Commercialisation and Biopiracy of Genetic Resources in the 21\textsuperscript{st} Century: The Imminent Need for Stronger Regulation

Divyangana Dhankar†
University of New South Wales (Australia), University of Delhi, India

Received 23 February 2015; accepted 17 April 2016

The commercialization of genetic resources (GRs) is a continuous and evolving process that promises high rewards to those engaged in it. In the 21\textsuperscript{st} Century, GRs and their relevant technology are commercialised either through grant of monopoly rights ingrained in patents and plant variety certifications or through benefit sharing mechanisms. Despite ongoing palavers assuring the free and fair nature of the current Intellectual Property (IP) regime, problems associated with commercialization persist. The lack of interest by the international community to address issues of biopiracy create new forms of deficit causing the imbalance of sovereign powers between nations and bargaining powers between multinational companies and Indigenous communities. Despite the best efforts of the IGC to facilitate text based negotiations for the purpose of reaching an agreement on an international instrument that would provide effective and balances protection to GRs, Traditional Knowledge (TK) and Traditional Cultural Expressions (TCE), recent attempts to gain monopoly rights over inventions developed from misappropriating GRs and associated traditional knowledge (ATK) sheds light on the rampant misuse of the IP regime and the imminent need for the international community to address it. The objective of the paper is to provide fresh evidence that would facilitate the dialogue.

Keywords: Genetic resources, biopiracy, misappropriation, access to benefit sharing, WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional knowledge and folklore

Genetic resources (GRs), as we know them today, have come to mean ‘genetic material with actual or potential value where genetic material is material of plant, animal, microbial or other origin containing functional units of heredity.’\textsuperscript{1} Internationally, regulation of GRs is ushered through a number of multilateral conventions. Prominent, in these are the International Convention for Protection of New Varieties of Plants 1961 (UPOV, revised in 1972, 1978 and 1991), the Convention on Biological Diversity 1992 (CBD), the Agreement on Trade Related Aspects on International Property Rights 1994 (TRIPS) administered by the World Trade Organisation (WTO) and the International Treaty on Plant Genetic Resources for Food and Agriculture 2004 (ITPGRFA).\textsuperscript{2} Of the Conventions listed, UPOV and TRIPS grant monopoly and protective rights to its holders augmenting their commercialisation and preventing their misappropriation through international recognition. UPOV provides protection to plant varieties that are novel, distinct and uniform (1961) or homogenous (1991) through the grant of PVP (Plant Variety Protection) certifications.\textsuperscript{3} On the other hand, TRIPS provides protection to inventions which are novel, have an inventive step and are capable of industrial applicability.

Biopiracy and misappropriation is analogous to each other for the purpose of the present paper. Biopiracy explored through noted case studies and descriptions provided by activists, academics and policy makers could broadly ‘either refer to the unauthorised extraction of biological resources and/or associated traditional knowledge from developing countries or to the patenting of spurious ‘inventions’ based on such knowledge or resources without compensation’.\textsuperscript{4} Misappropriation used in this context of biopiracy connotes the utilisation of GRs, their derivatives and ATK without prior informed consent (PIC) and equitable sharing mechanisms. Such an understanding of misappropriation would also be mutually supportive to Article 2 of the CBD which acknowledges that states have a sovereign right over the resources within their jurisdiction and if those resources were utilised in patents or in any other system without the consent of the sovereign then misappropriation or biopiracy is said to have taken place.

\footnote{Email: divyanganadhankar@gmail.com}
The need for discussing stringent regulation at the international level owes itself to the classic cases of biopiracy: *Azadirachta indica* (1990), *Curcuma longa* (1995) and *Oryza sativa* (1997). It was noted that Patent Offices in Western Countries, particularly, the United States Patent Office (USPTO) and the European Patent Office (EPO) were granting patents which were not inventions since they were obvious and lacked an inventive step, in light of available TK or traditional prior use. The alarming misappropriation of their GRs and the grant of patents on the blatant ignorance of their TK prompted developing nations to bring the issue in the Doha Agenda 2001. The issue was highlighted through the existence of a tension between TRIPS and CBD due to which developing countries faced difficulty in implementing the two in a mutually supportive manner. Discussions on the issue were delegated to the TRIPS Council at the end of the Agenda. Within the TRIPS Council special sessions were held between member nations and divergent positions seemed to have emerged. The developing countries advocated for the implementation of a disclosure mechanism within the IP regime where the utiliser of GRs was required to disclose the source of origin, evidence of PIC and equitable sharing mechanism in the patent application. Switzerland agreed to the implementation of a disclosure mechanism but narrowed disclosure only to the source of origin under the Patent Cooperation Treaty (PCT); EU also agreed to the implementation of a disclosure mechanism but limited disclosure to the source of origin under national regimes and the US was against any form of disclosure in national and international regimes but advocated for national Access to Benefit Sharing (ABS) Agreements. By 2008, it was noticed that a deadlock had reached the discussions.

Though disclosure under TRIPS would have led to a uniform regime that checked biopiracy and assisted countries to determine resources utilisation, its introduction could be considered premature. The situation was similar to negotiations for an amendment to the Paris Convention that reached a deadlock and negotiations under GATT took place which led to the enactment of TRIPS. Similar to the deadlock under GATT, discussions on protection of GRs and ATK shifted to the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). In 2009, the IGC was given a mandate to undertake text based negotiations for protection of GRs, TK and TCEs. In this regard, the IGC from 2001 to 2003 gathered information from various nations regarding their experience with GR and ATK. A single composite document based on the extensive surveys was released during the fifth session. A gap analysis was conducted in 2008 on the protection of TCEs and TK which demonstrated the existence of certain gaps between the IPR and ABS regimes. On an alternate platform, negotiations for better information sharing on ABS had culminated in the adoption of the Nagoya Protocol in 2014.

Despite the existence of a large number of international conventions regulating the protection of GRs and ATK, GRs and ATK continue to be vulnerable to exploitation. While the discussion in the IGC continues on the minimum documentation for the protection of GRs and ATK, new cases of biopiracy emerge. Since 1990, numerous cases of biopiracy have come to light and the Indian TKDL estimates that more than 2000 patents are granted world over based on the misuse and misappropriation of Indian GRs and ATK. Some notable cases of biopiracy from 1990s to early 2000s which were not inventions in light of Indian traditional knowledge and lacked synergistic effects included admixtures of commonly used plants such as *Syzygium cumini* (1999) (Common name: Java Plum, Popular Indian name: Jamun), *Solanum melongena* (1999) (Common name: Brinjal, Popular Indian name: Baingan), *Momordica charantia* (1999) (Common name: Bitter Gourd, Popular Indian name: Karela) and *Trigonellafoenum graecum* (2000) (Common name: Fenugreek, Popular Indian name: Methi).

The enforcement of the Nagoya Protocol also did not end the misappropriation of GRs and ATK. The Nagoya Protocol only regulated access of GR and ATK when an applicant voluntarily decided to enter into mutually agreed terms for PIC and equitable sharing of resources. A number of cases have arisen after 2005 bringing the focus back to the rampant misuse of GRs and ATK. In most instances, spurious inventions were claimed in patent applications which either lacked novelty or inventive step in the presence of traditional knowledge such as *Myristica fragrans* (2015) (Common name: Nutmeg, Popular Indian name: Jatiphal/Jaiphal), *Thymus vulgaris* (2015) (Common name: Garden Time, Popular Indian...

These cases highlight the two perspectives that form the theme of the paper. On one hand, certain developed and developing nations, Indigenous and local communities have a valid concern that their GR and ATK be legitimately accessed with fair and equitable returns. In order to substantiate the legitimacy they continue to demand the implementation of an internationally recognised disclosure regime. On the other hand, certain developed nations and industry representatives oppose the disclosure mechanism on grounds of shift in regulatory burden to the users of GRs and ATK, issues of timely and efficient accessibility of GR and ATK and legal certainty of any new instrument that required more information from the users.

In light of the new cases of biopiracy there is a tug of war between the need to curb biopiracy through stringent regulation and the urge to resist regulation on grounds of uncertainty. The present paper re-examines the issues of misappropriation of Indigenous traditional knowledge; the deafening silence and constant denial of biopiracy and the contractual imperialism of GRs that continue to plague the modern world.\(^{25}\) In conclusion, the paper attempts to draw attention to the recent cases of biopiracy or potential biopiracy with the need to create internal and external regulation through uniform international regimes and quality oriented risk management frameworks.

### Recent Cases of Biopiracy and Potential Biopiracy

**EP1962578- Cucumis melo** (Common name: Melon, Popular Indian name: Kharbooz)

The most recent case of an erroneous grant was the patent for a Closterovirus-Resistant Melon Plant to the US based company Monsanto with a right of using the patent for commercial purposes. The patent claimed a melon plant containing genes derived from melon accession PI313970. On 8 July 2008, the application claiming such a resistant variety was filed with the European Patent Office (EPO).\(^{26}\) Prior to the prosecution of the application, the applicant sought to amend the claims after receiving the Written Opinion and International Preliminary Report on patentability. The applicant even sought an extension of time for making the amendments which was subsequently granted. The claim was sharpened and made more concrete by specifying that the melon plant belonged to the category of species *Cucumis melo* with an introgression comprising of a CYSDV conferring QTL from accession PI 313970 where the QTL spanned from 1.9 to 17.2 cM and the QTL was linked to a marker specified from a selected group.\(^{27}\) In essence, the patent claimed a melon plant which demonstrated resistance to Clostero-virus. The examiner objected to the amended claim as it lacked an inventive step in light of non-patent literature such as an article published by J.D. Mc Creight from the U.S. Department of Agriculture on the progress in biotechnology for breeding melon that was resistant to yellow virus.\(^{28}\) The applicant sought an extension of time again for amending the claims. The applicant further deleted claims which did not meet the patentability criteria i.e. claims 9-11.\(^{27}\) After a pre-grant opposition and extensive amendment of claims, a patent was granted on 4 May 2011.

On 2 February 2012, a post grant opposition was filed by Nunheris BV\(^{29}\) and later by a group of researchers and activists led by Christoph Then.\(^{30}\) Vandana Shiva and her organisation, Navdanya which represents 500,000 seed producers from India also decided to support the opposition as a concerned member of the public.\(^{30}\) Nunheris BV, the group of activists and researchers together formed a joint opposition led by Christoph Then. There were a number of grounds for opposition under the European Patent Convention (EPC), primarily Article 53-the invention was contrary to public order and morality; Article 56-the invention lacked an inventive step since it was obvious to a person skilled in the art and
Article 100(b)- the invention claimed did not disclose the invention in a manner sufficiently clear and complete for a person skilled in the art to perform it.\textsuperscript{31} With respect to the first ground of opposition, the Opposition Division (OD) of the EPO held that patenting of plants such as melons was permitted under Article 52 (1) EPC and there was no barrier to patenting plants on the grounds of morality even if they restricted access to GRs with the closterovirus-resistance trait.\textsuperscript{32} The issue of limiting resources by the grant of a patent was a policy issue and beyond the scope and jurisdiction of the EPO. Neither the Nagoya Protocol which came into force in 2014 nor the EU regulations adopted pursuant to the Nagoya Protocol foresaw any role of patent offices to rule on the matter of granting patents that limited access to GRs. Taking a very contemporary interpretation of the European Patent Law, the EPO held that it was powerless to act on the economic effects of granting patents or the limitations they imposed on research. Further, the National Biodiversity Authority (NBA) of India had provided a letter to the OD that the melon germplasm had been accessed from India without PIC and equitable sharing mechanisms.\textsuperscript{33} The OD declined to comment on the issue of improper access under the patent regime since it was out of their jurisdiction and second, the letter from the NBA had come very late- a day before the post grant opposition hearing. As a result, the OD upheld the submission of the applicant that it was not aware of the claim made by the NBA.

With respect to the second ground of opposition, the opponent submitted that there was prior art disclosing crosses of PI313970 which could contain the intergression and the closterovirus resistance.\textsuperscript{34} The OD held that while, there was evidence from a variety of sources that the original accession PI313970 was not a variety but contained a number of traits including the resistance of the closterovirus trait in the heterozygous form, it was the inventor who showed the resistance trait in the homozygous form, in that sense, it was novel.\textsuperscript{35}

It was the third ground of opposition which settled the case in the favour of the opponents. The opponent argued that a person skilled in the art could not perform the invention since the applicant had not deposited any biological material with the resistance trait. What was accessible to the public was the heterogenous variety of PI313970 which showed a wide variety of genotypic characters including resistance. The trait for resistance could be lost during seed multiplication.\textsuperscript{36} The OD found merit in the argument and held that under Article 83 EPC, the applicant was required to deposit the biological material to ensure that it was available to the public without restriction. In determining whether the biological material was available to the public, the OD looked at the history of line PI313970 which had been supplied to it by the NBA.\textsuperscript{37} The OD accepted that even under perfect conditions a person skilled in the art would not be able to obtain PI313970 with the desirable trait since the strain available was in the heterozygous form and could be lost while breeding the melon. Furthermore, the exact conditions for performing the test for resistance were not known and thus, the patent was not sufficiently and clearly disclosed.

On 24 February 2016, the Patent was revoked by the opposition division of the EPO under Article 83 EPC that due to the non-disclosure of the source of biological material from which the invention was developed, a person skilled in the art did not know where to obtain starting material for the invention and as a result, could not perform the invention.\textsuperscript{38} The non-disclosure of the source of origin led back to the discussion of the disclosure regime promulgated by developing nations during the TRIPS Council sessions for better transparency and clarity. As demonstrated from this case, the disclosure of where the source was obtained from became critical for the determination of patentability as it would have assisted patent offices to decide whether a person skilled in the art could perform the invention and additionally, for national authorities to decide the issue of misappropriation.

**EP2689806- Myristica fragrans** (Common name: Nutmeg, Popular Indian name: Jatiphala/Jaiphal)

An application assigned to Colgate-Palmolive titled Oral Compositions Containing Extracts Of *Myristica fragrans* And Related Methods claiming ‘a combination of extracts from *Myristica fragrans* and a natural extract other than the extract from *Myristica fragrans* with an orally acceptable carrier’ was published on 29 January 2014.\textsuperscript{39} The invention simply added extracts of *Myristica fragrans* to various dentifrice compositions to form toothpastes and mouth rinses for the treatment of oral diseases and treating oral cavity soft tissue. Since, it was an oral composition which was an admixture of natural ingredients such as *Myristica fragrans*, natural extracts from dentifrice and an oral carrier, its
synergistic effects over and above prior art including prior art from traditional knowledge had to be demonstrated.

On 9 May 2014, CSIR-TKDL entered as third party observers and on 1 August 2014, a request for examination was filed. The CSIR-TKDL had submitted a number of documents from Indian traditional medicine where *Myristica fragrans* with other natural extracts from *Zingiber officinale*, *Roscoae*, species of *Cinnamomum*, *Piper*, *Accacia*, *Azadirachta*, *Seasmum* and *Syzygium aromaticum* either by themselves or with other ingredients were used to eliminate bad breath, treat gingivitis, gum boil, dental caries and other oral health care problems through their antibacterial and antioxidant properties. Traditional medicine from *Ayurveda* and *Unani* such as *Raughan Bara-e- Amraaz-e-Dahn* developed by Mohammad Najm Ghan Khan, a famous *Unmani* practitioner who authored *Khzanatul-Adviain* 1915 and *Qaraabaadeen Najma-al-Ghani*; *Khadiraditailam* from Agnivesa’s *Caraka Samhita*; *Dantaprabha* *Curna* (Manjana) from *Ayurveda* *Sarasamgrahah* and *Sahakaravati* from *Rasayoga sagara*, a compilation of formulations from 1000 B.C. contained *Mystica fragrans* and other natural extracts for treating dental carries and other oral healthcare problems.

In the presence of the prior art, novelty and inventive step was required to be proved. On 3 October 2014, the first examination report was issued which objected to the invention being novel or inventive since its synergistic effects could not be proved over and above the prior art. By 26 June 2015, the application was deemed withdrawn.

EP2192910A1- *Thymus vulgaris* (Common name: Garden Time, Popular Indian name: *Ajwain ke phul*), *Origanum vulgarae* (Common name: Oregano, Popular Indian name: *Van/Jangali/Pahadi Tulsi*) and *Cinnamomum zeylanicum* (Common name: True cinnamon, Popular Indian name: *Dalchini*)


After placing such a broad claim of the invention to all the species in these genera, the applicant specified a few species in its dependent claims. As the composition was an admixture of plant extracts, synergistic effects had to be shown to claim an inventive step. In fact, the Written Opinion of the International Searching Authority issued on 1 April 2010 stated that the patent application should sufficiently define the composition at the filing date as later restrictions to the long list were likely to be refused unless combinations were disclosed in the description. It also stated that there was no test data to support any medical activity as claimed, i.e. no synergistic effect was shown.

In case a medical activity was shown, it was covered in the prior art. Though, the Written Opinion was non-binding and the patent examiner was required to be satisfied on the novelty and inventive step; the case demonstrates how the scientific community may not be thorough in investigating its prior art and disclosing the invention with sufficient clarity.

In the examination report dispatched by the patent examiner on 28 July 2010, the admixture lacked an inventive step and novelty. In response, the applicant began removing the ingredients from the admixture till about 5-6 plant extracts remained. It sharpened the claims to include precise composition percentages, an act which should have been undertaken prior to filing the application. Many of the properties claimed as efficacious in the composition were from plants which were known in traditional Indian medicine to possess the said properties. Witnessing an attempt to appropriate ATK, objections were raised by CSIR-TKDL on 27 April 2011 to the novelty and inventive step of the invention. CSIR-TKDL provided evidence of traditional knowledge and use of claimed genera in oral healthcare through formulations documented in *Unani* and *Ayurveda*. Indian formulations such as *Sinoon Barae Khoon-e-Lissah* and *Nushka Barae-e-Taakul Asnaan* developed by Mohammad Akbar Arzani and *Qaraabaadeen Qadri*, both celebrated *sufi* physicians of 17 century AD used *Thymus vulagris* and *Origanum vulgarae* respectively for the treatment of Gingivitis and dental caries through local application. *Ayurveda* formulations such as *Dantasulahara Manjana-02, Dhankar: Commercialisation and Biopiracy of Genetic Resources*
Dantadosahara Manjana-a referenced in Rasatantrasarah Evam Siddhaprayog-asamgrahah, a compilation of traditional Indian formulations from 1000 B.C. to 20th century contained Cinnamomum zeylanicum along with a few other ingredients for the treatment of carious tooth, Gingivitis, Pyorrhea-alveolaris and spongy/bleeding gums. The examiner took note of these objections and found that the application lacked novelty and inventive step in light of the ATK and other prior art. The applicant relentlessly pursued to amend claims without once demonstrating the synergistic effects of the composition or the novelty it contained. It seemed that the applicant’s conjectural drafting and inability to demonstrate an inventive step led the examiner to refuse the claims. By September 15 2015, the application was deemed withdrawn.

EP2361602A2- Viinis vinifera (Common name: Grape Vine, Popular Indian name: Angoor), Curcuma longa (Common name: Turmeric Popular Indian name: Haldi), Seasome indicum (Common name: Sesame, Popular Indian name: Til)

In another case, Pangaea Laboratories Limited filed a national phase application on 11 February 2011 with the EPO for a method of treating hair by applying a hair building solid agent for altering and/or maintaining the electrostatic charge to induce a negative polarity. The invention claimed to treat loss of hair, thinning or hair loss or hair stages where one of the pharmacologically active ingredients in the hair building solid agent was one or more of beta-glucan, resveratol, procynadin, methionine, curcumin and plant sterol to name a few. With a broad claim to include pharmacologically active ingredients from Indigenous sources that have been traditionally used for treating hair fall, alopecia, premature grey hair, and other hair and skin related conditions, novelty and inventive step of the invention had to be proved. Many Indian variety of plants such as Viinis vinifera - a source of resveratol, procynadin and methionine; Curcuma longa - source of curcumin; Seasome indicum - a source of plant sterol, methandine and histradine had been used by practitioners of Indian medicine to produce formulations such as Nisadi lepa, Kesya ausadhi and Tila-e-Damaghthul Karam using the pharmacologically active ingredients from plants used in the invention. The formal examination of the application commenced on 12 January 2015 and the applicant had a period of 4 months to rectify the deficiencies in its claims to meet inventiveness and novelty. After the applicant failed to respond to the examination division to prove novelty and inventiveness, the EPO closed the application on 1 October 2015.

EP1827362- Physalis minima (Common name: Pygmy groundcherry, Popular Indian name: Rashbhhari), Plumbago indica (Common name: Red Plumbago/Scarlet leadwort, Popular Indian name: Lal Chitrak), Curcuma zedoaria (Common name: White turmeric, Popular Indian name: JangliHaldi/Kachur)

On 28 June 2007, an application titled ‘Compositions and Methods of Their Use for Improving the Condition and Appearance of Skin’ by Avon Cosmetics was filed with the EPO for prosecution at the national stage. The application claimed a topical composition comprised of an effective amount of a plant extract or a combination for increasing the expression of a gene from groups such as beta-catenin, collagen 4, collagen 7, frizzled 10, estrogen receptor alpha, hyaluronic acid synthase, and their combinations with an acceptable vehicle. The plant extracts claimed in the topical composition were from ‘Plumbago indica, Canangaudorata, Sapindusrarak, Curcuma xanthorrhiza, Physalis minima, Stephania rotunda, and any combinations thereof’. Some of the uses were to reduce signs of aging, wrinkles, treating crow’s feet, rejuvenating and revitalising the skin and restoring skin lustre and brightness.

In the supplementary search report issued by the EPO on 27 July 2012, some of the documents that disputed novelty and inventive step were studies on the Khanti tribe of Arunachal Pradesh and the medicinal plants used by the Kandha tribe of Orissa. Accordingly, the applicant began amending claims. Since, some of the plant extracts claimed were from the Indian variety of plants, third party observations were filed that showed use of pygmy groundcherry (Physalis minima), red plumbago (Plumbago indica) and white turmeric (Curcuma zedoaria) as anti-wrinkle, lustre promoting and complexion promoting agents. Physicians and practitioners of Indian traditional medicine used a number of formulations containing these plant extracts for improving skin and treating certain skin disorders. Some of the Indian formulations include Rakta Citraka Evam Krsna Citraka Prayoga, Thaumarai Thylam, Tila Bara-e-Tahabbuj-A, Kushtahara lepa.
inventiveness. The applicant thereafter, requested for an extension of time which was granted. The claims were amended on 16 February 2015 to remove all plant varieties except Plumbago indica. However, the examiner was of the opinion that the claims did not meet the requirements of patentability and on 18 March 2016, the applicant was granted an extension of 2 months to demonstrate the novelty and inventive step in the invention.

Types of Biopiracy

From the recent cases on biopiracy it is clear that more information is required from the end of the applicants to meet the criteria of patentability and also to prevent the misappropriation of GR and ATK. There are three types of biopiracy that can be traced for the purpose of the present paper. The first is misappropriation of GRs and ATK outside the patent regime through spurious means of access (misappropriation of GR and associated TK), second is an attempt to claim an invention that does not meet novelty or inventive step due to the presence of traditional knowledge (invalid patents/potential to be invalid patents) and third is a combination of the two where a patent is granted for its novelty and inventive step but does not meet the criteria of patentability and was developed from GRs and ATK without being properly accessed (misappropriation of GRs and ATK and invalid grant of a patent). The cases of biopiracy discussed above deal with the second and third forms of biopiracy.

Patent applications EP2689806, EP2192910A1, EP2361602A2 and EP1827362 are examples of the second form of biopiracy where patent applications are unable to meet the criteria of patentability in light of the prior art in the form of traditional knowledge. The question on whether GRs utilised in developing the invention were properly accessed in the patent applications is moot due to the lack of information in that respect. Giving the benefit of doubt, let’s assume that the GRs were accessed with appropriate PIC and equitable sharing mechanisms. Even with the appropriate access of resources as required under CBD and Nagoya protocol, there was an attempt to claim an invention with a blatant disregard to traditional knowledge of local and Indigenous communities. In this sense, even if there was no intentional misappropriation of GRs, biopiracy could have potentially occurred due to an attempt to gain monopoly over traditional Indigenous medicine and use.

Patent EP1962578B1 is an example of the third form of biopiracy where the patent did not meet the criteria of patentability and allegedly misappropriated the melon germplasm (GR) as it was accessed from the country of origin without authority. The melon case is a very unique case study since there was a pre-grant and post grant opposition to the invention. In the pre-grant opposition it was seen that the patent officers were concerned with the determination of novelty and inventive step. At the prosecution stage, little attention was paid to Article 100(b) and Article 83 on whether the invention was sufficiently disclosed for a person skilled in the art to perform the invention. It was only after the patent was granted and a post grant opposition instituted, that the patent office deliberated over whether a person skilled in the art would be able to perform the invention. Details that were required for the invention to be performed were not just additional information on the process of performing the invention but also information on where the biological material with the resistance material could be obtained from. In this instance, a disclosure mechanism which provided information on the source from where the material was obtained for the invention to be performed would have assisted in meeting the criteria of industrial applicability as a person skilled in the art would have been able to obtain the resource from the source and perform the invention. Disclosure of PIC and equitable sharing mechanism with the source/country of origin would have assisted in isolating the invention from an allegation of misappropriation. It would have also provide developing countries with an alternate method of generating data and conducting studies on the kind and nature of resource subject to scientific developments with identification of GRs that could be potential sources of further research. Studies would have revolutionised transfer of technology by ensuring that technologies developed through commercialisation of biodiverse resources were shared with source countries.

Second Form of Biopiracy and Broad Claims

In the second form of biopiracy, we note that inventors made very broad claim to inventions which went beyond the scope of the actual invention with a failure to assess the vast breadth of the prior art. Prior art in the form of traditional knowledge came up during examination or opposition proceedings. Broad claims were made to oral compositions and admixtures. For instance, in EP2689806 the original claim was made to natural extracts as orally
acceptable carriers from of Cinnamomum, Piper, Accacia, Azadirachta and many more which by themselves claimed over approximately 500 species. Out of these, many were used in Indian Ayurveda and Unani medicine for curing dental carries and oral health care problems that the applicant was seeking to claim. In this sense, the broad claim of the inventor was overlapping with Indian medicine and was beyond the scope of the invention.

Similarly, in EP2192910A1, the original claims of the inventor claimed 44 genera of plants without once conducting due diligence on whether the genera would overlap with Indian traditional medicine. As seen from the case, the broad claim prolonged prosecution time and at each instance, the applicant was left reducing and sharpening claims by removing the different genera from the oral composition. This is a classic example of inflating the scope of the invention without due diligence and poor drafting of claims. Even for scientists conducting research at the genera level, making claims to oral compositions which were mere admixtures with known properties required some synergistic effect to be shown for a claim of novelty and inventiveness. Making broad claims across entire genera which may include a number of Indian species that demonstrate the same properties claimed in the invention, not only pointed to a lack of inventive step and novelty but also raised concerns of inventors making claims to more than what they had ‘invented’. These claims either had to be narrowed or the work simply wasn’t an invention.

Cases in the second form of biopiracy raise concerns over two factors, one is a better and more comprehensive search of prior art by the inventor through stronger databases and two, succinct drafting of claims. It must be noted that in the second form of biopiracy, strengthening databases through better connectivity, expansion to traditional databases and better translation facilities itself would not be sufficient. Rather, it is a complementarity of good due diligence and succinct drafting by the inventor along with stronger databases for better prior art search that would curb the second form of biopiracy. Presently, the rationale adopted by many inventors is to claim admixtures and oral compositions over different types of plant genera taking the risk that if the patent officer was competent and vigilant, ready to spend time in searching for prior art and understanding the invention, the patent officer would be able to catch the claim beyond the scope of the invention requiring a reduction of the claim. If not, the inventors would be granted a broader claim and hence, a broader monopoly right for commercialisation. This takes away the credibility of the invention and that of the inventor’s. Further, with hypothetical extensions to species in the genus, prior art has to be submitted for each species to challenge the coverage over the broad range of plant material claimed in the composition.

For inventors working on plant extracts, it is prudent to expect prior art not just in the form of scientific or patent literature but also to Indian medicinal literature compiled in various Ayurvedic, Siddha and Unani books. To assist inventors in their prior art search, knowing the country of origin of the natural extract would clearly assist. If it was known that work was conducted on species such as Azadirachta indica, Curcuma longa, Seasome indicum which are well used in Indian medicine and daily care within the Indian subcontinent, prudence would demand a search of non-patent literature from the Indian subcontinent to distinguish the invention from the most potential source of traditional prior art to establish novelty and inventive step. Good due diligence coupled with good drafting that make realistic claims evidenced from the detailed description in the invention would serve two advantages- first, it would reduce prosecution time and expense for the applicant along with strengthening the credibility of the invention, the integrity of the inventor and ease of prosecuting before the patent office; second, it would reduce the time and burden of the patent officer in prosecuting the invention and making prior art searches. Clearly, no advantage would be served if the patent officer would take time to conduct prior art search, distinguish the invention from the prior art and send back claims for reduction, nor would there be any advantage for the applicant to continuously narrow its broad claims as per the prior art produced by the patent office. Instead, a practise should be adopted by applicants to make their claims succinct and within the scope of what they have actually invented. This would also provide more transparency to the patent system.

**Third Form of Biopiracy– Misappropriation and Inability to Meet the Criteria of Patentability**

In the third form of biopiracy there are concerns of broad claims but cases that fall under this category are those which are inventive and novel but misappropriate resources and were unable to meet the
criteria of patentability. The third form of biopiracy, in a way, is a step after the second form of biopiracy, where the primary issue of novelty and inventive step is treated with the broad claims being narrowed, the hypothetical assumption of misappropriation is discarded and other factors affecting patentability are raised. In treating the third form of biopiracy, strong databases for prior art do not play a significant factor since these inventions have met the threshold of novelty and inventiveness for which the databases were developed. EP1962578B1 serves as an example of this form where in the pre-grant opposition, concentration of third parties and the patent officer was on novelty and inventive step rather than whether the invention could be performed by a person skilled in the art. It was only during the post-grant opposition, when some attempt was made to perform the invention it was realised, one, the hypothetical assumption used in most prosecution cases that biological material used for performing the invention was obtained with PIC and equitable sharing mechanism stands tarnished with a grave concern of misappropriation of the GR being raised; second, the non-disclosure of the correct source of the biological material raised the issue that a person skilled in the art could not perform the invention and despite being novel and inventive, the invention did not meet the criteria of patentability.

It is the third form of biopiracy that many countries at the IGC are hoping to address through a disclosure mechanism. Today, there is no way of knowing whether a GR in a patent application is obtained with PIC and equitable sharing mechanism since the national authorities under the CBD and Nagoya Protocol which grant access to GRs are isolated from patent offices. As seen, in EP1962578B1, the issue of improper access of the genetic material in the patent application was raised quite late, perhaps because national authorities under the CBD and the Nagoya Protocol have information of only resources that were voluntarily accessed and shared with them. If an applicant has not accessed the resource properly, a very strong investigation division would be required under the CBD and Nagoya Protocol to monitor whether the resources accessed under the patent system were legal or not. This would reduce national authorities to sleuthing agencies with work of simply monitoring the magnanimous volume of patent applications, filed, prosecuted and granted every day. The investigative burden on these national authorities, primarily in developing and least developed countries is extraordinarily high and without some additional information from patent applicants to prove that GRs accessed were legal and equitable, misappropriation would continue. Furthermore, even if the issue of misappropriation is raised during opposition proceedings, the patent office does not have jurisdiction to address the concerns. The issue of improper access in EP1962578B1, thus, remained unaddressed. Most countries are demanding that an international system be developed to set up standards and policy objectives to address the issue of misappropriation of GRs and ATK. The standards are currently around some form of disclosure on the source of origin, evidence of access and equitable sharing in patent applications. From the perspective of national and international regulatory bodies, a transparent framework could be developed at protecting GR and ATK and from the perspective of inventors', a properly implemented disclosure regime could isolate them from claims of misappropriation and reduce reputational risk.

The disclosure of source is also tied to the criteria of patentability. In EP1962578B1, the applicant submitted that the biological material from original line PI31390 was the starting material of the invention that could be obtained from any ex-situ source such as a gene bank or a collecting society. This submission was proved to be incorrect since the starting material of the invention was biological material from PI31390 with the closterovirus-resistant trait. As seen in the decision of the OD, the information provided by the NBA on the historical origin of the biological material proved to be helpful in providing information on the difference between the material from the source of origin and the material actually used in the invention. The information, led to an understanding of the loss of resistance if the starting material as claimed in the invention was used. This was helpful in demonstrating that a person skilled in the art could not perform the invention.

**Biopiracy and Risk Management**

Studies indicate that the market value of shares for biotechnology companies is an estimated US$ 400 billion in the United States and US$ 25 million in EU.

The amount spent on R&D to develop biotechnological products is US$ 4.2 billion. Given that biotechnology is a fairly new and growing industry, the capital resources required for development of successful products and processes is
comparatively higher than other industries. For leading pharmaceutical companies that have launched three drugs within the last ten years, the median cost is US$ 4.2 billion and for those that have launched four drugs, the median cost is US$ 5.3 billion and if a company has launched only one drug, the cost is a substantial US$ 351 million. The statistics indicate that successful product launches have been established by large companies with deep pockets or joint ventures successful through venture capital funding. If biotechnology and pharmaceutical companies are spending substantial resources on R&D and launch of new products, they would want to protect their invention through the IP regime including grant of a monopoly right over the invention. On the contrary companies operating in personal care, cosmetics and hygiene segment largely utilise natural raw materials and biochemical extracts for direct commercial application. Studies at UEBT indicate that when patent applications are made in personal care and cosmetic segments many of them make claims to basic mixtures. In comparison with pharmaceutical and biotechnology companies, companies in personal care spend far less on R&D. In 2014, Colgate spent US$ 277 million on R&D and US$ 1,784 million on advertising while Avon spent US$ 62.5 million in 2014 for R&D and 177.1 million on advertising. The statistics indicate that many ingredients in the admixture demonstrate properties already known and, in most instances, form traditional knowledge of a number of local and Indigenous communities. Better understanding of traditional knowledge is required to prevent abandonment of the application and allegations of misappropriation. The risk frameworks of these companies have to factor R&D better to include an understanding of traditional knowledge in order to prevent claims that overlap with it.

Biotecnology and Pharmaceutical companies have strong R&D facilities, but better skill is required for drafting patent applications. The risk management framework needs to factor the relationship between ABS and the patent regimes. With an ABS framework implemented by a number of countries, the source of biological material may become a crucial factor in determining whether a person skilled in the art could perform the invention. On the question of industrial applicability, attention is drawn to whether the biological material was legally accessed through an equitable sharing mechanism as seen in the case of Monsanto. A case of alleged misappropriation leads to reputational loss that affects the business of the company. To prevent such claims having a risk management framework that re-analyses whether the criteria of patentability is met and that appropriate PIC and equitable sharing is in place, becomes useful. The cases discussed, demonstrate that strategic patent management is critical to large scale companies. Patents revoked or applications abandoned due to third party interventions are an attestation to market vigilance for efficiency and integrity.

What was needed in these cases was a risk framework that complemented the patent functions with the business and operational framework of the

<table>
<thead>
<tr>
<th>Patent application</th>
<th>Name of the company</th>
<th>Net income in 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>EP1962578B1</td>
<td>Monsanto</td>
<td>US$ 2,740 million</td>
</tr>
<tr>
<td>EP2689806</td>
<td>Colgate</td>
<td>US$ 2,180 million</td>
</tr>
<tr>
<td>EP2192910A1</td>
<td>Colgate</td>
<td>US$ 2,180 million</td>
</tr>
<tr>
<td>EP2361602A2</td>
<td>Pangea Laboratories Pvt. Ltd.</td>
<td>Not publically provided</td>
</tr>
<tr>
<td>EP2689767A1</td>
<td>Avon Cosmetics</td>
<td>US$ 388.6 million</td>
</tr>
</tbody>
</table>

Table 1—Patent applications and their net income in 2014
From cases discussed above, abandonment or factors only to those that threaten its existence and company. The provision narrows the scope of the risk company which may threaten the existence of the company. However, the inherent risk is that third party interventions may expose the patent applicants/holders to allegations of misappropriation and/or seeking monopoly rights over inventions which didn’t meet the criteria of patentability. Instead, the rationale should be to make claims more realistic based on thoroughly researched prior art including traditional knowledge and other requirements of patentability. Realistic and succinct claims would reduce prosecution time and expenditure and assist the applicant gain market integrity. Further, if an assessment on the criteria of patentability is more realistic, the risk of a patent being revoked at a much later gets reduced. As in the melon patent, the expenditure on holding a patent which did not meet the criteria of patentability could have been diminished if an early assessment of the entire patentability criteria had been undertaken.

From the net income, certain % could be set aside for risk management strategies in patents. Large companies operating in a number of jurisdictions are required by law to incorporate a uniform risk management framework in their organisational setup. In Australia, the ASX Corporate Governance Principles and Recommendations requires all listed companies to have a risk management committee that oversees the implementation, development and monitoring of a risk management framework enterprise wide. In case, a listed company decides not to recognise and manage risk, it needs to explain why it decided not to manage the risk. While the principles and recommendation require some form of internal risk regulation, the qualitative aspects of the risk management is largely in the hands of the risk management committee. In India, under section 134(1)(n) of the Companies Act 2013, a report by the Board of Directors in the General Meeting needs to contain a statement on the risks identified by the company which may threaten the existence of the company. The provision narrows the scope of the risk factors only to those that threaten its existence and from cases discussed above, abandonment or revocation, may not directly threaten the company. However, if a company spends millions for grant of patents then investors would want to know why patents were not granted and shareholders would want an explanation for the loss caused by the inability to receive monopoly rights. For listed companies in India, clause 49 of the Listing Agreement requires all companies with a share capital of 10 crore and net worth exceeding 25 crore that are not listed on SME and SME-ITP Platform to constitute a risk management framework and committee.

A good starting point for companies is to align their risk framework to the ISO 31000:2009 Risk management – Principles and guidelines tailored to the needs of the organisation. However, the tailoring of the frameworks is dependent on how well the risk management framework encapsulates reputational and economic risks associated with grant of patents at the planning stage itself. Broad ambiguous claims, third party oppositions and claims of misappropriation should be identified as potential risks with requisite treatments. The risk management framework needs to embrace the qualitative aspect of the invention beyond financial and marketability concerns. Risk management studies need to move beyond the rhetoric of post grant risk management. There is over-emphasis on preventing proprietary friction through prevention of litigation at the post grant stage; investigation and dispute settlement outside court and litigation pursuits. Risk management has to be incorporated into the company at the R&D stage itself. Inventors need to make claims to realistic inventions that do not overlap with prior art and the invention should clearly distinguish between prior art including traditional knowledge. Providing some evidence of whether PIC and equitable sharing mechanisms were adhered as a risk management component would assist in isolating claims of misappropriation of resources and TK. The information on PIC and equitable sharing would ally fears of misappropriation after grant of the patent with stakeholders such as licensees and investors being assured of the legitimacy of the resources in the patent application. Rather than reputation destroying, PIC and equitable sharing could be used by companies to attract stakeholders through evidence of legitimacy in obtaining resources and traditional knowledge subject to a patent application.

While companies can make their internal risk regulation stronger, regulation at the international level is required on the content covered in patent
applications with respect to the disclosure mechanism. In the 29th session of the IGC, the representative of the International Chamber of Commerce pointed out that there was ambiguity around the disclosure on the source of origin. The country of origin is the country from where the plant is found in-situ and the country of origin could be more than one depending on the resource. On the other hand, the source of the GR is the place from where the GR was directly obtained or physically accessed. The source includes gene banks, research centres and botanical gardens where resources are conserved ex-situ. Within the disclosure regime it is still to be decided whether disclosure should be made of the country of origin or the source. The country of origin may differ depending on whether studies are conducted with a specific genera or species. For example, the source of the potato genus was in the Andes but work may be conducted on a specific sample such as King Edward potato which is said to have originated in Lincolnshire, UK. Till this issue is decided, it would be prudent that the applicant make voluntary disclosure of at least the source from where the material is obtained to isolate claims of misappropriation. In cases where the origin of the GR could be material in determining whether a person skilled in the art would be able to perform the invention as the case of the melon patent, it would prudent to provide disclosure on how the sample from the country of origin is different from the sample used in the invention. This is a judgement call and needs to be taken at the planning stage of the R&D, prior to filing an application for a patent.

**Biopiracy and Concentration of resources**

Another issue of commercialisation is the concentration of resources. Unlike the plant variety protection provided in UPOV which allows free access to commercially traded seeds for further breeding, the grant of the melon patent shows that access to the melon seeds with the resistant trait could be blocked for farmers and other breeders for further breeding. This leads to the concentration of melon seeds with the closterovirus-resistance trait only with Monsanto. Farmers and breeders would need to procure a license from Monsanto before they could use the melon seeds with the resistant trait for development of new varieties. Thus, instead of promoting innovation and technology, the patent system leads to monopolisation of resources. Once a company has monopoly not just on the technology (resistant trait) but also the resource (germplasm of melon with the resistant technology) they can fix the price of the melon seed with the resistance technology at a higher price. Unlike exceptions in the UPOV to permit access to commercial seeds for research, the absence of such an exception in the IP regime restricts research on improving melon seeds with closterovirus-resistance unless the patent holder grants a license for research.

Studies comparing seed prices with production of the crop have revealed that prices of genetically engineered seeds subject to patents have increased dramatically but the growth in yields is comparatively slow. From 2010 to 2014, the cost of procuring corn seeds per acre in the US increased from US$ 81.48 to US$ 101.04 while the yield erratically decreased from 2010 to 2012 reaching a dramatic low to 118 bushels per acre before increasing again. Similarly, for rice the cost of purchasing seeds jumped dramatically from US$ 84.39 per planted acre to US$ 98.91 per planted acre in the year 2013-2014 and the yields declined from 83 to 82 cwt per planted acre. For cotton, the cost of seeds increased from US$ 60.34 per planted acre to US$ 100.82 from 2007 to 2014 and the cotton yield steadily declined from 911 pounds per planted acre to 685 per planted acre in just 7 years. To further add concerns to the issue of seed commercialisation, a report released in February 2014 revealed that since the introduction of patented technology in corn, cotton and soybeans the crops have been able to tolerate herbicides to control weeds more effectively but the yields of herbicide tolerant varieties may be occasionally lower than the conventional varieties.

Thus, farmers not only have to pay high prices for the seeds but have no choice but to purchase costly patented seeds or plants from patent holders that leads to low yield. Evidence based case studies undertaken have revealed several cases where smaller seed companies were bought by Monsanto and the traditional varieties were taken off the market. Furthermore, in the melon case, Monsanto was asked to disclose the biological material but it did not. The non-disclosure of the correct source, if undetected, would have given Monsanto monopoly over the seed and prevented others from performing the invention.

**Biopiracy and Disclosure**

In EP2192910A1, a claim was made to an oral composition composed of active ingredients extracted from two genera out of some 44 for their antibacterial
activities such as treatment of gingivitis, plaque formation and other such oral infections. Without making any attempt to distinguish how the composition was different from other patent literature and traditional prior art where oral healthcare compositions with the same antibacterial activities were shown, the composition then specifically claimed the composition to consist of commonly used species within the genera. In the claims made for demonstrating the antibacterial and anti-plaque forming activity, it was not once demonstrated what the inventor actually performed in the lab. Did the inventor access the thousands of species claimed in the composition to demonstrate their antibacterial activity or was there a hypothetical extension to all the species on the assumption that all species in the genera would demonstrate antibacterial and anti-plaque activities and hence monopoly rights should be claimed over compositions which used these plant extracts?

This leads to the question of what the inventor actually did in the laboratory as opposed to what is claimed. There is no doubt that what is claimed is required to be an invention and no monopoly rights are granted over plant species extracted. However, in composition claims which are dependent on use and development from plant extracts, hypothetical extensions of compositions to include plant extracts from the genera not only raise questions of novelty and inventiveness but also issues of access for a person skilled in the art to perform the invention. In the present instance, a person skilled in the art does not know what species are the starting points of the invention and how to access them. It becomes quite critical to know what the inventor actually performed in the lab so that the ‘technology’ claimed is on the basis of what was performed in the lab. There is no evidence, that the inventor accessed the entire genera or even the species claimed for the purpose of the invention but was simply making assumptions in the invention without demonstrating the strength of those assumptions. This raises concerns over the ambiguity of the invention along with raising concerns over future misappropriation.

A disclosure regime would seem apt to prevent ambiguous hypothetical claims by limiting claims to compositions of GRs which either the inventor was not permitted to exploit or for which special permission would be required from. In such circumstances, the applicant would be able to claim monopoly rights only to those compositions in which GRs have indeed been accessed. This would seem equitable in the light that some GRs are not open for research or commercial exploitation or if open would require permission of the relevant authority. Patent applications would have to be amended to the effect that expansion of claims beyond the ambit of the invention would be curtailed to exclude use of technology over GRs that are inaccessible (since the relevant authority did not authorise access) or were never accessed. As such, a person skilled in the art would know realistically the starting material for the technology to be performed. In future patent applications of nature similar to the cases in the second form of biopiracy, a more realistic shift would be seen with inventors specifying in the detailed description that the technology was capable of being applied to a wide range of biodiversity which was accessible and thus, capable of industrial applicability and free from misappropriation.

However, there is a concern that even if the inventor was to disclose the source or the country of origin and the equitable sharing mechanism to the limited species accessed for the purpose of the invention, given that a broad claim could be granted over the entire genera, there is still a concern that the inventor may access different species from the genera at a later point in time without providing information on its source, access and equitable sharing, thereby partly defeating the purpose of the disclosure mechanism. While, resources accessed at the start of the invention could be tracked, the resources accessed after the grant of patent still need to be tracked. In simple words, record of the resources accessed for the purpose of developing the invention say, the species used in the invention would be available within the disclosure framework but there would be no record under the disclosure regime of resources from genus accessed at a later point in time. An inventor could access resources not used in the invention but for which a claim is granted through a hypothetical extension in the patent without any obligation of providing a source of origin, ABS and equitable sharing mechanism. To strengthen the disclosure mechanism, the inventor would need to provide the patent office or the national authority granting access with a declaration that in the event a claim is beyond the resources physically accessed for the purpose of developing the invention, the source, evidence of PIC and equitable sharing mechanism would be provided when those resources are accessed.
The disclosure regime not only assists in tracking resources globally by checking misappropriation but also provides accountability for biodiversity subject to monopoly rights. It further provides clarity on what the inventor physically performed in the lab. The purpose of the patent regime is to grant monopoly to the inventor on technology actually invented and not technology that is assumed to be invented. The assumptions of access and therefore, industrial applicability of the invention is also dependent on disclosure of the starting point of the material as the starting material determines whether a person skilled in the art would be able to perform the invention. The disclosure regime is advantageous for, tackling issues of inventiveness and novelty in vague broad claims by ensuring that claims are made for inventions to which GRs have been physically accessed and technology is not extended hypothetically to plant extracts for which a person skilled in the art has no information on the source to obtain the material. This would make claims transparent and ensure that the applicant is claiming what was invented.

**Conclusion**

The commercialisation of GRs and ATK continues at a rapid pace but stands deficient in appropriately addressing well identified and antiquated issues of invalid grants and misappropriation. While, the proposals offered by different countries under the IGC demonstrate the efforts made to reduce the gap between ABS and IP regimes through disclosure, there is no consensus on the minimum documentation for protection of GR and ATK. In such circumstances, even after the lapse of 15 years since concerns over biopiracy were raised, regulation of the second and third forms of biopiracy continues to remain imminent. A balance needs to be maintained between protection of GR and ATK on one hand and the need to improve science and technology, encourage R&D and commercialisation new patented products. Recent cases of biopiracy or potentially being held as biopiracy demonstrate the need for better regulation through a disclosure mechanism which would require more than just disclosure on the source of the origin but also evidence of PIC and equitable sharing mechanism within the patent application to isolate the inventor from claims of misappropriation. As Namibia stated in the 29th session of IGC that there is an agreement on the requirement for a sound system to prevent grant of invalid or potentially invalid patents that lack novelty and inventive step through stronger databases (regulation of the second form of biopiracy) but from the perspective of legal provenance, PIC and equitable sharing mechanism in patent applications is fundamental to misappropriation (regulation of the third form of biopiracy). Otherwise, it would be like providing someone who has committed theft of the parts of a car to legally transfer ownership of the entire car. If the system used for theft is the patent regime then an international framework is required under that regime to prevent such thefts.

Till the negotiations are pending it would be the prerogative of the applicants to make the patent system more transparent through voluntary disclosure and provision of additional information under a risk management strategy. Even though there are many in the industry that might claim disclosure of information to be cumbersome, it is not as tedious as it seems. Documents on origin and ATK forming the patent application would be a part of a larger set of information available with the inventor and could be submitted to the patent office without undue hardship for transmittal to national authorities granting access. Disclosure norms would encourage inventors to describe how their invention is related to TK or distinguishing their invention from TK and assist in providing clarity for the determination of the inventive step(s) or the learning trails that led to their development. It would also be easier for patent officers who do not have access to all TK in assessing inventive step and novelty of the invention, particularly in cases where the prior art is traditional medicine. Disclosure rather than being a repulsive concept, if taken in the right spirit has advantages to promote better drafting of claims, isolation from allegations of misappropriation, timely and efficient grant of patents by reducing prosecution time, maintainability of the patent by reducing risk of revocation, better market integrity for the inventor, better reputation and ease of doing business with stakeholders made aware that inventions are developed with PIC and equitable sharing mechanisms.

**References**

Knowledge and Folklore’ provided a new mandate to the Intellectual Property and Genetic Resources, Traditional of WIPO held between October 5 to 14, 2015 in Agenda Item 17, (Oxford University Press, 4th Ed., Oxford), 2009, p. 399.

Information on national experiences with the intellectual property protection of traditional knowledge, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), WIPO /GRTKF/IC/5/INF/2 (4 April 2003).


DHANKAR: COMMERCIALISATION AND BIOPIRACY OF GENETIC RESOURCES


6 Das SK and Cohly H H, Method of promoting healing of a wound by administering turmeric to a patient afflicted with the wound, US Pat No. 5,401,504 (University Of Mississippi Medical Center), 28 March 1995.


8 The Relationship between the TRIPS Agreement and the CBD and the Protection of Traditional Knowledge, IP/C/W/356, Communication from European Communities And Their Members (17 October 2002).

9 Article 27.3(b), The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge, IP/C/W/400/Rev.1, Communication from Switzerland (18 June 2003).

10 Review of Article 27.3(b) of the TRIPS Agreement, and the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and folklore, IP/C/W/383, Communication from European Communities And Their Members (17 October 2002).

11 Article 27.3(b), relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore, IP/C/W/434, Communication by the United States (26 November 2004); Article 27.3(b), relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore, IP/C/W/449, Communication by the United States (10 June 2005) and Article 27.3(b), relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore, IP/C/W/469, Communication by the United States (13 March 2006).


14 Information on national experiences with the intellectual property protection of traditional knowledge, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), WIPO /GRTKF/IC/5/INF/2 (4 April 2003).

15 WIPO IGC survey forms were distributed through documents-WIPO/GRTKF/IC/5/2 and WIPO/GRTKF/IC/3/Q/1


22 Isacs E, A hair building solid agent, EP Application No. 2361602A2 (Pangaea Lab Ltd).

23 Dryer L & Petchintsev D, Compositions and methods of their use for improving the condition and appearance of skin, EP Application No. 1827362 (Avon Prod Inc.).


28 Hofstede R J M, Kraakman P J & De Sebaastiaan V J, Closterovirus-resistant melon plants, EP Pat No.1962578 (Monsanto Invest N.V.) 4 May 2011, Summons to attend oral


75 Initial Draft Report, WIPO/GRTKF/IC/29/8 PROV, Secretariat of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (21 March 2016) p. 47.

76 Initial Draft Report, WIPO/GRTKF/IC/29/8 PROV, Secretariat of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (21 March 2016) p. 46.
73 Initial Draft Report, WIPO/GRTKF/IC/29/8 PROV, Secretariat of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (21 March 2016) 45-47.


78 Dutfield G, Protecting Traditional Knowledge and Folklore (Paper No. 1, ICTSD- International Centre for Trade and Sustainable Development) 2003, p. 3.

79 The delegation of Bahamas speaking on behalf of GRULAC, Delegation of Brazil speaking on behalf of the Latin American countries, the Delegation of the Islamic republic of Iran and the Representative of HEP in the Initial Draft Report, WIPO/GRTKF/IC/29/8 PROV, Secretariat of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (accessed on 21 March 2016) p.17, 37, 39 and 40.

