SYMPOSIUM ON THE PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

Ithaca, New York

June 4 and 5, 1987

jointly organized by

the World Intellectual Property Organization (WIPO)

and Cornell University, Department of Agricultural Economics

WORLD INTELLECTUAL
PROPERTY ORGANIZATION
(WIPO)

Cornell University
Department of
Agricultural Economics

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PREFACE

The World Intellectual Property Organization (WIPO) organized, jointly with Cornell University (Ithaca, New York, United States of America), a two-day Symposium on the protection of biotechnological inventions. The purpose of the Symposium was to identify and discuss the various issues on the subject of adequate legal protection for biotechnological inventions. The Symposium took place on the Cornell University campus, on June 4 and 5, 1987.

Over 100 participants were in attendance. They came from various parts of the world, including the United States of America, Canada, Europe, Africa, Asia and Latin America.

The 10 lecturers were prominent experts from government, academic and private sectors in Europe and the United States of America. Each lecture was followed by a question and answer period.

The present volume contains the texts of the 10 lectures and other relevant information.

Arpad Bogsch

Director General

World Intellectual Property Organization (WIPO)

Geneva, 1987

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3.00 p.m.: Discussion

4.00 p.m.: Presentation by Mr. William Duffey (General Patent Counsel, Monsanto Company, St. Louis)

4.30 p.m.: Discussion

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5.30 p.m.: Discussion

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2.00 p.m.: Presentation by Dr. Charles Brim, Professor Emeritus, University of North Carolina

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3.00 p.m.: Presentation by Professor William Lesser (Associate Professor of Marketing, Department of Agricultural Economics, Cornell University, Ithaca)

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4.30 p.m.: Presentation by Dr. Otto Stamm (Head of Patent Department, Ciba-Geigy, Basel, Switzerland)

5.00 p.m.: Discussion

5.30 p.m.: Closing of the Symposium

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OPENING REMARKS

by Dr. Robert Barker
University Provost, Cornell University

On behalf of Cornell University and the College of Agriculture and Life Sciences, I warmly welcome to Cornell University the participants in the Symposium on the Protection of Biotechnological Inventions and the WIPO staff here present. It is a particular privilege to organize the Symposium jointly with the World Intellectual Property Organization, the United Nations specialized agency for intellectual property matters.

Cornell University is an independent Ivy League university and comprises thirteen coeducational colleges, of which four are State-supported and nine are privately endowed. Some eighteen thousand students, including almost six thousand graduate and professional students, are in residence at Cornell's Ithaca campus. Situated on a hill overlooking Ithaca in the Finger Lakes region of New York State, the campus is considered one of the most beautiful in the United States.

Cornell University is at present in a phase of expansion, which concerns in particular the biotechnology sector. A massive building program is currently under way, which is valued at over $500 million. The first phase of that program includes a building for new biotechnological research facilities.

Research in the field of biotechnology is indeed an important activity of Cornell University, and patenting of the University's inventions serves to generate funds to support that research. In this connection, we are well aware of the problems existing with regard to the legal protection of the results of biotechnological research, and we hope that the Symposium will promote adequate solutions to those problems.

It is with great pleasure that we put the facilities of Cornell University at the disposal of the Symposium. I hope that all those present, after participating in the stimulating discussions to take place during the Symposium, will also have an opportunity to enjoy the recreational facilities offered by Ithaca and its surroundings, and I wish full success for the Symposium.

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OPENING REMARKS

by Mr. Gust A. Ledakis, Legal Counsel,
World Intellectual Property Organization (WIPO)

Dr. Robert Barker, Provost of the University,

Professor David Call, Dean of the College of Agriculture and Life Sciences,

Professor Robert Kalter, Chairman, Department of Agricultural Economics,

Professor William Lesser, Associate Professor of Marketing, Department of Agricultural Economics,

Invited speakers,

Distinguished participants from the scientific community, industry, the legal profession and government, in the United States of America and abroad,

Fellow staff members of WIPO,

Ladies and Gentlemen,

It is a great honor for the World Intellectual Property Organization (WIPO) to join with Cornell University in the organization, in Ithaca, of this Symposium on the Protection of Biotechnological Inventions.

It is also an honor, a privilege and a pleasure for me, on behalf of the Director General of the World Intellectual Property Organization (WIPO), Dr. Arpad Bogsch, to welcome you to this Symposium and to deliver these opening remarks.

I would like, at the outset, to express the deep appreciation of the World Intellectual Property Organization (WIPO) to Cornell University for having agreed to jointly host the Symposium, and for the efficient arrangements and excellent facilities which the University has provided for the conduct of this Symposium and for the convenience and comfort of the participants.

A great deal of time, effort and thought have been committed to the planning and organization of the Symposium. Credit is due to the leadership of Provost Barker and to the able guidance of Dean David Call of the College of Agriculture and Life Sciences and of Professor Robert Kalter, Chairman of the Department of Agricultural Economics.

Special thanks are merited by Professor William Lesser of the Department of Agricultural Economics at Cornell University and by my colleague, Ludwig Baeumer, the Director of the Industrial Property Division at WIPO. Their unfaltering perseverance and skillful direction have brought to fruition the idea for this Symposium. They have sown and cultivated, and through their outstanding efforts, we will, I am sure, reap the benefits of what promises to be a most interesting Symposium.

This Symposium is part of a series of initiatives which the World Intellectual Property Organization (WIPO) started in the last nine months, and which it will further pursue during the remainder of this year and in the course of the next biennial program, in order to discuss the relationship of intellectual property to several topics which are of fundamental importance to the creation, well-being and quality of life.

The initiatives of WIPO have focused on the need to improve the understanding of the complex matters involved in the legal protection of innovations concerning such advanced technologies as biotechnology, integrated circuits and computer programs, and in the impact that new technological means for the dissemination of works of the mind--especially the use of computers, satellites and new devices for recording and reproducing--have on the legal protection of those works and on the rights of their creators. The discussion of those topics will contribute to the identification of the issues and to the formulation of appropriate policies in connection with the intellectual property aspects of those advanced technolgies and means.

The deliberations in this Symposium will deal with one very important and--I dare say--controversial topic of biotechnology. Its intellectual property implications have already been the subject of seminars organized by the World Intellectual Property Organization (WIPO) in Mexico City in September 1986 and in New Delhi in March 1987. A series of missions have also been undertaken in six Latin American countries in preparation for a meeting of experts on this topic, which is expected to take place in Caracas later this year. Meetings in other regions of the world will be held as soon as possible. Even before, and now in parallel with those activities, are the meetings in Geneva of the WIPO Committee of Experts on Biotechnological Inventions and Industrial Property. The first such meeting took place in November 1984, the second, in February 1986, and the third will take place in the last week of this month of June.

In addition, I should mention the work of an organization closely related to WIPO--the International Union for the Protection of New Varieties of Plants (UPOV). The Director General of WIPO is also the executive head--the Secretary General--of UPOV. Its Vice-Secretary General, Dr. Walter Gfeller, is amongst us today. UPOV is considering the impact of biotechnology on the protection of plant breeder's rights.

The Secretariat of WIPO and the Secretariat of UPOV each have prepared a number of valuable studies which can be put at the disposal of the participants.

For the present Symposium, we are especially fortunate to be assisted with presentations by ten specialists, each of whom has prepared an excellent paper. I would like, at this time, to formally introduce them to you (in the order in which they will make their presentations):

1. Ludwig Baeumer, Director, Industrial Property Division, World Intellectual Property Organization (WIPO).

2. William Duffey, General Patent Counsel, Monsanto Chemical Company, St. Louis, Missouri.

3. Alan Laird, Company Patent Agent, Legal Department: Patents, Imperial Chemical Industries PLC, Welwyn Garden City, United Kingdom.

4. Karl Josef Heimbach, Head of the Patent Department, Bayer AG, Leverkusen, Federal Republic of Germany.

5. Charles Van Horn, Director, Organic Chemistry and Biotechnology, Group 120, United States Patent and Trademark Office, Washington, D.C.

6. Rudolf Teschemacher, Head of the Legal Service for the Grant Procedure, European Patent Office, Federal Republic of Germany.

7. André Rémond, Director, Examination and Opposition, European Patent Office, Munich, Federal Republic of Germany.

8. Charles Brim, Professor Emeritus, North Carolina State University, North Carolina.

9. William Lesser, Associate Professor of Marketing, Cornell University, Ithaca, New York.

10. Otto Stamm, Head of the Patent Department, Ciba-Geigy, Basel, Switzerland.

Each of them brings to us a rich knowledge and experience, borne of their years of service in industry and commerce, in government, and in the academic, scientific and legal circles, as well as in the international community.

To each of these speakers, we are grateful for the time and effort which they have committed in preparing their presentations and for their willingness, at great sacrifice to their continuing obligations, to be with us at this Symposium.

I greet all the participants in the Symposium. We have before us a distinguished gathering from all those sectors concerned with research and development in the field of biotechnology and with the intellectual property aspects of that endeavor and its results. We are especially heartened by the interest which this Symposium has drawn not only from the many persons assembled here from the United States of America but from other countries--from Europe, from Africa, from Asia and the Pacific, and from Latin America--as well as from intergovernmental organizations, thus making this Symposium a truly international forum.

I could not begin to end these remarks without some reference to the City of Ithaca, New York, and to this beautiful campus of Cornell University.

For many of you this journey to the city of Ithaca, New York, to join us at this Symposium, may very well be told by you upon your return in the manner of the legendary hero Odysseus. It is said that in the Odyssey, there is described an island, with considerable coincidence of topographical detail to that of Ithaca, the smallest of the seven main Ionian islands in the nomos (department) of Cephalonia, Greece. It is after this ancient island, which is celebrated as the principality and home of Ulysses, that the city of Ithaca,

the site of this Symposium, is named. That Ionian island consists of two limestone masses, connected by a narrow, hilly peninsula that curves to include at one head a narrow, deep, horseshoe-shaped inlet of a gulf that faces the Greek mainland. The scarcely arable, mountainous island, with its steep and rocky coast, must import grain, but produces some olive oil, wine and currants and keeps a few goats, yet its life managed to survive a devastating earthquake in 1953. It stands in stark contrast to the site of this Symposium--the City of Ithaca, New York, perched at the southern end of Cayuga Lake, where deer abound in its lush green hills, cut by picturesque gorges and creeks. Its growth, stimulated by Cornell University's expanding program in the sciences, is testimony that nature and man, through his scientific inquiry and the spread of knowledge, can combine--that the elements and human genius--in short, the Greeks have a word for it, bioteknologia (biotechnolgy)--can create life, nourish mankind and preserve it from chaos.

Provost Barker, may I thank you, and through you, Cornell University for joining with the World Intellectual Property Organization (WIPO) in organizing this Symposium. I wish the speakers and participants a most pleasant stay in these hospitable surroundings. I wish you all a most enriching experience from what I am sure will be a stimulating discussion and a successful outcome of this Symposium.

* * *

CLOSING REMARKS

by Dr. Ludwig Baeumer,
Director, Industrial Property Division
World Intellectual Property Organization (WIPO)

This Symposium has offered its many participants from industry, universities and research institutions, government agencies, intergovernmental organizations and the legal profession an opportunity to assess recent developments in the field of biotechnology. It has given us an opportunity to evaluate existing legal protection for biotechnological inventions, to identify shortcomings of that protection and to seriously consider the possibilities for improving that protection.

As regards technical developments, it is necessary to consider not only the present state of the art, but to think ahead, since appropriate legal protection must be established before new types of technology are developed. If the legal system is adapted only after developments have taken place, new types of inventions will not have the benefit of industrial property protection.

Adaptation of the legal system can be achieved in two ways--by interpretation of the existing law and by legislative change.

In the field of biotechnology, important changes--or at least clarifications--have been effected in recent years through court decisions or developments in the practices of industrial property offices, without any modification of the applicable legislative provisions. It appears that this method of adaptation can be further pursued in order to keep pace with technological developments, in particular as regards the concept of invention and the requirement of an enabling disclosure.

However, there are obvious limitations to the adaptation of existing laws to provide adequate protection for biotechnological inventions. Thus, one has to examine to what extent legislative changes are required in both national laws and international conventions to adequately provide legal protection for innovations in this rapidly developing technology.

WIPO is at present examining solutions to the problems and limitations which are confronted when an adaptation of current laws to this new technology is attempted. These concerns are being addressed by a Committee of Experts which has been set up for this specific purpose. This Symposium has certainly helped to clarify issues and to better understand different points of view which must be considered if a meaningful and cohesive body of law is to be developed for adequate legal protection in this area.

On behalf of the World Intellectual Property Organization, I should like to thank the speakers in this Symposium for their outstanding presentations of the current issues concerning biotechnological inventions, and the participants for their most stimulating contributions in the discussions which followed the presentations. Our particular thanks go to Cornell University, the co-sponsors and co-organizers of this Symposium, here represented by Professor Robert Kalter, the Chairman of the Cornell Department of Agricultural Economics, and Professor William Lesser of the same Department. We extend our sincere thanks and appreciation to you for your time and effort in connection with this Symposium, and for the excellent facilities offered to us here on this beautiful campus in Ithaca, which we are certain greatly contributed to making this Symposium a success.

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CLOSING REMARKS

by Professor Robert J. Kalter
Chairman, Department of Agricultural Economics
Cornell University

We would like to thank WIPO for its generous support in co-hosting this symposium. WIPO's cooperation, interest and enthusiasm for the project is greatly appreciated. Cornell University and the Department of Agricultural Economics have been pleased to be your host and we hope that individually and as a group you have benefitted from the excellent presentations and discussions.

It is perhaps fitting that a symposium such as this should be held at Cornell, since the world's great universities are one group of institutions at the forefront of biotechnology research and technological innovation. Universities will increasingly be demanding a share of the rewards from their scientific discoveries and as such will want to play a vital role in structuring the "rules of the game."

As little as five years ago, holding a conference on the subject matter relating to biotechnology and property rights would probably have been unthinkable. Now we are discussing "precision agriculture," and the technology is moving rapidly. Today, by using biotechnology, we have the capability of increasing milk production by 30%, reducing backfat on hogs by 70%, and producing virus free plants, to name but a few of the exciting discoveries made. Now our institutions governing property rights in intellectual resources must strain to catch up.

As the last speaker, I should try to summarize the broad thrust of issues discussed. They have been many--ranging from policy concerns to technical legal issues. I will not, however, try to deal with these questions. Rather, as an economist, permit me to make just one central point which should be kept in mind as we contemplate our discussions and continue to take actions that will improve our institutional arrangements.

The market for "biotech" produced products, varieties and species is a truly international one. As such, rapid progress must be made on a system of uniform, consistent property rights applicable to all countries if the full extent of social benefits from this new technology is to be realized. Without this type of progress, entrepreneurial uncertainty and risk will be increased and inhibit further scientific work. For it is clear that the legal, financial, and environmental risks and benefits of biotechnology are closely bound to the "rules of the game."

And, as we all know, the existing structure of property rights has a great deal to say about the distribution of the net social benefits from a new set of techniques such as those embodied in biotechnology. The need of society for widespread benefit distribution must be balanced against the need for an incentive structure which will spur continued and rapid development.

Unless our existing institutional structure adapts to changing times, it will recede in importance. Other mechanisms will rise to take its place. It is our challenge to assist in making the necessary modifications, which in the end will be acceptable to the sponsoring public. I hope that this conference will serve as a springboard for future activity aimed at this objective. Thank you for coming and accept my best wishes for a safe trip home.

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PROTECTION OF INVENTIONS IN THE FIELD OF BIOTECHNOLOGY

Presentation by Dr. Ludwig Baeumer,
Director, Industrial Property Division,
World Intellectual Property Organization (WIPO)

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I. INTRODUCTION

1. Biotechnology is a field of technology whose importance has grown considerably in recent years. Indeed, it appears possible that biotechnological inventions will have a very significant effect on our future, in particular in the fields of medicine, food, energy and protection of the environment.

2. Biotechnology concerns living organisms, such as plants, animals and microorganisms, as well as non-living biological material, such as seed, cells, enzymes, plasmids (which are used in "genetic engineering") and the like. Biotechnological inventions fall into three categories. They are the processes for the creation or modification of living organisms and biological material, the results of such processes, and the use of such results.

3. Whilst biotechnology has assumed increasing importance in recent years, it is nevertheless one of the oldest technologies. For example, the production of wine or beer involves processes using living organisms, and such processes have been known for a long time. Likewise, the selective breading of plants and animals has an equally long history. However, as regards plant and animal breeding, there is no certainty as to the results because characteristic features of the organisms are transmitted from one generation to another according to the laws of heredity. These laws show that different combinations of features will produce a whole range of results.

4. Technology, strictly speaking, involves human control. Thus, processes which may be entirely controlled by man in a scientific 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.

5. In recent years, as a result of scientific discoveries, it has become possible to develop biological processes which manipulate living organisms. These processes may be entirely controlled by man. The most notable examples of such processes occur in the artificial modification of genes ("genetic engineering"). These processes are able to change the material determining the hereditary characteristics of living organisms, and thus it is possible to create--under particular circumstances--modified organisms which have certain desirable features. Genetic engineering processes are in particular used in the modification of microorganisms for the production of new medicines. Biotechnology is expected to lead to important breakthroughs in medicine which may be effective in combating diseases; it may also lead to new opportunities for obtaining food and energy, and may provide solutions to the problems of pollution of the environment.

6. If it is possible to control a biotechnological process and to describe such a process in a way that experts in the field can carry it out on the basis of the description, then an invention in the field of biotechnology has been made. Traditionally, in scientific circles, the concept of invention was

generally limited to the fields of physics and chemistry because living organisms were considered to be outside the scope of technology. However, with the possibility of controlling and describing processes in the field of biotechnology, the concept of invention will have to be enlarged to cover biotechnological inventions.

II. NEED FOR PROTECTION

7. As in other fields of technology, there is a need for legal protection in respect of biotechnological inventions. Such inventions are creations of the human mind just as much as are other inventions, and typically they are the result of substantial research and inventive effort and investment in sophisticated laboratories. When decisions on whether such investments for research are to be made, the question of the protection of the research may play an important role. Typically, enterprises engaged in research only make investments if legal protection is available for the results of their research. Thus, there is an obvious need for the protection of biotechnological inventions--as with other inventions--, not only in the interest of inventors and their employers, but also in the public interest in order to promote technological progress.

8. If biotechnological inventions are protected, this does not automatically mean that the government approves any kind of exploitation in practice. Ethical principles may restrict such exploitation, and government regulations may accordingly prohibit certain kinds of exploitation. Thus, this aspect may supersede a need for protection which is merely based on economic reasons; but ethical principles only concern certain specific applications, for example, genetic engineering in respect of human beings, if ever one were to seriously think of something like that.

III. EXISTING PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

9. Legal protection of inventions is normally effected through the grant of patents or other titles for the protection of inventions. However, inventors in the field of biotechnology are faced with several obstacles when seeking protection for their inventions. These obstacles do not exist to the same degree in other areas of technology.

10. The first obstacle is the problem of whether there really is an invention rather than just a discovery. If, for example, an as yet unknown microorganism is isolated by a sophisticated process, it may be argued that such a microorganism is not an invention but is a scientific discovery. The counter-argument would be that the isolation requires an important intervention by man using a highly sophisticated process, and that therefore the result is a solution of a technical problem.

11. Another obstacle faced by inventors of biotechnological inventions concerns the theory, already mentioned, that inventions can only be made in the fields of chemistry and physics but not in the field of biology because biological processes cannot be sufficiently controlled and described. This latter obstacle, however, now seems to belong to the past.

12. The third obstacle, which is the most important one, is the existence of express legislative provisions that exclude certain categories of biotechnological inventions from patent protection. Those provisions have their origin in developments which took place in Europe, but have also influenced countries outside Europe.

13. Article 53(b) of the European Patent Convention stipulates that European patents shall not be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals (with the exception of microbiological processes and the products thereof). This provision is to some extent the result of a provision in the Strasbourg Convention which was concluded in 1963 under the auspices of the Council of Europe and which concerns the unification of certain points of substantive law on patents for invention. According to Article 2 of that Convention, the Contracting States are not bound to provide for the grant of patents in respect of plant or animal varieties or essentially biological processes for the production of plants or animals (with the exception of microbiological processes and the products thereof). When the European Patent Convention was concluded in 1973, the Contracting States made use of their freedom under the Strasbourg Convention and did not permit the grant of patents for these particular categories of inventions.

14. There are two reasons for this approach. Firstly, it was considered that granting patents for inventions belonging to the categories referred to would create legal and administrative difficulties and that the newly created European system should not be burdened with such difficulties. Secondly, a special system of protection had been created in various countries with respect to plant varieties, and it was considered that this system should remain as the only applicable system with respect to that category of inventions.

15. The special system of protection for plant varieties is different from patent protection in that it only concerns the marketing of propagating material (seed, etc.) but not the growing and marketing of plants themselves. The system of plant varieties rights is also different in respect of the conditions for protection and the protected acts. The special nature of this system is demonstrated by the fact that an international convention was concluded for the protection of new varieties of plants which is administered by a special organization, namely the International Union for the Protection of New Varieties of Plants (UPOV).

16. The exclusion of plant and animal varieties and essentially biological processes for the production of plants or animals is a feature existing in a number of national laws, not only of the member States of the European Patent Convention, but also of other States such as Cuba, the German Democratic Republic, Mexico, Sri Lanka, Thailand and Yugoslavia. The Patent Law of China excludes animal and plant varieties, but not biological processes for their production.

17. In the United States of America, there are no such exclusions. Thus, as recently confirmed by the United States Patent and Trademark Offices, for all kinds of biotechnological inventions, patents are available in addition to the plant variety rights which are available for varieties of sexually reproduced plants. For asexually reproduced plants, special patents, called "plant patents," are available.

18. It is to be noted that other countries with important research in biotechnology, for example Japan, do not have an express exclusion of certain categories of biotechnological inventions from patenting.

19. A particular category of biotechnological invention, namely inventions concerning microorganisms (either the processes for obtaining a microorganism or the microorganism itself, or the particular use of a microorganism) are governed by special provisions. In view of the fact that it is difficult, if not impossible, to sufficiently describe a new microorganism, a system for depositing of microorganisms has been established. Thus, in many countries, applicants for patents do not need to describe a new microorganism but only have to refer to a deposit made with a recognized depositary authority.

20. This system is also the subject of an international treaty, namely the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, which provides for the setting up of international depositary authorities with which microorganisms can be deposited. A deposit with one of the depositary authorities will have effect in all Contracting States of the Budapest Treaty, and it is not necessary to make deposits in each country in which patent protection is sought. The international recognition of the deposit is accompanied by an obligation on international depositary authorities to keep deposits for at least 30 years and to release samples of deposited microorganisms once the conditions of the applicable national law (typically, the publication of the patent application) are fulfilled.

IV. WIPO'S ACTIVITIES IN RESPECT OF THE PROTECTION OF INVENTIONS IN THE FIELD OF BIOTECHNOLOGY

21. WIPO is responsible for the administration of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms, which in particular entails activities in connection with the establishment of international depositary authorities and any changes concerning them, the publication of a Guide to deposits under the Budapest Treaty and the revision of the Regulations under that Treaty.

22. In addition, in 1984, WIPO commenced a study concerning the protection of biotechnological inventions. The purpose of this study is to determine whether the existing protection is sufficient and whether any improvements should be recommended. As a first step, a memorandum on the industrial property protection of biotechnological inventions was submitted to a Committee of Experts in November 1984. Subsequently, an analysis of certain

basic issues was prepared, and a report was submitted to the second session of the Committee of Experts, which took place in February 1986. The report in particular deals with the question of whether the exclusion of certain categories of biotechnological inventions from patenting is justified and whether the system of deposit of microorganisms needs to be extended to all biological material which can be kept biologically active for a certain duration.

23. Following those two sessions, WIPO has carried through a fact-finding survey, on the basis of questionnaires sent to the Governments which participated in the work of the Committee and to interested organizations, with respect to the existing protection and desirable changes. As a result of this survey, WIPO has prepared a "Revised Report" on industrial property protection of biotechnological inventions, which analyzes in detail the existing situation with respect to the availability of protection for biotechnological inventions, the scope of protection and the system of deposit of microorganisms, summarizes the suggestions for improvement by non-governmental organizations, and presents suggested solutions concerning industrial property protection of biotechnological inventions. There are altogether 19 such suggested solutions. They deal with the following items:

- Processes for the Production or Use of Plants, Animals, Microorganisms or Varieties or Strains Thereof
- Surgical or Diagnostic Methods
- Industrial Applicability in Respect of Processes
- Enabling Disclosure (Repeatability)
- Essentially Biological Processes
- Microbiological Processes
- Living Matter
- Pre-existing Material
- Plants, Animals, Microorganisms
- Industrial Applicability in Respect of Products
- Effect of Deposit for Disclosure of a Product
- Extension of Process Patents to Products which are Living Matter, etc.
- Genetic Information as an Essential Characteristic of the Patented Product
- Exhaustion of Rights
- Dependency License

- Experimental Use

- Meaning of the Term "Microorganism"

- Requirement of Deposit

- Furnishing of Samples

24. It would go too far here to describe in detail the contents of each suggested solution. Let me however highlight some of the more important ones:

- suggested solution No. 7, entitled "Living Matter," states that a product shall not be excluded from patent protection or regarded as unpatentable only for the reason that it may be considered to be living matter;

- suggested solution No. 9, entitled "Plants, Animals, Microorganisms," states in its first paragraph that an invention shall not be excluded from patent protection for the reason only that it concerns a plant, an animal or a microorganism (or a plant or animal variety or a strain of microorganism) or, where applicable, any part or vegetative or generative propagating material of any of these;

- suggested solution No. 11, entitled "Effect of Deposit for Disclosure of a Product," states that a deposit of a product of a kind which is admitted for deposit with a recognized depositary institution under the proper conditions shall be able to replace, in a patent application, a written description of a process to obtain such a product, whether the said product is claimed per se or is a material necessary for carrying out the claimed invention;

- suggested solution No. 14, entitled "Exhaustion of Rights," states that, where a patent has been granted for a product which is living matter, replication or differentiation of, or derivation from, such a product which has been put on the market by the owner of the patent or with his consent shall not be considered as a permitted use on the ground of exhaustion of rights, unless, and only to the extent that, such replication, differentiation or derivation is unavoidable for a use which is different from replication, differentiation or derivation;

- suggested solution No. 15, entitled "Dependency License," states that a person who carries out an activity concerning a new plant or animal variety which represents significant progress compared with an invention in that area protected by a patent, shall have, to the extent that this is necessary in order to avoid infringement of the patent, a right to obtain a license under the said patent in order to carry out such an activity. Such a license shall be subject to the payment of reasonable remuneration, having regard to the nature of the patented invention and providing due reward to the inventor or his employer for the investment made in order to develop the invention. Where such a license has been granted, the owner of the licensed patent shall have a right to obtain a license under any patent, plant variety right or animal variety right that the licensee may have obtained in connection with the activity referred to above.

25. Considering these solutions in conjunction, the proposed system can be summarized as follows. Living matter should not be excluded from patent protection only because it is living matter. However, a patent can be obtained only on the basis of a sufficient disclosure. In this regard, a deposit can replace certain elements of disclosure. Patents granted for products which are living matter are not at the outset limited to the product as distributed by the owner of the patent or with his consent but may also cover products of replication or differentiation or derivation, provided, however, that the owners of dependent inventions have a right to obtain licenses in respect of the inventions which necessarily must be used in order to use the dependent invention.

26. With respect to the system of deposit of microorganisms, the Revised Report presents suggested solutions concerning the meaning of the term "microorganism" by stating, in suggested solution No. 17, that the term "microorganism," as used in national laws and international treaties concerning patent procedure, shall be understood in the widest sense, comprising

> "(i) any matter which is self-replicable, in particular viruses, replicons, cell lines, and hybridoma cells, and
>
> (ii) any matter which is contained in, or can be incorporated into, a host organism and which is replicable through replication of the host organism,

and which can be deposited. Moreover, suggested solution No. 19 deals with conditions for the furnishing of samples of deposited microorganisms and is intended to achieve a certain degree of harmonization in this area, which at present is characterized by a great diversity of national laws.

27. It is hoped that, as a result of the WIPO study, the protection of biotechnological inventions will be strengthened to the extent that this is desirable, and at the same time harmonized at the international level. The Committee of Experts will meet again at the end of this month, in Geneva, from June 29 to July 3, and this meeting will probably be decisive in order to reach concrete results in respect of the questions which have been studied so far.

[Annex follows]

ANNEX

LIST OF REFERENCE MATERIAL

I. WIPO DOCUMENTS

BioT/CE/I/2 - Industrial Property Protection of Biotechnological Inventions (Memorandum prepared by the International Bureau)

BioT/CE/I/3 - Report of the Committee of Experts on Biotechnological Inventions and Industrial Property (first session)

BioT/CE/II/2 - Industrial Property Protection of Biotechnological Inventions (Report prepared by the International Bureau)

BioT/CE/II/3 - Report of the Committee of Experts on Biotechnological Inventions and Industrial Property (second session)

BioT/CE/II/INF/2 - Decision of the Board of Patent Appeals and Interferences of the United States of America

BioT/CE/II/INF/4 - Observations on Paragraph 19 of Document BioT/CE/II/2 by the Representative of the World Federation for Culture Collections (WFCC)

BioT/CE/III/2 - Industrial Property Protection of Biotechnological Inventions; Revised Report prepared by the International Bureau of WIPO

BioT/CE/III/2 Annexes - Paragraphs 85 to 90 of document BioT/CE/II/3; Questionnaire BioT/Q1; Questionnaire BioT/Q2

BIG/281 - Industrial Property Protection of Biotechnological Inventions - Analysis of Certain Basic Issues (prepared by Dr. Joseph Straus, Head of Department, Max-Planck-Institut for Foreign and International Patent, Copyright and Competition Law, Munich) (available also in Spanish)

II. INTERNATIONAL CONVENTIONS

International Convention for the Protection of New Varieties of Plants, and Additional Act of November 10, 1972, and Revised Text of October 23, 1978 (UPOV)

UPOV General Information

Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, done at Budapest on April 28, 1977 and Regulations (as of January 31, 1981)

III. ARTICLES PUBLISHED IN "INDUSTRIAL PROPERTY"/"LA PROPRIETE INDUSTRIELLE"

"Patent Protection in the Field of Genetic Engineering" by A. Hüni and V. Buss, "Industrial Property/"La Propriété industrielle," December 1982

"Patenting Seeds in the United States of America" by W. Lesser, "Industrial Property"/"La Propriété industrielle," September 1986

"Genetic Engineering and Industrial Property" by F.-K. Beier and J. Straus, "Industrial Property"/"La Propriété industrielle," November 1986

[End of Annex and of document]

THE MARVELOUS GIFTS OF BIOTECH: WILL THEY BE NOURISHED OR STIFLED BY OUR INTERNATIONAL PATENT LAWS?

Presentation by Mr. William Duffey, General Patent Counsel, Monsanto Company, St. Louis

ABSTRACT:

Biotechnology is hailed as the most powerful technology since electronics. Its remarkable impact on mankind through human health care is just beginning. What it can offer to agriculture and to abatement of world hunger is equally exciting. New biodrugs for treating human disease and new biotech products for agriculture will require staggering R&D investments followed by clearance of stringent regulatory hurdles. Serious players in the new biotech need deep pockets, patience and staying power. Unless there is hope for product exclusivity through intellectual property protection, private investment will not support the science in these expensive and regulated environments.

Even before the biotech revolution, patent shelters have proven crucial to the relentless and highly successful quest of industrialized countries to conquer human disease. We believe that the new proteins and peptides produced through genetic engineering will cooperate with traditional drug science to remarkably enhance the welfare of mankind -- all within the established network of those countries which now have strong chemical patent laws.

Whether the great promise of biotech in agriculture and plant science will be allowed to grow and flourish is not nearly so clear from the patent lawyer's perspective.

This paper examines the current patent situation in these two diverse technical areas with suggestions for possible global improvement to ensure continued infusion of capital for exploiting the science.

Any attempt to assess the current patent climate for products of the new biotechnology must necessarily embrace a global perspective. It is not enough to examine the issue from merely a national viewpoint. The science of biotech is global and the market it serves is global. A breakthough cardiovascular drug; a new anti-cancer drug; or a vaccine against AIDS will each produce a global benefit for mankind which transcends national borders.

Much has been written and said about the adequacy of current patent laws to deal with the fast-breaking products of the new biotechnology. Indeed, with some astonishment we have heard more than one respected commentator say that patents are unimportant to biotech. Those commentaries simply reflect the aberrational patent trends surrounding the first generation group of biotech products --- an anomaly which will be discussed later in this paper.

Thus, if one is taking only a short-term view of the new biotech, the notion that patents are unimportant might have some appeal. However, those companies in the private sector which are investing hundreds of millions of dollars in this new science do not accept the theory that patents are unimportant. Such a concept is particularly repugnant to patent-conscious, research intensive pharmaceutical firms dealing in global markets with drugs which require staggering investments of time and money before ultimately yielding a commercial return. To them the patent shelter is paramount. It is quite literally their sole incentive for risk-taking.

Many published studies have documented the cost, research and development (R&D) period and statistical chances for success in discovering a new therapeutic drug by organic chemical synthesi and/or screening. For example, see the British Medical Journal, Vol. 285 at page 761 (18 September 1982). It was estimated in that article that the costs involved in developing a new drug, including the commercial failures prior to marketing, average 100 million pounds sterling.

A similar study was compiled by Dr. D. Bartling and Dr. H. Hadamik of Darmstadt in the Federal Republic of Germany and published 29 September 1982. Entitled "Development of a Drug", the study concluded that chances of finding a new commercial drug through chemical synthesis and/or screening were 1 in 8,000-10,000 potential candidate substances. The average elapsed development period was 8-10 years and the cost to develop a successful candidate approximated 100 million D-marks. The latter sum does not include the economic failures, i.e., products which are marketed unsuccessfully. If these costs are also considered, the figure of DM 100 million can approach DM 350 million.

In the U. S. today, the average cost of finding and developing a new organic chemical drug entity is estimated to be $80-90 million. Elapsed time is equal to or greater than that of the West German study.

A similar pattern is found in the development of agrichemicals such as herbicides, fungicides and insecticides. Published data confirm that only 1 out of 15,000 screened chemical compounds will ultimately provide economic value to agriculture. Discovery and development of a new agrichemical entity requires an average of 8 to 10 years at a cost of $40-50 million for a compound to reach the marketplace.

Stated another way, from the moment a patent application is filed on a new agrichemical compound, it takes approximately 6 years before any sales of that compound are achieved. Expenditures on R&D and regulatory clearance are often so great that it commonly takes 12 years or more from time of discovery before those costs are recovered and the developer can begin to make a profit on the product.

Without patent protection and the exclusivity it affords, there is little hope for the proprietor to recover the enormous costs of product discovery and development. Without a patent shelter it is very difficult to sustain the premium level of pricing so necessary to reach the break-even point on invested capital.

All of us are familiar with the depressed pricing patterns which occur when a popular prescription drug comes off patent. Generic drug producers march in to acquire instantaneous market share at the expense of the firm which pioneered the drug. This practice is regarded as acceptable because the drug pioneer was deemed to have received his fair reward during the period of patent exclusivity. However, without that crucial period of patent protection there would be little chance for the pioneer to break even because the generic producers and the imitators would have marched in much earlier to capture market share at his expense through price cutting.

Enough for the historical trends of drug pricing under the shelter of patent protection. These are well-documented. How does all of this translate to the emergence of the new biotechnology? And what can we expect to see as our current chemical patent laws are superimposed on the powerful new science of genetic engineering?

II - BIOTECH IN THE PHARMACEUTICAL ARTS

The earliest and most promising products of the new biotechnology are human pharmaceuticals, human diagnostics and products for animal science. Prominent among these are

recombinant human and animal proteins and peptides which mimic the body's natural agents and modulate cellular function. Examples are human insulin, human growth hormone, bovine growth hormone, human interferon, human interleukin, tissue plasminogen activator, erythropoietin, tumor necrosis factor and others. These recombinant proteins and peptides are often labeled "first generation" because they closely resemble the native proteins.

In remarkably short time, the nascent science of biotech has delivered a host of exciting first generation proteins and peptides which mimic so many naturally-occurring products and which offer such great promise for treating major diseases. The momentum of this science is staggering!

And I hasten to add that renowned universities like Cornell have contributed enormously to this new body of science through superior research and scholarship. The pioneering art of gene-cloning, for example, was born in a university setting in 1974. Scientists and administrators in academia indeed have a vested interest in maximizing the fruits of biotech because so much of the science is university-driven.

A large number of biodrugs are now in clinical trials throughout the world and many are being marketed. In the U. S. alone, for example, it was reported by the Food and Drug Administration (FDA) in April, 1987 that clinical trials were underway on about 150 drugs developed through biotech. By that same time the FDA had already approved or licensed almost 200 monoclonal antibody-based diagnostic kits and 6 each of therapeutic drugs and recombinant DNA probes for infectious agents. What a boon this tool has been to medical science! And biotech is still in its infancy.

From the above figures we can observe several lessons. First of all, the science itself is robust and fast-breaking with a substantial amount of equity investment supporting it.

Secondly, this early rash of first generation biodrugs tells us that genetic engineering offers unprecedented power for man to mimic nature in boundless fashion.

Thirdly, it has allowed many companies worldwide to bacterially produce proteins and peptides without the long and arduous chemical synthesis and screening procedure so traditional in the pharmaceutical arts.

From the patent perspective this proliferation of first generation proteins has created an unprecedented duplication of products being rushed to the marketplace. We believe this phenomenon is an aberration. Because many of these proteins were already known, understood and genetically sequenced, the drug development and approval process has often outrun the patenting process. Many of these proteins

have become far advanced by each of several competing firms before the patent picture has crystallized. And in many cases there is not expected to be any single dominant patent owner. Indeed, some of these overabundant first generation proteins may prematurely become generic.

Not surprisingly, however, as some early patents have begun to issue on important first generation proteins and diagnostic products, patent litigation has erupted. Courts are now being asked to decide whether the patentee has actually met the requisite standards of invention and patentability, i.e., novelty, utility, nonobviousness and enabling disclosure. "Nonobviousness" is an especially thorny issue in the early disputes.

Those same courts will be asked to decide the degree of exclusivity to be accorded a patent claim on a first generation protein, i.e., the scope of protection enforceable against an accused infringer. Persons skilled in molecular biology know that high molecular weight proteins such as human interferon, insulin, somatotropin and interleukin are readily susceptible to alteration through amino acid substitutions, deletions or additions; through changes in glycosylation; and through changes in disulfide bonding, folding and conformational structure. Query: What constitutes infringement and what avoids infringement? How does the patent lawyer guide and counsel his client?

Patent case law is not yet clear on what constitutes a "material" or "immaterial" (trivial) alteration in the amino acid sequence or the 3-dimensional structure of a protein. We're watching court decisions and waiting for judicial guidance. Meanwhile, neither the patentee or his competitors can be entirely clear on the limits of claim enforcement. This lingering uncertainty regarding patent claim scope for recombinant proteins is perhaps the major biotech issue today in the pharmaceutical arts.

But the runaway science of genetic engineering is not pausing to see what the patent courts decide on claim scope for first generation proteins and peptides. Most sophisticated players in today's biotech have already explored beyond these first generation products. They are developing second and third generation products which are improved designs over "mother nature's" version. Much of this futuristic bioscience is being conducted at leading universities throughout the world, often under sponsorship of governmental and industrial organizations.

Second and third generation bioproducts might be smaller, shorter molecules which feature improved active binding sites with special affinity for cell receptor sites within the human body.

Cell receptors are proteins on cell surfaces that bind messenger molecules like hormones or neurotransmitters to let a cell communicate with the whole animal. Cell receptor technology (RT) has recently come of age in conventional drug design. RT allows researchers to determine quickly whether a given compound is active in the body and, if so, where it acts. It is faster and cheaper than animal testing.

The timely arrival of genetic engineering has synergised with RT by facilitating the sequencing of various receptors such as those for insulin, adrenaline and the neurotransmitter acetylcholine.

With the simultaneous availability of all these powerful biomedical research techniques, one can expect dramatic and speedy advances in human therapeutics. Indeed, many scientists forecast that third generation biodrugs will employ large chemical groups to imitate natural molecules while avoiding the present-day need to administer therapeutic proteins through injection. Greater efficacy and fewer side effects are likely.

Thus, some molecular biologists predict that the interferons and interleukins of today's biotech will eventually be superseded by superior but more traditional chemical forms --- chemical forms which our established international patent systems have accommodated for decades. Should all of these predictions come true, our biotech patent trends will become more traditional and more orderly. Caution must tell us, however, that the arrival of third generation biodrugs may not be just around the corner. Indeed, it may be a number of years before those discoveries take place despite the fast-breaking progress of biotech.

In the meantime, therefore, we must continue to cope with the peculiar patent trends surrounding first generation proteins while gaining wisdom from emerging court decisions. Over the long term, the current chemical patent laws of industrialized countries should be generally capable of dealing with genetically-engineered proteins, recombinant microorganisms and other biological materials, thus affording exclusivity to the inventor and his sponsor commensurate with the scientific contribution. This will be their incentive for R&D investment and risk-taking. It has worked in the past and it can surely work for biotech.

Some fine-tuning of national patent laws to accommodate pharmaceutical biotech has already occurred and more changes will come. Deposit and protection of recombinant microorganisms, for example, will continue to receive attention in certain countries.

III - BIOTECH IN AGRICULTURE AND PLANT SCIENCE

Given the tens of millions of starving people in the world and hundreds of millions of malnourished people, the

goal of stimulating food development through the science of biotech is surely a worthy one. Unfortunately, however, today's global patent climate for genetically-transformed plants is not nearly as hospitable as the climate for recombinant human proteins, peptides and diagnostics. Perhaps this is because the latter products were able to find their niche under the auspices of established chemical patent practice.

Much has been written and said about current problems in the protection of inventions in plant biotechnology. The issues have been repeatedly examined in light of the European Patent Convention; the Japanese Patent Law; the U. S. Patent Law; and the International Union for the Protection of Plant Varieties (UPOV).

Many national patent laws contain provisions excluding plant varieties from patenting because of special systems which provide rights to plant breeders for new plant varieties which they create. Quite understandably, the present patent laws were not drafted with visions of today's sophisticated techniques for genetically transforming plants to achieve insect resistance, frost resistance, drought resistance, herbicide resistance and many other desirable properties. These desirable traits are not confined to a single plant variety but can affect a host of varieties of, e.g., soybeans, sugarbeet, etc. And herein lies the crux of today's commotion about plant biotech patents.

This exciting new science of plant biotech offers unprecedented pathways to "precision agriculture" for the betterment of mankind worldwide. The social and economic potential of this plant revolution is staggering. Yet, sadly, the patent laws of many important countries do not afford with certainty the proper generic protection to those who are investing so heavily in plant biotech. And ironically, the science of plant cell transformation is newer, more difficult and more experimental than bacterial expression of recombinant human proteins. Research moves slowly because the plant genome is complex and not well understood. So far there has been a paucity of plant science product launches compared to the avalanche of biomed launches. If ever there was a real need for patent protection as an incentive for risk-taking, plant biotech is the place.

It is bad enough that the plant biotech investor is facing severe doubts about global patent protection for his products. On top of that he faces three serious obstacles unknown to his counterpart in the biodrug field which are:

(a) Illicit use of the invention by those who exploit the progeny of proprietary seeds which are by nature self-replicating. This creates a real life enforcement dilemma. If the proprietor exhausts his further right to tribute by a single sale, others will be unjustly enriched by reselling the progeny.

(b) Painfully slow and expensive R&D timelines to discover and commercialize a seed or plantlet having the desired reproducible trait. This is caused by the perplexing level of scientific difficulty.

(c) Political and social resistance to the concept of generic plant exclusivity in the hands of private enterprise.

On the latter obstacle, there seems to be an unspoken fear that the large industrial firms specializing in plant bioscience will be tempted to manipulate or pervert the agricultural industry through misuse of their generic patent rights on genetically-transformed plants. But query: why would those firms be motivated to damage or destroy the very industry on which their revenues depend?

What those firms seek is simply a fair return on their enormous R&D investment as an incentive for risk-taking. Only the patent system can provide that return. In return for a period of patent exclusivity, the inventor discloses to the world his scientific contribution so that others may improve on the technology. Rather than taking something away from society, the patentee has made a contribution of something new for others to build upon.

If adequate patent protection is unavailable to provide a fair return on the proprietor's R&D investment, he will either stop innovating in the plant bioscience area or will resort to some form of trade secrecy to avoid illicit copying. Either alternative is certain to stifle the science. Traditional plant variety protection is a wholly inadequate shelter for a generic plant invention of the new biotech.

The use of hybrid varieties has traditionally served as an anticounterfeiting tool for the plant breeder. Hybrid plants are inherently protected from duplication because they do not reproduce completely and faithfully from seed. By keeping secret the identity of the parent plants from which the hybrid variety was bred, the proprietor forces the user to purchase new seed for each planting season. While this scheme may have appeal at first blush, it is an unnatural, slow and unsatisfactory substitute for generic patent protection.

IV - CONCLUSIONS

(a) Biotech in the Pharmaceutical Arts

While uncertainty still surrounds the chemical scope and enforceability of patent claims to certain first generation recombinant human proteins, we are optimistic that the patent laws and judicial decisions of the important industrialized

nations will soon offer a stable and predictable climate for pharmaceutical products of biotech.

We are confident that this climate will ensure continued investment of private capital with no loss of the current scientific momentum which is so crucial to finding cures for major diseases afflicting mankind.

Patent authorities, governmental organizations and intergovernmental bodies in major countries must remain alert, however, to legal roadblocks which could stifle innovation in this enormously important field of biotech. These authorities have already displayed commendable alertness during the infancy of pharmaceutical biotech and this fact fuels our optimism. The World Intellectual Property Organization (WIPO) in Geneva deserves particular credit for its broad and continuing efforts to improve laws for protection of biotech inventions.

(b) Biotech in Agriculture and Plant Science

The picture here is far from optimistic. Today's patent laws in many countries are woefully lacking in affording the proper degree of protection to those who are investing so heavily in the biology of plant science. It is naive to think that major corporations, investors or other sponsors anywhere in the world will continue indefinitely to fund such costly research in plant science unless they can point to an international patent system which affords a fair return on that investment. Exclusivity is the name of the game.

We believe that the long term potential of plant biotechnology is already in serious jeopardy simply because today's investor cannot point to a viable mechanism for ensuring the product exclusivity which is his sole incentive for such expensive risk-taking.

Unless our global patent laws and procedures are soon adjusted to provide generic patent protection for generic plant inventions coupled with meaningful enforceability, the enormous promise of this science will indeed become stifled. Private investment will gradually dry up. Government investment will never be sufficient to carry the day. Mankind will be the guaranteed loser and the undernourished on this planet will continue their suffering.

What a pity it would be if our own generation unwittingly squandered the marvelous gifts of plant science for sheer lack of a modern patent system!

* * *

PATENT PROTECTION FOR DEVELOPMENTS IN BIOLOGICAL SCIENCE; A VIEW FROM THE UNITED KINGDOM

Presentation by Dr. Alan Laird, Company Patent Agent,
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Introduction

This paper is entitled 'A View from the UK'. It is not the view of the United Kingdom, meaning the government of the UK, nor is it even the view of a section of the interested parties in the UK. It is a personal view. It is a view based upon a background of the development of patent law in the UK, but nevertheless it is a personal view.

The title also uses the expression 'biological science' rather than the more usual term ' biotechnology' because one of the current issues is indeed the extent to which biological science is technology. A consideration of the suitability of developments in biological science for patent protection involves consideration of whether, or when, the advances in biological science can be said to be technology. It is clear that many advances would be considered to be technological but the difficult question is "if there is a boundary, where is it?" Given that at least some advances in biological science are suitable for patent protection, the next question is "what should be the scope of that protection?"

'Invention' in UK Law

Taking up first the issue of the subject matter which should be available for consideration for the grant of a patent. For convenience this subject matter can be termed "an invention", but the term should not be confused with "patentable invention." The European Patent Convention and the UK Patents Act 1977 both refer[1] to an invention when defining the criteria of patentability, but the term itself is not defined. Some items such as scientific theories, aesthetic creations, or business schemes are said not to be inventions,[2] and some items such as those contrary to public order, plant varieties or essentially biological processes are simply said not to be available for consideration for the grant of a patent[3], but the term remains undefined.

Prior to the adoption of the European Patent Convention standard, an invention, in the sense set out above, was judged with reference to the expression used in the Statute of Monopolies of 1623.[4] That expression "a manner of new manufacture" is not really capable of interpretation in modern times by reliance upon the dictionary meanings of the words alone and has, in fact been developed by the courts without any prior restriction. Its original

meaning, articles or substances produced by manufacture, was expanded to cover manufacturing processes and later to the equipment used therein. The enquiry has however always focused upon the means employed rather than the merit of the results obtained.

In the 1940's the court put forward the 'vendible product' test, that is "Does the invention result in a vendible product, or improve, restore, or preserve a vendible product?"[5] The words used by the courts however never seemed to present a restriction. 'Product' was later interpreted as meaning "the result of an action";[6] an electrical ascillation was considered to be a product.[7]

By the 1960's the courts of Australia and New Zealand were taking an even broader view of manner of manufacture and were stressing features such as "utility in practical affairs",[8] "economic endeavour"[9] and "commercial significance."[9] Using this approach these courts found that a method of removing weeds from a crop by applying a selective weed killer[8] and a method of tenderising meat by injection of an enzyme shortly before slaughter[10] were fit subject matter for consideration for the grant of a patent. In other words these were inventions.

The English court did not proceed so rapidly in embracing biological subjects as inventions and in the key cases of the 1950's horticultural and agricultural processes were generally refused. However the merit of the arguments used in Australia and New Zealand was recognised and subsequently the practice was to allow claims to agricultural operations of a commercial character and to allow claims to the treatment of animals, other than humans. One commentator on these developments has noted that Australia and New Zealand, where the changes started, are agricultural countries. This is exactly the point. The courts responded to the economic needs of those appearing before them.

The historical treatment of manner of manufacture as a test for invention proceeded empirically. No attempt at a comprehensive definition was made. No subject matter was specifically excluded. At most various principles were developed and then adapted. This approach has the merit of flexibility and its greatest success has been its ability to recognise that economic need should influence the subject matter considered suitable for patenting.

Protection of Chemical Inventions in UK Law

It is, of course evident that patent law has to adapt, and that it has done so in the past. The development of patent law in relation to chemical inventions is a good example of that adaption. While the subjects of early patents were often mechanical devices or chemical processes for making existing chemicals, the rapidly advancing science of synthetic chemistry soon led to the appearance of new chemical products. As the science developed further it became evident that no real problem existed in making many chemical compounds; the real problem lay in choosing which chemical to make. As we all know, the development of the law protecting chemical inventions has not proceeded smoothly. Indeed chemical compounds as such have only recently become patentable in a significant number of countries. Since the beginning of the 20th century some chemicals as such have suffered at least periods of unpatentability in most countries apart from USA. Nevertheless the law in the UK as well as in other countries did come to recognise that the inventive contribution in a new chemical product lies in its purpose or use. The critical question as developed in English law can be expressed as:

> "Would researchers be expected to look for advantageous results or properties in the particular chemicals under consideration?"

Thus the inventive step made by researchers was recognised as being in the use or purpose of the new chemicals produced. However, the enterprises employing those researchers usually earn their return by selling the chemicals as such for use by others rather than by using the chemicals within the enterprise itself. Thus, as far as the enterprise is concerned there is a distinction between the technical achievement brought about by its efforts and the economic activity by which the enterprise earns its return on those efforts. The contribution which justifies a patent on technical considerations is the use of the chemical but the contribution which needs protection if economic reward is to be earned is the making of the chemical available for use.

The problem of providing protection for the economic activity and also encouraging research into the uses of new chemicals has been solved by permitting a product claim to be granted which is not restricted to a particular use of the chemical. This practice can be regarded as the key adaption which patent law has had to make in order to accommodate chemical inventions. It represents a development from the practice in relation to mechanical inventions in that whereas a new machine tends to have a limited number of uses, and so a claim to a new machine as such is not much broader than a claim

to the use of a machine, a new chemical is an entirely new entity with a variety of properties and potential uses. Even so, patent law in the UK and elsewhere has recognised that simple and effective protection of the relevant economic need is best provided by the grant of an unrestricted product claim.

Thus merely by considering the development of UK patent law it can be seen that both in relation to the concept of an invention and in relation to the protection to be provided, for chemicals the appropriate claim, the economic needs of those generating the advances have been recognised and the solutions adopted have not been limited by pre-conceived ideas. UK patent law has proceeded by adaption to the circumstances existing at the time.

Biological Science : The Problems

Turning now to biological science. In comparison with chemistry, the important difference is that biological science can lead to new entities which are alive. This is the most interesting aspect since it raises the direct question "when should subject matter being alive be considered as available for the grant of a patent?" The fact that a new biological entity is alive represents a fundamental difference from a chemical entity, not just because of that fact, but because of its consequences. Whenever it is desired to use a new chemical, it has to be manufactured and it is necessary to repeat the process, or a process, by which the originator made that chemical. However, in order to use a new biological entity, there is no need to repeat the process whereby it was obtained. It is merely necessary to obtain a sample and grow or reproduce that material.

In the context of patent law, this fact leads to pressure on two principles of patent law (a) the need for an adequate written description and (b) the implied licence to use purchased patented material for its intended purpose. The question therefore is the degree of adaption needed to accommodate within the patent system the living entities produced by advances in biological science.

The Description Requirement

The problem of providing an adequate written description of how to obtain a living entity has already been faced in relation to micro-organisms. The solution, to supplement a written description of the micro-organism by deposit

and release of that micro-organism to those interested, has worked well in relation to the patenting of antibiotics and their production. The deposit system already developed recognises, at least in part, that the classical requirement for a repeatable description is not entirely necessary in relation to a living entity and that the purposes of the patent system can be achieved by ensuring that the micro-organism is available. There are however already circumstances in relation to antibiotic technology, e.g. where the micro-organism has been isolated from a soil sample, when it is difficult to assert that the description, supplemented by deposit of the relevant micro-organism, provides instructions on how to repeat the original work.

More recent advances in biological science are producing biological material which is not easily described as a micro-organism but which can be deposited and the deposit used to supplement a written description by analogy with the practice already developed in relation to micro-organisms. However, while newer biological science in some areas, such as genetic engineering, offers the prospect of providing an adequate written description in the classical sense, there is much enthusiasm to use the deposit system to solve all the problems faced in the provision of an adequate written description of a biological procedure. If it is accepted that a sufficient description is provided when the living entity involved is made available to the public, then the requirement for an adequate written description as a criterion of patentability has been, in effect, replaced by a requirement for a deposit. When this is applied to an industrially or agriculturally useful living product the practical criteria of patentability would no longer include that of the need to provide an adequate description. Patentability of such a living product would therefore have to be judged by novelty and inventive step.

Given novelty, an inventive step usually involves a solution to a problem or at least some generic concept or aspect which enables the advance to be applied to a wider range of circumstances. But an inventive step can be present in a single empirical circumstance when an unexpected effect is found. In biology it can be asked whether an inventive step would be present in the activity of crossing two plants using pollen transfer with a pair of tweezers, or in the activity of crossing two animals by opening a gate to leave both animals in the same pen or field. In each case choice has been exercised, the hand of man is involved, the choice may be quite unusual, the effect quite unexpected, all features associated with inventive step. Is that enough for patentability? Are the activities just mentioned sufficient, or appropriate

to come within the patent system.

The question may be asked as to whether the adaption of the patent system whereby the deposit system is used to provide an adequate description, can in the limit bring within the patent system subject matter which is inappropriate. In other words, is adaption in danger of becoming distortion.

To consider this further it is desirable to return to the concept of an invention, and to ask what qualities are associated with inventions and what activities are associated with inventors. It is generally understood that inventions are associated with the useful arts rather than the fine arts, indeed with the industrial arts. The activity of making things again and again and particularly the activity of changing or converting one thing into another thing is a characteristic. Inventors are people who conceive ideas concerned with changing things; they exercise choice and have expectations that their ideas will produce the desired results. All of these features lead to the concept that an invention should have a technical quality, should relate to technology in the sense of being concerned with satisfying material wants by adapting materials or creating new materials.

Technical quality is an elusive property. Precise definition is very difficult. It can though be said to relate to the conversion of things with a degree of expectation or control or repeatability in the process and with a degree of choice exercised by the controller. This sort of technical quality is inherent in inventions and may be used to locate the boundary between invention and non-invention in relation to advances in biological science. It has not been much recognised or used as a criterion, but it is worth noting that the exclusion of plant and animal varieties and biological processes from patentability under the European Patent Convention can be attributed in part to an assumption that such subject matter could never be susceptible to repeatable description, and this can be seen as a hidden requirement for technical quality. The existence of a fully repeatable description of changing material things must mean that technical quality exists, but if degrees only of the essential qualities are needed, then strict causality is not required and technical quality can be recognised where a wholly repeatable description cannot be given. The example given earlier of the production of an antibiotic from an isolated micro-organism would surely be regarded as a thoroughly industrial activity with technical quality, but would nevertheless not be capable of total repeatable description.

Technical quality therefore is a feature of an invention which should be present irrespective of whether, or how, the description requirement of patentability is met.

The Implied Licence Rule

As stated earlier when living entities are considered for patenting, there is pressure on the principle that the purchaser of patented material is free to use it for its intended purpose. It was pointed out earlier that in respect of chemical products there is a distinction between the technical achievement of an enterprise that would justify a claim on strict technical considerations and the economic activity of that enterprise which requires protection. A similar distinction arises in relation to living entities. The technical achievement of an enterprise lies in converting living entity A into living entity B, which by virtue of its useful properties justifies the grant of a patent. The economic activity of the enterprise is the making of B available for its useful properties to be realised. However the enterprise is in an even less favourable position than with a chemical product because whereas users of a chemical product need to return to the enterprise for further supplies, the users of a living entity merely need to make one purchase and then grow or reproduce that entity as desired. Accordingly in order for the enterprise which has made the living entity available to engage in reasonable economic activity it is necessary for that enterprise to be allowed a claim to the entity as such and for the implied licence to be limited so that the enterprise can make reasonable future sales of the entity. Just as in the case of chemical products where patent law needed to adapt to recognise the economic needs of the originator, so in the case of living entities, patent law will need to adapt to the economic needs of the originator and limit the principle of the implied licence of the purchaser of patented material.

Proposals

By considering the development of patent law in the United Kingdom it can be seen that in two important respects, that of the subject matter considered to be an invention and that of the degree of protection afforded, patent law has proceeded by adaption. Further it can be seen that the economic needs of the originator of worthwhile advances have strongly influenced the nature of the adaptions.

In the case of advances in biological science, patent law must adapt further, but it must remain faithful to the basic principles if it is to avoid distortion. One of the adaptions already being made, use of the deposit system for living entities, raises the danger that its application to extreme cases could result in distortion. It is therefore proposed that not all advances in biological science which produce living entities should be regarded as inventions, that is as subject matter which should be considered for the grant of a patent. In order to be regarded as an invention the circumstances surrounding the generation of the living entity should show technical quality and an economic need which taken together justify qualification as an invention.

This approach returns to the need for an invention, but proposes, based on the development of UK patent law, the adaption of considering economic need together with technical quality. An advance with extensive technical quality would need little economic need and an advance with great economic need might qualify as an invention with little technical quality. However some technical quality should be present. It is suggested that opening a gate to permit two animals to occupy the same field and leaving the rest to nature is an activity lacking sufficient technical quality to be regarded as an invention.

The approach may be said to lack legal certainty, but legal certainty is difficult to achieve even in simpler aspects of patent law. The alternative, to attempt a precise definition or to use the approach of specific exclusions, faces the problem that the definition or exclusions can easily become outdated by new science. At present it may be said that genetic engineering science produces inventions; there is sufficient technical quality. No doubt this is so, but any definition of an invention which refers to genetic engineering as a feature risks excluding further advances which could be made in the near future. The proposal, which indeed leaves much to judicial interpretation, has the merit of being able to develop with the science and the economics. It retains the basic principle of the need for an invention and can avoid distortion.

The approach of adaption by recognition of economic need can also be applied to claims to living entities. It permits an invention to be formulated as an unrestricted product claim and that claim to be interpreted as to the protection given in the light of economic needs. It is proposed that the adaption required is to limit the implied licence conveyed on purchase of patented reproducible material so that the originator is not faced with

competing sales of material being the progeny of that material originally sold by the originator.

The new biological science presents the classical case for the need for patent protection. It produces valuable material which is extremely difficult to get to the market place but once there is extremely easy to copy.

Where the generation of that material has an element of technical quality the patent system is capable of responding to the economic protection without distortion of its existing principles. It is important for the implementation of the advances in biological science that it should do so.

SUMMARY

This paper deals with the issues of which apects of biological science should be available for consideration for the grant of a patent and what protection should be available.

The topics are considered in the context of the development of patent law in the UK, particularly the concept of an invention, as opposed to a patentable invention, as derived from a "manner of new manufacture" and the protection afforded to chemical inventions. From such consideration it is concluded that patent law has proceeded by adaption and that the economic needs of those generating the advances have been recognised both in relation to what should be regarded as an invention and what form of protection should be provided.

In relation to advances in biological science, the possibility of producing new living entities creates problems for patent law in relation to the usual need for an adequate written description and for the usual rule that the purchaser of patented material has an implied licence to use it for its intended purpose. These problems call for further adaptions in patent law.

In relation to the description, it is suggested that the existing adaption whereby the description is supplemented by deposit and release of the living entity could, in the limit, result in distortion of the patent system by bringing within its scope inappropriate subject matter. It is suggested that there is still a need for patentable subject matter to be an invention and that a feature of an invention is technical quality. The latter is not fully definable but relates to the conversion of material things with a degree of control and a degree of choice exercised by the controller.

In relation to the rule of implied licence, it is suggested that the adaption already present in relation to chemical inventions should be extended to provide product protection but with a limited implied licence.

It is proposed that the adaptions needed to accommodate living entities within the patent system without distortion of the basic principles are:-

a) to consider economic need as well as technical quality when deciding which aspects of biological science relating to living entities should be regarded as inventions, and

b) to consider economic need in relation to the interpretation of a claim to a living entity so that protection is provided against competing sales being the progeny of the originator's first sale.

REFERENCES

1 EPC, Article 52 (1); Patents Act 1977, Section 1 (1)

2 EPC, Article 52 (2); Patents Act 1977, Section 1 (2)

3 EPC Article 53; Patents Act 1977, Section 1 (3)

4 Patents Act 1949, Section 101 (1)

5 G.E.C. (1943) 60 RPC 1

6 Cementation (1945) 62 RPC 151

7 Rantzen (1947) 64 RPC 63

8 NRDC (1961) RPC 134

9 Joos v Commissioner (Australia) (1973) RPC 59

10 Swift (NZ) (1961) RPC 147

11 First formulated as the "Cripps Question" in Sharpe & Dohme v Boots 45 RPC 153 at 173 with reference to a process claim and modified by Graham J in Olin Mathieson v Biorex (1970) RPC 157 in relation to a product claim.

* * *

PROTECTION OF BIOTECHNOLOGICAL INVENTIONS; GRACE PERIOD AND SHIFT OF BURDEN OF PROOF

Presentation by Dr. Karl Josef Heimbach, Head of Patent Department, Bayer AG, Leverkusen, Federal Republic of Germany

Whereas we come to believe that biotechnological inventions made in connection with or relating to plants, animals, microorganisms and other biological material, require legal protection,

- whereas we may also be convinced that the principles of patent law are adequate to provide such protection, no matter how great the individual differences may be between the various countries which till today have arrived at a dissimilar stage of development or which possess different legal systems,

- whereas we may then come to the conclusion that the availability of comprehensive and enforceable protection for biotechnological inventions under our patent legislation merely requires the abandonment of inhibitory and restrictive principles dating from the last century in which the ideologies which prevailed in the field of technique and virtually

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formed the basis of our patent laws of today originated from a different and narrower view of the meaning of the words technique and technical activities,

- and whereas, let us say so, we may start to attempt to extend our horizon of what patents are to include plants, animals, microorganisms and other living material in our patent laws,

we must nevertheless not overlook the fact that, depending on the country concerned, various regulations of a general nature are or are not existent in our present patent laws as well as in the case law developed by the patent-granting authorities or by the courts which do not at first sight seem to bear any relationship with the subject with which we are at present concerned, namely the protection of biotechnological inventions.

With this in mind, I would like to pinpoint two problems which are clearly of considerable importance for the effective protection of biotechnological inventions and which are - and it may be said, fortunately - at present

at the centre of international discussion on harmonisation of national and - the small number of - supranational patent laws.

The problems to which I refer concern the terms "grace period" and "shift of burden of proof".

Let me first of all turn to the question of the "grace period" and quote two citations from the United States. The first is taken from an official statement of the American Intellectual Property Law Association, formerly known as the American Patent Law Association, and was delivered at the WIPO meeting of the Committee of Experts on Patent Harmonisation in Geneva in 1985. The following is an extract from this:

"AIPLA strongly supports an international grace period which would be added to the Paris convention priority year. In high technology areas such as the fields of recombinant DNA and monoclonals, many pioneers from the university communities whether in Northern California, Munich or Kyoto have contributed much to technological advance. As with most university professors there is the

need to publish the results of their work as promptly as possible. Many professors and scholars, like most inventors, are not familiar with the patent laws of their country, let alone the laws of other countries. In our view, there is no public policy reason to discriminate against these inventors with the requirement of absolute novelty, and thus barring that inventor from obtaining a patent. Instead of applauding him for making the earliest possible dissemination of information by prompt publication in a scientific journal, all to the benefit of mankind by increasing the knowledge in a particular field, we punish him by refusing to give him a patent. The patent-naive scientist is not the real loser; rather, the public loses because the extremely expensive development costs for a regulated product of biotechnology research often cannot be justified in the absence of a patent".

To add to this it may be said that many inventions in the biotechnological field by their very nature cannot be made without public knowledge, whether they concern animals or plants in the open field or microbiological processes which have to be tested.

To end the above citation I quote: "For the United States to adopt a grace period added to the Paris convention year, domestic legislation to revise our patent laws would be necessary. AIPLA is confident that such a change could be accomplished."

The final part of this resolution refers first and foremost to the fact that in the United States any patent or other printed publication describing the invention, whether published in the country or abroad, and any public use or sale of the invention in the country not more than one year prior to the date of the application for patent in the United States, constitutes a non-prejudicial disclosure; public use or sale abroad is not relevant for the state of the art regardless of when it occurs. In other words, the one-year grace period is general. In Canada the situation is largely the same, except for the duration of the grace period, which is two years.

Here it is important to note that this grace period is calculated backwards from the filing date and not from the priority date and is therefore irrelevant for foreign applicants who claim the priority year when filing their patent applications.

At this point it is important to remember that the United States, and otherwise only Canada and the Philippines, are the sole countries which adhere to the principle of the first-to-invent system, whereas the rest of the world follows the first-to-file principle.

The first-to-file system is only disadvantageous for the inventor who invented first but was slow in filing. It can only be objected to on the philosophical grounds that the first-to-invent principle is more just. Whether this holds true remains to be seen in view of the fact that proving the date on which the invention was made is usually complex, time-consuming and costly. The interference procedure is renowned for its complexity, length, high costs and sometimes non-satisfying results. In addition thereto, the inventor who made the invention outside the United States cannot offer evidence as to the date of making the invention. For most inventions made outside the United States the first-to-invent system in the United States is defacto not available. Under the first-to-file principle the applicant, being able to rely on the filing date coupled with his priority date under the Paris Convention, if any, and

with a grace period added thereto can henceforth disclose his invention without risk; the industrial property office will publish the application for a patent sooner if the application was filed earlier.

I do not wish to continue a detailed discussion of this problem. The ideal solution, to my mind, for all types of inventions including biotechnological inventions is to provide for a first-to-file system coupled with the priority year of the Paris Convention plus a grace period linked to the priority year, if any. Thus the inventor can publish and, if necessary, use and test his invention, without endangering the novelty thereof as long as he observes certain given time periods.

These considerations will become of utmost interest when I read you my second citation from Commissioner Quigg on the occasion of the WIPO Conference of Experts on the Harmonisation of Certain Provisions in Laws for the Protection of Inventions of March 1987. I quote from a press release:

"The United States has offered the possibility of dropping its 150-year-old practice of granting a patent to the first inventor of an invention instead of granting it to the first person filing an application for patent protection".
"Moving to a first-person-to-file practice would put foreign inventors on the same footing as US-inventors with respect to obtaining patent protection in the United States". Quigg continues by saying that this offer is part of a package deal around the world which, inter alia, includes at least a grace period for disclosures of an invention and the availability of a product patent for all technological fields, and the whole field of biotechnology.

The introduction of the first-to-file principle in the USA (which will soon also be adopted in Canada on the basis of a bill which is being reviewed by parliament, and also includes pharmaceutical product protection) will most certainly be welcomed not only by foreign applicants but also by many American applicants. Another important factor, in addition to those already mentioned, is that patents which have been granted after

lengthy interference procedures, and just these are frequently of great importance, are then valid for a further 17 years, an almost inacceptable period for competitors. Also an American inventor is no longer tempted to late filing of his invention in his home country where he can safely rely on the first-to-invent principle, only to experience a rude awakening upon filing subsequent applications abroad when he loses the battle against other applicants for the same invention because of an inadequate priority date.

If the first-to-file principle becomes reality in this country one must agree with Commissioner Quigg that a grace period for the disclosure of an invention is absolutely necessary, also and especially in connection with biotechnological inventions. The grace period should not however simply be that which is already contained in the US code and which I have cited above and which the AIPLA, in the statement quoted at the beginning of my present talk, therefore suggests should be amended.

What requirements may or must such a grace period fulfil for it to be beneficial and practicable?

It goes without saying that such a grace period must be adopted in as many countries as possible. This is, as is known, by no means the case at present. Besides the United States and Canada, Japan is the main other country where a grace period applies. The grace period of the European Patent Convention and, in compliance therewith, that of most European countries, is limited under the Strasbourg Convention: A disclosure of the invention shall not be taken into consideration if it occurred no earlier than six months preceding the filing of the application, and if it is the direct or indirect result of (I) an evident abuse in relation to applicant or his legal predecessor; or (II) the fact that applicant or legal predecessor has displayed the invention at an official or officially recognized exhibition falling within the terms of the Convention on International Exhibitions.

A period of grace defined in such restrictive terms is virtually worthless.

The second important requirement for an effective grace period is that it should be uniform throughout the patent laws of all countries, so that the applicant does not, despite the existence of a grace period, lose his patent rights in one or the other country because of national differences.

This uniformity of the grace period in all countries should most importantly include an identical duration, whether this be six months, as in Japan or formerly and at present in Europe, or whether this be one year, as in the United States. Two years, as in Canada, seem to me to be too long. It would seem particularly important to calculate the grace period, in the event of a priority claim, on the basis of the priority date, but not, as is the case in the United States and Japan and at present and formerly in the European countries, on the basis of the national filing date. It is self-evident that in such a case the applicant can only draw any benefit from the grace period in the country of his premier depot whereas in all other countries the grace period coincides with the priority year and would thus be of no use. A novelty-destroying event which has been

overcome in the country of first filing by reason of the grace period in that country would quite easily destroy novelty of a subsequent application in another country.

Finally, a last essential requirement must be mentioned which is that, contrary to the present situation in Japan, the grace period should not be dependent on a statement made by the applicant at the time of filing the patent application since, most of the time, applicants were not aware that an act qualifying as prior disclosure has taken place.

This is for the time being all that I wish to say on the notion of an international grace period for filing inventions, including those of a biotechnological nature. I would now like to express some thoughts concerning the other question mentioned at the outset, namely that of the shift of the burden of proof.

There has been much discussion whether and under what conditions biotechnological inventions can be patented. Far less consideration has been given to the question of how to prove whether a product patent and above all a process patent for a biotechnological invention has been infringed.

The same basic rule does of course apply to patent infringement processes as to other legal disputes: The plaintiff is generally required to provide evidence of patent infringement. In particular, as far as process patents are concerned the provision of such evidence can represent an insuperable obstacle which precludes any possibility of being able to conduct an infringement suit. As a result it is even possible that patent applications for inventions of this kind are not filed at all but are simply kept as secret as long it might be possible. Legislators on the long run surely cannot wish such a situation to continue indefinitely since it is of no benefit either to the inventor or to those members of the public with an interest in the fields concerned.

The procedural rules of some countries provide various possibilities of alleviating the burden of proof on the plaintiff once he has prima facie proved the probability of infringement. This does however to a large extent depend on the course of the proceedings and the judge concerned, but is, in effect, unsatisfactory.

In the United States the so-called discovery procedure enables the plaintiff and the defendant to discover all matters relevant to the suit of which the other party has knowledge or which is in the other party's possession. Discovery is usually very cumbersome, time-consuming and expensive, anyhow it appears to me to be not the best and easiest solution to the problem. To my mind there is no chance of introducing something like a discovery procedure into patent enforcement legislation on a world-wide basis. The same holds true for what some countries call a "preservation of evidence" or what the French and Belgian call "saisie contrefacon".

The simplest and, in my opinion, best solution to this problem lies in a procedure of the kind practised for example in the Federal Republic of Germany, in other European countries and in Japan. Here it is assumed that a product has been produced by a patented process if the patented process is directed to the production of a new product.

Such a shift of the burden of proof is not only of general importance for the protection of process claims

against infringement but its importance in particular for biotechnological inventions is undeniable.

Research work in the field of biotechnology and in particular that of molecular biology is to a large extent aimed at finding more economical, environmentally more acceptable and above all more productive methods of producing known substances or of, for example, obtaining stereospecific active ingredients in the medical and agricultural fields with greater ease than before. In all of these cases, however, only process protection is possible.

This also applies to the biotechnological production of substances which are already known to be present in the human and animal body but which, while having a highly desirable effect as medicines, are only available in the natural material in such small quantities that the task of isolating them therefrom in appreciable amounts seems virtually impossible. Here as well product protection cannot be obtained, but only process protection, while the patent holder has no possibility of proving infringement. In the end he has to rely on assumptions;

prima facie evidence cannot be given, not even if no other economically feasible manufacturing procedure is known.

Difficulties in furnishing proof are also encountered in a completely different area. New microorganisms protected as such have to be deposited in the same way as microorganisms used in claimed microbiological processes. They become freely available to all at the latest on the date of the patent grant, if not earlier. How can one prove that a third party who has verifiably and legally obtained a sample of the protected culture from a place of deposition has used this culture or one derived therefrom in a patent-infringing manner?

In my view this is only possible by introducing a world-wide shift of the burden of proof as a legal rule in the national patent laws. A procedure of the kind presently existing in West Germany or Japan is however inadequate. It applies only to new products of a protected process but not to the enforcement of process claims if the product of the process is part of the prior art. This can be explained by the history of patent law. At the

time when there was still no protection for chemical or pharmaceutical products in many countries such as Germany, Holland, Switzerland and Canada, the attempt was at least made to improve process protection for new per se non-patentable substances. This explains why Canada now wishes to abolish the shift of the burden of proof upon the introduction of product protection for new pharmaceutical substances on the grounds that it no longer complies with the Canadian legal system. Fortunately, the European countries, such as Germany and Switzerland, did not, unlike at that time Sweden, follow this type of thinking.

In the majority of countries which possess such a ruling it is however, in its present form, unsuitable for counteracting instances of infringement of biotechnological process inventions since the substances forming the product of the above-described biotechnological process inventions are not novel chemical individuals and the shift of the burden of proof only applies - presumably with the exception of Switzerland - when no other process is known for the production of the product of the process, i.e. when the product is new.

Consideration should therefore be given to extending the scope of application of the shift of the burden of proof to include known products-by-process or at least to widen it so that the shift of the burden of proof applies to known products which are produced, either for the first time or, better, as a general rule, by biotechnological methods. To protect deposited microorganisms which are freely accessible to third parties it is recommended to consider shifting the burden of proof in such a manner that a third party who has verifiably acquired a sample of the culture in question from a place of deposition must himself prove that he is not using this culture or one derived therefrom in a patent-infringing manner.

Coming now to the end of my talk, I am reminded of my friend Dr. Hüni, who formerly worked for Ciba-Geigy and who once said in Brussels: "We hear and read it every day: A new techno-scientific revolution is in progress. Biotechnology with its awe-inspiring tool, genetic engineering, is opening up new technical and industrial horizons. Large investments are being made. Many feel that we have arrived at a junction similar to the one

our grandfathers reached around the middle of the 19th century when through a new science, organic chemistry, a new industry was born, the dyestuffs industry and, with it, the chemical industry as a whole. We all know what an important role patent protection has played in the development of this industry in the various countries. Is out patent system adequate to play its role in this new revolution, namely to stimulate our research and innovation potential and to protect its fruits?"

Dr. Hüni is absolutely right in asking this question, which in my view can be answered with an optimistic "yes": We have to adapt our patent laws to the new technological generation, to the next century. We cannot stand still by thinking in terms of the year 1900. At stake are big issues such as the patentability of plants and animals, there are smaller issues like those I discussed here to make the law more practicable. The new future will fall into the hands of those countries which provide valuable legal protection for the new techno-scientific and, automatically associated therewith, social revolution. In preparation for the latter let us adapt our patent laws worldwide in honour of the year 2000.

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RECENT DEVELOPMENTS IN THE PATENTING OF BIOTECHNOLOGY IN THE UNITED STATES

Presentation by Mr. Charles Van Horn, Director,
Organic Chemistry & Biotechnology,
United States Patent and Trademark Office, Washington D.C.

Staff and Patent Application Activity

	January 1987	January 1986	January 1985
Examiners	31	32	28
Pending Applications			
New	3307	3155	2202
Amended	651	445	172
Rejected	1879	2173	1529
Total	5837	5773	3903
CALENDAR YEAR	1986	1985	1984
Applications Allowed	816	712	556
Total Completed	2044	1573	1171
% allowed	40.0%	45.3%	47.5%
Appeals	105	84	91
% appealed	5.1%	5.3%	7.8%

Patentable Subject Matter

Ever since the Supreme Court decision in Diamond v. Chakrabarty, 447 U.S. 303(1980) held that microorganisms produced by genetic engineering are not excluded from patent protection under the general patent statute (35 USC 101), it was clear that the question of whether or not an invention embraces living matter is not relevant to the issue of patentable subject matter. The principle consideration is whether the living thing is the result of human intervention.

The position of the Office with respect to products of nature is that the public should be free to use things that are found in nature. Thus, if an article or composition of matter occurs in nature it is not considered to be patentable subject matter under our general patent statute unless it is given a new form, quality, properties or combination thereof not present in the original article. A critical aspect of this issue is whether the article or composition of matter which might be considered to occur in nature has been changed or altered substantially. Purification has been held to be a basis of substantial change in the characteristics, functions or activity of a naturally occurring material to warrant patentability. The initial burden is on the examiner to show that a claimed product is likely to exist in nature as a result of natural processes.

The protection of plant life is now capable of protection under three separate laws. The 1930 Plant Patent Act (35 USC 161-164) for an asexually reproduced plant except a tuber propagated plant, generally follows the requirements of the general patent law except that the description of the invention need only be as complete as is reasonably possible. There are now almost 6000 plant patents that have been granted under the Plant Patent Act and are now being granted at a rate of almost 400 per year. The 1970 Plant Variety Protection Act is directed to sexually reproduced plants and is administered by the Plant Variety Protection Office in the Department of Agriculture. A patent-like Certificate is granted for a period of eighteen years. This certificate gives the owner the right to exclude others from sexually multiplying, using, selling, importing or exporting the protected variety in the United States, but also has several exemptions (e.g. farmer's crop exemption, research exemption, and compulsory licensing) which have no direct counterpart in the general patent law. About 2000 Plant Variety Protection Certificates have been issued, and are now being issued at a rate of about 200 per year (30% vegetables). Almost two years ago, the PTO Board of Patent Appeals held (Ex Parte Hibberd, 227 USPQ 443 (1985)) that plant subject matter in the form of plants, seeds, and tissue cultures were patentable subject matter under the general patent statute (35 USC 101). Protection under the general patent statute is available to an inventor even though the subject matter falls within the scope of protection afforded by the Plant Patent Act or the Plant Variety Protection Act. It is even conceivable that multiple forms of protection could be granted on the same plant invention so long as some provision is made to prevent extension of the exclusionary rights which are granted under each system and so long as there exists common ownership of the exclusionary rights.

The April 3, 1987 decision by the Board of Patent Appeals and Interferences (Ex Parte Allen) held that the claimed polyploid oysters are manufactures or compositions of matter within the scope of 35 USC 101. This reverses a long-standing policy of the PTO that multicellular animals per se did not constitute patentable subject matter under the general patent law.

The Allen application contained claims to a method of producing polyploidy in oysters which results in increased growth. The examiner determined that the process was patentable. The application also contained claims directed to a polyploid Pacific oyster produced by the method defined in the patentable process claims. The examiner had rejected these claims on two separate grounds of rejection: (1) 35 USC 101 - the claimed oysters were not patentable subject matter; and (2) 35 USC 103 - the claimed oysters were obvious over a printed publication that taught that it was known to chemically treat an American oyster to induce polyploidy as a way to increase growth. The Board reversed the first rejection, but agreed that the claimed oyster was not patentably different from the polyploid oysters taught in the prior art.

In reversing the rejection under 35 USC 101 the Board relied on observations made by the Supreme Court in the Diamond v. Chakrabarty decision. These observations included that the use of expansive terms "manufacture" and "composition of matter" modified by the comprehensive "any" in 35 USC 101 indicated that Congress "plainly contemplated that the patent laws would be given wide scope." The Supreme Court also had noted that the legislative history of §101 supports a broad construction and concluded that the committee reports accompanying the 1952 Act that Congress intended statutory subject matter to "include anything under the sun that is made by man." Finally, it should also be noted that the Supreme Court observed that the relative distinction regarding the scope of the general patent law was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. On April 7, 1987 the Commissioner of Patents and Trademarks signed a policy statement which is included at the end of this paper which defines in broad terms the policy that the Patent and Trademark Office will follow as a result of the Allen decision.

As you would note from that notice, this decision is not considered to disturb or alter the practice and policy of the Patent and Trademark Office that products found in nature will not be considered to be patentable subject matter under 35 USC 101. Although the PTO now considers nonnaturally occurring multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 USC 101, the issue will arise as to whether a claim directed to or including within its scope a genetically modified human being will be considered to be patentable subject matter. The position of the PTO is that the grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. While there may be other ways to exclude a human being from the scope of a broad claim directed to mammals, for example, one clearly appropriate mechanism would be to use the negative limitation "non-human" to exclude a human being from the scope of a claim and avoid a rejection under 35 USC 101.

We have estimated that there are about 15 applications pending with claims directed to animals per se. To the extent that such claims are directed to non-human nonnaturally occurring manufactures or compositions of matter - a product of human ingenuity, such claims will not be rejected under 35 USC 101 as being directed to non-statutory subject matter. Patents claiming new animals will be classified in class 800 - which is directed to multicellular living organisms. This class will also be original classification for most of the plant patents which are granted under 35 USC 101.

Application Disclosure Requirements

The application disclosure requirements for inventions related to biotechnology are the same as those for any other type of technology. There are three separate and distinct requirements that must be satisfied with respect to the claimed invention; (1) description requirement; (2) enablement requirement-or how to make and use the invention; and (3) best mode requirement.

The function of the description requirement is to insure that applicant had in their possession, as of the filing date of the application, the specific subject matter claimed by them. Although the law requires a written description of the invention, where the invention relates to living subject matter (unless the invention can be described by words only or relates to biological matter which is known and readily available) a deposit of the living subject matter may be required to satisfy this requirement.

The second requirement is that of enablement-how to make and use the claimed invention. The essence of this requirement is whether the disclosure contains sufficient teaching regarding the subject matter of the claims so as to enable one skilled in the pertinent art to make and use the claimed invention. One of the most prevalent standards for measuring sufficient enablement is whether there is sufficient working procedures in the application for one skilled in the art to practice the claimed invention without undue experimentation. A few decisions have applied this test to inventions concerning microbiology.

In Ex Parte Jackson, 217 USPQ 804 (Board of Appeals 1982) antibiotic was produced by fermentation using a newly discovered natural microbe. Some strains of the microbe were deposited, and others were not. The PTO Board of Appeals found that claims detailing the actually deposited microbes were allowable, broader generic claims to the newly developed genus and species were not. It reasoned that undue experimentation was required to discover other species of the invention that were not deposited, and were capable of producing the novel antibiotic, even in view of the taxonomic functional characteristics described in this specification.

In another case dealing with natural microbe, it was held that a deposit was not necessary to establish enablement. Tabuchi v. Nubel (194 USPQ 521). The issue in Tabuchi was whether the verbal description of certain yeast strains as belonging to a "citric acid accumulating, and hydrocarbon assimilating strain of yeast belonging to the genus Candida" was sufficient to enable the making and using of such strains for the production of citric acid. No deposit had been made, but it was determined that a large variety of yeast of the genus Candida were available through existing depositories and that only routine screening procedures were involved to determine whether they possess the desired property. This did not amount to undue experimentation, according to the Court, which held that a deposit was not necessary to provide enablement.

The issue of what is "undue experimentation" in biotechnology has received further analyses in the decision Ex Parte Forman, 230 USPQ 546 (Board of Appeals 1986). The invention in the Forman application was defined by two sets of claims. The first set was generic to hybrid bacteria comprising both their own typhoid antigens and foreign, non-typhoid antigens. These claims contain no reference to any deposit. The second set of claims were limited to certain specific hybrid bacteria on deposit. The examiner allowed the claims including a specific reference to a deposit. The examiner, however, had rejected the claims with no specific deposit and the Board of Appeals affirmed this rejection.

The Board summarized 8 factors to be considered in a determination of "undue experimentation":

A. Quantity of experimentation necessary
B. Amount of direction or guidance presented
C. Presence or absence of working examples
D. Nature of the invention
E. State of the prior art
F. Relative skill of those in the art
G. Predictability or unpredictability of the art
H. Breath of the claims

The Board acknowledged in this case that the level of skill in the art of molecular biology is high, but also observed that experiments in genetic engineering produce unpredictable results. In this case it was noted that there was no evidence to show how much effort it would take to isolate strain used to hyperconjugate the original strains in order to prepare the hybrids or whether there were a good screening method available to identify useful strains among the myriad of strains that were presumably produced. It was acknowledged that it would take about one year to construct most strains according to this invention. Although the Board indicated that the amount of time alone was not determinative of the issue of undue experimentation, it concluded that the disclosure lacked the guidance leading to predictability and found that the practice of the subject matter defined in the rejected claims would require undue experimentation.

Finally, the best mode requirement is a separate and distinct requirement from the enabling requirement. It is essentially an issue of concealment. In the absence of evidence of concealment (accidental or intentional) the patent examiner will assume that the best mode requirement has been satisfied. If the best mode contemplated by the inventor at the time of filing the application is not disclosed, such a defect cannot be cured by submitting an amendment seeking to put into the specification something required to be there when the patent application was originally filed. In the recent Hybritech case, the Federal Circuit found that the only evidence even colorably relating to concealment was testimony that competent people perform the screening and that the screening process is labor-intensive and time consuming. However, the Court found that it was not plausible that this evidence amounted to proof of concealment of a best mode for screening or producing Monoclonal Antibodies for use in the claimed process.

Deposits

It is now clearly recognized that when an invention relates to a new biological material, the material may not be reproducible even when the detailed procedures and a complete taxonomic description are included in the application. Deposits may be used to satisfy one or more requirements of the application disclosure where the written description itself is not sufficient or where the invention cannot be practiced using known and publicly available biological material. What must be deposited if any deposition must be made for the U.S. patent application is that which is necessary to place the public in possession of the patented invention upon issuance of the U.S. patent. The question of the availiabilty of the starting materials or the final product is important in the context of whether there exists a reproducible technique to create either one from readily available starting materials. The necessity for depositing various types of biological material may be substantially eliminated as technology develops and more knowledge exists on the basic nature of these biological materials and how to manipulate them in a reproducible manner. What requires undue experimentation today, may in the future become merely routine and predictable.

The existing operating guidelines for patent examiners on the deposit of biological materials for patent purposes appears in the Manual of Patent Examining Procedure in §608.01(p), as modified by the decisions in In re Lundak, 227 USPQ 90 (Fed. Cir. 1985). While other arrangements may be suitable, it will be sufficient if a statement is made by applicant, an attorney prosecuting the application or a person representing the assignee that a deposit has been accepted under the Budapest Treaty under conditions that all restrictions on the availability to the public of the deposit will be irrevocably removed upon the granting of the patent.

This would mean that a viable deposit has been made (Rule 10) in an acceptable depository (IDA) for a period of five years after the most recent request and at least 30 years from the date of deposit (Rule 9) under conditions that access to the deposit will be available during pendency of the patent applicaton to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 USC 122 (Rule 11.1), and all restrictions will be removed once the patent is granted. Assurance of permanent availability of the deposited material through the depository is reasonably assured through the deposit of a viable culture under the Budapest Treaty. The PTO is presently working on an advanced notice of proposed rulemaking which will require clearance at the Department of Commerce before publication.

The proposed regulations will define the biological material which is subject to those regulations in an open-ended manner that will include material that is capable of self-replication, either directly or after insertion into a host. We will probably ask for some assistance in defining, for example, an appropriate number of seeds that would be required to be on deposit at the time the patent is granted. The rules will also attempt to

define when a deposit is required in the sense that the mere reference to a specific organism or other biological material in a specification disclosure will not create any presumption that the specific material is necessary to satisfy one or more of the requirements of §112. If the examiner determines that a specific material is necessary, a deposit will not be required if the material was known and readily available to the public or could be made or isolated in a reproducible manner from known and readily available material. We will attempt to define some of the factors that can be utilized in showing that a specific material is known and readily available. Among these factors would be the availability of the material from commercial suppliers or evidence of widespread distribution to those working in the art to which the invention pertains.

Among the acceptable depositories would clearly be the International Depository Authorities recognized under the Budapest Treaty. The recognition of depositories other than an IDA represents a problem for the PTO in determining the adequacy of the staff and facilities to preserve the deposit under the terms and conditions that would apply to IDA's. There may be an opportunity here for some consultation with industry groups for the determination of the suitability of a depository.

The proposed rules will provide for an opportunity for replacement or replenishment of a deposit where the orginial deposit is determined to be no longer viable, will probably provide for the supplementing of an original deposit (not replacement) in situations where the original deposit is contaminated or will no longer function in the manner which is alleged to characterize the original deposit. The original deposit in these circumstances would not be destroyed or replaced since it would provide the best evidence of the character and identity of the original deposit. Replacement in a different depository would also be permitted in circumstances where the original depository defaults in the services it is required to perform.

The term of a deposit will be for a period of a least five(5) years after the most recent request for the furnishing of a sample of the deposited biological material and for a term of at least 30 years after the date of deposit. According to the Board of Patent Appeals decision in Lundak, the availability of the deposited biological material which is essential for the making and/or using of the subject matter claimed in the patent beyond the enforceable life of a patent is a legitimate ground for concern on the part of the Patent and Trademark Office. It is not believed that the period set forth in the Budapest Treaty was intended to permit a situation where the biological material would not be stored beyond the enforceable life of the patent.

We intend to propose a requirement for viability at the time of deposit since experience has shown that many of the materials that are tested on deposit are not viable when received at the depository.

The PTO will require that all restrictions on the availability of biological material will be irrevocably removed at the time of the patent grant. We intend also to solicit comments on the advisability of seeking legislation that would permit, for example, limitations on the access to such material and further transfer to third parties or countries which do not provide adequate protection for the technology embodied in the biological material on deposit.

Since the decision in Lundak, the deposit need not be made before the effective filing date in the United States. We will permit a deposit to be made up to the time the issue fee is paid in an application. If there is any disagreement between the examiner and the applicant with regard to whether a deposit is required, or the conditions under which it will be deposited, the examiner will make and maintain a rejection under 35 USC 112, first paragraph. In those situations where the application is in condition for allowance except for the actual deposit in a suitable depository, the examiner will allow the application, mail the Notice of Allowance and Issue Fee Due, and simultaneously require that the deposit be made before payment of the issue fee. This will also require an amendment under 37 CFR 1.312 to complete the description of the accession number and depository in the application specification. The specification should also include a written description of the biological material which is sufficient to identify and characterize that material. This description is desirable not only from the standpoint of examination, but also from the standpoint of using this particular disclosure as prior art.

The determination of foreign priority rights will be determined on the basis of whether the application in the country foreign to the United States would be considered to be regularly filed. Thus, most countries foreign to the United States require that a deposit be made prior to the time of filing, whereas the United States permits a deposit to be made subsequent to the filing date but before the patent is granted. This issue may also arise where an applicant in a country foreign to the United States applies for a breeder's rights certificate for a plant variety and decides to seek a utility patent under 35 USC 101 in the United States.

Several issues have arisen and will continue to arise directed to the deposit issue. It may be a question of judgement as to whether a deposit is required in any particular fact circumstances. This could arise from a situation as to whether the knowledge and skill in the art is sufficient to reproduce the claimed invention without undue experimentation, or whether the biological materials necessary are known and readily available to the public. Another issue in the deposit area is whether an applicant may act as their own depository even after the patent is granted so long as they provide the same assurances that must be met by a permanent depository according to the Office guidelines. Finally, the Office is considering the issue of what must be deposited in the context of a patent application claiming a

Monoclonal Antibody, where the antibody is deposited in a patent depository in accordance with our guidelines, but the hybridoma source for the antibody is separately deposited under procedures and conditions that would not make it publicly available until the expiration of the U.S. patent. The hybridoma source would be available for replenishment of the antibodies to assure continued availability of the antibodies during pendency of the application and to the public during the term of the patent. The Office has taken the position that this creative scheme is not sufficient to satisfy the requirement that the disclosure provide a description on how to make the claimed antibody.

Non-Obviousness

The determination of non-obviousness (35 USC 103) is a mixed question of fact and law. The legal conclusion of obviousness or non-obviousness of a claimed invention is based on four(4) factual inquiries: (1) scope and content of the prior art; (2) differences between the prior art and the claimed invention; (3) the level of skill in the art to which the invention pertains; and (4) evidence of secondary considerations such as commercial success, unexpected results, or long-felt need. The patent applicant has the opportunity, through Information Disclosure Statements or Affidavits/Declarations to timely provide factual evidence directed to any or all of these factual inquiries for consideration by the patent examiner and any reviewing authority.

The analytic approach to a determination of obviousness is the same regardless of which type of invention is being considered. The facts relie upon by the examiner generally must be derived from evidences known and accessible to the public at the time prior to applicant's invention or the filing date of the application.

The decision in Ex Parte Old, 229 USPQ 196 (Bd. of Appeals 1985) deals with hybridoma technology and the level of inventive skill required to establish unobviousness. The claims were limited to exemplified Monoclonal Antibodies and the examiner had established that polyclonal Antibodies which reacted with the cell-surface antigens were known. The analytic limitations of polyclonal antibodies were recognized and the cell antigens used to prepare antibodies were also known. It was the examiner's position that it would have been obvious to employ the Kohler and Milstein methodology to prepare monoclonals to the antigen. The majority opinion in this decision determined that hybridoma technology was an empirical art in which the practitioner is unable to foresee what particular antibodies will be produced and which specific surface antigens will be recognized by them. Further, the Board found that the examiner failed to establish that the character of the claimed Monoclonal Antibodies could be predicted or expected. In another as yet unpublished but related Board decision (Erlich) also dealing with hybridoma technology, the Board found that the level of skill to be such that once the antigen of interest is selected, the use of that antigen in the known method of Kohler and Milstein will result in the expected

hybridoma and the specific Monoclonal Antibodies. In this particular decision the Board concluded that the claimed Monoclonal Antibodies, cell line and method for producing Monoclonal Antibodies were obvious because one of ordinary skill in the art would had been motivated to produce Monoclonal Antibodies specific for the defined antigen using the method of Kohler and Milstein with reasonable expectation for success.

Patent Term Restoration

On September 24, 1984, the Drug Price Competition and Patent Term Restoration Act became law. It was designed to restore, to some extent, the reduction of the effective market life of a patent because of delays in the Federal regulatory review process through an extension of the patent term. The objective was to restore the diminished stimulus to innovation and research brought about by a decrease in the effective market life of a patent. The law provides that a patent may be extended for a period of up to five years if the patented drug, medical device, food additive or color additive has undergone regulatory review, but only two years if the patent was involved in the regulatory review process at the time of enactment of the law. In addition to the five year cap, in no case can the period of patent extension, when added up to the patent life left after approval of the product, exceed fourteen years.

The Office has received its first application for patent term extension of a biotech product - generic name MUROMONAB-CD3. The approved product is a murine monoclonal antibody to class CD3 antigen. The period of regulatory review was 812 days and the requested period of the patent term extension is 201 days. The law also provides for special treatment of a process patent which primarily uses recombinant DNA in the manufacture of the approved product. The law established separate rules for process patents which primarily use recombinant DNA because it was believed that such a new and important innovation should be rewarded, but that the discovery of other processes which do not utilize recombinant DNA as the essential and predominant technique do not warrant the same treatment as does the discovery of a new product.

Conclusion

In summary, the volume of patent application activity continues to be heavy and is leading to an increasing number of issued patents. The development of the law as it relates to the patenting of **biotechnology inventions is in its infancy, but hopefully it** will be developed in the future in an orderly manner that will give rise to greater predictability in the granting and enforcement of patent rights. The Patent and Trademark Office is **dedicated to making the patent system work to promote the progress** of this young biotech industry in an environment where research and developement will be fostered.

Animals - Patentability

A decision by the Board of Patent Appeals and Interferences in Ex parte Allen, ___ USPQ ___ (Bd. App. & Int. April 3, 1987), held that claimed polyploid oysters are nonnaturally occurring manufactures or compositions of matter within the meaning of 35 U.S.C. 101. The Board relied upon the opinion of the Supreme Court in Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980) as it had done in Ex parte Hibberd, 227 USPQ 443 (Bd. App. & Int., 1985), as controlling authority that Congress intended statutory subject matter to "include anything under the sun that is made by man." The Patent and Trademark Office now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101.

The Board's decision does not affect the principle and practice that products found in nature will not be considered to be patentable subject matter under 35 U.S.C. 101 and/or 102. An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article existing in nature in accordance with existing law. See e.g. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 76 USPQ 280 (1948); American Fruit Growers v. Brogdex, 283 U.S. 1, 8 USPQ 131 (1931); Ex parte Grayson, 51 USPQ 413 (Bd. App. 1941).

A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a non-plant muticellular organism which would include a human being within its scope include the limitation "non-human" to avoid this ground of rejection. The use of a negative limitation to define the metes and bounds of the claimed subject matter is a permissible form of expression. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Accordingly, the Patent and Trademark Office is now examining claims directed to multicellular living organisms, including animals. To the extent that the claimed subject matter is directed to a non-human "nonnaturally occurring manufacture or composition of matter - a product of human ingenuity" (Diamond v. Chakrabarty), such claims will not be rejected under 35 U.S.C. 101 as being directed to nonstatutory subject matter.

4-7-87
Date

Donald J. Quigg
Assistant Secretary and Commissioner
of Patents and Trademarks

* * *

PATENTABLE SUBJECT MATTER UNDER THE EUROPEAN PATENT CONVENTION (EPC) IN THE FIELD OF BIOTECHNOLOGY

and

DISCLOSURE AND MANNER OF CLAIMING OF BIOTECHNOLOGICAL INVENTIONS BEFORE THE EUROPEAN PATENT OFFICE

Presentations

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I. For applicants in the field of biotechnology the United States may appear as the Garden of Eden where everything which is achieved by biologists or microbiologists is eligible for protection. The well-known decisions Diamond v. Chakrabarty, In re Hibberd and recently In re Allen have established and further developed the principle that statutory subject-matter includes "everything under the sun that is made by man".

Applicants in the field of biotechnology are often active not only in their domestic market but also abroad. Therefore it is important for them to known what level of protection they may expect in other countries. The EPC plays an important role in this respect not only because under its provisions protection is available covering 13 countries with over 300 million inhabitants, but also because this set of law created in the sixties and seventies has become a model for harmonisation not only in the Contracting States to the EPC but also in other countries.

II. Legal Background

The EPC provisions on patentability are to be found in Articles 52 to 57 (Annex 1).

The key provision of Article 52(1) states that European patents are to be granted for any inventions which are susceptible of industrial application, which are new and which involve an

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Presentation given by Dr. Rudolf Teschemacher.

inventive step. Apart from the restrictions specified by the legislator, the concept of an invention is thus defined by reference to the criteria in Articles 54, 56 and 57, namely novelty, inventive step and industrial application. The provision expresses a general principle of the patentability of all technical innovations that meet the aforesaid criteria unless they are not regarded as inventions, such as the examples given in Article 52(2), or the legislator has excluded them from patentability under Article 53[1)].

If the general rule of Article 52(1) EPC had been left unqualified then the patent practice would have been free to integrate new technologies into the patent system. The exclusions from patentability stipulated by the legislator which aimed at a standard of patentability acceptable to the Contracting States, when the Convention was being drafted resulted in the creation of problems when technical development went into directions not foreseeable 20 or 30 years ago. For inventions in the field of biotechnology Article 53(b) EPC is relevant, which stipulates in its first clause that patents shall not be granted for plant or animal varieties and for essentially biological processes for the production of plants or animals. By this provision the legislator wanted to exclude from patent protection what he regarded as not being of industrial character[2)]. According to the second clause of the same Article the exclusion in the first clause shall not apply to microbiological processes and the products thereof. Inventions in this field were accepted as being of industrial character.

It should be noted that the EPC does not contain the principle that living matter in general is excluded from patentability.

III. Practice of the EPO

Having explained the legal background we can now discuss how the relevant provisions are applied by the EPO. Biotechnology covers such a large field that I can only touch upon certain fundamental areas.

1. Microbiological processes

As has already been mentioned, microbiological processes are expressly stated to be patentable in the second clause of Article 53(b). All conceivable forms of such processes can be claimed and patented.

As a result a wide variety of options are available to the applicant. The following are just some examples of the fields in which he can claim protection:

Microbiological processes:

- Production processes in the conventional field of fermentation;
- In connection with obtaining micro-organisms from nature: processes for isolating or selecting micro-organisms:
- In the field of the genetic alteration of micro-organisms:
  - -- Induced mutation processes; these may be of technical significance even when they do not lead to identical micro-organisms as the end product, in particular in conjunction with appropriate selection processes;
  - -- Genetic recombination processes - the separate steps may themselves constitute patentable inventions, such as obtaining a DNA sequence or a vector and insertion into a host cell;
  - -- Propagation of micro-organisms, whether they are naturally occurring micro-organisms or genetically altered micro-organisms, and propagation of a transformed host cell.

2. Micro-organisms per-se

The EPC does not contain any express provision on the patentability of micro-organisms per-se. When confronted with this question in its early days the EPO recognized that there was clearly a need for protection and it held that micro-organisms were patentable since they could not be classified as plants or animals within the meaning of the first clause of Article 53(b) and further they could be regarded, in view of the micro-biological reproduction process itself, as the products of a microbiological process within the meaning of the second clause of Article 53(b)[2]. Accordingly in 1981 the Guidelines were revised[3]. According to Chapter C-IV, 3.5, Article 53(b) is to be interpreted as meaning that the propagation of the micro-organism itself is to be construed as a microbiological process and consequently the micro-organism can be protected per se as it is a product obtained by a microbiological process. The same part of the Guidelines states that the concept of micro-organism is to be given a wide interpretation and thus also covers plasmids and viruses. In practice the concept has not been confined just to those forms. It is normally accepted that the term micro-organism covers:

cellular organisms:
- bacteria
- fungi, including yeast,
- algae,
- protozoa,
- animal and plant cells in vitro,
- hybridomas

non-cellular organisms:
- viruses
- phages
- plasmids

Due to the rapid scientific development in this field, any definition of the term "micro-organism" in a definitive way, would be rapidly obsolete. As far as patent law is concerned, this term should be interpreted in the broadest sense, taking into account the need to follow the technical development in the field. Such interpretation need not necessarily correspond to usage in other scientific circles.

A further problem of definition in connection with the protection of micro-organisms is raised by Article 52(2)(a) which excludes discoveries from patent protection. Can a micro-organism that occurs in nature be protected and if so in what circumstances? If discovery is construed as meaning the recognition of matter occurring in nature then merely finding a micro-organism is a discovery. Substances occurring in nature should remain freely accessible. But the fact that an invention is derived from a discovery is not necessarily prejudicial. One must consider to what extent human intervention was necessary to obtain it.

In general a micro-organism will not be suitable for its intended use in its natural form. It will not be fully available and ready for use until it has been isolated and possibly further processed. By that stage it is no longer a mere discovery. For the same reason, at least where a pure culture exists, no objection can be raised as to lack of novelty. The Guidelines at C-IV, 2.3 define a substance as new if it had no previously recognized existence in nature.

Genetic engineering is a specific case of human intervention in obtaining a substance from nature. Therefore a DNA sequence is eligible for patent protection and is not a mere discovery.

In summary the following living matter or components thereof can be claimed in the field of microbiology.

- Micro-organisms, whether isolated from nature or genetically altered;
- Components of micro-organisms such as DNA sequences, plasmids and other vectors, restriction enzymes;

Claims for a known micro-organism produced by a new process are not allowable because a product is not rendered novel merely by the fact that it is produced by means of a new process (Guidelines, C-III, 4.7(b)). Known micro-organisms are, however, protected as products directly obtained from a claimed production process - such protection is expressly provided for in Article 64(2).

3. Biological processes

For biological processes we have to come back to Article 53(b) first clause.

This provision refers to biological processes only insofar as they are directed to the production of plants and animals. These processes are excluded from patentability. The purpose of this provision is to exclude from patent protection the activities of plant and animal breeders in the traditional sense and the products thereof.

Consequently, it follows that biological processes for purposes other than producing plants or animals are patentable, if they meet the general criteria. For example, processes for the treatment of soil by technical means to suppress the growth of plants are patentable (Guidelines, C-IV, 3.4).

On the other hand, non-biological processes for producing plants or animals are patentable. This applies to processes of treating plants or animals to improve their properties or yield e.g. a method of pruning a tree, would not be essentially biological since although a biological process is involved, the essence of the invention is technical; the same could apply to a method of treating a plant characterised by the application of a growth-stimulating substance or radiation (Guidelines, C-IV, 3.4).

In the field of plant or animal production the borderline between biological and non-biological (i.e. technical) processes is decisive for patentability. One has to examine whether the claimed process remains in the area of natural crossing or whether it is determined by human intervention. In this context any method of genetic engineering is regarded as being of a technical character.

If both types of elements, biological as well as technical, are present in a process for the production of plants or animals, one has to examine where the core of the innovation lies. If human intervention plays the significant part in determining or controlling the desired result, the process is patentable subject-matter (Guidelines, C-IV, 3.4).

This applies, for example, to the production of plants by using somatic cell hybridisation techniques. Such a technique may make use of the laws of heredity and thereby have a certain relation to crossing and selection. When balancing the influence of biological forces and of human intervention on the final result it has to be taken into account that human intervention does not merely play a supporting role but serves to produce a genetic product that could not be created naturally. The relevant criterion set out in the Guidelines in C-IV, 3.4 is the degree of technical intervention in the process; if human intervention plays a significant part in determining or controlling the desired result, the exclusion of the first clause of Article 53(b) does not apply.

4. Plants

The question whether patent protection is available under the EPC for whole plants or their propagating material, in the form of seeds or cuttings for example, has been the subject of controversial discussion. A parallel has been drawn with the protection of micro-organisms per se[4]. It was argued that the EPO allows protection for micro-organisms because they are the products of microbiological processes. If the same also applies for plants produced using genetic engineering, then it is said that the exclusion from patentability in Article 53(b) is not applicable. Irrespective of whether genetic engineering and microbiology can be treated on the same footing and whether the genetic engineering processes are followed by biological steps right up to the production of the plant, that argument is to my mind untenable. The purpose of the first clause of Article 53(b) is to exclude from patent protection, matter that is eligible for protection under the legislation on the protection of plant varieties. The latter also extends to plants produced using genetic engineering since it takes no account of the origin of the plants.

It is essential not to lose sight of the object of the distinction between the protection of plant varieties and patent protection when applying Article 53(b) even though the first sentence of Article 2(1) of the UPOV Convention is not binding on the EPO.

In this field the intention of the Contracting States when adopting Article 53(b) is clear and it must be taken into account by the EPO. The EPO cannot disregard the intention of the Contracting States to exclude the grant of European patents in an area in which breeders' rights may be obtained under the UPOV Convention. That means, in my view, that plant varieties produced using genetic engineering and their propagating material are excluded from patentability under the first clause of Article 53(b).

In this respect the legal situation in the United States is quite different. The preservation of existing rights applicable to the

United States in Article 37 UPOV Convention 1978 does not apply to the EPC Contracting States and was not yet part of the UPOV Convention when the EPC was drafted. This is the reason why these States as legislators of the EPC had to exclude double protection whereas the United States is able to offer both types of industrial property rights for plant varieties.

On the other hand it should be borne in mind that Aticle 53(b) excludes only plant varieties from patentability. Thus there is no general exclusion for plants. This was confirmed by the Technical Board of Appeal which allowed a claim for propagating material for cultivated plants, characterised in that it is treated with a certain chemical substance[5]. The Board stated in that decision that plants and plant varieties cannot be treated in the same way for the purposes of Article 53(b); that provision prohibits only the patenting of plants or their propagating material in the genetically fixed form of the plant variety. Those principles are not confined to the propagating material externally treated with chemicals at issue in that case. They are also applicable in a case in which a genetic engineering process is not confined to a certain variety as basic material or end product. This approach has been followed in the new Swiss Guidelines[6] which state that the exclusion from patentability is not applicable "where animals, plants and parts thereof are claimed which are not characterized in the claims by characteristics specific to that variety, and the claims, apart from possibly specifying the subject-matter of the invention (e.g. wheat or potatoes), contain only such characteristics which altogether are appropriate to several animal or plant varieties. For example if a new gene is invented that is basically suitable for incorporation in existing varieties of wheat in order to increase resistance against a specific viral disease, a claim may be made for the new "family" of the modified wheat containing that gene".

This seems to be a reasonable distinction; for developments in the sector of plants or plant materials that cannot properly be protected by one or more varieties as a product, substantive patent protection is granted for a group of plants.

5. Animals

As before in the Chakrabarty and Hibberd cases, the United States has, in the Allen case, again taken the lead in opening the patent system to new areas of biotechnology. Whether the EPO will follow this step is not yet clear.

Article 53(b) excludes "animal varieties" from patent protection. So far, no general practice has been developed. The term "variety" is more vague for animals than for plants. There seems to be an inconsistency between the three languages in the Convention (Animal varieties - Tierarten - races animales). Furthermore, the use of the term in natural sciences is less defined. Finally, no parallel term for the purpose of special protection exists, because there is no animal variety protection system.

It is quite open whether the same considerations concerning the exclusion of plant varieties will also apply to the exclusion of animal varieties. At least the problem of double protection does not exist in the latter field. This should give enough flexibility to apply the patent system in a way which fulfils the legitimate interests of inventors.

III. Adapting the patent system to new areas like biotechnology is a burdensome process. It has to be approached step by step taking account of any consequences for the whole patent system and of the interests of the public.

Such a process implies that legal uncertainty will exist in controversial questions for a considerable period. The practice developed so far by the EPO will be open to revision by the Boards of Appeal in appeals brought against decisions of the first instance in the grant proceedings and also in opposition proceedings. Also national decisions in revocation proceedings may influence the practice of the EPO. This means that we will have to wait a considerable time until we have final answers on the patent questions in the field of biotechnology.

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1) Enlarged Board of Appeal, Gr 05/83, OJ EPO 1985, p. 64, at p. 66, point 21 of the reasons

2) Teschemacher, Patentability of micro-organisms per se, 13 IIC 27(1982)

3) OJ EPO 1982, p. 19

4) von Pechmann, Zum Problem des Schutzes gentechnologischer Erfindungen bei Pflanzen durch Sortenschutz und/oder Patente, GRUR 1985, 717, at p. 722

5) Technical Board of Appeal, T 49/83, OJ EPO 1984, p. 112

6) X-232.2 (March 1986)

PART II

SUBSTANTIVE PATENT LAW

Chapter I

Patentability

Article 52

Patentable inventions

(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(a) discoveries, scientific theories and mathematical methods;

(b) aesthetic creations;

(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

(d) presentations of information.

(3) The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Article 53

Exceptions to patentability

European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

Article 54

Novelty

(1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

(3) Additionally, the content of European patent applications as filed, of which the dates of filing are prior to the date referred to in paragraph 2 and which were published under Article 93 on or after that date, shall be considered as comprised in the state of the art.

(4) Paragraph 3 shall be applied only in so far as a Contracting State designated in respect of the later application, was also designated in respect of the earlier application as published.

(5) The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.

Article 55

Non-prejudicial disclosures

(1) For the application of Article 54 a disclosure of the invention shall not be taken into consideration if it occurred no earlier than six months preceding the filing of the European patent application and if it was due to, or in consequence of:

(a) an evident abuse in relation to the applicant or his legal predecessor, or

(b) the fact that the applicant or his legal predecessor has displayed the invention at an official, or officially recognised, international exhibition falling within the terms of the Convention on international exhibitions signed at Paris on 22 November 1928 and last revised on 30 November 1972.

(2) In the case of paragraph 1(b), paragraph 1 shall apply only if the applicant states, when filing the European patent application, that the invention has been so displayed and files a supporting certificate within the period and under the conditions laid down in the Implementing Regulations.

Article 56

Inventive step

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents are not to be considered in deciding whether there has been an inventive step.

Article 57

Industrial application

An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

Guidelines for Examination in the EPO

C-III,4.7b

4. Clarity and interpretation of claims

4.7b Claims for products defined in terms of a process of manufacture are admissible only if the products as such fulfil the requirements for patentability, i.e. inter alia that they are new and inventive. A product is not rendered novel merely by the fact that it is produced by means of a new process (see Technical Board of Appeal Decision T 150/82, OJ 7/1984, p. 309). A claim defining a product in terms of a process is to be construed as a claim to the product as such and the claim should preferably take the form "Product X **obtainable** by process Y", or any wording equivalent thereto, rather than "Product X **obtained** by process Y".

Art. 64(2) According to Article 64, paragraph 2, if the subject-matter of a European patent is a process, the protection conferred by the patent extends to the products directly obtained by such process. The provisions of this Article are understood to apply to processes producing products completely different from the starting materials as well as to the processes producing only superficial changes (e.g. painting, polishing).

C-IV,2.3

2. Inventions

2.3 The items on the list in Article 52, paragraph 2, will now be dealt with in turn, and further examples will be given in order better to clarify the distinction between what is patentable and what is not.

Discoveries

If a man finds out a new property of a known material or article, that is mere discovery and unpatentable. If however a man puts that property to practical use he has made an invention which may be patentable. For example, the discovery that a particular known material is able to withstand mechanical shock would not be patentable, but a railway sleeper made from that material could well be patentable. To find a substance freely occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. Moreover, if the substance can be properly characterised either by its structure, by the process by which it is obtained or by other parameters (see III, 4.7a) and it is "new" in the absolute sense of having no previously recognised existence, then the substance per se may be patentable (see also IV, 7.3). An example of such a case is that of a new substance which is discovered as being produced by a micro-organism. Plant or animal varieties, except products of microbiological processes, are excluded in any event by Article 53, sub-paragraph (b) (see IV, 3.4 and 3.5).

C-IV,3.4 et seq.

3. Exceptions to patentability

Art. 53(b) 3.4 Also excluded from patentability are *"plant or animal varieties or essentially biological processes for the production of plants or animals"*. One reason for this exclusion is that, at least for plant varieties, other means of obtaining legal protection are available in most countries. The question whether a process is *"essentially biological"* is one of degree depending on the extent to which there is technical intervention by man in the process; if such intervention plays a significant part in determining or controlling the result it is desired to achieve, the process would not be excluded. To take some examples, a method of crossing, inter-breeding, or selectively breeding, say, horses involving merely selecting for breeding and bringing together those animals having certain characteristics would be essentially biological and therefore unpatentable. On the other hand, a process of treating a plant or animal to improve its properties or yield or to promote or suppress its growth e.g. a method of pruning a tree, would not be essentially biological since although a biological process is involved, the essence of the invention is technical; the same could apply to a method of treating a plant characterised by the application of a growth-stimulating substance or radiation. The treatment of soil by technical means to supress or promote the growth of plants is also not excluded from patentability (see also IV, 4.3).

3.5 The exclusion referred to in the preceding paragraph does not apply to *microbiological processes or the products thereof*. The term "microbiological process" is to be interpreted as covering not only industrial processes using micro-organisms but also processes for producing new micro-organisms, e.g. by genetic engineering. The product of a microbiological process may also be patentable per se (product claim). Propagation of the micro-organism itself is to be construed as a microbiological
Art. 53(b) process for the purposes of Article 53(b); consequently, the micro-organism can be protected per se as it is a product obtained by a microbiological process (see IV, 2.1 under "Discoveries"). The term micro-organism covers plasmids and viruses also.

3.6 In the case of microbiological processes, particular regard should be had to the requirement of repeatability referred to in II, 4.11. As for micro-organisms deposited under the terms of Rule 28, repeatability is assured by the possibility of taking samples
Rule 28(3) (Rule 28, paragraph 3), and there is thus no need to indicate another process for the production of the micro-organism.

* * *

I. Disclosure of biotechnological inventions

The general principle that a patent application should disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art applies of course in the field of biotechnological inventions as well as in any other field of technology.

The particularity in this field is however that words are very often insufficient to give a description which would enable the man skilled in the art to carry out the invention. For that reason, it is now an internationally recognised practice to allow this condition of sufficiency of disclosure to be satisfied, at least partially, by a deposit of the biological material, and the Budapest Treaty signed in 1977 has, at the international level, organized the deposit of microorganisms for the purpose of the patent procedure.

We will now consider how the possibility to use a deposit as a disclosure for biological material generally applies before the European Patent Office (EPO). For details on the more practical aspects of the use of deposits in European patent applications one may refer to the Official Journal of the EPO (8/1986, page 269).

Presentation given by Mr. André Rémond.

I. 1 Limits of the possibility to disclose through a reference to a deposited microorganism

One should first keep in mind that the basic principle remains that the disclosure has to be made in writing whenever possible and this remains very often the case even in this field, and it is only when words become insufficient or inadequate that the possibility exists to rely on a deposit in order to provide a sufficient disclosure.

Rule 28 EPC which contains the provisions in the EPC relating to the deposit of microorganisms states: "If an invention ... involves the use of a microorganism ... which cannot be described ...".

Furthermore, even in cases where the biological material has been deposited, the patent application has to give in the specification the relevant information which is available to the applicant on the characteristics of the material.

Only in that case is a search for the relevant literature possible in order to assess novelty and inventive step.

I. 2 Where to make the deposit

In order to fulfil the requirements set out in Rule 28 of the Implementing Regulations to the European Patent Convention, the deposit has to be made, either with an internationally recognised deposit authority according to the Budapest Treaty, or with a depositary institution recognised by the President of the European Patent Office.

I. 3 When to make a deposit

The deposit has to be made not later than the date of filing of the patent application, in accordance with the basic principle that the disclosure has to be sufficient at the filing date.

The depositary institution and the file number of the culture deposit have to be stated in the application, within a delay of 16 months, after the date of filing or after the date of priority, when priority has been claimed.

I. 4 Need to make a deposit

No deposit with a recognised depositary institution is required if the invention involves the use of a commercially available microorganism or when the microorganism is described in the patent application in such a manner as to enable the invention to be carried out by a person skilled in the art.

I. 5 What can be deposited

The Implementing Regulations, in Rule 28, only speak of microorganisms without giving any precise information about what is to be understood under this word. The guidelines for examination in the EPO (Part C, Chapter IV, 3.5) are a little more precise "The term micro-organism covers plasmids and viruses also". In the same guidelines (Annex 2 to Chapter II) the "most important group of microorganisms" considered are : bacteria, actynomycetes, yeasts, fungi. This enumeration is in our view purely illustrative and not limitative.

.../...

The nature of what can be deposited, for the purpose of the european patent procedure is governed by the following general principles:

- only biological material which cannot be properly described in writing is liable to be disclosed in the patent application through a reference to a deposit of sample,

- the biological material deposited should be permanently available, (which implies that it is capable of autoreplication).

According to these criteria the EPO does accept reference to cellular organisms such as bacteria, fungi, i.e. yeasts, algae, protozoa, animal and plant cell lines, hybridoma cells. As far as fungi and algae are concerned we are still of the opinion that only single cell organisms, or aggregates of similar cells with only primitive differentiation can really fall under the concept of microorganism.

Non-cellular organisms such as viruses, phages or plasmids are also accepted. DNA which does not self-replicate can be defined in the patent application through a reference to the deposit of the host organism where the DNA is to be found, together with the necessary information in order to perform the replication and isolation of the DNA.

I. 7 Effect of the deposit on repeatability of the invention

According to the guidelines for examination before the EPO, (Part C, Chapter IV, 3.6) "as for micro-organisms deposited under the term of Rule 28, repeatability is assured by the possibility of taking samples, and there is thus no need to indicate another process for the production of the micro-organism".

.../...

This view was not shared by the German Supreme Court according to the two well-known decisions Rote Taube and Bäckerhefe. The German Supreme Court has now in the recent decision Tollwut virus (Rabies virus - 12 February 1987) abandoned its point of view and adopted the same line as the EPO in the matter of repeatability, also when the patent is for the micro-organism as a product per se.

I. 8 Deposit and priority right

When a patent application which needs a deposit for the sufficiency of its disclosure claims the priority of an earlier patent application according to the Paris Convention, the deposit should have been made not later than the date of filing of the earlier application. This deposit only needs to fulfil all the requirements of the EPC starting on the date of filing of the European application. Before this date it only needs to have been made according to the requirements of the national law of the priority country. Where the deposit referred to in the European application is not the same as the dèpôsit in the previous application it is up to the applicant to provide evidence that the two micro-organisms are identical.

I. 9 Conditions of release of samples

The deposit has to be such as to allow release of samples of the deposited material.

The earliest date at which samples of a deposited microorganism must be made available is the publication date of the European application which occurs 18 months after the filing date, or after the priority date if

.../...

priority has been claimed (Rule 28(3) EPC and Article 93 EPC). Exceptionally samples might have to be made available, according to Article 128(2) EPC, to persons proving that the application for a European patent has invoked the rights under the application against him.

This issue of a sample to a requester shall be made only if the requester has undertaken vis-à-vis the application for or proprietor of the patent:

- not to make a sample of the deposited microorganism available to any third party as long as the application is pending or the patent is in force;

- to use a sample for experimental purpose only as long as the application is pending and no patent has been granted on it .

The undertaking extends to cultures derived from the sample obtained. A derived culture, is deemed to be any culture of the microorganism which still exhibits those characteristics of the deposited culture which are essential to carrying out the invention. The applicant may request that samples of the deposited micro-organism only be made available to an expert, for experimental purposes for the period of time between the publication and the grant refusal, or withdrawal of the patent application. This constitutes the so-called "expert-solution".

The expert may be:

- any natural person approved on by the applicant and the requestor;

- any natural person recognised as an expert by the President of the European Patent Office.

.../...

I.10 Validity of the "expert solution"

Among the users of the European grant procedure, there is some concern that the so-called "expert solution" under Rule 28 (4) EPC might be found invalid by the national courts, especially in Germany, as being incompatible with Article 83 EPC.

It is correct that the "expert solution" under Rule 28 EPC has not been incorporated to date in the national patent law of the Federal Republic of Germany.

The immediate consequence of this is to preclude recourse to the expert solution in connection with German national patent applications. Delivering judgment in 1975 in the "Bäckerhefe" (baker's yeast) case the Bundesgerichtshof (Federal Court of Justice) rejected the idea of a neutral intermediary between the microorganism and the public as being incompatible with the principle of sufficient disclosure in the first publication of the patent application (publication of the unexamined patent application).

There is so far no case law relating to the validity of a European patent designating the Federal Republic of Germany in which the expert solution was used, so that it is impossible to say how the German courts would perceive the issue in such a case. In reaching their decision the courts would have to consider carefully the legislative history (travaux préparatoires) of the 1979 amendment to Rule 28 which introduced the expert solution.

Here it is worth noting that

- the amendment was adopted by the Administrative Council of the European Patent Organisation after

intensive discussion as to whether the expert solution could be reconciled with the substantive provisions of the EPC on sufficient disclosure; in a legal opinion submitted to the Council the EPO concluded that it could;

- within the Administrative Council the amendment secured an overwhelming majority, with only the Swedish and United Kingdom delegations abstaining; Sweden has since adopted the expert solution in its national law;

- the German delegation actively supported the amendment on the grounds that it was justified in order to prevent depositors' rights being abused.

The interested circles in the Federal Republic of Germany have approached the Federal Minister for Justice with a view to having the German Patent Law harmonised with the amended EPC Rule 28 incorporating the expert solution.

Not only was the Justice Ministry favourably disposed to this proposal but it described as unjustified fears expressed by the interested circles that a European patent designating Germany having made use of the expert solution might be invalidated.

The Commission of the European Communities is at present drawing up a Community Directive on biotechnological inventions which includes a provision relating to the expert solution on the EPC Rule 28 model; the EC States will have to bring their national law into line with this Directive if it is adopted.

.../...

II. MANNER OF CLAIMING

As everybody knows the claims are that part of the patent application in which the applicant tries to define, on the basis of the description, the matter for which protection is sought. In other words, they give the "boundaries" of the monopoly.

In the field of biotechnological inventions and even more when genetic engineering or hybridoma technology is involved, the claims are generalisations based on the results obtained on a limited number of particular experiments.

This generally accepted principal of authorizing generalisation, which is anyway a necessity in order to give an effective protection against infringement, becomes nevertheless difficult to use when micro-organisms are concerned. How is it possible and what is the reasonable generalisation on the basis of a single deposit of a microorganism for example.

I will not give here any rule which could apply in every case but simply want to draw your attention to the opened possibility to define the claimed subject-matter through functional limitations.

Claims are normally worded in terms of the technical features, through the use of which the expected result is achieved. However, and this has revealed itself very useful in the case where, as I have just mentioned, biological matter is involved, functional limitations may also be included, provided that a skilled man would have no difficulty in providing some means of performing this function without exercising inventive skill.

For instance, if the invention cannot otherwise be better defined, claims may define the invention, or a feature of it, by a result to be achieved, possibly in combination with other technical features.

A functional limitation was accepted by the Chemical Board of Appeal of the EPO (T 26/82, unpublished) in a claim for a process using certain microorganisms. The claim was of the form: "Producing compound T by the microbiological oxidation of compound X with a suitable aerobic microorganism".

The microorganism was not more precisely defined than by these terms: "a suitable aerobic microorganism". Despite the fact that not all aerobic microorganisms have the capability of effecting the transformation, it has been considered that the man skilled in the art was able, using a simple test, to define by himself those microorganisms which are "suitable".

This liability to use functional limitations has been confirmed in two very recent decisions of the Chemical Board of Appeal of the EPO, not directly concerned with biotechnologies but containing general conditions which make them worthwhile mentioning here.

In the first one (T 139/85 of 23.12.1986, not foreseen to be reported) the disputed claim was for a pharmaceutical composition containing an active compound A and a physiologically functional salt, ester or other derivative thereof B. This definition of B lead to the refusal of the patent application for lack of clarity. In its decision the Board takes this view that a limitation such as "physiologically functional" is acceptable. The said feature is "sufficiently clear

for the expert to reduce it to practice without undue burden; for the expert clearly understands its meaning and if in doubt with respect to a particular derivative whether it is "physiologically functional", he can without undue burden, i.e. by means of reasonably simply experiments, determine this.

In the second decision (T 68/85 of 27.11.86, to be reported in the Official Journal), the claim was for synergistic herbicides. Here again, the Board decided that

"Functional features defining a technical result are permissible in a patent claim if, from an objective viewpoint, such features cannot otherwise be defined more precisely without restricting the scope of the invention, and if these features provide instructions which are sufficiently clear for the expert to reduce them to practice without undue burden, if necessary with reasonable experiments".

Of course, there are always limits to how far functional limitations may be used as technical features in claims, but it is clear here that the EPO tries to be flexible in its approach to the manner of claiming taking due account of the need for protection in this rapidly evolving field of biotechnologies.

*Rule 28**

Requirements of European patent applications relating to micro-organisms

(1) If an invention concerns a microbiological process or the product thereof and involves the use of a micro-organism which is not available to the public and which cannot be described in the European patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, the invention shall only be regarded as being disclosed as prescribed in Article 83 if:

(a) a culture of the micro-organism has been deposited with a recognised depositary institution not later than the date of filing of the application;

(b) the application as filed gives such relevant information as is available to the applicant on the characteristics of the micro-organism;

(c) the depositary institution and the file number of the culture deposit are stated in the application.

(2) The information referred to in paragraph 1(c) may be submitted:

(a) within a period of sixteen months after the date of filing of the application or, if priority is claimed, after the priority date;

(b) up to the date of submission of a request for early publication of the application;

(c) within one month after the European Patent Office has communicated to the applicant that a right to inspection of the files, pursuant to Article 128, paragraph 2, exists.

The ruling period shall be the one which is the first to expire. The communication of this information shall be considered as constituting the unreserved and irrevocable consent of the applicant to the deposited culture being made available to the public in accordance with this Rule.

(3) The deposited culture shall be available upon request to any person from the date of publication of the European patent application and to any person having the right to inspect the files under the provisions of Article 128, paragraph 2, prior to that date. Subject to the provisions of paragraph 4, such availability shall be effected by the issue of a sample of the micro-organism to the person making the request (hereinafter referred to as the "requester"). Said issue shall be made only if the requester has undertaken *vis-à-vis* the applicant for or proprietor of the patent:

(a) not to make the deposited culture or any culture derived therefrom available to any third party before the application has been refused or withdrawn or is deemed to be withdrawn or, if a patent is granted, before the expiry of the patent in the designated State in which it last expires;

(b) to use the deposited culture or any culture derived therefrom for experimental purposes only, until such time as the patent application is refused or withdrawn or is deemed to be withdrawn, or up to the date of publication of the mention of the grant of the European patent. This provision shall not apply insofar as the requester is using the culture under a compulsory licence. The term "compulsory licence" shall be construed as including *ex officio* licences and the right to use patented inventions in the public interest.

(4) Until the date on which the technical preparations for publication of the application are deemed to have been completed, the applicant may inform the European Patent Office that, until the publication of the mention of the grant of the European patent or until the date on which the application has been refused or withdrawn or is deemed to be withdrawn, the availability referred to in paragraph 3 shall be effected only by the issue of a sample to an expert nominated by the requester.

(5) The following may be nominated as an expert:

(a) any natural person provided that the requester furnishes evidence, when filing the request, that the nomination has the approval of the applicant;

(b) any natural person recognised as an expert by the President of the European Patent Office. The nomination shall be accompanied by an undertaking from the expert *vis-à-vis* the applicant; paragraph 3 (a) and (b) shall apply, the requester being regarded as a third party.

(6) For the purposes of paragraph 3, a derived culture is deemed to be any culture of the micro-organism which still exhibits those characteristics of the deposited culture which are essential to carrying out the invention. The undertaking referred to in paragraph 3 shall not impede a deposit of a derived culture, necessary for the purpose of patent procedure.

(7) The request provided for in paragraph 3 shall be submitted to the European Patent Office on a form recognised by that Office. The European Patent Office shall certify on the form that a European patent application referring to the deposit of the micro-organism has been filed, and that the requester or the expert nominated by him is entitled to the issue of a sample of the micro-organism.

(8) The European Patent Office shall transmit a copy of the request, with the certification provided for in paragraph 7, to the depositary institution as well as to the applicant for or the proprietor of the patent.

(9) The President of the European Patent Office shall publish in the Official Journal of the European Patent Office the list of depositary institutions and experts recognised for the purpose of this Rule.

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* Amended by decision of the Administrative Council of November 30, 1979, which entered into force on June 1, 1980 (*Official Journal of the EPO* 11-12/79, p. 447).

IMPLEMENTING REGULATIONS
Rule 28a

*Rule 28a**

New deposit of a micro-organism

(1) If a micro-organism deposited in accordance with Rule 28, paragraph 1, ceases to be available from the institution with which it was deposited because:

(a) the micro-organism is no longer viable, or

(b) for any other reason the depositary institution is unable to supply samples,

and if the micro-organism has not been transferred to another depositary institution recognised for the purposes of Rule 28, from which it continues to be available, an interruption in availability shall be deemed not to have occurred if a new deposit of the micro-organism originally deposited is made within a period of three months from the date on which the depositor was notified of the interruption by the depositary institution and if a copy of the receipt of the deposit issued by the institution is forwarded to the European Patent Office within four months from the date of the new deposit stating the number of the application or of the European patent.

(2) In the case provided for in paragraph 1(a), the new deposit shall be made with the depositary institution with which the original deposit was made; in the cases provided for in paragraph 1(b), it may be made with another depositary institution recognised for the purposes of Rule 28.

(3) Where the institution with which the original deposit was made ceases to be recognised for the purposes of the application of Rule 28, either entirely or for the kind of micro-organism to which the deposited micro-organism belongs, or where that institution discontinues, temporarily or definitively, the performance of its functions as regards deposited micro-organisms, and the notification referred to in paragraph 1 from the depositary institution is not received within six months from the date of such event, the three-month period referred to in paragraph 1 shall begin on the date on which this event is announced in the Official Journal of the European Patent Office.

(4) Any new deposit shall be accompanied by a statement signed by the depositor alleging that the newly deposited micro-organism is the same as that originally deposited.

(5) If the new deposit provided for in the present Rule has been made under the provisions of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 28 April 1977, the provisions of that Treaty shall prevail in case of conflict.

(a) a statement indicating the designation of the subject-matter of the invention and those technical features which are necessary for the definition of the claimed subject-matter but which, in combination, are part of the prior art;

(b) a characterising portion – preceded by the expression "characterised in that" or "characterised by" – stating the technical features which, in combination with the features stated in sub-paragraph (a), it is desired to protect.

(2) Subject to Article 82, a European patent application may contain two or more independent claims in the same category (product, process, apparatus or use) where it is not appropriate, having regard to the subject-matter of the application, to cover this subject-matter by a single claim.

(3) Any claim stating the essential features of an invention may be followed by one or more claims concerning particular embodiments of that invention.

(4) Any claim which includes all the features of any other claim (dependent claim) shall contain, if possible at the beginning, a reference to the other claim and then state the additional features which it is desired to protect. A dependent claim shall also be admissible where the claim it directly refers to is itself a dependent claim. All dependent claims referring back to a single previous claim, and all dependent claims referring back to several previous claims, shall be grouped together to the extent and in the most appropriate way possible.

(5) The number of the claims shall be reasonable in consideration of the nature of the invention claimed. If there are several claims, they shall be numbered consecutively in arabic numerals.

(6) Claims shall not, except where absolutely necessary, rely, in respect of the technical features of the invention, on references to the description or drawings. In particular, they shall not rely on such references as: "as described in part . . . of the description", or "as illustrated in figure . . . of the drawings".

(7) If the European patent application contains drawings, the technical features mentioned in the claims shall preferably, if the intelligibility of the claim can thereby be increased, be followed by reference signs relating to these features and placed between parentheses. These reference signs shall not be construed as limiting the claim.

* Inserted by decision of the Administrative Council of November 30, 1979, which entered into force on June 1, 1980 (*Official Journal of the EPO* 11-12/79, p. 449).

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PLANT BREEDING AND BIOTECHNOLOGY IN THE UNITED STATES OF AMERICA: CHANGING NEEDS FOR PROTECTION OF PLANT VARIETIES

Presentation by Dr. Charles Brim,
Professor Emeritus,
University of North Carolina

HISTORICAL DEVELOPMENT

I have been invited to sketch one of civilization's oldest and most fundamental professions, plant breeding, and to touch on those aspects that relate to the issue of intellectual property protection. As a former soybean and corn breeder, I will develop my remarks and examples using primarily these two crops. Furthermore, I shall try to relate progress in breeding procedures with the size of the inventive steps and the legal protection appropriate to the new varieties these innovations produced (Table 1).

Table 1
A bird's-eye view on plant breeding development

Time frame	Genetic improvement procedures	Size of selection advances between generations of varieties	Type of appropriate legal protection
Pre-history	Gathering of wild fruit, grain roots. Some of it dropped around human dwellings and plants grew from it next season. These looked better than most of them in the wild. As a result domestication began	Very small	None
Historical times till mid-19th century	Selection by farmers within their crop for local adaptation	Small	None
Latter 19th century to early 20th century	Hybridisation followed by selection and progeny testing procedures by early professional breeders	Incremental	Plant variety protection (PVP) but not yet introduced
First quarter to 3rd quarter of 20th century	Improved breeding methodologies, including hybrid seed development and mutation breeding	Mostly incremental, occassionally large	Mostly PVP, occasionally patent[1] had it been available[2]
Last quarter of 20th century	Biotechnology-assisted breeding methodologies and other technologies turning seed into a carrier of protective and/or growth promoting biologicals (including genes) and of chemicals	Major ones interspaced with incremental ones	Patents and/or PVP to be judged by breeder from case to case

[1] Patent protection based on non-obviousness.

[2] Hybrid seed process might have qualified for patent protection, but as it was invented at public institutions, the question did not arise at the time.

You see, it all started way back in Paradise, when Eve selected the nicest apple she could find. Chased from Paradise, early man became a gatherer of fruit, grain and roots. Some of what he gathered, dropped near his abodes, germinated and reproduced the following season. In time, it was noticed that what grew from what had been selected in the wild looked better than average, and man began to nurse, reproduce and further select it. Thus, wild species of plants slowly evolved, over thousands of years, into domesticated species.

Selection in this way continued till about the mid-19th century. By then, varietal improvement was taken up professionally by botanists and progressive farmers, and seed houses became established in both North America and Europe. Their principal initial innovation was that they based selection on progeny-testing; i.e. not only the rating of the parents but of their off-spring as well.

Varietal improvement progressed slowly but steadily and received major boosts in the first half of this century through the application of Mendelian genetics, followed by that of biometrics and quantitative genetic theory. Disease and pest resistance breeding and the introduction of exotic germ plasm for the improvement of important traits, all contributed to a gradual improvement of varietal performance, as did the advances in seed conditioning technology and agricultural production techniques.

Cultivars succeeding one another generally demonstrated small improvements that were rarely non-obvious and therefore did not qualify for patent protection. But cumulatively over time, progress was nonetheless substantial. E.g. in the U.S.A., between 1930 and 1975, the average yield per acre increased as follows for:

soybeans	70%
wheat	115%,
corn	320%,
grain sorghum	358%.

Figures 1, 2 and 3 (facing page) for yearly average yields of the U.S. corn, sorghum and soybean crops show the progress attained from improvements in agricultural technology. Those on corn and sorghum illustrate that major innovative steps, such as hybrid technology, though exceptional in plant breeding, are possible. They merit rewards analogous to those in industrial technology. Such major innovations are expected to become a lot more common in the near future as biotechnology starts to bear fruit.

But whereas the introduction of hybrid seed in sorghum in the mid-fifties was accompanied by an immediate quantum jump in yield, this took longer to materialize for hybrid seed corn in the late thirties. At that time, cultural practices on the farms were not yet adequate to provide the basis for the yield potential of the new hybrids.

Figure 1
Average U.S. corn yields from 1880 to present.

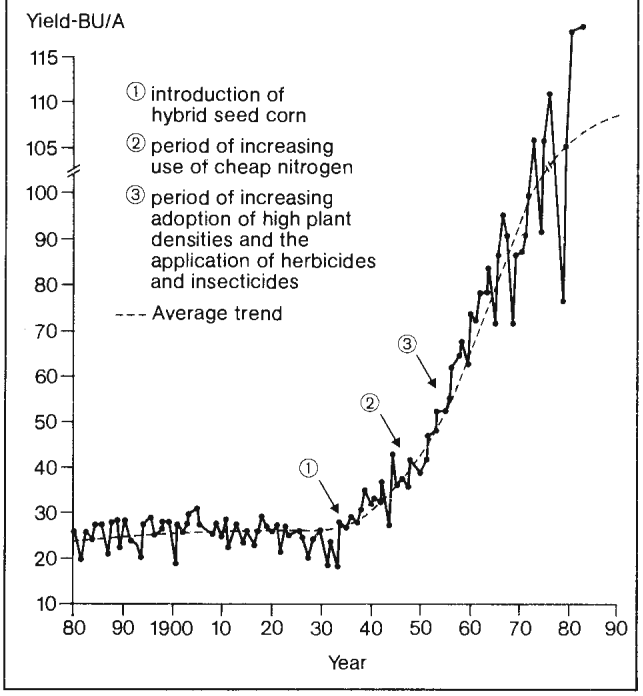


Figure 2
Average U.S. grain sorghum yields from 1940 to present. (Introduction of hybrid grain sorghum in the mid-fifties).

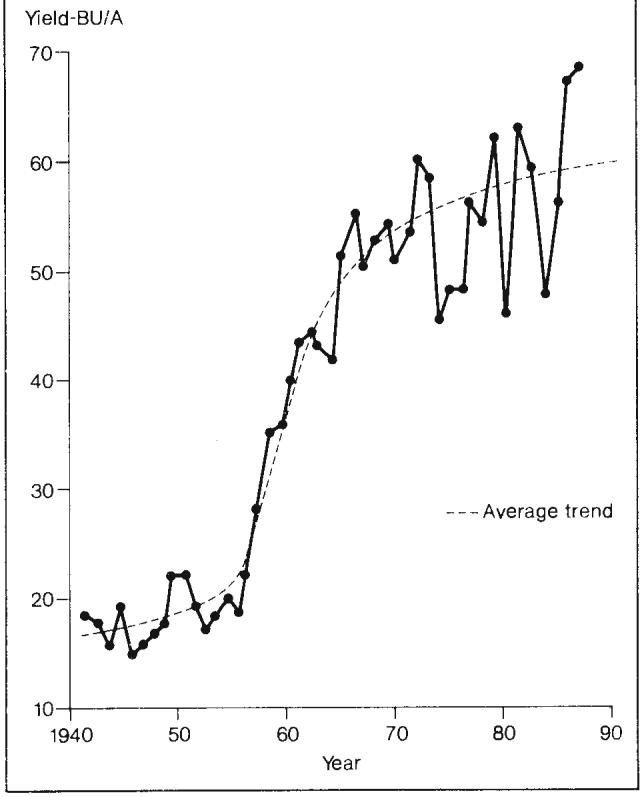
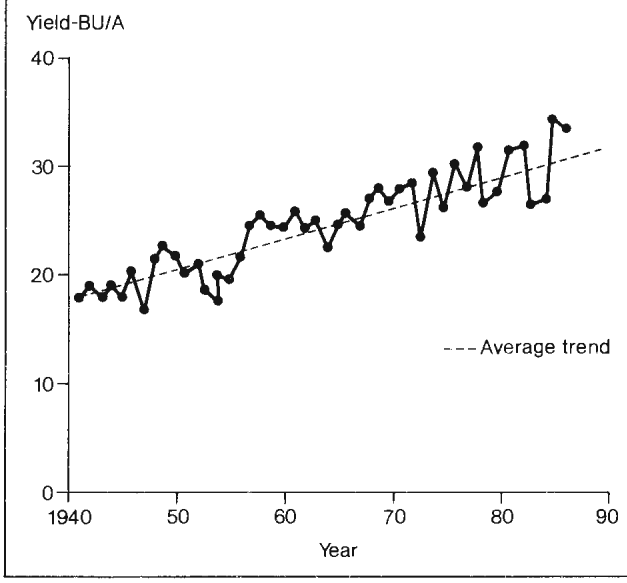


Figure 3
Average U.S. soybean yields from 1940 to present. (About half of the improvement is attributable to better cultivars).



The relatively slow, steady progress in soybean improvement (Figure 3) illustrates another aspect important to our discussion. Incremental improvements realized with conventional breeding are the general rule. Major advances are not common. While these small-step-innovations would generally not qualify for patent protection, the UPOV rules of plant variety protection (PVP) were formulated to provide some measure of protection for varietal improvements of this type (see Table 2).

Table 2
Propagating material for agricultural and horticultural use and the type of protection it enjoys in the U. S. A.

Type of propagating material	Type of crop	Type of protection available to the inventor of new cultivar
Pure line seed	Self-pollinated crops, such as: • soybeans • wheat • barley	Plant variety protection laws (PVP) based on UPOV convention since 1970
Hybrid seed	Cross-pollinated crops, such as: • maize (corn) • sorghum • sunflowers	• Biological protection for hybrid seed • PVP laws for inbred line seed • Patent protection possible in terms of Hibberd case
Vegetative material	Asexually propagated crops like • potatoes • sugar cane • flower bulbs	• PVP laws for most agricultural crops • Patent protection mostly for ornamentals
Tissue culture propagules	• Some horticultural crops • Some ornamentals	Patent protection possible

With cross-pollinated crops PVP is available for protecting new inbred lines. Additionally, the hybrids produced from the inbred lines carry a form of built-in biological protection against reuse. A competitor is unable to copy a new hybrid cultivar unless he gains access to both the inbred line combination and the inbreds needed to develop the hybrid. And the farmer, to capitalize on the substantially improved performance conferred by hybrid vigor, must return to the seed supplier each planting season. If you wish to prove this principle to yourselves, just raise the progeny of a hybrid tomato in your garden and observe the wide diversity you obtain. In agricultural crop production, such a plant type mixture and the accompanying drop in yield would be quite unacceptable. Unfortunately, this biological protection will be no barrier to a speedy misappropriation of major, simply inherited new traits transferred to hybrids through biotechnology.

CULTIVAR DEVELOPMENT BY GOVERNMENT AND PRIVATE PLANT BREEDERS

Public institutions, especially in the US, have traditionally been the primary contributors to varietal improvement. The originators from the public sector had no proprietary rights, nor did the institutions. And though, plant breeding expenses are high, now estimated to total about US $900,000 for a new maize hybrid and about $600,000 for soybean or wheat cultivars, recovery of research costs was not an issue. The underlying philosophy held that plant breeding was part of the public service to agriculture. Hence, public institutions worked successfully on all economic crops and their new germplasm developments were freely available to potential users. This unrestricted germplasm exchange enabled breeders to move valuable genes rapidly across U.S. maturity zones and to achieve major gains in cultivar performance over the past 50 years. In a similar way, new germplasm types have moved freely across international boundaries.

Private industry, till the 1970s focussed on breeding hybrid cultivars. As discussed earlier, the availability of plant variety protection was not so important for hybrid seed crops. Consequently, private seed companies became heavily involved in hybrid seed breeding right from the start. Even today, the advantages of hybrid seed continue to provide a strong incentive for research efforts to develop new strategies for converting vegetables, partially cross-pollinated crops such as sorghum and sunflowers, and even self-pollinated crops like wheat, barley or cotton into hybrid seed crops. This is done either genetically, especially via the introduction of cytoplasmic male sterility, or via male gametocides - the male pill for crop plants.

High R&D costs and the lack of legal protection on cultivars prior to 1970 discouraged private involvement in pure-line cultivar development of self-pollinated crops. The uncertainty of a reasonable return on the substantial R&D investments needed to remain competitive led private industry to ignore several important U.S. crops. Then in 1970, the U.S. decision to join UPOV and to introduce its own plant variety protection laws corrected the situation. The subsequent dramatic increase in private soybean breeding programs is illustrated by the numbers presented in Table 3. The increased activity by the

Table 3
The size of soybean breeding research by private industry in the U. S. before and after the introduction of plant variety protection laws in 1970

Year	Number of	
	Companies	Breeders
1966	2	2
1971	6	6
1984	30	63

Table 4
Number of plant variety protection certificates issued in the U. S. in the period 1971 to 1982

Crop	Number
Soybeans	243
Wheat	127
Peas	117
Cotton	106
Garden beans	100
All others	424
Total	1117

seed industry was soon translated into a string of new variety protection certificates as shown by Studebaker (Table 4). It may be assumed that most of the cultivars thus protected were bred by private breeders, since until recently public institutions made their new cultivars available without charge.

Table 5
Percent of total soybean acreage grown to proprietary cultivars in Indiana*

Year	Percent
1977	15.3
1981	36.4
1986	46.3

* USDA Crop Production Report, 1983, shows that the acreage grown to proprietary soybean cultivars increased from 10.6% in 1980 to 26.2% in 1983 in IL, IN, IA, MN, MO, NE, OH.

The acceptance of these new proprietary cultivars by farmers, in spite of generally slightly higher seed prices, is reflected in Studebaker's data by the increasing acreage planted to proprietary soybean cultivars in Indiana (Table 5). With the free choice of varieties of either public or private origin, it is obvious that these proprietary brands can only be successful if they are at least competitive in performance with those from puolic institutions. That this is indeed the case was shown by Studebaker from comparisons derived from a multi-year analysis of University of Illinois soybean variety tests (Table 6).

Table 6
Comparison of yield and lodging for soybean cultivars of equal maturity from public and private sources in the U. S.*

Source	Yield BU/A	Lodging score (1 = best to 9 = worst)
Private	47.4	2.0
Public	45.3	1.9

* In 64% of the comparisons, varieties from private sources were greater or equal to varieties from public sources for yield.
These data were obtained from University of Illinois "Performance of Commercial Soybeans in Illinois," (1978-1982) reported by J. Studebaker in Proceedings of the 14th Soybean Seed Research Conference, 1984.

From the foregoing it is evident that breeders within the private seed industry sector now have the financial incentive to actively push for the testing of their new cultivars in any production zone where these may demonstrate a competitive advantage and also enjoy royalty rights. This also benefits the farmers because varietal improvements reach them more quickly.

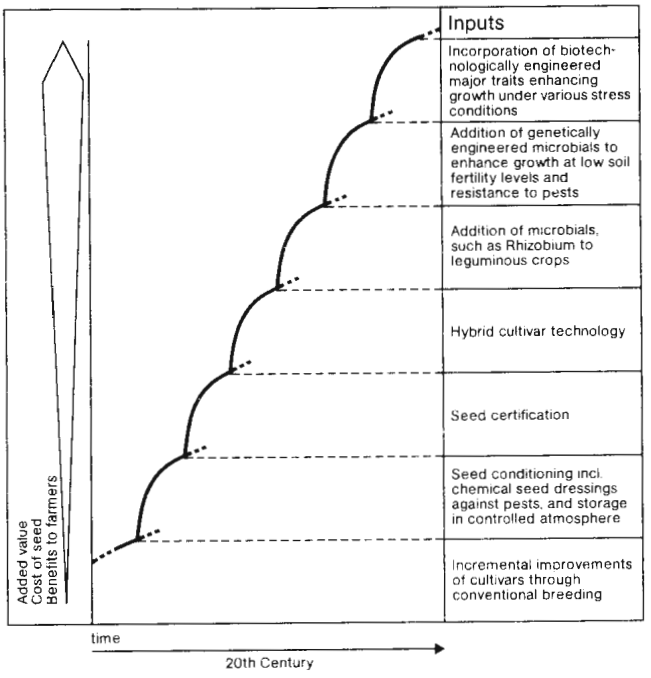
The diffusion of germplasm from public or private sources is not impeded by the umbrella of plant variety protection as feared by some opponents. Rule 5(3) of the UPOV convention, the so-called research exemption, ensures that. It gives anyone, anywhere the right to use a released cultivar as a germplasm base from which new cultivars may be bred. As progress thrives on competition, breeders are forced to use the entire existing germplasm as effectively as possible in their programs in order to be successful. PVP is thus stimulating rather than hindering germplasm diffusion.

Traditional crop improvement is a lengthy process, requiring six to 15 years from project initiation to market introduction.The exact length of time depends on the crop, available sources of germplasm , the breeding objective and methods and the business environment. Now, however, biotechnology has the potential to change the pace and nature of improvements to crop cultivars. Major advances through the introduction of foreign genes are expected, but these will, initially, be very expensive to attain. Unfortunately, because of the research exemption rule, PVP in the U.S. and UPOV provide no adequate protection for cultivars carrying these genes as soon as they are marketed. A competitor can use biotechnology skills to "fish" the new genes out of a cultivar released commercially and will soon be able to transfer the "pirated" gene and trait very quickly, perhaps in as short a time as six(6) months, and relatively cheaply into his own leading cultivar. Obviously, the negative impact of such a scenario on committed investment to biotechnology should not be underestimated.

SEED'S PROGRESS FROM A PLANT-BACK TO AN ADVANCED SPECIALTY PRODUCT

Over millenia, farmers retained a portion of the harvest for replanting the next season. Contamination from weeds and other varieties as well as physically damaged and low vigor seeds proved difficult to eliminate from the plant-back seed. These contaminants were recognized since early times as detrimental to the potential of the next crop, and measures were progressively evolved, as seen in Figure 4, to improve all seed properties.

Figure 4
Diagrammatic representation of successive added value inputs to seed this current century by seed breeders and conditioners.



Special machinery was developed for removing contaminants and for adding chemical seed treatments to reduce the ravages of pests and diseases encountered during storage and the germination process. As seed conditioning became more sophisticated, seed certification agencies were organized. Their operations are supervised by governmental agencies to guarantee high quality seed for both varietal purity and physical properties.

Over time, certified seed received several inputs. Breeders standardized the end product thus enabling varietal purity to be monitored more effectively, and seed conditioners added improved chemical and biological treatments. All these added values contribute to make today's high quality seed an essential element in modern, efficient crop production. In situations where high productivity counts, farmers are willing to pay for the extra cost of these seed-related inputs.

In the near future, plant seeds are expected to benefit from several biotechnology-based improvements. Seed may be used as a carrier for engineered microbials which lead to biological control of soil pests and diseases, assist the crop in taking up nutrients more efficiently or to protect it from unfavorable soil factors. Meanwhile, biotechnology laboratories will engineer valuable traits directly into the crop plants and license breeders to incorporate these traits into a wide spectrum of cultivars. Figures 5 and 6 illustrate examples of developments to come. In one of these break-throughs, Plant Genetic Systems of Belgium transferred a gene from Bacillus thuringiensis into tobacco. The new gene encodes an insecticidal toxin that serves to kill feeding tobacco hornworms (Protoparce sp.) (Figure 5). In another genetic engineering experiment (Figure 6) by PGS, a bacterial gene isolated by Biogen S.A. was introduced into potatoes (and other crops) to render them resistant to Hoechst's herbicide, Basta (Figure 6). The foreign gene contributes a new enzyme that can inactivate phosphinotricin.

By the time major food crops benefit from such gene manipulations, seed will have become, in the full meaning of the term, an advanced technology product, and as such, should be accorded the full benefits of intellectual property rights.

MODERN VARIETIES: WHAT LEGAL PROTECTION?

With this background on how variety breeding has evolved from a straight-forward amateur-type selection process to a very sophisticated and capital-intensive technology, and how seeds were turned from simple plant-back material from the previous season's crop to scientifically designed products, the question arises how this progress can best be sustained. It was shown that PVP had succeeded in encouraging private enterprise to play a major role in the conventional breeding of self-pollinated crops and that this has benefited the farmer.

To entice enterpreneurs to invest heavily in biotechnology, which is becoming an accepted tool of plant breeding, the comparatively narrow protection offered by PVP will not be enough. Major varietal improvements, expected to intersperse the traditional incremental steps with increasing frequency, need stronger protection to make their development worthwhile to the investor.

So let me highlight some major advantages and limitations of existing plant variety protection and suggest some modifications by which the existing framework of protection available under PVP can be adapted to offer stronger protection for the needs of the coming decades.

Figure 5: Bacillus thuringiensis toxin-based resistance to lepidopterous caterpillars. Genetically-engineered tobacco plant on the right exhibits resistance to tobacco hornworm, while the non-engineered control plant on the left is ravaged by the pest. (Photograph: Courtesy of Plant Genetic Systems, Brussels).

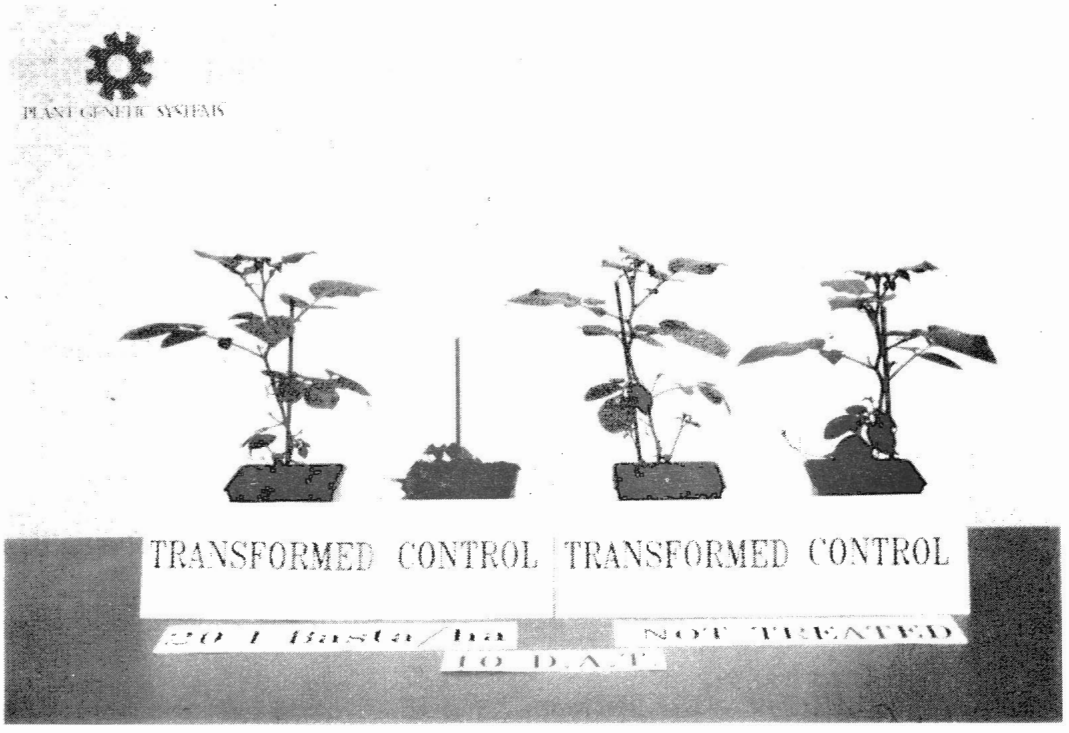


Figure 6: When expressed in a transformed plant a bacterial gene from a strain of streptomyces confers the ability to detoxify a herbicide that inhibits amino acid biosynthesis. On the right, transformed and non-transformed (control) potato plants are very similar in the absence of herbicide application. On the left, the control plant dies within 10 days after applying the broad spectrum, non-selective herbicide Basta, while the genetically-engineered plant is not damaged by the treatment.

Plant Variety Protection (PVP) for the State of the Art in the Pre-Biotechnology Era

To those concerned with the framing of legal protection for variety innovations over 50 years ago, the patent laws did not seem suited to protect incremental improvements in biological, self-replicating material. Therefore, specific plant variety protection (PVP) laws were drawn up in different countries and then harmonised under the UPOV Convention of Paris in 1961. In particular, plant variety protection rules took the following factors into account:

- Because varieties emerge from the random, and therefore unpredictable, assortment of genes through multiple generations in a plant breeding program, a seed sample of the new variety had to be deposited with the authorities in some countries to constitute disclosure for protection.

- The performances of varieties that dominate a market generally differ only incrementally from each other, and current introductions would rarely qualify under the requirement in patent law for an invention to be non-obvious. Instead, in PVP a protectable variety must be distinguishable from others, be homogeneous and stable.

- To breed new varieties, one needs as a starting base existing varieties, and the latest protected varieties contain not only the innovative contributions of their respective breeders, but also the accumulated improvements of their countless predecessors. For this reason UPOV rule 5(3), the Research Exemption, was adopted.

- Whereas under patent law a farmer could be prevented from using part of his harvest as plant-back seed for his own needs, this provision was considered unacceptable and therefore excluded from PVP. On the contrary, the right to use plant-back seed was guaranteed as the Farmer's Privilege.

- Finally, PVP, in contrast to patent protection, invariably extends only to propagating material and never to the products obtained from it.

While all of the provisions described above tend to limit the rights of the inventor, PVP also confers certain advantages. One of these is that no variety can be refused protection as long as it has not been commercialized before. The variety's traits or characteristics may have already been disclosed for some time, especially since extensive field trials may be necessary for registration. Also, PVP laws confer a period of protection which begins with the commercial release of the cultivar. This means that research and development do not chew up valuable years of protection.

Therefore, on balance PVP was well suited to the then prevailing situation in plant breeding.

Adjustments in PVP Rules to Accommodate New Technology Developments

In the near future, the most significant advances in the arena of plant breeding will come from the biotechnology-assisted development of new cultivars. Even now, patents can be filed for genetically engineered traits in the U.S. and some other OECD countries, but UPOV rules generally do not allow an extension of this protection into cultivars enjoying the right to PVP.

For major innovations this is inappropriate. Crop breeding today is primarily a seed industry responsibility. In the absence of stronger variety protection available to it, at the very least, it is unlikely to direct its biotechnology-based know-how at any but the major crops like corn. Consequently, many other economically less attractive seed crops, including indigenous crops of the Third World, may be largely left untouched by the biotechnology revolution. They are likely to become "orphan crops", in analogy to the pharmaceutical industry Orphan Drugs.

There are clear parallels between this proposed scenario and, as shown earlier, the reluctance of the seed industry to commit research resources into pure-line cultivar breeding before PVP was introduced. It is also fair to claim that later, thanks to PVP's stimulation of the seed industry into breeding self-pollinated crops, the negative impact of the markedly reduced public spending on plant improvement was significantly softened.

Therefore, to stimulate seed industry adoption of and investment in biotechnology-based innovations, a revision of the PVP laws is called for. Appropriate revisions must include the following changes:

- elimination of the double-protection bar in rule 2(1) of the UPOV Convention,

- granting free choice to the breeder/inventor to have a new variety protected by PVP, patent protection, or both, provided the material meets the necessary criteria to qualify for protection. It is likely that, as in the past, the majority of new varieties will continue to demonstrate only small, overall improvements and thereby only qualify for conventional PVP. However, breeders would probably also take advantage of patent protection when major non-obvious advances were involved.

It is interesting in this context to look at the recent Ex Parte Hibberd case decision by the Patent and Trademark Office in September 1985, indicating that at least in the U.S., a UPOV member, crop cultivars may be protected under either the Utility Patent Statute or the Plant Variety Protection Act. This is possible because of UPOV rule 37 and because the US had allowed patents and/or variety protection already prior to its UPOV membership. But we are still far from having the problem resolved because all other countries lag behind with corresponding legislation. The seed trade is very international, and unless the principle enunciated above is widely adopted, the benefits conferred by the U.S. policy will be of limited value to many of our breeders.

Responses to Proposals for Expanded Plant Protection

The current alternative to legal protection under PVP laws is the Patent Right. Like PVP, the Patent Right was evolved not only to provide the inventor with an adequate basis for a return on his investments, but also to serve the public interest. The latter was achieved largely through the disclosure requirement which provides all competitors with detailed information about the innovation. This, in turn, furnishes them a basis for further advances and stimulates these. The rapid progress of technology in our society bears witness to the effectiveness of the system.

Those proposing strengthened protection under PVP for the new innovations coming from biotechnology see that society will benefit as it has from strong patent laws. However, some sections of the seed industry and other quarters have expressed concern about possible negative impacts of strengthened varietal protection in the following areas:

- The Farmer's Privilege, a right accorded under PVP, might not be available for patented varieties.

- The Research Exemption, as now incorporated in PVP, would be eliminated in a patented variety. Thus, small seed companies, lacking the resources for in-house biotechnology, fear being excluded from using important genes in their breeding programs.

- Conventional seed breeders may be stopped by patents from freely using parental sources carrying genetically engineered traits, but those who engineered these traits would continue to enjoy free access to the advanced gene pool covered by PVP and generated by conventional breeders.

- Use of a cultivar carrying several patented traits as a parental source may obligate the breeder to pay multiple license fees, even though he is interested in only one or a portion of these traits.

These concerns must be addressed if a concensus amongst the parties concerned is to be reached.

Strengthening PVP Protection for Plant Improvements

It is clear to me as a plant breeder that we need strengthened protection over that available now. If competitors enjoy free access to transformed traits and can move them very rapidly into their own cultivars without license or payment, the R&D expenses, estimated to be at least four times as high as those for traditional breeding, stand little chance of being recovered.

However, at the same time strengthened PVP laws covering varietal improvement must address plant breeding's specific needs and take into consideration objections against extended protection on plant varieties. Therefore, modified plant variety protection should contain the following provisions:

- The Farmer's Privilege must be assured. The farmer must have the right to replant his own seed to produce food or feedstuffs for sale.

- Whereas existing PVP laws protect a cultivar based on a total phenotypic description, individual phenotypic traits can not be protected. Similarly, any form of extended protection under PVP for novel biotechnological inputs should be designed to protect a specific genotype rather than the phenotypic trait that results from a gene. This is preferred not only in the interests of a clear definition of the object of protection, but above all to encourage research towards the same objective by alternative routes. Every breeder knows how important this can be, for instance, in the case of disease and pest resistance.

- Additionally, traditional PVP laws would continue to grant access to all "generic" genetic material in a cultivar that existed prior to the insertion of a patented gene. This would allow plant breeders to still utilize unprotected portions of this germplasm as parent material under the terms of Research Exemption.

- To safeguard the traditional accessibility of germplasm and to encourage proprietary innovations to be widely used, a new form of extended protection under PVP might provide for some form of compulsory licensing of legally-protected genes after an initial period of exclusivity to the inventor. Provided there is a sufficient period of exclusivity, this would not seriously curtail the legitimate rights of the inventor for recovering a fair return on investment and would permit competitive access to the material.

- Due to the length of time needed for the field testing of transformed plants with a new gene and the time required to subsequently incorporate the transformed trait into cultivars of commercial value, the duration of protection should be extended to 25 years from filing. As proposed above, a form of compulsory licensing would ensure that other breeders have access to the new gene, while the inventor could recover his R&D expenses. Competitors would be paying an adequate royalty for the privilege of using the invention, as is already paid by seed companies for inbred lines or for added value inputs like seed safening chemicals. Any accompanying extension in protection life would also help to keep royalty fees lower, as it would provide the inventor with a greater safety margin for the recovery of his R&D expenses.

- There may be situations where a breeder wishes to use a germplasm source for further breeding that carries several legally protected genes. If he intends to introgress only one gene, or a subset of those protected genes, and eliminates the rest in the breeding process, he would only be liable for licensing fees for those traits ultimately appearing in his new, marketed cultivar.

With these provisions, it should be possible, without major objections, to modify and update PVP to provide adequate legal protection for novel, biotechnology-based varietal improvements.

CONCLUSION

Hopefully, then, this overview has shown that new measures for adequate intellectual property protection for all types of improved plant products must be developed and implemented to serve the needs of an old profession as it evolves with, and benefits from, new technologies. Certain elements of existing protection options continue to be well-suited for new plant cultivars with biotechnology-derived inputs, while others are clearly inadequate. We must all work together to ensure that the modified framework of laws, finally established, is fair to the inventor, his competitors and the public at large. Without strong protection for the innovative solutions that biotechnology can create, the full potential of agricultural biotechnology will never be realized.

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APPLYING ANIMAL PATENTS IN AGRICULTURE: LESSONS FOR FARMERS AND THE PATENT OFFICE FOR SELF-REPRODUCIBLE ANIMALS

Presentation by Professor William Lesser,
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Just two months ago, on April 3, 1987, the Board of Patent Appeals and Interferences of the U.S. Patent and Trademark Office, in a decisive decision, declared higher animal life to be patentable subject matter (Ex parte Allen, Appeal No. 86-1790). This was not an entirely unexpected position following, as it does, the pathbreaking 1980 Supreme Court decision in Chakrabarty (447, U.S. 303, 206 U.S.P.Q. 193, 1980) and a similar extension of patent protection to open-pollinated seeds in September 1985 (Ex parte Hibberd, Appeal No. 645-91, 1985). Indeed, the Canadian Patent Appeal Board has recognized animal varieties as potentially patentable subject matter, notwithstanding the rather limited scope of the Canadian patent law at this time (Straus, p. 75).

Yet the important fact remains that animal varieties may now be patented in the U.S. According to internal sources, 15 applications are currently awaiting processing (U.S. Dept. Commerce, p. 2). The deposit issue as a technical matter requires clarification, a process which will likely take a year or longer (Figg). Several years from now, in all likelihood, there will be a patented, multi-celled animal. The question is, how will this situation "play" in Peoria? Here my concern is not with the political and social image issues which will arise--and indeed are already arising--but with the impacts of this new policy. My objective then is to identify how property rights for this class of products are likely to be applied and the implications for users, for the PTO, and for the policy itself. Emphasis shall be on agricultural applications. This is done at the exclusion of laboratory specimens, purebred dogs and cats, and thoroughbred horses, to mention a few of the more obvious other animal classes where patents might be sought and effectively used. By implication, attention is placed on animals which are largely self-reproducible as this class presents far more complex legal and economic issues than do sterile animals. I begin by describing the domestic livestock sector and dividing it into classes.

THE U.S. LIVESTOCK SECTOR

Livestock is the single largest agricultural sector in the United States, measured both in terms of sales and geographic scope. Major contributors are beef cattle, hogs and dairy cattle with sheep and goats constituting relatively insignificant proportions. Geographically each of the 50 states has some commercial livestock activity, although concentrations exist in the Upper Midwest--hogs, High Plains--cattle feeding, New York, Wisconsin, Minnesota and California--dairy, and the Southeast--poultry, including eggs. Annually, animal agriculture

contributed, in 1982, $64.9 billion valued at farm level (Bureau Census, p. VIII). Total animal numbers on farms, as of January 1, 1986, was 168 million red meat animals and 647 million chickens (Ag. Stat. Board, a and b). Together this vast source permits per capita domestic meat consumption of 223 pounds (retail weight) (101 kilograms), of which 31% is poultry and 69% red meats in 1985. Egg disappearance is around 255 per capita (Bunch, Tables 2 and 8). Imports and exports are a modest component of this total.

Farm numbers in aggregate are equally staggering--some 1.2 million according to the 1982 Census of Agriculture (Bureau Census, Table 15). But like other agricultural commodities produced in this country, much of total supply is provided by a small proportion of large, specialized farms. For example, only 35 percent of these livestock farms had sales above $10,000 annually, and less than a half percent fit in the largest size category (more than 5,000 hogs or 2,500 cattle sold) (Bureau Census, p. VIII, Tables 23 and 30).

Breeding Practices

At this point it is convenient to limit attention to the major red meat species of cattle and hogs, while recognizing a fundamental distinction in cattle between those intended for meat and those used for milk production. Cows if properly managed produce one calf a year while sows should have two litters averaging 7-8 pigs. Based on economic considerations, dairy and hog producers typically provide their own replacement cows/sows. Beef cattle, however, are reared in two quite different stages, many calves on grasslands heavily in the West and fattened cattle near feed supplies in the Midwest and High Plains. Very different production practices and owners are involved with these two stages.

Dairy

In 1984 the national mean production per cow was 12,500 pounds (5,700 kilograms), a level which has been increasing at an average rate of one percent over the past generation (Crop Rpt. Board). One source of this improvement is genetic potential with some cows in commercial production able to yield 20,000 or even 24,000 pounds a year. Such supercows are scarce and expensive, but dairy farmers have available to them another source of improved genes, those from the male. For over half of dairy farmers in the latter 1980s, this is delivered through artificial insemination (AI) with the remainder using a bull. AI use is facilitated by the regular milkings needed, which makes identifying estrus ("heat") relatively easy. Several kits are available to assist in this process.

Supplying the semen is a large and sophisticated international industry, of which several of the largest firms are cooperatives. One very substantial cooperative with an international market, Eastern AI Cooperative, is located here in Ithaca. In brief the selection process followed by Eastern and similar firms is to identify top-producing cows and mate them with bulls with high producing daughters. The selection process for these matings is elaborate and involves not a small amount of judgment. Promising looking bulls are reared, mated and the production of their daughters monitored. Fathers of daughters with high yields in commercial herds, plus other desirable health and handling attributes, are retained for semen donation purposes. The semen is preserved in liquid nitrogen and generally administered by a staff of technicians.

Beef Cattle and Hogs

The situation for these species and classes of animals is quite different because they are typically kept in large lots making AI use difficult. This is especially true for beef cows which are often maintained on the range, although materials are available which stimulate ovulation and hence make group breeding possible. Yet the use of AI is low, about two percent for cattle and equally low for hogs in 1980-81 (Gilliam, Table 15; Van Arsdale and Nelson, p. 22). Instead, most producers rely on natural breeding, giving rise to an industry which produces breeding boars and bulls. Many of these are purebreds which producers use to gain the efficiency or heterosis, from cross-breeding or hybridization.

Figure 1 shows the approximate utilization of the sires and dams of beef and dairy cattle and hogs in three age groups. In general, all female dairy calves are reared for milk production while the males are slaughtered, mostly for veal. Male meat animals are typically castrated and fattened prior to slaughter. Females may be fed or held for breeding. The actual proportions of breeding and feeding use depends on the stage of the livestock cycle (see Beale, et al.). These use factors are important because of their possible influence on how patented animals will be utilized in these major branches of the livestock sector. As significant is the recognition of the complex coordination relationships in the sector, especially among the several vertical market levels. It is evident that patented animals must adapt to this system, not vice versa.

POSSIBLE PATENTABLE INNOVATIONS AND INHERITABILITY

As a final preliminary step, it is helpful to identify the kinds of "new" animals for agricultural uses which may be patented in the future. At the present time, the introduction of the ability to produce higher levels of growth hormone is being experimented with in hogs (Hammer, et al., 1986; Hammer, et al.,

FIGURE 1

Use of males and females by species, class and age,

U.S. red meat livestock sector, mid 1980s

SPECIES/CLASS	FEMALE			MALE		
	calf	heifer[1]	cow	calf	steer[2]	bull
Dairy Cattle	100% raise	95% raise	95% milk and calf production	90% slaughter for veal	9% slaughter for beef	1% breeding
Beef Cattle	100% raise	50%[3] fatten and slaughter	50% breeding	100% raise	98% fatten and slaughter	2% breeding
Hogs	pig	barrow[4]	sow	pig	gilt[5]	boar
	100% raise	50%[3] fatten and slaughter	50% breeding	100% raise	98% fatten and slaughter	2% breeding

1/ Female cattle which have not calved

2/ Castrated male cattle

3/ Proportion bred and slaughtered varies over time in relation to the cattle cycle

4/ Female hog which have not littered

5/ Castrated male hog

1985). Experience with administered Porcine growth hormone has shown that the animals convert feed more efficiently while producing a leaner, more marketable carcass (Boyd, et al.; Meltzer; Etherton, et al.; Fabry, et al.). Such an attribute, if it indeed can be introduced into the gene base of hogs and cattle, would be commercially attractive as well as seemingly eligible for the grant of a patent. A number of related production attributes providing stress resistance and/or productivity enhancement would seem to be equally desirable and patentable.

As a practical consideration, the reduction to practice of these modified animals is in its early stage. For single gene attributes, like growth hormone, the principal limiting factors are the low efficiency on the inoculation of the eggs (on the order of .2 percent) as well as the imperfect control over the secretion of the hormone throughout the growth cycle. According to one leading researcher, "We're still at the Orville Wright stage of this research." (quoted in Miller). Attributes dependent on the interaction of numerous (perhaps hundreds) of genes are quite distant in production as the controlling genes and interactions among them have yet to be identified (Wahl).

The inheritability of the traits also depends on the controlling genes. Single gene-based attributes, like growth hormone, will be inherited by half the progeny of one gene-carrying parent. However, even if both parents have the trait (unless they are brother and sister), less than all the offspring will inherit it due to the varied location of the coding of the gene. Many generations will be needed before the inheritance factor can be stabilized near 100 percent. For multiple gene-controlled attributes the inheritability will be far lower, probably on the order of the inheritance of major characteristics. Experimental evidence on naturally occurring traits shows these to be inherited on the order of 5 to 60 percent (Table 1).

TABLE 1: Approximate heritability rates for selected characteristics in livestock and poultry

	-Percentage-			
Characteristic	Dairy Cattle	Beef Cattle	Hogs	Poultry
Number born	--	5	10	--
Birth weight	60	40	5	--
Weight at weaning	--	25	10	--
Mature weight	60	--	--	50
Milk production	25	--	--	--
Egg production	--	--	--	35
Feed efficiency	--	40	30	--
Percent lean meat	--	40	35	--

Source: Compiled by Acker, Table 18-1

Inheritability is not an issue for the PTO beyond the effect it has on disclosure. For the patent holder it has major considerations for the extension of control to progeny. Patent holders are likely to wish to strengthen rights to offspring through the use of a contract, drawn at the time of sale, which specifies rights over succeeding generations. This would be a more secure approach than the use of the uncertainly defined "implied use" stipulation which passes with the sale of a patented product. Probably the stipulation will require a royalty to be paid on the birth of a calf or pig. Rights to subsequent generations may be sought as part of the same agreement, but would likely require that the customer serve as an enforcer of patent rights, as a collector of royalties and/or presenter of a contract to his/her buyer. One and more generations from the parent stock the likelihood the patented trait will be inherited can be expected to be quite low. Under these conditions the buyer will be hesitant to accede to a royalty payment without the assurance that the animal does indeed have the patented trait. Some traits may be readily observable, but many will require a confirmation test of some form. To be practical, these tests will have to be simple and very inexpensive.

While the inheritance of traits will create a patent-right enforcement problem, low inheritability would be even less desirable (see Miller). Low inheritance will require a regular purchase of trait-carrying sires whenever AI is not used. And the sires must be produced directly using genetic manipulation techniques, or selected from among a large number of potential breeding animals which do not carry the trait. Both approaches are costly as well as limiting on the sires which can enter the breeding pool, at the likely cost of reduced ability to select for other desirable attributes.

APPLICATIONS OF ANIMAL PATENTS BY LIVESTOCK SECTOR

Dairy

Dairy cows are relatively small in number and are handled frequently on an individual basis. This environment makes it conceivable that patent holders' rights to calves born to a patented cow could be enforced within a reasonable and economical system. Indeed, purebred production herds now exist which are registered on an ongoing basis. The system in its basis works this way for holsteins. The breeder registers the sire and dam number with the national association, which checks a random sample using a blood sample from the calf to verify parentage. Both parents must be registered; "upgrading" is not permitted for holsteins. Other breed associations function in much the same manner with the exclusion of the requirement for having both parents registered purebreds.

Ensuring rights over progeny would, as mentioned, likely require the patent holder to exercise a license and royalty agreement at the time of initial sale. This arrangement would further protect the patent owner in cases where a cow is used as a source of eggs for transplanting, becoming in the process the biological dam for multiple offspring. The licensing agreement would have to specify that equivalent conditions be placed on subsequent buyers--again roughly equivalent to the purebred registration system.

For dairy cows, this system is possibly workable. For bull calves, the prospects dim rapidly. Most dairy bull calves as noted are sold for veal, some for immediate slaughter, some after feeding for "white veal," while a very small portion is retained for breeding purposes. Conceptually, each use could have a different fee arrangement. In practice, it is inconceivable that a dairyman would permit a patent agreement to dictate how bull calves are to be handled. Male calves are treated as byproducts of the main enterprise, milk production, and are accorded little attention or value. The complexity in enforcing patent rights arises from the maintenance of identity and use through numerous changes of ownership. At a minimum, bull calves typically pass through an auction market where they are purchased by an order (commission) buyer who later resells to feeders or packers. The maintenance of a structured fee system, with covenants on subsequent purchasers, through this system seems highly suspect. It is done with purebreds and thoroughbred horses, but they are much less numerous and far more valuable, justifying individual treatment. For example, roughly 500,000 holstein calves are registered annually. Bull dairy calves, on the other hand, number some five million annually and their value is low; the market value is between $60 and $100.

Maintaining control through the first round sire lineage would be simpler, at least for those bulls used in AI. The artificial insemination firms maintain careful records and could easily pay a royalty to the patent holder for each "straw" of semen from a patented bull. Control of the dispersion of the resultant calves raises those problems as described above.

Hogs

The combination in most hog operations of activities from breeding through feeding within a single enterprise greatly facilitates the enforcement of patent rights for this species. Moreover, as breeding is internalized the producer has information about the genetic makeup of the stock. The multiplication rate for the breeding stock into marketable animals may be collected from farm records or based on national average litter size and periodicity data. Thus, a measure of the flow is relatively simple, the count of animals shipped, and may be used to assess a royalty. Barrows (castrated males) present

no further problems following sale as they have been neutered. What is potentially complex is the dispersion of gilts, young females, and cull sows, both of which are capable of reproducing. The majority of these animals--about 85 percent in 1985 (P&SA, Table 9)--are sold direct to pork packers permitting a relatively easy tracing of possible diversions to breeding. The remainder moves through a multiplicity of markets, including auctions and order buyers. Control of patent rights through these channels will be very difficult.

Beef Cattle

The imposition of patent rights on the U.S. beef cattle industry will be the most complex undertaking, due largely to the ownership/geographic split between calf producers and cattle feeders and the nature of calf production. In brief, the so-called cow calf operators maintain the cow herds, raising the calves on grass to about 600 pounds. From that point they are sold to a feedlot for final finishing prior to slaughter. Many cow-calf operations are land-extensive, operating in areas of sparse vegetation which can support one brood cow or less per acre. Breeding is done naturally with bulls wandering with the cows. In such an environment, there is great uncertainty about which bull mated with which cow and hence what property rights exist over the calves when mixed bulls are used. Typically, operators will vary bull breeds as a means of controlling the genetic mix of the calves.

If control is difficult for the first generation, it is more so for succeeding ones. This does not apply to males (steers) as they are castrated. Heifers, however, may be retained for replacement breeding cows, sold for breeding purposes, or sold for finishing and slaughter. The proportion moving to each market varies, depending in a large part on the cattle cycle. Again, the marketing of heifers moves through multiple channels and often over great distances. Maintaining identity through these channels will be difficult.

A second complexity affecting the utilization of these calves is the information exchange on the genetic basis and production potential. Cattle feeders buy calves largely by sight, selecting on certain visual characteristics like frame (skeletal) size. Official U.S. Department of Agriculture grade standards are of limited value in this selection process, and feeders generally prefer to purchase from a known calf producer as a means of identifying better the weight gain potential of the calves. As Van Arsdall and Nelson note for hogs, "the current marketing system seldom retains the identity of pigs between producer and finisher" (p. 23).

Marketing patented calves in this environment raises the information problem for cattle feeders unless the results are

visually apparent, such as a larger calf at a younger age. Without visual confirmation, buyers must rely on the integrity of the seller, a problematic arrangement when calves from different sources are typically mixed by middlemen. Reputation of the calf producer and/or dealer can substitute for product information, but the process is a slower one and will likely reduce the adoption rate of patented animals in this sector.

IMPLICATIONS FOR THE LIVESTOCK SECTOR

Patented animals will introduce a new organizational component in this large and complex sector. If the patented trait disappears rapidly after the first generation--that is, has a low inheritability level--then as a practical matter the trait must be introduced through the sire. This could be done alternatively through AI or natural breeding. The patent holder would sell the stock as breed animals either for a one-time charge (probably for hogs and beef bulls used in natural breeding) or a per-calf fee (especially applicable to breed animals used in AI). Incumbent on the patent holder will be the introduction of the patentable attribute into a number of breeds, especially for beef cattle and hogs. Only this will permit livestock producers to maintain some cross breeding programs which have been so successful in maintaining hybrid vigor, or heterosis. This could well be a protracted process which will delay the adoption process and reduce the value of the invention.

An inheritable trait would be far more efficient in a biological sense and would be disbursed far more rapidly. Yet the ability of the patent holder to capture the benefits would be reduced. Among seed breeders, a similar situation exists with farmer saved seed. But as farmers typically purchase new seed every two to three years anyway, it is possible to anticipate the production potential value of the patented variety over that period and incorporate it into the initial sale price (see Lesser). The small share of seeds of total crop production cost--around three percent--makes this practice acceptable to producers. This marketing approach would obviate the need to enforce rights to prevent farmers from reusing seed. For livestock breeders the situation is quite different. Traits which can be inherited may be introduced into the entire herd through on-farm breeding, while the relatively high cost of livestock would make it infeasible to "front load" the value of the patented attribute on the initial sales. Hence it is highly likely that animal patent holders will attempt to enforce patent rights over subsequent generations. Rather than rely on the uncertain interpretations of the "implied use" doctrine, a specific sales agreement is likely to be included with each sale. To be effective, this agreement must be extended to subsequent purchasers of progeny.

Such a royalty agreement signed at the time of sale makes the livestock producer a defacto component in the system of enforcing patent rights. This responsibility will not sit well with producers, nor is it clear they have sufficient control to be effective. Problems arise when animals are sold through multiple middlemen where maintaining identity is problematic and diversion from, say, slaughter to breeding possible at any stage. Compliance/enforcement becomes highly complex and questionable even with a single patented trait. Introducing multiple traits with separate ownership into a single animal--say the ability in a dairy cow to produce more milk and resist mastitis infection, a widespread bacterial infection in the udder--would create a far more difficult and complex system.

Roughly comparable post-sale conditions exist in the livestock sector for the registration of purebred animals, but these are sufficiently different in two respects so as not to be a clear indicator of the transferability to patents. Registration procedures are based on voluntary compliance, with the benefit the ability to register an animal as a purebred. Thus there is a positive incentive structure. The number of animals involved is a small portion of the total herd--probably much less than 10%. What may be successful on a relatively small scale may not be extendable potentially to the entire population. Conversely, precedence does exist for mandating that certain animals when sold go to slaughter (or export) rather than being diverted for production or breeding purposes. This was the case under the recent "Dairy Termination Program" established by the U.S. Department of Agriculture. Farmers electing this system were paid a premium to withdraw from dairying for five years, including disposing of their milking herd (see Kaiser and Novakovic). While this plan shows it is possible to maintain control of farm animals following sale, the circumstances may not apply to the entire sector. Cows sold under the buyout program were limited in number--about 15 percent of the national herd of eleven million, or 1.6 million head--and were granted a substantial premium making special marketing arrangements feasible. For routine sales of hogs and cattle, neither of these special conditions apply.

When examining the impact of animal patents on the U.S. livestock sector it is also important to recognize the narrow margins farmers operate within. Cost of production and profitability estimates are always difficult to estimate and vary over time with price changes among other factors, but in recent years they have been no higher than $33 for hogs and barely profitable for fed cattle. Marketing costs are presently a small percentage of total production costs, on the order of $1.14 (hogs) or $3.35 (cattle) (Econ. Res. Service, Tables 12, 27 and 28). What this says is that a patent enforcement system which imposes substantial extra costs on farmers will not be viable except in certain limited aspects of the livestock sector.

Indeed, volume is such that any patent enforcement system which imposes any costs on the purchaser/farmer will seemingly not be viable unless the potential net profit increase is large indeed. Overall then it is possible to say that animal patents for agricultural applications will indeed not play at all well in Peoria.

Nor will they likely play well in the remainder of the country, and not for ethical reasons alone. Patents in this subject area will have high enforcement (excludability) costs for regaining private investment. While such an approach is required in a free enterprise economy, it is not efficient in an economic sense, and hence will be subject to much public criticism. An economist would say this is an appropriate area for public investment (see discussion of public goods in e.g. Asch and Seneca), but that is not a feasible solution in an era of burgeoning public budget deficits. Moreover, even if substantial public investment were possible, there is reason to believe private involvement would speed the realization of an invention. Wherever the outcome of research is uncertain, and the result in part of chance, multiple independent efforts increase the likelihood that a successful outcome is discovered (see Lesser and Masson, pp. 35-37). Thus enforcement costs for private property returns must be accepted as a necessary evil, but much of the public will focus on the "evil," and not the "necessary."

Animal patents appear to provide but another and largely overlapping means of protecting a genetic transformation. Biotechnology companies now appear to have the option of patenting the altered genes directly or the animals which contain those altered genes (but not both simultaneously). This too is similar to seeds where the benefit of patenting the seed, as opposed to the altered genome, is debatable and seemingly dependent on how courts would interpret a patented gene in case of any challenge (see Lesser). With animals, to my mind, the enforcement of rights over a patented gene within the vast domestic cattle or hog herd would be essentially impossible. Enforcement over progeny to be effective must be tied to the offspring at the time of sale. Thus higher animal patents provide an important, and likely popular, means of protecting research developments in this expanding area.

The PTO does not have any direct responsibility for, nor control of, these matters related to commercialization of patents. Yet two factors fall within its jurisdiction and must be handled in an optimal fashion if patents are to serve the public interest as they are intended. First it is necessary that these patents be processed in an expeditious manner. The commercial life of an animal "variety" is brief, and much can be consumed while the patent application is in process. Delays serve no one's benefit, not the researcher nor the public. If the patent examination period is unduly long, then only very

major advancements will be patented. As a result, a stream of useful but individually less important improvements in breed characteristics will not receive the research and development attention they otherwise might. Studies have shown that patents serve a highly important role in stimulating routine research activity directed to noteworthy but nonetheless minor embellishments in existing products (Jewkes, Sauers and Stillerman). At the same time, it is essential that the PTO does not allow too broad a scope of patent protection. This applies also during the first applications in this new subject area. Broad patents could in time encompass much of the livestock sector causing major and costly changes in coordination procedures.

These points relate to future action by the PTO in which we all have the utmost confidence in the methods and judgments used. Where judgment was lacking, in my personal opinion, was announcing on April 3rd the status of multi-celled animals as patentable subject matter. Technically this decision is unassailable, but as a public relations effort it was seriously lacking. Experience with public response following the Chakrabarty decision and, subsequently, the proposed amendments to the Plant Variety Protection Act should have left no doubt but that there would be an outcry. To my thinking there was a gentler approach which could have been followed, especially since the deposit arrangements needed for the actual issuance of an animal patent are far from complete. Perhaps the Board of Patent Appeals and Interferences could have identified animals as patentable subject matter contingent on the acceptance of a deposit system. Ideally that would have been enough forewarning to begin public debate while not implying that the means of patenting animals was already established and largely beyond public influence. What is being proposed is something approaching the European system where matters of patent law are treated as public policy with a period of public reply allowed before the law is finalized. While that method does not fit directly within the U.S. common law tradition, the concept of public involvement is certainly applicable.

If the role of the PTO is rapidly approaching that of administration of this new directive, the role of the Congress remains incomplete. In my judgment there is a need for some form of intellectual property protection for sexually propagated animal "varieties." The products of traditional crossbreeding serve a useful role yet are probably unpatentable due to obviousness and the problem of satisfying disclosure requirements under the Patent Act. What is required is a separate body of law intended to protect this class of products. A direct parallel may be drawn between the forms of protection allowed for sexually-propagated seeds by the Plant Variety Protection Act and the Patent Act. But this is a separate topic which exceeds my purposes here today.

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RECENT ADVANCES IN EUROPE CONCERNING PATENT PROTECTION IN THE FIELD OF BIOTECHNOLOGY

Presentation by Dr. Otto Stamm, Head of Patent Department, Ciba-Geigy, Basel, Switzerland

A. General Remarks

In view of the spectacular results of scientists in recent years, one of the oldest technologies, namely biotechnology, has attracted much attention. This for two reasons: firstly, unscientific publicity has alerted people that this technology might be used to effect manipulations with human genetic factors to create new kinds of human beings. Secondly, industry became interested because of the potential of modern developments in this technology for industrial applications. This second feature has of course also sensitized those engaged in seeking protection for new industrial products by patenting.

However, soon it was recognized that present patent laws and concepts are not adapted to solve the problems created by the fact that the structure of the products and the phenomena involved are complex or unknown, and especially, that we are no longer concerned with inanimate matter but with living organisms, i.e. with materials that have the property of self-replication and no longer have to be created anew each time. As a consequence, the classical concepts of patent law, such as the requirement of the repeatibility of an invention, asssume another dimension and problems which did not exist previously are thus created. It must be the aim of the legislator and the courts to find a solution that satisfies the needs of research-based industry, i.e. the main user of the patent system.

B. Needs of research-based industry

What are the needs of research-based industry?
Before answering this question, first a pragmatic defintion of a patent. A patent is like an insurance policy. It promotes investment in high-risk projects where the investment needs to be safeguarded and where a return on investment is expected, at least in the long term. One does not invest in an art collection if the insurance coverage, for example against theft, is insufficient or not present at all.

Insurance must thus be adequate, otherwise it is worthless.

In other words, only good, efficient, patent protection is worth anything, promotes investment in applied R & D and, hopefully, ensures an appropriate return which is required for further R & D.

What constitutes efficient patent protection in the field of biotechnology?

1. No discrimination as to the subject matter.
   Anything that meets the criteria of patentability, i.e. novelty, capability of industrial application and presence of an inventive step (unobviousness), must be protectable by patent.

   It is purely arbitrary that in many countries only microbiology - itself an undefined word - should be available for patent protection while other fields of biology, for example botany and zoology, are not.

   If ethical reasons are cited against new developments in specific fields, then it is for special legislation to prevent such new developments and their use. It is not the object of a patent law to fix the limits between ethical and unethical inventions. The patent law is intended to provide the motivation for obtaining novel results which are accessible to the public in useful form in all fields of technology.

2. Disclosure requirements which meet the criterion of the capability of industrial application of the subject matter of the invention.

In the case of substance inventions the subject matter of the invention is a manufactured product and not its method of manufacture. It is therefore sufficient if obtaining the protected product, independend of the patentee does not present the skilled person with problems beyond his general specialised knowledge. As soon as the subject matter of the invention replicates itself, which is the typical feature of living matter, the availability of this matter must thus be sufficient for operability and reproducibility and hence in principle for the capability of industrial application of the invention. An additional reproducible description of a method of preparing the product from other substances is not necessary and, indeed, very often quite simply not possible.

3. Per se product protection.

Where the invention resides in the product obtained, patent protection must be granted for that product itself and not just for the process for its preparation or be dependent thereon.

4. Effective protection of industrial property.

As mentioned above, inadequate insurance is worthless. Yet it is precisely with respect to the effective protection of industrial property that patent protection for living organisms presents the greatest problems.

Whereas in the case of inventions for inanimate matter any amount of this subject matter has to be obtained from starting materials different from the end product anew each time inventive materials are desired, there is no longer the same quantitative relationship between final product and starting material in the case of living matter. For in the field of microbiology the production of a minimum amount of the inventive material - theoretically one single cell - is sufficient to gain by self-replication thereof possession of any amount of cells and of any material produced thereby, for example metabolites. Without adequate safeguards, any free

release of inventive living material therefore constitutes the famous giving away of the equivalent of a highly specialized factory to anybody free of charge.

This has considerable consequences:

1. Protection of the deposit against misuse by third parties

If a deposit of the subject matter which is capable of direct or indirect replication is necessary for the disclosure of the invention, then this deposit must be adequately protected (cf. Fig. 1) against misuse by third parties and should not be freely available to the public before effective protection is obtained and, in the event of a patent not being granted, should be returned to the depositor. The party entitled to receipt of the deposit must neither make the released materials, nor material derived therefrom and still serving the purpose of the invention, available to any third party, nor without the consent of the patent proprietor, export it to other countries.

If a third party manufactures novel or known substances which are products of a patented process carried out with the deposited material, the burden of proof has to reverse and rests with the alleged infringer if said deposited material had been released to any third party.

2. Protection of the product that is ultimately commercialized

A patent is worthless if it does not protect the product that is ultimately commercialized.

a) Protection for a process for obtaining living matter must extend not only to the direct final product obtained by that process, but must also extend to the products of any generation obtained therefrom by replication, cell differentiation or both (cf. Fig. 2). What is sold e.g. is not a plant cell, but a plant or its seeds. It is thereby also avoided that cells or seeds are produced in a patent-free country and the commercially interesting products derived therefrom, such as plants or plant material, can be imported into the patent country.

b) As is usual in patent law, any new product which contains, as an essential feature, a certain patent-protected specific piece of genetic information which determines its capability of industrial application must fall within the scope of protection conferred by the senior patent in question (cf. Fig. 2).

c) Likewise, a patent is worthless if the classical doctrine of exhaustion of patent protection for sold material commonly applied in current case law - also known as the doctrine of implied licence - applies. A patentee, after having made all the investments necessary, would not wish to sell a small portion of his self-replicable material, e.g. seeds, only once, and then to see afterwards the buyer, as his competitor, with replicated material on the market without any further compensation. Only where multiplication of the self-replicable material is unavoidable for a use different from that of its replication for the sake of replication can patent protection be exhausted by the sale of the material capable of multiplication. The sale of cereal seeds for sowing and harvesting and the use of that harvest for the production of flour exhausts the patent protection, but not the further sowing of the product of replication so obtained to obtain cereal grains once more, for this second replication was neither necessary nor intended for the original use (cf. Fig. 3).

Besides, the UPOV Convention likewise, at least, does not permit the production of new seed material for resale.

d) Equally, the exhaustion of a process or product patent under the pretext of use for experimental purposes must be prevented. Such exhaustion could occur as the result of a protected process or a protected product being used only once for the development of a novel product which, however, could then be commercialised in view of its self-replicating property. In other words, the use has to remain experimental on each level of activity.

3. Efficient means for proving infringement

A patent is worthless if a potential infringement cannot be effectively proved.

Owing to the difficulty of proving infringement in this field, it is necessary that effective means of securing evidence be introduced, such as the already mentioned extension of the reversal of the burden of proof in the case of patented manufacturing processes after removal of a deposited sample also to known products (the self-replicable deposited material need only be used once by the infringer), and saisie or discovery.

4. Appropriate Scope of the claims to avoid trivial circumvention

For effective protection against infringement it is also essential, on the one hand, to obtain acceptance of claims which put under protection an appropriate generic scope of the teaching given by the specific examples, since especially in this field it is simple to bypass specific claims, and thereby render excessively restricted patents worthless. Functional language will frequently not be avoidable for appropriate definitions, as was indeed confirmed in a recent decision of the Board of Appeal of the European Patent Office in favor of Ciba-Geigy, which is still to be published (November 27, 1986, T 68/85). Nevertheless, in the interests of legal security, on the other hand, the scope of claims must be clearly delimited, realistic and verifiable and may not just represent a formulation of the problem.

5. Vague or indefinable terms in exclusion provisions must be interpreted in favor of the applicant

The term "essentially biological" (Art. 53 (B) EPC) as an exclusion provision is vague and unnecessary. Originally meant were the classical breeding methods which were deemed not to be available for patent protection owing to the possibility of disclosure being considered insufficient.

If an inventive feature of a single-step or multi-step process resides in a human technical intervention, then the entire process must be seen as a technical, patentable process and not as an essentially biological one that occurs in nature.

C. Developments in Europe that contribute to meet the wishes of industry which relate to practical needs

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First of all it has to be said that the entire raft of problems is naturally still a matter for discussion in a very wide range of bodies and organisations. Concrete results which would, for example, make us competitive again vis-à-vis the USA and Japan in respect of certain requirements, have so far been few and far between. These requirements include e.g. patents for plants and the freedom to choose between patent and variety protection, availability to the public of deposited replicable material only after grant of patent, patent term restoration or extension, grace period, evidence-taking procedures and so forth. Nevertheless, mention must be made of the improvement to Rule 28 EPC requested by industry but only partially made in 1979, and of individual corresponding national laws (expert solution).

It is, however, important to realise that there are in Europe many national patent laws, some differing greatly from one another, although the EPC has had the effect of bringing about substantial harmonisation, at least within the 13 Contracting States. On the other hand, although the EPC at the present time is undoubtedly in need of revision, there is fear of undertaking any such revision, as the establishment of the Convention in 1973 with originally only 14 Signatory States was something of a minor miracle. After all, it is even difficult to find compromises within the European Community and I would cite as an example the fate of the Directive 65/65 for the Protection of Registration Know-how.

One country in which some really positive action was taken for improving patent protection for biological inventions at the patent office and the legislative level was Switzerland. The revision of the Guidelines for Examination of 1986 led to a narrow interpretation of the legal exclusion provisions for plant varieties. A similar trend is reflected by the decision of the Appeal Board of

the EPO, "Propagating material, Ciba-Geigy" of 1983, published in the Official Journal of the European Patent Office (OJEPO) 1984, p. 112, where plants in a general sense are distinguished from plant varieties. The latter only are considered as excluded from patentability. Thus the Swiss Patent Office will grant patents for plants and plant materials and likewise for animals, with the sole exception of specific varieties of plants and animals. Further, the open ended enumeration of what can be deposited has been expanded.

Since January 1st, 1987, a new set of patent rules is in force. It provides, inter alia, for the possibility of making the release of micro-organisms dependent on the recipient giving an undertaking not to make the strains available to third parties and not to use them outside Switzerland and, if these undertakings are violated, to accept the burden of proof.

The possible obligations of the recipient of the deposited strain can also be extended to cover strains derived thereform.

Now as before, however, the protection of microorganisms per se requires, in addition to the deposit, a reproducible description of the method of obtaining the micro-organisms.

This last point led me to take the initiative to obtain an appropriate amendment to the Swiss Patent Law by way of Parliament and the Federal Council. This led to a submission in the form of a parliamentary motion being made to the Federal Council on September 25, 1986. This motion is known as the "Auer motion", after the deputy who laid it before parliament. The motion requested the following changes in the law:

a) Product protection per se for biologically replicable material despite incomplete written disclosure, if reference is made to the deposit of a sample of the replicable material.

b) If the invention relates to a process, patent protection is to extend not only to the direct products of the process but also to the products which are obtained from this direct product by subsequent biological multiplication in identical or differentiated form.

c) No exhaustion of patent protection for biologically replicable products, provided the material obtained by replication is used only for the purpose of the further replication of this material.

Unfortunately, in such an emotional field any attempt to achieve something at the political level immediately calls for counteractions. Therefore it is not surprising that recently another parliamentary motion has been filed by a left-wing political party. It requested that any reproducible biological systems as well as genetic engineering techniques of analysing and/or altering biological systems and the products thereof have to be declared as non-patentable and that the Federal Council which, of course, with good arguments recommended the Parliament to reject this motion, should advocate such non-patentablility in all international bodies.

This is what happens in an industrialized country. In developing countries biotechnology is considered as the "second colonisation of the third world": "With multinationals monopolising these sectors there is serious danger of the further enslavement of the third world by the first world, and a violent disruption of the existing social and economic structures. If the Paris Convention was devised a hundred years ago to serve the imperialist policy of preventing the indigenous development of industry in the colonies, the bio-industry-sponsored property protection system as it is emerging now will provide the legal superstructrue for the second wave of colonisation that is about to sweep the third world" (The Times of India, April 19, 1987).

I do not believe that this kind of language merits too much comment.

Another active and positive step was recently made by the German Federal Court. It is true that as early as 1968, i.e. more than 10 years before the Chakrabarty decision in the USA (1980), this Court had held the entire field of biology as patentable in principle ("Rote Taube" decision), but until the "Tollwutvirus" decision of February 12, 1987 had adhered to the requirement of a reproducible description for obtaining the biological material, even if a deposit had been made, and in the case of a non-enabling written disclosure had not allowed product protection as still practiced in Switzerland and Ireland. Now the deposit and release of a replicable sample will suffice and, in a positive manner, the German Federal Court speaks of an abandonment of its earlier

practice as a step towards harmonisation with the provisions of the EPO in the interests of uniform Court practice within the purview of the EPC. Thus for the first time a Supreme court in Europe has abandoned its previous position in a partial sector of patent protection for biological materials and has conformed to the requirements of practice and harmonisation.

In Austria, in 1986, product protection for micro-organisms was introduced by an amendment of the Patent Law and the question of deposit settled in harmonisation with the practice of the EPO.

The Swedish Patent Office has amended its Guidelines to give a broader definition of "micro-organisms" which may be deposited and to make it clear that a "microbiological process" encompasses not only processes using micro-organisms, but also processes for producing or isolating micro-organisms. Such Guidelines, incidentally, have also been introduced in Denmark and Finland.

As I have mentioned, there are any number of organisations, associations and political bodies which have taken up the issue of patent protection for biological material, amongst which I only would like to mention ICC, AIPPI, UNICE, CEFIC, GIFAP, EFPIA, OECD and, in particular, the EEC and, last but not least, WIPO.

The Commission of the European Community is in the process of drafting a Directive, the governing principle of which appears to be that all proposals shall remain within the provisions of the EPC. Thus one of the three shortcomings of the EEC's move - which is, moreover, much to be welcomed - is established: the EPC, even when subjected to so-called flexible interpretation, at the present time no longer meets the requirements of modern technology. Thus the EPC via Art. 53(b) contains the inappropriate double patenting prohibition according to UPOV, Art. 2(1), and it does not recognise a grace period or patent term restoration, to mention only three important points. Further, the EEC does not comprise all countries of Western Europe, not to mention the East European countries, and finally, a directive usually ends in a compromise, a prize example being the already mentioned Directive 65/65 for the Protection or Registration Data.

The EEC directive would, for the member states, nonetheless impose the obligations on the part of national legislators to make respective adjustments.

WIPO is also very active. In addition and parallel to its efforts to achieve harmonisation of certain aspects of patent law, WIPO is taking stock of the situation and making proposals for achieving uniformity in the field of microbiology. After a first Conference in 1984 and a second session in 1986, questionnaires were sent to government and non-governmental organisations. The replies from industrial circles were virtually unanimous in expressing support for the complete protection of biological inventions in the field of microorganisms, plants and animals, provided the usual requirements of a patentable invention are met. In particular, the question of extending protection to plants or animals which contain patented DNA, plasmids or gene fragments was answered affirmatively.

As was to be expected, the replies from the different governments were not uniform in content.

The next session of the Committee of Experts on Biotechnological Inventions and Industrial Property took place in Geneva from June 29 to July 3, 1987. The advantage of the WIPO project is that it is very broadly based countrywise. Naturally, the more countries there are that have to agree on something the more difficult it is to find a consensus, the implementation of which is then anyhow left to the individual countries.

However, a mandatory harmonisation is urgently needed, as otherwise, for example, an effective protection of a deposit in country A can be circumvented via country B with poor depository protection and is therefore worthless.

As you can see, the question of adequate protection of biotechnological inventions is being taken up everywhere, in one form or another. So far relatively few significant improvements have been achieved in Europe as a whole. Important features are still missing and will have to occupy political bodies, legislators and in particular the courts for some time to come. I have in mind here not only the purely substantive criteria such as patentability, interpretation of inventiveness, term of protection and scope of protection, but in particular the problem of being able to effectively enforce a valid proper-

ty right against infringers. Especially this last point leaves many unanswered questions in the field of living matter. Finally, however, it is in Europe's interest to become competitive again in patent law vis-à-vis Japan and, above all, the USA. And it just does not make sense to request on the one hand, everywhere more innovation and, on the other, to leave important fields of technology without effective legal protection.

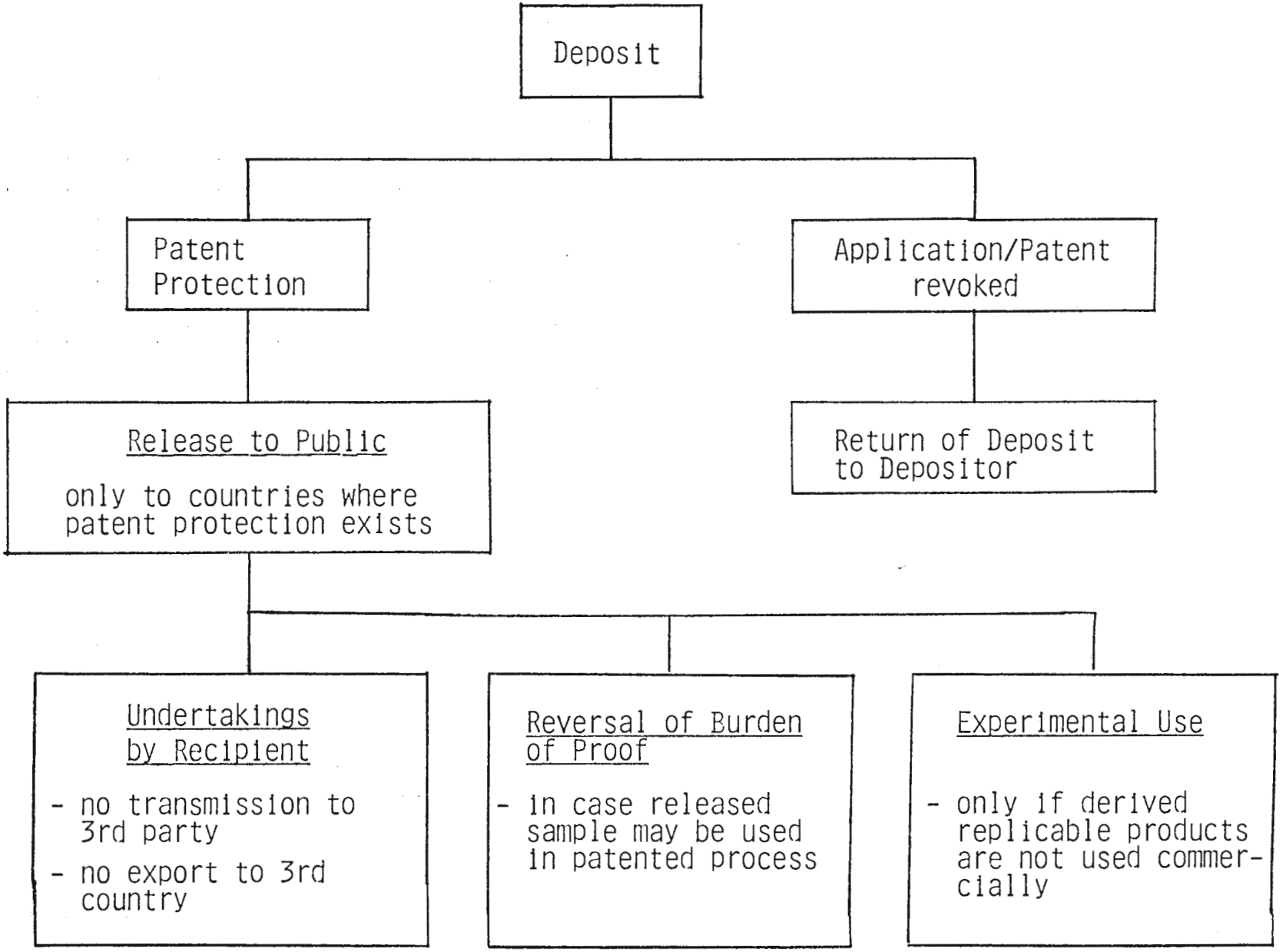
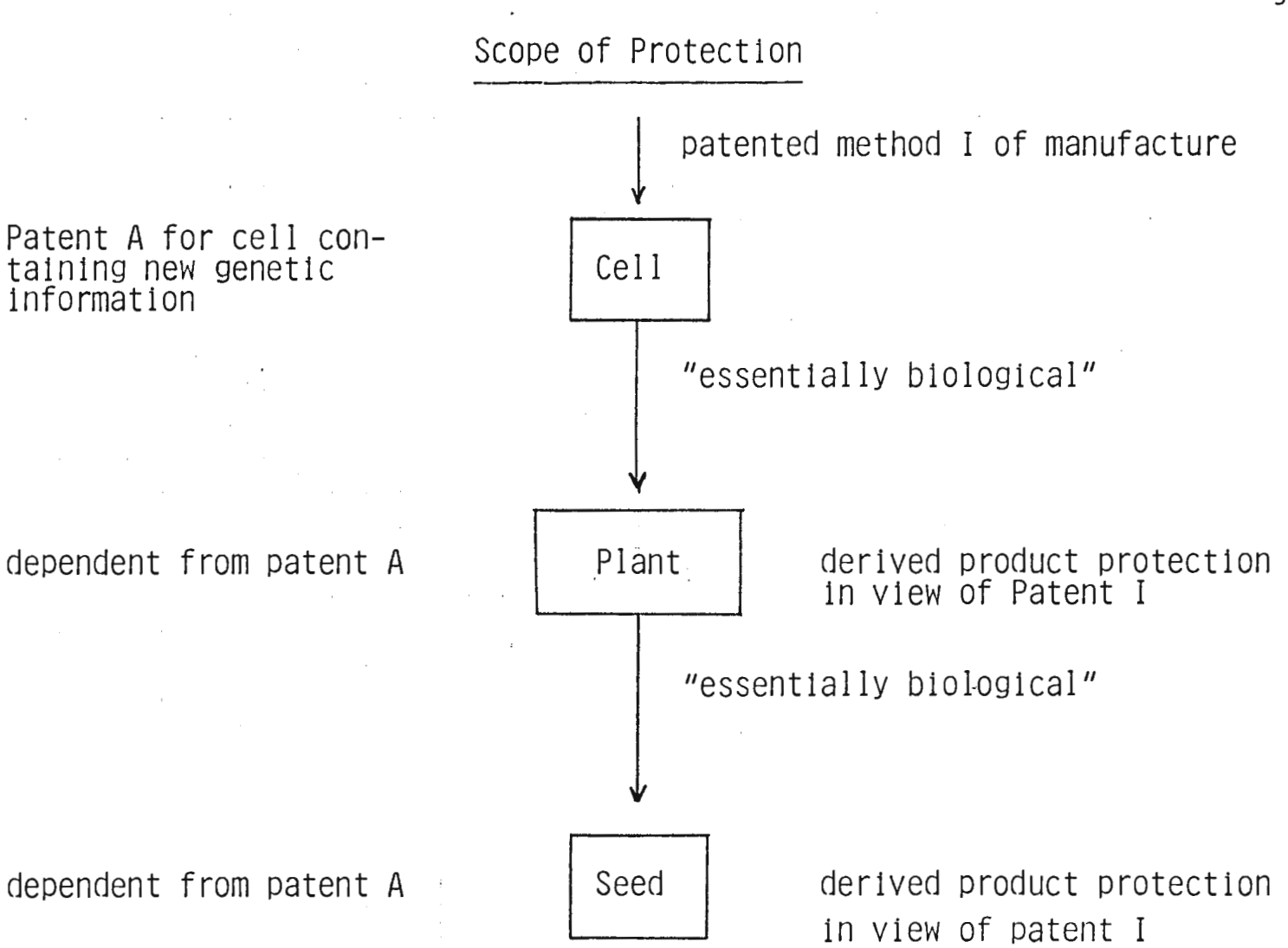
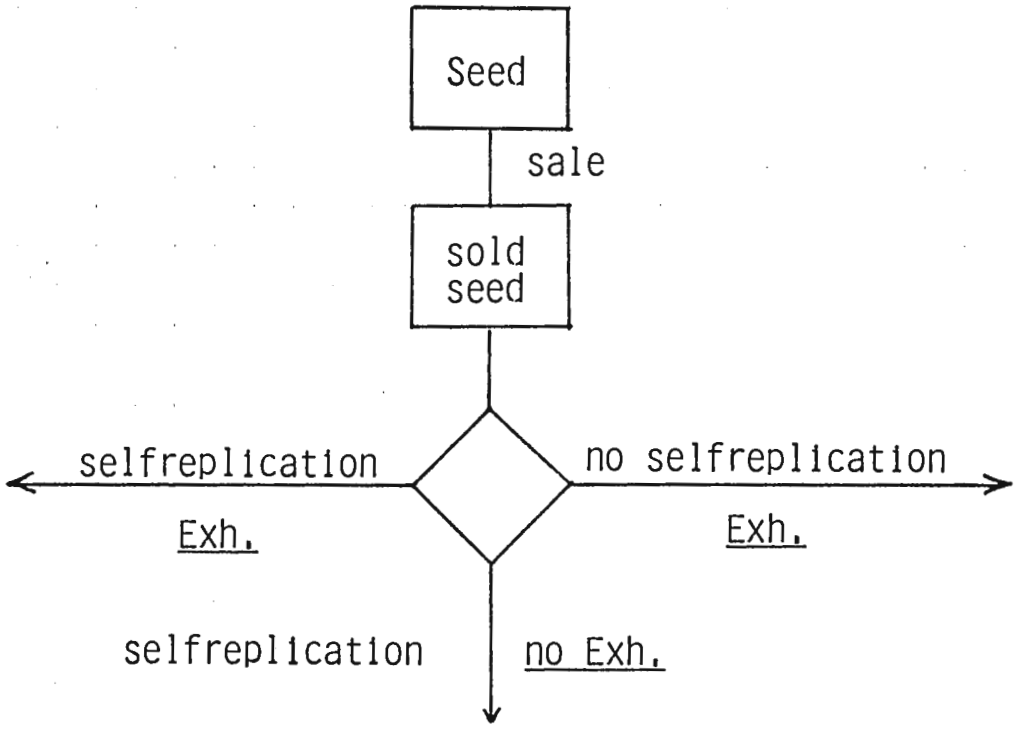

Deposit
Patent Protection
Application/Patent revoked
Release to Public
only to countries where patent protection exists
Return of Deposit to Depositor
Undertakings by Recipient
- no transmission to 3rd party
- no export to 3rd country
Reversal of Burden of Proof
- in case released sample may be used in patented process
Experimental Use
- only if derived replicable products are not used commercially

Fig. 2


Scope of Protection
patented method I of manufacture
Patent A for cell containing new genetic information
Cell
"essentially biological"
dependent from patent A
Plant
derived product protection in view of Patent I
"essentially biological"
dependent from patent A
Seed
derived product protection in view of patent I

Exhaustion of Patent Rights



necessary for use different from pure selfreplication (e.g. sowing for obtaining via crop seeds for milling to flour)

use different from pure selfreplication (e.g. milling for obtaining flour)

in view of obtaining selfreplicated material for sale as seed in competition with patentee or as seed for subsequent crop

THE LECTURERS AND MEMBERS OF WIPO STAFF AT THE SYMPOSIUM; BIOGRAPHICAL INFORMATION

Note
prepared by
the International Bureau
of the
World Intellectual Property Organization

This Note contains information on each of the 11 persons who spoke at the Symposium on the Protection of Biotechnological Inventions. They are listed in the order of the Program.

Mr. GUST A. LEDAKIS

Mr. Gust A. Ledakis, a citizen of the United States of America, has been Legal Counsel of the World Intellectual Property Organization (WIPO) since 1974. He joined WIPO in 1971. In addition to his responsibilities for the general legal work of WIPO's Secretariat, Mr. Ledakis has been actively engaged in advising governments of developing countries on their legal and administrative framework for industrial property and copyright and on the legal aspects of the negotiation of patent and trademark license contracts and technology transfer arrangements.

Mr. Ledakis received his professional education at the University of Washington (B.B.A., LL.B.) (in Seattle, Washington) and at the University of Michigan (S.J.D.) (in Ann Arbor, Michigan). From 1957 to 1965, he was Professor of Law at the National Law Center of the George Washington University (in Washington, D.C.) and a visiting Professor of Law at the University of Illinois (at Champaign, Illinois). Mr. Ledakis was a legal officer in Unesco in Paris from 1965 to 1971.

Dr. LUDWIG BAEUMER

Dr. Ludwig Baeumer, a citizen of the Federal Republic of Germany, is the Director of the Industrial Property Division of WIPO. His responsibilities include work concerning the preparation of new treaties in the field of industrial property and advice to governments around the world on questions of industrial property legislation.

Before joining the WIPO predecessor organization (BIRPI) as a Legal Assistant in 1968, he worked as a Research Associate in the Max-Planck-Institute for Foreign and International Patent, Copyright and Competition Law in Munich. He holds a Doctor Juris degree from the University of Münster in the Federal Republic of Germany and a Master of Laws degree from the University of California at Berkeley.

Mr. WILLIAM H. DUFFEY

Mr. William H. Duffey, a citizen of the United States of America, is the General Patent Counsel for Monsanto Company of St. Louis, Missouri. For the past 25 years he has dedicated his professional life to the patent profession, with the last 21 of these years being at Monsanto Company. As General Patent Counsel for Monsanto, Mr. Duffey is responsible for all intellectual property matters throughout the company. During his tenure at Monsanto and prior to assuming his current responsibilities, he was initially a chemical patent attorney and subsequently a manager in the patent department with special emphasis on the company's biotechnology portfolio.

Throughout his career, Mr. Duffey has been continiously active in the patent profession, particularly in promoting and supporting new ideas and concepts in relation to the protection of industrial property. Among his professional affiliations are the American Intellectual Property Law

Association; Bar Association of Metropolitan St. Louis; Licensing Executives Society; Association of Corporate Patent Counsel; and Intellectual Property Owners, Inc. (member of the Board of Directors). Recently, on two occasions, Mr. Duffey was a United States delegate and biotechnology consultant to WIPO. Also, in 1986 he was a speaker on biotechnology patents at the National Science Foundation Conference in San Antonio, Texas. In 1985, he was a United States panelist with the European Commission Working Group on biotechnology patents. Mr. Duffey has also been a speaker on panels of the American Bar Association on this topic of adequate protection of intellectual property rights.

Mr. Duffey received his professional education at the University of Notre Dame (B.S.) and Indiana University School of Law (J.D.). He is a member of the state bars of Missouri and Indiana and is registered to practice before the United States Patent and Trademark Office.

Dr. ALAN H. LAIRD

Dr. Alan H. Laird, a citizen of the United Kingdom, has been a part of the patent department for Imperial Chemical Industries PLC in Hertfordshire, England, since 1964. Since 1978 he has been the Company Patent Agent. In this position, Dr. Laird has full responsibility for the legal aspects of all patent matters for all business areas of Imperial Chemical Industries. From 1976-1978, Dr. Laird was manager for the patent department of the Pharmaceutical Division for Imperial Chemical Industries.

Prior to Joining the Imperial Chemical's patent department, Dr. Laird worked as a research chemist in the Pharmaceutical Division of Imperial Chemical's Research Department. In this position he acquired practical experience in the industry which later enabled him to benefit Imperial Chemical, in particular, and the pharmaceuticals industries, in general, in the patent area.

Dr. KARL JOSEF HEIMBACH

Dr. Karl Josef Heimbach, a citizen of the Federal Republic of Germany, has been in the patent profession for the past 35 years. For the past 18 years, Dr. Heimbach has been the Head of the patent department of Bayer AG Leverkusen, a post from which Dr. Heimbach has just recently retired.

Dr. Heimbach was born in Cologne, Germany. He studied Chemistry in Cologne with Nobel Prize Winner, Prof. Alder. He is a registered European patent attorney and was one of the promoters of the European patent system. He is a member of the Advisory Committee of the Ministry of Justice of the Federal Republic of Germany, and a member of the Advisory Committee of the European Patent Office. He is also a member of the German Government Delegation for the revision of the Paris Convention.

Mr. CHARLES E. VAN HORN

Mr. Charles E. Van Horn, a citizen of the United States of America, has been in the patent profession for more than 23 years. In 1964, Mr. Van Horn joined the United States Patent and Trademark Office as a patent examiner. Since that time, he has served as a first level supervisor, a petitions examiner and a member of the Board of Patent Appeals. In 1979, he became Director of Patent Examining Group 120 where he is responsible for a staff of one hundred thirty (130) patent examiners and thirty-two (32) support staff, all having responsibilities in the examination of patent applications in the areas of organic chemistry and biotechnology.

Mr. Van Horn received his professional education at Lehigh University (B.S., Chemical Engineering), American University (J.D., Law) and George Washington University (M.B.A., Behavioral Science).

Dr. RUDOLF TESCHEMACHER

Dr. Rudolf Teschemacher, a citizen of the Federal Republic of Germany, is the Head of the Legal Service for the Grant Procedure in the General Directorate 5 of the European Patent Office in Munich, Federal Republic of Germany. His responsibilities include giving advice to patent applicants and their representatives on legal questions of procedure before the European Patent Office, cooperating with the Examination and Opposition Divisions in the application of the European Patent Convention.

Before joining the European Patent Office in 1980, Mr. Teschemacher worked as a Legal Assistant for the Patent Senate of the Federal Supreme Court of Justice and as Head of the Search Division in the German Patent Office. Previously, he had been a Research Associate in the Max Planck Institute for Foreign and International Patent, Copyright and Competition Law in Munich. He holds a Doctor Juris Degree in Law from Munich University.

Mr. ANDRE REMOND

Mr. André Rémond, a citizen of France, is currently the Director of Examination in the European Patent Office in Munich, Germany. In this position, he is in charge of the examination of all patent applications in the field of genetic engineering.

Prior to joining the European Patent Office, Mr. Rémond was a research scientist with Rhône-Poulenc in France. Subsequently he was a member of the patent department of a large chemical firm.

Mr. Rémond was born in France and graduated as a chemical engineer in 1965. In 1967, he received a degree from the Paris Institute for Business Administration.

Dr. CHARLES A. BRIM

Dr. Charles A. Brim, a citizen of the United States of America, is Emeritus Professor (Retired) at North Carolina State University. Dr. Brim was a soybean breeder and professor of Crop Science at North Carolina State University for 27 years.

After retiring from North Carolina State University, Dr. Brim joined Funk Seeds International, a Ciba-Geigy company in Bloomington, Illinois, where he recently retired as the company's vice-president of Research. Currently, he is a consultant in agricultural biotechnology to a number of entities, including the Research Unit of Ciba-Geigy.

Dr. Brim received all of his professional education at the University of Nebraska (B.S., Agronomy; M.S., Agronomy/Plant Pathology; PhD, Agronomy/Genetics). He is a fellow of the American Society of Agronomy and in 1983 was awarded the Genetics and Plant Breeding Award by the National Council of Commercial Plant Breeders.

Professor WILLIAM LESSER

Professor Lesser, a citizen of the United States of America, has been an Associate Professor in the Department of Agricultural Economics at Cornell University since 1978. His responsibilities include research and teaching, in addition to the administration of the graduate program for the Department. His current research activities are focused on marketing with a specialization in patents for living organisms, notably seeds and animals used in commercial agriculture. A sabbatical in Europe in 1986 was used by him to develop an international focus to this research.

Other areas of Prof. Lesser research activity include projecting the impacts of biotechnological products on agriculture. Some of this past research has focused on livestock marketing and food distribution. In the international arena he has worked with the International Agriculture program at Cornell and with other groups in Guyana, Guatemala, Costa Rica, the Philippines and Bolivia.

Prof. Lesser received his professional education from the Universities of Washington (B.A.); Rhode Island (M.S.); and Wisconsin (PhD, Agricultural Economics).

Dr. OTTO A. STAMM

Dr. Otto A. Stamm, a Swiss citizen, is the Head of the Patent Department of Ciba-Geigy AG, Basel, Switzerland.

Dr. Stamm was born in Switzerland. He took his doctorate in chemistry at the University of Basel. After further studies abroad, he was appointed lecturer in the Department of Chemistry at the Federal Institute of Technology in Zurich in 1964. In 1967 he joined the Patent Department of Ciba-Geigy AG in Basel, and in 1969 earned his Patent Attorney's Diploma after further studies at the University of Strasbourg, France.

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