol and if this could be realized, this will up to a great extent, adequately address the gap prevailing in the Nagoya Protocol. The third objective is to link the patent system with the available information on GRs and associated TK through internationally recognised certificate of compliance\textsuperscript{149}. The principle behind it is that the IP office should consider all relevant prior art\textsuperscript{150} and among the two available options for the principle, one view asserts that to facilitate prior art assessment, the patent applicant should disclose the background information which can be regarded as useful for understanding, searching and examination of the invention. The negative side of this option is that it allows a possible

\textsuperscript{148} Id. Principle of Objective 2
\textsuperscript{149} Id. Objective 3
\textsuperscript{150} Id. Principle of Objective 3
argument that disclosure in relation to PIC and benefit sharing has nothing to do with the patentability requirement. But the other option is more stringent, providing that IP offices should consider all relevant prior art information relating to GRs, their derivatives and associated TK when assessing the eligibility for the grant of IPRs. Further, it imposes a mandate on the IP applicants to disclose all background information on GRs, their derivatives and associated TK relevant for determining eligibility conditions. The fourth objective is to promote a mutually supportive relation with international agreements and regional arrangements dealing with IPRs, GRs and associated TK. This objective is based on the principle of bringing in consistency between TRIPS and other international instruments on GRs and associated TK. The fifth objective is to recognise the role of IPR in promoting innovation, and transfer and dissemination of technology and use the same for the mutual advantage of holders and users of GRs, their derivatives and associated TK conducive to social and economic welfare. This is based on the principle that a mandatory disclosure obligation in relation to the country of origin, PIC and benefit sharing would increase the legal certainty and transparency of the IP system. The attempt is to develop a legal text linking these objectives and principles to the cluster of options identified in the document dealing with Options for Future Work on Intellectual Property and Genetic Resources. There are many proposals on the table on mandatory disclosure which are similar to those tabled in the TRIPS Council, including the draft Articles presented by the Like-Minded Countries. These documents are going to be considered together in the next IGC for development of a legal instrument on GRs. Now the WIPO has

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151 Id. Objective 4
152 Id. Principle of Objective 4
153 Id. Objective 5
154 Id. Principle of Objective 5
155 Switzerland, Further Observations by Switzerland on its Proposals Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications, WIPO/GRTKF/IC/7/INF/5
156 Supra n.143
adopted a draft negotiation text on Intellectual Property and the Protection of Genetic Resources [Their Derivatives] and Associated Traditional Knowledge in February 2012 containing many items discussed on the interrelationship between IPR and CBD as discussed in previous chapters. So the present chapter omits similar discussions on WIPO negotiations as it stands today.

A close look at the recent WIPO initiatives on GRs gives the impression that the effort is mainly to address the gap created in the Nagoya Protocol as much emphasis is given to disclosure requirements and to impose obligation upon the patent office as a check point in the process of ABS. It is interesting to note that on GRs, WIPO is specifically looking into the interrelationship between IP and GRs and no other issues. The positive protection of GRs lies in the CBD based domestic framework. The present work concentrates on the grant of IPR for inventions based on GRs and associated TK. WIPO is also addressing the issue of developing a *sui generis* law for the protection of TK including TK associated with GRs\(^\text{157}\). In Article 3 dealing with scope of protection some countries suggested positive protection including linking TK protection with grant of IB\(^\text{158}\). In case of GRs what becomes more important is the link between IP and GRs and associated TK through mandatory disclosure requirements which the IGC is rightly focussing in the GRs document. Given the differences reflected in the objectives and principles it is doubtful whether there is going to be any agreement on developing appropriate legal instrument for solving the issues relating to IP and GRs. Assuming that there is a positive outcome its inability lies in the impossibility of the forum to offer any binding obligations. Further and more pertinent is the principle that its work should

\(^{157}\) Secretariat, *The Protection of Traditional Knowledge, Draft Articles* WIPO/GRTKF/IC/19/5 dated 20 May 2011

\(^{158}\) *Id.* Article 3
not prejudice the work pursued in other fora\textsuperscript{159}. As such there is no linkage between the WIPO initiatives and the TRIPS Council deliberations which makes the status of WIPO efforts uncertain. In light of this uncertainty, TRIPS seems to be the best platform to deal with the issue of conflict between CBD and IP protection.

\textsuperscript{159} Supra n.145 Option for Principle of Objective 4.