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MACRO PERSPECTIVE AND CROSS COUNTRY COMPARISON OF PATENTING ISSUES*

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IMPORTANCE OF INTELLECTUAL PROPERTY RIGHTS

The need for a clear intellectual property rights system that rewards creativity and ingenuity to spur technological development is a current concern of both developed and developing countries. This is especially felt in countries with limited technological capability since technological flows are a part and parcel of investments and financial decisions on sources of new inventions, products and processes.

It is not surprising, therefore, that in many international fora, issues on patenting in particular, and IPR in general, are dissected and articulated within the context of the needs of poor and developing countries for better access to technologies and for a more sympathetic response from the developed countries which want a well-defined system of IPR protection to owners. Thus, the proposed International Code of Ethics for the Transfer of Technology suggests an approach that will mitigate the problems of underdevelopment by requesting the developed countries to consider the technology needs of less developed and developing countries within the framework of the "most-favored nation clause." On the other hand, developed countries want trade related matters correlated with IPR protection which is still the subject of intensive discussions in international trade fora and which will continue to be so in the policy and trade agenda in the years to come.

In the UNCTAD Meeting held a few months ago, nonreciprocal relationships that will adjust the IPR system according to the level of technological requirements of needy countries were discussed. The thinking of the developing countries (which believe that a reciprocal approach must be modified because of the disadvantaged circumstances of less developed and developing countries vis-à-vis the developed ones) is

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still along this line. On the other hand, countries in our region cannot ignore the fact that rewards are necessary for the owners of technologies and that business opportunities will expand when technology-oriented companies are assured of IPR protection for their inventions or intellectual property creations. Technology-owners often invest substantial amounts of time and money for R&D which may be recouped in royalty fees or licensing arrangements.

One of the instruments which protect the IPR is the patent. A patent is granted to an owner not only as a reward for a new invention but also as an exclusive right of exploitation to launch the invention in the market and to gain a market lead over those who have not incurred any R&D expenditure toward a similar creation. Patents are incentives to the investment of human, technical and financial resources in research and development which may lead to commercial advantages should a viable invention result from such research and development (Gurry 1989). A review of the patent laws of some countries shows that there is a vacuum in patent coverage. Current statutes, somehow, have not been updated to respond to the tremendous strides in technological development. In biotechnology, for example, many countries have not yet enacted appropriate laws that will encompass new patentable inventions arising from the creation of new life forms. In the absence of a clear language in the statutes, issues are resolved through administrative or judicial interpretation. When cases are elevated to the courts, judges and lawyers enter the exciting world of sciences, weave through the intricacies of formulas and laboratory findings while scientists unravel legal concepts and situations as their researches/inventions are "judicially" analyzed. Thus, there is a need for simple and clear laws on the patentability of new life forms in many jurisdictions, taking into account the diversities of the circumstances of each country.

THE UNITED STATES PATENT LAWS

While patents are universally recognized as instruments of ownership, their legal scope varies depending on the statutes of each country and the conventions or international agreements to which it is a signatory.

The US Patent Law is one of the oldest in the world. Approved in 1793, it underwent many amendments, but its broad scope has essentially been retained. There are three types of patents available in the United States: *first*, the utility patents covering processes, machines, manufactures and compositions of matter; *second*, the patents for plants, including mutants, hybrids and newly-found seedlings; and *third*, the patents for designs (Office of Technology Assessment 1991).

A patent lasts for 17 years. However, for patent claims for a human drug product, medical device, food or color additives that have been reviewed for commercial availability or use by the US Food and Drug Administration (FDA), the patent is extendible for another five (5) years (OTA 1991)

The US Congress passed the Plant Patent Act in 1930. The law extends patent protection to most new and distinct asexually propagated varieties. To date, this is the only law passed by the US Congress which provides patent protection for living matter. So far, 6,500 patents for plants have been issued (OTA 1991).

Forty years thereafter, Congress passed the Plant Variety Protection Act of 1970 which provides protection for certain types of new, sexually reproducible plant species. The US Department of Agriculture, upon application and after evaluation, issues a plant variety protection certificate on any novel variety of sexually reproducible plant. Other than in the case of fungi, bacteria, or fruit generation patents, the novel variety must have *distinctiveness, uniformity,* and *stability* (emphasis supplied). Plant breeders who hold a certificate issued by USDA can exclude others from selling, offering for sale, producing and reproducing a hybrid from the variety, and importing or exporting the protected variety, except researchers who will use the protected variety to develop new varieties and farmers whose primary occupation is to grow crops.

The leading case in the United States which touched on the patentability of biotechnological processes and products is *Diamond v. Chakrabarty* (447 U.S. 303, 65 b. Ed. 144, 100 S CE 2204). In this case, a microbiologist had genetically engineered a bacterium capable of breaking down multiple components of crude oil, a property possessed by no naturally occurring bacteria, and therefore believed to have a significant value in the treatment of oil spills.

Chakrabarty and an associate discovered that plasmids, which are hereditary units physically separate from the chromosomes of the cell, control the oil degradation abilities of certain bacteria. In particular, they discovered plasmids capable of degrading camphor and octane, two components of crude oil. In the work represented by the patent application at issue in the case, Chakrabarty discovered a process by which four different plasmids, capable of degrading four different oil components, could be transferred to, and maintained stably in, a single *pseudomonas bacterium*, which by itself has no capacity for degrading oil. While the Chakrabarty case was before the court, the method for biological control of oil spills required the use of a mixture of naturally occurring bacteria, each capable of degrading one component of the oil complex. In this way, oil is decomposed into simpler substances which can serve as food

for aquatic life. However, for various reasons, only a portion of any such mixed culture survived to attack the oil spill. By breaking down multiple components of oil, Chakrabarty's organism promised a more efficient and rapid oil-spill control.

While the Patent Office allowed the process claims for the method of producing the bacteria, the claims to the bacteria themselves were rejected by the examiner on the ground that microorganisms were products of nature and that, as living things, they were not a patentable subject matter under the law. The United States Supreme Court ruled that such live, human-made microorganisms are a patentable subject matter because they constitute either a "manufacture" or a "composition of matter" within the meaning of the patent statutes. The court further stated that "Congress contemplated that the patent laws should be given wide scope, and the relevant legislative history supports a broad construction, while laws of nature, physical phenomenon, and abstract ideas are not patentable, respondent's claim is not to a hitherto unknown natural phenomenon but to a non-naturally occurring manufacture or composition of matter and product of human ingenuity having a distinctive name, character and use."

The ruling of the US Supreme Court in the Diamond vs. Chakrabarty case subsequently opened the doors to biotechnologists and other researchers whose creativity produced "products and processes" that were registered and given patents. It also liberalized the scope of the definition of patentable inventions in American patent jurisprudence, ushering in an era of patentability of biotechnological "inventions."

The US is a signatory to the Paris Convention, the Patent Cooperation Treaty, the Budapest Treaty and the International Union for the Protection of Plant Varieties.

MEXICAN PATENT LAWS

In Mexico, after the changes made in 1987 to the Law on Inventions and Marks, which remained in force until June 27, 1991, protection was afforded to patented inventions for a period of 14 years counted from the date of the grant of the patent.

The Law on the Promotion and Protection of Industrial Property, which came into force on June 28, 1991, provides that patents have a term of 20 years counted from the date on which they were applied for. This now makes the legal protection of inventions in Mexico comparable to that available in the main industrialized countries, enabling the country to compete on conditions that are no less favorable.

It should be mentioned that, compared with the protection already available for inventions in Mexico in 1942 (or half a century ago), the life

of a patent under the new law is five years longer. Compared with the legislation that preceded it, the duration of protection remains practically unchanged, as 20 years from the time of application and 14 years from the time of the grant are, in actual practice very similar terms (Villareal-Gonda 1991).

Mexican Law on Biotechnological Inventions

The new Law on the Promotion and Protection of Industrial Property would, for the first time, allow the granting of patents which takes effect in 1997 for inventions involving the following:

- biotechnological processes and their products in the industries manufacturing pharmaceutical chemicals, medicines in general, foods and beverages for animal consumption, fertilizers, pesticides, weedkillers, fungicides and products with a biological action such as hormones and vaccines;
- genetic processes for the production of animal and plant species, or varieties of such processes;
- plant varieties;
- microorganisms; and
- chemical compounds.

This provision of the new law substantially reduces the number of technological areas that are excluded from patent protection. It conforms to a trend that has been going on in many countries, the fundamental purpose of which is to give equal stimulation in all technology-related areas to investments in the industrial development of new groups and manufacturing processes.

The new law also provides that no patents are to be granted for the types of invention that involve live materials for which there is as yet no international consensus as to their patentability. Specifically, patents will not be granted in Mexico for animal species or breeds, genes, parts of the human body, etc. Indeed, the patentability of biotechnological inventions is confined to the types of invention mentioned above regarding which there is already sufficient familiarity and experience at the world level. (*The New Mexican Law on Industrial Property,* R. Villareal Gonda, WIPO, Geneva, November 1991.)

OTHER COUNTRY PATENT LAWS

In India, the Indian Patents Act of 1970 is being reviewed to consider developments in biotechnology. The country recently established

Biotechnology Consortium Ltd. to promote the transfer and commercialization of biotechnology.

In Korea, they are deliberating on the international joint research promotion law to ensure biotechnology development and funds for R&D.

PHILIPPINE PATENT LAWS AND BILLS

Republic Act No. 165 is the present law regulating the issuance of patents in the Philippines. It was enacted 44 years ago and had undergone six revisions, namely those under Republic Act Nos. 637, 864 and 5434, Presidential Decree Nos. 1263 and 1520, and Batas Pambansa Blg. 129.

Before R.A. 165 came into force on June 20, 1947, the controlling law on patents was Act No. 2235 enacted by the Philippine Legislature on February 10, 1913. Act No. 2235 made the United States Patent laws applicable in the Philippine Islands. Section 1 of this Act provides that "owners of patent. . . which have been issued or may hereafter be issued, duly registered in the United States Patent Office under the laws of the United States relating to the grant of patents, shall receive in the Philippine Islands the protection accorded them in the United States under said laws."

Inventions Patentable Under Act No. 2235 and R.A. 165

The United States Act of Congress of March 3, 1897 which was amendatory of section 4886 of the US Revised Statutes, declared as patentable inventions:

> . . . any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvements thereof (29 Stat. L., 692, 2 Fed. Stat. Ann., 2nd ed., p. 23)

The legislative history of the foregoing provision may be traced to the Patent Act of 1793 authored by the very distinguished American statesman and jurist Thomas Jefferson. On February 10, 1913, this same provision entered the Philippine legal system through the enactment into law of Act No. 2235.

When Republic Act No. 165 came into effect in 1947, the following under Section 7 thereof became the new definition of patentable inventions, viz.:

> Any invention of a new and useful machine, manufactured product of substance, process, or an improvement of any of the foregoing.

It might be noted that the Philippine Congress that enacted Republic Act No. 165 modified the provision of the American statute which contained the words *art, composition of matter,* and substituted "manufactured product" for the word *manufacture*. The American Law does not have the word "process" which is explicit in the Philippine Law. One can assume, therefore, that in the Philippines, patent application for a process may be justified since the law already provides for this. In any event, steps have been taken to clarify Section 7 of R.A. 165.

Pending Bills Amending Section 7 of R.A. 165

During the Second Regular Session of the present Congress, the House of Representatives passed on first reading House Bill No. 24489 which is An Act ilnstituting and Ordaining An Intellectual Property Code sponsored by Congressmen Yap (J.), Yap (R.), Romualdo, Cua and Romero.

Chapter III, Section One, Article 84, of House Bill No. 24489 reads:

> What may be patented. — (1) Any invention of a new and useful machine, manufactured product, process, or any new and useful improvement of any of the foregoing, shall be patentable.
> (2) New strains of microorganisms or of any other living matter produced with the intervention of human ingenuity shall also be patentable.

Essentially, the first paragraph is a restatement of the present law. However, it is interesting to note that the authors of the bill made it an important matter to add another paragraph on the scope of what may be patented. Clearly, there is already a tacit recognition by the authors themselves of the need to include these "new strains of microorganisms or of any other living matter produced with the intervention of human ingenuity" to widen the scope of the definition of what subject matters should be patented. To put it conversely, the authors give the impression that the present law on patents does not include these "new strains of microorganisms." However, the Bureau of Patents, Trademarks and Technology Transfer (BPTTT) accepts patent applications for biotechnological products and processes. The stand of the BPTTT is anchored on the accession of the Philippines to the Budapest Treaty, discussed in the later part of this paper, which establishes the mechanisms and guidelines for the deposit of microorganisms in authorized intemational depositories.

Meanwhile, the Senate passed during the Second Regular Session on first reading a counterpart bill introduced by Senator Laurel which is

An Act Revising Republic Act 165, As Amended, Otherwise Known As the Patent Law. Section 4 of Senate Bill No. 998 reads:

> Inventions patentable. - Any new technical solution of a problem in any field of human activity which involves an inventive step and is industrially applicable shall be patentable. It may be, or may relate to, a machine, product, or process, or an improvement of any of the foregoing.

On the other hand, Section 5 of Senate Bill No. 998 explicitly enumerates the nonpatentable areas which are as follows:

(a) discoveries, scientific theories and mathematical methods;
(b) schemes, rules and methods of performing mental acts, playing games or doing business, and programs for computers;
(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic practices on the human or animal body. This provision shall not apply to products for use in any of those methods;
(d) plant or animal varieties or essentially biological process for the production of plants or animals. *This provision shall not apply to microbiological processes and the products of said processes* (underscoring supplied);
(e) aesthetic creation;
(f) a substance used as medicine which is a mere mixture of two or more known ingredients or of a process for producing such by mere admixtures; and
(g) anything which is contrary to public order or morality.

Senate Bill No. 998, like House Bill No. 24489, contains expansive definitions of patentable matters. There seems to be a consensus among the authors of the aforementioned bills that R.A. 165, on patentable inventions is inadequate and not comprehensive and responsive enough to modern technological trends.

It is worth noting that Senate Bill No. 998 excludes from the scope of patentable inventions "plant or animal varieties or essentially biological process[es] for the production of plants or animals" (first sentence of Section 5[d]). However, microbiological processes and the products of the said processes can be the proper subjects of a patent since Section 5 is not applicable to them.

As regards protection for plant and animal breeders, Chapter 7 of H.B. 24489 provides for the granting of protection to new plant varieties or animal breeds. Article 165, Chapter VII, of the said bill provides:

"Grant and Requisites of Protection." Protection shall be granted in accordance with this Chapter to any new variety of plant or any new animal breed which is stable and homogenous as herein defined.

The protection granted under this chapter is not the same as that of patents granted but the rights therein are closely similar to those of the latter. The scope of protection for plant and animal breeds consists of the exclusive right to the production of the propagating material of the protected variety. Article 170 thereof provides:

"Scope of Protection" - Upon the grant of protection under this Chapter, no one may, without the consent of the holder of the right of protection, produce propagating material of the protected variety with a view to marketing, offering for sale or selling it in the course of business, nor may anyone otherwise distribute material to the prejudice of the title holder.

As in patents, the right to protection of a variety belongs to the breeder or discoverer, or his successor in interest. When two or more persons have bred or jointly discovered a variety, the right shall belong to them jointly. In case two or more persons have bred or discovered separately and made jointly a variety, the person who can prove that he was the first breeder or discoverer will have the right of protection but if they happened to have done it simultaneously, the first-to-file rule shall be applicable. The right of protection is represented by a "Title of Protection", which is similar to a letters patent. Unlike patents, however, the life of protection for plant and animal breeds lasts only for fifteen (15) years and eighteen (18) years in the case of vine and trees. For some species or groups of plants, the Intellectual Property Commission (created under the bill) may extend the period by five (5) years.

The distinction between patents for invention and the protection granted to plant and animal breeds under H.B. 24489 is an important aspect of modern development in IPR. It will be helpful to remember this in order that the layman will not be confused between the two forms of IPR protection on the proposed bill.

Modern Trends in IPR Protection in Biotechnology

As mentioned earlier, the BPTTT already accepts applications for patenting of biotechnological matters despite the fact that the bill dealing with these areas is still pending in the legislature. The justification for such practice is the fact that the current patent law, R.A. 165, does not expressly exclude biotech matters as among those not patentable. As mentioned also, the fact that the Philippines is a signatory to the Buda-

pest Treaty buttresses the fact that the patent may be available to such matters. Moreover, the Chakrabarty case has a persuasive effect in this jurisdiction and may be used by the BPTTT as basis for its view.

Nevertheless, the patentability or nonpatentability of life forms and other biotechnology products and processes remains as a major issue for debate in the international arena. There are marked differences in the views of IPR experts and biotechnologists from different parts of the world.

In an April 5, 1978 decision in Germany, for example, the Federal Patent Court of Germany acted favorably on a patent claim for a group of natural occurring organisms called "lactobacillus bavaricus." The claim defined the microorganisms as *obtainable by production of bacteria* by carrying out certain specified selection steps that result in the production of bacteria which predominantly produce the L(+) sources of lactic acid. Although naturally occurring, the new microorganisms had previously been undiscovered and required human technical intervention to recognize and produce them. This German decision seems to be in conformity with the "special characteristics of the microorganism" rule in the Diamond vs. Chakrabarty case (Strauss 1985).

The Canadian ruling on the matter was first formulated by the Canadian Appeals Board in the case of *In re: Abitibi* dated March 18, 1992. The Board said in this case that "an inventor who creates a new and unobvious insect which did not exist before (and this is not a product of nature) and can recreate it uniformly and at will, and it is useful (to destroy the specie of budworm), then it is every bit a new tool of man as a microorganism." Note that the Board based its decision on what it perceived as the novelty and usefulness of the insect. However, according to the courts in some countries, the novelty of microorganisms can be based on the fact that those skilled in the art are not aware of their existence, despite the fact that they have been in nature all along. Microorganisms and such other substances, according to experts, appear in nature in very complex surroundings which do not allow direct technical use to be made of them. In such cases, therefore, the merit of the claim is to be seen in the original isolation and identification of the product, providing an indication of its industrial application and making the product available to the public (Strauss 1985). Such criteria were also used as one of the bases for a US decision which declared that plants, seeds and plant tissue cultures resulting from an entirely new biotech process are patentable (Ex Parte Hibberd, 227 USPG 443).

On the other hand, while the process itself is generally considered patentable, its result may not necessarily be so. The European Patent Office has set as one of its guidelines, that "substances freely occurring

in nature...[are] mere discovery and therefore inpatentable. However, if a substance found in nature has first to be isolated from the surroundings and a process for obtaining it is developed, that process is patentable." In fact, in 1989 it granted a patent in favor of Lubregal Genetics, covering a process for the rapid development of hybrid plants and for the commercial production of hybrids. The totality of the sequence of operations described did not occur in nature nor did it correspond to the classical processes for obtaining varieties since it did not claim an essential biological process.

However, despite the granting of biotech patents in several countries in the world, there are still those who maintain that biotech products and processes do not actually fall under the category of patentable matters. According to them, the patent laws that evolved during the Industrial Revolution in Europe were envisioned to protect machines and inventions that were normally used for the production system. Such laws, therefore, were not contemplated to apply to products, especially those naturally occurring in nature. The patentability of microorganisms itself pose serious difficulties in the technical aspects of patenting. Microorganisms, for one, could not be seen with the naked eye. They are a complex form of matter. As defined, they could be any matter which can be deposited, and which is self-replicable, or which can be contained in or can be inseparated into a host organism and which is replicable through the self-replication of the host organism.

One of the problems in the patenting of microorganisms is the difficulty of describing accurately the invention in writing to comply with the requirement that a patent application disclose the invention so that one skilled in the art can carry it out. There are, likewise, morality and public order issues involved.

HIGHLIGHTS OF THE BUDAPEST TREATY

The Budapest Treaty provides that the contracting states which allow or authorize the deposit of microorganisms for the purpose of patent procedures shall recognize for such purpose deposits of microorganisms with any international depository authority. The Treaty further provides that the recognition shall include the acknowledgment of the fact and date of the deposit as indicated by the international depository authority as well as a recognition of the fact that what is furnished as a specimen is a sample of the deposited microorganism (Article 3, Chapter I).

The deposit complements a written specification or description of a sample, which for patenting purposes constitutes compliance with the requirement of accurate description of the microorganism being sought to be patented. The Budapest Treaty facilitates the patenting of microor-

ganisms among members of the Union or member-countries acceding to the Treaty.

Under Article 6 of the said Treaty, a public institution acquires the status of an International Depository Authority under the following conditions, viz.:

(a) The depository institution must be located in the territory of a contracting State and must benefit from assurances furnished by that State to the effect that the said institution complies and will continue to comply with certain requisites;
(b) The said assurances may also be furnished by an intergovernmental industrial property organization: in that case, the depository institution must be located in the territory of a member-State of said organization.

Furthermore, a depository institution which serves as an International Depository Authority must meet the following requirements:

(a) It must have a continuous existence;
(b) It must have the necessary staff and facilities, as prescribed in the Regulations, to perform its scientific and administrative tasks under the Treaty;
(c) It must be impartial and objective;
(d) It must be available for the purposes of deposit to any depositor under the same conditions;
(e) It must accept for deposit any or certain kinds of microorganisms, examine their viability and store them as prescribed in the Regulations;
(f) It must issue a receipt to the depositor and any required viability statement as prescribed in the Regulations;
(g) It must comply, in respect of the deposited microorganisms, with the requirement of secrecy as prescribed in the Regulations; and
(h) It must furnish samples of any deposited microorganism under the conditions and in conformity with the procedures prescribed in the Regulations.

CONCLUSION

Developing countries like the Philippines should be alerted to the developments in patenting especially in the field of biotechnology in advanced nations which are presently the principal sources of high-biotechnology R&D. Without a reasonable IPR protection, it is almost a

foregone conclusion that these nations would not share the results and fruits of their R&D efforts.

At the national level, the active participation of the government, the private sector, the academe, and the entire local scientific community must be forged in the presentation of policy proposals that will be incorporated in a new Intellectual Property Code of the Philippines. Specifically, the local scientific community should help in the formulation and clarification of policy issues such as those involving the first- to-file rule vis-à-vis the first-to-invent rule under Republic Act No. 165 which very few countries still adhere to, notably the Philippines and the United States.

Furthermore, the scope and coverage of the existing intellectual property rights laws must be redefined to keep pace with modern technological trends. The definition of what are patentable inventions under our present patent law needs a clearer reformulation so that shades of doubt on the patentability or nonpatentability of some inventions could be dispensed with. In addition, better incentives and rewards for deserving inventors should be given.

There is a pressing need, then, for a national dialogue among all sectors encompassing the government, the private sector, the academe, and the scientific community in general for a consolidated national position on important patenting issues. In adopting a multisectoral approach, it is imperative that we consider the following actions:

(a) Develop the capability of scientists and institutions to acquire knowledge and information on IPR and current trends;
(b) Develop and enhance the capacity of scientists, policymakers, and R&D executives to negotiate for favorable technology acquisition and transfer contracts;
(c) Explore the commercial benefits from inventions and research outputs with appropriate IPR protection.
(d) Evaluate bills on IPR pending in Congress and propose a position that will reflect the stand of the science community; and
(e) Mobilize existing institutions such as the Science and Technology Coordinating Council (STCC), scientific and professional associations and chambers or industry associations, to organize regular fora for discussions of IPR developments.

In this regard, the STCC has created a multisectoral Committee on Intellectual Property Rights through STCC Resolution No. 2, series of 1992. Due to the emerging developments in IPR protection, the said committee was created to study current IPR issues, including proposed

legislation on the subject, and to come up with a clear national consensus that will further promote the state policy to protect the rights of Filipino scientists, inventors, artists, and other gifted citizens to their intellectual properties and creations. It is also one of the objectives to enhance the awareness of Filipino scientists, inventors and researchers of their intellectual property rights which will contribute to the development of S&T and of the economy as a whole, as well as to promote the availment of their services.

The membership of the Committee is composed of representatives from the government, the academe and the private sector. It has already been organized with representatives from the Department of Science and Technology (DOST) and the Department of Trade and Industry (DTI) as co-chairmen. It has divided itself into three areas of concerns: the industrial sector; health, pharmaceutical and nutrition; and biotechnology and advanced technology. One member of the Committee was chosen to act as coordinator for each of the three areas of concern.

With the creation of the IPR Committee, it is hoped that a clear national position on IPR issues will be formulated to enable the Philippines to firm up its stand on the matter, especially on the GATT agreement. In this regard, one of the activities lined up is to organize a workshop to thresh out the differences in the positions of the members of the science, legal, and business communities.

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