Intellectual Property Protection of Biotechnology and Sustainable Development in International Law

Young-Gyoo Shim

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Intellectual Property Protection of Biotechnology and Sustainable Development in International Law

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Intellectual Property Protection of Biotechnology and Sustainable Development in International Law

Young-Gyoo Shim*

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I. Introduction

From the dawn of human history, human beings have lived in both natural and man-caused fear of "disease, famine, and war." These menaces have engendered crucial turning points in human history, on occasion seriously threatening the existence of mankind. Despite the collaborative efforts of the international community to tackle these menaces, they still remain serious impediments to the sustainable welfare and peace of the global community. However, the biotechnological revolution launched in the second half of the last century has provided us with new chances to cope with at least the natural calamities of disease and famine more effectively. It is a palpable fact that, in the twentieth century, newly advanced biotechnological innovations in the fields of agricultural and pharmaceutical industries have radically accelerated production of food and significantly improved pharmaceuticals through revolutions of the agricultural and medical industries.¹

As we have already recognized since the late twentieth century, modern biotechnology, born with the advent of genetic engineering, has highly influenced human society. In particular, it is envisioned that modern biotechnology will play a very significant role in providing solutions to baffling problems regarding food productivity, health, nutrition,² medicine, energy, protection of the environment,³ etc. Moreover, it is expected that, in the near future, a myriad of newly produced genetically modified organisms (GMOs) made possible by genetic engineering will very likely be applied to agricultural products, pharmaceuticals, medical treatment, environmental protection,


² WATAL, supra note 1, at 128.

alternative fuel, and other purposes. In fact, these biotechnological applications will likely help alleviate human hardships concerning food, energy, health, and the environment, and may ultimately promote human welfare worldwide.\(^4\)

The future itinerary of biotechnological advance is, however, not always rosy. Although it is true that modern biotechnology may be a high-powered engine that can increase food productivity and facilitate production of more effective medicines, it remains questionable whether modern biotechnology can conclusively contribute to solving the problems of global environmental conservation, economic development of the developing world, and inequity between parties taking the profits of biotechnological innovation. Notwithstanding numerous promising products of biotechnology, many people are still apprehensive about the results of massive dispersion of genetically engineered products into the environment. Will biotechnological applications actually guarantee nothing but a mere promise to help the future of humanity?

Indeed, biotechnology, as one of the oldest technologies in human history, has been exploited in manufacturing wine and beer involving processes using living organisms, as well as in the selective breeding of plants and animals. However, its technical importance has grown considerably in recent years.\(^5\) In comparison to modern biotechnology, the above mentioned classical methods of biotechnology and traditional selective breeding of animals and plants, usually applied to produce dairy products, bread, wine, or any desired genetic traits, have not been distinctively problematic in terms of either national or transnational regulations.\(^6\) However, various critical issues, questions, and problems surrounding modern biotechnology\(^7\) have

\(^4\) Murphy, *supra* note 1, at 47.

\(^5\) *INTRODUCTION TO INTELLECTUAL PROPERTY: THEORY AND PRACTICE, supra* note 3, at 587.

\(^6\) Murphy, *supra* note 1, at 50.

\(^7\) Modern biotechnology was developed based on two basic techniques of recombinant deoxyribonucleic acid (DNA) and hybridoma in the 1970s. In brief, the recombinant DNA technology, as also referred to genetic engineering, is the technology of inserting the foreign gene materials into cells, thereby making certain desired proteins. The hybridoma technology is used to blend different types of immune cells, producing a hybrid cell line creating monoclonal antibodies. GRUBB, *supra* note 1, at 225.
kindled severe controversies with both domestic and international dimensions.\(^8\)

On the one hand, genetic engineering, midwife for the birth of modern biotechnology, has made it possible to achieve more benefits of biotechnological applications than classical breeding. On the other hand, it has provoked keen controversies regarding the technological aspect itself, its unknown results, and basic policies controlling technological development. This paradoxical feature mainly seems to come from its technological manipulation, splicing gene materials from different varieties or species to cause genetic recombination overthrowing the natural obstacle of sexual incompatibility.\(^9\) More recently, scientists, applying genetic engineering technology such as microinjection to higher life forms, began to create transgenic plants or animals with improved or transformed genetic characters for certain purposes. Sometimes, this kind of technology has been applied even to humans.\(^{10}\) As a result, newly developed transgenic animals, such as pigs and other animals containing human genes, have been created.\(^{11}\) In this respect, it has become possible for humans to intervene in the process of alterations of biological materials or the natural course of evolution, which has never before occurred in a natural ecosystem.

More recently, cloning techniques, which were developed from modern genetic engineering and have been used to clone genes, plants, animals,\(^{12}\) or even human beings, have triggered public contention. Stem cell research, nuclear transfer technology, and their resulting "fabrication" of Dolly the sheep opened the door to human cloning using an adult somatic cell.\(^{13}\) The application of this "Dolly method" to human cloning compels us to rethink the conventional notions of regeneration of life and

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\(^{8}\) See Murphy, supra note 1, at 50.


\(^{10}\) See generally Grubb, supra note 1, at 225, 243-44, 249-51 (discussing, among other things, the use of gene therapy to address genetic defects).


\(^{12}\) Westerlund, supra note 9, at 8.

\(^{13}\) In vitro fertilization works using a technique of embryo splitting has been employed for human cloning since the early 1990s.
human dignity, as well as many unresolved scientific and technical problems. Although there is great promise for medical breakthroughs, we can anticipate that this application of modern biotechnology will soon raise daunting challenges to existing legal definitions of life, humanity, and personality.

As mentioned above, according to the rapid pace of high-biotechnology developments, both technical and legal problems specific to biotechnology have arisen. In particular, the legal issues surrounding modern biotechnological innovations have centered mostly on strengthening protection of intellectual property rights. This new tide of issues also requires us to take a new look at the concept of traditional patent law systems in this field. Globally speaking, on the other hand, a more fundamental question whether modern biotechnology can help maintain or promote sustainable development of human beings, as well as agriculture, has been raised. This proposition also tends to take a composite phase in that legal consideration of biotechnology commonly demands triangular analysis within the interrelated framework of international intellectual property laws, international trade laws, and international environmental laws.

The protection of biotechnological products is of immense significance in commercial and industrial contexts. Arguably, genetically modified products should also be protected as intellectual property resulting from human creativity. But the intellectual property protection of biotechnology, which has undoubtedly been a pivotal incentive stimulating research, innovations, investments, inventions, and release of such inventions, has lagged behind the current industrial developments in the field of biotechnology. Even though patents

14 See Cripps, supra note 1, at 124-25.
15 Id. at 123-24.
16 PHILIPPE G. DUCOR, PATenting the REcombinaNT products oF biotechnology aNd OTHER MOLeCULES 1 (1998).
17 GRUBB, supra note 1, at 225.
19 In addition, the intellectual property rights within the biotechnological field can be a negotiating tool between the investors and researchers, and an organizing tool of
on gene sequences, higher levels of life,\textsuperscript{20} or gene-technological products have been bitterly controversial, useful products could be commercially produced from genetically engineered transgenic plants or animals.\textsuperscript{21}

As we have seen, there have been extreme pros and cons regarding new biotechnological development and its full exploitation. This discord mainly stems from the unforeseeability of the development and the unrevealed risks in biotechnological areas that will evolve in the future.\textsuperscript{22} While it is rather paradoxical that development of modern biotechnology may have both promises and perils, these contradictory arguments are being made worldwide. In the end, there is a strong probability that transnational concerns over biotechnological applications, such as whether and on what grounds countries may regulate international trade of GMOs, whether genetic engineering will give rise to environmental harm through "genetic pollution," and whether GMOs have adverse effects on worldwide biological diversity, will be a tremendous challenge to the global society.\textsuperscript{23}

The controversial issues surrounding modern biotechnology include consumer and environmentalist concerns regarding GMOs, ranging from public health and environmental protection quality and quantity controls. Moreover, it is pointed out that recent intellectual property needs to be appreciated not only in terms of international, cultural, social, and environmental dimensions, but also within the context of global trade and investment flows. ARUP, \textit{supra} note 1, at 219-20.

\textsuperscript{20} Unlike that of the higher life-forms, the patenting issue of microbiological inventions, which encompass microbiological processes and the products of such processes (e.g. micro-organisms), is comparatively less problematic. The term micro-organism has broad meaning to include animal and plant cells as well as bacteria, fungi, and viruses. At both the national and international levels, these microbiological processes and micro-organisms are usually patentable and protected more strongly than plant and animal varieties if they meet the general requirements for patents. GRUBB, \textit{supra} note 1, at 226-28.

\textsuperscript{21} WESTERLUND, \textit{supra} note 9, at 7-9, 16.

\textsuperscript{22} "Technology, strictly speaking, involves human control. Thus, processes which may be entirely controlled by man in a specific way, or products which are made by man according to scientific principles involve the use of technology. The field of biology, however, was traditionally considered to be beyond the scope of technology as it could not be controlled in a predictable way by man." INTRODUCTION TO INTELLECTUAL PROPERTY: THEORY AND PRACTICE, \textit{supra} note 3, at 587.

\textsuperscript{23} Murphy, \textit{supra} note 1, at 47-48.
Consumers and environmental groups, in fear of currently hidden but arguably intrinsic risks to both humans and the environment, insist that broad introduction of GMOs into the environment without proof of environmental harmlessness be restricted. Environmentalists also argue that it should not be overlooked that diffusion of GMOs can also threaten biological diversity because of its unanticipated environmentally unfriendly effects. With regard to medical applications of modern biotechnology, particularly cloning and transgenic techniques, more profound questions of the moral and ethical issues like identity or dignity of life have proved to be similarly controversial.

The international community has scrutinized, in terms of morality (or ordre public), ethics, and human dignity, both the commercialized uses of biotechnology, such as commodification of genetic resources, genetic information, human genes, human beings, and higher life forms, and the application for patents for these uses. Accordingly, the scope and ground for granting or denying the intellectual property protection of genetic materials have been divergent among different groups, organizations, research institutions, industrial entities, regions, jurisdictions, and countries. To date, ethical, legal, and social implications of

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24 MacMillan, supra note 1, at 139.
25 Murphy, supra note 1, at 57.
26 See Cripps, supra note 1, at 126.
27 See id. at 123-26.
28 For more details concerning this discussion, see generally Arup, supra note 1, at 230-33; Deryck Beyleveled & Roger Brownsword, Human Dignity in Bioethics and Biolaw 196-205 (2001); Grubb, supra note 1, at 252-60; Rebecca S. Eisenberg, Genomic Patents and Product Development Incentives, in Human DNA: Law and Policy 373, 373-78 (Bartha Maria Knoppers et al. eds., 1996); Jean-Christophe Galloux, The Patentability of the Human Genome: A European Perspective, in Human DNA: Law and Policy 361, 361-71 (Bartha Maria Knoppers et al. eds., 1996); Ruth Macklin, The Ethics of Gene Patenting, in Genetic Information: Acquisition, Access, and Control 129, 129-37 (Alison K. Thompson & Ruth F. Chadwick eds., 1999); Marilia Bernardes Marques, Ethical Impacts of Human Health-Related Biotechnology in Brazil, in Genetic Information: Acquisition, Access, and Control 163, 163-74 (Alison K. Thompson & Ruth F. Chadwick eds., 1999); Randall W. Marusyk & Ariadni Athanassiadiis, Patenting of Human Genetic Sequences in Canada, in Human DNA: Law and Policy 343, 343-60 (Bartha Maria Knoppers et al. eds., 1996); Godfrey B. Tangwa, Genetic Information: Questions and Warnings from an African Background, in Genetic Information: Acquisition, Access, and Control 275, 275-81 (Alison K. Thompson & Ruth F. Chadwick eds., 1999).
patent application to genetic resources and commercialization of genetic materials have been universally studied. In the near future, however, neither a legally nor an ethically general consensus concerning the problems of commercial exploitations of genetic materials will probably be achieved. In addition, the legal status of genetic resources as a commodity is likely to remain uncertain. After the advent of Dolly the sheep, in particular, the issues of legitimacy and the admissible scope of protection of human DNA cloning technology and its results have been one of the hottest potatoes in international intellectual property regimes, as well as in the scientific world.29

We may find ourselves in the turmoil of the new biotechnological millennium. In this biotechnological age, technical and legal handling of modern biotechnology and its resulting products, such as GMOs, is one of the major "socio-scientific" issues.30 As of now, the global community has established no international legal regime comprehensively dealing with all of these "socio-scientific" issues. Instead, fragmentary treaties or conventions regulate the relevant issues, respectively. Therefore, global society urgently demands a formation of standardized multilateral norms. These norms beyond the existing legal regime should cover intellectual property protection, trade, and environmental concerns to grapple more effectively with emerging questions in the field of biotechnology.31

Of these "socio-scientific" issues relating to biotechnology,

Thompson & Ruth F. Chadwick eds., 1999).


30 MACMILLAN, supra note 1, at 138.

31 Steve Charnovitz addresses the policy linkage like the so-called "trade and" as an old phenomenon or a long tradition since the beginning of international trade regimes, including the General Agreement on Tariffs and Trade (GATT). In fact, according to his explanation, international trading systems have incorporated non-trade concerns as well as the trade liberalization purpose, and the linking issues are inherently appropriate. Particularly, the link between trade and intellectual property and the link between trade and environment can arguably be good examples of profitable linkage. He further insists that the WTO itself may be the greatest institutional model of policy linkage, including lots of trade-related issues such as intellectual property rights. Four main reasons set forth for this linkage are i) policy effectiveness, ii) balancing spillovers, iii) political coalitions, and iv) economies of scale. STEVE CHARNOVITZ, TRADE LAW AND GLOBAL GOVERNANCE 11-25 (2002).
environmental issues mostly concern protection of biodiversity within the context of sustainable development. As modern biotechnology has developed strikingly in these days, it is necessary to take into more careful account adverse environmental impacts made possible by biotechnological applications. As the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement), which is one of the annexed multilateral agreements to the World Trade Organization (WTO), makes obvious, the ethical issues of biotechnology have, in part, included environmental concerns such as sustainable use of resources and sustainable development.

Sustainable development has become one of the major themes in many international conventions and conferences concerning environmental protection. Recently, the World Court referred to it as a principle of international environmental law, recognizing the need for balancing between environmental protection and development. Sustainable development, however, should be re-examined in this biotechnological era because the miraculous advance of modern biotechnology may eventually turn out to have a seriously adverse influence on the environment. Protection of biological diversity is another environmental issue surrounding

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32 As a result of the Uruguay Round (UR) negotiations, the TRIPs Agreement, an integral part of the WTO, was concluded. Compliance with the TRIPs Agreement is a condition of membership of the WTO and it automatically binds all WTO members. ARUP, supra note 1, at 178; BERNARD M. HOEKMAN & MICHEL M. KOSTECKI, THE POLITICAL ECONOMY OF THE WORLD TRADING SYSTEM: THE WTO AND BEYOND 285-90 (2d ed. 2001); see MACMILLAN, supra note 1, at 27-28.

33 The TRIPs Agreement says "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment..." Agreement of Trade-Related Aspects of Intellectual Property Rights, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994 art. 27.2, available at http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm.


35 See, e.g., Gabcikovo-Nagymaros Project (Hung. v. Slovk.), 1997 I.C.J. 92 (Sept. 25). In particular, the separate opinion of Vice-President Weeramantry concerning the concept of sustainable development is noteworthy. See DAVID HUNTER ET AL., INTERNATIONAL ENVIRONMENTAL LAW AND POLICY 336-46 (2d ed. 2002).
Biotechnology. Biotechnology and GMOs may be a double-edged sword involving both promises for sustainable use of resources through environmentally sound technologies and perils to biodiversity through unexpected harmful interactions with the environment.

Biotechnology, therefore, on the one hand will be helpful to biodiversity by slowing down the decline of biological diversity, but on the other hand, it can speed up the deterioration of biodiversity. Somewhat ironically, decreases of biological diversity may be more likely to happen when GMOs enjoy strong international intellectual property protection. Consequently, international intellectual property protection systems may have a paradoxical feature in the context of sustainable development. For example, an international depositary system of patented genetic materials cannot be desirable for biodiversity because access to deposited genetic materials will be suspended for the time being. On the contrary, this regime provides a means to preserve those materials for future generations. Thus, biodiversity-friendly technology based on sustainable use of gene varieties in sustainable methods may be a significant thrust for food security and human survival.

Sustainable development, which emerged as an international environmental discipline in the 1980s, and its more recent version, "environmentally sustainable development," are products of an enthusiastic experiment to reconcile the interests between development and environmental protection and between developing and developed countries which are conflicting at first

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36 Cripps, supra note 1, at 126. Sustainability includes a biodiversity aspect. A principal question is how many different or various breeds are used in the agroecosystem overall. Ellen Messer, Food Systems and Dietary Perspective: Are Genetically Modified Organisms the Best Way to Ensure Nutritionally Adequate Food?, 9 IND. J. GLOBAL LEGAL STUD. 65, 85-86 (2001).

37 Cripps, supra note 1, at 119, 121-23, 126-27.

38 Murphy, supra note 1, at 95-96.

39 See id. at 96.

40 Cripps, supra note 1, at 122-23. On the one hand, plant genetic resources, application of recombinant DNA technology to agricultural research, and bioprospecting may be important sources for future biodiversity. On the other hand, dissemination of bioprospecting may spur the loss of biodiversity. MACMILLAN, supra note 1, at 118-19.

41 See Cottier, supra note 18, at 558.
The problem of harmonizing them is still disputable. In this respect, it has also been questionable whether globalization of patent systems and commercial interests concerning biotechnology will be able to contribute to the protection of genetic diversity and equitable use of and sustainable access to genetic materials without prejudice to biodiversity.

Accordingly, it should be equally noted that sustainable development issues surrounding intellectual property protection of biotechnological inventions concern issues of equity. Broadly speaking, these equity concerns can be divided into two related but distinct categories: equity between developing and developed countries, and equity between present and future generations. The former means fair and equitable sharing of benefits between developing countries with rich genetic resources and developed countries exploiting and patenting the genetic materials from developing countries. The latter represents even-handedness in splitting the profits from genetic resources in such a manner as will promote sustainability.

The topic of intellectual property protection of modern

43 Id.
45 Concerns about equity have been the heart of the issues of international environmental law and sustainable development. Edith Brown Weiss, Environmental Equity: The Imperative for the Twenty-First Century, in SUSTAINABLE DEVELOPMENT AND INTERNATIONAL LAW 17, 17-18 (Winfried Lang ed., 1994).
46 “[F]uture generations are a silent but important party to debates about equity,” and “[s]ustainable development is inherently intergenerational.” Id. at 21. Further, biotechnology can also have the meaning of equity between consumers, between users and patentees, and between trade and the environment.
47 WATAL, supra note 1, at 129.
48 Cottier, supra note 18, at 564. In the context of sustainable development, the consideration of future generations has been discussed in the theoretical, economic, and legal perspectives, and insisted to be a “new global ethic.” And also the welfare or benefit of future generations and the notion of protecting nature for the future generations have been suggested within the international environmental law aspect. Finally, the concept of “the rights of future generations,” as a ground for protecting the environment, was presented. ALEXANDER GILLESPIE, INTERNATIONAL ENVIRONMENTAL LAW, POLICY AND ETHICS 107-10 (1997).
biotechnology, in the context of sustainable development, is so broad that it spans areas of trade, environment, biodiversity, equity, ethics, and humanity, as well as patent systems. To conclude, intellectual property rights of biotechnology should not be harmful, but only beneficial to all of these sides. Accordingly, from the perspective of a multilateral legal approach, intellectual property protection of biotechnology should be the most appropriate instrument for promoting environmental protection, biodiversity, and, ultimately, sustainable development. Biotechnology, which may be one of the key technical codes to sustainable development in the twenty-first century, represents a "socio-scientific" dilemma in the existing global legal system. In the context of sustainable development, future international legal regimes for biotechnology, therefore, should equivalently embrace essentials of "diversity" and "equity."

Among the global issues surrounding intellectual property protection of biotechnology, its arguably adverse impacts on the environment and sustainable development are the most controversial. In brief, whether it can promote or destroy biological diversity is still pending. With due regard to this situation, this paper attempts to take an overview of the notion of sustainable development in the context of modern biotechnological developments. The paper also suggests an evolutionary approach to the harmonization of intellectual property protection of biotechnology and sustainable development. To do this, the paper analyzes the implications of existing rules, reappraises the current definition of sustainable development, and reviews the applicability of evolving principles in relation to modern biotechnology, with special reference to biodiversity and equity between parties.

Chapter II begins with technical, legal, social, and ethical contemplations on modern biotechnology in this new biotechnological era. In addition, the paper reviews the debates concerning applications of biotechnology and the general definition and status of sustainable development in international legal instruments.

Chapter III discusses the appropriateness of current definitions and the scope of sustainable development in light of recently advanced biotechnology. In particular, the paper considers the redefinition and extension of the meaning of sustainable
development with regard to very rapid and varied developments in the field of biotechnology. The paper then reviews the existing international legal provisions that may be applied to biotechnology and sustainable development concerns. This discussion focuses on the relevant provisions in the WTO structure with concomitant reference to multilateral environmental treaties and major transnational patent law systems.

Chapter IV addresses the appropriate intellectual property protection of biotechnology for promoting sustainable development, particularly by a polysynthetic approach to biodiversity and equity. This chapter also analyzes globally developing rules which may be contributory to the achievement of harmonization and balance between intellectual property protection of biotechnology and sustainable development.

This study mainly concludes that sustainable development, as Professor Cripps suggests, should be redefined or modified with regard to current biotechnological development. At the same time, the scope and extent of intellectual property protection of biotechnology should be decided in conformity with the principle of sustainable development. Accordingly, this work seeks to explore the relationship between patenting biotechnological inventions and sustainable development, based on a three-dimensional approach: intellectual property protection, biodiversity, and equity. At this point, it should also be noted that one has to take into full consideration all the relevant factors when determining the appropriate scope of the protection.

In conclusion, not only sustainable developments of agriculture and humans, but also economically sustainable development and environmentally sustainable development may be converged by adopting an evolutionary interpretation of 'biotechnologically sustainable development.' In addition, sustainable development, as an evident conservation-relevant factor, should be taken into ample account in interpreting and applying the relevant provisions, such as patentable subject matter

49 Professor Cripps argues that the concept of sustainable development has been somewhat mistakenly confined to sustainable agriculture in spite of the consensus about its context. For her, the definition and perceptions of sustainable development should be reconsidered according to the recent development of genetic engineering and human cloning techniques to include sustainable development of humans outside the agricultural context. See generally Cripps, supra note 1, at 121-26, 133.
in the TRIPs Agreement, as well as other international instruments, to regulate and avoid abuse or misuse of modern biotechnology.

II. Implications of Modern Biotechnology on Sustainable Development in the New Biotechnological Millennium

A. Changes in Technological and Legal Environments

The modern biotechnological revolution is one of the most important technological advances in the late twentieth century. Indeed, biotechnology, as one of the oldest technologies in human history, has been commonly used to produce useful products from living micro-organisms and traditionally adopted to systematic cross-breeding of sexually compatible plants within the same varieties or species for a long time. Since the second half of the last century, however, this kind of technology has extended to the innovation of so-called "genetic engineering," whereby it becomes possible to remove a specific gene of one variety or species and insert it into other varieties or species.

Due to the scientific development of these biotechnological processes, scientists can artificially manipulate living organisms or modify genes. Through the processes of genetic manipulation, which came to be entirely controlled by man, we are able to change the hereditary characteristics of living organisms to create GMOs containing certain desirable genetic features. As a result, there is a stronger possibility that modern biotechnology will play a very important role in our future, particularly in the fields of medicine, food, energy, protection of the environment, and so on. Scientists, applying genetic engineering techniques such as microinjection (used to introduce foreign genes into the cells of

50 DUCOR, supra note 16, at 1.
51 INTRODUCTION TO INTELLECTUAL PROPERTY: THEORY AND PRACTICE, supra note 3, at 587.
52 GRUBB, supra note 1, at 224-25.
53 ARUP, supra note 1, at 215-16.
54 INTRODUCTION TO INTELLECTUAL PROPERTY: THEORY AND PRACTICE, supra note 3, at 587-88.
55 Id. at 588.
56 Id. at 587-88.
higher life forms), have created transgenic plants and animals with improved or transformed genetic characters for certain purposes. More recently, those techniques have been applied to medical treatment of human diseases, namely gene therapy methods.

The advent of modern biotechnology, born with genetic engineering techniques, means that it becomes possible that biological materials can be artificially changed or the natural course of evolution can be more radically altered under human control, which has never been able to occur in natural ecosystems. Consequently, newly developed transgenic animals, such as pigs and other animals including human genes, have been created. It is anticipated, however, that these results of biotechnological applications will cause a serious challenge to the existing legal definitions of life, humanity, and personality in the near future. Moreover, cloning techniques, which have been used to clone genes, plants, animals, and more recently applied even to clone human beings, have triggered severe public contention. Stem cell research and nuclear transfer techniques, through which Dolly the sheep was created, are likely to open the door to cloning a human being from an adult somatic cell.

In fact, the modern biotechnology of genetic engineering, particularly that developed during the last two decades, has extensively influenced human life. It cannot be denied that the newly improved techniques have made the most remarkable contributions to both food production, through agricultural innovation, and the medical field, through the industrial advance of pharmaceuticals. It is surely true that intellectual property protection of biotechnological inventions has been an essential element in the current development in the field of biotechnology.

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57 GRUBB, supra note 1, at 225, 243-44, 249-51.
58 Id.
59 Cripps, supra note 1, at 123.
60 Id. at 123-24.
61 WESTERLUND, supra note 9, at 8.
62 In vitro fertilization work using a technique of embryo splitting has been employed for human cloning since the early 1990s. See generally Cripps, supra note 1, at 124-25.
63 See generally MACMILLAN, supra note 1, at 138; Murphy, supra note 1, at 51-56; WATAL, supra note 1, at 128; see also ARUP, supra note 1, at 216-17; Cripps, supra note 1, at 121-24; GRUBB, supra note 1, at 249-51.
industries.\textsuperscript{64} However, since useful products could be commercially produced from genetically engineered transgenic plants or animals, patents on gene sequences, higher levels of life, and gene-technological products have been the center of controversies.\textsuperscript{65}

As biotechnology has developed enormously in the late twentieth century, the legal systems concerning intellectual property protection of modern biotechnology, particularly patent law focusing on patentability of biotechnological inventions, have extensively changed in both the national and international spheres. These changes in legal aspects have, of course, stemmed from the complexity of biotechnological processes and inventions.\textsuperscript{66} Indeed, the importance of biotechnology has grown considerably in recent years.\textsuperscript{67} Because of the rapid pace of modern biotechnological development, which is one of the most important technological breakthroughs in the last century, not only technical but also legal problems specific to biotechnology have been created.\textsuperscript{68} The legal issues surrounding modern biotechnological innovations have mostly centered on reinforcement of protection of intellectual property rights.\textsuperscript{69} These changes in the technological and legal aspects of biotechnology have also required taking a new look at the concept of traditional patent law systems in this field.\textsuperscript{70}

Unlike classical methods of biotechnology or traditional selective breeding of animals or plants, which have not been especially problematic for either national or transnational regulations,\textsuperscript{71} modern biotechnology, which was developed based on the two basic techniques of recombinant DNA and hybridoma in the 1970s, has fueled various critical issues, questions, and

\textsuperscript{64} See generally \textit{Arup}, supra note 1, at 219; \textit{Westerlund}, supra note 9, at 9-11; see also \textit{Cottier}, supra note 18, at 569.

\textsuperscript{65} \textit{Westerlund}, supra note 9, at 7-9, 16.

\textsuperscript{66} \textit{Id.} at 1-21.

\textsuperscript{67} \textit{Introduction to Intellectual Property: Theory and Practice}, \textit{supra} note 3, at 587.

\textsuperscript{68} \textit{Ducor}, supra note 16, at 1.

\textsuperscript{69} \textit{Id.}

\textsuperscript{70} \textit{Id.} at 1-4.

\textsuperscript{71} \textit{Murphy}, supra note 1, at 50.
problems with transnational as well as national dimensions. In particular, genetic engineering, the midwife for the birth of modern biotechnology, provokes keen controversies about the technique itself, its unknown results, and the basic policies controlling the technological development, despite its more effective benefits than ever. As already pointed out, this paradoxical character of modern biotechnology mainly seems to result from the capacity of genetically recombining genetic materials between different varieties or species despite the fact that they are sexually incompatible.

Socially speaking, it should be noted that benefits derived from modern biotechnological developments, in many cases, will largely make a very limited number of enterprises in the developed world richer rather than improve the general welfare of mankind. This is the reason that biotechnological issues in modern society should be analyzed based on both aspects of "diversity" and "equity." As of now, the global community has established no international legal regime comprehensively dealing with all of these "socio-scientific" issues. Instead, fragmentary treaties or conventions regulate the relevant issues individually.

This era can be characterized as "the biotechnological millennium" of scientific, technological, industrial, economic, social, moral, ethical, cultural, and legal transitions of evolution caused by the modern biotechnological revolution. The global society urgently demands formation of standardized multilateral norms. These norms, of course, should equally consider all biotechnologically relevant factors – intellectual property protection, trade, environment, biodiversity, equity, and sustainable development concerns – beyond the existing legal regime to more effectually tackle emerging puzzles in the field of biotechnology.

B. Debates

As already discussed, there have been severe pros and cons
regarding the new biotechnological development and its full exploitation. This conflicting viewpoint is generally due to the unforeseeability of future development and hidden risks which will probably be caused by technological applications in the area of biotechnology.\(^\text{77}\) While it is arguably paradoxical that applications of modern biotechnology may have both promises and perils, lots of contradictory debates are being widely spread throughout the world. In the near future, transnational concerns over whether traditional concepts of property rights that permit private entities to exercise exclusive control over genetic resources in the world can still be admissible, whether and on what grounds countries may regulate international trade in biotechnologically produced products, whether genetic engineering will give rise to environmental harm through so called "genetic pollution," and whether GMOs have adverse effects on global biological diversity will be tremendous challenges to the world society.\(^\text{78}\)

Advocates of biotechnology claim that agricultural biotechnology can be applied to both crops and animals so as to improve the quality and quantity of agricultural products.\(^\text{79}\) Ultimately, this may arguably contribute to enhancement of food security.\(^\text{80}\) Globally speaking, this means that biotechnological applications in agriculture can curtail the agricultural production costs and lower the use of chemicals considered to have an adverse effect on human health and the environment.\(^\text{81}\) In particular, both lowering costs and increasing productivity in agricultural production have very significant implications on developing and the least developed countries because most of them can meet their increasing demand for food by using

\(^{77}\) See INTRODUCTION TO INTELLECTUAL PROPERTY: THEORY AND PRACTICE, supra note 3, at 587.

\(^{78}\) Murphy, supra note 1, at 47-48.

\(^{79}\) For example, they may be the crops with strengthened resistance to diseases, insects, weeds, adverse weather, and pesticides, as well as the food of higher quality and taste. See generally ARUP, supra note 1, at 216; see also Murphy, supra note 1, at 54-55.

\(^{80}\) Proponents of biotechnology particularly focus on the biotechnological ability to increase food supply through higher yielding crops and improved animal husbandry techniques including production of disease resistant organisms. MACMILLAN, supra note 1, at 138.

\(^{81}\) Murphy, supra note 1, at 55-56.
environmentally sound agricultural biotechnology.\textsuperscript{82}

Also, according to the proponents of biotechnology, products of modern biotechnology may make greater contributions to the advancement of medical science than they did before. Animals and plants are being genetically engineered for medical research, new drugs, new therapy, and reducing and curing diseases.\textsuperscript{83} These applications of biomedical engineering may help treat many obstinate diseases more simply and effectively worldwide. This development, in particular, makes it easier for developing countries to gain access to specific medicines more inexpensively and safely.\textsuperscript{84} Furthermore, through genetic engineering in the field of biomedicine, the spread of major and common diseases in developing countries, such as malaria, yellow fever, trypanosomiasis, dengue, and other epidemics, can be more effectively prevented.\textsuperscript{85} More recently, cloning techniques have preeminently contributed to the developments of medicines, diagnostic instruments, vaccines, and remedies for heart attack, hemophilia, anemia, various cancers, AIDS, and other intractable diseases in modern society.\textsuperscript{86} From the above-mentioned biotechnological developments, mankind will be able to make more forcible medicines to fight diseases such as cancer and HIV/AIDS and protect public health.\textsuperscript{87}

Critics of biotechnology, however, hold a skeptical view about the enhancement of food security through biotechnology, and simultaneously emphasize embryonic or unknown hazards to sustainable development, agriculture, environmental biodiversity, and public health.\textsuperscript{88} According to their arguments, even though it

\textsuperscript{82} \textit{Id.} It is estimated that around 790 million people in developing countries are chronically undernourished, and that by the year 2050, traditional plant-breeding techniques without modern biotechnology may not meet increasing food production necessary to feed the estimated world population of 9.4 billion. \textit{Id.} at 47.

\textsuperscript{83} \textit{Id.} at 51-52.

\textsuperscript{84} \textit{Id.} at 53.

\textsuperscript{85} It is reported that reengineered insects have been developed for this purpose. \textit{Id.} at 53-54. According to a recent report, a mosquito was genetically transformed to exterminate the mosquitoes carrying malaria. MACMILLAN, \textit{supra} note 1, at 138.

\textsuperscript{86} LONG & D'AMATO, \textit{supra} note 29, at 178.

\textsuperscript{87} INTRODUCTION TO INTELLECTUAL PROPERTY: THEORY AND PRACTICE, \textit{supra} note 3, at 588.

\textsuperscript{88} MACMILLAN, \textit{supra} note 1, at 138.
is true that monoculture of genetically improved crops is deemed to be more efficient in increasing food productivity and alleviating starvation, due to the lack of biological diversity resulting from monoculture and its characteristic susceptibility to catastrophic diseases or weather, this kind of commercial exploitation of agro-biotechnology may lead to diminished foodstuffs productions.

Additionally, crops genetically engineered to be resistant to herbicides and insecticides may result in an extravagant use of herbicides or insecticides without sufficient consideration of environmental harms. This effect may be rather a disaster to the environment and human health by destroying the ecological balance and degenerating biodiversity.

The controversies surrounding modern biotechnological applications include consumer and ethical issues in addition to environmentalist concerns about GMOs, public health, and environmental protection. The GMO issue is now in the middle of the debates and concerns of a great number of non-governmental organizations and civil society in this new millennium. Generally speaking, the GMO industry, particularly producers and companies in the U.S., has repeatedly stressed the safety of genetically modified products. Nevertheless, farmers and consumers, especially in Europe and developing countries, who worry about not only genetically modified products' unidentified hazards to human health and the environment, but also its economic and social impacts, such as losses of market dominance, competitive advantage, power of price control, and increase of dependence on the U.S. biotechnology industry, are in opposition to the extensive introduction of GMOs.

89 See generally Arup, supra note 1, at 217-18; see also Cripps, supra note 1, at 122.

90 See generally Cripps, supra note 1, at 122.

91 Id. See also Murphy, supra note 1, at 59.

92 Macmillan, supra note 1, at 139.

93 Hoekman & Kostecki, supra note 32, at 456.

94 Id.

95 Id. For instance, the use of a "terminator gene" to prevent consumers' regeneration of genetically developed seeds can allow producers to control the sale and use of the seeds. However, Monsanto's use of this technology has been the target of furious social criticism. Eventually, the application of the technology has been withheld. Arup, supra note 1, at 218.
Farmers and consumers, in fear of currently unrevealed but arguably intrinsic risks to both humans and the environment which may be caused by "potential hazards with legs," insist that the broad dissemination of GMOs into the environment without proving environmental harmlessness be prevented.\textsuperscript{96} It is a critical issue, not to be overlooked, that diffusion of GMOs can threaten biological diversity because of its unanticipated, environmentally unfriendly effects.\textsuperscript{97} In addition, such national regulations and measures concerning GMOs as labeling programmes or import bans, prompted by consumers’ requests, have increasingly become a noteworthy cause of international trade disputes.\textsuperscript{98}

As already noted, with regards to medical applications of modern biotechnology, particularly cloning and transgenic techniques, more profound questions of moral and ethical issues, including identity or dignity of life, have proven to be seriously debatable.\textsuperscript{99} Internationally, patent applications for economic property rights to – as well as commercialization, commodification, and industrial use of – genetic resources, genetic information, human genes, parts of human beings, and higher life forms have had to be reviewed in terms of morality (or ordre public), ethics, and human dignity. The scope of and ground for granting or denying the intellectual property protection of those genetic materials have been disputable and divergent among different groups of people, research institutions, industrial entities, regions, jurisdictions, and countries.\textsuperscript{100}

To date, ethical, legal, and social implications of patenting genetic resources and commercially exploiting genetic materials as a commodity have been universally studied. In the future, however, establishment of a legally and ethically general consensus concerning the problems of commercial exploitation of

\textsuperscript{96} Murphy, \textit{supra} note 1, at 57-59.

\textsuperscript{97} Cripps, \textit{supra} note 1, at 126.

\textsuperscript{98} \textit{See} Hoekman \& Kostecki, \textit{supra} note 32, at 456. \textit{See also} Murphy, \textit{supra} note 1, at 48.

\textsuperscript{99} \textit{See generally} Cripps, \textit{supra} note 1, at 123-26.

\textsuperscript{100} \textit{See generally} Arup, \textit{supra} note 1, at 230-33; Grubb, \textit{supra} note 1, at 252-60. \textit{See also} Beyleveld \& Brownword, \textit{supra} note 28, at 196-205; Eisenberg, \textit{supra} note 28, at 373-78; Galloux, \textit{supra} note 28, at 361-71; Macklin, \textit{supra} note 28, 129-37; Marques, \textit{supra} note 28, at 163-74; Marusyk \& Athanassiadis, \textit{supra} note 28, at 343-60; Tangwa, \textit{supra} note 28, at 275-81.
genetic materials will probably be difficult. Additionally, their legal status as a commodity will likely remain questionable for the time being. Moreover, after the advent of Dolly the sheep, the issues of the legitimacy and admissible scope of protection for human DNA cloning techniques and their technological applications have been the hottest potatoes in international intellectual property regimes as well as the scientific world. Conclusively, the above altercations reflect our anxiety and/or fear about the uncertainty and/or unpredictability of the results stemming from the unnatural conversion of nature itself.

C. General Definition and Status

The term “sustainability,” seldom clearly defined, is often used in the discussion of emerging social concerns regarding overpopulation and excessive consumption and their adverse effects on environmental conservation. “Development,” modified by “sustainable” in the term “sustainable development,” has a somewhat broad meaning which has covered at least four related concepts – peace and security, economic development, social development, and national governance that secures world peace and development – in multilateral legal texts since the end of World War II. More generally, from the perspective of general international law, the concept of sustainable development has always been a fundamental issue in the discussion of environmental law. This discussion has centered mostly on the role of developing countries in environmental protection and the relationships among the impacts upon ethics, economic development, and effective environmental controls. Now, the concept of sustainable development arguably ranks as “a candidate emergent principle of general international law.” More specifically, international law in the field of sustainable development has developed to embrace three aspects: international

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101 LONG & D'AMATO, supra note 29, at 178-79.
103 These elements have been increasingly mutually interdependent and interrelated. For this general concept of “development,” see generally John C. Dembach, Sustainable Development: Now More Than Ever, 32 Envtl. L. Rep. (Envtl. L. Inst.) 10003, 10004-05 (2002).
cooperation, economic development, and the environment and human rights, all of which have been interdependently treated. 105

Although there exists no general definition of sustainable development accepted in international law or global society, its theoretical background has a long history and the term itself has emerged in treaties since the 1980s. 106 In particular, the Brundtland Report adopted in the World Commission on Environment and Development (WCED) 107 in 1987, provided what is probably the most widely used, 108 frequently quoted, 109 and generally cited 110 definition relating to sustainable development. According to the report, sustainable development is defined as: "[D]evelopment that meets the needs of the present without compromising the ability of future generations to meet their own needs."

This report also urged that "sustainable development' become the foundation for all human economic activity, and thus that concern for the environment and concern for lifting the standards of the world's poor were inextricably linked." 111 This definition has implications that represent the interrelationship between development and the environment and between the needs of present generations and those of successors in global society. 112 At the present stage, however, it is believed that under the traditional concept of sustainable development, reductions in both poverty and global environmental degradations have proven largely unsuccessful. Poverty issues include a continuously increasing gap between the rich and the poor. Environmental issues cover health risks and environmental problems including

106 Id. at 57-58.
108 Sands, supra note 105, at 58.
109 Lowenfeld, supra note 107, at 304.
110 Agrawala & Cane, supra note 102, at 309.
111 Lowenfeld, supra note 107, at 304.
112 Agrawala & Cane, supra note 102, at 309.
exhaustion of natural resources such as plant and animal species. On this point, as the Brundtland Report clearly addressed, the four basic elements of development — peace and security, economic development, social development, and national governance — are primarily related to environmental concerns and protection.

The one-sentenced expression in the Brundtland Report, the first beginning to get significant international attention as a definitive explanation of sustainable development, however, did not put an end to the debate regarding the general definition of sustainable development. The concept of sustainable development was further elaborated upon at the United Nations Conference on Environment and Development (UNCED), or Earth Summit, held in Rio de Janeiro in June 1992. This conference, by clearly incorporating another element — environmental protection, the fifth component of sustainable development — attempted to extend the notion of sustainable development. For example, the Rio Declaration declared that every human being has the right to health and productive life "in harmony with nature." Additionally, Agenda 21 affirmed that protection of the environment and resources for the benefit of future generations can be achieved through "socially responsible economic development." This approach suggests that a new formula is needed for understanding sustainable development, triangulating three components — the environment, economy, and equity.

113 Dernbach, supra note 103, at 10005-06.
114 Id. at 10006-07.
115 Id. at 10003.
116 Although legally nonbinding, two texts, which were adopted at the UNCED, the Rio Declaration on Environment and Development, consisting of statements of 27 principles for sustainable development, and Agenda 21, which is a global plan of action for sustainable development, were adopted by attending nations agreeing to promote sustainable development at the international as well as the national level. Id.
117 Id. at 10007.
120 Dernbach, supra note 103, at 10008.
Since this landmark on international environmental legal progress, the concept of sustainable development has acquired a status of "grundnorm" in global environmental law.\textsuperscript{121}

Concurrently, in the international environmental legal framework, equity issues concerning "environmental justice," a source of severely contradictory arguments in considering sustainable development, have increasingly emerged. In international environmental legal instruments, equity concerns have driven traditional concepts of equity\textsuperscript{122} to be challenged and engendered a new kind of equity notion.\textsuperscript{123} Traditionally, states have the sovereign right to use and control natural resources within their territorial jurisdiction, and first claimants over resources not covered by national sovereignty have the exclusive rights to exploit them. However, the more recent meaning of equity in environmental law encompasses new issues such as the "allocation of natural resources" and "responsibility and liability for pollution."\textsuperscript{124}

Therefore, the general principles that provide a philosophical basis for sustainable development consist of principles of intergenerational equity, sustainable use, equitable use, and integration. These are now considered the four key components of sustainable development.\textsuperscript{125} However, the legal status of each principle will vary according to its normative character: whether it is based on or reflects customary law, whether it is a new or emerging international legal concept, or whether it is a simple intention to affect future conduct.\textsuperscript{126} In conclusion, the general

\textsuperscript{121} "Grundnorm" means basic norm in English, which, in the context of international environmental law, is the fundamental rule of law for all international environmental legal validity or legitimacy. Lakshman D. Guruswamy, \textit{Sustainable Agriculture: Do GMOs Imperil Biosafety?}, \textit{9 IND. J. GLOBAL LEGAL STUD.} 461, 463 (2001).

\textsuperscript{122} The notion of equity in public international law is used in the sense of considering fairness, reasonableness, and policy which is often necessary for the sensible application of the rules of law. It may also be an important element, as a supplementary part of law or judicial reasoning, in international judicial decisions. Brownlie, \textit{supra} note 104, at 25-26.

\textsuperscript{123} Weiss, \textit{supra} note 45, at 17.

\textsuperscript{124} \textit{Id.} at 18.

\textsuperscript{125} Sands, \textit{supra} note 105, at 57-61.

\textsuperscript{126} \textit{Id.} at 57-58.
definition of sustainable development, to the extent that international law recognizes the concept of sustainable development, should principally approve the following interests: 127

(a) the need to take into consideration the needs of present and future generations;
(b) the acceptance, on environmental protection grounds, of limits placed upon the use and exploitation of natural resources;
(c) the role of equitable principles in the allocation of rights and obligations; and
(d) the need to integrate all aspects of environment and development.

At the same time, in the modern context, we cannot ignore relevant trade factors in considering sustainable development. As the Rio Declaration and Agenda 21 described, interests of international trade liberalization and sustainable development have been mutually connected. 128 The Rio Declaration calls on countries "to promote a supportive and open international economic system that would lead to economic growth and sustainable development in all countries . . . ."129 Agenda 21 asks states to promote trade liberalization to support sustained economic development and "to make international trade and environment policies mutually supportive in favour of sustainable development."130

Particularly after the launch of the WTO legal system, sustainable development has been a core issue in the discussion concerning the interaction between trade and the environment. During this discussion, arguments for changing international trade rules and practices to improve the environment and promote sustainable development have been continuously raised. The WTO, a newly established comprehensive multilateral trading system, hopes to achieve harmonization between trade and the environment to enhance the concept of sustainable development.131

127 Id. at 62.
128 Dernbach, supra note 103, at 10009.
129 The Rio Declaration, Principle 12, supra note 118, at 878.
131 See Jennifer Schultz, Current Development: The GATT/WTO Committee on Trade and the Environment – Toward Environmental Reform, 89 AM. J. INT'L L. 423,
The WTO, explicitly acknowledging sustainable development as a policy objective, requires member states to recognize the importance and legitimacy of environmental protection. According to the WTO Appellate Body, provisions of the GATT should be interpreted in light of "the objective of sustainable development." However, these contradictory policy goals—trade liberalization, environmental protection, and sustainable development—still remain somewhat incompatible. Thus, a more integrated policy approach to make trade liberalization and environmental protection programs reciprocally supportive to sustainable development is needed. More recently, it has been observed that the essence of sustainable development is increasingly sought in the international trade context. For example, the WTO Appellate Body, in principle, approves countries' rights to environment-related trade restriction measures on the ground that such a conservation policy is compatible with

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133 They must be read by a treaty interpreter in the light of contemporary concerns of the community of nations about the protection and conservation of the environment. While Article XX was not modified in the Uruguay Round, the preamble attached to the WTO Agreement shows that the signatories to that Agreement were, in 1994, fully aware of the importance and legitimacy of environmental protection as a goal of national and international policy. The preamble of the WTO Agreement—which informs not only the GATT 1994, but also the other covered agreements—explicitly acknowledges 'the objective of sustainable development.'

WTO Report of the Appellate Body, United States-Import Prohibition of Certain Shrimp and Shrimp Products, WT/DS58/AB/R paras. 129-30 (Oct. 12, 1998), available at http://www.sice.oas.org/Dispute/wto/58abr.asp [hereinafter WTO Report on U.S. Prohibition on Shrimp]. "From the perspective embodied in the preamble of the WTO Agreement, we note that the generic term 'natural resources' in Article XX(g) is not 'static' in its content or reference but is rather 'by definition, evolutionary.'" Id.

protection of endangered species and promotion of biodiversity. In this respect, we can find the phenomenon of a sustainable development-oriented international trade regime.

For the present, since the intellectual property protection system was incorporated into the WTO legal framework through the TRIPs Agreement, provisions with the aim of protecting biodiversity by international intellectual property protection rules, beyond the conventional trade and environmental legal regime, can play a critical role in promoting sustainable development. For example, the TRIPs Agreement Article 27.2 offers some incentives for conservation schemes and supports biodiversity protection. Thus, trade rules on intellectual property protection of biotechnology such as the TRIPs Agreement can and should be a supportive element for sustainable development.

In conclusion, in modern society, from the standpoint of sustainable development, the environment itself is deemed a fundamental source of human welfare, and natural capital – including both renewable and nonrenewable resources, living organisms, and ecological systems – has to be protected for the benefits of present and future generations. In addition, sustainable development should be beneficial for protection and restoring the environment as well as removing large-scale poverty. This notion should be a decisive constraint on human activities artificially altering nature itself.

Now, despite the absence of a globally accepted consensus on environmental principles or policies relating to sustainable environments, it should be noted that "[f]itting biotechnology regulation into the context of sustainable development is an

136 Gaines, supra note 134, at 10331.
137 "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment . . . ." Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization art. 27.2, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994), available at http://www.wto.org/english/tratop_e/trips_e/t_agm3_e.htm [hereinafter TRIPS Agreement].
138 Schultz, supra note 131, at 436.
139 Dernbach, supra note 103, at 10009.
important international goal, both from an environmental and economic perspective.” Therefore, “encouragement of the development and diffusion of environmentally friendly technologies” should be more emphasized in both the contexts of economically and environmentally sustainable development. On this point, modern biotechnology, as one of the keys to sustainable development in the twenty-first century, represents an economic-environmental dilemma in our global community.

III. Evolutionary Approach to Modern Biotechnology and Sustainable Development

A. Relevant Rules

1. Sources of Law

In general, Article 38(1) of the Statute of the International Court of Justice (ICJ Statute) has been primarily referred to in discussions of what the international law is or what the sources of international law are. Although the article itself does not include the term “sources” and does not explicitly enumerate the “sources of law,” it is generally considered a “complete statement of the sources of international law.” The provisions read as follows:

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140 On the contrary, it is pointed out that, in the process of policy and rule making in the U.S., sustainable yield, maintenance of biological diversity, internationalization of environmental costs of economic activity through liability or administrative rule, transparency of policy, and public participation are generally accepted as factors supportive of creating environmental equilibrium or balance for sustainability. George Van Cleve, Regulating Environmental and Safety Hazards of Agricultural Biotechnology for a Sustainable World, 9 WASH. U. J.L. & POL’Y 245, 251-57 (2002).


144 BROWNLIE, supra note 104, at 3.
Article 38

1. The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply:

a. international convention, whether general or particular, establishing rules expressly recognized by the contesting states;

b. international custom, as evidence of a general practice accepted as law;

c. the general principles of law recognized by civilized nations;

d. subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.

In the case of international trade of all kinds of genetically modified products made possible by biotechnology, WTO rules, as rules of general international law or a legal framework for global trade relations constituting "lex specialis vis-à-vis certain rules of international law," obviously apply. Consequently, in international trade disputes regarding issues of domestic public health, safety, and environmental protection caused by biotechnological products such as GMOs, the WTO and its annexed relevant multilateral trade agreements primarily apply. For example, general exceptions under the GATT 1994, General Agreement on Trade in Services (GATS), Agreement on Application of Sanitary and Phytosanitary Measures (SPS Agreement), Agreement on Technical Barriers to Trade (TBT Agreement), and TRIPs Agreement have substantial relevance.

Those aforementioned instruments, dealing with trade in

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146 Therefore, the WTO rules have basic policy objectives of regulating the trade between countries and trade liberalization. JOOST PAUWELYN, The Role of Public International Law in the WTO: How Far Can We Go?, in NEW DIRECTIONS IN INTERNATIONAL ECONOMIC LAW: ESSAYS IN HONOR OF JOHN H. JACKSON 535, 539-40 (Marco Bronckers & Reinhard Quick ed., 2000).

goods, services and intellectual property protection within the framework of the WTO legal system, can manifestly fall under the "particular international conventions . . . expressly recognized by the contesting states" to which Article 38(1)(a) of the ICJ Statute refers. Thus, within the context of the WTO, basic legal sources regulating biotechnology and its possibly resulting products are texts of the relevant agreements and provisions themselves, which are the most preferentially and directly applicable. The WTO Appellate Body also recognizes that the words and texts of the treaty are the basis for the interpretation, and that the textual interpretation is the most appropriate.

Of course, strictly speaking, the WTO Agreement and its annexed multilateral agreements were not established primarily for protecting the environment or promoting sustainable development, but to achieve trade liberalization based on free trade values and market-oriented principles. As the preamble to the WTO Agreement elucidates, however, the WTO explicitly recognizes

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148 Professor Pauwelyn, personally, argues that the WTO law is "just a branch of public international law" which creates "international legal obligations that are part of public international law." Thus, in his opinion, WTO rules are general or "les generalis" at least in dealing with the trade relations between countries. Pauwelyn, supra note 146, at 538-40. However, in the context of the ICJ Statute, it is apparent that the WTO Agreement and its annexed agreements are a sort of "particular international conventions" binding the member states.

149 Palmeter & Mavroidis, supra note 143, at 398.

150 Id.

151 Among other things, international conventions and custom are obviously important. The former, however, has a priority because it represents not general applications of rules but specifically reciprocal obligations between contracting parties. The priority of application of the sources in the Article 38(1) of the ICJ Statute is simply subject to the order (a) to (d) in that clause. Brownlie, supra note 104, at 3-4.


153 "The proper interpretation of the Article is, first of all, a textual interpretation." Id. § G.

154 "The Parties to this Agreement . . . while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking . . . to protect and preserve the environment . . . ." WTO Agreement, supra note 132, at 15.
the connection between promoting free trade and securing sustainable development as well as protecting the environment.\textsuperscript{155} The TRIPs Agreement was reached initially for the purpose of protecting personal creative products and regulating trade of pirated or counterfeited goods according to the WTO's trade liberalization principle.\textsuperscript{156} However, through the incorporation of agriculture, health, culture, and human life provisions into the TRIPs Agreement,\textsuperscript{157} use and application of modern biotechnology likewise have closely relevant implications on sustainable development in the context of the WTO legal system. Therefore, as far as the issues concerning modern biotechnology and its sustainable use are concerned, the relevant WTO provisions and rules should be interpreted and applied together.

The WTO rules, however, do not exhaust international conventions as a source of law applicable to the issues of biotechnology. Rather, the more specific rules of international law are likely to be highly related. These include preexisting treaty law confirmed by the WTO rules\textsuperscript{158} and non-WTO rules that already existed when the WTO treaty was concluded (on April 15, 1994) or have been created subsequent to the WTO treaty (post-April 1994), all of which are relevant to and may have a certain impact on the WTO rules.\textsuperscript{159} Moreover, the Vienna Convention on the Law of Treaties (Vienna Convention) states that "any relevant rules of international law applicable in the relations between the parties" together with the context of the treaty itself should be

\textsuperscript{155} In addition, WTO has several institutions such as the Committee on Trade & Environment that treat trade and environment issues. According to recent developments, the Dispute Settlement Body of the WTO also tends to be favorable to the environmental protection issues when tensions or clashes between trade and the environmental concerns occur. Besides these phenomena, many environment-related provisions are dispersed in the WTO multilateral trading agreements such as the GATT 1994 Articles XX (b) and (g), TRIPs Agreement arts. 27.2, 27.3 and 31(b), SPS Agreement arts. 2.2 and 2.3, and TBT Agreement, etc. MACMILLAN, \textit{supra} note 1, at 1-2, 7-41.

\textsuperscript{156} See TRIPS Agreement Preamble, \textit{supra} note 137.

\textsuperscript{157} ARUP, \textit{supra} note 1, at 13.

\textsuperscript{158} For example, certain parts of the World Intellectual Property Organization (WIPO) conventions were incorporated into the TRIPs Agreement.

\textsuperscript{159} As a result, the WTO panel has to scrutinize these factors as a legal source to be applied to resolve the WTO claims submitted by the parties. PAUWELYN, \textit{supra} note 146, at 540-41, 559-60.
taken into account.\textsuperscript{160} The Uruguay Round Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) directs the "panels to address the relevant provisions in any covered agreement or agreements cited by the parties to the dispute."\textsuperscript{161}

The fact that these other relevant international agreements are referred to in the covered agreements of the WTO or the parties concerned are also contracting parties to the WTO legal system makes it possible for them to be sources of the WTO law.\textsuperscript{162} Among other things, multilateral environmental agreements (MEAs) may be considered as significantly relevant rules, agreements, or provisions in the context of biotechnology. After the 1990s, in particular, the relationship between the MEAs and the GATT and WTO has been considerably discussed in the WTO jurisprudence.\textsuperscript{163} Until now, there have been no MEA provisions appearing to invalidate the WTO concessions. Nonetheless, MEAs, as subsequent agreements or arguably subsequent practices\textsuperscript{164} having an interpretative significance or possibly binding effects, may be taken into account in interpreting relevant provisions in the WTO legal regime.\textsuperscript{165}

Similarly, the WTO Appellate Body suggests a new model for the interpretation of the GATT by taking an implicit attitude to understand the GATT provisions within a broader framework of international law and policy relevant to the environment and development.\textsuperscript{166} It also evidently has recourse to the relevant

\textsuperscript{160} The Vienna Convention on the Laws of Treaties, May 23, 1969, art. 31(3)(c), 8 I.L.M. 679 (1969) [hereinafter The Vienna Convention].


\textsuperscript{162} Palmeter & Mavroidis, supra note 143, at 409.

\textsuperscript{163} The main issue has been potential conflict between the MEAs and trade obligation. James Cameron & Kevin R. Gray, Principles of International Law in the WTO Dispute Settlement Body, 13 INT’L & COMP. L.Q. 248, 263-66 (2001).

\textsuperscript{164} The Vienna Convention arts. 31(3)(a) and (b), supra note 160, at 692.

\textsuperscript{165} Cameron & Gray, supra note 163, at 265-66.

MEAs in the WTO lawsuit.\textsuperscript{167} By explicit reference to and adoption of the relevant MEAs in interpreting the WTO law and resolving the disputes, the WTO is trying to not only make up the gap between trade and the environment, but also open the possibility of incorporating environmental concerns into the WTO legal system.\textsuperscript{168}

The texts of the above-mentioned international instruments, however, do not cover all sources of law applicable to the issues concerning biotechnology. Rather, the texts themselves are just "first of all."\textsuperscript{169} Particularly in the contexts of both intellectual property protection of biotechnology and its implication for sustainability, other transnational agreements at the regional as well as the global level beyond the WTO legal framework may be of equal importance. Additionally, according to the subparagraphs of Article 38(1) of the ICJ Statute, former and subsequent practices including dispute resolution reports of the GATT and WTO, custom, general principles of law, and teachings of highly qualified publicists are possible sources of law\textsuperscript{170} applicable to modern biotechnology issues.

2. Trade in GMOs and Multilateral Trade Agreements

a. The GATT 1994 and the SPS and TBT Agreements

When the issue arises of whether a certain trade restrictive measure on GMOs\textsuperscript{171} imposed by a WTO member state is contrary

\textsuperscript{167} In interpreting the modern meaning of the term "exhaustible natural resources" in the GATT 1994 Article XX(g), the WTO Appellate Body addresses, as relevant conventions and declarations, the Unite Nations Convention on the Law of the Sea, United Nations Convention on Biological Diversity, Agenda 21, Resolution on Assistant to Developing Countries adopted in conjunction with the Convention on the Conservation of Migratory Species of Wild Animals and Appendix 1 of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. See WTO Report on U.S. Prohibition on Shrimp, supra note 133, paras. 130, 132.

\textsuperscript{168} Cameron & Gray, supra note 163, at 266-67.

\textsuperscript{169} Palmeter & Mavroidis, supra note 143, at 399.

\textsuperscript{170} \textit{Id.}

\textsuperscript{171} In practice, products from genetic resources such as the patented biotechnological inventions, pharmaceutical products, and agricultural varieties have an obvious implication on trade. MACMILLAN, supra note 1, at 117. These products and resources are evidently goods that can be traded between countries. Traditionally, trade in goods has been regulated by the GATT provisions.
to general obligations under the GATT (such as the obligations of most-favoured nation treatment, national treatment, or prohibition of quantitative restrictions), relevant provisions in the GATT 1994 have direct applicability.

Apart from the GATT 1994, both the SPS Agreement and the TBT Agreement may affect regulation of biotechnological products. Although there is a basic difference between the SPS Agreement and the TBT Agreement in that the former seeks to limit health restrictions while the latter attempts to limit technical restrictions, both of them have a direct relation to the controversy and measures concerning GMOs, such as the issue of labeling genetically modified products. In particular, the SPS Agreement is most applicable to measures relating to biodiversity protection, agriculture, and agricultural biotechnology. While it is not yet certain whether the WTO Dispute Settlement Body would directly apply the agreements to the GMO debates, they are, at least at the international level, playing an important role in

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173 Id. art. III.

174 Id. art. XI.


176 MACMILLAN, supra note 1, at 139.

177 Id. at 9.


180 As of April 2000, it is reported that there have been three WTO panels and Appellate Body decisions resolved under the SPS Agreement. Two cases included “sanitary” measures surrounding food safety and fishery ecology and the remaining one bore on “phytosanitary” measures centering on agricultural diseases. Steve Charnovitz, The Supervision of Health and Biosafety Regulation By World Trade Rules, 13 TUL. ENVTL. L.J. 271, 273-75 (2000).
the development and adoption of food safety and labeling standards.\textsuperscript{181}

The TBT Agreement is normally concerned with labeling requirements and nutritional issues regarding agricultural products, and the SPS Agreement may also apply to some packaging and labeling issues, if directly related to health or food safety concerns.\textsuperscript{182} The GATT 1994 provisions, as a defense in an SPS dispute, may not be preferred to the SPS Agreement provisions since the disciplines in the SPS Agreement are more rigid than those in the GATT 1994.\textsuperscript{183} With respect to trade in biotechnological products, when provisions of both agreements similarly apply, the SPS Agreement will have a priority over the TBT Agreement (similar to the relationship between the GATT 1994 and the SPS Agreement).\textsuperscript{184} The SPS Agreement “explicates and tightens” the GATT Article XX exceptions, and the TBT Agreement, mainly applying to labeling programmes, “can be seen as a subset” of the SPS Agreement.\textsuperscript{185}

\textit{b. The GATS and TRIPs Agreement}

The GATS, as in the case of the general exceptions clauses in the GATT 1994, has a provision permitting violation of general obligations in the GATS when it is necessary to protect human, animal, or plant life or health.\textsuperscript{186} The scope and extent of interpretation of the two provisions are very similar.\textsuperscript{187}

\begin{thebibliography}{9}
\bibitem{181} Teel, \textit{supra} note 178, at 683-84.
\bibitem{183} Charnovitz, \textit{supra} note 180, at 273.
\bibitem{184} “The TBT Agreement does not supervise any measures covered by the SPS Agreement.” \textit{Id.} at 277. “In practice, as is the case with GATT Article XX(b), the more recent SPS Agreement has overshadowed the TBT Agreement in the current dialogue on transnational biotechnology trade.” York, \textit{supra} note 182, at 457.
\bibitem{185} Applegate, \textit{supra} note 147, at 237.
\bibitem{187} MACMILLAN, \textit{supra} note 1, at 8-9.
\end{thebibliography}
The TRIPs Agreement is, with its implications of multilateral regulations for biotechnology, trying to converge and reinforce intellectual property protection based on a trade-oriented approach. As for patents on biotechnological inventions, the TRIPs Agreement provisions are basically taking a dual structure: first “it requires members to make patents available for any inventions, whether products or processes, in any field of technology” covering highly advanced modern biotechnology; and second, certain national exclusions from patentability. However, the fact that the TRIPs Agreement does not expressly address genetically modified products may result in inconsistent interpretations, particularly concerning patents on living organisms, genetically engineered gene materials, or the legal status of GMOs. Moreover, incorporation of intellectual property issues into the trade-oriented TRIPs Agreement has led to ambiguity in interpretation of the treaty norms.

c. The GATT and WTO Practices

As the subparagraphs of Article 38(1) of the ICJ Statute states, the national and international practices, custom, general principles of law, and teachings of highly qualified publicists may be relevant rules applicable to the issues surrounding modern biotechnology. Among them, practices including judicial decisions of the GATT or WTO, as the WTO Agreement evidently addresses, may have the potential to be applied to the interpretation of the relevant provisions. When it is fully taken into consideration that the history of the interpretation and application of intellectual property protection of biotechnology in the GATT/WTO legal framework is so short, the prior practices will be a particularly useful indicator for future interpretation of the provisions in the TRIPs Agreement.

188 ARUP, supra note 1, at 238-40; TRIPS Agreement arts. 27.1, 27.2, and 27.3, supra note 137.
189 Murphy, supra note 1, at 68-69.
190 Palmeter & Mavroidis, supra note 143, at 399.
191 “Except as otherwise provided under this Agreement or the Multilateral Trade Agreements, the WTO shall be guided by the decisions, procedure and customary practices followed by the CONTRACTING PARTIES to GATT 1947 and the bodies established in the framework of GATT 1947.” WTO Agreement art. XVI.1, supra note 132, at 1152.
In that sense, the two recently published WTO declarations resulting from the WTO Ministerial conference in Doha, Qatar – the WTO Ministerial Declaration192 (Doha Declaration) and the Declaration on the TRIPs Agreement and Public Health193 – deserve special attention in our discussion of whether their legal status can be subsequent practices or custom, which may exert substantial influences on future practices in relation to biotechnology.194

3. Multilateral Environmental Agreements

Again, the fact that other relevant international agreements outside the framework of the WTO are referred to in the covered agreements of the WTO and the contracting parties to the other international agreements are also member states to the WTO makes it possible for them to be sources of law195 on modern biotechnology issues. Beyond the WTO legal framework, in fact, there are diverse and numerous international organizations and agreements tackling GMO issues.196 Among them, particularly from the perspectives of biotechnology and GMOs, the United Nations Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety to the CBD (Biosafety Protocol) seem to be the most important and directly relevant.

The CBD197 intends not only to conserve biological diversity


195 See Cameron & Gray, *supra* note 163.


197 The CBD is arguably one of the international legal instruments in which the international law in the field of sustainable development is addressed in an integrated
and promote sustainable use of biodiversity components, but also to share the benefits arising out of utilization of genetic resources. In particular, with regard to biotechnology, the CBD contains provisions regulating access to genetic resources, intellectual property rights protecting patents on biotechnologies, and technology transfer facilitating equitable sharing of interests derived from biodiversity. Thus, the CBD can be deemed an international scheme for conservation and use of global biological resources in a sustainable manner in company with recognition of the relationship between intellectual property rights and use of genetic resources.

The subsequently concluded Biosafety Protocol is a result of specific attempts to regulate living modified organisms (LMOs), which may cause negative effects to the environment as well as human health. However, it is pointed out that the Biosafety Protocol has an immanently weak point of applying only to trade in LMOs, in contrast with the original intent to establish a comprehensive global system dealing with the relevant problems.

4. International Instruments for Intellectual Property Protection

To date, several international or regional agreements have been established regarding intellectual property protection of biotechnological inventions. In the contexts of modern
biotechnology and sustainable development, of course, these instruments have a direct applicability. The International Convention for the Protection of New Varieties of Plants (or the International Union for the Protection of New Varieties of Plants) (UPOV\textsuperscript{203}) grants plant variety rights to plant breeders, concurrently focusing on the balance between the owners’ rights and others’ need to have access to and use of the varieties.\textsuperscript{204} This balance is sought in terms of farmers’ and breeders’ rights.\textsuperscript{205} The UPOV has a strong point in that it covers both developed and developing countries, not merely a few major developing countries, mainly because it recognizes the \textit{sui generis} system for the protection of plant varieties.\textsuperscript{206} Therefore, this convention has substantially influenced the formation of national laws in that field.\textsuperscript{207}

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 1977 (Budapest Treaty), which became effective in 1980 and with which 48 countries, including the majority of developed countries, have been affiliated as of July 2000,\textsuperscript{208} may also have an important meaning to biotechnological sustainability.\textsuperscript{209} The establishment of an internationally recognized depository system for biological materials like microorganisms and the sustenance of breeding are the main objectives of the treaty.\textsuperscript{210} This standardized scheme for the deposit of microorganisms, which executes disclosure of patented materials and access to deposited materials,\textsuperscript{211} in a certain sense, contribute to the conservation or promotion of biological diversity.

\textsuperscript{203} This convention is commonly called the UPOV Convention, the French acronym for the treaty (Union Internationale pour la Protection des Obtentions Végétales). \textsc{Paul Goldstein, International Intellectual Property Law: Cases and Materials} 103 (2001) [hereinafter UPOV].

\textsuperscript{204} \textsc{Arup, supra note 1, at 234}.

\textsuperscript{205} \textsc{Macmillan, supra note 1, at 49}.

\textsuperscript{206} \textit{Id}.

\textsuperscript{207} \textsc{UPOV, supra note 203, at 311}.

\textsuperscript{208} \textit{See generally Watal, supra note 1, at 157; see also Grubb, supra note 1, at 228}.

\textsuperscript{209} \textit{See, e.g., Cripps, supra note 1, at 122-23}.

\textsuperscript{210} \textsc{Grubb, supra note 1, at 228}.

\textsuperscript{211} \textsc{Watall, supra note 1, at 157-60}.
Although they are only regionally applicable, the Convention on the Grant of European Patents (or European Patent Convention) (EPC) and the European Biotechnology Invention Directive (European Directive) provide us with useful interpretational tools for determining the reasonable scope of intellectual property protection of biotechnology to assist sustainable development. Both are in part contriving to protect a certain category of social order and environmental value by allowing exceptions to patentability based on the concept of “ordre public” or “morality.” Therefore, it is obvious that ethical issues are incorporated into these two European instruments in patenting biotechnological inventions.

In comparison with the EPC, the European Directive broadens the scope of patent protection for biotechnological inventions. The directive, however, still takes into account compromises between economic interests and ethical or environmental concerns more than the EPC does. More specifically, the European Directive excludes patents on parts of the human body, processes for cloning human beings or modifying the identity of human beings or modifying the identity of human beings.

212 Convention on the Grant of European Patents, reprinted in INTERNATIONAL LEGAL MATERIALS ON INTELLECTUAL PROPERTY 314 (Paul Goldstein ed., 2002 ed. 2002) [hereinafter the EPC].


214 According to the EPC provisions, patents shall not be granted in respect to “inventions the publication or exploitation of which would be contrary to “ordre public” or morality” and “plant or animal varieties or essentially biotechnological processes for the production of plants or animals.” See the EPC arts. 53 (a), (b), supra note 212. The European Directive considers “plant and animal varieties” and “essentially biological processes for the production of plants or animals” unpatentable. The directive additionally excludes the patentability of the inventions of which “commercial exploitation would be contrary to ordre public or morality.” See European Directive arts. 4.1(a), 4.1(b), 6.1, supra note 213.

215 Although, in the European Directive, the exception to plant and animal varieties continues, the eligibility for patenting plants, animals, and their separate elements is further enhanced, particularly by including the provisions of arts. 4.2 and 4.3. WATAL, supra note 1, at 154.

216 WATAL, supra note 1, at 154.
beings, and commercial exploitation of human embryos.\textsuperscript{217} The directive concedes the need for transfer of biotechnology,\textsuperscript{218} farmers’ privilege to reuse farm-saved seed,\textsuperscript{219} and breeders’ rights when seeking a compulsory license.\textsuperscript{220} This statutory rebuilding, probably established according to the developments of modern biotechnology, may be a clue to understanding the relationship between modern biotechnology and sustainable development. This trend, conveying relevant interpretational elements to biotechnological sustainability connotes a substantial change of the definition of sustainability in the context of patent protection of modern biotechnology.

\textbf{B. Evolutionary Interpretation of Sustainability}

\textit{1. Principle of Evolutionary Interpretation in International Law}

As the WTO Appellate Body correctly pointed out in interpreting the Preamble to the WTO Agreement and GATT provisions,\textsuperscript{221} evolutionary interpretation of some provisions of treaties is “well established public international law.”\textsuperscript{222} Provisions in a treaty should be interpreted in light of the contemporary concerns of a society.\textsuperscript{223} From this perspective of evolutionary interpretation supplemented by modern biological sciences, “renewable” living species or resources should be included in the category of “exhaustible natural resources” to be protected as follows:

\begin{footnotesize}
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\item[\textsuperscript{217}] European Directive arts. 5.1, 5.2 and 6.2, \textit{supra} note 213, at 18.
\item[\textsuperscript{218}] European Directive Preamble, \textit{supra} note 213, at 13.
\item[\textsuperscript{219}] European Directive art. 11, \textit{supra} note 213, at 19.
\item[\textsuperscript{220}] \textit{Id.}
\item[\textsuperscript{221}] “From the perspective embodied in the preamble of the WTO Agreement, we note that the generic term ‘natural resources’ in Article XX(g) is not ‘static’ in its content or reference but is rather ‘by definition, evolutionary.’” WTO Report on U.S. Prohibition on Shrimp, \textit{supra} note 133, para. 130.
\item[\textsuperscript{222}] Howse, \textit{supra} note 166, at 520.
\item[\textsuperscript{223}] “The words of Article XX(g) [of the GATT 1994], ‘exhaustible natural resources,’ were actually crafted more than 50 years ago. They must be read by a treaty interpreter in the light of contemporary concerns of the community of nations about the protection and conservation of the environment.” WTO Report on U.S. Prohibition on Shrimp, \textit{supra} note 133, para. 129.
\end{footnotes}
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One lesson that modern biological sciences teach us is that living species, though in principle, capable of reproduction and, in that sense, "renewable," are in certain circumstances indeed susceptible of depletion, exhaustion and extinction, frequently because of human activities. Living resources are just as "finite" as petroleum, iron ore and other non-living resources.224

Similarly, the objective of sustainable development in the Preamble to the WTO Agreement extends the scope of exhaustible natural resources to be conserved to include living natural resources or biological resources.225 Currently, diversity in the human population, as well as diversity in non-human biological resources, is considered a contributory element to biodiversity.226 Biodiversity, which on the one hand has been perceived to have an intrinsic value in international environmental legal systems,227 on the other hand has demanded protection of the "essentially random nature of the composition of [human] genes." From the perspective of genetic diversity in human beings, biodiversity is probably presented as an ideal to ensure more freedom for humans.228

Nature and ecology are ceaselessly changing, even evolutionary. It is now well known that global ecological systems are not a self-balanced, stable, or "fixed equilibrium," but rather constantly unstable and mutable. Thus, the earlier definition of

224 Id. para. 128.
225 [R]ecalling the explicit recognition by WTO Members of the objective of sustainable development in the preamble of the WTO Agreement, we believe it is too late in the day to suppose that Article XX(g) of the GATT 1994 may be read as referring only to the conservation of exhaustible mineral or other non-living natural resources.

Id. para. 131.


sustainable development based on "equilibrium paradigm," which required letting the natural environmental system be untouched as far as possible without human intervention, should be changed to further integrate the notion of sustainable development built upon a "non-equilibrium" view in ecology that recognizes appropriate interaction between humans and nature whereby human culture and activities can practically contribute to achieve more desirable environmental structures and maximize ecological conservation.229

2. Evolutionary Restatement

Historically, the concept of sustainable development has, as we have already seen, acquired a firm position as a policy objective for the future of our global community.230 Notwithstanding its established status as a fundamental policy objective in both national and international environmental legal regimes, sustainable development has a "potentially self-contradictory" character, which encompasses contradictory notions of conservation and economic development.231 In fact, as indicated as follows, the concept of sustainable development still remains questionable: "For the present, the concept [of sustainable development] remains problematic and nebulous, appearing more as a statement of the issues than as a resolution of the basic problems. As the literature reveals, the concept is protean in character."232

Moreover, the traditional concept of sustainable development is also on the verge of new challenges in the social, legal, and political contexts. Presumably, this change of situation has been

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229 For more details regarding these "equilibrium" and "non-equilibrium" paradigms in approaching sustainable development, see generally Guruswamy, supra note 121, at 464-65.

230 Under the WTO Agreement, environmental protection and sustainable development are recognized as policy objectives as follows: [T]he preamble attached to the WTO Agreement shows that the signatories to that Agreement were, in 1994, fully aware of the importance and legitimacy of environmental protection as a goal of national and international policy. The preamble of the WTO Agreement – which informs not only the GATT 1994, but also the other covered agreements – explicitly acknowledges “the objective of sustainable development.”

WTO Report on U.S. Prohibition on Shrimp, supra note 133, at VI (B)(1)(3).

231 Guruswamy, supra note 121, at 464.

232 BROWNLIE, supra note 104, at 287.
due partly to the inherently double-sided features of sustainable development, and mainly to the evolutionary developments of modern biotechnology. Consequently, sustainable development must be redefined in an evolutionary manner to be compatible with recent biotechnological revolutions. It is also required that provisions in a treaty should be interpreted in light of contemporary context.\(^2\) Therefore, in light of recent developments of genetic engineering, such as cloning technologies, sustainable development needs to be reconsidered in novel contexts.\(^3\)

In addition, according to continuous changes in the concept of sustainable development, sustainable development has recently evolved to involve wise use of genetically-engineered human capital as well as natural resources. This kind of redefinition means that various policies with the aim to promote sustainable development should assist innovations to help satisfy human needs and intergenerational equity.\(^4\) As a result, the recent restatement of sustainable development further emphasizes intervention of human intellectual activities into the natural world and pays more attention to the role of science, knowledge, and modification of nature for sustainable development. This policy approach, of course, will significantly affect relationships between sustainable development and biotechnology and its resulting products, GMOs.\(^5\)

In conclusion, the revolution of modern biotechnology instructs us that living resources, including biological or genetic resources, as well as non-living resources, can be exhaustible, and that modern biotechnology can either promote or destroy sustainable development of those biological materials. In particular, according to the evolutionary characteristics of modern biotechnology, it will be more reasonable that biological and genetic resources, including human genetic resources, be treated within a category of exhaustible natural resources, to be protected to promote sustainable development. This approach would also be in conformity with the recently published WTO Ministerial

\(^2\) See WTO Report on U.S. Prohibition on Shrimp, supra note 133, at VI (B)(1)(3).
\(^3\) See generally Cripps, supra note 1, at 123-26, 133.
\(^4\) Guruswamy, supra note 121, at 463-64.
\(^5\) Id. at 465-66.
Declaration on the TRIPs Agreement and Public Health, which requires flexibility particularly in interpretation of each provision in the TRIPs Agreement for the purpose of protecting public health in light of the objective and purpose of the Agreement.\(^\text{237}\)

\[C. \hspace{1em} \textbf{Sustainability in Agricultural Development}\]

\[1. \hspace{1em} \textbf{Implications of Agro-biotechnology on Sustainable Agriculture}\]

In practice, sustainable development has been discussed principally in the agricultural dimension.\(^\text{238}\) Agriculture arguably has more direct impacts on the environment and sustainable development than any other industry because cultivation may release various materials into the earth’s land which can seriously affect environmental ecosystems.\(^\text{239}\) Materials such as pesticides, insecticides, fertilizers, or GMOs may be toxic chemicals having adverse effects on the environment.

From the perspective of agricultural development, narrowly speaking, sustainability means “resource-conserving, socially supportive, commercially competitive, and environmentally sound” farming systems whereby productivity and usefulness to society can definitely be maintained.\(^\text{240}\) Broadly speaking, sustainable development of agriculture has to be understood in the context of food production that calls for increasing agricultural productivity, in a sustainable manner, which can on the one hand significantly meet the additional food demand of future generations and on the other hand conserve the environment.\(^\text{241}\)

Agricultural unsustainability may accelerate the losses of arable land essential to produce needed food and existing plant and animal species whose genetic resources can help make agriculture more sustainable or produce many other useful products, such as improved medicines.\(^\text{242}\) In this respect, it has been argued that

\(^{237}\) See The Declaration on the TRIPs Agreement and Public Health, supra note 193, paras. 4-5.

\(^{238}\) Cripps, supra note 1, at 121.

\(^{239}\) Barton, supra note 179, at 95.

\(^{240}\) Guruswamy, supra note 121, at 466.

\(^{241}\) Id. at 466-67.

\(^{242}\) Dembach, supra note 103, at 10007.
biotechnology and its resulting GMOs can bring adverse effects\textsuperscript{243} as well as various advantages\textsuperscript{244} to the sustainability of agricultural development. Despite the long history of traditional biotechnological farming practices to produce more desirable crops or fruits, the peculiarly modern biotechnology of genetic engineering, such as techniques for transplanting foreign genes into other species beginning around the second half of the twentieth century, has fundamentally changed classic cultivation practices, resulting in our discovery of the utility of ample genetic resources in the world. This modern biotechnology has been applied to the agricultural field with a deliberate goal to achieve fruits or crops resistant to herbicides, insecticides, pests, and severe weather.\textsuperscript{245}

2. Promises and Perils of Modern Agro-biotechnology

For the present, it is argued that biotechnology and genetically modified agricultural plants can be an attractive means to increase crop yields and produce food with better taste and nutritional quality, concomitantly reducing production costs and environmental harm. These promising developments include stronger and healthier crops containing medicinal properties, as well as genetically engineered crops, fruits, and vegetables with enhanced taste, preservation, and nutritional ingredients.\textsuperscript{246} Despite its alleged potential risks, some insist that biotechnology is not “inherently dangerous.”\textsuperscript{247} Additionally, it is also argued that agricultural biotechnology can create health and environmental risks similar to those that can be caused by conventional agriculture.\textsuperscript{248}

Counterarguments have been constantly raised by groups against application of modern biotechnology to agriculture and the

\begin{itemize}
\item \textsuperscript{243} See generally Guruswamy, supra note 121, at 474-77.
\item \textsuperscript{244} See generally id. at 469-74.
\item \textsuperscript{245} See generally id. at 467-68.
\item \textsuperscript{246} See generally id. at 468-74.
\item \textsuperscript{247} Van Cleve, supra note 140, at 257.
\item \textsuperscript{248} Under this premise, it should be equally noted that risks and costs are also common in conventional agricultural practices, and therefore, the total social costs must be measured in comparison benefits and costs between agricultural biotechnology and conventional agriculture. \textit{Id.} at 257-59.
\end{itemize}
introduction of GMOs into farming systems. They harbor suspicions about the yet unverified adverse effects of genetic modifications in agricultural systems.\textsuperscript{249} In particular, industrialization of agriculture based on the economic theory of "minimum cost and maximum production," promoted by biotechnology and GMOs, prefers monoculture and increases use of agricultural chemicals with no consideration for genetic safety. This kind of commercialization of agriculture has been a disaster to biological diversity.\textsuperscript{250}

In addition, intellectual property protection of agro-biotechnological inventions may arguably have a significant meaning for sustainability in agricultural development. Sometimes application of intellectual property protection to agro-biotechnologies, such as a genetically modified seed that contains a "terminator gene" or that is resistant to specific chemical herbicides or pesticides may be a menace to agricultural biodiversity, as well as poor farmers. At the end of the 1990s, the United States granted a patent on a genetic "technology protection system" that made seeds to work only one growing season. This technology applied to transgenic and ordinary varieties of seeds, and even to self-pollinating crops. These genetically modified plant seeds containing "terminator genes," which compel farmers to buy new seeds from the biotech seed companies holding patent rights every year, require a radical change in the traditional seed saving practices of farmers for the next season. Moreover, the spread of cultivation using these seeds increases monoculture, which may cause adverse effects to agricultural biodiversity.\textsuperscript{251}

Patented crop seeds or plants that are genetically engineered to resist specific pesticides or herbicides produced by a specific agrochemical company, which will be destroyed if other products manufactured by other companies are sprayed on them, have potential vulnerability caused by a disastrously monocultured seed stock.\textsuperscript{252} Of course, these kinds of patent rights will be adverse to

\textsuperscript{249} See generally Guruswamy, supra note 121, at 468-69.

\textsuperscript{250} Id. at 474.


\textsuperscript{252} Actually, these kinds of herbicide and insect resistant cotton seeds genetically engineered by Monsanto, which is a multinational agrochemical corporation based in the
“genomic crop diversity” as well as farmers’ interests.\textsuperscript{253}

Criticisms against agricultural biotechnology are mainly based on unidentified dangers and disadvantages of GMOs to the environment and human health, such as the long-term effects of herbicide, insecticide, or pest resistant plants. Critics are warning that expanding the use of GMOs without securing biosafety will seriously impair ecological and biological stability. Resistance enhanced by transgenic techniques, according to their arguments, can make herbicide resistant crops themselves weeds and increase the use of environmentally harmful chemicals.\textsuperscript{254} Similarly, genetically modified crops containing pesticides such as Bt-corn were proved to harm Monarch butterfly larvae, “unintended targets” which are beneficial insects. Further, more powerful pesticides can produce undesirable new creatures such as new resistant pests of “killer gene” or “killer weed” that are out of human control and ultimately lead to serious imbalances in ecology.\textsuperscript{255}

Accordingly, it should be noted that these kinds of applications of biotechnology to farming practices may result in a vicious circle: GMOs give rise to a contaminated ecological system, the contaminated ecological system to contaminated agricultural products, contaminated agricultural products to contaminated food, and contaminated food to contaminated human bodies.

\textbf{D. Sustainable Use of Human Genetic Resources}

\textit{1. Human Cloning and Sustainable Development of Human Beings}

\textit{a. Application of Technologies}

In the case of human cloning, more careful and special attention needs to be paid to issues of sustainable development.

\textsuperscript{253} Id.

\textsuperscript{254} For example, Round-up Ready soybeans, a herbicide resistant crop, will be a good example of the need to increase the spray of herbicides in the environment. Guruswamy, \textit{supra} note 121, at 476.

\textsuperscript{255} \textit{See generally id.} at 475-76.
Particularly since the advent of the cloned sheep, Dolly, human cloning has been one of the most controversial issues in social, ethical, and legal debates. The total ban on human cloning first proposed by the Council of Europe\textsuperscript{256} does not end the debates. Rather it ignites severe controversies with regard to two conflicting policy objectives: protection of social ethics and morality and protection of technological and scientific advancement.\textsuperscript{257}

Today's cloning techniques,\textsuperscript{258} in general, involve two methods.\textsuperscript{259} First, the embryo splitting technique, the classical method, is the technology that divides an embryo into two pieces, each of which has identical nuclear genes and a small number of mitochondrial genes. Second, the nuclear transfer technique, the revolutionary method, is the technology that transfers the nucleus of a foreign cell into a reproductive cell so that identical nuclear genes are produced.\textsuperscript{260}

Human cloning techniques of somatic cell nuclear transfer have paralleled more recently developed techniques of embryonic transfer and embryonic stem cell manipulation. Embryonic transfer technology is different from that of somatic cell nuclear transfer in that it transfers the nucleus of an egg rather than a somatic cell. Specifically, this technology blends nuclei from an older woman's egg with surrounding cell materials of a younger woman, fertilizes these mingled egg materials in vitro, and then implants them in the older woman.\textsuperscript{261} The technology of


\textsuperscript{257} Somekh, supra note 256, at 397-99.

\textsuperscript{258} While the specific meaning of the term "cloning" will be defined in respective provisions of individual legislation, it, commonly speaking, means "the scientific process of genetically replicating molecules or cells in biological research" from which a whole organism is created. Id. at 399. When applied to human cloning, it refers to the reproduction of a completely identical human being. Id.

\textsuperscript{259} For more details about the types of human cloning, see generally Tracy Williams, Cloning and the Conservation of Species, 2001 Y.B. COLO. J. INT'L ENVTL. L. & POL'Y 215, 220-22 (2002).

\textsuperscript{260} Somekh, supra note 256, at 400.

\textsuperscript{261} Susan Greenlee, Dolly's Legacy to Human Cloning: International Legal
embryonic stem cell manipulation mixes undifferentiated embryonic stem cells from humans with other animals' cells or eggs to produce a new type of human cell. It is recently reported that human DNA was fused with a cow's egg. However, there has been no sufficient evidence of the results of these experiments.\(^{262}\)

As we have already observed from the case of Dolly,\(^{263}\) by using cloning methods, human beings as well as sheep can be cloned from an adult somatic cell,\(^{264}\) going beyond the natural law of evolution of life. Moreover, creation of a cloned human by using embryonic transfer technology is criticized because it may have defects in both technological and ethical aspects in that the newborn baby will receive genetic materials from two mothers and there is a danger that the mothers' genetic diseases will transfer to the baby.\(^{265}\)

\(b.\) Unsustainability of Humanity

Human cloning from artificially adapted and selected human genes can produce more desirable human beings with improved genetic characters.\(^{266}\) However, this kind of reform in humanity is likely to court another long-term disaster to mankind caused by mono-genetics.\(^{267}\) In this respect, the following remark is noted as an alarm to the people of the world:

Although enhancing human characteristics could benefit people on an individual level, it might adversely affect the human


\(^{262}\) \textit{Id.} at 540-41.

\(^{263}\) When cloning the sheep, the scientists implanted the nucleus extracted from somatic cells of an adult sheep into an unfertilized egg from which the nucleus was removed. After that, this egg was artificially inseminated into a surrogate mother. Through this genetic manipulation, Dolly, a genetically identical sheep, was born. See Somekh, \textit{supra} note 256, at 400.

\(^{264}\) A somatic cell is generally defined as one of the cells of the body that compose the tissues, organs, or other body cells rather than an egg or sperm cell. Greenlee, \textit{supra} note 261, at 538-39.

\(^{265}\) \textit{Id.} at 539-40.

\(^{266}\) Somekh, \textit{supra} note 256, at 400.

\(^{267}\) For more detailed debates on human cloning including ethical, moral, psychological, social, human rights, legal, and religious concerns, see generally \textit{Id.} at 411-20.
species as a whole. Genetic manipulation could put the human species at risk by eventually creating a genetically uniform population. Such genetic uniformity would increase the human species' susceptibility to annihilation by disease, thereby weakening its evolutionary fitness and chances of survival as a species.\(^{268}\)

Although it is contradictorily argued that cloning techniques, particularly so-called "conservation genetics," may significantly contribute to the conservation of endangered species,\(^{269}\) utilization of human genetic resources for the purpose of genetic uniformity is, in the long run, contrary to the sustainable development of humanity.

Proponents of human cloning particularly focus on its potential to reduce human suffering. For example, this technology could provide alternative treatments for infertility, cures for genetically inheritable diseases, and the means for producing organs and tissues needed for transplantation.\(^{270}\) On the contrary, among the commonly proposed arguments for prohibitions on human cloning,\(^{271}\) is the idea that the societal harm, in the context of human genetic diversity, deserves our attention. Human cloning used for eugenic purposes to achieve preferable genetic traits will probably result in commodification of humans and long-term decreases of human genetic diversity, varieties of ideas, and the genetic fitness of the human species. This kind of diminution of genetic diversity will, in the long run, endanger the existence of human society as a whole.\(^{272}\)

Despite international efforts to regulate creation of genetically

\(^{268}\) Id. at 400.

\(^{269}\) Williams, supra note 259, at 222-23.


\(^{271}\) For example, there have been assertions that a cloned child has arguable health and mental defects originated from the cloning technology itself and knowledge of the clone of one's self. In addition, in religious and philosophical aspects, the question of trespass on the divine sectors of creating life and destruction of personality, individuality, and human dignity resulting from commodification of human beings has been proposed as a general ethical argument against human cloning. See generally id. at 168-71.

\(^{272}\) Id. at 169-70.
identical human beings, responding to human cloning (including eugenic uses of it), there has been no legal or theoretical consensus for a prohibition on human cloning. However, under the so called "environmental human rights" concept which emerged as an alternative mechanism for this legal and theoretical vacuum and which was used to justify international intervention, human cloning technology for eugenic purposes will often be a violation of the right to life.

"Human cloning is not something that once done can be undone. Any changes in the field are permanent. Once a human is cloned, it will be hard, if not utterly impossible, to turn back." In the sense of sustainability, therefore, human cloning may be far from maintenance of the status quo. In addition, in the context of "environmental human right[s]," human cloning for eugenic ends will probably create a biological underclass through making society more genetically uniform, which results in harm to the genetic diversity of mankind. This elimination of physical and behavioral varieties can further deprive human society of cultural diversity. In the field of human cloning, which makes human gene pools homogenous, there are always possibilities of rendering the human species more vulnerable to the external environment and weakening the genetic fitness of the population. Thus, it should be equally noted that creation of a cloned human may, through monoculture of humanity, carry risks of a decrease of genetic diversity as well as the degradation of humans into commodities.

273 For more details of both domestic and international responses to human cloning, see generally Greenlee, supra note 261, at 541-51.

274 For the history of eugenic practices including human cloning as a mechanism of social control worldwide, see generally Wang, supra note 270, at 171-77.

275 Id. at 177-80.

276 Id. at 181-85.


278 Wang, supra note 270, at 185-86.

279 Id. at 185, 187.

280 Id. at 185, 188.
2. International Regulations

There have been controversies regarding the technologies of cloning humans and other animals for the purpose of conservation.\textsuperscript{281} Although international regulations on the problem of human cloning are confusing due to a lack of legislative uniformity at both the national and international levels, some countries have regulated or even totally banned human cloning.\textsuperscript{282} In particular, the European region takes a positive attitude toward regulation of cloning technologies. In fact, even in the U.S., in which patenting biotechnology is broadly accepted, claiming patents on a chimera carrying both animal and human genes has been rejected on the ground that patents on humans or creatures that are essentially human are not allowed by Congress, and that patents on humans are contrary to the U.S. Constitution’s Thirteenth Amendment prohibiting slavery.\textsuperscript{283}

In the United States, a bill totally banning any form of human cloning was adopted in the House of Representatives on July 31, 2001.\textsuperscript{284} According to the bill, not only reproductive cloning used for replicating human beings but also therapeutic cloning, particularly including nuclear transfer technology and stem cell research, will be prohibited.\textsuperscript{285} However, opponents of this bill criticize the enactment, contending that the bill neglects the advantages of somatic stem cell research for medical treatments to cure various intractable ailments. They also argue that the creation of cloned humans can be sufficiently prevented under the current legal system.\textsuperscript{286} On the contrary, from the perspective of the environmentalists, cloning technologies for conservative purposes, whether they are applied to human beings or other

\textsuperscript{281} See generally Williams, supra note 259, at 215-56.

\textsuperscript{282} Hawkins, supra note 277, at 244-45.


\textsuperscript{285} Williams, supra note 259, at 217.

\textsuperscript{286} Id. at 217-18. For more details concerning the status and usefulness of the stem cells, see generally id. at 219.
animals, will not help achieve conservation and protection goals. Moreover, it cannot allegedly be a conclusive answer for the survival of all species in the world, but only a "Band-Aid." 287

In Europe, statutory blockage on application of human cloning technologies has already been tried. The Council of Europe's Draft Additional Protocol, passed by the Council of Europe on September 22, 1997 and signed by nineteen states on January 12, 1998, was the first attempt to create a legally binding instrument that would prohibit human cloning at an international level. 288 In particular, under the Council of Europe's Explanatory Report to the Draft Additional Protocol, human cloning, including use of embryonic cells for the purpose of reproducing humans, is essentially forbidden. 289 Additionally, the European Union's Resolution on Human Cloning, proposed by the European Parliament, emphasizes an individual right to one's own genetic diversity and concludes that a ban on human cloning is necessary to maintain such fundamental rights. 290

Unlike the former Convention on Human Rights and Biomedicine, 291 which allowed human cloning for "preventive, diagnostic or therapeutic purposes," 292 the Council of Europe's Draft Additional Protocol, modifying Article 13 of the Convention on Human Rights and Biomedicine, was aimed to eradicate human cloning in all circumstances. 293 The Council of Europe's Draft Additional Protocol prohibits the creation of a genetically identical human being by splicing the nuclear gene set of another, whether living or dead. 294 Natural genetic combination, allowing every individual to have various genetic characteristics, can guarantee

287 See id. at 219-20.
290 See Resolution on Human Cloning, 1998 O.J. (C 34) 164.
292 See id. art. 13, 36 I.L.M. at 821-22.
human freedom more than genetic uniformity which would seriously threaten the identity of humanity.\(^{295}\) Therefore, under the Council of Europe's Draft Additional Protocol, requirements of sustainable use of human genetic resources to secure genetic diversity of humanity should also apply to human cloning.

However, the European Directive,\(^{296}\) as with the TRIPs Agreement,\(^{297}\) does not block the possibility of patent protection for human DNA and gene sequences.\(^{298}\) This part of the Directive is thought to be the most significant. Opponents generally consider such patents to be illegal because they constitute "patents on life."\(^{299}\) On this point, accordingly, it is necessary that the sustainable use of human genetic resources should be taken into further consideration in intellectual property protection of biotechnology.

The European Directive expressly adopts "ordre public" or morality grounds for denying the granting of patents.\(^{300}\) In addition, the Directive more specifically enumerates human cloning, modifying the genetic identity of humans or other animals, and the commercial use of human embryos as non-patentable inventions.\(^{301}\) These provisions suggest advances in the context of sustainable development of humans. Nonetheless, it should be noted that stem cell procedures can still be patented unless stem cells are regarded as clones or present embryos within the meaning of the existing provision.\(^{302}\)

To conclude, in light of the irreparable harm to society that


\(^{296}\) See European Directive, supra note 213.

\(^{297}\) Under the Article 27.1 of the TRIPs Agreement, "any inventions, whether products or processes, in all fields of technology" are patentable if the inventions meet the general patentability requirements. TRIPS Agreement art. 27.1, supra note 137. As a result, human DNA and gene sequences, in principle, are not excluded from the patent protection.

\(^{298}\) See European Directive art. 3, supra note 213.

\(^{299}\) However, it is also pointed out that this argument violates basic principles of patent law. Tade Matthias Spranger, Europe's Biotech Patent Landscape: Conditions and Recent Development, 3 MINN. INTELL. PROP. REV. 239-41 (2002).

\(^{300}\) European Directive art. 6(1), supra note 213.

\(^{301}\) Id. art. 6(2).

\(^{302}\) Spranger, supra note 299, at 243.
would probably be caused by human cloning and the international discrepancy in regulations on it, international agreement is urgently needed to regulate cloning technologies for the moral and ethical integrity of the global community as well as for the sustainable development of humanity. Therefore, particularly in the field of human cloning techniques, in light of multinational developments, universal efforts to standardize legislation is essential.

IV. Patenting Biotechnology, Biodiversity, and Equity Between Parties

A. Protection of Biodiversity and Equitable Sharing of Benefits

As previously discussed, intellectual property protection of biotechnology, from the perspective of an evolutionary interpretation, should be understood in the novel contexts of sustainable development, in which concerns of both diversity and equity are incorporated. Therefore, review for future rectification of the legal regime, as well as interpretation of existing legal provisions concerning intellectual property rights of biotechnology should promote sustainable development, biodiversity, and equitable profit sharing. In that sense, the following brief but suggestive excerpt from Professor Cripps is on point:

In any attempt to renegotiate these provisions of TRIPS, attention must be devoted to the importance of protecting biodiversity and of sharing the benefits of innovation with the countries that provide the biological resources.

Intellectual property laws of biotechnology, whether they are national or international, can be a crucial tool to promote conservation of biological diversity, equitable sharing of benefits, and ultimately sustainable development. Intellectual property protection systems that are in place for biotechnological inventions

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303 Hawkins, supra note 277, at 245.
304 Greenlee, supra note 261, at 547.
305 For example, TRIPS Agreement arts. 27.2, 27.3, supra note 137. See, e.g., Cripps, supra note 1, at 132.
306 Cripps, supra note 1, at 132.
are also effective legal devices for human rights protection and environmental conservation, in addition to their primary purposes—promoting innovations and industrial developments.\textsuperscript{307} From the perspective of biodiversity, intellectual property laws may be applied to all components of the global environmental ecosystem: species comprising ecosystems and relevant knowledge; inventories of plants, animals, and microbe species; information about a species' usefulness; extracts and purified compounds; methods of preparing such materials; methods of administering them; seeds, plasmids, and isolated genes; pure-bred or hybrid crops or animals; synthetic derivatives of compounds and genetic materials; and products prepared from such compounds. All of these components, of course, are important in the fields of medicine, agriculture, and industry.\textsuperscript{308}

Issues surrounding modern biotechnology are so various and broad that they embrace almost all social concerns. Legal aspects have mostly centered on intellectual property protection of biotechnological inventions, which may provide an economic incentive for commercial exploitation of biotechnological innovations.\textsuperscript{309} However, the question of legal protections of biotechnologically-modified products and the processes or use of them\textsuperscript{310} has concomitantly provoked ethical as well as technical debates. While the technical issues have included the patentability of life forms, the ethical issues have focused on whether and to what extent biotechnological inventions should be protected.\textsuperscript{311}

In principle, when a new biotechnological invention meets the basic patentability criteria, patent rights may be granted. However, existing international patent laws allow certain categories of exceptions based on ethics, public health, and


\textsuperscript{308} See generally id.

\textsuperscript{309} ARUP, \textit{supra} note 1, at 219.

\textsuperscript{310} Generally speaking, it has been said that biotechnological inventions fall into three categories: the processes for the creation or modification of living organisms and biological material, the results of such processes, and the use of such results. \textit{INTRODUCTION TO INTELLECTUAL PROPERTY: THEORY AND PRACTICE}, \textit{supra} note 3, at 587.

\textsuperscript{311} UPOV, \textit{supra} note 203, at 309.
environmental requirements. In this respect, it is questionable whether the present patent system as interpreted is appropriate or sufficient to ensure biodiversity and equitable sharing of benefits from biotechnological applications.

Indeed, the more biotechnology develops, the more it should take into account sustainable development concerns based on both biodiversity and equity. Consequently, provisions stipulated in the existing international legal instruments to promote sustainable development (such as patentable subject matter, technology transfer, protection of indigenous knowledge, preventing biopiracy, and protection of breeders’ and farmers’ rights) should be interpreted and applied with full consideration for biodiversity and equitable sharing of profits derived from the use of biotechnology.

In addition to the issues of patentable subject matter, the matters of promoting technology transfer, protecting indigenous culture, preventing biopiracy, and protecting breeders’ and farmers’ rights may have special meanings to sustainable development. All of these issues must also be discussed in the contexts of biodiversity and equity. The next chapter, therefore, will review these issues within the contexts of existing norms and future renegotiations, particularly from the perspectives of biodiversity and equity concerns.

B. Equity Between Generations

1. Intergenerational Equity

A revolutionary consensus that both present and future generations have equitable rights to share their developmental and environmental benefits was first attempted in the documents signed in Rio de Janeiro, introducing a new legal concept: “intergenerational equity.” This principle of intergenerational equity, which is considered to be an element of sustainable development, is articulated in many international instruments aiming to preserve natural resources for the profits of this and

future generations.313

As defined in the Brundtland Report314 and Rio Declaration,315 the principle of intergenerational equity, which is considered inherent in sustainable development, has intergenerational implications.316 This intergenerational nature of equity in sustainable development is succinctly expressed as follows:

[F]uture generations are a silent but important party to debates about equity. Sustainable development is inherently intergenerational. The agreements we negotiate are inherently intergenerational. Yet the interests of future generations have not been identified and adequately represented in the negotiations, either in the implementing measures, or in the compliance mechanisms of international environmental agreements. The present generations has a bias in favour of itself. . . . Thus, as we consider the future, it will be important to develop an international consensus on the definition and outline of the concept of intergenerational equity.317

As far as the future risks flowing from the present use of biotechnology are concerned, the interests of future generations should be considered. The existing gene varieties and food stuffs that are available today must be preserved for future generations. Sustainable use of present genetic resources is our obligation to future generations based on the concept of intergenerational equity.318 This kind of equity should be read in the following modern context, which requires the present generation to ensure sustainable life for future generations:

The founders of the United Nations set out to promote social progress and better standards of life in larger freedom – above all, freedom from want and freedom from fear. In 1945, they could not have anticipated, however, the urgent need we face
today to realize yet a third: the freedom of future generations to sustain their lives on this planet.  

2. Intragenational Equity

The negotiation of the CBD revealed that the best reservoirs of biodiversity exist within developing countries' territories. This fact made it possible for them to exert control over resources that are important to the developed world. On the other hand, it should be equally noted that developing countries are generally apt to suffer from environmental degradation stemming in part from their poverty. Poor people, who live in developing and/or developed countries, exposed to the worst environmental conditions, are likely to commit harmful acts to the environment for their survival. Therefore, so called "intragenational" equity, in seeking to reduce poverty and environmental degradation, is also needed to achieve substantially "intergenerational" equity.

Intragenational equity, in particular, affirms "the essential needs of the world’s poor, to which overriding priority should be given" and extends the notion of equity to "equity within each generation." Both concepts are closely connected to trade policy for poverty alleviation of the world’s poor people in the present generation. Therefore, an absolute reinforcement of intellectual property rights to biotechnology without consideration of equitable compensations for biologically rich countries for their genetic resources should be restrained because very limited number of companies in developed countries can monopolize the benefits acquired from the resources. Thus, international patent instruments containing effective measures to prevent biopiracy from the biologically rich but economically poor countries may be

320 See generally Weiss, supra note 45, at 21.
321 Dernbach, supra note 103, at 10014.
322 "The principle of intragenational equity, often overlooked, complements intergenerational equity as a basic pillar of sustainable thinking." Gaines, supra note 134, at 10331.
323 Dernbach, supra note 103, at 10014.
324 OUR COMMON FUTURE, supra note 314, at 43-44.
325 Gaines, supra note 134, at 10331-32.
needed for the protection of the global environment.\footnote{Schultz, supra note 131, at 436.}

C. Patentable Subject Matter

1. Fundamental Policy Tools

The patentable subject matter issues can and must be the most fundamental policy tool in promoting sustainable biotechnological development, because the basic scope and direction of biotechnological developments will depend on how and to what extent biotechnological inventions are legally protected. Basically speaking, the scope and extent of protection will be decided according to requirements for granting patent rights, i.e. 'patentable subject matter.'

During the biotechnological revolution of the last two decades, the patent system has headed the list of stimuli to industrial development in the field of biotechnology, including growth of small businesses, because patent protection of biotechnological inventions has offered economic incentives for research and development.\footnote{Chambers, supra note 283, at 223-25.} Therefore, determination of patent eligibility of biotechnological inventions will be one of the most effective methods of managing the growth of biotechnological developments in terms of sustainability.\footnote{It is said that the U.S. protects biotechnological inventions more broadly than any other country in the world. As a result, the U.S. leads the revolutionary development of the biotechnology industry worldwide. \textit{Id.} at 241.}

2. The U.S. and EU

The breadth and degree of protection of biotechnological inventions varies widely and differs depending on country, region, and stage of economic development. Grant of a patent in the United States, which as noted provides the broadest patents on biotechnological inventions, generally covers human gene therapy, genetically engineered plants and animals, and their respective production processes\footnote{\textit{Id.} at 226.} based on the premise "anything under the sun that is made by man."\footnote{Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).} Since the landmark case of \textit{Diamond...

\textit{Id.} at 226.
v. Chakrabarty in 1980, allowing the patenting of unicellular microorganisms, the United States has extended patent protection to complex multicellular living organisms like plants and animals, and even to transgenic mice.

More recently, human gene therapy, as a process, is broadly patented under U.S. patent law. When discussing patentable subject matter, the U.S. authorities hardly address public policy or morality considerations except in the case of human/non-human chimera. Therefore, the U.S. has not excluded the possibility of invoking public policy and morality grounds in rejecting patentability of a human/non-human chimera. Patenting chimeric inventions can be considered to be "injurious to the well being, good policy, or good morals of society."

In Europe, in contrast with the United States, certain kinds of biotechnological inventions are obviously excluded from being patentable inventions under relevant legal provisions. For example, "methods for treatment of the human or animal body," including gene therapy, "inventions the publication or exploitation

331 The U.S. Supreme Court approved patentability of genetically engineered oil-eating bacteria, dictating that the decisive condition in granting a patent is whether the claimed invention is a result of human manipulation. See id. at 309-10.

332 Chambers, supra note 283, at 228-26.

333 For example, first animal patent on a genetically engineered mouse, the so-called "Harvard Onco-mouse." See U.S. Patent No. 4,736,866 (issued Apr. 12, 1988).

334 In brief, gene therapy is the insertion of a functional gene into a patient whose defective gene causes a specific disease. While the entire process may be claimed in the U.S., the patentable subject matter is a question under ethical debate in Europe, although the process is used as a method of medical treatment. GRUBB, supra note 1, at 243-44.

335 Chambers, supra note 283, at 231-32.


337 Chambers, supra note 283, at 226-27.

338 Id. at 230.


340 It is reported that, in Europe, from the early 1980s to the beginning of 1998, many patent applications, totaling up to 15,000, had been filed for biotechnological inventions. Of these applications, a considerable number of cases are relevant to genetic engineering, transgenic plants and animals, and human DNA sequences for the purpose of medical treatment. Gitter, supra note 11, at 5.

341 The EPC art. 52(4), supra note 212.
of which would be contrary to "ordre public" or "morality,"342 and "plant or animal varieties or essentially biological processes for the production of plants or animals"343 shall not be patented. Although the concept of "ordre public" still remains uncertain, EPC's adoption of this morality requirement has been said to have significantly influenced the development of European patent law concerning these kinds of biotechnological inventions.344

In interpreting the meaning of "ordre public" or "morality" in the context of the patent application for a transgenic mouse named the "Harvard Onco-mouse," which was genetically engineered to have an oncogene in its genome,345 the Examining Division of the European Patent Organization (EPO), employing the balancing test suggested by the Technical Board of the EPO, decided that "the invention's usefulness to mankind outweighed animal suffering and risks to the environment."346 Accordingly, we can find that the EPO has already adopted environmental factors in applying patents to modern biotechnology, particularly in patenting higher life forms. Since then, the EPO has defined the notion of "ordre public" as covering environmental protection as well as protections of public security and the physical integrity of individuals. Therefore, under the EPO, inventions which are likely to involve serious prejudice, the environment would violate the "ordre public" requirement.347

The European Directive348 was prepared to harmonize European patent policy so as to ensure a competitive advantage in the field of biotechnology and establish a standardized guide for patenting modern biotechnological products.349 Compared to the

342 Id. art. 53(a) (emphasis added).

343 This exception, however, does not apply to "microbiological processes or the products thereof." See id. art. 53(b).


345 See supra note 333.

346 Chambers, supra note 283, at 235.

347 However, the EPO emphasized the necessity of sufficient substantiation of the prejudice to the environment. Cynthia M. Ho, Splicing Morality and Patent Law: Issues Arising From Mixing Mice and Men, 2 WASH. U. J.L. & POL'Y 247, 267 (2000).

348 For more details concerning the history of its enactment, see generally Gitter, supra note 11, at 9-13.

349 Chambers, supra note 283, at 236-37. "Fearing that the United States would
former EPC, the directive more specifically enumerates exceptions to patentability of biotechnological inventions with stricter ethical aspects. Under the directive, "plant and animal varieties" and "essentially biological processes for the production of plants or animals" are not patentable. The human body, its elements, and the sequence of a gene cannot constitute patentable inventions, but an isolated element from the human body falls within patent protection. In addition, when the commercial exploitation of the inventions is contrary to "ordre public" or morality, the inventions are excluded from patent protection. This "ordre public" or morality requirement further applies to the following instances:

(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;
(c) uses of human embryos for industrial or commercial purposes;
(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Obviously the ethical and moral standards in the European Directive are the most controversial and remain uncertain. Moreover, vagueness in interpretation of the terms may impede the directive's objectives: harmonized and appropriate protection consolidate its lead in the biotechnological field... [t]he Directive is expected to guarantee legal uniformity and certainty in providing patent protection for biotechnological inventions." Spranger, supra note 299, at 235-56. The directive is designed for effective and harmonized patent protection for biotechnological inventions and takes into account the ethical dimension in granting patent on the inventions. Gitter, supra note 11, at 1-2.

350 European Directive art. 4.1(a), supra note 213.
351 Id. art. 4.1(b).
352 Id. art. 5.1.
353 Id. art. 5.2.
354 Id. art. 6.1.
355 Id. art. 6.2.
356 "Germ line" is defined as "the sequence of cells in the line of direct descent from zygote to gamete (egg or sperm), as opposed to somatic cells (all other cells in the body)." Chambers, supra note 283, at 237 n.114.
of biotechnological inventions. Although the present European Directive is, on the one hand, criticized in that "it fails to expel ethical considerations from patent law," sustainable development-relevant factors within the biological diversity and equity contexts should necessarily be taken into consideration in interpretation and application of the provisions. Further, Article 6.2 of the directive enumerates exclusions from patentability.

3. Operation of the TRIPs Agreement Provisions

Under the TRIPs Agreement, which was established to harmonize and strengthen international intellectual property protection, all kinds of technological inventions that meet general conditions for patent should be broadly protected with the following types of exceptions:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.

Of these exceptions, from the perspective of sustainable

357 Gitter, supra note 11, at 2-4.
358 Spranger, supra note 299, at 249.
359 Gitter, supra note 11, at 16.
360 Cripps, supra note 1, at 131.
361 TRIPS Agreement art. 27.1, supra note 137.
362 ld. art. 27.2.
363 Id. art. 27.3.
development, protection of "ordre public or morality"\textsuperscript{364} including protection of "human, animal or plant life or health"\textsuperscript{365} or avoidance of "serious prejudice to the environment"\textsuperscript{366} deserves special attention. These words, according to their ordinary meanings, which should be the basis of a general rule of treaty interpretation,\textsuperscript{367} can be interpreted to have environment-relevant implications.\textsuperscript{368} In particular, this provision, in contrast to the EPC

\begin{enumerate}
\item \textit{Id.} art. 27.2.
\item \textit{Id.}
\item \textit{Id.}
\end{enumerate}

\textsuperscript{364} \textit{Id.} art. 27.2.
\textsuperscript{365} \textit{Id.}
\textsuperscript{366} \textit{Id.}

\textsuperscript{368} The GATT 1994 art. XX provides similar provisions read as follows:

\begin{enumerate}
\item Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: . . .
\item (b) necessary to protect human, animal or plant life or health; . . .
\item (g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption; . . .
\end{enumerate}

GATT 1994 art. XX, \textit{supra} note 172.

Although these provisions do not apparently include the term "environment" anywhere, these provisions have been regarded as environmental protection-relevant provisions. See Andreas R. Ziegler, \textit{WTO Rules Supporting Environmental Protection}, in \textit{INTERNATIONAL ECONOMIC LAW WITH A HUMAN FACE} 203, 210-11 (Friedl Weiss et al. eds., 1998). In practice, in many environment-related trade disputes of the GATT and WTO, these provisions have been directly invoked by the parties. See, e.g., Report of
and European Directive, by addition of protecting "human, animal or plant life or health" and avoiding "serious prejudice to the environment" as examples of "ordre public or morality," can be deemed to make a meaningful step forward in taking account of environment-relevant factors. It is unquestionable that biological diversity mainly concerns both protecting "human, animal or plant life or health" and avoiding "serious prejudice to the environment."

Therefore, although the exact meaning and scope of the words still leave room for more definite interpretations, sustainable development-relevant factors should be fully reflected in the future interpretation and application of this provision for patenting biotechnological inventions. This approach will be more compatible with the WTO panels and Appellate Body rulings, as well as with the WTO Agreement, which evidently recognize sustainable development as an objective of the WTO legal system and a principle of evolutionary interpretation in international law in light of the recent revolution of modern biotechnology.

D. Access to Genetic Resources and Technology

1. Access to Genetic Resources

One of the old arguments relating to biotechnology concerns equity between developed and developing worlds and access to

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369 TRIPS Agreement art. 27.2, supra note 137.
370 Id.
371 Id.
372 Id.
373 Id.
374 See generally supra Chapter 3, Part I of this thesis.
375 See generally supra Chapter 3, Part II of this thesis.
biotechnology or technology transfer. This issue has been generally raised by developing countries, most of which are biologically rich or gene abundant countries, as a "quid pro quo" for access to their genetic resources.\(^{376}\) In principle, states have sovereign and exclusive rights over natural resources, at least within their territories. This principle of "sovereignty of states over their own natural resources" is favorably upheld by general rules of international law. Several international instruments declare this principle as "a valid norm of international law."\(^{377}\) However, the problem of the legal status of indigenous biological resources, over which the local community has sovereign rights, remains unsettled. Are these resources international common heritage or can the concept of biopiracy be applied to these resources? Can biological samples deposited in gene banks or under private control be available for public access?

Although the question of whether the meaning of natural resources in international legal provisions includes biological or genetic resources is uncertain, they have to be treated as natural resources under the evolutionary interpretation of biotechnology and sustainable development in light of developments of modern biotechnology.\(^{378}\) Furthermore, it is pointed out that, in general, states' rights over biological or genetic resources are not restrained under existing international legal rules.\(^{379}\) The Rio Declaration also recognizes both the sovereign authority of countries over natural resources within their territories and their obligations to prevent transboundary damage to the environment.\(^{380}\)

Access to biological resources associated with the notion of


\(^{377}\) See BROWNLIE, *supra* note 104, at 542-46; see also Ntambirweki, *supra* note 376, at 108-09.

\(^{378}\) Contrary to the case of natural resources, there is an argument that genetic resources have an intrinsic attribute of a common heritage of mankind by which any exclusive or sovereign right is denied, consequently to which every member in the world can have access with certain restrictions in international law. However, this claim is pointed out to conflict with the doctrine of sovereignty over natural resources and the UPOV under which breeders of new varieties of plants are protected. Ntambirweki, *supra* note 376, at 110-13.

\(^{379}\) Id. at 108.

sovereign rights over resources, as well as technology transfer, is a very controversial issue in relation to balancing biotechnology concerns. Both developed and developing countries’ attention to the significance of access to genetic resources in light of recently accelerated biotechnological advances and the enhancement of legal protections in the field of living organisms resulted in the establishment of the CBD. The CBD tried to compromise the issues of access to resources and technology transfer, sovereignty over biological resources, conserving biodiversity, and state responsibility to conserve and utilize biological resources in a sustainable manner. Under the CBD, conservation of biological diversity is “a common concern of humankind” and states have an obligation for conservation and sustainable utilization of their resources.

Despite the fact that the relevant provisions still remain vague, there lacks a sufficient device assuring practical implementation, as the CBD declares sovereign rights over genetic resources within their jurisdiction, and requires fair and equitable sharing of profits derived from the exploitation of resources. In fact, strengthening developed countries’ access to genetic resources and extending intellectual property rights for biodiversity will likely limit developing countries’ access to those resources. The CBD, affirming that biodiversity is a sovereign national resource and that profits arising out of biodiversity and technology should be shared with the source country, seeks to negotiate conflicting interests between developing and developed countries. Agenda

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381 Ntambirweki, supra note 376, at 117.
382 WATAL, supra note 1, at 172.
383 See CBD Preamble, arts. 15, 16, supra note 198.
384 See CBD Preamble, supra note 198.
385 WATAL, supra note 1, at 172. “Reflecting the uncomfortable political deal which was struck in bringing the CBD to conclusion, the language of the CBD is unfortunately vague.” MACMILLAN, supra note 1, at 119-20.
386 See CBD arts. 3, 5, supra note 198. Article 3 specifically announces sovereign national right to exploit domestic biological resources. Id. art. 3
387 See id. arts. 1, 16. Article 1 specifically addresses the goals of conservation of biological diversity, sustainable use of its components, fair and equitable sharing of the benefits, and reciprocity between access to genetic resources and transfer of relevant technology. Id. art. 1.
388 Gollin & Laird, supra note 307, para. 7.
21 also requires equitable allotment of the benefits resulting from biotechnological development and commercial exploitation of genetic resources.\textsuperscript{389}

In the CBD, Article 15 governs the problem of access to genetic resources. It mandates that access to genetic resources should be conducted based on "mutual agreed terms"\textsuperscript{390} and "prior informed consent."\textsuperscript{391} And the results and benefits from utilization of the resources are required to be fairly and equitably shared with the country of origin of the resources, on mutually agreed terms.\textsuperscript{392} Although this precondition of mutuality may be a major contributor to making these provisions ineffective, it can help prevent unilateral expropriation.\textsuperscript{393} The CBD, however, deals with access to genetic resources as a "juxtaposition" against technology transfer requirements, including biotechnology.\textsuperscript{394}

In the case of the TRIPs Agreement, developing countries, which repeatedly argued that the GATT was not the proper forum to address intellectual property rights, did not actively participate in the process of negotiations. As a result, the developing countries are now seeking to actively take part in future review procedures of the TRIPs Agreement and the CBD, having indicated that the TRIPs Agreement does not appropriately deal with the CBD's dual objectives of access to genetic resources and equitable sharing of benefits.\textsuperscript{395} Although tension between conservation and utilization (which are contradictory objectives), may be aggravated due to the recognition of national sovereignty over exploitation of genetic resources, facilitation of access to genetic resources, and preconditions of mutuality and prior informed consent,\textsuperscript{396} equitable sharing of benefits should be considered at least as a condition for conferring access to genetic

\textsuperscript{389} See generally Agenda 21, supra note 119.

\textsuperscript{390} Id. art. 15.4.

\textsuperscript{391} Id. art. 15.5.

\textsuperscript{392} CBD art. 15.7, supra note 198. In this context, however, what the terms "fair and equitable" mean is not certain mainly because mutual agreement is a precondition of these terms. WATAL, supra note 1, at 172.

\textsuperscript{393} MACMILLAN, supra note 1, at 120.

\textsuperscript{394} WATAL, supra note 1, at 172. See CBD art. 16, supra note 198.

\textsuperscript{395} MACMILLAN, supra note 1, at 129.

\textsuperscript{396} Id. at 121.
resources.

2. Technology Transfer

Modern technology, particularly biotechnology, can be a potential – or a critical – factor to both degrade and restore the environment, to say nothing of economic development. This means that easy access to environmentally sound technologies, including access to special finance plans, is developing into a critical point of sustainable development policy. In this respect, technology transfer consistent with sustainable development is increasingly becoming an important and persuasive policy objective. Consequently, an effective technology transfer scheme should be an integral part of conventions addressing sustainable development.

The issue of access to technology or technology transfer in the international intellectual property protection regime has been among the most crucial issues in relevant multilateral negotiations and legal instruments. In particular, the issue of technology transfer was discussed in relation to the concept of equity in global society and development of the developing world. Fair and favorable transfer of technology is an essential element in sustainable use of biological diversity and environmental protection, and providing and/or facilitating technology transfer is an obligation of contracting parties for the conservation and sustainable use of biological diversity and genetic resources. These requirements of access to and transfer of technology shall, of course, be consistent with the adequate and effective protection of intellectual property rights.

From the perspective of developing countries, agricultural biotechnology is one of the most significant components for their economic development as well as the general welfare of their populations. In particular, cutting edge agricultural biotechnology and its products, such as "Golden Rice," are
powerful engines that can help the developing world escape from fears of poverty and famine.\textsuperscript{401} Moreover, advanced agricultural biotechnology can play an important role for sustainable agricultural development. This mechanism can be functioned well with adequate intellectual property management systems.\textsuperscript{402} However, to the present, most agricultural biotechnologies, which have been subject to patent protection, have been in the hands of the private companies of developed countries, which have been shrinking from transferring their patented technologies to the developing world.\textsuperscript{403} Hence, a more harmonized patent system is needed not only to implement appropriate intellectual property protection, but also to facilitate technology transfer from the industrialized world to the underdeveloped world.\textsuperscript{404}

Additionally, in the field of genetic engineering of crops, so called "second generation transgenic crops" represented by "Golden Rice," which are known as "value-added innovations," have occupied an important position together with so called former "first generation transgenic crops."\textsuperscript{405} "Golden Rice," as a representative model of "value-added innovations," is a genetically engineered crop containing a higher percentage of vitamin A. It has a significant value in developing countries, most of which are suffering from chronic vitamin A deficiency.\textsuperscript{406} Therefore, it is necessary that this kind of modern biotechnology and its products should be effectively, efficiently, and equitably distributed and transferred from the developed world to the developing world for the general welfare of the global community. This strategy, however, can only be successfully implemented when it is based on mutual trust and an understanding of intellectual property protection and technology transfer, as well as ultimately reasonable harmonization of the patent systems of the

\textsuperscript{401} See id. at 51.
\textsuperscript{402} Id.
\textsuperscript{403} Id.
\textsuperscript{404} See generally id. at 47-50.
\textsuperscript{405} In comparison to the first generation, transgenic crops genetically engineered to contain herbicide tolerance, insect resistance, virus resistance, or fungi resistance, the second generation crops are genetically engineered to contain much more beneficial nutrition. "Golden Rice" containing a high percentage of vitamin A represents a model case of the second generation. Id. at 51.
\textsuperscript{406} See generally id. at 51-52.
In this respect, it should be noted that "[t]he genetic engineering of value-added nutritional quality into Golden Rice is a turning point both scientifically and in terms of international technology transfer." \(^{408}\)

More recently, technology transfer concerns have become an environmental issue since the United Nations Environment Programme (UNEP) started to approach the issue based on more practical purposes, which are conservation of the environment and equitable sharing of the burden to protect the environment. \(^{409}\) As a corollary concerning environmental protection, the antagonistic relationship between the North and South in environmental protection policies mostly stems from the claims that developing countries cannot implement the same commitments of MEAs as those of developed countries because of a lack of human, financial, and technical resources necessary for implementation of required obligations under those agreements. \(^{410}\) Addressing these allegations, many MEAs include provisions dealing with "transfer of environmentally sound technology," which require special commitments of developed countries to promote transferring environmentally sound technology to developing countries. \(^{411}\)

During the negotiations of the CBD, the relationship between access to biodiversity and technology transfer was emphasized as "two sides of the same coin," which were necessary to be discussed together. \(^{412}\) More specifically, it was insisted that a balance between the rights and interests of the owners of genetic resources and technology be recognized. \(^{413}\) In the process of the CBD negotiations, the necessity of transfer technology in utilizing biodiversity for human benefits was suggested as follows:

[T]he economic dimension including, inter alia, the question of adequate financial transfers from those who benefit from the

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407 See generally id. at 63-67.
408 See id. at 67.
409 Ntambirweki, supra note 376, at 114-16.
410 See id.
412 Ntambirweki, supra note 376, at 121.
413 Id.
exploitation of biological diversity, including through the use of
genetic resources in biotechnology development to the owners
and managers of biological resources and appropriate means to
facilitate the transfer of technical means of utilizing biological
diversity for human benefit . . . .

After the above-mentioned discussion, Agenda 21 recognized
the need of technology transfer in addition to protecting
intellectual property rights. The CBD's Article 16 adopts a
broad and general definition of "technologies that are relevant to
the conservation and sustainable use of biological diversity or
make use of genetic resources" instead of making reference to
specific technology. As a result, this provision can be
interpreted to include technology transfer aiming to both develop
biotechnological activities and conserve biological diversity.
However, it should be noted that the former kind of technology
transfer can cause conflict with intellectual property protection.

Under the CBD, issues of technology transfer and access to
genetic resources are linked closely together. The CBD
provides contracting parties an obligation to transfer technology,
which is relevant to conservation and sustainable use of biological
diversity without causing significant damage to the
environment. In particular, in the event of technology subject to
patents and other intellectual property rights, such access and
transfer should be provided consistently with the effective
protection of intellectual property rights.

414 Decision 15/34 of the Governing Council of the UNEP, Preparation of an
International Legal Instrument on the Biological Diversity of the Planet, May 25, 1989,
DocumentID=71&ArticleID=785.
415 See Agenda 21 ch. 34, supra note 119.
416 Verhoosel, supra note 411, at 56.
417 Id.
418 "Under Article 16 of the CBD, access to genetic resources is juxtaposed against
requirements on the transfer of technology, including biotechnology." WATAL, supra
note 1, at 172. Both access to and transfer of technology are "essential elements for the
attainment of the objectives of this Convention" that must be fairly and favorably
provided and facilitated on a reciprocal basis. See generally CBD art. 16, supra note
198.
419 See CBD art. 16.1, supra note 198.
420 See id. art. 16.2.
Developing countries, possessing ample genetic resources, should be supplied with the technology necessary to use those resources. Each contracting party shall take measures to encourage the private sector to facilitate technology transfer for the profit of both the private sector and governmental institutions in developing countries. The contracting parties, however, recognizing that patents and other intellectual property rights may have an influence on the implementation of the CBD, have obligations to cooperate, subject to national and international laws, in order to ensure that such rights are supportive and do not run counter to the objectives of the CBD. The fact that Article 16 of the CBD attempts to reconcile the contradictory interests of both developing and developed countries predicts the difficulties in the future negotiations.

The TRIPs Agreement lightly touches the technology transfer issue, only recognizing the need for technical cooperation. Similarly, the TRIPs Agreement, by requiring developed member countries to provide incentives to their enterprises and institutions to promote and encourage transfer of technology to least-developed country members so as to enable them to create a sound and viable technological base, takes a somewhat indirect attitude. However, when considering that the basic objectives and principles of intellectual property protection are promotions of not only technological innovation but also international technology transfer, more attention should be paid to the interests of technology transfer.

To conclude, when considering the means to sustainable growth, technology transfer will be one of the critical issues in international environmental law in the future. Thus, the issue of technology transfer needs to be treated in both the contexts of

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421 See id. art. 16.3.
422 See id. art. 16.4.
423 See id. art. 16.5.
424 See WATAL, supra note 1, at 172-73.
425 See TRIPS Agreement art. 67, supra note 137.
426 Id. art. 66.2.
427 ARUP, supra note 1, at 244.
reducing poverty in the developing world and sustainable development of a global environment system. However, although the term "technology transfer" is not a new item on the international agenda, but instead is one of the old businesses in international relations, the vagueness of its definition has led to ineffective commitments relating to technology transfer.\footnote{Verhoosel, supra note 411, at 49, 51.}

Therefore, a reasonable compromise between access to genetic resources and technology transfer should be sought on the basis of appropriate protection of intellectual property rights of biotechnology. At the same time, intellectual property rights should not be barriers to the transfer of environmentally sound technology required to promote sustainable development. A patent system for biotechnology should be a further stimulus to research, development, innovation, diffusion, and transfer of new technologies. Future plans for intellectual property protection must be compatible with more enhanced scheme for transfer of environmentally sound technologies.

\section*{E. Indigenous Knowledge and Biopiracy}

\subsection*{1. Protection of Indigenous Culture}

From the perspective of biodiversity with relation to sustainable development, it is insisted that indigenous peoples, in general, have the rights "to control their land and the natural resources on those lands" and "to control and receive benefits from the dissemination and use of their knowledge."\footnote{Gollin & Laird, supra note 307, para. 33.} Therefore, it should not be disregarded that indigenous peoples play a significant role in promoting biodiversity, and their traditional knowledge must be protected as a result of their intellectually creative activities.\footnote{\textit{Id.}} Although it is pointed out that intellectual property protection of indigenous knowledge and biological resources may have potential dangers, such as keeping technology out of the public domain, increasing costs of technologies, creating monopolies, and making it difficult to grant patents to inventions involving living organisms, medical therapeutics, traditional knowledge, etc., it is also true that intellectual property rights for

\footnotesize{\begin{itemize}
  \item \footnote{Verhoosel, supra note 411, at 49, 51.}
  \item \footnote{Gollin & Laird, supra note 307, para. 33.}
  \item \footnote{\textit{Id.}}
\end{itemize}}
them can be an effective engine to propel utilization of biological materials. Consequently, national as well as international intellectual property laws should be adequate legal tools to promote biodiversity.\textsuperscript{432}

Conventional practices and traditional knowledge of farming and conservation activities, which succeeded for generations in a sustainable manner, and preserving and expanding the gene pool, may be imperative elements for "long-term food security" and, ultimately, "long-term survival."\textsuperscript{433} Transcended plant and animal varieties and traditional information of them within a community should be respected as a treasure-house: a natural reservoir of genetic resources.\textsuperscript{434} As a matter of fact, without appropriate protection of this traditional knowledge and localized genetic materials, neither legitimate protection of intellectual property for biotechnology nor balancing interests can be expected.\textsuperscript{435} Nevertheless, to the present, due attention has not yet been paid to the role and protection of these rural and traditional cultures.\textsuperscript{436}

Studying, experimenting, commercially exploiting, and elsewhere patenting a biological sample obtained from gene-rich developing countries can remove the new invention from the public domain. As a result, this application precludes indigenous farmers from using existing species or practicing traditional agricultural methods. Hence, patents on this kind of material or information should be properly and restrictively issued to cover only the new aspects of an invention in order to prevent monopoly of the creation, and to leave the prior materials in the public domain as much as possible.\textsuperscript{437} The patent system applied to such cases, therefore, should take into sufficient account special compensation for indigenous peoples' contribution to sustaining genetic resources which may have spiritual, traditional, and customary meanings to them.\textsuperscript{438}

At the international level, there have already been efforts to

\textsuperscript{432} See id. paras. 41-44.
\textsuperscript{433} Cottier, supra note 18, at 558.
\textsuperscript{434} ARUP, supra note 1, at 223.
\textsuperscript{435} Cottier, supra note 18, at 563.
\textsuperscript{436} Id. at 560.
\textsuperscript{437} Gollin & Laird, supra note 307, para. 56.
\textsuperscript{438} ARUP, supra note 1, at 223.
protect traditional knowledge and intellectual creations of indigenous peoples. These include recognition of property rights for flora and fauna and a moratorium or prohibition on commercial utilization of biogenetic resources without indigenous peoples' consent. In addition, there are cases in national courts concerning protection of traditional resources, which are assessed to have a significant implication, particularly in protecting the residences of indigenous peoples. Traditional notions of legal protection in both the fields of resource allocation and traditional knowledge, however, require review.

Of the existing legal regimes that can be used to protect indigenous peoples' interests, both environmental and intellectual property laws are the most relevant. However, the existing intellectual property legal system is deemed to be inadequate for protecting traditional (or "existing") knowledge since patent rights are generally granted to "novel" creations. Thus, protection of indigenous peoples' traditional knowledge and their creativity must be sufficiently taken into consideration in future negotiations for reforming international intellectual property protection of biotechnology.

To date, some international declarations have dealt with issues of indigenous property rights, yet most of them have allegedly acquired a position of "soft law." The Rio Declaration obviously recognized that indigenous peoples and communities, and their traditional knowledge and practices have an essential role in both contexts of environmental management and development. Agenda 21 tried to protect indigenous and traditional knowledge, arguably by some kind of intellectual property rights. Under Agenda 21, member states are directed to adopt national policies and laws with aims to protect indigenous

439 Gollin & Laird, supra note 307, para. 56.
440 Id. para. 30.
441 Cottier, supra note 18, at 568.
442 Id. at 560.
443 Gollin & Laird, supra note 307, paras. 34-36.
444 ARUP, supra note 1, at 245.
445 See The Rio Declaration, Principle 22, supra note 118, at 880.
446 See Agenda 21 ch. 26, supra note 119.
447 Gollin & Laird, supra note 307, para. 16.
intellectual and cultural property.\textsuperscript{448} More specifically, Agenda 21, emphasizing the relationship between indigenous peoples and their lands,\textsuperscript{449} asks for establishment of national processes to strengthen indigenous and traditional knowledge to promote and ensure environmentally sound and sustainable development.\textsuperscript{450}

The CBD, which is probably the most important international legal instrument concerning indigenous knowledge issues, shows the difficulties in managing this problem.\textsuperscript{451} The CBD, on the one hand recognizes the intimate relations between indigenous communities and their biological resources, and the equitable sharing of benefits arising from the use of traditional knowledge relevant to the conservation and sustainable use of components of biodiversity.\textsuperscript{452} On the other hand, it directs each contracting party to respect, preserve, and maintain indigenous knowledge relevant to the conservation and sustainable use of biological diversity.\textsuperscript{453}

Additionally, like the case of traditional knowledge, rights over traditional resources and innovations in the fields of agriculture and pharmaceuticals relating to genetic engineering probably have a significant meaning in the international trading system. Consequently, protection of them will also be closely related to the WTO legal system.\textsuperscript{454} Therefore, present trade rules, as well as intellectual property rules, should be rebuilt to promote sustainable use of diverse biological resources by allowing the indigenous people and national governments of biologically rich countries to be granted a certain amount of intellectual property protection and economic benefits for their optimal use of the genetic resources, traditional knowledge, and indigenous culture to conserve "biodiverse ecosystems."\textsuperscript{455} The future TRIPs Agreement negotiations should therefore take into full consideration the issue of protection of indigenous knowledge in the field of genetic engineering, as well as genetic resources in the

\textsuperscript{448} See Agenda 21 ch. 26, supra note 119.
\textsuperscript{449} MACMILLAN, supra note 1, at 127.
\textsuperscript{450} See Agenda 21 ch. 26.3(a), supra note 119.
\textsuperscript{451} ARUP, supra note 1, at 245.
\textsuperscript{452} See CBD Preamble, supra note 198.
\textsuperscript{453} See id. art. 8(j).
\textsuperscript{454} Cottier, supra note 18, at 581-82.
\textsuperscript{455} Schultz, supra note 131, at 436-37.
2. Prevention of Biopiracy

Very frequently, imprudent biopiracy by the developed world purely for economic benefits may result in deterioration of biodiversity and infringement of indigenous peoples’ rights in developing and the least developed countries. For example, the U.S. and Japanese companies’ patents on a number of useful products extracted from the “neem tree,” an Indian plant which has versatile medical and agricultural usefulness,\(^{457}\) led to monopolized massive consumption of neem seed by a limited number of corporations and wealthy people in developed countries.\(^{458}\) This exclusive exploitation by a small number of companies fanned price increases of the seed that local users cannot afford, and ultimately made it possible for companies holding patents to control access to and use of the neem tree.\(^{459}\)

In fact, it is rather ironic that “property-rich” countries’ piracy of “gene-rich” countries’ traditional properties is likely to occur more frequently.\(^{460}\) Another interesting example of this so called “biocolonialism” may be the case of “African Soapberry” which

\(^{456}\) See generally Cottier, supra note 18, at 556, 581-84.
\(^{457}\) Traditionally, its bark, flowers, seeds, and fruit have been used as various medicines, branches as an antiseptic toothbrush, oil as an ingredient in toothpaste and soap, and residue as a potent insecticide against locusts, nematodes, mosquito larvae, boll weevils, and beetles. Aoki, supra note 251, at 51.
\(^{458}\) In October 1993, the Indian farmers who had used neem seed in their traditional farming communities severely protested against and objected to patenting neem seed. See id. at 53.
\(^{459}\) Id. at 51-52.
\(^{460}\) “[I]nvaluable biological and cultural resources flowing out of the countries of the South as ‘raw material’ into the developed nations of the North where there are magically transformed in the laboratories of pharmaceutical and agricultural corporations into protected intellectual properties whose value is underwritten by provisions of multilateral agreements such as TRIPs.” Id. at 49. This phenomenon has been straightforwardly demonstrated in the following testimony:

The United States has accused the Third World of piracy. The estimates for royalties lost are $202 million per year for agricultural chemicals and $2.5 billion annually for pharmaceuticals. . . . However if the contributions of Third World peasants and tribespeople are taken into account, the roles are dramatically reversed: the United States would owe Third World countries $302 million in agriculture royalties and $5.1 billion for pharmaceuticals.

has for generations been used as insecticide and fish intoxicant. An Ethiopian researcher found that the African Soapberry had effective toxicity to kill water-snails carrying the disease bilharzia. However, the original discoverer and reporter in the resource country was never rewarded for his discovery after an English institute patented an extraction process to produce commercial material to kill zebra mussels that clog North American waterways.\(^{461}\)

If just the discoverers of traditionally recognized species are compensated for their discoveries, indigenous peoples’ rights can be easily infringed and the profits from discovered species will be mainly devoted to outsiders’ pockets. Consequently, rewarding discoverers can contradict the idea of biodiversity conservation and equitable sharing of benefits.\(^{462}\) Recently, developing countries faced with this kind of biopiracy by private companies have attempted to pass legislation to protect their indigenous biological resources.\(^{463}\)

Under the existing international legal “regime,” this practice of biopiracy is inevitably adverse to traditional farming systems and environmental conservation.\(^{464}\) The current legal system cannot defend against daily-occurring biopiracy or the unfair activities of biotechnology companies pirating genetic resources, patenting them, and monopolizing the benefits which originally belong to indigenous communities. For example, according to the TRIPs Agreement, Indian original basmati rice on which U.S. companies hold patent rights cannot be exported from India or Pakistan. Consequently, Indian local farmers’ market interests are denied.\(^{465}\)

Biopiracy can also be applied to human beings in relation to modern biotechnological developments. After granting patents to genetically engineered oil-eating bacteria\(^{466}\) and to genetically

\(^{461}\) Aoki, supra note 251, at 52.


\(^{463}\) See generally Aoki, supra note 251, at 50-51.


\(^{465}\) Id. at 134.

\(^{466}\) See supra note 331 and accompanying text.
modified mice, there is a question of whether genetically engineered humans or human parts can be patented. The U.S. attempt to patent a cultivated cell line from the blood of a woman of the Guayami tribe in Panama caused global repercussions. In the early 1990s, U.S. researchers cultivated a cell line from blood samples of a woman infected with hairy-cell leukemia which was widespread among the tribe, and applied for a patent on it. As a result, the European Parliament began to ban patenting life-forms, and all strata of society, particularly the press, religious world, and indigenous communities, sharply opposed the grant of a patent.

Additionally, in the contexts of public health and sustainable development of humans, the developed world's interests in the exclusive exploitation of traditional medicinal resources can represent a type of biopiracy. Also, modernized use of indigenous medicines by pharmaceutical companies in developed countries can be a critical obstacle to easy access to traditional medicine because of a rise in costs due to intellectual property protection.

As illustrated in the above cases, allowing this kind of biopiracy will oppose international cooperations for sustainable development. Application of intellectual property rights to traditional cultures does not fit because in those communities traditional knowledge is shared among all of their members. Therefore, genetic resources and grassroots innovations in the developing world should be legitimately respected and protected. Indigenous people have to be compensated and rewarded for their supplies of biological resources. An intellectual property protection scheme incorporating just remuneration for indigenous knowledge will thus help promote sustainable development.

F. Breeders' and Farmers' Rights

Plant breeders' rights over new sexually reproduced plant varieties have a significant role in promoting biodiversity because

467 See supra note 333.
468 Aoki, supra note 251, at 52-53.
469 Id.
471 Cripps, supra note 1, at 129.
472 Id.
a wild variety locally bred for several generations can be protected by these rights.\textsuperscript{473} This kind of variety is primarily subject to UPOV, and exclusive rights may be granted to a breeder who breeds a novel, distinct, uniform, and stable plant variety.\textsuperscript{474} UPOV, which was recently revised in 1991, concerns protection of plant breeders’ rights. It tends to reinforce the protection of breeders’ rights following the current international trend of strengthening intellectual property protection.\textsuperscript{475} Therefore, the recently revised UPOV strengthens the breeder’s rights over access to resources.\textsuperscript{476}

Under UPOV, “breeder” means “the person who bred, or discovered and developed, a variety.”\textsuperscript{477} When the variety is “new, distinct, uniform and stable,” breeders can claim breeders’ rights. Similarly, the TRIPs Agreement requires member countries to provide protection for plant varieties by patents. However, more adequate principles of international norms are needed to effectively regulate these issues.\textsuperscript{479}

UPOV has made an effort to balance owners’ rights and the need to provide access to the varieties. In addition, the UPOV system has offered a positive incentive to the breeders who have been left out by patent protection, which mainly focuses on high technologies.\textsuperscript{480} A plant variety must meet the requirements of being distinct, homogenous, and stable in order to be protected. These requirements mean that a new plant variety has to be sustainable for generations as well as different from existing plant species.\textsuperscript{481} Plant breeders’ rights, therefore, may, in part, contribute to the promotion of biological diversity.

Historically, the notion of farmers’ rights has stemmed from attempts to recognize their rights arising from their contributions

\textsuperscript{473} Gollin & Laird, supra note 307, para. 57.
\textsuperscript{474} See UPOV art. 5(1), supra note 203.
\textsuperscript{475} Ntambirweki, supra note 376, at 120.
\textsuperscript{476} ARUP, supra note 1, at 236.
\textsuperscript{477} UPOV art. 1(iv), supra note 203.
\textsuperscript{478} Id. art. 5(1).
\textsuperscript{479} Protection by an effective sui generis system is also allowed. See TRIPS Agreement art. 27.3(b), supra note 137.
\textsuperscript{480} ARUP, supra note 1, at 234-35.
\textsuperscript{481} Id. at 235.
to conservation, improvement, and utilization of plant genetic resources.\footnote{482} It particularly focuses on promoting more equitable relations between the parties\footnote{483} in addition to the farmers' rights of using plant genetic resources and gaining profits from the use.\footnote{484} Farmers who have played an important role in developing genetic resources over generations should be given proper reward for their contribution. In fact, profits as well as responsibility concerning the conservation and exploitation of genetic materials, in the sense of sustainable development, should be equitably shared in global society. Recognition of farmers' rights can help achieve this policy goal through the sustainable use and improvement of genetic resources.\footnote{485}

As developing countries generally argue, their farmers, who have traditionally discovered, cultivated, and bred plant varieties for generations based on genetic materials in their territories, have priority over such genetic resources. Further, there is no just rationale for allowing developed countries' free access to the genetic materials without any payment to the farmers.\footnote{486} The CBD does not specifically articulate farmers' rights or considerations for collaboratively innovated plant varieties in a local community. Instead, member countries can autonomously establish their own legal framework regarding the problem.\footnote{487} However, as of now, no agreement has existed to enforce compensation for farmers and finance it in spite of the general acceptance of the concept.\footnote{488}

V. Conclusion

Sustainable development is not a simple goal, but is and should be a real normative objective in the modern context of the

\footnote{482} See, e.g., Annex II, Res. 3/91, 25th Sess. of the FAO Conference, Rome, 11-29, Nov. 1989. "The concept . . . was formulated . . . as a basis for recognizing and rewarding the contribution of farmers to the conservation and management of plant genetic resources." See also MACMILLAN, supra note 1, at 126.

\footnote{483} MACMILLAN, supra note 1, at 126.

\footnote{484} Cottier, supra note 18, at 564-65.

\footnote{485} For this function of farmers' rights, see generally Ntambirweki, supra note 376, at 112.

\footnote{486} Ntambirweki, supra note 376, at 111-12.

\footnote{487} WATAL, supra note 1, at 173.

\footnote{488} MACMILLAN, supra note 1, at 127.
new biotechnological millennium. From the perspective of the modern biotechnological revolution, sustainable development needs to be redefined to include all relevant factors: sustainability in agriculture and human genetic resources, promotion of biological diversity and equity between parties, and balancing between intellectual property protection of biotechnological inventions and sustainable development. This restatement should be based on an evolutionary interpretation in light of modern biotechnological development. In this respect, a more evolutionary interpretation of and approach to biotechnology and sustainable development, which incorporates all factors relevant to sustainable development in light of recent biotechnological revolution, is needed.

The evolutionary interpretation supplemented by modern biological science urges us to include renewable living species or resources, such as genetic resources in the human body, as well as biological resources in the ecosystem, into exhaustible natural resources to be protected under existing international laws. Therefore, intellectual property protection of biotechnology should further take into account the conservation of biodiversity of all kinds of natural resources, including human genetic resources. Moreover, in light of recent innovations of biotechnology, steady and long-term endeavours in order to interpret and apply the existing relevant norms to encompass the concept of sustainable development, which is based on both sustainable development of agriculture and sustainable use of human genetic resources, should be made.

In the case of genetic modification of human beings, more careful and special attention needs to be paid. In particular, it should be noted that human cloning for the purpose of artificial selection or adaptation of human genes may bring an unexpected

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489 The concept of sustainable development has always been ill defined, some would say empty, but there has been consensus about its context. It has been assumed that the topic is confined to agriculture . . . . [T]he rapid development of the technologies of genetic modification and cloning and the patenting of genetically modified animals, human gene sequences, and stem cells impel us to consider the concept of sustainable development in novel contexts that include the cloning of creatures and embryonic stem cells for use as spare parts.

Cripps, supra note 1, at 133.
long-term disaster to human society caused by mono-genetics. Consequently, genetic manipulation of human beings, which could result in reckless genetic uniformity of the human species, must be strictly regulated and controlled in both the domestic and transnational legal systems. In light of irreparable harm to the sustainability of human society, an international legal consensus to regulate human cloning technologies should be quickly established because elimination of cultural as well as physical diversity in human society resulting from the monoculture of humanity will be contrary to the sustainable development of human beings.

Intellectual property protection of biotechnology – more specifically speaking, patenting biotechnology – should be understood in the novel contexts of sustainable development in which protection of biodiversity and equitable sharing of benefits are equally incorporated. Thus, whether it would be national or international law, intellectual property protection laws of biotechnology must be more favorable to the harmonization of an integral triad of policies: conservation of biological diversity, assurance of equitable sharing of profits, and sustainable development. These legal regimes should also cover not only all components of the global environmental ecosystem, but also social concerns, including ethics, morality, public health, etc. However, the political function of intellectual property protection providing economic or commercial incentives for legitimate exploitation of biotechnological innovations should not be ignored. This premise may help draw a line of equilibrium between development and conservation.

Indeed, when contemplating desirable uses of global biological resources in a sustainable manner, a generally accepted definition of sustainable development in global society is needed. In this respect, in addition to biodiversity, equity should be given priority in sustainable development concerns because this approach can secure greater approval from more members of the global community. Therefore, equity issues surrounding intellectual property protection of biotechnology must seek to balance interests between present and future generations, providers and users of the biotechnological inventions in question, and developing and developed countries. This is the very reason why patenting biotechnology should take into consideration the promotion of biodiversity, patentable subject matter, access to
genetic resources, technology transfer, and protection of indigenous knowledge. To achieve all of these policy objectives, the patent system of biotechnology should also be compatible with the goals of conservation, sustainable use, and equitable sharing of the benefits of biodiversity.

To promote biological diversity, first of all, the patentable subject matter of biotechnological inventions, which can decide the basic scope and direction of biotechnological applications, should be interpreted and applied in a sustainable manner. On this point, in particular, the "ordre public" or morality requirement, including protection of "human, animal or plant life or health" and prevention of "prejudice to the environment" contained in existing national or international norms, should be fully reflected in granting patents to biotechnological inventions. More specifically, patentable subject matter provisions must be interpreted to include environmentally sound technologies but exclude environmentally unfriendly technologies from patentable technologies. Hence, the patent system, through patentable subject matter provisions, should perform its substantial function to distinguish environmentally unfriendly technologies from environmentally friendly ones.

In addition to the protection of biodiversity, sustainable development in modern contexts requires balancing interests between the parties. Therefore, benefits from the global biological resources and exploitation of them should be equitably shared between providers and users of the resources. In particular, legal programs for more effective access to genetic resources and technology transfer should be an integral part of agreements regulating intellectual property protection of biotechnology. These schemes must also promote sustainable uses of biological diversity and genetic materials. This political strategy requires a harmonized patent system in the world, based on mutual trust and understanding regarding both appropriate intellectual property protection and technology transfer. At the same time, intellectual property rights should not be barriers to the technology transfer, which is required to promote the sustainable development as well as the reasonable access to biodiversity necessary for biotechnological advances.

More practically, in future discussions for reforming the international patent regime of biotechnology, sufficient incentives
to conserve indigenous biological resources and local culture in the source countries, which can contribute to promote sustainable development in global society, should be taken into account. Existing intellectual property legal systems, on both national and transnational levels, allowing biopiracy by the developed world to take the underdeveloped world’s traditional and biological resources and transform them into patented intellectual properties without just compensation for resource countries under the name of intellectual property rights, must be re-examined. In this regard, future negotiations for multilateral trading legal systems such as the TRIPs Agreement, as well as MEAs, have to seek consistency and harmony among obligations of technology transfer, rights of access to genetic resources, protection of indigenous knowledge, and protection of intellectual property rights to biotechnological inventions. In particular, this policy approach should aim to reduce the economic developmental gap between the North and the South, which is still a negative element for sustainable development in the global society.

As for uses of human genetic resources and human cloning technologies, the question of whether any trials to clone human beings violate human rights, degrade human dignity, impair human identity, or demote the sustainability of humanity should be repeatedly scrutinized by the global community. Particularly, human cloning for the purpose of reproducing human beings should be put under the consistent surveillance of international organizations, whether intergovernmental or nongovernmental.

In conclusion, future negotiations for intellectual property protection of biotechnology should be founded on a new policy approach for sustainable development integrating all kinds of concerns surrounding modern biotechnological innovations such as the environment, biodiversity, trade, agriculture, medicine, equity, and humanity. This integral approach will be applied to a triad of policies – trade, environment, and development – in future international trade negotiations. Both national and international regulations on biotechnology such as intellectual property laws, accompanying this political integration, should be an effective

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490 Gaines, supra note 134, at 10347.
491 Greenlee, supra note 261, at 554.
492 Gaines, supra note 134, at 10346.
policy tool to maximize social benefits, yet minimize social expenses, taking into account both profits and costs derived from intellectual property protection of biotechnology in the context of sustainable development.