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NEEDED REFORMS IN THE HARMONIZATION OF U.S. PATENT LAW

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INTRODUCTION

It is a great pleasure to have this opportunity to discuss the significant area of intellectual property. The time allotted to me though is brief so my remarks must be limited. What I shall attempt to do is to identify major areas where, in my judgment, intellectual property laws need change, or at least attention. Please remember that I speak as an economist, not as a lawyer, and my comments will reflect that focus on the general economic role of intellectual property, not on the particulars of any case. Specifically, emphasis shall be on the role of intellectual property in the stimulation and commercialization of agricultural biotech products and changes which would (could) enhance that stimulative effect.

In particular, I shall comment on the following topics:

- imports of "products-by-process",
- broad protection for pioneering inventions and the rush to invent,
- the U.S. first-to-invent system and international harmonization,
- clarification of the experimental exception from infringement, and
- implications of revisions to UPOV.

Those who follow these matters will recognize that my comments are directed principally to patents and related forms of intellectual property rights, not to copyrights and trademarks. That seems appropriate as patents are the most suitable form of protection for the types of products represented at this conference. However before discussing patents in some detail, it may be helpful for those in the audience whose only direct contact with patents is the notice on a can opener reading "patent pending" (incidentally a legal status in the U.S. which has no real

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[1]This paper was presented by William Lesser at the third annual NABC Meeting "Agricultural Biotechnology at the Crossroads", Sacramento, California, May 30 - June 1, 1991.

significance whatever), to give some broad overview of what intellectual property is and how the laws function.

INTELLECTUAL PROPERTY

Intellectual property refers to creations of the mind – inventions, music, books, etc. Such things require special attention because, unlike other more tangible forms of property, they have a "common good" attribute – "consumption" by another person does not directly diminish the amount available. We can all sing a hit song without its availability to anyone being reduced. Clearly we cannot all drive the same car or live in the same house without someone being disadvantaged.

Common property is one of the theoretical (and practical) justifications for government involvement. National defense is a common property good provided by governments. So is agricultural research like plant breeding which worldwide is and remains largely government funded.[2] The private sector can of course involve itself, but the catch is no profits can be claimed. If everyone can sing my song free of charge, I have little economic incentive to be a composer/lyricist. At best I would be a part time one, working the remaining time to support my song writing "hobby."

This is where intellectual property comes in, providing an incentive for private entities to engage in creative activities. This is done by providing the creator/inventor, the holder of the right, with the option of prohibiting others from using his/her creation, in parallel with the right we have of excluding others from using our private real property. From this perspective two major conclusions can be drawn about intellectual property:

–its intent is economic, the provision of a monetary incentive to attract private investment to

[2]For a further explanation of these issues see any text on public finance economics, e.g. Herber 1975.

creative endeavors,[3] and

–it works by **exclusion**, the ability to prohibit others from using one's invention.

Intellectual property law then allows a limited (in scope), temporary (for a specified period) monopoly right over inventions. Of course, there is little real benefit in simply excluding others, so permission is generally given for compensation – the royalty payment.

Intellectual property laws then are a form of economic incentive which operate through the ability to exclude others. The legislation says nothing about one's freedom to use the invention. That right might be limited by regulation (as described by the preceding speaker), by a related, prior grant of protection, or by other means. Nor does the grant of protection say anything about the practical significance of the invention/creation. It is not, nor could it be, the responsibility of government employees in, say, the Patent Office to predict the economic viability of an invention. That decision is made by the market. The inventor has the opportunity to profit from the invention, but no guarantee. Indeed, only something like 20-30 percent of patents are ever commercialized and few of these are really lucrative. Moreover, it is the responsibility of the holder of the right to enforce it. We do not have a police force for infringers; rights must be protected through court proceedings initiated by the involved parties.

This all says intellectual property is less than many assume it to be. It is important, but generally not that important. Referring again to patents, businesses often rank patents low on lists of decisions on where/how to invest in R&D (surveys in Scherer 1980, p. 446; Nogués 1990, pp. 11-14). But note that where it is ranked high is for pharmaceutical products and living organisms, which are easily copied. As these products are the underpinning of much of the biotechnology industry, that sector is especially concerned with the form and operation of intellectual property protection.

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[3]Another approach to intellectual property is that of inherent rights – an inventor should have the exclusive right to use his or her invention. That approach is not treated here in favor of the economic incentive concept.

Since intellectual property laws serve as an economic policy tool, a device to spur private R&D spending, it would be satisfying to know how well this policy works. Regrettably that question cannot be answered with any real clarity. We have some evidence, including that provided by one of the organizers of this meeting, Bees Butler, that such laws do spur investment (Butler and Marion 1983). What is largely lacking is evidence that existing laws are anywhere near optimal in terms of scope or length of protection (see the literature review by Braga in Siebeck 1990). This is an important issue because intellectual property laws consist of many detailed aspects for which we have little economic evidence to guide us. Many of my comments below deal with just such aspects, but recognize there is no firm evidence to point to in support of one position or the other.

Since intellectual property comes in numerous forms – music, inventions, books, computer programs, data bases, etc. – several laws are required to cover this breadth. The major of these, and the principal creative areas they apply to, are as follows, recognizing that any terse list like this does grave injustice to the nuances of these issues:

Patents:	inventions for products and processes (a special form for selected plants is known as Plant Breeders' Rights);
Copyright:	books, music, recordings, computer programs;
Trademark:	product names and other identifiers;
Trade secrets:	anything of economic value which is actively kept from the public.

The first three of these have their separate requirements and functions, but those details exceed our scope at this point. The fourth category, trade secrets, acts fundamentally differently for it relies on secrecy rather than disclosure. It is also perpetual, so long as the secret can be maintained (as with the formula for Coca Cola syrup). But perhaps most significantly trade secrets in the U.S. are based on state rather than national law and hence protection is more variable. Contracts often substantiate the basis for this protection or extend it into other realms.

When considering the overall protection allowed by intellectual property laws it is important to recognize that they are often used jointly. For example, technologies can be licensed with a patent licensing agreement for the base technology accompanied by trade secrets (possibly involving non-disclosure agreement) providing some "tricks of the trade" of the most efficient use of that technology. Thus intellectual property protection involves a range of types of laws. Adding to that the difficulty of enforcement in some instances, the determination of the actual degree of protection for a particular product/technology in a specific country is indeed a complex matter.

That said, the U.S. has the broadest protection available in the world. The breadth applies particularly to higher plants and animals where patenting is a matter of policy and practice. Contrast that with the European Community which is still struggling with the patentability of these products (see the OECD Directive 1988) although progress is now being made. In fact let me make the broad statement, without much specific substantiation, that limitations to intellectual property protection in the U.S. has not been a major factor in delaying private R&D investment here in biotechnology. Those who are looking for a major source of the problem will have to look elsewhere, in my judgment. This of course does not say everything is fine in this area. Let us now look at where improvements seem to be needed.

IMPORTS OF PRODUCTS-BY-PROCESS

For many years, U.S. inventors lacked effective protection for products produced overseas by a technology patented in the U.S. The rights granted read as follows (35 U.S.C. Sec. 271-Infringement of Patent): "...Whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent...". Clearly, as the use of the technology did not occur in the U.S. there is no violation of this statute. Contrast this position with the rights specifically granted in many countries. The European Patent Convention for example reads in Article 64 (2), "If the subject-matter of the European patent is a process, the

protection enforced by the patent shall extend to the products directly obtained by such a process." Protection for U.S. inventors however exists outside the patent act – specifically in the 1988 Omnibus Trade and Competitiveness Act (*Biotechnology Newsletter* Nov. 1988).[4] That Act purposely avoids the term "directly obtained", substituting two provisions delineating when infringement has not occurred:

(1) [the product] is materially changed by a subsequent process, or

(2) [the product] becomes a trivial and nonessential component of another product.

While these matters may seem esoteric, they have a direct bearing on agrobiotechnology. For example, as Bent et al. (1987, pp. 320-22) discuss, how are the products of a potential breeding process or gene insertion system to be interpreted? The first generation (the direct product) using these technologies would almost certainly be covered. But what of succeeding products or generations which are the creation of the patented technology but did not directly employ it? In the U.S. this matter can be partially avoided by claiming the propagation method, but that necessitates identifying all the possible products of the invention. In Europe the ban on the protection of the products of "essentially biological processes" (EPC Article 53 (b)) prevents that approach.

The matter is a complex one for limiting protection to only the direct products likely gives too limited protection. The extension to all future generations however gives a potentially enormous scope, something that clouds the ownership of many living organisms. That extent of protection seems excessive and will in some cases chill further research. The normal pattern is for case law to resolve these matters, but that is a slow and imprecise method. Better to write the legislation more specifically to identify for example how many generations are to be covered in a product-by-process claim. My preference for the U.S. is to place such legislation within the Patent Act.

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[4]An earlier version, the Tariff Act of 1930 in Section 337 did grant similar protection, but its breadth raises problems, especially with GATT (see Barton 1989).

BROAD PATENT PROTECTION FOR PIONEERING INVENTIONS

If my preceding comment could be broadly supported, this one will be far more controversial. It has to do with the essentially "defensive" position from which U.S. patent examiners operate. In brief, they must grant the claims made by the inventor unless specific reasons (evidence) for denying them can be established. The evidence required is prior knowledge or prior inventions. Inventors in new, pioneering endeavors will typically claim broadly, and the very newness of the field means examiners have no basis for denying those claims. A key example is that of the "Harvard mouse" – the one and only higher animal patent to date – which claims "A[ny] transgenic non-human mammal..." (claim #1, U.S. Patent No. 4,736,866).

At one level this sort of broad claim granting seems equitable – something pioneering after all deserves a greater reward. However, the purpose of intellectual property is not equity to the creator, it is the social good to which these laws are directed. Society benefits by bringing forth an invention at the least cost, that is, by granting the smallest degree of monopoly rights needed to induce an invention. From what we know about fundamental inventions, they are inspired by some form of creative drive, not solely by financial motives. Patents seem best suited to stimulate the repetitive work required to refine inventions and make small ongoing improvements (Scherer 1980; Jewkes, Sauers and Stillerman 1969). Therefore it is not clear if society is receiving a proper return for the broad protection granted.

This matter touches on two issues of patent law and patent economies known as the rush to invent and undue experimentation. The rush-to-invent analysis recognizes that the patent system grants great benefits to the successful – the first – and little to others (but see comments under the first-to-invent system below). This in turn can stimulate hurried, duplicated research by multiple firms, a social waste. Secondly, firms fearing they are late entrants may desist from entering altogether. Counterbalancing these, the race tends to bring forth inventions more rapidly than otherwise, a societal gain. It has not been possible to determine theoretically or empirically where

the balance lies (Siebeck 1990; Scherer 1980, Chap. 15; Dasgupta and Stiglitz 1980). The granting of large value to pioneering inventions however exacerbates these issues although again the societal outcome is not clear.

"Undue experimentation" is a patent term which says in essence that the invention must be replicable in some reasonable time or economic frame (see Van Horn 1987). It provides a way that examiners can limit a patent scope by requiring proof of duplicability. This issue for example might arise in the "Harvard Mouse" patent where all non human mammals are claimed, but to date (to my knowledge) only a mouse has actually been produced. Can indeed the procedure be extended to primates without undue experimentation? This matter will likely be reviewed in appeal or in the courts in the future.

If the theoretical issue is not clear, the practical considerations are becoming so. Without attempting to comment on the merits of any particular patent, broad legal battles are emerging now in the area of agricultural biotechnology. This is particularly true for broad claims to a method of achieving some goal, that is to say to a claim to the dominance of a technology or procedure. It is not clear, at least to me, that society benefits from such broad grants. What it may lose are the costs of the litigation along with the chilling such unclear rights have to related research. Narrower but clearer protection would seem to be preferable in business planning to broad but fuzzy protection. I call for a reform in Patent and Trademark Office practices in this area.

THE U.S. FIRST-TO-INVENT SYSTEM

One of the steps in awarding a patent is determining who is the inventor. Most of the world follows a simple system – the first to file is presumed to be the inventor (the first-to-file system). The U.S. is nearly alone in granting patents to the first-to-invent. At an extreme that allows a transfer of the patent even after it has been granted. The process followed is one of interferences (35 U.S.C. Sec. 135). Considerable documentation, including detailed, dated lab roles, is required to substantiate the date of invention.

Conceptually and theoretically speaking, the first-to-invent system is preferable. It awards the patent to the true inventor and reduces some of the pressure for the race to invent, mentioned above. Moreover, the first-to-file system combined with a grace period (the time prior to the first patent application) allows some opportunity for a strategic revealing of the invention to foreclose rights to others (Lesser 1987).

That said, the first-to-invent system too raises problems, the greatest of which is protracted court battles. One was recently concluded in favor of Amgen over ownership of the patent for recombinant erythropoietin (EPO) (*Nature* 350 (1991):99; *Biotechnology* 9(1991):327). Moreover the documentation process is unfair to foreign inventors as certain lab documents must be certified in the U.S. and burdensome to small inventors. It is in my judgment time for the U.S. to abandon our first-to-invent system and join the rest of the world.

CLARIFICATION OF THE EXPERIMENTAL EXEMPTION

It is not necessary to convince agricultural researchers of the need for access to prior developments – patented or not – as part of the continuum of developmental work. To this group the words of the Patent Act (35 U.S.C. sec. 271) "...whoever without authority makes, uses or sells..." is indeed chilling. What will their access be to patented plants and animals? This issue of the so called research exemption is a key one, in perception if not reality.

As the research exemption is not specified in U.S. patent law, it is open to interpretation. Here there is widespread disagreement due to the opinion in *Roche Products v. Bolar Pharmaceutical Co.* (Fed. Cir. 1984). However, the particular case (which as a precursor to marketing a generic drug had clear and specific commercial intentions) did not apply to experimental use so that some consider the extensive and often quoted commentary as *not dicta* – that is not applicable in other instances.[5] I agree with Bent (1989) in the regard that not allowing

[5]The case identified in *Roche Products* was rectified by a 1984 amendment to the U.S. Patent Act (Sec. 271(e)) giving specific rights for testing pharmaceutical products.

experimental use flies in the face of the evolutionary nature of inventions and the whole purpose of the patent system. Nevertheless that belief/interpretation is not widely held; many are concerned by this issue.

The concern has arisen in the proposed (but not enacted) amendment to the Patent Act (Transgenic Animal Patent Reform Act). A 1989 workshop sponsored by the Crop Science Society of America similarly recommended a clarification of this matter, through legislation if need be (ASA 1989, pp. 186-87).

There is an urgent need to clarify this matter, to researchers if not in the law. Legitimate concerns exist and need to addressed.

REVISIONS TO UPOV

UPOV is the international convention for Plant Breeders' Rights (PBR). PBR are patent-like grants with some additional exemptions (especially the right of farmers to plant seed held over from harvest) which reduces the scope of protection compared to patents. In the U.S., UPOV is implemented as the Plant Variety Protection Act of 1970.

UPOV is significant here because in Europe, and where European-type law is applied, it acts as a "separate but equal" system where UPOV covers plants and patents other inventions. This is done through the ban on so-called double protection (UPOV Article 2) (from which the U.S. has an exemption).

The point of raising this is to note that major revisions have been proposed and are being discussed at this time (UPOV 1990). Like many changes, this revision promises benefits as well as possible problems for U.S. agricultural biotechnology firms. Among the major benefits, the ban on double protection is proposed to be dropped, facilitating the way for the much needed patenting of plants in Europe.[6] Of possible concern is the institution of dependency rights (Article

[6]Other approaches to this end are being taken currently – see Council Directive (OECD 1988).

14 (2) – Alternative A). Dependency rights define the opportunity for the developer of the "initial" variety to authorize or not the sale, offering for sale, etc., of "essentially derived varieties". That latter term refers to changes which preserve the essential characteristics of the variety, such as variety selection, back-crossing or transformation by genetic engineering. Varieties are not to be sequentially dependent (A-B-C), but rather dependent on the initial variety (A). My concern is that the holder of the rights to "A" will gain quasi-intellectual property rights to the thousands of attributes of the variety which he/she did nothing to create. It is just this potential coopting for individuals of plants in the public domain which is so feared and criticized by breeders and others.

At the same time, proposed rights extend only to the "products made directly from harvested material" (Article 14 (1) - Alternative A). One can imagine that the breeder of a new maize variety would be powerless to prevent the importation of foodstuffs using corn starch made from that variety. Thus the proposed revisions, at least in one alternative, appear to provide too much protection in one respect and too little in another. Yet until such time as the patenting of all plants is widely granted around the world, UPOV will remain the available form of protection for U.S. inventors in this sector. Close attention to these changes and their effects is needed immediately. This is not an abstract exercise that is underway.

CONCLUSIONS

My attempt has been to establish the state of intellectual property protection in the U.S. , and especially that for agricultural biotechnology, as being quite extensive. Its shortcomings in my view are not principally responsible for slow commercialization of these products. That point aside, intellectual property legislation is evolving also and I have identified several areas where, in my opinion, further attention needs to be directed to achieve a better balance between private incentive and public well being.

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