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INTELLECTUALPROPERT Y,TRADITIONALKNOWL EDGEAND GENETIC RESOURCES

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1. PRELIMINARYCO NSIDERATIONS

Nowadaysintellectualproperty,traditionalknowledgeandgeneticresourcesarea challengingtopicthatcoversagreatnumberofelementsoflegal,cultural,technical,social andhistoricaloriginand,inaddition,hastotakeintoaccount variousapproachesinturn partlydependentonamorespecificfocusingononeorotherelementamongthosealready mentioned.

Theabovetitleitselfgivesrisetoabasicquestionderivingfromthesamelarge numberofaspects. That question may be as kedas follows: Aretraditional knowledge and genetic resources part of intellectual property, in other words, with reference to the WIPO Convention, dothey belong to the categories of intellectual property so well defined in the Convention's Article 2(v iii)?

"Intellectualproperty" shall include the rights relating to:

- literary, artisticand scientific works,
- performances of performing artists, phonograms, and broadcasts,
- inventionsinallfieldsofhumanendeavour,
- scientificdiscoveries,
- industrialdesigns,
- trademarks, servicemarks, and commercial names and designations,
- protectionagainstunfaircompetition,

and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

Alternatively, aret heymerely somethingelsethat interferes with orisperhaps related to intellectual property rights?

Althoughthequestionmightseemsuperfluousandnotatallbasic, astraditional knowledge, genetic resources and folklore could clearly be incorporate dinother rights deriving from intellectual activity in the industrial, scientific, literary and artistic fields, it does have a great many ramifications towards well -defined categories of intellectual property; for instance, we often speak about in telle ctual property and genetic resources, traditional knowledge and folklore (see the wording of the WIPO Intergovernmental Committee) or indeed about the relationship between intellectual property, on the one hand, and genetic resources and traditional knowledge on the other, which tends to indicate conceptual interference rather than a subordination of the concepts to that of intellectual property.

Anotherseriouslycomplexelementderivesfromthefactthatallthewell -defined categoriesofintellectualp ropertyrights, whether copyrightorrelated rightsorrights in inventions, designs, trademarks, trademares, geographical indications and soon, include elements that are subject to protection, those elements being in one form or another, generally subordinated to the concept of novelty (or originality) when filed, where a straditional knowledge by definition has a totally different, historical make -up.

Last but not least of only some of the challenging aspects of the topic that concerns us, in tellectual property generally works with one or a limited number of creators, inventors, artists, and so on who actually apply for rights.

Moreover, whenever they are granted such rights, whenever they transfer them to a well-defined legalentity, the common intellectual property laws based on current treaties and conventions grantholders exclusive rights of exploitation which materialize as the right to prevent others from exploiting the intellectual property subject matter without their consent.

Eveninthecas eofcollectivecreations, such as those of teams of inventors or applicants, collective trademarks, geographical indications, teams of designers or creators of literary or artistic works, teams of performers, etc., the key is finiteness and/or precise definition of their number and name with a view to the acquisition of intellectual property rights, consisting of economic and/or moral rights.

Fromthatpointofviewtheconceptoftraditionalknowledgeisquitedifferent,lying midwaybetweensharedand collective.

The vast majority of international treaties and conventions in and around the intellectual property field, national legislation too, on the one hand, and industrial property theory as dealt within specialized literature on the other hand, have built up a system that defines in tellectual property rights, grant stitles of protection and enforces rights based on those basic concepts and values.

International development initiated 20 years a go and vigorously pursued during the past two or three years revealed the need for a complex approach, essentially based on the fact that large communities of indigenous people, allower the world, have undeniable merit in the intellectual, cultural, scientificand artisticachievements of mankind.

Andwith outanticipating the conclusion, which in fact is already known to every body, namely that the challenging solutions to the problem are to be found in the future, it seems essential to me to make a brief presentation of the current status of that problem.

The delicacy and the scale of the problem for which a strategy and a coherent solution have to be laid down at the international level (and the national level too, of course) are such, unfortunately, that I am left with only a limited capacity for impart in gmy views on the subject.

2. DEFINITIONOFTRADIT IONALKNOWLEDGE(TK) ANDGENETIC RESOURCES(GR)

Acoherentsystemofanykind, whetherlegal, philosophicalorscientific, canonlybe builtonthebasisofanexact, and if possible, widely or unanimo usly accepted, definition of the basic concepts that under liethesystem. Let us see what the situation is in this field.

2.1 Traditionalknowledge(TK)

Ashasbeenalreadypointedoutin[1],TKisaworkingterm,averygeneralone,that coversknowl edgeinscience,technology,agriculture,theenvironment,medicine, environmentalbiodiversity,expressionsoffolklore,andsoon,whichbelongstoaspecific people,populationorterritory,hasbeentransmittedfromgenerationtogenerationandwill evolveinthefutureasaresultofchangingcircumstances.

Themostsignificantsubsectionoftraditionalknowledgeisrepresentedbyindigenous knowledge,ormoreaccuratelybytheknowledgeofanindigenouspeople,and,asthecase maybe,expressionso ffolklore.

Obviously, assome expressions of folklore have been created by natives, one can expect occasional overlaps between expressions of folklore and indigenous knowledge.

Traditionalknowledgeisitselfasubsetofthecommonheritageofmankind .That heritageshouldbehandleddynamically,thatis,ashavingnotonlyyesterday'svaliditytoday butalsotoday'svaliditytomorrow.

Asfarasthetraditionalknowledgeconceptisconcerned, it is worthmentioning that the 1992 Convention on Biologi cal Diversity (CBD), in its Article 8(j), uses the terms traditional knowledge, innovations and practices while the preamble to the UND raft Declaration on the Rightsof Indigenous Populations speaks of indigenous knowledge, culture and traditional practices.

Strictlyspeaking, the two concepts could be comparable with one another if the word in digenous were given the meaning, which more over is a perfectly suitable one, of pertaining or specific to a particular place.

Ishallrepeatmyself,however,and saythatthemeaningattachedbyWIPOin[1]tothe wordindigenoushasmoretodowithanindigenouspopulation,makingindigenous knowledgeasubsetoftraditionalknowledge.

Withoutmakinganyattempttopresentyouwithanexhaustivelistoftraditi onal knowledge,herearesomeofthemostimportantTKcategories:

- methodsandtechnologiesinmedicine,agricultureandtheenvironment;
- workmanshipandhandicraft:textiledesigns,carpets,folkcostumes,masks, ceramics,glassware,building,etc.;
- expressionsoffolklore.

WithoutriskingadefinitionoftraditionalknowledgeonthebasisgiveninChapter4,I shallalsosaythatitencompassesknowledgeandpracticesthathavenotbeensystematically writtendownbuttransmittedorally,eitherexplici tlyorimplicitly,andaregenerallyspecific toalocalorindigenouscommunity.

Itisalsocharacterizedbythefactthatithashistoricalcharacterontheonehand, throughbeingtransmittedfromgenerationtogeneration, and dynamic characteronthe usually developing under the influence of historical, social, geographical or even political factors.

Asfortheconceptofexpressionsoffolklore, it is actually used exclusively (or at least has been up to now) with the meaning specified in the e1982 UNESCO - WIPO Model Provisions for National Lawson the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions.

ThoseProvisionshaveitthatexpressionsoffolkloreshouldbedeemedproducts embodyingchara cteristicelementsofthetraditionalartisticheritage, developedorpreserved byacommunityinthecountryorbyindividuals, which mirrors the traditionalartistic expectations of that community.

The Model Provision specify four important groups of the manner of their expression, namely:

- (a) verbalexpression:folktales,folkpoemsandriddles,etc.;
- (b) musicalexpression:folksongsandinstrumentalmusic;
- (c) expressionsofthehumanbody(byaction):folkdance s,playsandtheartistic formofrituals;
- (d) expressionsincorporatedinamaterialmediumortangibleexpressions:drawings, paintings,sculpturesandcarvings,mosaics,jewels,textiles,carpets,folk costumes,etc.

2.2 GeneticResources

Besidestr aditionalknowledge, the common heritage of mankindincludes genetic resources as a basic constituent.

That is clear, for example, in Article 1 of the International Undertaking on Plant Genetic Resources which lays down the universally accepted principle that plant genetic resources formpart of the heritage of the mankind and consequently should be available without any restriction.

According to Article 2 of the CBD, genetic resources means genetic material of actual or potential value.

Initsturn geneticmaterialmeansanymaterialofplant,animal,microbialorother origincontainingfunctionalunitsofheredity;inordertogiveafulldefinitionoftheassembly ofconceptsinvolvedinthenotionofgeneticresources,thefunctionalunitsofher edity includingwholeorganisms,partsoforganismsandbiochemicalextracts,tissuesamples containingDNAorRNA,suchasgenes,plasmids,etc.,havetobeincluded.

Generallyspeaking, genetic resources constitute a category of biological resources. As we are at present confronted with fabulous biological diversity, Article 2 of the CBD defines it as variability among living organisms from all sources including, interalia, terrestrial, marine and other aquatice cosystems and the ecological complexes of which they are part; this includes diversity within species and between species, and of ecosystems.

Fromaconceptualpointofviewgeneticresourceshaveadoublenature[2]:

- ontheonehand,theyarephysicalmaterialsoverwhichtheGRsupplierswa ntthe rightofcontrol,whileex -situGRend -users,applyingmodernbiotechnologicalor reproductivetechniques,havesucceededinimprovinggermplasm,consequently beingableandentitledtoclaimintellectualpropertyrightsintheapplied technology;
- ontheotherhand, they are carriers of hereditary information which is capable of self-reproduction and which may itself be the subject matter of intellectual property rights.

Giventhissituation, the genetic resources conceptits el fisof no particul arrelevance because either element of the two fold nature of GR may lead to a claim of IP rights as accepted in the development of modernte chnology: patents for inventions, varieties of plants or breeds of animals, tradenames, etc.

Asyouwillseein Chapter3, two other concepts are relevant, as they be a raspecial relation to IP rights, namely access to the genetic resources and the equitables having of the benefits resulting from that access.

3. THEINTERNATIONALCO NTEXTOFINTELLECTUA LPROPERTY - TRADITIONALKNOWLEDG E -GENETICRESOURCESR ELATIONSHIP

Ishallusetheinternationalcontextconcepttodiscussthemeaningoftheproblem beforeusintermsofanyprovisionsthatmayhavebeenagreeduponinternationallyattreaty, agreementorconvent ionlevel,andalsointermsofnationallegislationinindividualcountries asaconsequenceofinternationalenactments.

It is clear that traditional knowledge (TK) and genetic resources (GR), because they are not concepts specific to intellectual property but have been more and more felt by the modern world as playing an important role in it, have caused an unprecedented increase in recent attempts to outline a clear, specific international context for the IP attempts to a context of the IP and the the IP

The essential parameters of the international context, in terms of its first meaning, are summarized below.

3.1 Basic provisions of international treaties and conventions

Ashasalreadybeenmentioned, Article 20fthe WIPO Convention defines explicitly in its first part the categories of rights constituting intellectual property and, implicitly in its last part, any other rights associated within tellectual activity that have not been mentioned in the first.

The Paris and Berne Conventions and the TRIPS Agreement explain the very essence of the listed rights.

Additionally, Article 27.3(b) of TRIPS provides for the possibility of revision four years after the entry into force of the WTO Agreement, and contains remarkable provisions concerning the patenta bility of genetic resources.

Itprovidesexpresslythatplantsandanimalsotherthanmicroorganisms, and essentially biological processes for the production of plantsoranimals, other than non biological and microbiological processes, shall be excluded from patentability.

The Article further provides that Members shall provide for the protection of plant varieties either by patents or by an effective suigener is system or by any combination thereof.

The pillar outside the IP system which permits and requires the establishment of a triangular IP-TK-GR relationship is the CBD, whose Article 1 specifies that the objectives of the Convention are the conservation of biological diversity, the suitable use of its and the fair and equitables having of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies.

Article 8(j) of the CBD is esse ntial, as it accords national legislation great freedom of action in the establishment of a coherent policy on the IP -TK-GR triangle.

Itprovidesthat, subject to its national legislation, each Contracting Party shall respect, preserve and maintain knowledge, innovations and practice of indigenous and local lifestyles relevant for conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices, and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

Access to GR is a fundamental issue for the CBD: the authority to determine access to genetic resources rests within ational government and issubject to national legislation.

AdetailedanalysisoftherelationbetweenTRIPSandtheCBDisbeingmadeinthe contextoftheTRIPSCouncildiscussionsontherevisionofArticle 27.3(b).

Nowthat TRIPS includes the basic concepts of intellectual property as defined in the Parisand Berne Conventions, we can say that promoting this is sue is undoubtedly aimed at bringing the genetic resource concepts, particularly access to resources and equitables having, including the traditional knowledge and folklore component, into the purview of intellectual property.

ItishighlysignificantthattheConferenceofthePartiestotheCBDof May 15-26, 2000,calledforspecificsurveysontherelationbetweenintellectualpropertyan CBDobjectives,technologytransferandthesharingofbenefitsinclusivelywithlocaland indigenouscommunities.

AttentionismainlyfocusedontheinterferenceoftheCBDwithpatentlaw,namelythe mannerinwhichthepriorartpresentedinadescr iptionreferringtoormakinguseof traditionalknowledgeorabiologicaldiversityissuemayandmustrefertoit,ontheonehand, andwhetherandifsohowtheexerciseoftheIPrightcanhaveafavorableeffectonthe sharingofbenefits.

3.2 Nationaland/orRegionalViewpoints

Whileusingslightlydifferentshadesofmeaninginexpressingtheiropinions, the developed countries stated that ([6] and [8]):

- the CBD and TRIPS did not conflict and had different objectives;
- theydidnothavethesameo bject;
- neithertreatycontainedanexplicitreferencetotheother;
- the provisions of one treaty did not prevent meeting the requirements laid down in the other;
- therewasconsiderableinteractionbetweenbothtreaties, mainlyinthefieldof inventionsco ncerningbiotechnology, plantvarieties, the environmentand ecology;
- thetreaties should not be detrimental to each other; on the contrary, they should be implemented in such a manner as to favor one another.

Anessentialaspectthathadbeenpointed outwasthatintellectualpropertyrights, notablyinventionpatents, were highly effective instruments for genetic resources suppliers in securing major benefits from the entities processing those resources in order to manufacture new products and in providing agood basis for the conclusion of equitable contracts controlling access to resources.

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ParticularattentionispaidtothequestionwhetherornottherevisedArticle27ofthe TRIPSAgreementshouldincludeaprovisionongovernmentauthorization asmentionedin thepatentapplication, butwithreferencetothesourceandoriginofthegeneticmaterial and the employed traditional knowledge, subject to proof of fair and equitable sharing of benefits and of the prior authorization by the government or local or in digenous authorities of the exploitation of the genetic resources and traditional knowledges pecified and incorporated in the description included in the patentapplication.

Thatgroup of countries is decisively against government authoriz ation, but is ready to explore the possibility of finding complementary solutions for the disclosure of information on the geographical origin of the biological material or of the traditional knowledge embodied in the patented solution.

Twoothertrends arealsodistinguishableinthecountries' position, namely:

- supportforthedevelopmentandenforcementofstrongandeffectivenational legislationinTKandGRdonorcountrieswhichalsoprovidesadequateconditions ofaccessandbenefitsharing;
- thed raftingofguidelines,recommendationsorsimilarapproachestothesettingup ofaconcretelegalbasisforaccesstoresourcesandknowledgeandthedistribution ofthebenefitsderivedfromtheiruse.

 $\label{thm:contribution} The developing countries ([5] and [12]) are marked \qquad lyinclined to favor suigeneris TK and GR protection systems.$

Withoutgoingintodetail,thisaspectderivesfromthefactthattheprinciplesunderlying thegrantandobservanceofIPrights,i.e.applicant,holder,exclusiverighttoexploitandto preventothersfromunauthorizedexploitation,areperceivedbymostoftheTKandGRdonor countriesasmeansofpromotingtheinterestsofend -usersandevenasrestrictingthe equitablesharingofbenefits. Theuseoftraditionalknowledgeisalsoperceiv edinmany situationsasenhancingtheconceptofthecommonheritage,totheextentofminimizingor cancellingtherecognitionofeconomicormoralrights,itselfbasedonaguaranteeof unlimitedaccesstoknowledgeandresources.

Most suigeneris protection, except for some slight conceptual variations, is based on TK and/or GR registration that clearly specifies the collective identity of the GR and TK supplier, the consent of the supplier or the competent government authority for the use of the TK or GR, and finally guarantee or access contracts providing for an equitable distribution of the benefit deriving from access to the above.

However, there is a strong consensus in favor of forms of TK and GR protection by means of suigenerisd at a bases containing knowledge, innovations and practices relevant to the preservation and sustainable use of biological diversity ([5] and [8]).

Inthatrespect, the compilation of a huge digital database of traditional knowledge in India (the Traditional Knowledge Digital Library or TKDL) is highly significant.

Thisdatabaseisaimedfirstatidentifyingtraditionalknowledgeofmedicinalplants (herbs)aspartofpriorart, which is therefore public property, with a view to avoiding the grant of patents for solutions that are already retrievable.

Certainly, themere fact of incorporating TK and GR in a database could make a major contribution for example to knowing prior art, including such knowledge or information as will determine the novel ty of the invention to be patented.

Asaconcept, this is only one side of the problem, however, because in factitis necessary to create rights in the registered knowledge [5]. The adequate protection of such knowledge is a sine quanon of fair and equitable access to an dsharing of benefits.

4. PREDICTABLEEVOLUTIO N

Intenseactivitycarriedonoverthepastthreeyearsunder WIPO auspices, including the recent setting upof the Intergovernmental Committee Concerning Intellectual Property and Genetic Resources, Traditi on al Knowledge and Folklore and the start of its work, has made it possible for an action plan to be drawn up for the immediate future, with all the possible options being explored and eventually adequate forms of international standards found for the conceptualization and enforcement of IP in its relationship with TK, GR and F.

4.1. Geneticresources

FourelementsoftheinterfacebetweenIPandaccesstogeneticresourceshavebeen identified,namely [2]:

- (a) contractual agreements for access to genet icresources and sharing of benefits; a possible future task for the Intergovernmental Committee under the seconditions may be the working out of aguide to contractual practice, guide lines and model IP clauses for contractual agreements on access to gen eticresources and sharing of benefits, with specific interests and conditions being taken into account;
- (b) layingdownlegal,administrativeandpoliticalmeasuresdesignedtocontrol accesstogeneticresourcesandthesharingofbenefits;startingwi ththe identificationoftwobasicsub- elements,namely:
 - (i) intellectualpropertyrightsaspossibleinternationalmeasuresofsupportfor thegivingofpriorinformedconsent;
 - (ii) recordofinterestintheinventionderivingfromaccesstooruseofge netic resources:

ithasbeenpossibletodecideonthedraftingofadequateprovisionsorguidelinesreferringto accesstogeneticresourcesthatareconsistentwithinternationalstandardsintheIPfield;

- (c) developmentofmultilateralsystemsforea sieraccesstogeneticresourcesand sharingofbenefits,thosesystemsbeingconsistentwithinternationalIPstandards, withspecialemphasisonplantgeneticresourcesforthefoodindustryand agriculture;
- (d) protectionofbiotechnology:asfarast hissubjectmatterisconcerned,twomajor taskshavebeenidentified,namely:
- $(d_1) \ \ revision of the application of legal standards concerning the availability and extent of patent protection for structures and compositions derived or separated from live organisms and for inventions in the field of biotechnology in its early and the control of the$

stages, with a view to devising guidelines on the application of such standards to the field of genetic resources;

 $\label{eq:d2} d_2) \quad improvement of the administration of genetic resources through expension of methods where by genetic resources in the form of protected plant varieties may be integrated in the general plans for effective preservation.$

4.2 TraditionalKnowledge

Startingfromtwofundamentalissuesarisinginconnectionwithtraditio nalknowledge, namely:

- (A) availabilityofIPprotectionforTKholders;
- (B) acquisition of IP rights in TK based creations and innovations by parties other than the TK holders themselves.

fourmaincategoriesofissueswereidentified,namely:

- (a) identification of the terminological and conceptualissues;
- (b) design of standards in relation to the availability, extent and use of IP rights in TK:
- (c) revisionofcurrentanddevelopmentofnewcriteriaforintegratingTK -related documentationinsearc hablepriorart;
- (d) enforcementofrightsinTKthroughidentificationofspecificwaysinwhichTK holdersmayasserttheirIPrights.

4.3 ExpressionsofFolklore

Although, as I have already said, expressions of folk lore are a subset of traditional knowledge, and as the guidelines devised for TK can therefore be applied, over all, the existence as a positive and distinct fact of the UNESCO - WIPO Model Provisions of 1982, which are to be updated 20 years after their enactment, clearly becomes useful in relation to the identification of specific future areas of concern.

The Model Provisions are expected to be updated with two basical ms in mind [2]:

- (i) improvementinthesystemfortheprotectionoftangibleexpressionsoffolklore, particularlyhan dicraft;
- (ii) extension of the protection of a certain country's expressions of folklore beyond its borders.

Aparticularlysignificantitemforconsiderationwillbetheelaborationof recommendationsforthelegalprotectionoffolklore,basedonthede velopmentofaformof suigenerislegalprotectionattheinternationallevel.

5. PROTECTIONOFTRADIT IONALKNOWLEDGEAND GENETICRESOURCES INROMANIA

Inmycountry,Romania,whereIcarryoutmyindustrialpropertywork,theconcepts thatweareconce rnedwithareprotectedfromwithintheintellectualpropertyprotection system.

Completelyamendedafter 1990, and to agreat extent harmonized with the legislation of European Union Member States, European directives and Community Regulations, the Romanian intellectual property protectionsystem, viewed in relation to our subject matter, has the advantages, and unavoidably also the disadvantages, of a traditional approach within well-defined categories of IP rights.

Beforeexplainingtheseissuesbrie fly, Iwanttosaythat Romaniaisa country where there is remarkable unity within its diversity of historical, geographical, social and other factors which has led to the development of wealth of traditional knowledge, including both expressions of folklore and genetic resources.

Whilestillhavinganimportantagrarianpopulation, whichinitsturnisgrafted onto various geographical areas within portant local peculiarities and significant individual characteristics, in Europe Romania can boastauni que in digenous production, an extremely varied folklore and abiodiversity deserving of attention.

Togiveyouoneexample,theproductionofpharmaceuticalandcosmeticproducts basedonbothindigenousgeneticresourcesandalsoknow -howoriginatingin localloreand traditionisenjoyingthebenefitsofenormousexpansion.

Thenetwork of APLAFAR shops (APLAFAR is our acronymfor pharmaceutical plants) has been highly successful in Romania.

Iamparticularlyproudtobelongingtoacountrywhosefol kloreisremarkablefromthe pointofviewofitsqualityandthediversityofitsexpression.

The fact that Romania ratified the CBD in Law 58/1994 is relevant to the manner in which TK and GRare protected in Romania.

5.1 ProtectionwithInventionPaents

The Patent Law (Law No.64/1991), as amended in 2001, and its Implementing Regulations, which will soon be passed by Government Decision, have introduced the concepts of patenta bility of biotechnological inventions in a manner fully consistent with ECD irective 98/44 on the legal protection of biotechnological inventions. Consequently, without going into greater detail, inventions relating to plants and an imals are patenta ble if the technical feasibility of the invention does not relate to a certain plant variety or an imal breed, with the corollary that plant varieties and an imal breeds, and also essentially biological processes for producing plant varieties and an imal breeds, are not patenta ble.

Thefollowingsubjectmatterislikewisenotpatenta ble:

- (a) thehumanbodyinits various stages of formation and growth, or themere discovery of one of its elements, including a complete or partial genes equence;
- (b) processes for cloning human beings;
- (c) processes formodifying the genetic identity of human beings;
- (d) useofhumanembryosforindustrialorcommercialpurposes.

Asignificantstepincreatingadirectconnectionbetweenprotectionbypatentandtraditional knowledgeaspartofthestateoftheartconsiststheinsertionofaprovisi onintheamended lawspecifyingthatthestateofthearttobeconsideredshallbeheldtocompriseeverything madeavailabletothepublicbywrittenororaldescription, useoranyothermeansbeforethe filingdateor, asthecasemaybe, the priority date of the patent application.

It is worth mentioning that the law has hither to require daw ritten description with a precise is sued at e.

The Implementing Regulations of the Patent Law, which are now being adopted, will have a provision that reflects item 27 of the preamble to ECD irective 98/44 which, in essence, stipulates that: "Where as if an invention is based on biological material of plant or an imaloriginorifituses such material, the patent application should, where appropriate, include in formation on the geographical origin of such material, if known; where as this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents...".

Untilnewconceptionsandconceptsregardingtheprote ctionoftraditionalknowledge and access to genetic resources, and also the sharing of benefits at international level, are complete, the three aspects mentioned are specific steps towards recognition of the role of traditional knowledge as a basic asset of the worldstate of the art on the one hand, and towards a dequate protection for genetic resources by means of invention patents on the other.

5.2 ProtectionbyIndustrialDesignLegislation

The Law on the Protection of Industrial Designs, (Law No. 12 9/92) introduces a system of protection, based on filing and substantive examination of our richtraditional knowledge, including expressions of folklore such as folk furniture, folk costumes, handicraft items and soon.

The Law does not preclude protect ion by means of other intellectual property rights, and so leaves open the opportunity of granting composite protection, not only by copyright and trade mark but also by other future, suigeneris forms of protection.

5.3. ProtectionbyNewPlantVarietyCe rtificate

TheentryintoforceoftheLawontheProtectionofNewPlantVarietieslaidthe foundationsofasuigenerissystemofprotectioninRomania,fullycompatiblewith EC Regulation2100/1994,whichreplacedtheprevioussystemofprotectionensh rinedin LawNo.64/1991.

The conditions for the grant of protection are those that are known for this category of genetic resources, namely novelty, distinctness, uniformity and stability.

The Law provides a dequate protection for plant genetic resourc esby granting the breeder at it leof protection that confers on him the exclusive right to exploit in its most specific form, and also the right to prevent exploitation by third parties without his consent.

The definition of novel tywith in the meaning of Article 5 of the UPOVC onvention, which is that "aplant variety shall be deemed to be new if, at the date of filing of the application for the breeder's right, propagating or harvested material of the variety has not be ensold or otherwise disposed of the others, by or with the consent of the breeder, for purposes of exploitation of the variety, "makes it possible and probable that this form of protection will be relatively widely used for plant genetic resources, including those characterized as traditional knowledge.

5.4 ProtectionbyTrademarkandGeographicalIndicationLegislation

 $The relatively new Law on the Protection of Trademarks and Geographical Indications \\ (Law No. 84/1998) provides for the protection of the concepts of collective mark on one and geographical indication — with its basic meaning as fundamentally defined by Article 7 bis of the Paris Convention and Article 22 of the TRIPS Agreement — on the other.$

Iamthereforepleased to have noticed real growth in the number of request sfor protection from local associations and communities, which, subject to rule stobe filed with the State Office for Inventions and Trademarks, agree to acquire exclusive rights incertain signs or geographical indications, as the case may be, capable of representing the products incorporating traditional knowledge in a manner certified in an official document, the protection certificate.

5.5 ProtectionbyCopyrightandRelatedRightsLegislation

Article7oftheRomanianCopyrightandRelatedRights Law(LawNo.8/1996) providesthatthegenuineintellectualcreationsintheliterary,artisticorscientificfield, regardlessofthemanneroftheircreation,themannerorspecificformofexpressionortheir valueanddestination,suchas:

- (a) literaryandadvertisingworks(...)andanyotherwrittenororalworks(...);
- (b) writtenororalscientificworks;
- (c) musical compositions with or without words;
- (d) dramatic, dramatico musical, choreographicand mimedworks;
- (e) worksofthree -dimensionalartsuchassculpture, painting, graphicart, engraving, choreography, tapestry and ceramics, and glass and metalworks as well as works of artapplied to intended for practical use.

Article6alsobringsinthenotionofcollectivework,asthework inwhichthepersonal contributionsoftheco -authorsformanentitywithoutthepossibility,giventhenatureofthe work,ofattributingtoanyoneoftheco authorsadistinctrightinthewholeworksocreated.

These provisions thus expressly affor dcopyright protection to artistic, literary or scientific subject matter, even that of TK holders, whether individuals or members of indigenous or local communities.

Article95oftheLawalsospecifiesthatperformersmeansactors, singers, musicians, dancersoranyotherpersonswhopresent, sing, dance, imitate, recite, play, interpret, direct, conductor performaliterary or artistic work, aperformance of any kind, including folk performance in any other way.

Farbeitfrommetoconsiderelaborati ngonparticularnationalaspectsatan internationalforum, so Ishallconfinemy selftosaying that, although the outstanding Romanian specialistin IP rights, Professor Yolanda Eminescu, states inherbook Copyright [10] that, as far as we are concerned , we reject the idea of folklore protection by copyright, mypersonal view is much more qualified.

According to that view, I plead for recognition of the literary, artistic or scientific qualities of traditional knowledge, including expressions of folklo re, at the highest level, with all the legal and administrative consequences resulting the refrom and from another point of view, due regard being also had to performers as far a straditional knowledge is concerned.

5.6 ProtectionbyTradeNameLegislatio n

Craftsmen,professionals,manufacturers,producers,andtradespeoplewhobelongeither tolocalorindigenous communities holding or producing traditional knowledge, or to the legalentities that represent them, can protect themselves make their produc tsknown by means of tradenames, which are protected in Romania by the Lawon the Register of Commerce (Law No. 26/1990), as a mended by Law 12/1998, the Lawon Commercial Companies (Law No. 31/1990) and a mended and completed by Law 195/1997, the Lawon the Repression of Unfair Competition (Law No. 11/1990) and Article 301 of the Criminal Code.

5.7 ProtectionbyUnfairCompetitionLegislation

The inclusion of some important amendments on tradesecre cyinthe Romanian Lawon the Repression of Unfair Compet ition (Law No.11/1990) open supthehighly important possibility of protecting the know -how or the secrecy of the traditional knowledge, if I may put it that way.

Invillages, particularly the mountain villages of Romania, there are still large or smalle local communities that know the effect of certain plants or compositions on the treatment of certain diseases, and hold these cretofspecific manufacturing processes in local production and so on which, by virtue of a flexible approach to the notion of tradese crecy, may be protected against misapproopriation or abuse.

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6. CONCLUSION

Thispaperisageneralpresentation of the framework required for the establishment of a coherent relationship between IP rights, traditional knowledge and genetic resources.

Asmayhavealreadybeengatheredfromthepresentation, it is necessary to approach the subject matter cautiously, as it will be nefit from international treatment in the short or longer term on foundations that are being laid under the aegis of WIPO.

Itisextremelyimportantthattheinternationalcommunityisnowawareofandhas takendecisivestepstowardsrecognizingTKandGRastremendousassetsintheintellectual andspiritualheritageofmankind,eitherbyexploringtheextensionofthes copeofprotection ofIPrightsasdefinedintheWIPO,ParisandBerneConventionsandintheTRIPS Agreement,bymeansofsuigenerislegalstructuresorbyelaboratingguidelinesand recommendationstoassistTKandGRholdercountriesingrantingadequ aterightstotheir localandindigenouscommunities.

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