Patents, plant diversity & protecting proprietary interests:

Can biotechnology be coextensive with biodiversity under the Rio Convention[1] ?

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1CONVENTION ON BIOLOGICAL DIVERSITY, Selected Documents of the United Nations, 22 Environmental Law and Policy 251, Vol.4 (1992).

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Medical literature is replete with examples of serendipitous phytochemical2-based wonder drugs. Multinational pharmaceutical companies have already begun to forge ethnobotanical "prospecting rights" agreements with nations in Latin America to access virgin germplasm.3 Perhaps of greater significance, albeit decidedly less glamorous, are longstanding international intellectual property disputes relative to food crops.

This is particularly true in light of our present ability to literally combine desired genetic sequences with existing organisms to form such agricultural products4 as the

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2 Phytochemistry is the study of the chemistry of plants. Phytochemicals, from Morphine (found in Papaver somniferum) at the turn of the Eighteenth Century to the contemporary super drug Vinblastine [Rosy periwinkle (Catharanthus roseus derived) - for Hodgkin's disease and pediatric leukemia] have been randomly derived from chemicals naturally occurring in plants.

3 Well known 'joint-ventures' include Merck & Company and the Costa Rican Government, and Shaman Pharmaceuticals and several nations in Latin and South America. SEE Kadidal, S. "Plants, Poverty and Pharmaceutical Patents", 103 THE YALE JOURNAL (No. 177) 223, 232 (1993).

See also Stevens, W.K. "Botanical Garden Joins Drug Company in Drug Search", N.Y.TIMES, September 21, 1993, C5. Pfizer Inc., and the New York Botanical Garden have a similar agreement for North American plants. Pfizer is putting up $2 million for the collection and screening of native plants of the United States for potentially valuable drug extracts.

4 "C. Manley Molpus, president of the Grocery Manufacturers of America ... predicted that over the next six years, some 50 genetically engineered products would be ready for market, including a variety of oils and salad dressing with less

by the FDA for marketing5, utilizes antisense codons to block the plant's own degenerative mechanisms. Having disabled the plant's own DNA's ability to produce enzymes which degrade tomatos ripened on the plant's vines - normal senescence patterns are arrested. This longer life cycle produces a tomato that has a higher commercial utility, and the potential to provide more food at a lower cost.

I. TECHNOLOGY, SCIENCE AND THE LAW

New developments in genetic engineering permit the creation of hybrid genetic sequences imparting unique functional characteristics useful in agriculture, pharmaceuticals, and biomedicine. Patenting technology incorporating new sources of materials, created through genetic engineering, has increased rapidly as the sources of genetic starting materials have rapidly diminished.6

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saturated fat; potatoes that absorb less fat when fried; grains with more protein; ; plants that require fewer pesticides and fertilizers; and foods that stay fresher longer."
McGinley, L. "U.S. Clears Calgene Tomato, the First Genetically Engineered Food to be Sold", THE WALL STREET JOURNAL, May 19, 1994, B8.

5 Id.

6 A prime example of this may be found in the field of corn genetics. During the 1970's Zea diploperennis, a wild 'land race' of corn was first discovered in Jalisco, Mexico. Studies proved it to be quite resistant to disease, and possessing perenial growth - a characteristic heretofore undiscovered in living corn. Domestic corns, such as the common Zea mays, could

innovation, it is essential to acknowledge an ongoing need to foster access to as many sources of genetic starting materials as possible. Generally, isolating genes is the first step in processes variously designed to replicate, disable, or fortify the genes and thus to impact upon characteristics encoded by the genes. Naturally occurring biological systems provide the source for genes which can often be manipulated across and between different species and even organisms in search of the desired results.

In specific, applied protein engineering involves the dissection and reassembly of biologically active proteins to yield hybrids which may have a multiplicity of useful and enabling applications. This technology, by necessity includes newly discovered proteins and modified variants based upon these originals. "Native proteins", or those which occur naturally within organisms, thus have become an essential starting material for the innovative process.

An underlying basis for the Convention on Biological Diversity of the United Nations Conference on Environment and Development, and its unique mandates concerning sustainable use

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be substantially approved with the addition of the Zea diploperennis genes. The plot of land on which Zea diploperennis was found to exclusively exist comprised less than 25 acres. The area was in the final stages of a slash and burn-type agriculture. Plainly, any delay in discovering Zea diploperennis may have resulted in its extinction, and the permanent loss of its genes. Wilson, E.O. THE DIVERSITY OF LIFE, The Belknap Press of Harvard University Press (Cambridge, 1992), page 281.

degradation of resources has to occur with exploitation of germplasm, as it necessarily does with depletable natural resources, owing to the fact that one seed contains the entire genetic code of a native strain in replicable form.7 This characteristic is essential in understanding the establishment of intellectual property rights in genetic material, and the relationship between biotechnology and biodiversity.

A plurality of factors have figured into the ongoing loss of biodiversity, which now leads experts to opine that greater than 27,000 species of flora and fauna are being irretrievably lost each year.8 Biodiversity is an important part of the resource base of our planet. It is only recently that it has begun to be appreciated, although it has been an object of study in fields such as evolutionary biology and related disciplines for years. Three principal causes of this situation which are generally accepted include direct overexploitation, poverty, and warfaring.9

It is likewise the consensus of experts that the extent genetic and molecular basis of existing organisms has taken

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7 SEE Kadidal, S., "Plants, Poverty, and Pharmaceutical Patents", 103 THE YALE LAW JOURNAL (No. 177) 223, 229 (1993).

8 "The Biodiversity Crisis and its Causes", remarks of Cracraft, J.L, Ornithology Department Curator, Acting Director of the Center for Biodiversity and Conservation, Department of Education, AMERICAN MUSEUM OF NATURAL HISTORY, New York, New York, May 12, 1994.

9 Id., at page 238.

billions of years to create. In other words, creation of today's evolutionarily advanced levels of organization of species is not replicable. This is to say that the generation of "...biological diversity takes long stretches of geologic time and the accumulation of large reservoirs of unique genes."10

A global biodiversity strategy has recently been generated which is finally responsible for the first mention of preservation of genetic diversity in a binding international treaty.11 By 94/03/23, 53 nations had ratified the Convention on Biological Diversity.

II. PREFATORY REMARKS

At the Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity, "Biological Diversity" was defined as "the variability among living organisms from all sources, including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are a part; this includes diversity within species, between species and of ecosystems."12

By embracing such a broad scope, the drafters clearly

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10 Wilson, E.O., THE DIVERSITY OF LIFE, The Belknap Press of Harvard University Press (Cambridge, 1992), page 74.

11 This first biodiversity treaty was presented at Rio de Janeiro on 92/06/05, and entered into force on 93/12/29, 90 days after it was ratified by its 30th signatory county - Mongolia.

12 THE CONVENTION ON BIOLOGICAL DIVERSITY, Article 2, paragraph 1 (Nairobi, 1992).

intranational issue. To these ends, conservation of biological diversity, to the extent possible in light of existing national law, was set forth as paramount. Additionally, the sustainable use of genetic resources, coupled with equitable sharing of the benefits arising out of these genetic resources were specifically enumerated as prime objectives of the Convention on Biological Diversity.13

The issue thus presents itself as to whether a global system can be developed to insure a proper valuation of biodiversity prior to implementation of sufficient mechanisms to achieve the same in actual legal or commercial terms. Further details are required for such an analysis. This undertaking is but a mechanism to facilitate establishment of a conceptual basis for understanding the question presented.

III. BACKGROUND OF THE CONVENTION ON BIOLOGICAL DIVERSITY

The initial Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity was held at Nairobi on May 22, 1992. Historically, this event shall hold significance as the first instance when steps were taken to ratify, on an international level, an acknowledgement of the value of biodiversity. This discussion intends to explore the

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13 THE CONVENTION ON BIOLOGICAL DIVERSITY, Article 1, paragraph 1.

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possibility of third party claims to the above-described [illegible]

in terms of existing intellectual property laws.

Similar to the prefatory language of the Patent Cooperation Treaty14,(the "PCT") the Convention on Biological Diversity (the Rio Convention, hereafter "Convention") initially sets forth a broad range of goals to be followed by its multinational signatory body. Driving both the Convention and the PCT was the limitation that clearly intellectual property systems had been heretodate national in effect. Additionally, both systems were constrained by the historical concept of intellectual property as an entitlement, subject to administrative determination and weighted with social obligations (like the 'working obligations' or compulsory licenses known for patents).15

The PCT also made reference to the desire,

> to foster and accelerate the economic development of developing countries through the adoption of measures designed to increase the efficiency of their legal systems.16

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14 The PCT was done at Washington, District of Columbia on 19 June, 1970; amended on 2 October, 1979; and modified on 3 February 1984. REGULATIONS UNDER THE PCT were in force from 1 July, 1992.

15 Prager, F.D., "A History of Intellectual Property from 1545 to 1787", XXVI JOURNAL OF THE PATENT OFFICE SOCIETY (No.11) 711, 727 (November 1944).

16 The PCT, Preamble, at page 6 (WIPO, Geneva 1992).

Likewise, both the PCT and the Convention clearly enumerate the primacy of the laws of the individual contracting states.17

At the implementation stage, unfortunately, the analogy breaks down. While the Patent Cooperation Treaty sets forth specific benefits to be gained in exchange for the cost of participation, the Convention ostensively is silent. Additionally, it is axiomatic that any system of laws must have some mechanism of enforcement to be functionally operational.

However, this apparent gap may be interpreted otherwise. By leaving the sovereignty of the laws of the individual states intact, the convention operates to foster generation of systems of laws in each of the contracting states which provide an effective level of intellectual property protection. Such strong intellectual property protection will provide some of the incentive base required to facilitate creation of technology making usage of the genetic resources in the first place, and encouraging technology transfer.18 This is the position taken by leading organizations representing large scale biotechnology interests in the United States.19

One can envision a scenario in which U.S. Letters Patent cover genetic sequences further comprising improved characteristics of subject matter covered under the national

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17 THE CONVENTION ON BIOLOGICAL DIVERSITY, Article 3

18 "CLINTON STRESSES IP PROTECTION UPON SENDING BIODIVERSITY TREATY TO SENATE" 47 PTCJ 113,114 (BNA December 2, 1993).

19 Id., at 117.

patent law of its country of origin in such a way as not to preclude novelty. Thus, classical acts of invention are rewarded while the original intellectual property rights of the native germplasm discoverer remain intact.

While the United States must ratify the Convention within 13 months of the treaty's entry into force on December 29, 1993, hearing are scheduled for early 1994 before the Senate Foreign Relations subcommitee.20 Earlier American legislative attempts to create international schemes of intellectual property rights in natural resources are demonstrative of the proposition that such native patent rights are needed.21

It is equally apparent that,

> Unless we act we face the extinction of untold numbers of species that might support our livelihoods and provide medications to save our very lives.22

However, a plain reading of the text of the Convention calls to attention the fact that the Convention creates no adequate legal basis for the interface of putative rights under national patent laws and the "common law" or uncodified intellectual property rights of indigenous persons which it is

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20 Id., page 116.

21 SEE the PVPA, discussed below

22EXCERPTS FROM PRESIDENT CLINTON'S EARTH DAY ADDRESS, 14 Inside E.P.A. (No. 16) 19, April 23, 1993.

Convention be interpreted to have any actual impact within the context of today's global intellectual property law schema?

Is it sufficient to set forth a series of protocols and to enumerate objectives for conservation of biodiversity, or is more required in light of existing national and international patent laws? Therein lies the crux of the problem whose resolution may not be addressed prior to divining a principled basis for considering "genetic material"24 as property.

Thomas Jefferson authored the first United States Patent Act.25 Had Jefferson realized that the United States

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23 The Convention provides, at Article 16, paragraph 5:

> The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

24 "GENETIC MATERIAL means any material of plant, animal, microbial or other origin containing functional units of heredity." CONVENTION, Article 2, paragraph 9.

25 The Patent ACT OF 1790. Jefferson would likely have been in favor of providing a share of intellectual property to one merely having possession of the starting materials who had yet to manifest an intention to invent, based upon his plethoric writings on the subject, to wit:

"He who receives an idea from me, receives instructions himself without lessening mine, as he who lights his taper at mine...[this]seems to have been peculiarly and benevolently designed by nature." Washington, H.A. (Editor) 6 WRITINGS OF THOMAS JEFFERSON 180 (1954). Is it possible that Jefferson understood more of genetics than is historically known?

would later be in the position to be part of a convention designed to safeguard biodiversity, he may have understood that giving natives intellectual property rights in their indigenous species would incentivise their participation in conservation. Jefferson certainly would have agreed that plant diversity is a source of wealth, and that the U.S. Patent system is designed to aggrandize that wealth, without necessarily depleting its ex-situ sources.

IV. ARGUMENT

This paper respectfully proposes, inter alia, that classical acts of invention may include new uses of old compositions[26], and that conservation of genetic resources[27] (insofar as expressly set forth in the text of the body of the Convention) necessarily provides for a continued ability to preserve biological diversity. In order to further simplify this discussion, and for purposes of illustration, plants are considered as paradigmatic of biological organisms.

What is the relationship between conserving the maximum

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[26] See the line of biotechnology cases generated following Diamond v. Chakrabarty, 447 U.S. 303 (1980), which have held that structural similarity precludes patentability unless the relative significance of the newly discovered uses outweighs the prima facie obviousness, in light the case as prosecuted. Recent cases have refined these rules. See for example, In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

[27] As defined in the text of the Convention at Art. 2, para. 10 .

diversity) and patent law? First a normative basis underlying current theories on biodiversity must be visited. A brief sketch of philosophical underpinnings of the two main schools of thought on biodiversity sets the stage.

V. ENVIRONMENTALISM v. EXEMPTIONALISM

Views that had been considered extreme until the beginning of this decade have now gained broad based support and acceptance within the scientific community. The perspective of the enthnobotanical conservationist has been succinctly summarised at numerous places in the current literature, to wit:

> The human species depends on plant species for its own welfare and ultimately for survival. Each living species is the repository of organic molecules that are the products of the plant's irreproducible evolution. Science should intensify its study of these chemicals, because there is little time left to learn; when a plant becomes extinct, the opportunity to learn is lost forever. It is only common sense that we who can apply technical analyses to problems should learn from peoples who are intimately familiar with their floral environment and its useful properties for the benefit of all mankind.28 [Emphasis added and explained below.]

28Schultes, R.E., BURNING THE LIBRARY OF AMAZONIA: The encyclopedic botantical knowledge of the Amazon Indians is in danger of being lost. A student of that knowledge for forty-seven years argues that it must be preserved, 34 THE SCIENCES (No. 2) 24 (1994).

For heuristic purposes, one may divide proponents of the preservation and maintenance of biodiversity and those indifferent to it, or opposed to it, into two general categories. The groups have been conveniantly labeled the exemptionalists and environmentalists by those knowledgeable in the field.29

According to this general classification scheme, the exemptionalists view the human race, in virtue of its intelligence and problem solving ability, as able to resolve the ostensive crisis with the depletion of the variety of genetic resources on Earth. Alternatively, this school would likely opine that debasing the global environment is not problematic, and that preservation of plant (or genetic) variety is of no great import.

Environmentalists, on the other hand, take the position that important aspects of the bioactivity of plants have been generated from the selection pressures of the process of evolution. They would assert that to prevent the loss of potentially irreplaceable types of heterozygous combinations30,

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29SEE, for example;
Wilson, E.O. "Is Humanity Suicidal?", THE NEW YORK TIMES MAGAZINE, THE NEW YORK TIMES, 5, May 30, 1993, at page 27.

30 Plants have been subject to 'genetic manipulation' since the dawn of time, which is to say that they have been cross-bred to produce desired characteristics.
Unfortunately, although breeders have been combining plant types for centuries, it is only most recently that our understanding of genetics has compelled us to take note of the original genetic starting material which may not be ascertainable following several generations of crossing. This is in turn due

preserved.

V. THE CONVENTION

The Convention is specifically addressed to the issue of "the intrinsic value of biological diversity" and the responsibility of the contracting states "for conserving their biological diversity". CONVENTION, preamble, paragraphs two and five. But, what does this mean, and how does it relate to laws designed to protect intellectual property?

Under the Convention it is necessary to create incentives for those who have the most to lose. In other words, in developing countries where subsistence drives daily activities, monitoring and collecting genetic samples must somehow be induced. If inducements to conserve biodiversity are erected, through mechanisms such as a system of intellectual property laws that established property rights ab initio in genetic starting materials, sustainable development could be achieved.

One must, however, distinguish positive from perverse incentives for sustainable development. Maintaining biodiversity necessarily enables the continued provision of genetic starting materials which then remain available for potential

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to the fact that plants do not breed true to type, so that generations may not be 'reversed engineered' because their phenotypes (expressed characteristics) are not necessarily indicative of their underlying genotypes (actual genetic make-up).

biotechnological innovation. Likewise, intellectual properties in genetic resources will generate income to help compensate locals for income lost due to conservation efforts.

Education must proceed hand in hand with establishment of native intellectual property rights. Article 7 of the Convention mandates surveying and inventory taking by each member state of its respective genetic resources. Education and computer literacy are required to maintain and organize such data.

It thus is further respectfully submitted that, within the scope of the intention of the Convention, a rational goal of biotechnology should be maintaining the largest possible degree of genetic variety, to bolster diminishing reserves of genetic starting materials. It is further respectfully submitted that sustainable use of biological resources does not conflict with the spirit or meaning of the national Patent Laws, either in practice or in procedure.

Thus, a first cut analysis of the potential for harmony between existing Intellectual Property Laws and the stated goal of the treaty known as the Convention on Biological Diversity31 ("that biodiversity resources are to be valued highly and that such resources should therefore be protected by patent rights.") operates on several working assumptions. Initially it is important to understand that the Convention requires that less

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31 RIO CONVENTION ON BIOLOGICAL DIVERSITY OF THE UNITED NATIONS CONFERENCE ON ENVIRONMENT AND DEVELOPMENT, 92/06/05 date opened for signature, 31 I.L.M. 818.

property rights generated at the cost of their resources. Additionally, that such intellectual property rights are inherently consistent with " a more equitable and more efficient method of valuing these resources than any that can be achieved without such rights."32

Since the present intellectual property schemes may be read as operating in response to the needs of the economics of vanishing resources,it is not difficult to understand the need for the language of the convention essentially basing intellectual property rights upon the source of genetic starting material in addition to the individual invention/labor/ creation/discovery standard.

Plants are protected not only by several discrete branches of the patent statute and international law, but also tacitly contain trade secret protection33 which may enable their legal status under both the Convention and national patent laws to be harmonized.

This treatment has briefly reviewed some of the language of the Convention itself to provide support relative to

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32 SEE Note 1, page 1.

33The legal opinion of the author is that Title 35 of the Unites States Code can be read as drawn to include within its scope 'patentable' uses of compounds, derived from nature, which are recombinantly synthesized into one of "anything under the sun created by man" through minor, albeit necessary structural modification . The germplasm itself is only protected as a biotechnological product once sequenced, inserted and responsible for new properties.

reservations expressed by sceptics and respectfully assert that affording some native ownership rights does not necessarily (constitute or result in an resource degradation) and supports the view of the 53 nations who signed the convention. 34

VI. THE CONVENTION AND PATENT LAW

The Convention mandates provision of a share of intellectual property rights to one having possession of the starting materials needed to invent, irrespective of pre-existing manifestations of an effective effort to invent.35

In establishing far reaching obligations to preserve biodiversity, the Convention has placed on emphasis on the sovereign powers of the individual contracting states. Article 8 of the Convention stresses in-situ conservation, including preservation and maintenance of the knowledge and innovations of indigenous communities. Article 9 stresses ex-situ conservation which should include such measures as seed banks and related genetic warehouse mechanisms.

Articles 15 and 16 clearly set forth that access to genetic resources, while under the control of the contracting states, should be used to enhance global biodiversity. This includes technology transfer mechanisms as well

This treatment reasserts that the language of the

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34 SEE Note 1, page 1.

35 The Convention, Articles 1,8,7,15, 16 and 21.

to reservations expressed by the United States signatory and further posits that affording some native ownership rights does not conflict with existing patent laws, as believed by the 166 nations who have signed the convention to date.

It is further respectfully proposed that even the U.S. Patent Law, the most pervasive and dominant force in global intellectual property systems, can accommodate the mandates of the Convention. A brief example suggests that mechanisms may already be in place to enable other national patent laws to follow suit and encourage plant breeding research and development which does not in any way compromise the integrity of the genetic starting material.

VII. THE PVPA, AND Asgrow Seeds

The United States has such a pervasive intellectual property scheme in place for plants, that most flora is coverable by at least two of the legislative enactments covering plants. For example, Title 35 of the United States Code provides two modes of coverage, which are not mutually exclusive 36.

In addition to the utility patent law, the U.S. system comprises; the Plant Patent Act, 35 U.S.C. 161 - 164 (1984), and

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36 Ex Parte Hibberd, 227 USPQ 443 (USPTO Bd. App. & Int. 1985) . In re Abitibi 52 CPR 2d 81 (1982).

(1970). One may patent specific asexually reproducing strains under the Plant Patent Act, get a patent of the gene sequence novelly distinguishing a plant under 35 U.S.C. 101, and protect the seeds of the variety under the PVPA.

Further, farmers may make personal, or 'brown bag' usage of patented seeds. This allows commercial seed producers to provide farmers with new varieties to test, while allowing the seed companies still to recoup their research and development dollars.

Since the Convention respects the dictates of national patent law, it may be in the interest of large commercial interests to become involved in assisting developing countries to put analogous systems of protection into place.

It is respectfully submitted that a system of National Plant Patent Laws analogous to the PVPA would allow for the concurrent existence of indigenous people's rights in genetic starting materials, and alienable rights which would be appropriate for multinational investment.

The PVPA constitutes a legislative compromise between the interests of farmers and the seed industry. The legislative purpose of the act was to encourage plant breeding research providing American farmers with a steady stream of improved varieties of plants. Under the PVPA, novel, sexually reproducing varieties get eighteen years of protection. Such varieties can offer dramatic increases in production and

to use, and instead permitted to utilize seeds garnered from originally protected varieties for their own use. Infringement generally occurs when seeds are used commercially, not merely for a farmer's personal planting, and no acknowledgment is made of those with proprietary rights in the seeds.

The United States Supreme Court has recently decided to hear a case of first impression arising under the Plant Variety protection Act.37 In the case the issue is whether a farmer's use of seeds is an infringement under the act, or governed by the statutory exception which allows usage of seeds for all except commercial purposes by farmers.

The Court of Appeals for the Federal Circuit, which later refused rehearing en banc, held that the Farmer's use of the seed was noninfringing, despite the fact that the amount of seed saved was easily several times as much as needed, and despite the fact that no notice had been given that the involved seeds were covered by patents owned by Asgrow.38 Judge Newman dissented from the majority, opining that the entire purpose of the PVPA was to create encourage the seed business by creating a legal distinction between commercial and personal uses of seeds, which distinction is crucial for infringement purposes.39

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37 Asgrow Seed Company v. Winterboer, U.S. Sup. Ct. No. 92-2098, cert granted 94/04/18, 989 F.2d 478, 26 USPQ2d 1227 (CAFC 1993).

38 Id.

39 Id.

legislative history is clearly demonstrative of the fact that intellectual property protection for novel varieties of plants can exist concurrently with farming or other personal usage of same.

A perusal of Judge Newman's dissent provides a basis for developing nations to model intellectual property laws that do not run afoul of the mandates of the Convention.

VIII. CONCLUSIONS

It is apparent from the plain language of the Convention that genetic resources must be appraised, valued, and shared through technology transfer if the erosion of biodiversity is to be deterred. Patent law is a key to creation of biological wealth, and genetic starting materials essential to keep the innovation cycle running at full steam. Likewise, the United States patent system for plants is demonstrative of the fact that intellectual property laws can concurrently provide the basis for expectation backed investments and protect the rights of the smaller scale, or not-soley-profit-operator within the system. This provides the conceptual basis for any analysis of the ability of current national patent laws to interact with the Convention. AB INITIO rights in genetic starting materials can coexist with exploitation of genetic under existing patent laws.

In conclusion, biodiversity can be coextensive with

intellectual property rights ab initio in genetic starting materials. Further, since native know how has to be the basis for any effective survey of plant genetic resources, it may be possible to implement the Convention without offending national patent laws.