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Contents

(continued overleaf)

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INDUSTRIAL PROPERTY LAWS AND TREATIES
(INSERT)

Notifications Concerning Treaties

Budapest Treaty

I. Change in the Name and in the List of Kinds of Microorganisms Accepted for Deposit

AGRICULTURAL RESEARCH CULTURE COLLECTION (NRRL)

The Government of the United States of America has notified the Director General of WIPO on May 21, 1987, of the change in the name of the "Agricultural Research Culture Collection (NRRL)" to the "Agricultural Research Service Culture Collection" and that the list of kinds of microorganisms accepted by that Collection under the Budapest Treaty (see Budapest Notification No. 12, of December 8, 1980, *Industrial Property,* 1981, p. 22) is as follows:

1. All strains of agriculturally and industrially important bacteria, yeasts, molds and *Actinomycetales,* except:

a. *Actinobacillus* (all species);
Actinomyces (anaerobic/microaerophilic, all species);
Arizona (all species);
Bacillus anthracis;
Bartonella (all species);
Bordetella (all species);
Borrelia (all species);
Brucella (all species);
Clostridium botulinum;
Clostridium chauvoei;
Clostridium haemolyticum;
Clostridium histolyticum;
Clostridium novyi;
Clostridium septicum;
Clostridium tetani;
Corynebacterium diptheriae;
Corynebacterium equi;
Corynebacterium haemolyticum;
Corynebacterium pseudotuberculosis;
Corynebacterium pyogenes;
Corynebacterium renale;
Diplococcus (all species);
Erysipelothrix (all species);
Escherichia coli (all enteropathogenic types);
Francisella (all species);
Haemophilus (all species);
Herellea (all species);
Klebsiella (all species);
Leptospira (all species);
Listeria (all species);
Mima (all species);
Moraxella (all species);
Mycobacterium avium;
Mycobacterium bovis;
Mycobacterium tuberculosis;
Mycoplasma (all species);
Neisseria (all species);
Pasteurella (all species);
Pseudomonas pseudomallei;
Salmonella (all species);
Shigella (all species);
Sphaerophorus (all species);
Streptobacillus (all species);
Streptococcus (all pathogenic species);
Treponema (all species);
Vibrio (all species);
Yersinia (all species).

b. *Blastomyces* (all species);
Coccidioides (all species);
Cryptococcus neoformans;
Cryptococcus uniguttulatus;
Histoplasma (all species);
Paracoccidioides (all species).

c. All viral, Rickettsial, and Chlamydial agents.

d. Agents which may introduce or disseminate any contagious or infectious disease of animals, humans or poultry and which require a permit for entry and/or distribution within the United States of America.

e. Agents which are classified as plant pests and which require a permit for entry and/or distribution within the United States of America.

f. Mixtures of microorganisms.

g. Fastidious microorganisms which require (in the view of the Curator) more than reasonable attention in handling and preparation of lyophilized material.

h. Phages not inserted in microorganisms.

i. Monoclonal antibodies.

j. All cell lines.

k. Plasmids not inserted in microorganisms.

2. The Agricultural Research Service Culture Collection will accept recombinant strains of microorganisms, strains containing recombinant DNA molecules, strains containing their own naturally occurring plasmid(s), strains containing inserted naturally occurring plasmid(s) from another

host, strains containing inserted constructed plasmid(s), and strains containing viruses of any kind, excluding those already listed as nonacceptable, only if the deposit document accompanying the microbial preparation(s) includes a clear statement that progeny of the strain(s) can be processed at a Physical Containment Level of P1 or less and Biological Containment requirements meet all other criteria specified by the U.S. Department of Health and Human Services, National Institutes of Health; "Guidelines for Research Involving Recombinant DNA Molecules, December 1978" (*Federal Register,* Vol. 43, No. 247—Friday, December 22, 1978) and any subsequent revisions.

[End of text of the notification of the Government of the United States of America]

The change in the list of kinds of microorganisms accepted for deposit by the Agricultural Research Service Culture Collection will take effect from the date (August 31, 1987) of the present publication.

Budapest Communication No. 35 (this Communication is the subject of Budapest Notification No. 61, of June 10, 1987).

* * *

III. Acquisition of the Status of International Depositary Authority

USSR RESEARCH INSTITUTE FOR GENETICS AND INDUSTRIAL MICROORGANISM BREEDING OF THE USSR MINISTRY OF THE MEDICAL AND MICROBIOLOGICAL INDUSTRY (VNIIGIMI)

INSTITUTE OF MICROORGANISM BIOCHEMISTRY AND PHYSIOLOGY OF THE USSR ACADEMY OF SCIENCE (IBFM AS USSR)

USSR RESEARCH INSTITUTE FOR ANTIBIOTICS OF THE USSR MINISTRY OF THE MEDICAL AND MICROBIOLOGICAL INDUSTRY (VNIIA)

The following written communication addressed to the Director General of WIPO by the Government of the Union of Soviet Socialist Republics under Article 7 of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure was received on June 24, 1987, and is published by the International Bureau of WIPO pursuant to Article 7(2)*(a)* of the said Treaty:

USSR RESEARCH INSTITUTE FOR GENETICS AND INDUSTRIAL MICROORGANISM BREEDING OF THE USSR MINISTRY OF THE MEDICAL AND MICROBIOLOGICAL INDUSTRY (VNIIGIMI)

1. Pursuant to the provisions of Article 7 of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, the Government of the Union of Soviet Socialist Republics hereby designates the USSR Research Institute for Genetics and Industrial Microorganism Breeding of the USSR Ministry of the Medical and Microbiological Industry as an international depositary authority.

2. The collection of industrial microorganisms at the aforementioned Institute complies and will continue to comply with all the conditions set forth in Article 6(2) of the Budapest Treaty.

3. Name and address of the depositary institution:

USSR Research Institute for Genetics and Industrial Microorganism Breeding;

Address: USSR, 113545, Moscow, Dorozhnaya Street, No. 8, USSR Research Institute for Genetics and Industrial Microorganism Breeding, USSR Collection of Microorganisms.

4. Information concerning the conditions set forth in Article 6(2) of the Budapest Treaty:

The USSR Collection of Industrial Microorganisms was created in 1969 as the central collection of the General Directorate of the Microbiological Industry of the USSR Council of Ministers; it collects industrial microorganism strains and also genetically-marked strains necessary for the execution of research work in the field of molecular genetics, microorganism genetics, genetic engineering, etc.

Since 1976 it has been performing the functions of microorganism depositary body for the purposes of patent procedure, pursuant to the provisions of the USSR legislation on inventions.

The USSR Collection of Industrial Microorganisms is a subdivision of the USSR Research

II. Extension of the List of Kinds of Microorganisms Accepted for Deposit

IN VITRO INTERNATIONAL, INC. (IVI)

The Government of the United States of America has notified the Director General of WIPO on May 21, 1987, that the list of kinds of microorganisms accepted for deposit under the Budapest Treaty by In Vitro International, Inc. (IVI) (see Budapest Notification No. 34, of November 3, 1983, *Industrial Property,* 1983, p. 306) has been extended to include seeds.

The said extension of the list of kinds of microorganisms accepted for deposit by In Vitro International, Inc. will take effect from the date (August 31, 1987) of the present publication.

Budapest Communication No. 36 (this Communication is the subject of Budapest Notification No. 62, of June 10, 1987).

Institute for Genetics and Industrial Microorganism Breeding; its expenses are defrayed by the budget of the State.

The staff assigned to the Collection are highly qualified: eight persons are holders of science degrees or doctorates.

The Collection comprises seven sections organized according to taxonomic or functional criteria: (1) fungi, (2) yeasts, (3) actinomycetes, (4) industrial bacteria, (5) genetically-marked bacteria, (6) phages, (7) producers of ferments from nucleic acid exchange. The head of each section is the holder of the title of Biological Science Licentiate, or has at least engaged in university studies. The Collection further has a microorganism cytology group and a department for the verification and recording of strains.

The Collection carries out its functions impartially and objectively, observing the necessary rules regarding secrecy and, for the purposes of deposits under the Treaty, it accords the same terms to all depositors.

The collection has four microbiological research laboratories, one room for the lyophilization of microorganisms, one storage area for the preservation of lyophilized cultures at a temperature of +12°C and another for the storage of cultures at low temperature (+5°C, -20°C, -70°C and -196°C).

5. Types of microorganisms accepted for deposit:

Bacteria (including actinomycetes) and microscopic fungi (including yeasts) for essentially industrial and non-medical purposes are accepted for deposit, to the exclusion of microorganisms that cause disease in man and animals and microorganisms that have a toxicogenic effect on plants or require them to be quarantined.

6. Types of fee and amounts:

	Roubles
— for the deposit of a microorganism and its storage for 30 years	800
— for each additional five-year period of storage	100
— for the furnishing of a sample of a deposited microorganism	50

The above amounts do not include mailing charges, which are invoiced separately at cost.

7. Official language:

The official language is Russian. Correspondence may also be exchanged in English.

INSTITUTE OF MICROORGANISM BIOCHEMISTRY AND PHYSIOLOGY OF THE USSR ACADEMY OF SCIENCE (IBFM AS USSR)

1. Pursuant to the provisions of Article 7 of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, the Government of the Union of Soviet Socialist Republics hereby designates the Institute of Microorganism Biochemistry and Physiology of the USSR Academy of Science as an international depositary authority.

2. The collection of microorganisms of the aforementioned Institute complies and will continue to comply with all the conditions set forth in Article 6(2) of the Budapest Treaty.

3. Name and address of the depositary institution:

Institute of Microorganism Biochemistry and Physiology of the USSR Academy of Science;

Address: USSR, 142292, Moscow Region, Pushchino-na-Oke, Institute of Microorganism Biochemistry and Physiology of the USSR Academy of Science, USSR Collection of Microorganisms.

4. Information concerning the conditions set forth in Article 6(2) of the Budapest Treaty:

The USSR Collection of Microorganisms was created in 1958 as a model cultures section of the Microbiology Institute of the USSR Academy of Science, and since 1981 it has been operating as a USSR Collection of Microorganisms at the Institute of Microorganism Biochemistry and Physiology of the USSR Academy of Science. Its expenses are defrayed by the budget of the State.

The staff assigned to the Collection are highly qualified: 12 persons are holders of science degrees or doctorates.

The Collection comprises subdivisions specialized by microorganism category (actinomycetes, bacteria, fungi, yeasts and cells embodying recombinant DNA) and according to storage methods and chemotaxonomic characteristics; its premises are located in Moscow and in Pushchino-na-Oke. It has laboratories for the storage of lyophilized cultures, a room equipped for the lyophilization of microorganisms and special areas for the storage of microorganisms either in liquid nitrogen or at a temperature of +4° to +5°C. The Collection has a separate depot in which duplicates of all microorganism cultures are kept. This measure is designed to afford more reliable storage for microorganism cultures in the Collection or on deposit.

The Collection is highly experienced in the deposit of microorganisms for the purposes of patent procedure in the USSR. It carries out all its functions in compliance with all the necessary rules of secrecy, impartially and objectively, and accords the same terms to all depositors, which is fully in keeping with the conditions set forth in the Budapest Treaty and the Regulations under it.

5. Types of microorganism accepted for deposit:

Bacteria (including actinomycetes) and microscopic fungi (including yeasts), also if they are car-

riers of recombinant DNA, are accepted for deposit, to the exclusion of microorganisms that cause diseases in man and animals and microorganisms that have a toxicogenic effect on plants or require them to be quarantined.

6. Types of fee and amounts:

	Roubles
— for the deposit of a microorganism and its storage for 30 years	800
— for each additional five-year period of storage	100
— for the furnishing of a sample of a deposited microorganism	50

The above amounts do not include the mailing charges, which are invoiced separately at cost.

7. Official language:

The official language is Russian. Correspondence may also be exchanged in English.

USSR Research Institute for Antibiotics of the USSR Ministry of the Medical and Microbiological Industry (VNIIA)

1. Pursuant to the provisions of Article 7 of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, the Government of the Union of Soviet Socialist Republics hereby designates the USSR Research Institute for Antibiotics of the USSR Ministry of the Medical and Microbiological Industry as an international depositary authority.

2. The collection of microorganisms of the aforementioned Institute complies and will continue to comply with the conditions set forth in Article 6(2) of the Budapest Treaty.

3. Name and address of the depositary institution:

USSR Research Institute for Antibiotics;
Address: USSR, 113105, Moscow, Nagatinskaya Street 3-a, USSR Research Institute for Antibiotics, Collection of Microorganisms.

4. Information concerning the conditions set forth in Article 6(2) of the Budapest Treaty:

The Collection has existed since 1956 as a subdivision of the USSR Research Institute for Antibiotics. Its expenses are defrayed by the budget of the State.

The Collection has been taking care of the deposit of microorganisms for the purposes of patent procedure since 1966.

The highly-qualified staff assigned to the collection have sufficient qualifications for the accomplishment of the scientific and administrative tasks incumbent on them under the Budapest Treaty. The Collection is highly experienced in the preservation of the taxonomic properties and of the activity of antibiotic-producing strains. It carries out its functions impartially and objectively, observing the necessary rules concerning secrecy and, for the purposes of deposits under the Budapest Treaty, it accords the same terms to all depositors.

The Collection has the necessary premises, which comprise a cold room and a lyophilization plant for microorganisms. All the cultures in the collection are stored in their lyophilized state at +5°C; the storage of the duplicates takes the form of storage in the ground, in mineral oil, or periodical re-seeding. There are also plans to make use of the method of storage in liquid nitrogen in the future.

5. Types of microorganism accepted for deposit:

Bacteria (including actinomycetes) and microscopic fungi (including yeasts) for essentially medical purposes are accepted for deposit, to the exclusion of microorganisms that cause disease in man and animals and microorganisms that are toxicogenic for plants or require them to be quarantined.

6. Types of fee and amounts:

	Roubles
— for the deposit of a microorganism and its storage for 30 years	800
— for each additional five-year period of storage	100
— for the furnishing of a sample of a deposited microorganism	50

The above amounts do not include mailing charges, which are invoiced separately at cost.

7. Official language:

The official language is Russian. Correspondence may also be exchanged in English.

Regulations on the Collection of Payments (Fees) Charged for the Services Provided by the International Depositary Authorities in the USSR under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

1. Pursuant to the provisions of Article 7 of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, the following institutions are hereby designated as international depositary authorities in the USSR:

— USSR Research Institute for Genetics and Industrial Microorganism Breeding of the USSR Ministry of the Medical and Microbiological Industry (VNIIGIMI);

— Institute of Microorganism Biochemistry and Physiology of the USSR Academy of Science (IBFM AS USSR);

— USSR Research Institute for Antibiotics of the USSR Ministry of the Medical and Microbiological Industry (VNIIA).

Pursuant to Rule 12 of the Regulations under the Budapest Treaty, the aforementioned three institutions charge payments (fees) in the following amounts for the deposit of microorganisms for the purposes of patent procedure and for the other services that they provide:

	Roubles
— for the deposit of a microorganism and its storage for 30 years	800
— for each additional five-year period of storage	100
— for the furnishing of a sample of a deposited microorganism, except where the sample is furnished under Rule 11.1 of the Regulations under the Budapest Treaty	50
— charge for dispatch by post	according to real cost

2. The prescribed fees have to have been settled on the date of the submission of the corresponding declarations to the international depositary authority.

Payments relating to the initial deposit may be made later, but before the expiry of a month from the day on which the depositor receives confirmation of receipt of the microorganism from the international depositary authority.

By way of confirmation of payment, the depositor sends the corresponding bank advice to the international depositary authority.

3. If the depositor allows the time limit for payment for the initial deposit, mentioned under 2 in these Regulations, to expire, he may still pay the fee, increased by 10%, on condition that he does so within six months following the date on which the declaration of deposit was submitted.

If the international depositary authority does not, within a period of six months following the date of submission of the declaration of deposit, receive proof of payment of the fee, the declaration of deposit is treated as if it has not been submitted.

4. The sums paid by way of fees may be repaid at the request of the person who filed the declaration in the following circumstances:

(a) if the payment was made by mistake;
(b) if the depositor requests the return of the microorganism that he has submitted for deposit before a certificate attesting the receipt and acceptance of the microorganism is issued to him;
(c) if the sample of the microorganism furnished on request proves non-viable:

The amount paid is repaid after deduction of any expenses that may have been incurred.

5. Foreign natural persons and legal entities that have their domicile or permanent headquarters abroad make the payment provided for in these Regulations by transferring the corresponding sums in currency to account No. 71.680.084 of the USSR Academy of Science at the USSR Foreign Trade Bank (IBFM AS USSR collection) or to account No. 716.300.030 of the USSR Ministry of the Medical and Microbiological Industry, also at the USSR Foreign Trade Bank (VNIIGIMI and VNIIA collections).

6. Expenses arising from the deposit of microorganisms for the purposes of patent procedure by natural persons and legal entities of the USSR, and also from the furnishing to natural persons or legal entities of the USSR of samples of deposited microorganisms, are met by the IBFM AS USSR, the VNIIGIMI and the VNIIA within the limits of available finance.

7. On request, the prescribed amount of fees may be reduced by 50% for depositors from developing countries.

The decision to reduce the amount of a fee is taken by the President of the USSR Academy of Science or by the USSR Minister of the Medical and Microbiological Industry.

The request for a reduction in the amount of fees has to be accompanied by a declaration stating that the depositor is a natural person or legal entity of a developing country, with domicile or permanent headquarters in that developing country, and that the isolation or production of the microorganism is in no way associated with the activity of natural persons or legal entities of countries other than developing countries.

(Translation)

[End of text of the notification of the Government of the Union of Soviet Socialist Republics]

Pursuant to Article 7(2)*(b)* of the Budapest Treaty, the USSR Research Institute for Genetics and Industrial Microorganism Breeding of the USSR Ministry of the Medical and Microbiological Industry (VNIIGIMI), the Institute of Microorganism Biochemistry and Physiology of the USSR Academy of Science (IBFM AS USSR) and the USSR Research Institute for Antibiotics of the USSR Ministry of the Medical and Microbiological Industry (VNIIA) acquire the status of international depositary authority as from August 31, 1987.

Budapest Communication No. 37 (this Communication is the subject of Budapest Notification No. 63, of July 28, 1987).

WIPO Meetings

WIPO Permanent Program for Development Cooperation Related to Industrial Property

Permanent Committee

Eleventh Session
(Geneva, May 5 to 8, 1987)

NOTE*

The WIPO Permanent Committee for Development Cooperation Related to Industrial Property (hereinafter referred to as "the Permanent Committee") held its eleventh session in Geneva from May 5 to 8, 1987.[1] The following 60 States members of the Permanent Committee were represented: Algeria, Argentina, Australia, Bangladesh, Benin, Brazil, Bulgaria, Burkina Faso, Cameroon, Central African Republic, China, Colombia, Costa Rica, Côte d'Ivoire, Cuba, Egypt, France, Gabon, Gambia, German Democratic Republic, Germany (Federal Republic of), Ghana, Guatemala, Guinea, Honduras, India, Indonesia, Italy, Japan, Kenya, Libya, Malawi, Mauritania, Mexico, Morocco, Netherlands, Niger, Pakistan, Panama, Paraguay, Peru, Republic of Korea, Rwanda, Senegal, Somalia, Soviet Union, Spain, Sudan, Sweden, Switzerland, Togo, Tunisia, Uganda, United Kingdom, United Republic of Tanzania, Uruguay, Venezuela, Yugoslavia, Zaire, Zambia. In addition, the following six non-member States also attended: Ecuador, Lebanon, Madagascar, Saudi Arabia, Syria, Trinidad and Tobago. Eight intergovernmental organizations (African Intellectual Property Organization (OAPI), African Regional Centre for Technology (ARCT), African Regional Industrial Property Organization (ARIPO), European Patent Organisation (EPO), General Agreement on Tariffs and Trade (GATT), Latin American Economic System (SELA), League of Arab States (LAS), United Nations Development Programme (UNDP)) and one international non-governmental organization (International Association for the Protection of Industrial Property (AIPPI)) were also represented. The list of participants follows this Note.

The Permanent Committee reviewed activities carried out, since its last session, under the WIPO Permanent Program for Development Cooperation Related to Industrial Property, as well as orientations and plans for future activities.

The Permanent Committee noted with satisfaction the activities carried out under the Permanent Program since its previous session and the expansion of the Program which had taken place during that period and invited the International Bureau to continue to pursue the expansion of the Program, with special emphasis on training, support for the strengthening of national and regional institutions, including patent documentation centers, advice on legislation, and assistance for the study and better understanding of the implications of the legal protection of emerging technologies. The Permanent Committee expressed its gratitude to the numerous governments and organizations, including the UNDP, which make extra-budgetary cash contributions or contributions in kind to the Permanent Program, and noted with appreciation the statements made by the representatives of several of those governments and organizations that they intended to continue and, if possible, increase such contributions. The Permanent Committee again underlined the importance that it attached to annual meetings of the Permanent Committee as an effective forum for the review and orientation of the Permanent Program.

The Permanent Committee considered that training remained a major priority for the Permanent Program. In that respect, the Permanent Committee supported the efforts of the International Bureau to continue to diversify and make more specialized the training program (both in terms of subject matter (e.g., patent information, licensing, new technologies, trademarks, use of industrial property for the promotion of exports) and the groups of individuals to whom training opportunities are addressed (such as the judiciary, university professors, the legal profession, etc.)) and to bring the training program closer to the users (through an increasing number of training activities in developing

* Prepared by the International Bureau.

[1] For a note on the preceding session, see *Industrial Property*, 1986, p. 297.

countries). At the same time, the Permanent Committee stressed that the International Bureau should nevertheless continue to offer a sufficient number of introductory courses.

The Permanent Committee invited the International Bureau to continue to organize seminars, forums or similar meetings, at a regional level, on matters of specific concern to countries in the region, including matters involving the effective use of the industrial property system for the development of industry and external trade, and emphasized that the inclusion in such meetings of representatives from the public and private economic sectors concerned would be desirable.

The Permanent Committee noted with satisfaction the information provided by the International Bureau on the directions and objectives for the training program in the medium and long term, with particular reference to the establishment of curricula and related teaching material in the field of industrial property and the progressive creation of a network of training centers located in both developing countries (on a regional basis) and in industrialized countries.

As regards activities for the promotion of inventive and innovative activity in developing countries, the Permanent Committee invited the International Bureau to accelerate the preparation of the study on the patent management and licensing operations of research and development institutions in developing countries, and of the study on possible arrangements for the promotion of technological innovation in developing countries. Several delegations expressed interest in seeing the results and recommendations of the two studies implemented and tested in the framework of a pilot project. The International Bureau stressed that the promotion of inventive and innovative activity would continue to be a major task and item in future activities under the Permanent Program.

At its tenth session, in April 1986, the Permanent Committee had recommended that it should devote part of some of its future sessions to examining certain specific matters affecting the orientation or implementation of the Permanent Program and had suggested, as such possible matters, licensing, industrial property protection of new subject matter, patent information and documentation, and utilization of human resources and institutions in developing countries within the framework of the Permanent Program. At its eleventh session, the Permanent Committee was invited to indicate how it intended to deal with the task referred to in the above recalled recommendation. The Permanent Committee decided that it would devote one day of its five-day 1988 session to the examination of patent documentation and information matters and one day of its five-day 1989 session to the examination of licensing matters, and it requested the Director General to take appropriate measures to organize the examination of those matters in the form of a symposium.

In the course of the discussions of this agenda item, several delegations stated that, whatever the subject matter chosen for discussions, the International Bureau should facilitate the participation of specialists and officials directly involved from developing countries. Also, several delegations, referring to the proposed restructuring of the WIPO Permanent Committee on Patent Information (PCPI), expressed the wish that the financial means formerly available to developing countries to participate in the meetings of the Working Group on Patent Information for Developing Countries of the PCPI should continue to be made available to those countries in order to enable them to participate in the work of the Working Groups contemplated in the new structure of the PCPI.

The Permanent Committee emphasized the importance of cooperation among developing countries in the field of industrial property, as well as the need to continue to promote and support it in all aspects of the Permanent Program. The utilization of experts and lecturers from developing countries in other developing countries, the promotion and implementation of regional and subregional projects, training within regions and the organization of regional meetings on industrial property subjects of common concern to countries of the region were, in particular, mentioned as positive factors in such promotion. With specific reference to the participation of experts from developing countries as consultants in WIPO development cooperation projects and as lecturers in WIPO training courses, seminars and workshops, the Director General informed the Permanent Committee that he intended to send a circular to all developing countries, requesting them to identify experts from their countries.

Delegations of ARIPO member States expressed their gratitude for the assistance rendered to ARIPO following the appeal made at the tenth session of the Permanent Committee in 1986 to all States members of WIPO, the UNDP and International Bureau in order that ARIPO could be given assistance enabling it to overcome its difficult financial situation.

Finally, the Permanent Committee paid a warm tribute and expressed its gratitude to Mr. Marino Porzio, Deputy Director General of WIPO, who left the Organization in May 1987, shortly after the session of the Permanent Committee.

LIST OF PARTICIPANTS**

I. States

Algeria: H. Redouane. **Argentina:** M.R. Solanet; J.M. Giacone; D. Chuburu. **Australia:** S.H.R. Hume. **Bangladesh:** M. Rahman. **Benin:** F.M. Adande. **Brazil:** R. Stille; J.C. Muricy. **Bulgaria:** O. Delev. **Burkina Faso:** A. Seye. **Cameroon:** W. Eyambe. **Central African Republic:** M. Lamine. **China:** Zhao-Qi Zhang. **Colombia:**

** A list containing the titles and functions of the participants may be obtained from the International Bureau.

L.-A. Luna. **Costa Rica:** E. Soley Soler; J. Rhenan Segura. **Côte d'Ivoire:** K.F. Ekra. **Cuba:** M. Jiménez Aday. **Ecuador:**[2] R.A. Rivadeneira. **Egypt:** W.Z. Kamil. **France:** M. Guerrini; J.-B. Mozziconacci. **Gabon:** J. Obounou-Mbogo. **Gambia:** M.A. Ceesay. **German Democratic Republic:** K.-D. Peters. **Germany (Federal Republic of):** D. Schennen. **Ghana:** A.M. Abdullah. **Guatemala:** L. González. **Guinea:** F. Bangoura. **Honduras:** N. Valenzuela; I. Juarez de Oqueli; M. de los A. Narváez. **India:** A. Malhotra. **Indonesia:** H. Wayarabi; B. Prayitno. **Italy:** M.G. Fortini. **Japan:** Y. Masuda. **Kenya:** J.N. King'Arui; H.B.N. Gicheru. **Lebanon:**[2] N. Fattal. **Libya:** G. Ferjani. **Madagascar:**[2] R.G. Razafimahefa. **Malawi:** I.J. Mtambo. **Mauritania:** M. Diaby. **Mexico:** M.A. Arce de Jeannet. **Morocco:** A. Bendaoud. **Netherlands:** W. Neervoort. **Niger:** G. Hassane. **Pakistan:** M.A. Khan. **Panama:** I. Aizpurua Perez; M. Saavedra. **Paraguay:** L. González-Arias; R.A. Bogado Vázquez; M. Frutos Britos. **Peru:** R. Carrillo Valdes. **Republic of Korea:** S.M. Cha; J.K. Kim; T.-C. Choi. **Rwanda:** B. Murekezi. **Saudi Arabia:**[2] A. Omair. **Senegal:** A.M. Dieng. **Somalia:** B.A. Osman. **Soviet Union:** B.V. Smirnov; V.A. Blatov. **Spain:** S. Jessel. **Sudan:** M.A. El Tahir. **Sweden:** U. Jansson. **Switzerland:** E. Caussignac; T.-L. Tran-Thi. **Syria:**[2] N. Chaalan; S. Chahabi. **Togo:** K.A. Kato. **Trinidad and Tobago:**[2] J.-E. George. **Tunisia:** H. Boufares; M. Baati. **Uganda:** P.L. Nsibirwa. **United Kingdom:** D.M. Haselden. **United Republic of Tanzania:** R.B. Mngulwi; E.E.E. Mtango; K.J. Suedi. **Uruguay:** A. Prat Gutiérrez; C. Sarlabos; R. González Arenas. **Venezuela:** H.C. Azócar. **Yugoslavia:** R. Tešić. **Zaire:** Massele La Lobato; Mukuna Kakolela. **Zambia:** A.R. Zikonda.

II. United Nations Organizations

United Nations Development Programme (UNDP): E. Bonev; D. Charleson.

[2] State not member of the Permanent Committee.

III. Other Intergovernmental Organizations

African Intellectual Property Organization (OAPI): V. Efon; G. Meyo M'Emane. **African Regional Centre for Technology (ARCT):** B. Thomas. **African Regional Industrial Property Organization (ARIPO):** J.H. Ntabgoba. **European Patent Organisation (EPO):** J. Amand. **General Agreement on Tariffs and Trade (GATT):** F. Roessler. **Latin American Economic System (SELA):** L. Herrera Marcano. **League of Arab States (LAS):** Z. Tlili.

IV. International Non-Governmental Organizations

International Association for the Protection of Industrial Property (AIPPI): G.E. Kirker.

V. Officers

Chairman: A.R. Zikonda (Zambia). *Vice-Chairmen:* E. Caussignac (Switzerland); O. Delev (Bulgaria). *Secretary:* B. Machado (WIPO).

VI. International Bureau of WIPO

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Paris Union

A. Committee of Experts on the Harmonization of Certain Provisions in Laws for the Protection of Inventions

Third Session
(Geneva, March 23 to 27, 1987)

A Note prepared by the International Bureau on the third session of the Committee of Experts on the Harmonization of Certain Provisions in Laws for the Protection of Inventions followed by three memoranda prepared by the International Bureau appeared in the June 1987 issue of *Industrial Property* on pages 204 to 234.

Four additional memoranda prepared by the International Bureau and submitted to the above-mentioned session of the Committee of Experts are reproduced below.

I. REQUIREMENTS IN RESPECT OF THE MANNER OF CLAIMING IN PATENT APPLICATIONS

(HL/CE/III/2 Supp. 1)

Memorandum by the International Bureau of WIPO

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I. Introduction

1. Under most, if not all, national laws and international treaties on the protection of inventions, the applicant must state in a claim what he considers to be the invention for which he seeks protection or, in other words, the subject matter which he desires to be protected.

2. In order to adequately define the invention or the subject matter to be protected, usually several claims are necessary.

3. The claims must develop their contents from the description, in other words, they must in some way be based upon the description.

4. Since the claims are the basis for the protection granted, they must have sufficient clarity.

5. Since patentability and infringement searches are made on the basis of the claims, the number of the claims and the way they are combined may influence the amount of time required for such a search and are, therefore, subject to regulation.

6. For the purposes of this memorandum, the expression "manner of claiming" encompasses both substantive aspects (indication of what is desired to be protected, connection between description and claims, clarity) and formal aspects (categories of claims, number and numbering of claims, structure and formal contents of claims, claims dependency).

7. To the extent that the manner of claiming is differently regulated under different national laws or treaties, the applicant who seeks protection in a number of countries is confronted with the task of formulating the claims accordingly, either at the time of filing or, by amendment, after filing, which places a considerable burden of work on him. It would therefore seem to be appropriate to examine possibilities for uniform rules (harmonization) at the international level.

II. Purpose of the Memorandum

8. The purpose of this memorandum* is to examine and compare the requirements regarding the manner of claiming under the national laws and regulations of eight countries (enumerated in paragraph 10, below), as well as under the Patent Cooperation Treaty (PCT), the European Patent Convention (EPC) and the Agreement on the Unification of Requirements for the Execution and Filing of Applications for

* Prepared by the International Bureau with the help of Mr. A. Hüni (Switzerland) and Mr. A.T. Puister (Netherlands) as consultants.

Inventions concluded in Leipzig on July 5, 1975, within the framework of the Council of Mutual Economic Assistance (hereinafter referred to as the "Agreement on Unification") with a view to evaluating the possibilities of harmonization in this regard.

9. The comparative analysis focuses primarily on the following questions: (i) the contents of the claims, (ii) the relation of the claims to the description, (iii) the style of the claims, (iv) claims dependency, and (v) fees. However, the question of fees, while included in the comparative analysis in order to make it complete, is not proposed to be included in the envisaged harmonization effort.

III. Existing Legislative Provisions

A. Information Used in the Present Memorandum

10. Before any uniform solutions are proposed, it may be useful to examine the requirements under existing laws in respect of the manner of claiming and primarily the questions identified in paragraph 9, above. For this purpose, the following information has been taken into account:

(i) the provisions of the PCT;
(ii) the provisions of the EPC;
(iii) the provisions of the Agreement on Unification; and
(iv) the legislation (laws, regulations, etc.) of those eight countries in which or for which, according to the statistics published by WIPO (IP/STAT/1983/B), more than 10,000 titles of protection for inventions were granted in 1983. Those countries are Canada (20,999), France (25,043), Germany (Federal Republic of) (20,913), Japan (54,701), the Soviet Union (74,200), Switzerland (11,768), the United Kingdom (28,254) and the United States of America (56,862). The figures indicate the number of patents granted in 1983, except for the Soviet Union, where they indicate the total number of patents and inventors' certificates granted in the said year.

11. In general, the present memorandum is based on legislative provisions (treaties, laws, regulations, etc.) and does not take into account the interpretation given to the said provisions by courts and industrial property offices or the practice of industrial property offices. The present memorandum only presents a short summary of the said provisions; the summaries have not been verified by the industrial property offices concerned.

12. In the following paragraphs, a short explanation is given with respect to the meaning of the following technical terms: (i) category of claims, (ii) independent claim, (iii) dependent claim, and (iv) multiple dependent claim.

13. Four *categories of claims* are recognized, namely: the category of a claim for a *product*, for example, a particular chemical substance or an article such as a particular glove; the category of a claim for a *process*, for example, a process for manufacturing the chemical substance or the glove; the category of a claim for a *use*, for example, the use of the chemical substance as a herbicide or of the glove for manipulating very hot objects; and the category of a claim for a *means*, for example, a particular vessel, in which the process for the manufacture of the chemical substance can be carried out, or an apparatus for manufacturing the glove. The distinction between those four categories of claims is primarily relevant to unity of invention, which is the subject of a separate study (see document HL/CE/III/2 Supp.2, below).

14. An *independent claim* is a claim which recites all technical features which define the subject matter to be protected. Although it usually does not refer to any other claim, it may contain such a reference but without stating an additional, limiting feature (see the next paragraph); for example, assuming a first claim relates to a certain product, a second claim can relate to a process for the manufacture of the product as claimed in claim 1, or to another product defined by a reference to the product as claimed in claim 1 wherein feature X is replaced by feature Y. Such a claim, which is an independent claim, must be distinguished from a dependent claim (see the next paragraph).

15. A *dependent claim* is a claim which includes all the features of an independent claim or another dependent claim by reference to that other independent or dependent claim and states an additional, limiting feature. Thus, an application may contain an independent claim for a new hammer, characterized by a head of a particular shape; a dependent claim will refer to that claim, thereby including the feature of the particularly shaped head, and will state a limiting feature, for example, that the head is made of iron.

16. A *multiple dependent claim* is a claim which (i) refers to more than one other claim (each of which can be an independent claim or, itself, a dependent claim), which (ii) includes all features of a given claim in connection with which, among the claims it refers to, it is considered, and which (iii) states an additional, limiting feature. Thus, one may add to the independent claim for a hammer and the dependent claim stating that its head is made of iron, which are mentioned in the previous paragraph, a multiple dependent claim referring to those two claims and stating that the handle in a hammer corresponding to the definition given in either one of those two claims is of a particular shape.

B. The Patent Cooperation Treaty (PCT)

17. Article 6 of the PCT stipulates that the claim or claims must define the matter for which protection is sought. This definition must be in terms of the technical features of the invention (Rule 6.3(a) of the Regulations under the PCT). The claims must be clear and concise (Article 6). They must not[1] contain drawings, but may contain chemical or mathematical formulae; they may also contain tables, if desirable (Rule 11.10).

18. The claims must be fully supported by the description (Article 6).

19. The claims must not unnecessarily rely, in respect of technical features, on references to the description or drawings and particularly not on references such as "described in ... of the description" and the like (Rule 6.2(a)).

20. Technical features in claims must, if the description contains drawings, be followed by the reference signs (preferably in parentheses) relating to such features, but only if the understanding of the claims is facilitated thereby (Rule 6.2(b)).

21. The claims must be structured in a statement indicating the features of the invention which, in combination, are prior art, and a characterizing portion, preceded by the words "characterized by" or the like, stating concisely the technical features which, in combination with the features stated in the statement, define the subject matter to be protected (Rule

[1] It should be noted that "it must not" means "it is not allowed to" and not "it is not required to."

6.3(b)); the designated States, however, may allow a different manner of claiming (Rule 6.3(c)).

22. Subject to PCT Rule 13.1,[2] the application may contain two or more independent claims of the same category which cannot readily be covered by a single generic claim (Rule 13.3) and/or two or more independent claims of different categories (Rule 13.2).

23. Subject to PCT Rule 13.1, it is permitted to include in the same application a reasonable number of dependent claims to specific forms of the invention contained in an independent claim, even if the features of any dependent claim could be considered an invention in themselves (Rule 13.4).

24. A claim which includes all the features of one (or more) other claims is called a "dependent" (or "multiple dependent") claim; it must include the features of the other claim(s) by reference—being placed if possible at the beginning—to those claims and must then state the additional features claimed (Rule 6.4(a)).

25. A multiple dependent claim must refer to the other claims in the alternative only (Rule 6.4(a)).

26. A multiple dependent claim cannot serve as a basis for any other multiple dependent claim (Rule 6.4(a)).

27. It is to be noted that any failure to use the manner of claiming referred to in paragraphs 25 and 26, above, has no effect in a designated State if the manner of claiming used satisfies the national law of that State (Rule 6.4(a)).

28. A dependent claim must be construed as including all the limitations contained in the claim in relation to which it is considered (Rule 6.4(b)).

29. All dependent claims referring back to a single previous claim, and all dependent claims referring back to several previous claims, must be grouped together to the extent and in the most practical way possible (Rule 6.4(c)).

30. The number of claims must be reasonable in consideration of the nature of the invention; the claims must be numbered consecutively in arabic numerals (Rule 6.1(a) and (b)).

C. The European Patent Convention (EPC)

31. Article 84 of the EPC provides that the claims must define the matter for which protection is sought and that they must be clear and concise.

32. The claims must be supported by the description (Article 84).

33. The claims must define the matter for which protection is sought in terms of the technical features of the invention (Rule 29(1) of the Implementing Regulations to the EPC, first sentence).

34. Wherever appropriate, the claims must contain a statement designating the subject matter of the invention and the technical features necessary for defining the claimed subject matter but which, in combination, are prior art and must contain a characterizing portion preceded by the expression "characterized by" or the like, stating the technical features which, in combination with the features stated in the above-mentioned statement, it is desired to protect (Rule 29(1), second sentence).

35. Subject to the requirement of unity of invention, the application may contain two or more independent claims of the same category where it is not appropriate to cover the subject matter by a single claim (Rule 29(2)) and/or two or more independent claims of different categories (Rule 30).

36. Any claim stating the essential features of an invention may be followed by one or more claims concerning particular embodiments thereof (Rule 29(3)).

37. Any claim including all features of any other claim is a dependent claim; it must contain, if possible at the beginning, a reference to the other claim and then state the additional features to be protected; a dependent claim is also admissible if the claim it refers to is itself a dependent claim (Rule 29(4), first two sentences).

38. A dependent claim can refer to more than one other claim; it may also contain an independent invention (*Guidelines for Examination in the European Patent Office*, Part C, Chapter III, 3.5 and 7.8).

39. All dependent claims referring back to a single previous claim, and all dependent claims referring back to several previous claims, must be grouped together to the extent possible and in the most appropriate way possible (Rule 29(4), third sentence).

40. The number of claims must be reasonable considering the nature of the invention; they must be numbered consecutively in arabic numerals (Rule 29(5)).

41. The claims must not unnecessarily rely in respect of technical features on references to the description or drawings and particularly not on such references as "as described in ... of the description" and the like (Rule 29(6)).

42. Technical features in the claim must, if the description contains drawings, preferably be followed by reference signs relating to the features and placed between parentheses, but only if the intelligibility of the claim can thereby be improved; those reference signs are not to be considered as limiting the claim (Rule 29(7)).

43. For each claim over 10, a claim fee is to be paid within one month after filing (Rule 31(1)), otherwise the claim concerned is deemed abandoned (Rule 31(3)).

D. The Agreement on the Unification of Requirements for the Execution and Filing of Applications for Inventions (Agreement on Unification)

44. The claims must begin with the title of the invention (Rule 4 of the Rules under the Agreement on Unification).

45. The claims must be based wholly on the description (Rule 4).

46. The claims should not unnecessarily contain references to the description (Rule 4).

47. The claims must not contain drawings, but they may contain chemical and mathematical formulae; they may also contain tables, if necessary (Rule 16).

[2] PCT Rule 13.1 reads as follows: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')."

48. If an application contains drawings, the claims may, if this facilitates the understanding, contain references to the corresponding parts of the drawings in brackets (Rule 4).

49. There may be one or several claims in an application (Rule 4).

50. All claims must contain a restrictive part and a distinctive part connected with the phrase "characterized by" (Rule 4).

51. The restrictive part of the first (main) claim must contain the title of the invention and, if possible, its known features common to the nearest prior art (Rule 4).

52. An application may contain several inventions of different categories, the features of which must be given in the main claims (Rule 4).

53. The main claims should be given in a sequence corresponding to the title of the invention and must each be followed by any additional claims in sequence (Rule 4).

E. National Legislation

54. *Canada.* Section 36(2) of the Patent Act, 1952, as amended up to 1972, provides that the claims must state distinctly and in explicit terms what the applicant regards as new and for which he claims protection.

55. Claims must be fully supported by the disclosure and will only be allowed if all characteristics set forth in the claims are described in the disclosure (Section 25 of the Patent Rules).

56. Claims must be complete independently of any reference to any document referred to in the disclosure (Section 24 of the Patent Rules).

57. Subject to the requirement of unity of invention, an application can claim a product and a process for making the product, or a process and an apparatus especially adapted for carrying out the process (Sections 58 and 59 of the Patent Rules).

58. A dependent claim may refer by number to not more than three preceding claims (Section 26(1) of the Patent Rules).

59. A claim so referred to by number shall not refer by number to more than one preceding claim (Section 26(1) of the Patent Rules).

60. *France.* The claims must define the matter for which protection is sought; they must be clear and concise (Section 14*ter* of the Patent Law of 1968, as last amended and supplemented in 1984).

61. The claims must be supported by the description (Section 14*ter* of the Patent Law).

62. Unless the nature of the invention warrants a different procedure, a claim cannot be based with regard to its technical features on simple references to the description or drawings (Section 11 of the Decree on Applications for Patents and Utility Certificates and the Grant and Maintenance in Force of Such Titles).

63. Unless the nature of the invention warrants a different procedure, any claim must contain a preamble, setting forth the object of the invention and the characteristic features of a technical nature which are necessary for the definition of the claimed elements but which in combination are part of the prior art, and a characterizing portion setting forth the technical features which in connection with the characteristic features given in the preamble are those for which protection is sought (Section 11 of the Decree).

64. The application may contain several independent claims of the same category, if the subject matter of the application cannot appropriately be covered by a single claim (Section 11 of the Decree). It may also contain independent claims of different categories, subject to the requirement of unity of invention (Section 12 of the Decree).

65. Any claim setting forth the essential characteristic features of the invention may be followed by one or more claims concerning specific embodiments of said invention (Section 11 of the Decree).

66. Where the application contains drawings, technical features in the claim must, in principle, be followed by reference signs relating to the features and placed between parentheses, if the intelligibility of the claim can thereby be improved; those reference signs are not to be construed as limiting the claim (Section 11(3) of the Order on the Filing of Applications for Patents and Utility Certificates and on the National Patent Register).

67. The claims must be numbered consecutively in arabic numerals (Section 11(1) of the said Order).

68. For each claim over 10, a claim fee must be paid (Order on Fees Collected by the National Institute of Industrial Property).

69. *Germany (Federal Republic of).* The claims specify what will be protected (Section 35(1) of the Patent Law of 1981).

70. The claims must not unnecessarily rely, in respect of technical features, on references to the description or drawings and particularly not on references such as "as described in ... of the description" and the like (Rule 4 of the Order Concerning Patent Applications of 1981).

71. If the application contains drawings, the features mentioned in the claims must preferably be followed by reference signs, if the intelligibility of the claim can thereby be increased (Rule 4).

72. Unless another form of drafting the claims is expedient, the claims must contain a statement indicating the distinguishing features of the subject matter on which the invention is based, if said subject matter is part of the prior art or if the protection sought should not extend to one or several of said features separately, and a characterizing part indicating the other features of the invention for which protection is sought in connection with the first statement; the characterizing portion must be introduced by words such as "characterized in that" (Rule 4).

73. A patent application can contain several claims (Section 35).

74. The essential features of the invention must be indicated in the first claim (principal claim) (Rule 4).

75. Any principal (or independent) claim may be followed by one or more dependent claims concerning particular embodiments of the invention; such dependent claims must contain a reference to a preceding claim (Rule 4).

76. The enumeration of features in the distinguishing statement of a claim may be replaced by a reference to another preceding claim or statement consisting of the same features (Rule 4).

77. A dependent claim may refer to more than one preceding claims (Rule 4).

78. The dependent claims must be grouped together in the most appropriate way (Rule 4).

79. The claims must be numbered consecutively in arabic numerals (Rule 4).

80. *Japan.* The claim(s) must state only the indispensable constituent features of the invention or inventions described in the detailed explanation of the invention (Section 36(4) of the Patent Law of 1959, as last amended in 1985), which may be of different categories, subject to the requirement of unity of invention (Section 38).

81. For each of the inventions, a statement of the indispensable constituent features must be made in a numbered separate paragraph (Rule 24*bis*(i) of the Regulations under the Patent Law).

82. A specific form of the invention must be stated with reference to the indispensable constituent features of the invention stated in a claim or to another specific form of the invention and then specify a further technical limitation of the same (Rule 24*bis*(ii)).

83. For each specific form of the invention, a separate numbered paragraph must be used (Rule 24*bis*(iii)).

84. A specific form of an invention may refer to the indispensable constituent features of the invention and one or more specific forms of the invention or two or more specific forms of the invention and must be stated with the same technical limitations attached thereto (Rule 24*bis*(iv)).

85. In the case of the preceding paragraph, a multiple reference must be in the alternative only (Rule 24*bis*(iv)).

86. The references mentioned in paragraphs 84 and 85, above, must be made by number (Rule 24*bis*(v)). Claims referred to must precede claims referring to them (Rule 24*bis*(vi)).

87. The claims must be numbered in consecutive order (Rule 24*bis*(vii)).

88. No references to statements concerning other inventions are permitted in any claim (Rule 24*bis*(viii)).

89. *Soviet Union.* The description must end with the claims which must be the only criteria for defining the scope of the invention; the claims must be in the form of a briefly worded statement indicating the essence of the invention from a technical viewpoint; in the claims, a device must be characterized by reference to the features of its design, a process by reference to a certain sequence of actions (methods, and operations with the help of material objects), and a substance by reference to its ingredients and their quantitative ratios (Section 44 of the Statute on Discoveries, Inventions and Rationalization Proposals of 1973, as amended in 1978).

90. The Soviet Union is party to the Agreement on Unification (see paragraphs 44 to 53, above). Reference is therefore made to the more detailed provisions of that Agreement.

91. *Switzerland.* The invention is defined in one or more claims (Section 51(1) of the Federal Law on Patents for Inventions of 1954, as revised in 1976). They indicate the technical features of the invention and must be as clear and as concise as possible and must be supported by the description (Section 29(1) and (2) of the Ordinance on Patents for Inventions).

92. The claims must not, in general, contain references to the description or drawings or in particular to expressions such as "as described in part ... of the description" (Section 29(4) of the Ordinance).

93. Reference signs in the drawings pointing to the technical features of the invention must be set forth in parentheses in the claims if this makes them more easily understandable; they do not limit the claims (Section 29(5) of the Ordinance).

94. The claims must be structured in a systematic, clear and intelligible way (Section 29(3) of the Ordinance).

95. Subject to the requirement of unity of invention, the application can contain several independent claims of the same category or of different categories (Section 52(2) of the Law, Section 30(2) of the Ordinance).

96. Special embodiments of an invention defined in an independent claim can be set forth in dependent claims (Section 55 of the Law).

97. A dependent claim must refer to at least one preceding claim and contain the additional features which define the particular embodiment of its object (Section 31(1) of the Ordinance).

98. A dependent claim may refer in distinct form to several preceding dependent claims (Section 31(2) of the Ordinance). According to the practice of the Swiss Federal Intellectual Property Office, this reference may be cumulative or alternative (*Schweizerisches Patent-, Muster- und Markenblatt*, 1977, 69).

99. According to the practice of the said Office, dependent claims referring to several other dependent claims in a cumulative or alternative manner (multiple dependent claims) may serve as a reference basis for other multiple dependent claims (*Schweizerisches Patent-, Muster- und Markenblatt*, 1977, 69).

100. The dependent claims that refer to the same independent claim must be grouped together in a clear manner (Section 31(3) of the Ordinance), and must be numbered consecutively in arabic numerals (Section 29(6) of the Ordinance).

101. For each claim over 10, a fee must be paid (Section 55a of the Law).

102. *United Kingdom.* The claim or claims must define the subject matter for which protection is sought (Section 14(5)(a) of the Patents Act 1977). They must be clear and concise (Section 14(5)(b)). Subject to the requirement of unity of invention, independent claims of different categories are permitted (Rule 22 of the Patent Rules 1982, as last amended in 1985).

103. The claims must be supported by the description (Section 14(5)(c)).

104. The claims must not contain drawings, but may contain chemical or mathematical formulae; they may contain tables only if their subject matter makes the use of tables desirable (Rule 20(12)).

105. *United States of America.* The specification must conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention (Section 112 of the United States Code, Title 35 (Patents) (35 USC)). Subject to the requirement of unity of invention, claims of different categories are permitted (Section 1.141(b) of the Code of Federal Regulations, Title 37 (Patents, Trademarks and Copyrights) (37 CFR)).

106. The claim(s) must conform to the invention set forth in the description and the terms used in the claims must be clearly supported by the description so that their meaning is ascertainable (37 CFR 1.75(d)(1)).

107. Reference characters corresponding to elements recited in the description and drawings may be used in conjunction with the corresponding recitation of elements in the claims; they should be in parentheses; they are considered to have no effect on the scope of the claims (Paragraph 601(h) of the *Manual of Patent Examining Procedure*).

108. If appropriate, an independent claim should contain, *first*, a preamble setting forth all elements or steps of the invention which are conventional or known, *second*, a phrase like "wherein the improvement comprises" and, *third*, those elements, steps and/or relationships which the applicant considers the improved portion of the subject matter claimed (37 CFR 1.75(e)).

109. A claim may be written in independent or in dependent or multiple dependent form (35 USC 112).

110. A dependent claim must contain a reference to a preceding claim and then specify a further limitation (35 USC 112).

111. A multiple dependent claim must refer in the alternative only to more than one preceding claim and then specify a further limitation; it must not serve as a basis for another multiple dependent claim (35 USC 112).

112. Dependent or multiple dependent claims must be construed to incorporate all limitations of the claim(s) to which they refer or in relation to which they are considered (35 USC 112).

113. The claims must not be unduly multiplied and must be numbered in a consecutive order in arabic numerals; dependent claims should be grouped together with the claim(s) to which they refer to the extent possible (37 CFR 1.75(b), (f) and (g)).

114. A fee must be paid in respect of each independent claim in excess of three and for all claims exceeding 20; a multiple dependent claim or a claim depending on a multiple dependent claim will be calculated for those purposes as comprising as many claims as the multiple dependent claim refers back to (37 CFR 1.75(c)). In addition, if the application contains a multiple dependent claim(s), a special fee must be paid (37 CFR 1.16(d)).

F. Comparative Analysis

115. In the following, the major aspects of the manner of claiming are investigated as to their acceptance in the systems examined. In making this comparison, preference is given to the gist of the various provisions over the exact wording.

116. The laws of all eight countries examined consider the claims to indicate the invention or, in other words, the subject matter for which protection is sought, as do the PCT, the EPC and the Agreement on Unification.

117. The PCT, the EPC and the laws of two countries (Soviet Union, Switzerland) specifically require that the claims must define the technical features of the invention.

118. The claims must be clear and concise (PCT, EPC, Switzerland, France, United Kingdom), explicit, distinct (Canada), particularly pointing out and distinctly claiming (United States of America), brief (Soviet Union).

119. The claims must not unnecessarily refer to the description (PCT, EPC, Agreement on Unification, France, Switzerland).

120. The claims must contain reference signs relating to corresponding features in drawings if this facilitates the understanding of the claim (PCT, EPC, Agreement on Unification, France, Germany (Federal Republic of), Switzerland, United States of America).

121. Reference signs in the claims relating to drawings must not be regarded as restricting the scope of the claims (EPC, France, Switzerland, United States of America). In the opinion of the International Bureau, this provision is of particular importance to applicants, because it avoids misinterpretation of the scope of such claims.

122. The claims must be supported by the description (PCT, EPC, Agreement on Unification, Canada, France, Germany (Federal Republic of), Japan, Switzerland, United Kingdom, United States of America). Among the said laws and treaties, the PCT, the Agreement on Unification, Canada and the United States of America require "full support." Since the word "full" has a strongly subjective quality, the unqualified term "support" is preferable in the opinion of the International Bureau.

123. The structuring of claims into a preamble indicating the main elements of the invention and a second, distinguishing part introduced by words such as "characterized in that" is provided for in the PCT, the EPC and the Agreement on Unification, as well as by the laws of France, Germany (Federal Republic of) and the United States of America. With the exception of the PCT and the Agreement on Unification, the relevant provisions state, however, that this solution is to be used only if appropriate. The PCT expressly permits the designated States to accept other solutions.

124. In the opinion of the International Bureau, a claim structured in the way described in the preceding paragraph has the distinctive advantage of enabling the reader to grasp very quickly the feature(s) considered by the applicant to impart novelty to what may be a complicated process, product or apparatus with many conventional features. Thus, it may be known to manufacture compound X by reacting compound A with compound B and compound C in a mixture of solvent D and water at a temperature of 70-90°C and under high pressure. The invention consists in carrying out this process in the presence of a catalyst E which results in increased yields of X. This process could (undesirably) be claimed as follows: "Process for the manufacture of X, wherein A is reacted with B and C in a mixture of D and water at a temperature of 70-90°C and under high pressure in the presence of catalyst E." Using the structure recommended, the claim would read: "Process for the manufacture of X by reacting A with B and C in a mixture of D and water at a temperature of 70-90°C and under high pressure, characterized in that it is carried out in the presence of catalyst E." The reader immediately recognizes that it is not the choice of the different compounds used or the solvent or the temperature or the pressure which is the gist of

the invention, but that the gist of the invention consists in the use of catalyst E.

125. A dependent claim is a claim which includes all the features (limitations) of another claim by reference to that claim and states the additional feature(s). This is provided for with minor variations in the PCT, the EPC, the Agreement on Unification, and the laws of Canada, France, Germany (Federal Republic of), Japan, Switzerland and the United States of America, and is consistent with the practice of the United Kingdom Patent Office.

126. A dependent claim can refer to more than one preceding claim (multiple dependent claim) (PCT, EPC, Canada, Germany (Federal Republic of), Japan, Switzerland, United Kingdom (practice), United States of America). However, the law of Canada restricts the number of claims, to which a dependent claim refers, to not more than three, and it provides that a claim referred to by number must not refer by number to more than one preceding claim.

127. The rule that a multiple dependent claim must contain the references in the alternative form only is contained only in the PCT and in the laws of Japan and the United States of America. However, claims not corresponding to that requirement are allowed under the PCT if they are accepted by the designated States.

128. The rule that a multiple dependent claim must not serve as a basis for reference for another multiple dependent claim can be found only in the PCT and the laws of Canada and the United States of America. However, claims not corresponding to that requirement are allowed under the PCT if they are accepted by the designated States, which is the case, for example, in the practice of the European Patent Office and the Swiss Federal Intellectual Property Office.

129. The requirements referred to in the preceding paragraph and in the second sentence of paragraph 126, above, and in particular the combination of those requirements, cause in practice a large increase of claims with repetitive contents. Such sets of claims are difficult to read and evaluate, much more so than the corresponding sets of claims using a logical system of multiple dependencies without those limitative requirements.

130. The following is a simple practical example illustrating the problem: the invention concerns a process, in which compound A is reacted with compound B in the presence of a solvent. The solvent is preferably water. Whether or not water is used as a solvent, a temperature of 70-80° is optimal, and, regardless of the other conditions, use of high pressure gives improved results.

(i) If no multiple dependent claims were possible, *eight* claims would be necessary:

Claim 1: Reaction of A + B in a solvent.

Claim 2: Reaction as claimed in claim 1, wherein water is used as the solvent.

Claim 3: Reaction as claimed in claim 1, wherein the reaction is carried out at 70°-80°.

Claim 4: Reaction as claimed in claim 2, wherein the reaction is carried out at 70°-80°.

Claim 5: Reaction as claimed in claim 1, wherein the reaction is carried out at high pressure.

Claim 6: Reaction as claimed in claim 2, wherein the reaction is carried out at high pressure.

Claim 7: Reaction as claimed in claim 3, wherein the reaction is carried out at high pressure.

Claim 8: Reaction as claimed in claim 4, wherein the reaction is carried out at high pressure.

(ii) If multiple dependent claims were possible but could not serve as a basis for reference for another multiple dependent claim, *five* claims would be necessary:

Claim 1: Reaction of A + B in a solvent.

Claim 2: Reaction as claimed in claim 1, wherein water is used as the solvent.

Claim 3: Reaction as claimed in claim 1 or 2, wherein the reaction is carried out at 70°-80°.

Claim 4: Reaction as claimed in claim 1 or 2, wherein the reaction is carried out at high pressure.

Claim 5: Reaction as claimed in claim 3, wherein the reaction is carried out at high pressure.

(iii) If multiple dependent claims were possible and could also serve as a basis for reference for other multiple dependent claims, *four* claims would suffice:

Claim 1: Reaction of A + B in a solvent.

Claim 2: Reaction as claimed in claim 1, wherein water is used as the solvent.

Claim 3: Reaction as claimed in claim 1 or 2, wherein the reaction is carried out at 70°-80°.

Claim 4: Reaction as claimed in claim 1, 2 or 3, wherein the reaction is carried out at high pressure.

Thus, with a minimum of claims and wording, the preferred embodiments can be presented in a logical, clear and transparent manner. Repetitions become unnecessary: in the first situation, the additional feature "70-80°" has to be repeated once and the further additional feature "high pressure" three times; in the second situation, the additional feature "high pressure" has still to be repeated once. How far the necessity of repetition can go with an increase in additional (or preferred) features is shown in the example given in the Annex to this document.

131. A dependent claim may set forth features which in themselves constitute an invention (PCT, EPC).

132. Subject to the requirement of unity of invention, the application may contain two or more independent claims of the same category (PCT, EPC, France, Japan, Switzerland, United States of America) and/or of different categories (PCT, EPC, Agreement on Unification, Canada, France, Japan, Switzerland, United Kingdom, United States of America). In the PCT, the EPC and under the law of France, two or more claims of the same category are permitted only if the subject matter cannot readily be covered in a single claim which, according to the PCT, must be generic.

133. All dependent claims should be grouped together in the most practical fashion (PCT, EPC, Germany (Federal Republic of), Switzerland, United States of America).

134. The number of claims should be reasonable considering the nature of the invention (PCT, EPC, United States of America).

135. The claims must be numbered in consecutive order in arabic numerals (PCT, EPC, France, Germany (Federal Republic of), Japan (which, however, does not prescribe the use of arabic numerals), Switzerland, United States of America).

136. Any claims stating the essential features of an invention may be followed by one or more claims to particular embodiments thereof (PCT, EPC, Agreement on Unification, Canada, France, Germany (Federal Republic of), Japan, Switzerland).

137. For each claim above a certain number, a claim fee is required (EPC, Canada, France, Switzerland, United States of America).

138. The claims must not contain any drawings but may contain chemical or mathematical formulae and, if desirable, tables (PCT, Agreement on Unification, United Kingdom).

139. Claims must be independent of any document referred to in the description (Canada).

140. In conclusion of this comparative analysis, and as a principal remark, it could be said that the selected countries may be divided, in general terms, into two groups, as far as the manner of drafting claims is concerned: a first group of countries in which the provisions of the national laws and regulations are basically the same as or similar to those of the EPC or at least do not seem to contain any provisions contrary to those of the EPC; and a second group of countries, together with the PCT and the PCT Regulations, which differ substantially from the provisions of the EPC with respect to multiple dependency.

IV. Arguments in Favor of a Uniform Solution

141. It is clearly in the interest of the users of the industrial property system to have a wide and far-reaching harmonization of the rules and requirements concerning the manner of claiming.

142. A treaty which would deal with the harmonization of the manner of claiming should be based on relatively liberal principles in the sense that applicants should, on the one hand, have clear principles concerning the structure of claims and possible dependencies of claims but, on the other hand, should not have to comply with too strict requirements and should dispose of enough flexibility to choose the manner of claiming which they consider to be most appropriate. A harmonization on that basis would greatly facilitate the drafting and reading of claims. The uniform principles should permit to concentrate on the gist of the invention, and the effect of the uniform principles should be that they reduce considerably the number of claims to be scrutinized and that they make clear the relationship between the contents of the different claims. Such principles would not only be of benefit to applicants but also to third parties who have to evaluate patents in order to avoid infringement.

V. Principles of a Solution

143. The principles of a solution to be embodied in an international treaty and in regulations under that treaty could be drafted as follows:

Treaty

Article 104

"(1) An application shall contain one or more claims. The claim or claims shall define the matter for which protection is sought. The claim or claims shall be clear and concise, and shall be supported by the description.

"(2) The definition of the matter for which protection is sought shall be in terms of the technical features of the invention."

Regulations under the Treaty

Rule relating to Article 104

"(1) If there are several claims, they shall be numbered consecutively in arabic numerals.

"(2)(a) Whenever appropriate, claims may contain:

(i) a statement indicating those technical features of the invention which are necessary for the definition of the claimed subject matter, whether or not those features are part of the prior art;

(ii) a characterizing portion—preceded by the words 'characterized in that,' 'characterized by,' 'wherein the improvement comprises,' or any other words to the same effect—stating concisely the technical features which, in combination with the features stated under (i), it is desired to protect.

(b) The national law may prescribe that claims shall not, except where absolutely necessary, rely, in respect of the technical features of the invention, on references to the description or drawings, particularly not on such references as: 'as described in part ... of the description,' or 'as illustrated in figure ... of the drawings.'

(c) The claims shall not contain drawings but may contain chemical or mathematical formulae and/or, if desirable, tables.

(d) If the 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 those features and preferably placed between parentheses. Such reference signs shall not be construed as limiting the claim.

"(3) Any claim which does not include all the features of one or more other claims shall be referred to hereinafter as 'independent claim.' An independent claim may refer to one or more other claims.

"(4)(a) Any claim which includes all the features of one or more other claims shall be referred to hereinafter as 'dependent claim' or 'multiple dependent claim' depending on whether it refers to one or more other claims. It shall contain, if possible at the beginning, a reference to the other claim or claims and shall then state the additional features claimed.

(b) Dependent claims or multiple dependent claims may depend on independent claims, dependent claims or multiple dependent claims.

(c) A dependent claim shall be construed as including all the features contained in the claim to which it refers, and a multiple dependent claim shall be construed as including all the features contained in the claim or claims to which it refers and in relation to which it is considered.

(d) All dependent claims referring to a single other claim, and all multiple dependent claims referring to several other claims, shall be grouped together in the most practical way possible.

(e) A dependent claim or a multiple dependent claim may set forth features which in themselves constitute an invention.

"(5) Where any requirement prescribed in Article 104 or in this Rule is not complied with, the applicant shall be given an opportunity to amend the application, except where Article 101(2)(a)(i) applies and the application does not contain any part which, on the face of it, appears to be a claim or claims."

144. With respect to the requirement of unity of invention, referred to in several occasions in this document, for instance in paragraph 143, above (Article 104(1)(b)), attention is drawn to the special study contained in document HL/CE/III/2 Supp. 2 (see below).

ANNEX

Comparison of Claim Series in EPO and USA*

The following items 1, 2 and 3 are mandatory in USA (and PCT) filings. In EPO filings, item 1 is mandatory, item 2 is desirable for clarity, but item 3 is not mandatory.

1. A claim which includes all the features of one or more other claims shall do so by reference to the other claim or claims and shall then state the additional features claimed—such claims are dependent claims.

2. A dependent claim which refers to more than one other claim (multiple dependent claim) shall refer to such claims in the alternative.

3. Multiple dependent claims shall not serve as a basis for any other multiple dependent claim.

On this basis, the following are series of claims for EPO and USA in respect of a process, the main feature of which is A to which subsidiary features B, C, D, E and F can be added singly or in any combination.

EPO Claims		*Combination Covered*	*USA Claims*	
Claim 1	A process of A	A	Claim 1	A process of A
Claim 2	A process as claimed in claim 1 +B	A+B	Claim 2	A process as claimed in claim 1+B
Claim 3	A process as claimed in claim 1 or 2+C	A+C A+B+C	Claim 3	A process as claimed in claim 1 or 2+C
Claim 4	A process as claimed in claim 1, 2 or 3+D	A+D A+B+D	Claim 4	A process as claimed in claim 1 or 2+D
		A+C+D A+B+C+D	Claim 5	A process as claimed in claim 3+D
Claim 5	A process as claimed in claim 1, 2, 3 or 4+E	A+E A+B+E	Claim 6	A process as claimed in claim 1 or 2+E
		A+C+E A+B+C+E	Claim 7	A process as claimed in claim 3+E
		A+D+E A+B+D+E	Claim 8	A process as claimed in claim 4+E
		A+C+D+E A+B+C+D+E	Claim 9	A process as claimed in claim 5+E
Claim 6	A process as claimed in claim 1, 2, 3, 4 or 5+F	A+F A+B+F	Claim 10	A process as claimed in claim 1 or 2+F
		A+C+F A+B+C+F	Claim 11	A process as claimed in claim 3+F
		A+D+F A+B+D+F	Claim 12	A process as claimed in claim 4+F
		A+C+D+F A+B+C+D+F	Claim 13	A process as claimed in claim 5+F
		A+E+F A+B+E+F	Claim 14	A process as claimed in claim 6+F
		A+C+E+F A+B+C+E+F	Claim 15	A process as claimed in claim 7+F
		A+D+E+F A+B+D+E+F	Claim 16	A process as claimed in claim 8+F
		A+C+D+E+F A+B+C+D+E+F	Claim 17	A process as claimed in claim 9+F

* This comparison has been established by Mr. Donald Vincent (United Kingdom) and WIPO expresses its gratitude to him for permitting its reproduction in this document.

* * *

II. REQUIREMENTS IN RESPECT OF UNITY OF INVENTION IN PATENT APPLICATIONS

(HL/CE/III/2 Supp. 2)

Memorandum by the International Bureau of WIPO

TABLE OF CONTENTS

I. Introduction

1. In most countries having a patent law, the applicant for the grant of a patent has to meet the requirement of "unity of invention," i.e., the requirement that a patent application can relate to one single invention only.

2. Normally, this requirement is laid down in the patent law, but some countries provide for it in the regulations or in other legal texts (e.g., ordinances, decrees, administrative instructions) which are legally binding on patent applicants.

II. Purpose of the Memorandum

3. The purpose of this memorandum* is to examine the existing requirements and the possibility of finding a uniform solution which could easily be applied by national and regional industrial property offices and which would have the advantage for applicants that they do not have to comply with different requirements as to unity of invention if they seek protection for the same invention in several countries. The uniform solution would also be of benefit to third parties who have to examine patents with a view to any potential infringement and to those who want to study patent documents as a source of technical information. One would have to study, at a later stage, whether such a uniform solution, which would be expressed in treaty provisions supplemented by regulations—which, by their nature, cannot regulate the matter in all its details—should not be supplemented by a set of guidelines aiming at achieving a uniform application of those provisions.

4. The solutions to be proposed for adoption should be the same for the largest possible number of countries. In this connection, reference is made to the significant achievements in respect of the harmonization of certain provisions of patent law already obtained as a consequence of the Patent Cooperation Treaty (PCT) (1970) and the European Patent Convention (1973).

* Prepared by the International with the help of Mr. A. Hüni (Switzerland) and Mr. A.T. Puister (Netherlands) as consultants.

III. Existing Legislative Provisions

A. Information Used in the Present Memorandum

5. Before proposing any uniform solution, it may be useful to examine the requirements under existing laws in respect of the unity of invention. For this purpose, the following information has been taken into account:

(i) the provisions of the Patent Cooperation Treaty (PCT);

(ii) the provisions of the European Patent Convention (EPC);

(iii) the provisions of the legislation (laws, regulations, etc.) of those eight countries in or for which, according to the statistics published by WIPO (IP/STAT/1983/B), more than 10,000 titles of protection for inventions were granted in 1983. Those countries are Canada (20,999), France (25,043), Germany (Federal Republic of) (20,913), Japan (54,701), the Soviet Union (74,200), Switzerland (11,768), the United Kingdom (28,254) and the United States of America (56,862). The figures indicate the number of patents granted in 1983, except in the case of the Soviet Union, where they represent the total of the number of patents and inventors' certificates granted in said year.

6. In general, the present memorandum is based on legislative provisions (treaties, laws, regulations, etc.) and does not take into account the interpretation given to the said provisions by courts and industrial property offices or the practice of industrial property offices. The present memorandum only presents a short summary of the said provisions; the summaries have not been verified by the industrial property offices concerned.

B. The Patent Cooperation Treaty (PCT)

7. Article 3(4)(iii) of the PCT provides that the international application must comply with the prescribed requirement of unity of invention. That requirement is defined in Rule 13.1 of the Regulations under the PCT, which provides that the "international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." Furthermore, Rule 13.2 provides that this requirement of unity of invention is in particular complied with in all cases where the following types of claims of different categories are combined:

> "(i) in addition to an independent claim for a given product, the inclusion in the same international application of an independent claim for a process specially adapted for the manufacture of the said product, and the inclusion in the same international application of an independent claim for a use of the said product, or
>
> "(ii) in addition to an independent claim for a given process, the inclusion in the same international application of an independent claim for an apparatus or means specifically designed for carrying out the said process, or
>
> "(iii) in addition to an independent claim for a given product, the inclusion in the same international application of an independent claim for a process specially adapted for the manufacture of the product, and the inclusion in the same international application of an independent claim for an apparatus or means specifically designed for carrying out the process."

8. Subject to the requirement of unity of invention, it is also permitted to include in the same international application two or more independent claims of the same category (i.e., for product, process, apparatus, or use) which cannot readily be covered by a single generic claim (Rule 13.3).

9. Subject to the requirement of unity of invention, it is furthermore permitted to include in the same international application a reasonable number of dependent claims, claiming specific forms of the invention claimed in an independent claim, even where the features of any dependent claim could be considered as constituting in themselves an invention (Rule 13.4).

C. The European Patent Convention (EPC)

10. Article 82 of the EPC expresses the same requirement as PCT Rule 13.1 with respect to the requirement of unity of invention (see paragraph 7, above).

11. Furthermore, Rule 30 of the Implementing Regulations to the EPC, which has the same contents as PCT Rule 13.2, permits in particular one and the same European patent application to include the combinations of independent claims of different categories as mentioned for the PCT in paragraph 7(i), (ii) and (iii), above.

12. Like in the PCT, subject to the requirement of unity of invention, the Implementing Regulations to the EPC (Rule 29) allow a single European patent application to 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; furthermore, any claim stating the essential features of an invention may be followed by one or more claims concerning particular embodiments of that invention (dependent claims). A dependent claim may contain an independent invention (*Guidelines for Examination in the European Patent Office*, Part C, Chapter III, 7.8).

D. National Legislation

13. *Canada.* According to Section 38 of the Patent Act, 1952, as amended up to 1972, a "patent shall be granted for one invention only but in an action or other proceeding a patent shall not be deemed to be invalid by reason only that it has been granted for more than one invention."

14. Also here the Rules (Sections 58 and 59 of the Patent Rules) give further details, namely: an application that claims a product and a process for making the product or an application that describes and claims a process and an apparatus especially adapted to carry out the process shall not, for that reason only, be deemed to be directed to more than one invention.

15. *France.* Here the requirement of unity of invention is expressed in Section 14 of the Patent Law of 1968, as last amended and supplemented in 1984, which states that the patent application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

16. Additional regulations are to be found in Sections 11 and 12 of the Decree on Applications for Patents and Utility Certificates and the Grant and Maintenance in Force of Such Titles, as last amended in 1982, which follow almost literally the EPC Implementing Regulations (see paragraphs 11 and 12, above).

17. *Germany (Federal Republic of).* The Patent Law of 1981 briefly states (Section 35(1), second sentence) that for "every invention, a separate application shall be required." In actual practice, however, a plurality of claims are allowed, either of one and the same category or of different categories.

18. *Japan.* "A patent application shall relate to a single invention" under Section 38 of the Patent Law of 1959, as last amended in 1985. The same provision, however, specifies that the requirement of unity of invention is also complied with where the following inventions have the relationship indicated below with a first invention ("the specified invention") in the application:

> "(i) inventions which have, as a substantial part of their indispensable constituent features, the whole or a substantial part of the indispensable constituent features of the specified invention and which have the same purpose as the specified invention;
>
> "(ii) where the specified invention relates to a product, inventions of processes for manufacturing the product, inventions of processes of using the product, inventions of machines, instruments, equipment or other devices for manufacturing the product, or inventions of products solely utilizing the specific properties of the product;
>
> "(iii) where the specified invention relates to a process, inventions of machines, instruments, equipment or other devices used directly in the working of the specified invention."

19. *Soviet Union.* The requirement of unity of invention is laid down in the Law (Section 45 of the Statute on Discoveries, Inventions and Rationalization Proposals of 1973, as amended in 1978) using the same wording as PCT Rule 13.1 (see paragraph 7, above).

20. The implementing instructions show a more liberal attitude than the law would suggest, in that under certain circumstances two or more inventions related to different objects can be combined (e.g., a device, method, substance); in such a case, a single title—an inventor's certificate or patent—is issued with the denomination of the invention compiled in the following sequence: substance, method, device (Item 28 of the Instructions for the Drafting of Applications in Respect of Inventions, EZ-1-74, 1974).

21. *Switzerland.* A patent may contain several independent claims (for a process; or a product, a means for performing a process, or a device; or the application of a process; or the utilization of a product) where they define a group of inventions so linked as to form a single general inventive concept (Section 52 of the Federal Law on Patents for Inventions of 1954, as revised in 1976).

22. The conditions specified in Section 52 of the Law are deemed to have been met when the patent application contains one of the following combinations of independent claims (Section 30(1) of the Ordinance on Patents for Inventions):

> "(a) in addition to a first claim for a process: a claim for a means of implementing that process, a claim for the product resulting therefrom, and a claim either for an application of the process or for a use of the product;
>
> "(b) in addition to a first claim for a product: a claim for a process for the manufacture of that product, a claim for a means of implementing the process and a claim for the use of the product;
>
> "(c) in addition to a first claim for a device: a claim for a process for the operation of the device and a claim for the manufacture of the device."

23. "Where a patent application contains another combination of independent claims, of the same category or of different categories, the overall idea common to both inventions defined therein shall be clearly apparent from the claims themselves" (Section 30(2) of the Ordinance on Patents for Inventions).

24. *United Kingdom.* The requirement of unity of invention is defined by providing that the claim or claims in one patent application must relate to one invention or to a group of inventions which are so linked as to form a single inventive concept (Section 14 of the Patents Act 1977).

25. The Rules further indicate what, in particular, is permitted in an application without violating the requirement of unity of invention, using the wording of the EPC Implementing Regulations (Rule 22 of the Patent Rules 1982, as last amended in 1985) (see paragraphs 11 and 12, above).

26. *United States of America.* The patent law states that if two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions (Section 121 of the United States Code, Title 35 (Patents) (35 USC)). In respect of international applications filed under the PCT which designate, but do not originate in, the United States of America, the determination of unity of invention is governed by a reference to the requirements of the PCT Regulations (Section 372(b)(2) of the United States Code, Title 35 (Patents) (35 USC)).

27. The patent regulations spell out, at length, what is allowed and what is not in respect of national applications:

"(a) Two or more independent and distinct inventions, that is, inventions which do not form a single general inventive concept, may not be claimed in one application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form ... or otherwise include all the limitations of the generic claim.

"(b) A group of claims of different categories in an application so linked as to form a single inventive concept are considered to be one invention. In particular any of the following groupings of claims of different categories may be included in the same application:

(1) in addition to a claim for a given product,

(i) a claim for one process specially adapted for the manufacture of the said product, as where the process of making as claimed cannot be used to make other and materially different products;

(ii) a claim for one use of the said product, as where said use as claimed cannot be practiced with another materially different product; or

(iii) both (b)(1)(i) and (ii);

(2) in addition to a claim for a given process, a claim for one apparatus or means specifically designed for carrying out of the said process, that is, it cannot be used to practice another materially different process.

"(c) If the situation of paragraph (b)(1) of this section exists where claims to all three categories, product, process and use, are included, and the product claims are not allowable, the use and process claims are not so linked as to form a single general inventive concept. Where the process and use claims are not so joined by an allowable linking product claim, the applicant will be required to elect either the use or the process for prosecution with the product claim." (Section 1.141 of the Code of Federal Regulations, Title 37 (Patents, Trademarks and Copyrights) (37 CFR))

E. Comparative Analysis

28. In this analysis, a comparison will be made of the legal provisions and regulations valid under the two treaties and in the eight countries considered. In this comparison, no distinction will be made as to whether a binding rule emanates from the law or from regulations.

29. The analysis will start with a consideration of the general principle and will be followed by a more detailed analysis of the following three topics which would seem to constitute the problem areas:

(i) claims of different categories (paragraphs 36 to 40, below);

(ii) claims of one and the same category (paragraphs 41 to 48, below);

(iii) dependent claims (paragraphs 49 to 52, below).

30. The importance of these three topics is also clearly demonstrated by the fact that both the PCT and the EPC, as well as the laws of the eight countries considered, have dedicated much attention to them.

31. *General Principle.* The essence of the requirement of unity of invention, as such, is that a patent application should claim only one invention or a group of inventions linked by a general inventive concept. The difficult question that arises is what actually constitutes "one invention" or a "general inventive concept."

32. The PCT, the EPC and the legislation of the eight countries all have a general requirement of unity of invention of the nature stated above. The treaties and the legislation establish that general principle and then normally provide for rules and guidelines as to how such principle should be interpreted, construed and applied.

33. Despite all the differences which exist, it seems to be clear that, although the wording of the relevant provisions may differ, a patent application need not, speaking in the numerical sense, relate to "one" invention only but may cover several "inventions" or "objects" that are "linked," "related" or "interdependent." In other words, for the purposes of the requirement of unity of invention, the emphasis is on the term "unity" rather than on "invention." A patent application must relate to a single general (i.e., unified) inventive concept, which may or may not be composed of several inventions each requiring its own category of claim.

34. Hence the efforts made already, both at the international and national levels, on making it clear which types of claims and combinations of claims are allowed. Since both the PCT and the EPC have the same requirements, these will be used as a starting point and a point of reference against which the rules of the other countries will be examined with respect to the three items mentioned in paragraph 29, above.

35. This way of comparing the different legislations offers the additional advantage that four of the eight countries considered (France, Germany (Federal Republic of), Switzerland, United Kingdom), which are parties to both the PCT and the EPC and have their national legislation and practice in line with those treaties and their regulations, or are, as in the case of Switzerland, more liberal, do not need any separate comments and can be considered to have been discussed together with the PCT/EPC.

36. *Claims of Different Categories.* There are basically four different categories of claims, namely, (i) the category of a claim for a product, (ii) the category of a claim for a process, (iii) the category of a claim for a use and (iv) the category of a claim for a means. Since a means can be used for carrying out a process or for carrying out a use of a product, those four categories may lead to five independent claims (e.g., a claim for a new dough, a claim for a process for baking said dough, a claim for the use of said dough for making pastry, a claim for an oven suitable for baking said dough, and a claim for a special utensil to be applied for the use of said dough for making said pastry). Those five independent claims will be identified below by the following letters: A (claim for a product), B (claim for a process for the manufacture of the product), C (claim for a use of the product), D (claim for a means for carrying out the process) and E (claim for a means for carrying out the said use). In D and E, the word "means" has been used rather than the word "apparatus" because the former is broader than, and covers, the latter.

37. Among the laws and treaties considered, only the Japanese and Swiss laws mention explicitly the possibility of including the four categories of independent claims, as referred to in the preceding paragraph, in one application. The PCT and the EPC mention explicitly three combinations of independent claims, two of which comprise a maximum of three independent claims of different categories, namely, the combination "product + process + use" (A + B + C) and the combination "product + process + means for carrying out the process" (A + B + D).

38. As to the laws of the non-EPC countries other than Japan (Canada, Soviet Union, United States of America), the law of the Soviet Union follows the PCT, whereas the laws of Canada and the United States of America seem to have stricter requirements than those provided for in the PCT. Canada specifically mentions only the combination "product + process" (A + B) and the combination "process + means for carrying out the process" (B + D) as fulfulling the requirement of unity of invention, whereas the United States of America does not consider the combination "product + process + means for carrying out the process" (A + B + D) as fulfilling *per se* the said requirement despite the fact that the PCT expressly mentions such combination (see the preceding paragraph) which, therefore, should be allowed at least in international applications (both for the purposes of international search and for the purposes of the national phase of the PCT procedure).

39. Although the above picture—somewhat oversimplified—looks rather simple, the actual situation is not quite so simple. This is due to the fact that both the PCT and the EPC prescribe "minimum" rules. More may be allowed, and the laws of some countries do so, as has been stated. However, other countries interpret the minimum rules in a restrictive way. It is therefore obvious that it is highly desirable to try to reach a uniform system allowing, *expressis verbis*, as fulfilling the requirement of unity of invention, a combination of independent claims of all the four categories (product + process + use + means for carrying out the process). In addition, an independent claim for a means for carrying out a given use may also be included as long as there is a single general inventive concept. As stated in paragraph 36, above, a combination of up to five independent claims (A + B + C + D + E) may have to be allowed. Needless to say, if less is wanted, applicants are free to claim less.

40. Although, for the sake of easier reading, some shorthand expressions like "for the manufacture of the product" or "for carrying out the process" were used in paragraphs 36 to 38, above, it has to be remembered that, in the pertinent (PCT and EPC) rules on permitted combinations, the qualifications "specially adapted" or "specifically designed" appear. These words have caused some confusion since they are interpreted differently in various industrial property offices. Thus, according to the practice in the United States of America (37 CFR 1.141), as interpreted by the United States Patent and Trademark Office, a process is specially adapted to the manufacture of a given product only if, on the one hand, the process is an obvious process of making the product and cannot be used to make other and different products and, on the other hand, the product cannot be made by another process (Paragraph 806.05(f) of the *Manual of Patent Examining Procedure* (MPEP)). In the practice of the European Patent Office, it seems to be sufficient if the product is the result of the process. The words "specially adapted" only imply that the claim for the process specifies technical features which result in the production of the product. The same holds true for the requirements set forth in MPEP, Paragraph 806.05(g), with respect to the relation between "apparatus" and "product made" by the apparatus. The requirement that the product cannot be produced by any other process is not contained in PCT Rule 13.2. Since, moreover, no other country interprets the said PCT Rule in this way, and in order to avoid such different interpretations, it is suggested to delete these qualifications.

41. *Claims of One and the Same Category.* Paragraphs 36 to 40, above, dealt with claims of different categories, namely claims for a product, a process, a use or a means. The claim of any of those categories which appears first in the application is normally an independent claim in that it does not refer back to any other claim.

42. It is possible that an invention, or a group of inventions so linked as to form a single general inventive concept, is of such a nature that it cannot be covered by one single (independent) claim of any of these four categories.

43. An example of such a situation is an invention relating to a new compound which can polymerize to give a new plastic. In such a case, there is a clear justification and need for two independent product claims, namely: (1) a claim for the new compound *per se* and (2) a claim for the new plastic *per se*.

44. To these claims, can of course be added independent process claims (1) for making the new compound and (2) for making the new plastic from the new compound, without violating the requirement of unity of invention.

45. An independent claim for the use of the new plastic as well as an independent claim for a means for carrying out either or both of the processes claimed further constitute inventions so linked with the other(s) as to form a "single inventive concept."

46. It is clear that such claims of the same category, for example, for the new compound *per se* and for the plastic *per se*, cannot be covered under the umbrella of one single claim covering them both (such an umbrella is usually referred to as a "generic claim"). They must remain separate, but their combination in one patent application complies with the requirement of a "single inventive concept."

47. Those cases of claims of the same category have already been recognized and are in fact allowed by PCT Rule 13.3 (see paragraph 8, above), by the EPC Implementing Regulations and by the regulations of the countries party to the EPC. Also Canada, Japan and the United States of America accept this.

48. In addition to the examples given in paragraphs 43 to 45, above, there are other typical combinations of independent

claims of one and the same category which can satisfy the "single inventive concept." Examples of such combinations are: claims for inventions one of which has, as a substantial part of its features, all or a substantial part of the features of the other and serves the same purpose (Law of Japan, Section 38; see paragraph 18, above) (for example, a cutting machine, and a particular form of the blade of the knife used in it); or a claim for a product in combination with a claim for another product solely utilizing the specific properties of said product (Law of Japan, Section 38; see paragraph 18, above) (for example, an insecticidal compound as such, and a product comprising said insecticidal compound in combination with diluent material, which combination is the ready-for-use form in which the insecticide is normally used); or a claim for a product serving as a starting material to produce another product covered by another claim, provided the former product imparts distinguishing features to the latter product (although such a case is not expressly covered by any treaty or law analyzed in this memorandum, it is allowed in the practice of at least the European Patent Office) (for example, a new compound suitable as a starting material for making a new plastic, and that new plastic); or claims for separate products which are interrelated or interdependent and are to be used together (for example, a lock and its key, a weapon and its ammunition, a transmitter and a receiver for a special coded signal, or a special data carrier and a related reading device).

49. *Dependent Claims.* So far, only the so-called "independent claims" have been discussed, namely: the claims of different categories (paragraphs 36 to 40, above) and the claims of one and the same category (paragraphs 41 to 48, above). They are related, since they all go back to one single inventive concept, but they do not refer back, in a subordinate way, to any other claim; they are all, so to speak, of the same rank, hence the term "independent claims." The claims to be studied in the following paragraphs are what one might call subordinate ones, in that they refer, for technical details, back to at least one other claim on which they depend; they are therefore called "dependent claims."

50. Dependent claims are—by their very nature, since they incorporate all the features of the independent claim they refer to—claims for the same invention as that claimed in the independent claim. They are more specific embodiments thereof (for example, if there is an independent claim for a new method for making cast iron, a specific embodiment could be to make said cast iron according to said new method at a temperature within a certain range; in that case, a dependent claim could be drafted for that temperature range). Even if any of their specific features could be considered an invention in itself, still the "single inventive concept" applies. Also, if a dependent claim spells out an additional limiting feature, not expressly referred to in the independent claim, this does not mean that such dependent claim would be for another invention or would not satisfy the "single inventive concept" (for example, if, in the above example of the new method for making cast iron, no reference to temperatures would have been made in the main claim, a dependent claim on said temperature range would nevertheless be permitted).

51. The PCT, the EPC, and the legislation of all the eight countries considered allow dependent claims. As explained above, dependent claims are by definition for the same invention as the independent claim(s) they refer to. They therefore should not present a problem within the context of the requirement of unity of invention.

52. The formal requirements with regard to dependent claims are not considered here, as they are dealt with in document HL/CE/III/2 Supp.1 (see above).

IV. Arguments Against and in Favor of a Uniform Solution

53. The treaties and laws studied reflect a general acceptance of a requirement of unity of invention and a relative consensus as to the meaning of the principle as such. The ambiguities and discrepancies seem to arise when one begins to compare the practice of the industrial property offices. The question, therefore, presents itself whether a uniform international approach and standard for the application of the requirement of unity of invention would be desirable.

54. It is, indeed, well known to the practitioner that there are considerable differences in the interpretation of the "single inventive concept," even under the rules of the PCT, for permissible combinations of claims. Not only do those differences exist amongst the various patent granting authorities but sometimes also amongst individual examiners within one and the same industrial property office. Such different interpretations concern, for example, the combination of independent claims for a composition of products and a constituent part of that composition (for example, the insecticidal compound and the composition containing it together with a diluant; see paragraph 48, above), or for an apparatus and a part thereof, or for a starting material and the final product (for example, the compound and the plastic referred to in paragraph 48, above). Such combinations seem to be usually allowed by the European Patent Office but less often by the United States Patent and Trademark Office. Furthermore, the latter Office is interpreting the possibility of combining claims of different categories, as given under the PCT (see paragraph 40, above), in a different way from other industrial property offices such as the European Patent Office. This just illustrates the discrepancies existing even between systems aligned to the PCT.

55. Therefore, a uniform solution is obviously desirable.

A. Arguments Against

56. The principal reasons for providing for a requirement of unity of invention are fiscal (to prevent applicants from obtaining protection for several inventions by paying a single set of patent fees) and technical (to facilitate search and classification). Some patent offices fear financial losses and complications for search and examination if they have to apply more liberal rules and are of the opinion that a financial loss, if any, which a patent office might suffer as a result of a harmonized rule on unity of invention could lead to a general increase of certain fees. Furthermore, since the application of the requirement of unity of invention is rather technical and depends on objective as well as subjective criteria, it is difficult to arrive at uniformity. Hence, it could be argued that the requirement of unity of invention should be left to national legislation and practice, the more so as it is already difficult to apply it uniformly and consistently within one and the same industrial property office.

B. Arguments in Favor

57. From an international point of view, that is, if an applicant files patent applications for the same invention in several countries and under the PCT or the EPC, the complications that the lack of uniformity in the interpretation and application of the requirement of unity of invention presents to him as the user of the patent system, but also to the offices involved, are obvious.

58. Given the diversity in the approach, standards and terminology of the relevant legislative and treaty provisions, and given also the differences in the practical application of the

general principle of unity of invention, it is already difficult to determine how the requirement is applied under any given law or treaty. Nevertheless, the applicant must draft his application, in particular his claims, in a different manner for each country (and/or under each treaty) where—in respect to his given application—the law or only the actual practice differs in this respect.

59. Furthermore, those interested in obtaining information on corresponding patent applications filed in different countries for the same invention or group of inventions may find such information of limited use or complicated to evaluate if the corresponding applications do not cover the invention or group of inventions in the same way and to the same extent, simply because the countries where they were filed interpreted and applied the requirement of unity of invention in different ways. Moreover, it is important to ensure to the greatest possible extent that all members of a patent family comprise the complete disclosure of all inventions combined in the original application. More and more search files contain only one member of a patent family (in order to reduce the volume of paper and avoid duplication). In addition, more and more references are made to patent family members for language reasons (in order to have an easier access to the technical content of a document cited if it cannot be readily understood without a translation).

60. Public interest favors that patent protection relating to one invention or to one single inventive concept be embodied in one patent. A tendency to require division of applications would increase the number of patents and thus create an additional burden on the public at large. On the other hand, it is to be noted that Article 4G(2) of the Paris Convention for the Protection of Industrial Property allows the voluntary division of an application by the applicant.

61. From an international perspective, a uniform approach and standard for applying the requirement of unity of invention is highly desirable and advantageous, primarily for reasons of simplification and of standardization of the subject matter of claims permissible in a single application.

62. Harmonization is difficult at the international level and even at the national level, within the same office. One should therefore study the possibility to have basic provisions in a treaty, and to supplement them with regulations and in a set of guidelines which would give examples and aim at harmonization of the practical implementation of the treaty provisions. Such guidelines would be the subject of a separate study, to be conducted once the principles for a uniform solution are generally agreed upon.

V. Principles of a Solution

63. A uniform international standard could be formulated in an international treaty and in regulations under that treaty along the lines of the following principles:

Treaty

Article 105

"(1) An application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention').

"(2) The requirement of unity of invention shall be construed as permitting the inclusion in the same application:

(i) of claims of different categories, to the extent prescribed in the Regulations;

(ii) of claims of the same category, to the extent prescribed in the Regulations;

(iii) of dependent claims and of multiple dependent claims, even where the features of a dependent claim or of a multiple dependent claim constitute in themselves an invention.

"(3) Failure to comply with the requirement of unity of invention shall not be a ground for invalidation or revocation of a patent."

Regulations under the Treaty

Rule relating to Article 105

"(1) The requirement of unity of invention shall be deemed to be complied with where the following combinations of claims of different categories are included in the same application:

(i) the combination of an independent claim for a given product with:

(a) an independent claim for a process for, or also for, the manufacture of the said product (combination A + B);

(b) an independent claim for a use of the said product (combination A + C);

(c) an independent claim for a process for, or also for, the manufacture of the said product, and an independent claim for a use of the said product (combination A + B + C);

(d) an independent claim for a process for, or also for, the manufacture of the said product, and an independent claim for a means for, or also for, carrying out the said process (combination A + B + D);

(e) an independent claim for a process for, or also for, the manufacture of the said product, an independent claim for a means for, or also for, carrying out the said process, and an independent claim for a use of the said product (combination A + B + D + C);

(ii) the combination of an independent claim for a given process with an independent claim for a means for, or also for, carrying out the said process (combination B + D).

"(2) If the requirement of unity of invention is complied with in a given case, the following combinations, in particular, of claims of different categories can be included in the same application:

(i) the combination of an independent claim for a given product with:

(a) an independent claim for a use of the said product, and an independent claim for a means for, or also for, carrying out the said use (combination A + C + E);

(b) an independent claim for a process for, or also for, the manufacture of the said product, an independent claim for a use of the said product, and an independent claim for a means for, or also for, carrying out the said use (combination A + B + C + E);

(c) an independent claim for a process for, or also for, the manufacture of the said product, an independent claim for a means for, or also for, carrying out the said process, an independent claim for a use of the said product, and an independent claim for a means for, or also for, carrying out the said use (combination A + B + D + C + E);

(ii) the combination of an independent claim for a use of a product with an independent claim for a means for, or also for, carrying out the said use (combination C + E).

"(3) The order in which the claims appear in any of the combinations referred to in paragraph (1) or paragraph (2)

may be different from the order used in those paragraphs.

"(4) If the requirement of unity of invention is complied with in a given case, claims of the same category can be included in the same application.

"(5) Guidelines in respect of the requirement of unity of invention shall be laid down in Guidelines Concerning Unity of Invention."

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III. PRIOR ART EFFECT OF PREVIOUSLY FILED BUT YET UNPUBLISHED PATENT APPLICATIONS (HL/CE/III/2 Supp.3)

Memorandum by the International Bureau of WIPO

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I. Introduction

1. It is generally recognized that patents[1] are granted only for inventions that are new and involve an inventive step. An invention is considered new if it does not form part of the state of the art; it is considered to involve an inventive step if, having regard to the state of the art, it would not have been obvious to a person having ordinary skill in the art. In other words, the novelty and inventive step of an invention are determined with respect to what is comprised in the state of the art.

2. As a general rule, the state of the art consists of everything disclosed to the public before a specified date. This date is, under the laws of the overwhelming majority of countries, the filing date or (where applicable) the priority date of the application claiming the invention under examination. However, with respect to certain elements of the state of the art, under the laws of three countries (Canada, Philippines, United States of America), this date is the date of the invention.

3. Thus, establishing what elements form part of the state of the art is essential in determining the patentability (novelty and inventive step) of an invention. Consequently, modern patent laws usually define expressly what matter is to be included in the state of the art and determine the relevant date for such inclusion.

4. This memorandum deals with one possible element of the state of the art, namely, the contents of patent applications which benefit from a filing or a priority date that is earlier, and which are published later, than the filing or priority date of the patent application under examination. Such patent applications will be referred to hereinafter as "previously filed but yet unpublished patent applications."

5. Normally, the state of the art is comprised of anything published in printed form or otherwise disclosed to the public, orally or by use, as of the date the information is made available to the public. Moreover, under many modern laws, the state of the art also comprises the contents (or, depending on the particular law, only the claims) of patent applications whose filing or, if applicable, priority date is earlier than the filing or, where applicable, priority date of the application under examination (or, depending on the particular law, is earlier than the date of invention of the invention therein claimed), on the condition, however—and this is essential—that the contents of the former application are published[2] subsequently, either as such (i.e., as an application) or in the form of a granted patent. Another way of stating this rule is that, for purposes of determining what constitutes the state of the art, published applications (or patents) are antedated to a date that is earlier than their actual date of publication (i.e., the filing or, if applicable, priority date). With the exception of the German Democratic Republic and the United States of America, the laws of the countries covered by this memorandum which provide for the prior art effect of previously filed but yet unpublished applications apply this effect only for purposes of evaluating novelty, but not in respect of inventive step because the requirement of inventive step is considered to be too demanding in relation to the contents of not yet published patent applications which normally are not known to an inventor.

6. The principal question examined in this memorandum is whether, under any given law, the contents of previously filed but yet unpublished patent applications are considered to form part of the state of the art and, if so, on which date the contents of patent applications enter the state of the art. Depending on the particular law, this can be their actual filing date in the country, regardless of whether or not the application has an earlier priority date; or it can be their priority date, if applicable. The effect that the contents of a previously filed but yet unpublished patent application enter the state of the art is called "prior art effect" of the application. The term "prior art" is used, under the Patent Cooperation Treaty (PCT) and some national laws, as synonymous with "state of the art" and is used in this memorandum except where legislative texts use the term "state of the art."

7. Two further questions are also examined in this memorandum with respect to which the laws show some disparity: whether the whole contents, or only the claims, of previously filed but yet unpublished patent applications are taken into

[1] In this memorandum, "patents" is meant to include patents for invention as well as inventors' certificates (see Article 2(i) of the draft Treaty contained in document HL/CE/III/2, which is not reproduced here).

[2] "Published" is understood in this memorandum as made available to the public by reason of an official act of the industrial property office whereby the application is made available to the public, whether that be prior to or by reason of the grant of a patent on that application and whether the public access to the application or the patent was achieved by a printed publication or through laying it open for public inspection.

account as prior art; and whether they are to be taken into account only in respect of determining novelty or also inventive step. The solution of only taking into account the claims hereinafter is, following the usual terminology, referred to as "prior claim approach."

II. Purpose of the Memorandum

8. The purpose of this memorandum is to examine the existing provisions, under the laws of certain selected countries and under the Patent Cooperation Treaty (PCT) and the European Patent Convention (EPC), in respect of the prior art effect of previously filed but yet unpublished patent applications. The memorandum compares the relevant provisions and points out some of the problems that arise as a result of differences among the national laws and the PCT and the EPC in this regard, particularly at the international level. Finally, it explores the possibility of finding a uniform solution to the question, which could easily be applied by national and regional industrial property offices and which would have the advantage that patent applicants would no longer be confronted with different rules regarding the prior art effect of previously filed but yet unpublished patent applications.

III. Existing Legislative Provisions

A. Information Used in the Present Memorandum

9. Before exploring any uniform solutions, the existing rules concerning the prior art effect of previously filed but yet unpublished patent applications will be examined. While recognizing that rules may be found in the legislation of a great number of countries, the present memorandum, in view of the great amount of material involved, covers only the laws of some of them, selected on the basis of statistical criteria. Thus, the following information has been taken into account:

(i) the provisions of the Patent Cooperation Treaty (PCT);

(ii) the provisions of the European Patent Convention (EPC) and of the legislation of those 18 countries in which or for which, according to the statistics published by WIPO (IP/STAT/1984/A), more than 4,000 titles of protection for inventions were granted in 1984. Those countries are Australia (7,252), Austria (8,565), Brazil (4,887), Canada (20,545), Czechoslovakia (6,601), France (23,666), German Democratic Republic (11,544), Germany (Federal Republic of) (21,758), Greece (9,153), Japan (61,800), the Netherlands (10,257), Poland (4,185), the Soviet Union (62,907), Spain (8,213), Sweden (11,670), Switzerland (13,977), the United Kingdom (18,867) and the United States of America (67,201). The figures in parenthesis following the names of all States except the Soviet Union indicate the number of patents granted in 1984; the figure concerning the Soviet Union represents the total number of patents and of inventors' certificates granted in 1984.

10. The present memorandum is mainly based on legislative provisions (treaties, laws, regulations, etc.). Unless otherwise indicated, such as in the case of the United States of America where it is difficult to understand the question under examination without considering applicable court decisions, the present memorandum does not take into account the interpretation given to legislative provisions by courts and industrial property offices or the practice of industrial property offices. The present memorandum only presents a short summary of the said provisions.

B. The Patent Cooperation Treaty (PCT)

11. Under the PCT, each international application filed pursuant thereto is subject to what is called an "international search," which results in an "international search report." The objective of an international search is to discover "relevant prior art," namely, prior art which may affect the patentability of the invention claimed in the international application (Article 15). Rule 33.1 of the Regulations under the PCT defines what constitutes relevant prior art for the purposes of international search and, in addition, in paragraph (c), provides that any published application or any patent whose publication date is later but whose filing date, or, where applicable, claimed priority date, is earlier than the international filing date of the international application searched, and which would constitute relevant prior art for the purposes of the international search had it been published prior to the international filing date, must be specially mentioned in the international search report. It should be noted that Rule 33.1(c) does not as such define previously filed but yet unpublished applications as prior art; it just states that such applications must be mentioned in the international search report.

12. In general, the applicant of an international application under the PCT can request an "international preliminary examination report," which gives an opinion on the questions whether the claimed invention appears to be novel, to involve an inventive step and to be industrially applicable; for such purposes, a claimed invention is considered novel if it is not anticipated by the prior art, and the prior art has to be taken into account for the evaluation of the inventive step (Articles 31, 33 and 35 PCT). In this connection, Rule 64.1 of the Regulations under the PCT contains a definition of prior art. Furthermore, Rule 64.3 provides that, in cases where any application or any patent which would constitute prior art had it been published prior to the filing or priority date of the international application under examination was published, as such, after that date but was filed earlier than such date or claimed the priority of an earlier application which had been filed prior to such date, such published application or patent is not to be considered part of the prior art; nevertheless, the international preliminary examination report must call attention to such application or patent.

13. On the basis of the international search report and, where applicable, the international preliminary examination report, the national offices then apply the standards of their respective national laws in order to determine the patentability of the invention claimed in the international application. The PCT does not, however, impose on the Contracting States what those standards should be. In fact, the PCT expressly states that "... any Contracting State is free to apply, when determining the patentability of an invention claimed in an international application, the criteria of its national law in respect of prior art and other conditions of patentability not constituting requirements as to the form and contents of applications" (Article 27(5) PCT).

14. The PCT does, however, set certain requirements concerning the recognition of the international filing date. These requirements also concern the prior art effect of a previously filed but yet unpublished international application. Article 11(3) PCT provides that, subject to the reservation under Article 64(4), Contracting States must consider international applications which fulfill the requirements for granting an international filing date and thus are accorded such a date to have the effect of a regular national application in each designated State as of the international filing date, which date must be considered to be the actual filing date in each designated State.

15. However, Article 64(4) PCT provides for a possibility of a reservation, which reads as follows: "Any State whose national law provides for prior art effect of its patents as from a date before publication, but does not equate for prior art purposes the priority date claimed under the Paris Convention for the Protection of Industrial Property to the actual filing date in that State, may declare that the filing outside that State of an international application designating that State is not equated to an actual filing in that State for prior art purposes." Any State making such a declaration is, to that extent, not bound by the provisions of Article 11(3) PCT. The United States of America is the only PCT Contracting State which has made such a declaration.

C. European Patent Convention and National Legislation

16. *European Patent Convention (EPC).* Pursuant to Article 54(3) EPC, in connection with Article 89, the content of European patent applications as filed, of which the priority dates are prior to the priority date of the European patent application under consideration, and which were published after that date, is comprised in the state of the art. However, according to Article 56 EPC, this provision does not apply in determining inventive step; it only applies in determining novelty. It is to be noted that Article 54(3) applies only insofar as a Contracting State is designated in respect of both applications (Article 54(4)). As regards international applications under the PCT, designating one or more Contracting States of the EPC with an indication of the wish to obtain a European patent, these are considered as comprised in the state of the art only if the conditions for entry into the national phase are fulfilled (i.e., the international applications must be submitted to the EPO in one of its official languages and the national fee must be paid to the EPO) (Article 158).

17. *Australia.* Section 100(1)(f) of the Patents Act of 1952, as amended up to 1982, provides that a patent may be revoked on the ground that the invention, so far as claimed in any claim of the complete specification, is subject of a valid claim of an earlier priority date contained in the complete specification of a standard patent or in the petty patent specification of a petty patent. Thus, there is no prior art effect of the whole contents of previously filed but yet unpublished patent applications but only the effect that a patent is not valid if it has been granted for what has been validly claimed in a prior application or in an application benefiting from an earlier priority date.

18. *Austria.* The Patents Act of 1970, as amended in 1984, provides in its Section 48(1) that a patent is to be declared null and void if the invention is the subject matter of a patent belonging to a prior applicant. Thus, there is no prior art effect of the whole contents of previously filed but yet unpublished patent applications but only a prior art effect of the claims of such applications.

19. *Brazil.* Section 6 of the Industrial Property Code of 1971 defines prior art as anything made available to the public, including the contents of patents in Brazil and abroad. There is no prior art effect of previously filed but yet unpublished patent applications. Section 55 only provides that a patent is null where the grant prejudices rights of third parties.

20. *Canada.* The Patent Act of 1952, as amended in 1972, does not contain any provision dealing with the prior art effect of previously filed but yet unpublished patent applications. Section 45 deals with conflicting patent applications in the situation where the claims of concurrent applications are so nearly identical that separate patents cannot be granted thereon but the subject matter of the claims would be patentable if examined with reference to the prior art. In such cases, the patent is to be granted to the "prior inventor." According to Section 45, a conflict also exists when one or more claims of one application describe the invention disclosed in another pending application.

21. *Czechoslovakia.* The Law on Discoveries, Inventions, Rationalization Proposals and Industrial Designs of 1972 does not address the question of the prior art effect of previously filed but yet unpublished patent applications.

22. *France.* Sections 8(3) and 15(5) of the Patent Law of 1968, as last amended and supplemented in 1984, provide that the content of French patent applications and of European or international patent applications which designate France, as filed, of which the filing or priority dates are prior to the filing or priority date of the patent application under examination and which were published on or after that date, are considered as comprised in the state of the art. Such documents are not to be considered in deciding whether there has been an inventive step (Section 10).

23. *German Democratic Republic.* According to Section 5(2) of the Law of 1983 on the Legal Protection of Inventions (Patent Law), technical solutions are not regarded as new if, before the day of filing of the patent application, the same solution has already been the subject of a patent application filed with the Office of Inventions and Patents, which results in the grant of a patent. It appears that, according to the interpretation given to this provision, the whole contents of the previously filed application are to be considered as a bar to novelty and inventive step as from the filing date or, where priority is claimed, from the priority date.

24. *Germany (Federal Republic of).* According to Section 3(2) of the Patent Law of 1981, the content of the following patent applications, which have an earlier priority and which were published only on or after the date relevant for the priority of the application under examination, are considered as comprised in the state of the art: (i) national applications, as originally filed with the German Patent Office; (ii) European applications, as originally filed with the competent authority, seeking protection in the Federal Republic of Germany, unless the European patent application is based on an international application under the PCT and the conditions for entry into the national phase before the EPO have not been fulfilled (see last sentence of paragraph 16, above); (iii) international applications under the PCT, as originally filed with the receiving Office, where the German Patent Office is a designated Office with respect to the application but only if the conditions for entry into the national phase are fulfilled (i.e., the application fee must be duly paid and, if the application is not in German, a translation into German must be filed) (Law on International Patent Treaties of 1976, Article III 8(3)). If the priority of an application is based on a claim of priority of an earlier application, those rules are only applicable to the extent that the contents of the application in question do not exceed the contents of the earlier application. The aforementioned documents are not to be considered in deciding whether there has been an inventive step (Section 4).

25. *Greece.* The Law on Patents of Inventions of 1920 does not provide for a prior art effect of previously filed but yet unpublished patent applications.

26. *Japan.* Pursuant to Section 29*bis* of the Patent Law of 1959, as amended in 1985, if an invention claimed in a patent application is identical with an invention or device (not made by the inventor of the invention claimed in the patent application) that has been described in the specification or drawings of another application for a patent or for a utility model registration (a specification, under Section 36, meaning claims and

description) and where such other application was filed earlier than the patent application concerned and was published or laid open for public inspection after the filing of the patent application concerned, a patent shall not be granted for the first-mentioned invention. However, this provision does not apply where, at the time of filing of the patent application, the applicant in this and in the other earlier application is one and the same person. Section 29*bis* appears to be interpreted to the effect that, for purposes thereof, earlier unpublished applications are taken into consideration as of their priority date. Where the earlier application is an international patent application without a priority, Section 29*bis* expressly provides that such application is a bar to patentability as of its "international filing date."

27. Section 29*bis* is applied for the purpose of determining novelty. Furthermore, when the invention claimed in the latter application is identical with the invention which is described in the specification or claim of the former application, the earlier application is a bar to the grant of a patent on the later application.

28. *Netherlands.* According to Sections 2(3) and 7(4) of the Patents Act of 1910, as last amended in 1978, the state of the art comprises the content of applications with an earlier filing or priority date than the application under examination, which were laid open to public inspection on or after such filing or priority date. It also comprises the content of European patent applications or of international applications whose filing, priority or international filing date, as the case may be, is prior to the filing or priority date of the application under examination and which have been published on or after that date, provided that the Netherlands has been designated and, in case of an international application under the PCT, designating the Netherlands for a national patent or a European patent, the applicant has fulfilled the conditions for entry into the national phase (Section 2(4)). Those provisions do not apply for purposes of determining obviousness (Section 2A(2)).

29. *Poland.* The Law on Inventive Activity of 1972, as amended in 1984, does not contain any provision dealing with the prior art effect of previously filed but yet unpublished patent applications.

30. *Soviet Union.* Pursuant to Section 1.08 of the Guidelines on State Scientific and Technical Examination of 1974 (EZ-2-74), when determining the novelty of a claimed invention, the following is to be considered as being in the state of the art: (i) earlier filed applications for which the State Committee has decided to grant an inventor's certificate or a patent but which have not yet been published—from their internal priority date; and (ii) earlier filed applications with an "established" Convention priority for which a decision has been taken to grant a title of protection—from the Convention priority date.

31. *Spain.* Section 6(3) of the Patents Law of 1986 provides that prior art includes the contents of Spanish applications for patents and for utility models, as originally filed, whose filing or priority date (see Section 28(3)) is earlier than that of the application under examination and which are published on that or a later date. Such applications are to be taken into account for purposes of determining novelty (Section 6), but not for purposes of evaluating inventive step (Section 8).

32. *Sweden.* Pursuant to Sections 2 and 6 of the Patents Act of 1967, as amended in 1983, the contents of a patent application filed in the country, with an earlier filing or priority date than the filing or priority date of the application under examination, are to be considered as known, if the former application becomes available to the public pursuant to its being laid open. The condition that the invention must differ essentially from what was known before does not, however, apply in respect of the contents of such an application.

33. For purposes of applying the above rule, international patent applications under the PCT, designating Sweden for a national patent, which are accorded an international filing date have the same effect as applications filed in Sweden on the same day, provided that the conditions for entry into the national phase are fulfilled (submission of the prescribed translation or copy of the application and payment of the prescribed fee) and the application has been laid open to the public by the Swedish Patent Office (Sections 29 and 31). European patent applications which have been accorded a filing date by the EPO or international applications under the PCT designating Sweden for a European patent which have been accorded an international filing date have the same effect as applications filed in Sweden on the said date, provided that they have been published by the EPO or by the International Bureau of WIPO, if that publication by the International Bureau is equivalent to publication by the EPO pursuant to Article 93 of the EPC (Section 87).

34. *Switzerland.* Section 7a of the Federal Law on Patents for Inventions of 1954, as revised in 1976, provides that an invention is not deemed to be new if, while not included in the state of the art, it is the subject of a valid patent granted in respect of Switzerland as a result of a prior filing, or enjoying earlier priority. In other words, Swiss law recognizes the prior art effect of previously filed patent applications as of their priority date but only for purposes of determining novelty, not inventive step. On the other hand, in contrast to the EPC and most other laws under examination, only the claims (not the description) are taken into account (see Article 139 of the EPC).

35. *United Kingdom.* Pursuant to Section 2(3) of the Patents Act of 1977, the state of the art in the case of an invention to which a patent application or a patent relates comprises matter contained in an application for another patent which was published on or after the priority date of that invention, if the following conditions are satisfied: (a) that matter was contained in the application for that other patent both as filed and as published; and (b) the priority date of that matter is earlier than that of the invention.

36. An application for a European patent designating the United Kingdom and having a filing or priority date under the EPC is treated as an application for a patent under the Patents Act having that date as its filing or priority date (Section 78(1)). An international application for a patent designating the United Kingdom for which a filing or priority date has been accorded (whether by the Patent Office or by any other body) under the PCT is treated as an application for a patent under the Patents Act having that date as its filing or priority date, but such an application is treated as published for the purposes referred to in paragraph 35 only if the conditions specified for entry into the national phase have been met; where the application is not in English, a translation into English must have been filed (Section 89). Similarly, an international application for a European patent designating the United Kingdom is so treated only if it has entered the regional phase and a copy of the application in English, French or German has been supplied to the EPO (Section 79(2)).

37. Previously filed but yet unpublished patent applications are not to be taken into account for purposes of determining inventive step (Section 3).

38. *United States of America.* According to Section 102(e) of Title 35 (Patents) of the United States Code, a patent cannot

be granted for an invention which was described in a patent granted on an application filed by another in the United States of America before the invention thereof by the applicant, or on an international application by another who has fulfilled certain specified requirements (see paragraph 41, below) before the invention thereof by the applicant. The aforementioned provision constitutes a condition of patentability without any distinction as to whether it is to be applied for purposes of determining novelty or inventive step (Sections 102(e) and 103). The whole contents (claims and description) of previously filed applications are taken into account.

39. However, special attention should be drawn to two particular aspects of the law of the United States of America. First, in order for a previously filed but yet unpublished patent application to be included in the state of the art to be examined with respect to another application, it must have been filed in the United States of America before the making of the invention claimed in the application under examination. As regards inventions made in the United States of America, the date of invention is established by reference to knowledge or use or other activity in the country. Therefore, this date can be much earlier than the filing date of the application for the grant of a patent for that invention. On the other hand, as regards inventions made abroad, the date of invention cannot be established by reference to knowledge or use or activity in a foreign country (Section 104). Therefore, for an application under examination claiming an invention made abroad, the effective date of invention is usually the foreign priority date of the application for the grant of a patent for that invention, correspondingly, a date that is later than the actual date of invention.

40. The second important aspect of the law of the United States of America is that the prior art effect of previously filed but yet unpublished patent applications takes place only as of their filing date in the United States of America and not their priority date. In other words, the effective date of reference for purposes of Section 102(e) is the actual date of filing in the United States of America. This is so, although Section 119 provides that an application validly claiming the priority of an earlier foreign filing has the same effect as the application would have had if it had been filed in the United States of America on the priority date, since Section 102(e) is applied independently of Section 119. This literal interpretation of Section 102(e) was reaffirmed *In re Hilmer* (149 U.S.P.Q. 480 (1966)). In the said decision, the Court of Customs and Patent Appeals distinguished the situation where a prior application is used as a prior art reference under Section 102(e), in which case the time of the application's prior art effect must be the actual filing date in the United States of America, and the situation where a prior application is involved in a priority contest with a subsequent application, in which case the prior application can benefit from its priority date based on an earlier filing in another country. The benefits of an earlier filing date in another country can be invoked under Section 119 in a priority contest with a subsequent application or, also, as a defense against events which would prevent patenting, such as a publication during the priority period, i.e., after the earlier filing date in another country. However, Section 119 cannot be invoked for purposes of determining the effective date for prior art purposes of a previously filed application. The Court stated that the prior art effect of previously filed applications is taken into account as of "the actual filing date when the disclosure is on deposit in the United States Patent and Trademark Office and on its way, in due course, to publication in an issued patent."

41. As regards international applications under the PCT, the international filing date is not equated, for prior art effect purposes, to a filing date in the United States of America. An international application has a prior art effect in the United States of America as of the date on which the following elements are submitted to the United States Patent and Trademark Office: the prescribed national fee, a copy of the international application (unless not required), a translation into English of the application if the latter was filed in another language, and an oath or declaration (Sections 102(e) and 371(c)(1), (2) and (4)). These requirements are stricter than those which must be fulfilled in order to obtain a filing date in the United States of America for a national application (for information concerning requirements for granting a filing date under the law of the United States of America, see document HL/CE/II/2 Supp.1, above).

D. Comparative Analysis

42. The relevant provisions of the PCT are to be distinguished from those of the EPC and the national legislation covered in this memorandum because the PCT establishes a centralized (and, therefore, uniform) system for the initial phase of the processing of patent applications filed pursuant thereto ("international applications"). For that purpose, and specifically for purposes of the international search and of the international preliminary examination, it defines "prior art" in Rules 33.1 and 64.1 under the PCT. Although the PCT does not actually prescribe that previously filed but yet unpublished patent applications are to be treated as prior art, Rules 33.1(c) and 64.3 do require that such documents be mentioned in the international search report and that any international preliminary examination report call attention to such documents. The definition of prior art in Rules 33.1 and 64.1 is not binding on the Contracting States. On the contrary, in its Article 27(5), the PCT expressly leaves the "definition of prior art" and the determination of the "patentability of an invention claimed in an international application" to national law.

43. As regards the prior art effect of international applications, each Contracting State, unless it makes a declaration under Article 64(4), gives to international applications under the PCT the effect of a regular national application as of the international filing date (Article 11(3)) (see, however, paragraph 47, below).

44. The EPC and the laws of France, the German Democratic Republic, Germany (Federal Republic of), Japan, the Netherlands, the Soviet Union, Spain, Sweden, the United Kingdom and the United States of America recognize the prior art effect of the whole contents of previously filed but yet unpublished patent applications. On the other hand, the laws of Australia, Austria, Brazil, Canada, Czechoslovakia, Greece, Poland and Switzerland, even though some of them provide for the prior claim approach, do not provide for a prior art effect of the whole contents of previously filed but yet unpublished patent applications.

45. In countries where a previously filed but yet unpublished patent application constitutes prior art, it does so on the condition that it eventually is published; in other words, such application must physically become prior art at a later stage.[3] In effect, what the relevant legislative provisions do is that they establish a legal fiction whereby, for prior art effect purposes, the relevant date of published applications or patents is antedated to a date earlier than their actual date of publication.

46. The prior art effect of applications, however, occurs with certain limitations. Previously filed but yet unpublished

[3] For the Soviet Union, the condition is formulated somewhat differently. In order for an application to have a prior art effect, a decision must have been taken to grant a title of protection thereon, the consequence being the publication of the contents of the application in the form of the title of protection applied for.

patent applications do not become prior art in the same way as they do after their date of publication. For purposes of comparison, two important distinctions can be identified among the relevant provisions. The first distinction concerns the date as of which the prior art effect occurs (i.e., the priority date or the actual filing date in the country). The second distinction concerns the purpose of the prior art effect (i.e., for purposes of determining only novelty or also inventive step).

47. As regards the first distinction, under the EPC and the laws of all the countries examined herein that recognize the prior art effect of previously filed but yet unpublished patent applications, except for the United States of America, such patent applications are considered prior art as of their priority date, if any priority is claimed. In the case of international applications under the PCT, the international filing date or, if priority is claimed, the filing date of the earlier application, is recognized by the EPC and the laws of some EPC Contracting States as the prior art effective date only if, in addition to international publication, the conditions for entry into the national phase are fulfilled, i.e., only if the national fee is paid and the translation of the international application, where required, is furnished. Under the law of the United States of America, as interpreted by the United States Patent and Trademark Office and the courts, the prior art effect of previously filed but yet unpublished patent applications takes place only as of the actual filing date in the United States of America, even if a priority based on an earlier foreign filing is claimed; in the case of international applications filed under the PCT, such date is the date on which certain specified requirements are satisfied (see paragraph 41, above).

48. As regards the second distinction, under the EPC and the laws of most of the countries examined and which recognize the prior art effect of previously filed but yet unpublished patent applications, such prior art effect is recognized for purposes of determining novelty, not inventive step. Under the laws of the German Democratic Republic and the United States of America, there is no such restriction.

IV. Arguments in Favor of a Uniform Solution

49. The diversity of rules provided for under national legislation and the EPC regarding the prior art effect of previously filed but yet unpublished patent applications constitutes a serious difficulty for the users of the patent system when they wish to apply for patents in several countries, whether under the PCT or through national routes.

50. If the rules defining the scope of the prior art differ in various countries, then what is patentable and the protection granted for the same invention may not be the same in all countries. This can be a handicap for international trade and the transfer of technology.

51. The law of the United States of America raises additional questions. Foreign applicants who wish to establish the effective date for prior art purposes of their applications in the United States of America (i.e., the date as of which their applications will enter the state of the art) cannot rely on their foreign priority date. For such purposes, they must rush to file in the United States of America in order to obtain as early a filing date in that country as possible, since the contents of their applications will constitute prior art against any other applications only as of that date. In the reverse situation, applicants from the United States of America can rely on their filing date in the United States of America, which is the priority date in the other countries party to the Paris Convention for the Protection of Industrial Property, as the date on which the contents of the application become prior art under the EPC and in all the countries covered in this memorandum that recognize the prior art effect of previously filed but yet unpublished applications. However, under the EPC and the laws of those other countries (except the German Democratic Republic), the application in the United States of America, in such a case, can be used as a prior art reference only to challenge the novelty and not the inventive step of the invention claimed in a later application.

52. Filing an international application under the PCT does not avoid the above problem; moreover, it delays the prior art effect even further. When using the PCT and having designated the United States of America as a State for which protection is desired, applicants likewise cannot rely, if priority is claimed, on the priority date as the date on which the contents of their international applications become prior art in the United States of America. But they cannot even rely on their international filing date, as the prior art effect for an international application is only obtained once requirements to which even national applications are not subject are fulfilled (see paragraph 41, above). Although this legal situation is permitted by the PCT because of the declaration under Article 64(4) PCT which the United States of America has made, the result is not in line with one of the basic principles of the PCT, namely, that international applications which are accorded an international filing date are equivalent to regular national applications as of that date.

53. Thus it is proposed to solve the above problems by establishing the rule that the whole contents of an application constitute prior art, for the purpose of determining the novelty of an invention claimed in another application, from the filing or validly claimed priority date, to the extent that the former application or the patent granted thereon is published subsequently.

54. It is suggested not to include in the proposed solution the requirement, contained in the EPC and some national laws (see paragraph 47, above), that the conditions for entry into the national phase must be fulfilled for an international application under the PCT to obtain a prior art effect as of the international filing date or, if priority is claimed, the filing date of the earlier application. Firstly, the condition that a translation must be furnished and, even more, that a fee must be paid, is not consistent with the concept of prior art, according to which technological information becomes prior art by mere publication, irrespective of the language of publication and of the payment of any fee. Secondly, the said requirement is not in line with one of the basic principles of the PCT, namely, that international applications which are accorded an international filing date are equivalent to regular national applications as of that date.

V. Principles of a Solution

55. The principles of a solution to be embodied in an international treaty could be drafted as follows:

> "(1) The whole contents of an application as filed in, or with effect for, a Contracting State shall, for the sole purpose of determining the novelty, but not the inventive step, of an invention claimed in another application filed in, or with effect for, that State, be considered under the national law applicable in the said State as prior art from the date on which the former application was filed or, to the extent priority is validly claimed, from the priority date for matter contained in both the former application and the application on which the priority claim is based, to the extent that the former application or the patent granted thereon is published subsequently.

"(2) For the purposes of paragraph (1), 'published' shall mean any first act of making available of the application to the public by reason of an official act, including any making available of the application to the public for purposes of public inspection without reproduction of the application, whether such act occurs prior to or by reason of the grant of a patent on that application.

"(3) For the purposes of paragraph (1), 'whole contents' of an application shall refer to the description and any drawings, as well as the claims, but not to the abstract.

"(4) Paragraph (1) shall not apply to applications which were withdrawn prior to their publication but which were nevertheless published.

["(5) Paragraph (1) shall not apply when the applicant of the former application and the applicant of the application under examination is one and the same person."]

* * *

IV. EXTENSION OF PATENT PROTECTION OF A PROCESS TO THE PRODUCTS OBTAINED BY THAT PROCESS; PROOF OF INFRINGEMENT OF A PROCESS PATENT

(HL/CE/III/2 Supp. 4)

Memorandum by the International Bureau of WIPO

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I. Introduction

1. This memorandum deals with a special category of inventions, namely, inventions that consist of, or that relate to, processes (hereinafter referred to as "process inventions"). It is generally recognized that a process, if it complies with the conditions of patentability of inventions, can be protected by a patent.[1] A "process" typically is a technical solution consisting of a series of steps, and the result of a process may be a product.[2] Processes may be of a chemical nature, leading to chemical compounds, or may belong to other fields of technology (for example, mechanical engineering, nuclear technology, microbiology, etc.). Several different processes may be used, one after the other, in order to produce a product; therefore, a "product" may also be an intermediate form of a product. Moreover, processes may effect the transformation or finishing of existing products (for example, the painting, drying, etc., of a product). In addition to processes that produce products, there also exist processes that have other technical effects, such as the creation of energy, heat, sounds, etc., the analysis of substances or the measuring of temperature, etc. For the purposes of this memorandum, however, only processes that result in products are to be considered, and the expression "process invention," unless otherwise stated, hereinafter is used only for such particular processes.

2. As regards patents for process inventions (hereinafter referred to as "process patents"), two questions arise which are examined in this memorandum.

3. The first question concerns the definition of the exclusive right conferred by a process patent. In a number of countries (however with important exceptions), the exclusive right of the owner of a process patent not only covers the use of the process but also—in respect of a product obtained directly by means of the patented process—certain acts which are protected under a product patent, typically the acts of importing, offering for sale, selling and using the product.[3] This broad definition of the exclusive right conferred by a process patent is meant when this memorandum speaks of "extension of patent protection of a process to the products obtained by that process." The extension seems to be an exception to the principle that the protection conferred by a patent for an invention is defined by the object of the invention. In the case of a process invention, a strict application of the said principle would mean that the owner of a process patent could only exclude others from using the patented process. The legal provisions which extend process protection to products obtained by the patented process are based on practical economic considerations. A process which leads to a specific product presents an economic value only through the product. However, it is not always possible to obtain a patent for the product; for example, the product may not be new or may—although new—lack inventive step. The invention of a new and inventive process for the production of such a product which is not patentable constitutes an important technological advance but the reward granted through a process patent is not important because—without an extension to the product—the process patent would be difficult to enforce (since infringement of the process is difficult to prove) and could even be circumvented by use of the process in another country and sale of the products produced in the country where the process is protected. In order to make patent protection of a process meaningful, it is therefore necessary to consider the patented process and the resulting product as a whole, with the consequence that process protection is automatically extended to the resulting product even if the said product has not been claimed. Relevant legal provisions are considered in Part III of this memorandum (see paragraphs 6 to 53, below).

4. The second question concerns the proof of infringement of a process patent. Whereas the infringement of a product patent normally is proven by the fact that the infringing product is imported or offered for sale, difficulties arise with respect to the proof of the infringement of a process patent, whether or not the process results in a product. The use of the patented process by a competitor typically does not take place in public. Normally, information on such use is available only through an inspection of the premises of the competitor or

[1] In this memorandum, "patents" mean both patents for inventions and inventors' certificates, and the expression "patented" is used in this sense.

[2] See Model Law for Developing Countries on Inventions (hereinafter referred to as the "WIPO Model Law"), Commentary e. on Section 112.

[3] See Section 135(2) of the WIPO Model Law.

through witnesses, for example, employees of the competitor who are involved in the use of the patented process. Where the patented process is a process producing a product, the importation or offering for sale of the said product cannot as such be considered as proof of the use of the process since another process may have been used for producing the product. For these reasons, infringement of a process patent frequently cannot be pursued because the plaintiff[4] cannot prove use of the patented process. In order to overcome this problem, the laws of some countries provide that, where a patent relates to a process for obtaining a new product, the same product, when produced by any other party (the defendant[4]) is deemed to have been obtained by the patented process, unless that other party can prove the contrary. This provision amounts to a reversal of the usual burden of proof (which is that the plaintiff has to prove the existence of an infringement): where the product is the same, the plaintiff is relieved from proving the use of the patented process by the defendant; instead, the defendant must prove that the product was obtained by a process other than the patented process and, consequently, *not* by the patented process. Relevant legal provisions will be considered in Part III of this memorandum (see paragraphs 6 to 53, below).

II. Purpose of the Memorandum

5. The purpose of this memorandum is to examine the existing provisions in respect of extension of patent protection of a process to the products obtained by that process and proof of infringement of the patented process and to suggest a uniform solution which could easily be applied by courts, and which would have the advantage that owners of process patents would no longer be confronted with differences of legal protection in the various countries. The solution proposed should be acceptable to the largest number of countries. In this connection, reference is made to the significant achievements in respect of the harmonization of certain provisions of patent law already obtained as a consequence of the European Patent Convention (1973) and the Community Patent Convention (1975; not yet in force).

III. Existing Legislative Provisions

A. Information Used in the Present Memorandum

6. Before any uniform solution is proposed, the existing provisions—in respect of (i) the extension of process patents to products obtained by the patented process and (ii) proof of infringement of a process patent—are examined. While recognizing that rules may be found in the legislation of a great number of countries, the present memorandum, in view of the great amount of material involved, covers only the laws of some of them, selected on the basis of statistical criteria. Thus, the following information has been taken into account:

(i) the provisions of the Stockholm Act (1967) of the Paris Convention for the Protection of Industrial Property (hereinafter referred to as the "Paris Convention");

(ii) the provisions of the European Patent Convention (EPC), the Community Patent Convention (CPC) and of the legislation (laws, regulations, etc.) of those 18 countries in which or for which, according to the statistics published by WIPO (IP/STAT/1984/A), more than 4,000 titles of protection for inventions were granted in 1984. Those countries are Australia (7,252), Austria (8,565), Brazil (4,887), Canada (20,545), Czechoslovakia (6,601), France (23,666), German Democratic Republic (11,544), Germany (Federal Republic of) (21,758), Greece (9,153), Japan (61,800), the Netherlands (10,257), Poland (4,185), the Soviet Union (62,907), Spain (8,213), Sweden (11,670), Switzerland (13,977), the United Kingdom (18,867) and the United States of America (67,201). The figures in parenthesis following the names of all States except the Soviet Union indicate the number of patents granted in 1984; the figure concerning the Soviet Union represents the total number of patents and of inventors' certificates granted in 1984.

7. In general, the present memorandum is based on legislative provisions (treaties, laws, regulations, etc.) and only exceptionally takes into account the interpretation given to the said provisions by courts and industrial property offices or the practice of industrial property offices. The present memorandum only presents a short summary of the said provisions.

B. The Paris Convention for the Protection of Industrial Property

8. Article 5*quater* of the Paris Convention reads as follows:

> "When a product is imported into a country of the Union where there exists a patent protecting a process of manufacture of the said product, the patentee shall have all the rights, with regard to the imported product, that are accorded to him by the legislation of the country of importation, on the basis of the process patent, with respect to products manufactured in that country."

This provision does not require Paris Union member States to provide for an extension of patent protection of a process to the products obtained by that process, nor does it require the provision of a reversal of the burden of proof as described in paragraph 4, above. However, Article 5*quater* obliges those Paris Union member States which in their national law *provide* for an extension of patent protection of a process and/or a reversal of the burden of proof *to recognize* the effects of the extension of patent protection of a process and/or the reversal of the burden of proof with respect to *imported* products in the same way as with respect to products manufactured in the country. In other words, Article 5*quater* becomes operational only in a Paris Union member State that has decided to adopt certain provisions in its national law, namely, provisions concerning the extension of patent protection of a process to products obtained by the process and/or provisions on the reversal of proof of infringement of a process patent. In such a State, Article 5*quater* has the effect that a process patent is infringed through the importation of products manufactured according to the patented process in another country and—where the national law provides for the reversal of the burden of proof—that the importer of the said products has to prove that the patented process was not used in manufacturing the products. Without the effect prescribed by Article 5*quater*, the provisions of national laws concerning the extension of patent protection of a process and/or the reversal of the burden of proof could easily be circumvented by using the patented process in another country and importing the products obtained into the country where the process is patented. However, as already stated, Article 5*quater* of the Paris Convention does not achieve a harmonization of national laws in respect of the extension of process protection to products obtained by the patented process and proof of infringement of a process patent.

[4] In this memorandum, "plaintiff" means the owner of the patent and "defendant" the alleged infringer.

C. European Patent Convention, Community Patent Convention and National Legislation

9. *European Patent Convention.* The European Patent Convention (EPC) needs to be considered in this memorandum because, in spite of the basic principle according to which the rights conferred by a European patent are determined by the national law of each Contracting State in respect of which the European patent has been granted (see Article 64(1) and (3) EPC), a relevant provision is contained in Article 64(2) EPC, which reads as follows:

> "If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process."

10. The European Patent Convention does not deal with the infringement of European patents, leaving this matter to the applicable national law (see Article 64(3) EPC). Consequently, the question of proof of infringement of process patents is not dealt with in the EPC.

11. *Community Patent Convention.* The Community Patent Convention (CPC), which was concluded in 1975 between the Member States of the European Community in order to establish uniform rules concerning European patents for the said States and which is not yet in force, provides in its Article 29(c) for the right of the proprietor of a Community patent "to prevent all parties not having his consent ... from offering, putting on the market, using, or importing or stocking for these purposes the product obtained directly by a process which is the subject-matter of the patent."

12. As regards the burden of proof, the CPC contains in its Article 75 a provision which reads as follows:

> "1. If the subject-matter of a Community patent is a process for obtaining a new product, the same product when produced by any other party shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process.
>
> "2. In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and business secrets shall be taken into account."

13. *Australia.* The Patents Act 1952, as amended to 1982, does not provide for an extension of process patent protection to a product obtained by the patented process or for a reversal of burden of proof concerning infringement of a process patent.

14. *Austria.* The Patent Law of 1970, as amended in 1984, provides in Section 22(2) that, if a patent has been granted for a process, it shall be effective also in respect of the products manufactured directly by that process.

15. According to Section 155 of the Patent Law, in the case of a patent for a process for the manufacture of a new substance, any substance with the same composition shall, pending proof of the contrary, be regarded as having been manufactured according to the patented process.

16. *Brazil.* The Industrial Property Code of 1971 does neither provide for an extension of process patent protection to a product obtained by the patented process nor for a reversal of burden of proof concerning infringement of a process patent.

17. *Canada.* The Patent Act of 1952, as amended in 1972, does not contain a provision extending process patent protection to a product obtained by the patented process. Such an extension therefore can only be achieved by claiming, when the process is of a certain kind (see below), the resulting product in addition to the process. Section 41(1) contains a special rule concerning the possibility of claiming, in addition to the process, the product obtained by the process. It reads as follows:

> "In the case of inventions relating to substances prepared or produced by chemical processes and intended for food or medicine, the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents."

This provision establishes the principle that substances prepared or produced by chemical processes and intended for food or medicine are excluded from patent protection. As an exception to this principle, such a substance may nevertheless be patented if it is prepared or produced by a method or process of manufacture particularly described and claimed or by their obvious chemical equivalents. The exception permits patenting of the substance together with the process for its manufacture. Although this is not the kind of extension of process protection considered in this memorandum, the result is practically the same. Courts, however, have accepted that the Patent Act does provide for extension of process protection; see *Farbwerke Hoechst v. Halocarbon (Out), Ltd.* 15 CPR 105 Headnote (d) (1974), page 6.

18. As regards proof of infringement, Section 41(2) of the Patent Act provides the following:

> "In an action for infringement of a patent where the invention relates to the production of a new substance, any substance of the same chemical composition and constitution shall, in the absence of proof to the contrary, be deemed to have been produced by the patented process."

19. *Czechoslovakia.* The Law on Discoveries, Inventions, Rationalization Proposals and Industrial Designs of 1972 does not provide for an extension of process patent protection to a product obtained by the patented process or for a reversal of burden of proof concerning infringement of a process patent.

20. *France.* Section 28(2) of the Patent Law of 1968, as last amended and supplemented in 1984, provides that, where the subject matter of the patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process. Consequently, Section 29(c) of the Patent Law extends the exclusive right conferred by a process patent to the offering, putting on the market, using, or importing or stocking for these purposes, of a product obtained directly by the patented process.

21. The Patent Law does not contain a provision concerning proof of infringement of a process patent. However, Section 56 of the Patent Law provides indirectly for a reversal of the burden of proof in certain cases.

22. *German Democratic Republic.* According to Section 12(2) of the Law of 1983 on the Legal Protection of Inventions (Patent Law), the right to use an invention under an economic patent or an exclusive patent includes the right to produce, use, offer for sale and sell the subject matter of the invention; where a manufacturing process is protected, those rights also extend to the products manufactured directly by that process.

23. As regards proof of infringement, Section 29(2) provides that, where an action for discontinuance or for damages concerns an invention for the process of manufacture

of a new substance, any substance of the same nature shall be considered, until there is proof to the contrary, as having been produced by means of the patented process.

24. *Germany (Federal Republic of).* According to Section 9(3) of the Patent Law of 1981, the exclusive right conferred by a patent covers the offering, putting on the market, using or importing or stocking for these purposes, of the product manufactured by a process which is the subject matter of the patent.

25. Section 139(3) of the Patent Law provides that, if the subject matter of a patent is a process for obtaining a new product, the same product when produced by any other party shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process; in the adduction of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and business secrets shall be taken into account.

26. *Greece.* According to Section 5 of the Law of 1920 on Patents of Invention, if a patent has been granted in respect of a method of production, the products directly obtained by that method also enjoy protection.

27. Section 34, second paragraph, of the Law provides that, in the case of an invention which relates to a method of production of a new product, any product of the same nature shall be deemed, until otherwise proven, to have been manufactured by the patented method.

28. *Japan.* Section 2(3) of the Patent Law of 1959, as amended in 1982, contains a definition of the term "working," which term is used in Section 68 for the purposes of defining the exclusive right of the patentee. According to Section 2(3)(iii), working of an invention means, in the case of an invention of a process of manufacturing a product, acts of using, assigning, leasing, displaying for the purpose of assignment or lease, or importing, the product manufactured by the process, in addition to using the process.

29. Section 104 of the Patent Law provides that, in the case of a patent for an invention of a process of manufacturing a product, where such product was not publicly known in Japan prior to the filing of the patent application concerned, any identical product shall be presumed to have been manufactured by that process.

30. *Netherlands.* Section 30(1)(b) of the Patents Act of 1910, as last amended in 1978, provides that a patent confers on its proprietor the sole right to apply the patented process in or for his business or to make, use, put on the market, resell, hire out or deliver the product obtained directly as a result of the application of the patented process, or deal in any other way, in or for his business, in the product, or to offer it or stock it for these purposes, with the exception of any product excluded from the grant of a patent as a result of Section 3(2).

31. As regards the burden of proof of infringement of a process patent, Section 43(5) of the Patents Act provides that, where proceedings are brought for the enforcement of a patent relating to a process for the manufacture of a new product, it shall be assumed that the product in question has been manufactured by using the patented process, unless the defendant can establish the plausibility of the contrary; the contents of patent applications filed and later published shall not be taken into consideration in a judgment relating to the novelty of a product. Thus, the law of the Netherlands does not completely reverse the burden of proof; if the defendant establishes the plausibility that the product has not been manufactured by using the patented process, the owner of the patent has to prove that the patented process was used.

32. *Poland.* The Law on Inventive Activity of 1972, as amended in 1984, provides, in Section 16(4), that a patent granted for a manufacturing process also covers products directly obtained from the process. Section 12(1)(ii), however, excludes from patent protection food stuffs, pharmaceuticals and chemical products.

33. According to Section 57(3) of the same Law, in the case of a patent for a process of manufacturing a new product, any product which can be obtained by means of the patented process is presumed to have, in fact, been produced by that process.

34. *Soviet Union.* The Statute on Discoveries, Inventions and Rationalization Proposals of 1973, as amended in 1978, does not provide for an extension of process protection to products obtained by the protected process, nor does it regulate the proof of infringement of a process patent.

35. *Spain.* Law 11/1986 of March 20, 1986, provides, in its Section 50, that a patent confers upon its proprietor the right to prevent any third party, without his consent, from offering, putting on the market or using a product directly obtained by means of the patented process, or importing or processing such a product for any of the said purposes. Section 61 further provides that, when a product for the manufacture of which a process patent exists in Spain is imported into the country, the patent owner has, with respect to the product so imported, the same rights as are granted to him in relation to products manufactured in Spain. Where a patent relates to a process for the manufacture of new products or substances, it is presumed, in the absence of proof to the contrary, that any product or substance of the same characteristics has been obtained using the patented process. When effecting the necessary formalities for the proof to the contrary, the legitimate interests of the defendant are taken into consideration for the protection of his trade or industrial secrets.

36. *Sweden.* According to Section 3, first paragraph, item (3), of the Patents Act of 1967, as amended in 1983, the exclusive right conferred by a patent covers the offering, putting on the market, or using, of products made by a process protected by the patent, or the importing or possessing of the product for these purposes.

37. There is no provision in the Patents Act concerning proof of infringement of a process patent.

38. *Switzerland.* Section 8(3) of the Federal Law on Patents for Inventions of 1954, as revised in 1976 (hereinafter referred to as the "Patent Law"), provides that, if an invention concerns a process, the effects of the patent shall extend to the immediate products of the process.

39. According to Section 67(1) of the Patent Law, if an invention concerns a process for the manufacture of a new product, every product of the same composition is presumed to have been made by the patented process until proof to the contrary has been adduced. Section 67(2) provides that Section 67(1) applies by analogy in the case of a process for the manufacture of a known product if the patentee shows *prima facie* evidence of infringement of the patent. According to Section 68(1) of the Patent Law, manufacturing or business secrets of the parties are to be safeguarded, and Section 68(2) provides that evidence which would disclose such secrets may be made available to the adversary only to such an extent as is compatible with the safeguard of the secrets.

40. *United Kingdom.* Under Section 60(1)(c) of the Patents Act 1977, a person infringes a patent if, where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

41. As regards proof of infringement of a process patent, Section 100(1) of the Patents Act provides that, if the invention for which a patent is granted is a process for obtaining a new product, the same product produced by a person other than the proprietor of the patent or a licensee of his shall, unless the contrary is proved, be taken in any proceedings to have been obtained by that process. Section 100(2) stipulates that, in considering whether a party has discharged the burden imposed upon him by Section 100(1), the court shall not require him to disclose any manufacturing or commercial secrets if it appears to the court that it would be unreasonable to do so.

42. *United States of America.* According to Section 154 of Title 35 (Patents) of the United States Code, as last amended in 1984, a patent confers the right to exclude others from making, using, or selling the invention, and Section 271(a) provides that whoever without authority makes, uses or sells any patented invention infringes the patent. These provisions do not establish an extension of process patent protection of the kind considered in this memorandum, and, therefore, such an extension has not been admitted by the courts.

43. There is no provision concerning proof of infringement of a process patent.

44. However, Section 1337a of Title 19 (Customs Duties) of the United States Code, which concerns unfair trade practices in respect of importation of products, contains a provision according to which products of processes that are patented in the United States of America receive the same treatment as products patented in the United States of America. This provision has the effect of an extension of process patent protection to products obtained by the patented process. It applies not only to products manufactured abroad but also to products manufactured in the United States of America, exported and reimported into the country. Moreover, the legal consequences of the said provision—namely, measures to be taken by the United States International Trade Commission—are different from the sanctions for patent infringement as provided under the Patent Law. Legislation is under preparation in the United States of America with respect to extending process patent protection to products.

D. Comparative Analysis

45. When comparing the provisions of the European Patent Convention, the Community Patent Convention and the 18 national laws referred to in the preceding Chapter, it appears that the industrial property laws of 13 countries (Austria, Canada, France, German Democratic Republic, Germany (Federal Republic of), Greece, Japan, Netherlands, Poland, Spain, Sweden, Switzerland, United Kingdom), the EPC and the CPC provide for an extension of patent protection of a process to products obtained by the patented process, whereas the laws of five countries (Australia, Brazil, Czechoslovakia, the Soviet Union, the United States of America) do not provide for such extension. As far as the reversal of the burden of proof concerning infringement of process patents is concerned, the laws of 12 countries (Austria, Canada, France (with some qualifications), German Democratic Republic, Germany (Federal Republic of), Greece, Japan, Netherlands (with some qualifications), Poland, Spain, Switzerland, United Kingdom) and the CPC provide for such reversal, whereas the laws of six countries (Australia, Brazil, Czechoslovakia, the Soviet Union, Sweden, the United States of America) and the EPC (the latter because of its limited objective) do not provide for such reversal of proof.

46. Although the provisions concerning the two questions dealt with in this memorandum are basically the same in the national laws referred to in the preceding paragraph, as well as in the EPC and the CPC, certain differences exist. They are analyzed in the following paragraphs (paragraphs 47 to 53).

47. *Extension of Process Protection to Products Obtained by the Protected Process.* Two aspects of the relevant provisions deserve particular attention, namely, the question of whether the result of the patented process is a "product" and the question of whether the product must be "directly" obtained by the process.

48. As regards the result of the process to which the protection extends, all laws, and the EPC and the CPC, use the expression "product." It is to be noted, however, that the laws of Austria and the German Democratic Republic, while extending process protection to "products," use the expression "substance" in connection with the reversal of the burden of proof and that the law of Canada, which only provides for a reversal of the burden of proof but not for an extension of process patent protection, refers to a "substance of the same chemical composition and constitution."

49. As regards the link between the process and the product, generally national laws, the EPC and the CPC require that the product must be "directly obtained" by the process. The following are exceptions: the laws of Austria, Germany (Federal Republic of) and the German Democratic Republic speak of "products manufactured directly" by the process; the law of Japan does not use the term "directly" but speaks only of a "product manufactured by the process"; the law of Sweden refers to "products made by a process protected by the patent"; the law of Switzerland speaks of the "immediate products of the process." Thus, the laws of Japan and Sweden seem to differ somewhat from the laws of the other countries and from the EPC.

50. *Reversal of the Burden of Proof.* Three aspects of the relevant provisions deserve particular attention, namely, (i) the question of whether the defendant's product on which the reversal of the burden of proof is based must be the same as the one described in the process patent, (ii) the question of whether the plaintiff's product must be new[5] and (iii) the question of whether the defendant must prove that he did not use the patented process or whether he only has to make plausible that he did not use the process and whether he can avoid disclosing manufacturing or business secrets.

51. As regards the identity of the kind of product, the law of Austria speaks of "any substance with the same composition"; the law of Canada expressly refers to "any substance of the same chemical composition and constitution"; the law of the German Democratic Republic uses the expression "any substance of the same nature"; the CPC and the laws of Germany (Federal Republic of) and the United Kingdom refer to "the same product"; the law of Greece speaks of "any

[5] It appears that the term "new" is meant in the absolute (worldwide) sense but does not necessarily have the same meaning as the term "new" in the context of novelty as a condition of patentability (see paragraph 52). In particular, products which are the subject of pending but not yet published patent applications and which therefore are considered as prior art in respect of subsequent patent applications (see document HL/CE/III/2 Supp. 3, see above) do not seem to be treated as lacking novelty for the purposes of the reversal of the burden of proof.

product of the same nature"; the law of Japan uses the expression "any identical product"; the law of the Netherlands refers to "the product in question"; the law of Poland speaks of "any product which can be obtained by the patented process"; the law of Spain speaks of "any product or substance of the same characteristics" and the law of Switzerland of "every product of the same composition." Whether this diversity of expressions reflects an intended diversity of substance, so that, on the one hand, complete identity is required, whereas, on the other, unimportant deviations would be irrelevant, does not seem to deserve further examination for the purposes of this memorandum.

52. As regards the question whether the product must be new, such a condition is provided for in the CPC and in the laws of Austria, Canada, the German Democratic Republic, Germany (Federal Republic of), Greece, Japan ("product not publicly known prior to filing of the patent application concerned"), the Netherlands (with a special provision concerning the contents of patent applications that have not yet been published, to the effect that the said contents are not to be taken into consideration), Poland, Spain and the United Kingdom. Under the law of Switzerland, there are two rules concerning the proof of infringement, one establishing a reversal of the burden of proof in respect of a new product and the other establishing a reversal of the burden of proof in respect of a known product if the patentee shows *prima facie* evidence of infringement of the patent. With the exception of Japan and the Netherlands, neither the CPC nor any of the aforementioned countries specifies what is meant by "new."

53. As regards the proof of having or not having used the patented process, the law of the Netherlands does not provide for a reversal of the burden of proof but establishes an assumption of infringement unless the defendant establishes the plausibility of the contrary. A provision protecting the defendant who receives the burden of proof, because of a legal provision reversing the burden, against a requirement to disclose manufacturing and business secrets is contained in the laws of Germany (Federal Republic of), Spain, Switzerland and the United Kingdom.

IV. Arguments in Favor of a Uniform Solution

54. The diversity of provisions of the national laws covered by this memorandum, the European Patent Convention and the Community Patent Convention presents obvious disadvantages for inventors of process inventions and owners of process patents. In a number of countries, applicants can rely on the legal provision extending patent protection of a process to the product obtained by the process. In other countries, where such an extension is not provided for by the law, inventors of process inventions must claim, in addition to the process, also the resulting product. Where this is not possible, for example, because the product in question is not new or lacks inventive step or because a patent for a product cannot be obtained and, therefore, protection of the process is particularly important, the protection is limited to the process with the known difficulties of proving infringement of a process. Therefore, an internationally accepted uniform solution in respect of the two questions examined in this memorandum would greatly facilitate the situation that inventors of process inventions have to face when they seek protection for their inventions in more than one country. Moreover, it would give true effect to the underlying intention of Article 5*quater* of the Paris Convention.

V. Principles of a Solution

55. The principles of a solution to be embodied in an international treaty could be drafted as follows:

"(1)(a) If the subject matter of a patent is a process, the protection conferred by the patent, under any national law, shall extend to products directly obtained by the said process, even if for such products patents are not available.

(b) The acts of importing and distributing the product directly obtained by the patented process shall be covered by the protection referred to in subparagraph (a).

"(2)(a) If the subject matter of the patent is a process for obtaining a new product, the said product, when produced by any party other than the owner of the patent, shall, under any national law, in the absence of proof to the contrary, be deemed to have been obtained by the patented process.

(b) In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and business secrets shall be taken into account.

(c) Any Contracting State shall be free to apply subparagraphs (a) and (b) also to the case where the product obtained by the process is not new."

B. Committee of Experts on Intellectual Property in Respect of Integrated Circuits

Third Session
(Geneva, April 27 to 30, 1987)

NOTE*

The third[1] session of the Committee of Experts on Intellectual Property in Respect of Integrated Circuits (hereinafter referred to as the "Committee of Experts") took place in Geneva, at the headquarters of WIPO, from April 27 to 30, 1987. Experts from the following 38 States participated: Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Cameroon, Canada, Colombia, Denmark, Finland, France, German Democratic Republic, Germany (Federal Republic of), Ghana, Greece, India, Ireland, Italy, Japan, Luxembourg, Madagascar, Mexico, Morocco, Netherlands, Norway, Pakistan, Panama, Republic of Korea, Soviet Union, Spain, Sweden, Switzerland, United Kingdom, United Republic of Tanzania, United States of America, Uruguay, Yugoslavia. In addition, experts from three intergovernmental organizations and 17 non-governmental organizations participated in an observer capacity. The list of participants follows this Note.

The purpose of the third session of the Committee of Experts was to review and discuss the draft of a Treaty on the Protection of Intellectual Property in Respect of Integrated Circuits. The draft considered was a draft revised in the light of the discussions of the second session (June 1986) of the Committee of Experts. It was prepared by the International Bureau. The aim of the Treaty is to provide a system of international protection for the layout-design of integrated circuits. In the discussions of the third session, reference was also made to the conclusions prepared by the participants in technical consultations held at the headquarters of WIPO in January 1987, a proposal of the United States of America on consultation procedure, a draft codicil to the Berne Convention for the Protection of Literary and Artistic Works for the protection of integrated circuit designs presented by the Delegation of India and proposals by the same Delegation concerning Articles 2 and 4(3) of the draft Treaty, a proposal by the Delegation of Japan concerning Article 4(3) and (4)(i) of the draft Treaty, a proposal by the Delegation of Denmark on behalf of the Member States of the European Communities concerning Article 4(3) and (4) of the draft Treaty, a memorandum of the Director General of WIPO on preferential treatment for developing countries and the relevant legislative texts of Japan, Sweden and the United States of America and the European Communities, compiled by the International Bureau. The documents containing the draft Treaty and all the texts mentioned in this Note may be obtained, free of charge, from the International Bureau.

I. General Discussion

In the third session of the Committee of Experts, discussions started by general observations made by government delegations and observers on the draft Treaty and on recent national developments in the area of protection provided for layout-designs of integrated circuits.

The Delegations of Australia, Austria, Belgium, Bulgaria, Canada, Denmark, Finland, France, the German Democratic Republic, Germany (Federal Republic of), Greece, Ireland, Italy, Japan, the Netherlands, Norway, the Soviet Union, Spain, Sweden, Switzerland, the United Kingdom and the United States of America, and the observers of five non-governmental organizations expressed support for the draft Treaty as a whole. Among those delegations and observers expressing support for the draft Treaty were several which urged the convening of a diplomatic conference to adopt the Treaty under consideration. The Delegation of the United States of America extended, on behalf of its Government, an invitation to hold a diplomatic conference for that purpose in the United States of America, in 1988.

On the other hand, the Delegations of Argentina, Brazil, India, Mexico, the United Republic of Tanzania and Yugoslavia expressed serious doubts about the need for a new treaty to protect intellectual property in the area of layout-designs of integrated circuits and, in any case, asked for further studies. This position was confirmed and specified in a declaration presented by the Delegation of Ghana on the last day of the session on behalf of the 15 developing countries represented in the session.

That declaration reads as follows:

"The delegations of the developing countries present at the third session of the Committee of Experts on Intellectual Property in Respect of Integrated Circuits,

* Prepared by the International Bureau.

[1] For notes on the first and second sessions of the Committee of Experts, see *Industrial Property*, 1986, p. 110 and 373, respectively.

Having participated in the process of discussion of a draft Treaty for the protection of integrated circuit layout-designs prepared by the WIPO Secretariat and circulated for the first time in June 1985;

Taking note of the concern expressed by many developed countries as to the lack of an international framework to prevent the copying of original layouts and the trade related to such copies;

Recalling the conclusions of the technical consultations held in Geneva in January 1987 (see document IPIC/TC/I/2);

Consider it necessary to express to the Committee of Experts on Intellectual Property in Respect of Integrated Circuits the following:

1. While it is manifest the large agreement existing among developed countries as to the approach and content of an eventual treaty on the matter, the preparatory materials, including the draft treaties and commentaries, have failed to take into account the concerns, doubts and views expressed by developing countries.

2. By no way our countries desire to put any obstacles to the reaching of an understanding among developed countries on integrated circuit protection. Given the universal character of WIPO, and being this organization the appropriate forum for this matter, the work under its auspices, however, cannot be conceived without a real consensus including developing countries.

3. The majority of developing countries lack any industrial experience or technological infrastructure on this matter. The speed with which the process has evolved, the newness and complexity of the issue and the lack of concrete response to developing countries' demands for previous and deeper studies and clarification, are major limitations to our countries to accept the proposed text as drafted.

4. The rationale for developing countries to follow the proposed approach of protection is still unclear. On the one side, there seems to exist a strong unbalance between the low standards of creativity required for protection and the strong exclusive rights claimed. On the other, alternative approaches, including those based on existing international conventions or on the concept of unfair competition, have not been thoroughly explored and many doubts still remain thereon. Arguments based on the general concept of justice or on the protection of investments in developed countries are insufficient to sustain the present approach.

5. In order to facilitate a final decision on the proposed texts by our countries, a number of analyses and clarifications are still needed. We therefore request WIPO to assist in the preparation of a deep study and to organize technical consultations focusing, *inter alia*, on the issues indicated in the Annex."[2]

II. Discussion of the Proposed Draft Treaty

Each of the 12 articles of the draft Treaty as had been proposed by the International Bureau and the corresponding passages reflecting the discussions concerning each of them in the report are quoted in the following.

Definitions. Article 1 of the proposed draft read as follows:

"For the purposes of this Treaty:

(i) 'Contracting State' means a State party to the Treaty,

(ii) 'proprietor' means the natural person who, or legal entity which, according to the applicable national law, is to be regarded as the beneficiary of the protection referred to in Article 4,

(iii) 'Director General' means the Director General of the World Intellectual Property Organization,

(iv) 'microchip' means a manufactured integrated circuit,

(v) 'integrated circuit' means a circuit in which the active elements, some or all of the interconnections and any passive elements are integrally formed in and/or on a piece of material and which is intended to perform an electronic function,

(vi) 'layout-design' means the three-dimensional disposition of the active elements, interconnections and any passive elements of an integrated circuit, in whichever form such disposition is fixed or encoded."

The corresponding passage in the report reads as follows:

"A number of the delegations expressed the view that the present wording of Article 1 could stay as contained in the draft Treaty. Most of the delegations and observers that suggested amendments on specific points declared that they were in agreement with the remainder of Article 1.

The question was raised whether the expression 'Contracting States' would be appropriate if intergovernmental organizations such as the European Economic Community were to be admitted to become parties to the Treaty. For that purpose it would be appropriate to replace the term 'Contracting State' by 'Contracting Party.'

It was pointed out that the term 'Contracting Party' seemed to be an expression which was specifically used within the framework of GATT and that it therefore might be preferable to use the term 'State Party to this Treaty.'

It was noted that the question of the participation of the European Community in any diplomatic conference on integrated circuits and the question of whether not only States but also the said Community could become a party to any treaty on the protection of integrated circuits were questions in the jurisdiction of the Governing Bodies of WIPO rather than in that of the present Committee of Experts.

In this context, it was noted that the question of whether the representative of the Commission of the European Community could, in meetings organized by WIPO, have the same status as representatives of States members of WIPO and speak for all States members of the European Community was also a question within the jurisdiction of the Governing Bodies of WIPO.

It was stated that the definitions contained in items (iv) to (vi) reflected concepts that had developed in the specific field of technology and that it might be appropriate to include other concepts in order to take into account further developments. For that reason, some delegations suggested that it should be considered to transfer provisions on technical definitions to a special protocol which could be amended more easily than the Treaty. One delegation expressed its preference for the term 'topography' over the term 'layout-design.'

Whereas a number of delegations agreed with the omission of the word 'semiconductor' which had been used in the draft of the Treaty considered by the Committee of Experts in its second session, some delegations expressed doubts whether the note in paragraph 25 would be sufficient in order to clarify that a country which only protected semiconductor integrated circuit layout-designs would comply with its obligations under the Treaty. It was stated that the Treaty, as an alternative approach, should allow countries to declare, at the time of accession or ratification, that they would only protect semiconductor integrated circuit layout-designs. One delegation suggested adding, in (v), after the words 'piece of,' the words 'single crystal material or materials,' and/or reinserting the word 'semiconductor' at appropriate places, thus ensuring that certain old technological achievements such as printed circuit boards and possible future achievements such as bubble memories would not be within the scope of the Treaty.

One delegation pointed out that any definition of a layout-design should take into account not only a physical description of a pattern, but also refer to all its attributes related to intellectual property issues, namely:

(a) that it is the result of a given manufacturing process, which is unique;

[2] The declaration quoted above is accompanied by an annex. That annex is part of the report of the Committee of Experts, copies of which may be obtained free of charge from the International Bureau.

(b) that it is the result of a behavioral, functional description, that is also unique;

(c) that it is the result of a given design strategy implemented with specific tools.

It was pointed out that the definition of 'integrated circuit' in item (v) should be enlarged by adding the term 'in its final or intermediate form' so that certain intermediate forms such as gate arrays and cells would also be protected. It was noted that integrated circuit and layout-design in items (v) and (vi) may not contain any passive element."

Subject Matter of Protection. Article 2 of the proposed draft read as follows:

"The provisions of Articles 3 to 6 shall not apply to layout-designs of integrated circuits that are not the result of the creator's intellectual effort or are commonplace in the integrated circuit industry at the time of their creation or are exclusively dictated by the functions of the integrated circuit to which they apply."

The corresponding passage in the report reads as follows:

"A number of delegations expressed support for the draft of Article 2 subject to minor amendments.

It was noted that the term 'commonplace' needed clearer definition and/or elaboration to avoid needless dispute and that the International Bureau should study this.

Other delegations pointed out that Article 2 could be accepted only if it were substantially redrafted. In this connection, the Delegation of India made the proposal contained in document IPIC/CE/III/7 and reading as follows:

'The provisions of Articles 3 to 6 shall apply to layout-designs of integrated circuits, provided that:

(a) they are not direct copies of protected layout-designs,

(b) they are not commonplace at the time of first commercial exploitation, and do not so become during the term of protection specified in Article 6, and

(c) they are not one of only a limited number of ways of expressing the function that they perform.'

This proposal gave rise to the following comments:

(a) As regards the word 'direct' in subparagraph (a), it was pointed out that that word should be deleted or, if maintained, required clarification. It was clarified by the Delegation of India that the word 'direct' was necessary as otherwise many designs would be excluded from protection in view of technological progress as a result of which derivative works may well be considered copies.

(b) The word 'protected' in subparagraph (a) was considered as not being appropriate because it would mean that copies of layout-designs which were not protected could enjoy protection under Articles 3 to 6.

(c) With respect to the first part of subparagraph (b), it was pointed out that the decisive point in time should be either the first commercial exploitation or the registration, whichever occurred first.

(d) The proposal, contained in subparagraph (b), according to which a layout-design could lose its protection because it became commonplace after the beginning of the protection, was considered to be unacceptable by a number of delegations.

(e) The drafting of subparagraph (c) was considered as requiring improvement; preferably, this clause could be replaced by a provision which would follow the example of Article 8 of the EEC Directive.[3]

(f) One delegation pointed out that the suggested drafting, in its positive formulation, may not mean the subject matter of protection.

[3] Council Directive of December 16, 1986, on the Legal Protection of Topographies of Semiconductor Products (87/54/EEC) (referred to in the present text as "EEC Directive") *(Editor's note).*

With respect to Article 2 contained in the draft Treaty, several delegations expressed the view that it should start out by a positive statement of the rule (namely, that layout-designs must be protected) and that the limitations provided for in the draft of Article 2 should be presented as provisos to the rule.

Several delegations felt that the third of the three conditions contained in Article 2, namely, that layout-designs are not protected if they are exclusively dictated by functions of the integrated circuit to which they apply, should be deleted. Moreover, several delegations suggested that a provision along the lines of Article 8 of the EEC Council Directive should be included in an appropriate place.

Some delegations believed that the drafting of the functional exclusion might be too broad since the design of all chips was dictated by functional considerations. It might be more useful to speak of an exclusion from protection when the layout-design can only be expressed in a limited number of ways.

It was agreed that the French text should use '*courant*' rather than '*banal*,' where the English text uses the term 'commonplace.'"

National Treatment. Article 3 of the proposed draft read as follows:

"Each Contracting State shall, in respect of the layout-design of integrated circuits, grant to nationals or residents of the other Contracting States the same protection that it grants to its own nationals, and it may subject such protection to the same formalities, if any, that the protection of its own nationals is subjected to."

The corresponding passage in the report reads as follows:

"Reference was made to a consequential change required with respect to the expression 'Contracting State,' if that expression were to be replaced by another expression, as discussed in connection with Article 1.

Several delegations suggested that Article 3 be reviewed in respect of its application to legal entities which are resident of a Contracting State. It was pointed out that the definition of the concept of a legal entity was required to be included in the Treaty and that it was not sufficient to leave this matter to the notes.

It was agreed that Article 3 should be reviewed, taking into account similar provisions in treaties administered by WIPO, in particular Article 2 of the Paris Convention for the Protection of Industrial Property."

Protection of Layout-Designs. Article 4 of the proposed draft read as follows:

"(1)(a) Subject to paragraphs (3) to (6), any Contracting State shall consider unlawful at least the following acts if performed without the authorization of the proprietor:

(i) copying the layout-design,

(ii) incorporating the layout-design in a microchip,

(iii) importing, selling or otherwise distributing copies of the layout-design, such a microchip or industrial articles containing such a microchip.

(b) Any Contracting State shall provide for measures to ensure the prevention and repression of acts considered unlawful under subparagraph (a).

(2) The authorization referred to in paragraph (1)(a) may not, under any circumstances, be replaced by a non-voluntary license.

(3) Notwithstanding the provisions contained in paragraph (1)(a)(i), any Contracting State may consider lawful the copying of a layout-design, without the authorization of the proprietor, if the copying is solely for the purposes of teaching or research concerning the said layout-design.

(4) Notwithstanding the provisions contained in paragraph (1)(a), no Contracting State shall consider unlawful

(i) the copying of the layout-design without the authorization of the proprietor if the copying is solely for the purposes of analysis, evaluation or reverse engineering, provided that, where the reverse engineering results in the production of a layout-design, such layout-design is, in itself, not excluded from the application of Articles 3 to 6 according to Article 2,

(ii) the incorporating of the latter layout-design in a microchip and the importing, selling or otherwise distributing of copies of the layout-design, of such a microchip or of industrial articles containing such a microchip.

(5) Notwithstanding the provision contained in paragraph (1)(a)(iii), no Contracting State shall consider unlawful the performance, without the authorization of the proprietor, of any of the acts referred to in that provision:

(i) where the act is performed, and as long as it is performed, without actual knowledge of the fact, or without reasonable grounds for believing, that the layout-design is protected, provided that, after the party who performs the act has obtained actual knowledge of the fact, or reasonable grounds for believing, that the layout-design is protected, the performance of such acts in respect of microchips or industrial articles acquired before such event shall entail the obligation to pay reasonable remuneration to the proprietor but no other sanctions,

(ii) where the act is performed in respect of microchips or industrial articles that have been put on the market by, or with the consent of, the proprietor.

(6) Where an industrial article referred to in paragraph (1)(a)(iii) is part of a land vehicle, vessel, aircraft or spacecraft registered in a Contracting State, and when the land vehicle, vessel, aircraft or spacecraft of which the said article is a part enters, temporarily or accidentally, the territory, waters, or airspace of another Contracting State, the latter State shall not consider such event as an importation in the sense of paragraph (1)(a)(iii)."

The corresponding passage in the report reads as follows:

"A number of delegations expressed support for the text contained in the draft Treaty. As regards possibilities of improving that draft, the following comments were made.

It was suggested that the title of Article 4 be changed in order to bring it into conformity with the contents of that Article, for example, by saying 'scope of rights.'

Paragraph (1)(a). It was pointed out that the provisions of that paragraph should be limited to acts committed for commercial purposes. In this connection, it was suggested that the restricted act of importing in paragraph (1)(a)(iii) should be limited to importing for the purpose of selling or otherwise distributing. In addition, the wording of Article 5(2) of the EEC Directive would be taken into account in order to allow an exemption for private reproduction for non-commercial aims.

One delegation asked for clarification of the difference in meaning between paragraphs (1)(a)(i) and (1)(a)(ii).

One delegation proposed that in paragraph (1)(a), following the words 'the following acts if performed' the words 'for commercial purposes and' be inserted.

Several delegations proposed that the phrase 'industrial articles' be deleted throughout Articles 3 to 6 as they felt that it extended the chain of liability and created a vicarious liability.

One delegation suggested adding the words 'as defined by national law,' after the word 'acts' in the second line of that paragraph. One delegation proposed to add to paragraph (1)(a)(i) the words 'in their entirety' and to change Note 39 in document IPIC/CE/III/2 accordingly.

Several delegations expressed the view that a copy of a part of a layout-design should be an act requiring the authorization of the proprietor, and that this should be expressly mentioned in the Treaty, the Note contained in paragraph 39 of document IPIC/CE/III/2 not being sufficient in order to ensure protection against copies of parts.

Some delegations objected to paragraph (1)(a)(iii), in particular as regards the inclusion of the act of importing copies of the layout-design or microchips or industrial articles. In their view, it would be difficult for an importer to determine whether a layout-design incorporated in a microchip or the microchip contained in an industrial article would violate third party rights. Therefore, the said provision should either be deleted or, at least, be amended, for example, by replacing the word 'importing' by the word 'exporting,' since only an exporter but not an importer should be responsible for infringement.

It was suggested that the act of distributing layout-designs by means of telecommunications should be expressly mentioned in the Treaty, since that case was of practical importance, and would not fall under the present text of the draft Treaty, which only mentioned the distribution of copies of the layout-design.

In connection with paragraph (1)(a), the question was raised whether, instead of establishing a list of acts which required the authorization of the proprietor, it was not possible to rely on protection against acts of unfair competition.

In response to this question, it was stated that protection against unfair competition was applicable only between competitors and therefore could not apply in most of the situations envisaged by the draft Treaty. This was the reason why countries had adopted special laws for the protection of layout-designs of integrated circuits, as protection against unfair competition was also not sufficient for the protection of inventions, trademarks and literary and artistic works—objects of intellectual property for which special laws had been enacted.

The Delegation of Switzerland informed about an amendment of its country's law against unfair competition which, once enacted, possibly could provide for certain remedies in the case of copying of layout-designs of integrated circuits. The said provision would be applicable even without a relationship of competition between the parties, and it would in general apply to the reproduction of a technical achievement of somebody else. The Delegation further pointed out that, in spite of various other special features of the new Swiss law which did not correspond to traditional unfair competition principles, one had come to the conclusion that, with respect to the protection of integrated circuit layout-designs, the new law would not meet the required standard. This was essentially due to the fact that the Swiss law would basically allow the manufacturing of a copy of a layout-design and would not provide for a specified term of protection. Further, one also had to take into consideration that unfair competition law would not grant any exclusive rights to owners of layout-designs. Therefore, Switzerland was also making efforts to set up a *sui generis* legislation for the protection of integrated circuit layout-designs.

One delegation suggested that the term 'copy' should be defined as otherwise there would be considerable room for argument as to the meaning of that term.

Paragraph (1)(b). It was suggested that the expression 'repression' be replaced by 'prohibition' or 'suppression.'

One delegation pointed to the need that enforcement of rights required full due process, and wondered whether such a safeguard should not be expressly mentioned in the Treaty.

Paragraph (2). Some delegations referred to the discussions on the corresponding paragraphs during the second session of the Committee of Experts, and wondered why the said discussions, and in particular the proposal by the Delegation of India supported by the Delegations of Ghana, Brazil, Argentina, Morocco and Nigeria (document IPIC/CE/II/7), had not been fully reflected in the revised draft of the Treaty.

It was replied that the issue of non-voluntary licenses was highly controversial and that it was not possible for the draft Treaty to present entirely contradictory positions. Thus, a choice had to be made. However, the Notes not only gave the reasons for the suggested solution, but also referred to the proposal by the Delegation of India which had been made during the second session of the Committee of Experts which was opposed to the solution presented in the draft Treaty. Moreover, it was possible for each delegation to obtain information on the discussions during the said

second session through the report of that session (document IPIC/CE/II/8). In order to recall the relevant passages of the said report, document IPIC/CE/III/2 Add. was issued, which contains an extract from the said report reproducing the relevant passages.

Whereas some delegations expressed support for paragraph (2), other delegations pointed out that there might be a need for provisions correcting abuses and that relevant provisions should be directed against specific acts, and should safeguard due process and a fair remuneration. Some delegations proposed that paragraph (2) be omitted from the draft Treaty.

It was suggested that it should be examined whether the draft provision contained in paragraph 56 of document IPIC/CE/II/2 could not be included in the Treaty.

As an alternative solution, reference was made to Article 7 of the Convention Relating to the Distribution of Programme-Carrying Signals Transmitted by Satellite. Several delegations expressed interest in examining this possibility.

In conclusion, it was agreed that there was a need to find a compromise solution on this point, and that the matter should be further studied, taking in particular into account the suggestions made for alternative provisions.

Paragraphs (3) and (4). A detailed discussion took place on those two paragraphs, and proposals for alternative drafting were presented by the Delegations of Bulgaria and India (document IPIC/CE/III/8 Rev.), the Delegation of Japan (document IPIC/CE/III/9) and the Delegation of Denmark on behalf of the Member States of the European Communities (document IPIC/CE/III/10).

In addition, it was pointed out that an exemption from paragraph (1) should also be made with respect to single copies made for private use. The Chairman noted that the proposal in document IPIC/CE/III/8 would cover the situation.

It was agreed that the International Bureau should further study the three proposals contained in documents IPIC/CE/III/8, 9 and 10 and the suggestion for an exemption of single private copies, in particular examining the questions whether the exception for the purposes of teaching or research should be made mandatory and whether the expression 'reverse engineering' should be used in the treaty, an expression which, although currently used in industrial circles and contained in the title of Section 906 of the Semiconductor Chip Protection Act of the United States of America, had not been adopted in any of the legislative texts so far enacted.

Paragraph (5). With respect to item (i), it was pointed out that the draft could be improved by replacing the text starting with the words 'the performance' by the following: 'the continuing performance of such acts in respect of microchips or industrial articles acquired in good faith before such event and still in the possession of such party shall entail the obligation to pay reasonable remuneration to the proprietor but no other sanctions.'

Thus, it should in particular be clarified that (as this was already the intention of the draft) there was in no case an obligation to pay remuneration for articles already distributed in good faith.

It was suggested that paragraph 55 of the Notes be amended, in order to bring it into line with the provision of paragraph (5)(i), by deleting the words 'copies of layout-designs' in the sixth line of that paragraph.

Some delegations suggested that the provision of paragraph (5)(i) be made optional, in view of strict provisions concerning the payment of remuneration, existing under certain national laws, or as an alternative, to delete the words 'but no other sanctions.'

With respect to item (ii), it was suggested that this provision be made more explicit, in particular as regards the question whether or not it concerned unauthorized copies of layout-designs.

The question was raised why the draft Treaty provided for the principle of exhaustion of rights in paragraph (5)(ii) without any territorial restriction. It was observed that such an unrestricted international exhaustion could cause serious problems, and that the application of the exhaustion principle should at least be limited to first marketing in Contracting States. Moreover, reference was made to Article 5, paragraph 5, of the EEC Directive, according to which exhaustion only applied where products had been put on the market in a Member State of the EEC. However, support was also expressed for the existing text of paragraph (5)(ii) as it was considered to be an important element of the balance struck in the draft Treaty. Some delegations expressed doubts about the inclusion of the principle of exhaustion in the draft Treaty.

Paragraph (6). Reference was made to the proposed deletion of paragraph (1)(a)(iii), which would have the consequence that paragraph (6) would also have to be deleted. Some delegations found this paragraph superfluous, if the unlawful act in Article 4(1)(a)(iii) of importation was limited to importation for selling or otherwise distributing."

Formalities. Article 5 of the proposed draft read as follows:

"(1) Any Contracting State may make protection conditional upon the filing of material allowing the identification of the layout-design and, where commercial exploitation precedes such filing, of a statement concerning the date of first commercial exploitation with a national or international public authority and the registration of the proprietor's claim to protection by such authority, provided that the time allowed for effecting such filing shall be at least two years from the date on which the proprietor first exploits commercially the layout-design, the microchip that incorporates that layout-design or the industrial article that contains such microchip. Registration may be subjected to the payment of a fee. Where part of the identifying material would contain confidential information, the proprietor cannot be obliged to file such part, as long as the filed material is sufficient to allow the identification of the layout-design.

(2) Any Contracting State may require that changes concerning the information on the proprietor contained in the initial registration be registered with the said authority to be effective against third parties.

(3) No Contracting State shall make protection conditional upon the fulfillment of any formality other than those referred to in paragraphs (1) and (2)."

The corresponding passage in the report reads as follows:

"The text of this Article was supported by a number of delegations. In particular, the following comments were made.

Paragraph (1). Attention was drawn to the fact that, under provisions of a particular national law, the filing and registration of material allowing identification of the layout-design were required to be effected with a non-profit organization which had been entrusted with certain functions of public authority. It was recognized that this system is in conformity with the draft Treaty.

Several delegations suggested that the period allowed for filing the identifying material after first commercial exploitation should be reduced from two years to six months.

Several delegations proposed that the last sentence of paragraph (1) should be deleted because withholding identifying material would be contrary to the purpose of the system of filing such material which, in the view of these delegations, served to disclose the relevant technology and was not consistent with the practice in other intellectual property treaties that require full disclosure.

Attention was drawn to the system under consideration in several countries according to which the entire identifying material (including confidential parts) had to be filed but the proprietor can request that confidential parts be kept as such unless a disclosure was ordered by a court because of important reasons, for example, in connection with an infringement suit. On the other hand, several delegations underlined the importance of retaining the last sentence of paragraph (1).

One delegation suggested adding the words 'as disposed in its national law' after the word 'material' in the second line.

Paragraph (2). In view of the fact that the registration of changes concerning the information on the proprietor was not a condition of protection, it was proposed to delete the reference to paragraph (2) in paragraph (3). It was suggested simplifying the draft of paragraph (2) by speaking of the registration of the transfer of the right.

Paragraph (3). It was suggested that the possibility should be studied of allowing an internationally recognized notice requirement which would replace any national formality requirement, following the example of the copyright symbol referred to in Article III(1) of the Universal Copyright Convention.

The question was raised whether paragraph (3) could be understood as excluding the possibility for national laws to require that foreign applicants be represented by local agents. If that was so, an amendment should be made in order to clarify that the said requirement should be permitted.

Some delegations suggested that countries should be free to require, as a condition of protection, that copies of layout-designs or microchips be actually offered for sale in the country where protection was sought. This suggestion was opposed by other countries."

Term of Protection. Article 6 of the proposed draft read as follows:

"(1) The protection provided for in Article 4 shall last at least 10 years counted from either of the following two dates:

(i) the date of the registration, in the Contracting State in which protection is claimed, of the proprietor's claim to protection,

(ii) the date on which, anywhere in the world, the proprietor first exploits commercially [and without conditions of confidentiality] the layout-design of an integrated circuit, the microchip that incorporates such layout-design or the industrial article that incorporates such microchip.

(2) Where, under the national law of a Contracting State, protection starts only upon registration, but where commercial exploitation has started before registration, the proprietor shall have the right to a reasonable remuneration in respect of any act performed in that State before registration which, after registration, requires his authorization by virtue of Article 4.

(3) Any Contracting State may provide that, where a layout-design has not been commercially exploited, anywhere in the world, within a period of 15 years from its [creation] any protection provided for in Article 4 shall come to an end, and that no such protection shall come into existence unless a filing according to Article 5(1) has been effected where the Contracting State makes protection conditional on such a filing."

The corresponding passage of the report reads as follows:

"*Paragraph (1).* With regard to the term of protection, several delegations expressed the view that a duration of 10 years as foreseen in the draft Treaty was far too long, taking into account the relatively short lifespan of integrated circuits, and that the term of protection should be reduced to five years.

One delegation, supported by some other delegations, proposed that the duration of the protection should be fixed at five years, but that it should be possible to extend the protection for another period of five years where the protected layout-design had preserved its commercial value.

Several delegations, on the other hand, expressed their strong support for the term of 10 years as proposed by the International Bureau, underlining that only a sufficiently long duration of the protection would enable the proprietor to derive rewarding benefits from his creation with regard to the high investments involved in such creation.

One delegation proposed that, in the first sentence of paragraph (1), the words 'from the earlier of the following dates' should be added, and that, in subparagraph (ii), the words put in brackets should be deleted. Another delegation proposed that, in paragraph (1), a subparagraph (iii) should be added, making reference to the date of creation of the layout-design, or to the date of the first fixing or encoding of the layout-design, a wording used in Article 7(1)(c) of the EEC Directive. Several delegations said that, in paragraph (1)(i), rather the date of the filing of the application for registration should be referred to, in order to avoid that a delay in the processing of the registration might negatively affect the starting of protection for the applicant.

Paragraph (2) was not the subject of any observations.

With regard to *paragraph (3)*, the question was raised of what the period of 15 years was supposed to mean, and whether a term of protection of up to 25 years would have to be envisaged under that provision. Some delegations expressed the view that, in fact, the term of protection, though as such restricted to 10 years under their national laws currently in force or under preparation, might reach into the 25th year after the creation of the layout-design, but under the proviso that the protection had commenced within the period of 15 years prescribed in national or regional legal instruments which had the same wording as paragraph (3), and that no protection could be obtained after the lapse of the period of 15 years. Some delegations suggested to make the provision mandatory.

Several delegations proposed that this period should be changed from 15 years to two years for consistency with the grace period in Article 5(i), as this period related to non-registration and non-exploitation commercially.

It was agreed that the wording of paragraph (3) should be reconsidered in order to clarify its concrete meaning, and to study the repercussions of that provision."

Assembly. Article 7 of the proposed draft read as follows:

"(1)(a) An Assembly consisting of all Contracting States is hereby established.

(b) The Government of each Contracting State shall be represented by one delegate who may be assisted by alternate delegates, advisors and experts.

(c) The expenses of each delegation shall be borne by the Government that has appointed the delegation.

(d) Each Contracting State shall have one vote in the Assembly.

(e) The Assembly shall meet in ordinary session once every two years.

(2) The Assembly shall deal with matters concerning the application and operation of this Treaty.

(3)(a) The Assembly may decide the convocation of conferences for revising this Treaty.

(b) The Assembly may, by unanimous decision, amend the definitions contained in Article I, items (iv) to (vi).

(4) The Assembly shall establish its own rules of procedure.

(5) The International Bureau of the World Intellectual Property Organization shall be at the disposal of the Assembly to prepare its sessions and to service such sessions. It shall assemble and publish information concerning the protection of layout-designs including the texts, and translations of the texts, of pertinent national laws and regional regulations."

The corresponding passage in the report reads as follows:

"With regard to this and the following Articles, and in particular also Article 8, the desire was recalled that the Treaty should allow for participation by the European Community. These provisions should therefore be adapted to accommodate the Community as a possible party to the Treaty."

Becoming Party to the Treaty. Article 8 of the proposed draft read as follows:

"(1) Any State member of the World Intellectual Property Organization or of the United Nations may become party to this Treaty

(i) by signature followed by the deposit of an instrument of ratification, or

(ii) by the deposit of an instrument of accession.

(2) Instruments of ratification or accession shall be deposited with the Director General.

(3) No reservations to this Treaty are permitted at the time of signature, ratification, accession or at any other time."

The corresponding passage in the report reads as follows:

"The Delegation of Ghana raised the question of why paragraph (3) expressly excluded reservations from the Treaty, as this seemed to be quite unusual.

It was answered that it was the general treaty-making practice of the Organization to expressly state whether reservations to a treaty or convention were permitted or not, as otherwise the silence of the text in this respect could be interpreted as if any reservation might be admissible. As the draft Treaty as it stood did not contain any provision with the possibility of a specific reservation, the draft was therefore in accordance with the generally accepted practice to expressly clarify that no reservations were permitted. Pending a decision of a diplomatic conference, if any, that certain reservations were allowed, the text at least for the present stage of discussions was without doubt correct."

Entry Into Force of the Treaty. Article 9 of the proposed draft read as follows:

"(1) This Treaty shall enter into force three months after ... States have deposited their instruments of ratification or accession.

(2) Any State which is not among those referred to in paragraph (1) shall become bound by this Treaty three months after the date on which it has deposited its instrument of ratification or accession or at any later date indicated by the State at the time of the depositing of its instrument of ratification or accession.

(3) Any Contracting State shall have the right not to apply this Treaty to any layout-design that exists at the time that State becomes bound by this Treaty, provided that this provision does not affect any protection that such layout-design may, at that time, enjoy in that State by virtue of the national law or international obligations of the said State."

The corresponding passage in the report reads as follows:

"A delegation expressed the view that a high number of ratifications should be required for the entry into force of the Treaty as the Treaty should reflect a broad consensus of the international community. Therefore it would like to support a proposal already made by another delegation during the last session of the Committee of Experts which foresaw that ratification of the Treaty by at least one third of the Member States of WIPO should be required. It was agreed, however, that this question had to be decided by a diplomatic conference and went beyond the competence of the Committee of Experts."

Denunciation of the Treaty. Article 10 of the proposed draft read as follows:

"(1) Any Contracting State may denounce this Treaty by notification addressed to the Director General.

(2) Denunciation shall take effect one year after the day on which the Director General has received the notification."

There is no passage in the report dealing with the above draft article.

Signature and Languages of the Treaty. Article 11 of the proposed draft read as follows:

"(1)(a) This Treaty shall be signed in a single original in the English, Arabic, Chinese, French, Russian and Spanish languages, all texts being equally authentic.

(b) Official texts shall be established by the Director General, after consultation with the interested Governments, in such other languages as the Assembly may designate.

(2) This Treaty shall remain open for signature at Geneva until [six months after its adoption]."

There is no corresponding passage in the report dealing with the above draft article.

Depositary Functions and Notifications. Article 12 of the proposed draft read as follows:

"(1) The original of this Treaty shall be deposited with the Director General.

(2) The Director General shall transmit two copies, certified by him, of this Treaty to the Governments of all the States referred to in Article 8(1) and, on request, to the Government of any other State.

(3) The Director General shall register this Treaty with the Secretariat of the United Nations.

(4) The Director General shall notify the Governments of the States referred to in Article 8(1) of:

(i) signatures under Article 11;

(ii) deposits of instruments of ratification or accession under Article 8(2);

(iii) the date of entry into force of this Treaty under Article 9(1);

(iv) denunciations received under Article 10."

The passage in the report concerning Articles 10 to 12 reads as follows:

"These Articles were not the subject of any observations."

III. Discussion of a Provision Concerning "Consultation Procedure"

The report of the Committee of Experts contains the following on this subject:

"The Delegation of the United States of America introduced its proposal contained in document IPIC/CE/III/4,[4] underlining the particular importance it attached to this proposal. The Delegation pointed out that the procedure foreseen in that document was meant to settle problems of the interpretation and implementation of the Treaty arising between States party to the Treaty. The draft Treaty contained a lot of options, and therefore it seemed to be absolutely necessary to clarify the rights and obligations for the States party to the Treaty. The procedure in no way should serve to deal with private litigation or merely trade-related issues. The functions assigned to the Assembly and the decisions to be taken by a panel of experts in the framework of the consultation procedure clearly would strengthen the role of these organs.

[4] The proposal contains draft treaty provisions for "Consultations," "Dispute Settlement" and "Enforcement."

Several delegations stated that they could not accept the proposal put forward by the Delegation of the United States of America. Disputes with regard to the protection of layout-designs of integrated circuits normally would arise between private parties, would not involve the States party to the Treaty and should be dealt with by the competent domestic judicial authorities. It was not appropriate to draw a parallel to the dispute regulations in the framework of GATT as such disputes concerned trade-related aspects and involved the political and economic interests of the States party to GATT. In addition, some delegations stated that they would not be in a position to accept a normal dispute clause making reference to the competence of the International Court of Justice or another international court as it was the policy of their governments not to be bound by clauses on obligatory international arbitration. If the draft Treaty would contain such a clause, an express reservation would have to be foreseen in the Treaty as well.

Several other delegations expressed the view that, in principle, they could support the proposal for a consultation procedure, subject to a closer study of the details of the proposal and subject to satisfactory answers to such questions as the question of who should bear the cost of the procedure.

Consequently, the Delegation of the United States of America requested that the International Bureau prepare a new text on consultation procedure taking into account the views expressed at the meeting."

IV. The Proposal of India

The Delegation of India presented the draft of a "Codicil to the Berne Convention for the Protection of Integrated Circuit Designs."

The draft Codicil—38 pages long—was presented to the Committee of Experts by the Delegation of India but it was only briefly discussed. The report of the Committee of Experts contains the statement of the Delegation of India made when introducing the draft Codicil.

LIST OF PARTICIPANTS**

I. States

Argentina: C.M. Correa; D. Chuburu. **Australia:** L.G. Honcope. **Austria:** C. Thun-Hohenstein. **Belgium:** D. Vandergheynst. **Brazil:** C.I.Z. Mammana; R. Stille; M.F. Cruz; R. Gaspary Torres. **Bulgaria:** T. Makedonski. **Cameroon:** W. Eyambe. **Canada:** H.P. Knopf; P.K. Ebsen; M.J. Piattelli. **Colombia:** L.-A. Luna. **Denmark:** L. Østerborg; N.H. Svendsen. **Finland:** J. Liedes; K.M. Tarhio; S. Lahtinen; H. Räihä. **France:** B. Vidaud; C. Girard. **German Democratic Republic:** F. Jonkisch. **Germany (Federal Republic of):** I. Koch; H.J. Klier. **Ghana:** A.M. Abdullah. **Greece:** A. Bizas. **India:** G. Soni; P.G. Hebalkar; A. Malhotra. **Ireland:** A. Coleman-Dunne. **Italy:** M.G. Fortini; C. Pompi. **Japan:** Z. Kitagawa; Y. Masuda; S. Kamogawa; M. Nagao. **Luxembourg:** F. Schlesser. **Madagascar:** R.G. Razafimahefa. **Mexico:** M.A. Arce de Jeannet. **Morocco:** A. Bendaoud. **Netherlands:** M. Martin; E.C. Nooteboom; J. Meijer-van der Aa. **Norway:** J. Bing. **Pakistan:** M.A. Khan. **Panama:** I. Aizpúrua Pérez. **Republic of Korea:** T.-C. Choi. **Soviet Union:** N. Popov; V.V. Varfolomeev. **Spain:** J.-D. Vila Robert. **Sweden:** R. Halvorsen; J.-E. Bodin. **Switzerland:** J.-L. Comte; F. Probst. **United Kingdom:** D.M. Haselden. **United Republic of Tanzania:** E.E.E. Mtango; K.J. Suedi. **United States of America:** R. Oman; D. Schrader; M.S. Keplinger; M. Dadant; W.H. Skok; P. Behnke; E.H. Baxter; A.M. Harkins; R.R. Rader. **Uruguay:** R. González-Arenas. **Yugoslavia:** R. Tešić.

II. Intergovernmental Organizations

Commission of the European Communities (CEC): R.J. Coleman; B. Schwab; M. Langer; C. Bail. **Council of European Communities:** R.-J. Meijer. **European Free Trade Association (EFTA):** S. Norberg; L. Ólafsdóttir.

III. Non-Governmental Organizations

British Computer Society (BCS): R.J. Hart. **Committee of National Institutes of Patent Agents (CNIPA):** W. von Willich. **Computer and Business Equipment Manufacturers Association (CBEMA):** E.W. Brown. **Electronic Industries Association of Japan (EIAJ):** O. Fujii; K. Nakamura. **Industrial Property Cooperation Center (IPCC):** S. Yamaguchi. **International Association for the Protection of Industrial Property (AIPPI):** T. Mollet-Vieville. **International Chamber of Commerce (ICC):** S. Bernhard; J.W. Veerman; E.H. Brown; A. Koerber; J.M.W. Buraas. **International Federation of Industrial Property Attorneys (FICPI):** K. Raffnsoe; T.D. Jennings; H. Bardehle. **International Law Association:** B. Colas. **International League for Competition Law (LIDC):** J.-F. Léger. **International Patent and Trademark Association (IPTA):** R.S. Laurie. **International Publishers Association (IPA):** J.A. Koutchoumow. **Max Planck Institute for Foreign and International Patent, Copyright and Competition Law:** T.K. Dreier. **Semiconductor Industry Association (SIA):** R.M. Gadbaw. **The Chartered Institute of Patent Agents (CIPA):** R.J. Hart. **Union of European Practitioners in Industrial Property (UEPIP):** H.-E. Böhmer. **Union of Industries of the European Community (UNICE):** R.J. Hart; A. Koerber; J.W. Veerman; M. Colombe.

IV. Officers

Chairman: J.-L. Comte (Switzerland). *Vice-Chairmen:* G. Soni (India); N. Popov (Soviet Union). *Secretary:* L. Baeumer (WIPO).

V. International Bureau of WIPO

A. Bogsch *(Director General)*; M. Porzio *(Deputy Director General)*; A. Schäfers *(Deputy Director General)*; L. Baeumer *(Director, Industrial Property Division)*; C. Rogers *(Consultant, Industrial Property Division)*; M. Weil-Guthmann *(Consultant, Industrial Property Division)*.

** A list containing the titles and functions of the participants may be obtained from the International Bureau.

Vienna Union

Committee of Experts for the International Classification of the Figurative Elements of Marks

First Session
(Geneva, May 11 to 13, 1987)

NOTE*

The Committee of Experts set up under Article 5 of the Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks held its first session in Geneva from May 11 to 13, 1987.

The following member countries of the Vienna Union were represented: Luxembourg, Netherlands, Sweden (3). China, Denmark, Germany (Federal Republic of), Madagascar, Spain and Switzerland were represented by observers. The Benelux Trademark Office was also represented by observers. The list of participants follows this Note.

The Committee of Experts adopted its rules of procedure and a Recommendation to the countries of the Vienna Union for the purpose of facilitating the use of the Classification and promoting its uniform application, in conformity with Articles 5(2)*(b)* and 5(4) and with Article 5(3)(ii), respectively, of the Vienna Agreement. It also adopted a list of international non-governmental organizations which should be invited to be represented by observers at its meetings.

The Committee of Experts adopted the draft amendments and additions to the Classification that had been made by the Provisional Committee of Experts at its sessions held in Geneva from December 15 to 19, 1975, and from June 28 to July 2, 1976. Finally, the Committee of Experts studied and adopted a number of proposals for changes in the Classification submitted by the Benelux Trademark Office.

The Committee of Experts decided that the changes in the Classification would enter into force on January 1, 1988. A new edition of the Classification will then be published and be considered the second edition.

* Prepared by the International Bureau.

LIST OF PARTICIPANTS**

I. Member States

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II. Observer States

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Studies

Protection of Confidential Information Required to be Disclosed to Government Authorities

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A subject of acute—and increasing—importance to the chemically-based industries, including the pharmaceutical industry, is the protection afforded to the innovating, research-based company for its extensive safety and efficacy data. This information frequently costs the innovator tens or even hundreds of millions of dollars to generate and in most countries must be submitted to a government agency in order to obtain approval to sell the product in question.

The fact is that regulatory authorities in the majority of countries waive the need for those who would sell their own versions of the innovator's product ("generic" companies) to repeat all those tests which are already on file from the innovator. Regulators often merely seek evidence from the generic sources that their products are chemically the same, and work in the same way, as the innovator's product. In other words, these authorities effectively "take cognizance" of the innovator's data files for the benefit of generic companies. Their doing so weakens the incentive for the innovator to make the large investments that are involved and discourages innovation generally.

Balancing these arguments are the arguments of regulatory authorities and their supporters who want to make available possibly less expensive drugs, pesticides and other chemicals to the general population and, in some cases, who want to encourage domestic industry.

The purpose of the paper is to present a discussion of the law and practices followed in several key markets in the world. Since the United States of America probably has the most developed law across the field of chemicals, the paper will begin with a description of the situation in several areas involving chemical products in the United States. A discussion of the law and practices relating to pharmaceuticals in a number of other countries will follow, together with a few concluding remarks.

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I. United States of America

A. Introduction

United States law contains numerous situations where information must be disclosed in submissions to federal agencies under regulatory requirements. Where that information is considered to be confidential by the person or company submitting it, a complex statutory network determines whether and to what extent the information can be protected against disclosure to others. Companies need protection for the confidential information that they submit to the agencies, but the general policy under United States law favors full disclosure. While most people recognize that any balancing must take into account the need to preserve trade secrets, at the very least, the law is unsettled as to the coverage and meaning of the protected area.

The three federal laws that are of primary interest to the chemical and pharmaceutical industries are the Food, Drug and Cosmetic Act (the "Food and Drug Act")[1]; the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA")[2] and the Toxic Substances Control Act ("TSCA").[3] While these statutes provide some specific provisions protecting certain information (or, in some cases, requiring its disclosure), an overarching concern is another statute that applies to all federal agencies, the Freedom of Information Act ("FOIA").[4]

FOIA is a general disclosure statute. Subject to certain exceptions, a federal agency *must* disclose all data in its possession that is requested by *any* person or company. Thus, a party seeking protection for its confidential data must make a two-step analysis: first, is the

[1] 21 U.S.C. §301 *et seq.*

[2] 7 U.S.C. §136 *et seq.*

[3] 15 U.S.C. §2601 *et seq.* There are, of course, other federal and some state regulatory statutes with information submission requirements. To the extent that a company is involved with them, the specific provisions of such statutes (and any state FOIAs) should be consulted.

[4] 5 U.S.C. §552.

data subject to mandatory disclosure under the statute controlling the relevant agency; second, even if there is no such mandatory disclosure requirement, since the data is presumptively disclosable under FOIA, is there an FOIA exemption applicable to protect the data? Finally, one should be sensitive to the situation where, although the data is not directly disclosed, it is indirectly disclosed in that it is used by the agency to grant approval to products competing with those of the company submitting the data.

B. FOIA and the Trade Secrets Act

The FOIA is a vivid demonstration of United States public policy in favor of open government. It represents a conscious decision by Congress that the public has a right to know what the federal agencies do, how they do it and on what basis they are making decisions. The operative language provides that:

> "[E]ach agency, upon any request for records which (A) reasonably describes such records and (B) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person."[5]

The federal courts have jurisdiction to order such production if the agency does not make it voluntarily or completely.[6] If the agency believes that the records sought are covered by an exemption from disclosure, the agency has the burden to establish such exemption.[7]

For our purposes, the most relevant exemptions[8] are those covering: (A) matters specifically exempted from disclosure by some statute other than the Freedom of Information Act (often referred to as Exemption 3); and (B) trade secrets and commercial or financial information obtained from a person and privileged or confidential (Exemption 4).

The situation where other statutes prohibit disclosure (Exemption 3) will be discussed under the specific statutory headings below. However, one statute applies across the board and has been the subject of some controversy. The Trade Secrets Act[9] establishes criminal penalties consisting of possible fines, imprisonment and removal from office or employment, for the release by an officer, employee, department or agency of the United States

> "...to any extent not authorized by law of any information... which information concerns or relates to trade secrets...."[10]

The current Act stems from an 1864 revenue statute for which there is little relevant history, and which was subsequently reenacted several times. What history is available indicates that Congress was seeking to impede the unauthorized disclosure of business information by government agents.[11]

The term "trade secret," however, is nowhere defined in the Trade Secrets Act, or in FOIA or its legislative history.[12] In fact, the question of what is a trade secret is rather confused at present. This is due in large part to the relationship between substantive

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[5] *Id.* §552(a)(3).

[6] *Id.* §552(a)(4)(B).

[7] *Ibid.*

[8] The full list of exemptions as stated in 5 U.S.C. §552(b) and (c) reads:

"This section [requiring disclosure] does not apply to matters that are—

(1)(A) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and

(B) are in fact properly classified pursuant to such Executive order;

(2) related solely to the internal personnel rules and practices of an agency;

(3) specifically exempted from disclosure by statute (other than section 552b of this title), provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on tbe issues, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld;

(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;

(6) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) investigatory records compiled for law enforcement purposes, but only to the extent that the production of such records would (A) interfere with enforcement proceedings, (B) deprive a person of a right to a fair trial or an impartial adjudication, (C) constitute an unwarranted invasion of personal privacy, (D) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (E) disclose investigative techniques and procedures, or (F) endanger the life or physical safety of law enforcement personnel;

(8) contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(9) geological and geophysical information and data, including maps, concerning wells.

Any reasonably segregable portion of a record shall be provided to any person requesting sucb record after deletion of the portions which are exempt under this subsection.

(c) This section does not authorize withholding of information or limit the availability of records to the public, except as specifically stated in this section. This section is not authority to withhold information from Congress."

[9] 18 U.S.C. §1905.

[10] *Id.* Whether disclosure is "authorized by law" pursuant to some other statute can be a fine exercise in judicial construction. In *Chrysler v. Brown*, 441 U.S. 281 (1979), the Court held the regulations issued by the Department of Labor's Office of Federal Contract Compliance Program did *not* provide the authorization by law required because it did not find that Congress intended to provide the agency with the power to make the disclosure at issue.

[11] H.R. Rep. No. 304, 80th Cong., 1st Sess., A127-128 (1947).

[12] The closest that Congress came was a general statement in House Rep. No. 1497 accompanying P.L. 89-489 (FOIA), reprinted at U.S. Code and Cong. Adm. News, 89th Cong. 1966, Legisl. Hbt. Vol. 2, p. 2427. The courts have fairly well ignored it.

There is a list of factors to be used by EPA in defining what is a trade secret in the 1986 amendments to the Superfund Legislation; P.L. 99-499 (1986) at §322(b), but it has not been applied under FOIA. The same comment applies to the definition in the TSCA regulations, discussed in text accompanying notes 45 and 46, *infra.*

property rights (normally created under state law) and the disclosure rules incorporating those rights under federal law.

For example, most states have traditionally adopted a definition of trade secret originally proposed by the American Law Institute in its Restatement of the Law of Torts. That document states that a trade secret is:

> "[A]ny formula, pattern, device or compilation of information which is used in one's business and gives him an opportunity to obtain an advantage over competitors who do not know or use it."[13]

However, in the context of a case seeking the release of testing data on intraocular lenses from the Food and Drug Administration, a Court of Appeals rejected that broad Restatement definition stating that it was unclear that Congress intended to adopt it for use under FOIA.[14] The court then stated:

> "Accordingly, we define trade secret, solely for the purpose of FOIA Exemption 4 [the trade secret exemption], as a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort [citation omitted].[15]

The court felt that if a trade secret could be any information which gives competitive advantage, there was little or no information left that could qualify as "commercial or financial information" under the second category of the exemption. In other words, everything would be a trade secret. In that regard, the court did note that simply because the information requested did not constitute trade secrets did *not* mean that it was ineligible for protection under Exemption 4. In its view, information other than trade secrets falls within the second prong of the Exemption if it is shown to be (1) commercial or financial, (2) obtained from a person, and (3) privileged or confidential. It held that the terms "commercial" and "financial" should be given their ordinary meanings, and therefore, that commercial information is confidential for the purposes of Exemption 4 if its disclosure would either impair the Government's ability to obtain necessary information in the future, or cause substantial harm to the competitive position of the person from whom the information was obtained.[16] The parties opposing disclosure were not required to show actual competitive harm; evidence showing actual competition and the likelihood of substantial competitive injury would be sufficient.

Although it may appear that all this decision did was to take data that one would like to call trade secrets and protect it under a different heading (confidential, commercial or financial information), such a conclusion would be unduly sanguine. In an earlier case,[17] the Supreme Court had held that FOIA is exclusively a disclosure statute, and that Congress did not design the Act's exemptions to the mandatory bars to disclosure. If the information at issue qualifies for treatment as a trade secret under the Trade Secrets Act, a party may challenge the disclosure under the Administrative Procedure Act[18] as being not authorized by law. If the information is only covered by the exemption to FOIA (and is not covered by the Trade Secrets Act), the party seeking to prevent disclosure must show that disclosing it would constitute agency action that is arbitrary, capricious, or an abuse of discretion, a more difficult test to meet.[19]

The U.S. Supreme Court did not review that Court of Appeals' decision on the intraocular lens data, but it may have substantially undercut it in a later case concerning a different statute, but one that also involved the question of trade secrets.[20] Recall that the Court of Appeals decision purported to establish a uniform definition of trade secrets for all questions relating to disclosure of data under FOIA. However, in its later decision the Supreme Court held that the question of whether data constituted trade secrets was to be determined by *state* law. And, as noted, many states have a broader view of what constitutes a trade secret than did the Court of Appeals.

To a certain extent, the problems noted above are mitigated by the fact that the agencies do not routinely purport to disclose trade secret information. Most disclosure situations have come about when a particular party has requested information, the agency has refused to provide it (citing an exemption under the FOIA), and the party seeking the information has filed suit. At that point, the disclosing party often is permitted to intervene in the suit and defend the confidential character of its data. Still, there are other problems under the specific statutes involved, and it is to these that we will now turn.

C. Specific Statutes and Agencies

1. The Food, Drug and Cosmetic Act. Before new human or animal drugs, or any food additives, may be sold in interstate commerce in the United States, United States Food and Drug Administration ("FDA") approval is required.[21] The statute and regulations spell out the kind and quantity of data that must be submitted to get such approval (including health and safety test information, manufacturing process information, and components). In addition, the holder of any such FDA approval must regularly file certain reports with FDA.

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[13] *Restatement of Torts* §757.

[14] *Public Citizens Health Research Group v. FDA*, 704 F.2d 1280 (D.C. Cir. 1983).

[15] *Id.* at 1288.

[16] *Id.* at 1289-1291.

[17] *Chrysler v. Brown*, 441 U.S. 281 (1979).

[18] 5 U.S.C. §702.

[19] *Id.*

[20] *Ruckelshaus v. Monsanto*, 467 U.S. 986 (1984).

[21] 21 U.S.C. §355 (human drug); §360(b) (animal drug); §348 (food additive). Premarket approval also is required for certain medical devices.

The main area of dispute concerning data submitted to FDA has been over disclosure of health and safety testing information. Testing to establish the efficacy of a potential new product represents an enormous investment of time and money by the company seeking approval. It often views such data as highly proprietary. As noted earlier, a Court of Appeals decided that such information did not constitute trade secrets, but could be deemed commercial information subject to protection under FOIA.[22] That decision was made in 1983. In 1984, Congress substantially amended the Food and Drug Act. It changed the disclosure provisions, and codified certain FDA regulations.[23] Under the new law, safety and effectiveness data that has not previously been disclosed to the public by an applicant shall be made available to the public upon request under certain circumstances, unless "extraordinary circumstances" are shown by the holder of the new drug application ("NDA").

Since 1938, FDA regulations have stated that the data and information submitted to FDA in an NDA to demonstrate the safety and effectiveness of a drug constitute trade secrets and confidential commercial information that cannot be released to the public or used by FDA to approve a generic version of the drug until the drug is no longer a "new drug" under the law. Under the statute as amended, safety and effectiveness data retain their status as trade secrets or confidential commercial information, unless they are otherwise disclosed to the public, until such time as the FDA approves an abbreviated new drug application or could approve such an application for the drug.[24] At that time, the data contained in the pioneer NDA are potentially available for public disclosure, and will be disclosed unless the holder of the pioneer NDA can show extraordinary circumstances justifying the continuing confidential treatment of the data.

The statute does not define "extraordinary circumstances." However, FDA regulations allow that such circumstances included a situation in which safety and effectiveness data had commercial value as confidential business information. There is some view that the term should be given the same definition here.

Although there is no law on point yet, even if raw safety and effectiveness data are disclosable, the research techniques and protocols that result in the data may well represent trade secrets or confidential commercial information.

It appears that in amending the Food and Drug Act Congress did not intend to change the other FDA regulations implementing FOIA.[25] Thus, if a person objects to the proposed release of information that the FDA believes to be disclosable, but that the submitter believes to be a trade secret or confidential commercial information, FDA will give that person five days after the receipt of notification of the decision to disclose in which to institute a suit in the United States court to enjoin release of the information. If such suit is brought, the FDA will not disclose the records until the matter and all related appeals have been concluded.[26]

The rules governing food additives overtly favor disclosure. Under the Food and Drug Act, no food additive may be sold in interstate commerce until FDA has approved it. The vehicle for such approval is a food additive petition.[27] That petition includes all reports of investigations on the effect and safety of the food additive. With certain narrow exceptions, the data in that petition are made available to the public when the petition is accepted by FDA for filing (that is, at the start of the formal regulatory review period).[28] What is not disclosed are manufacturing methods or processes; production, sales, distribution and similar data; and quantitative or semiquantitative formulas. These are withheld *if* they represent trade secret or confidential business information under FOIA Exemption 4.[29] Other data may be protected if "extraordinary circumstances" are shown,[30] a term whose lack of definition has been dealt with earlier.

2. The Federal Insecticide, Fungicide and Rodenticide Act. FIFRA was first enacted in 1947, and was originally primarily a licensing and labeling statute. It required all pesticide products (defined broadly to include any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest) to be registered with the Secretary of Agriculture prior to their sale in interstate commerce. In 1970, the responsibilities for administering FIFRA were transferred to the Environmental Protection Agency (EPA).

In 1972, Congress substantially amended the law and included the provision most relevant to us here, section 10, which governs public disclosure of data submitted to support an application for registration.[31] The 1972 amendments authorized EPA to consider data submitted by one applicant in support of another application pertaining to a similar chemical, provided that the subsequent applicant offered to compensate the original applicant; however, any data exempt from disclosure as confidential business information could not be so considered by EPA to support another registration unless the original data submitter agreed.[32] The amendments did not specify what constitutes confi-

[22] *Public Citizens Health Research Group v. FDA, supra.*

[23] P.L. 98-417 (1984).

[24] The statutory provisions governing when an abbreviated new drug application may be approved are outside the scope of this paper.

[25] 21 C.F.R. Part 20.

[26] 21 C.F.R. §20.46.

[27] 21 U.S.C. §348.

[28] 21 C.F.R. §171.1(h)(1).

[29] *Id.* §171.1(h)(2).

[30] *Id.* §171.1(h)(1).

[31] 7 U.S.C. §136h.

[32] *Id.* §136a(c)(1)(D).

dential business information, and considerable litigation ensued. Congress reacted in 1978 with further amendments.

Under the 1978 amendments, applicants receive a 10-year period of exclusive use for data concerning new active ingredients contained in products registered after September 30, 1978.[33] All other data submitted after December 31, 1969, may be cited and considered in support of other applications for 15 years after the original submission if the applicant makes an offer to compensate the original submitter.[34] Data that does not qualify for either the 10-year exclusive use period or the 15-year compensation period may be considered by the EPA without limitation.[35] Thus, in any event, after 15 years all of the data is freely available for use.

Also in 1978, Congress added a new subsection which provides for disclosure of health, safety and environmental data concerning registered pesticide products to qualified requesters, but did not authorize disclosure of information that would reveal manufacturing or quality control processes unless EPA determined that disclosure was necessary to protect against an unreasonable risk of injury to health of the environment.[36]

This rather elaborate statutory scheme was challenged as constituting an unconstitutional taking of property under the Fifth Amendment of the United States Constitution.[37] When the case reached the United States Supreme Court, the Court upheld the statute in all respects.[38] In so doing, it considered four issues: (1) whether the Company had a property interest protected by the Fifth Amendment to the Constitution in the pesticide data submitted to EPA; (2) whether EPA's use or disclosure of such data effected a taking; (3) whether any such taking was for a public use; and (4) whether the statute adequately provides for just compensation.

As to the first issue, the Court held that the data submitted to EPA are "property" potentially protected by the United States Constitution, if applicable state law recognizes them as such. The parties had stipulated that under the applicable state law, which recognized trade secrets as property, much of the information submitted by the Company contained or related to trade secrets.

As to the period after September 30, 1978 (the effective date of the 1978 amendments), the Court concluded that data submitters were aware of FIFRA's data use and disclosure provisions and therefore could have no reasonable investment-backed expectation that EPA would protect the data from use or disclosure. Accordingly, disclosure or use by EPA of data submitted after that date was not a "taking" of property. As to such data, therefore, questions 3 and 4 were moot.

The Court's decision that there was no "taking" is enormously significant. The Court held that a company that chooses to submit data in order to obtain a registration, knowing that the governing statute permits much of the data to be disclosed to the general public or used by EPA in support of other applications, waives any rights to confidentiality or proprietary treatment. The company had argued that requiring a submitter to surrender its property interest placed an unconstitutional condition on its right to a valuable government benefit. The Court rejected that contention.

3. The Toxic Substances Control Act. TSCA has two main features: acquisition of sufficient information by EPA to identify and evaluate potential hazards from chemical substances; and regulation of the production, use, distribution and disposal of such substances where necessary.

The heart of TSCA is the requirement for pre-manufacture notification ("PMN"). A manufacturer must notify EPA 90 days before producing a new chemical substance (defined as any chemical not listed on a specially compiled inventory list).[39] Notification is also necessary, even for older chemicals already on that list, if EPA concludes that there is a significant new use of the substance which increases human or environmental exposure. Within five days of receiving the notice, EPA must publish in the Federal Register an item identifying the chemical substance, its intended uses, and a description of the toxicological tests performed to demonstrate that there will be no "unreasonable risk of injury to health or the environment."[40]

The inventory list referred to earlier was prepared as a baseline, listing pre-existing chemicals produced from January 1975 until the 1978 enactment of TSCA. Under the statute, the EPA promulgates rules under which a person who manufactures or processes or proposes to manufacture or process a chemical substance must keep records and make reports. Such reports may require such information as molecular structure, categories of use, amounts produced, description of by-products, disposal methods, and all existing data concerning the environment and health effects of each substance.[41]

Since a principal function of TSCA is the collection of voluminous information on chemical substances, concern for the protection of genuine trade secrets was and is a hotly debated topic. The statute provides that EPA may not release any information which is exempt

[33] *Id.* §136a(c)(1)(D)(i).

[34] *Id.* §136a(c)(1)(D)(ii). The statute provides a mechanism for determining the level of compensation if the parties do not agree.

[35] *Id.* §136a(c)(1)(D)(iii).

[36] *Id.* §136h(d)(1)(A)-(C).

[37] That amendment provides, in relevant part, that no person shall be deprived of life, liberty and property without due process of law; nor shall private property be taken for public use, without just compensation.

[38] *Ruckelshaus v. Monsanto*, 467 U.S. 986 (1984). Much of the decision deals with how to handle data submitted before the 1978 amendments, and will not be discussed in this paper.

[39] 15 U.S.C. §2604.

[40] *Id.* §2604(d)(2).

[41] *Id.* §2607(a).

from mandatory disclosure under FOIA.[42] This, of course, protects trade secrets and commercial and financial information obtained from a person and privileged or confidential (FOIA Exemption 4). That protection is subject to several exceptions, and specifically does *not* prohibit disclosure of health and safety studies.[43]

Interestingly enough, the EPA regulations governing disclosure of information specifically provide that an EPA office may, at its discretion, release requested records *despite* the applicability of one or more of the FOIA exemptions, but will not do so as a matter of policy except when ordered to do so by a federal court or in exceptional circumstances with the approval of the Office of General Counsel or Regional Counsel.[44]

The EPA regulations go into considerable detail with respect to how a claim for confidentiality of data is to be resolved,[45] and in fact have a definition of business information entitled to confidential treatment. They hold that information is entitled to such treatment if:

(a) the business has asserted a business confidentiality claim which has not expired, been waived or withdrawn;
(b) the business has satisfactorily shown that it has taken reasonable measures to protect the confidentiality of the information, and that it intends to continue to take such measures;
(c) the information is not and has not been reasonably obtainable without the business' consent by other persons by use of legitimate means;
(d) no statute specifically requires disclosure;
(e) either the business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to its competitive position, or the information is voluntarily submitted and its disclosure would be likely to impair the Government's ability to get necessary information in the future.[46]

II. European Economic Community (EEC)

A. Introduction

In December 1986, the EEC Council of Ministers adopted a number of Directives[47] which will have the effect, in certain circumstances, of requiring generic companies either to furnish their own complete safety and efficacy dossiers in support of health registrations, or await the elapse of an "exclusivity period" granted to innovators. The three most recent members of the EEC—Greece, Spain and Portugal—are exempt from the requirement of implementing the above rules until 1992. All other EEC Member States are required to do so by July 1, 1987.

Prior to these recent developments, Directive 65/65, dated January 26, 1965, was the primary operative EEC legislation.[48] Article 4 of Directive 65/65 required health registration applicants to furnish

> "...results of physico-chemical, biological or microbiological tests, pharmacological and toxicological tests, and clinical trials."

Article 4 went on, however, to provide that a bibliography of such trials, conducted on another (i.e., innovating) company's identical pharmaceutical product can be substituted for the required tests where the pharmaceutical in question is already known to be safe and effective through established use. Directive 75/319, as amended, supplemented this by enabling second applicants to request a national health authority to take account of a health registration already issued in another Member State.[49]

B. The New Directives

The four Directives promulgated by the Council on December 16, 1986, cover both "biotechnological" and other "high-technology" pharmaceutical products. At this point, it may be advisable to focus on the effect that these Directives may have on the ability of generic companies to access innovators' safety and efficacy files.

The first of the four Directives gives a definition of the kinds of pharmaceutical products the Directives cover. This definition is divided into two parts, A and B.

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[42] *Id.* §2613(a).

[43] The data may be disclosed for law enforcement purposes to government contractors where required to enable them to perform their contracts, if necessary to protect health or the environment against an unreasonable risk, and where relevant in an EPA proceeding. Section 2613(a) does *not* prohibit disclosure of health and safety data; *id.* §2613(b).

[44] 40 C.F.R. §2.119.

[45] 40 C.F.R. §§2.201-2.215.

[46] *Id.* §2.208.

[47] Council Directive 87/22—on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology. *Official Journal* (OJ), No. L 15, 17.1.1987, p. 38.

Council Directive 87/19—amending Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products. OJ No. L 15, 17.1.1987, p. 31.

Council Directive 87/20—amending Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products. OJ No. L 15, 17.1.1987, p. 34.

Council Directive 87/21—amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. OJ No. L 15, 17.1.1987, p. 36.

[48] Council Directive 65/65 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. OJ No. 22, 9.2.1965, p. 369/65.

[49] Council Directive 75/319/EEC of May 20, 1975, on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. OJ No. L 147, 9.6.1975, p. 13.

Part A defines the biotechnologically-produced pharmaceuticals embraced by these Directives. Part B defines the "other high-technology medicinal products" to which the Directives refer. Among "high-technology medicinal products," Part B includes the following:

> " — medicinal products containing a new substance or an entirely new indication which, in the opinion of the competent authority concerned, is of significant therapeutic interest;
> — medicinal products administered by means of new delivery systems, which, in the opinion of the competent authority concerned, constitute a significant innovation;
> — medicinal products the manufacture of which employs processes which, in the opinion of the competent authority concerned, demonstrate a significant technical advance...."

The definition of "high-technology medicinal product" is therefore vague, and leaves considerable latitude to the health authorities in the EEC Member States. By the same token, innovating pharmaceutical companies are given some scope to argue that new products they develop are worthy of the benefits accorded by the Directives.

C. The Specific Directives

The two Directives of primary interest to the chemical and pharmaceutical industries are Directive 87/22 and Directive 87/21.

1. *Directive 87/22* provides that at the request of the health registration applicant for a "high-technology medicinal product," the national health authorities shall, before granting (or refusing) a health registration, refer the application, together with its supporting safety and efficacy data, to the EEC Commission's Committee for Proprietary Medicinal Products (CPMP) "for an opinion." Thus, this Directive establishes a "voluntary concertation" process for "high-technology" pharmaceuticals (that process, incidentally, is compulsory in the case of products derived from biotechnological processes).

2. *Directive 87/21* is the key instrument governing generic use of proprietary health registration data, because its major purpose is to amend Article 4 of Directive 65/65. Point 8 of the second paragraph of Article 4 had provided that full safety and efficacy data need not be furnished by a second applicant if that applicant could produce a bibliography of safety and efficacy tests and trials. Those provisions have been removed by Directive 87/21 and now, in order to avoid having to provide full safety and efficacy data, the second applicant must be able to demonstrate qualification under one of the following exceptions:

(i) that the innovator has *consented* to having the original safety and efficacy dossier referenced; or

(ii) that "by detailed references to published scientific literature presented in accordance with the second paragraph of Article 1 of Directive 75/318,[50] the constituent or constituents... of the proprietary medicinal use, with recognized efficacy and an acceptable level of safety"; or

(iii) that the generic copy is "essentially similar" to an innovator's which has been authorized within the Community for at least six years and is marketed in the relevant State. This period is extended to 10 years in the case of biotechnologically-produced products (Part A) or Part B "high-technology medicinal products" which have been reviewed by the CPMP as mentioned above. Member States may extend the six-year period to 10 years for all products irrespective of expired patents, and, conversely, may limit the period for non-biotechnological and non-high-technology products to six years *or* expiration of the innovator's product patent, whichever happens first.

Hence, assuming that the innovator has not consented to a generic company referring to its original health registration dossier, the generic company must either produce a full safety and efficacy dossier repeating all the tests and trials performed by the innovator, or fall within exception (ii) or (iii), above.

Exception (ii) is vague in its meaning, and hence difficult to assess in precise terms. However, it appears to provide a heavy burden on an applicant to provide "detailed references" to published scientific literature which, in sum, are equivalent in force and effect to the results of safety tests and clinical trials. This exception therefore appears to enable a generic applicant to gain registration based upon a bibliography, rather than on tests and trials on the particular generic product, provided the applicant can assemble the bibliography—which in turn necessitates publication of critical data by the innovator. It may, therefore, be difficult for a generic applicant to qualify under exception (ii), but much depends upon how this exception is implemented in the laws of the Member States.

Exception (ii) could be interpreted to mean that any second applicant would have to produce evidence of pharmacological and toxicological tests as well as clinical trials by reference to the scientific literature which, in practice, might be extremely difficult to establish. This view appears to be supported, for example, by Mr. Fernand Sauer, a Principal Administrator at the Commission, who is also an attorney and pharmacist, and who has been responsible for the Directive's progress through the European Parliament and Council.[51]

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[50] Council Directive 75/318/EEC of May 20, 1975, on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products. OJ No. L 147, 9.6.1975, p. 1.

[51] Fernand Sauer, "Rules Governing Pharmaceuticals in the European Community," *Industrie Santé*, No. 117, December 1986.

Exception (iii) places a premium first on the ability of innovators to establish that their new chemical entities, processes and delivery systems are indeed "high-technology medicinal products" and, secondly, on the deliberate selection by the innovator of the CPMP procedure described above.

D. Implementation by Member States

1. United Kingdom

The Medicines Act of 1968 requires a marketer of prescription medicines to obtain a product license, and provides that the Licensing Authority is obliged to consider safety, efficacy and quality when dealing with license applications.[52] The 1968 Act also provides that the Authority may not refuse a license on price grounds. The details of the pertinent law are contained in Regulations passed under the Act and in published guidance notes.

Regulation 4 of the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971 permits the omission of certain categories of safety, efficacy and quality data which the Regulations may otherwise indicate as being required. Guidance notes published by the Licensing Authority have used this statutory provision to permit an abridged application procedure for products which are widely used and well established or for which the relevant information has already been provided by the original applicant in relation to the substance.[53]

In a memorandum dated December 12, 1986,[54] prepared by a leading London law firm, the opinion is expressed that the 1971 Regulation permitting the abridged procedure may be questionable if the Licensing Authority—which happens also to be virtually the sole purchaser of prescription pharmaceutical products in the United Kingdom—is thereby considered to be taking into account price as a factor in determining the grant of a license. The memorandum concedes that such a contention may be hard to prove.

In the referenced memorandum, attention is drawn to Section 107 of the Medicines Act of 1968, which excludes the prospect of questioning any of the Licensing Authority's decisions in legal proceedings, except by "the person to whom such decision relates" (i.e., the applicant). While the High Court has an overriding supervisory jurisdiction, the only possible ground would appear to be that the Licensing Authority, when considering a generic application, discloses information which may involve a breach of confidence. This entails a problem of proof for the plaintiff, and the courts are not anxious to overturn an administrative body's decision in the absence of evidence of impropriety.

One practical basis for a complaint appears to be the use by the Licensing Authority of the innovator's confidential information. The memorandum mentioned above draws a distinction between the Licensing Authority *relying on* confidential information supplied by the innovator, and the *positive use* of such information when processing a generic application under the abridged procedure (by disclosure or other active assistance to the applicant). Assuming, however, it can be shown that some degree of positive use is made by the Licensing Authority of the innovator's confidential data during the processing of a generic application by the abridged procedure, an action for breach of confidence appears to lie against the Authority.

The Association of the British Pharmaceutical Industry (ABPI) has asked the Licensing Authority (Department of Health and Social Security (DHSS)) to confirm that, when considering a generic application, the Licensing Authority makes absolutely no use of the information submitted by the original applicant. The DHSS has not yet replied.

With respect to the implementation of the new Directives, it would appear that the current expectation as to exception (iii) is that the Government of the United Kingdom will favor the 10-year exclusivity provision for all medicinal products whether or not the CPMP review mentioned earlier has occurred. One interpretation that has been mentioned concerning exception (ii) is that any second applicant relying on this exception will have to produce evidence of pharmacological and toxicological tests as well as clinical trials by reference to the scientific literature.[55]

2. Federal Republic of Germany

The Federal Board of Health announcement of May 30, 1979, provided that "secondary" applicants could refer to documentation submitted by a primary applicant without the primary applicant's consent, in order to "avoid repetition of animal experiments and clinical trials of patients and volunteers."[56]

On August 21, 1986, the Drug Law of the Federal Republic of Germany was amended in various respects. On the subject of health registration data submissions, the amendments provide for a 10-year embargo on the reference to an innovating pharmaceutical company's health registration by or on behalf of a generic party.[57] The 10-year period begins on the date of the innovator's registration. The effect of this provision is that, without the consent of the innovator, generic companies cannot obtain registration of their products during the 10-year period unless they produce their own self-generated, safety and efficacy data package.

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[52] Medicines Act 1968 c. 67 §19.

[53] Department of Health and Social Security Ref. MAL 2.

[54] Richards Butler, Memorandum: Product Licenses—Misuse of Proprietary Information, December 12, 1986.

[55] Fernand Sauer, *ibid.*, note 51, *supra.*

[56] Dr. Otto May, *"Die Regelung der Zweitanmelderfrage im Arzneimittelgesetz"* (Secondary Applicant Status under the Medicinal Drugs Act), *Pharma Recht*, No. 6, 1986, pp. 254-261.

[57] Specifically, by adding s.s. 24a and 24b to the Second Amendment of the Medicines Act.

The new amendments cover only pharmaceuticals originally registered under the Drug Law since 1976 and, in particular, do not apply to generic applications made prior to August 22, 1986, but they do apply even if the innovator's German patents on the product expire during this 10-year exclusivity period.

It is important to note, however, that the Berlin Administrative Court on February 10, 1987, granted a temporary injunction against the Federal Board of Health, ruling that the Federal Board of Health must undertake not to grant drug applications that were still pending on August 22, 1986, where reference has been made to the innovator's data without the innovator's consent. It is not clear whether or not the Federal Board of Health will appeal this decision.

When a generic applicant makes an incomplete registration application, intending a partial or total referral to the innovator's data submission, the Federal Board of Health must so inform the innovator. The inventor then has a two-month period in which to object to that generic application. The effect of such opposition on the part of the innovator is that the 10-year embargo, running from the date of the innovator's registration, becomes applicable.

3. France

Under French law, the health registration data package is the property of the filing company and a third party cannot use that data without the authorization of the innovator. An *Arrêté* dated March 13, 1986, provides that health registrations are among the administrative files that cannot be communicated under French law by the Health Authorities without a breach of secrecy.[58] Thus, this *Arrêté* confirms the strictly confidential character of the health registration data.

The above-mentioned protection is effectively eliminated, however, by Section R.5133 (Decree of September 20, 1978) of the French Public Health Code which provides that a generic company attempting to register a generic version of a known and proven innovator product can provide limited information consisting of a bibliography and a bio-availability study that compares the proposed generic to the known and proven product. In other words, Section R.5133 enables generic companies to avoid having to generate all the safety, toxicological, pharmacological and clinical data where the innovator's drug already has been adequately tested on human beings so that its effects, including its side effects, are well known. Use of the bibliographical data must be justified and there must be a demonstration made that the appropriate norms and protocols have been complied with.[59]

As to the implementation of the new Directives, the PMA in France apparently has written to the Health Authorities requesting a 10-year exclusivity period for all pharmaceutical products. The results of this request are not yet known.

4. Spain

In theory, all applicants who wish to register pharmaceutical products in Spain are legally required to submit to the Directorate General of Pharmaceuticals precisely the same standard of pharmacological and analytical data, pursuant to Sections 1 to 5 of Decree No. 1416/73.[60] No distinction is drawn between innovating and generic applicants. The potential remedies available, at least in theory, to an innovator complying with Decree No. 1416/73 when the Authorities allow generics to file abridged applications in the light of data already filed by the innovator might include a suit for breach of confidence, a claim of unjust enrichment or unlawful competition, and a charge of abuse of rights.

Legal theory is difficult, however, to translate into practice for a number of reasons, including lengthy proceedings. By far, the most critical problem from a practical standpoint is the highly formalistic approach taken by Spanish procedural law. For example, it would be necessary to provide evidence, in the manner required by settled practice, that generic applications are indeed admitted and processed on an abridged basis.

III. Other Jurisdictions

Two other jurisdictions that provide noteworthy examples concerning protection of confidential information that is required to be disclosed to Government officials under regulatory requirements are Canada and New Zealand.

A. Canada

Regulations C.08.002(1)(a) and (b), issued pursuant to the Food and Drugs Act (Act) provide that no one may sell or advertise a new drug unless a satisfactory New Drug Submission (NDS) has been submitted to the Health Protection Branch (HPB) and a Notice of Compliance (NOC) has been issued. Regulations C.08.002(2)(g) and (h) provide that detailed tests to establish the safety and substantial effectiveness of the new drug must be submitted as part of the NDS.[61]

The Act speaks of a "New Drug" but there is no definition as to when a "New Drug" becomes an "Old Drug," the latter term not being used in the Act. HPB has suggested that such factors as unresolved problems of efficacy and changing concepts of usage or newly detected adverse effects would cause a drug to remain as a "New Drug." There is no specific provision in the Act

[58] *Journal officiel de la République française*, March 19, 1986.

[59] *Ibid.*, October 6, 1978.

[60] *Boletin Oficial del Estado*, June 30, 1973.

[61] Food and Drugs Act, R.S.C. 1970, Chap. 527.

whereby a generic manufacturer is permitted to file an NDS containing less data than that required of any other (innovative) manufacturer pursuant to the above-mentioned Regulations.

It has long been believed that HPB is making reference to the innovator's file when processing a generic NOC. An internal HPB legal opinion obtained in 1985 under the Access to Information Act states that there was no provision in the Act to make such a reference and that basically each NDS must stand on its own. Despite this, and HPB "Guidelines" which state to the contrary, it appears that HPB may access innovators' files and adopt a scheme of bio-equivalence under which one new drug is considered on the merits of another new drug.

Canadian common law relating to the protection of innovators' proprietary health registration data in theory, at least, provides universal causes of action which may be used against the generic non-innovator seeking to gain health registrations without having conducted full safety and efficacy tests. Moreover, there are potential rights of action against the HPB. These possible actions are, however, in this context still virtually untested.

B. New Zealand

Although a small country and a minor pharmaceutical market in relative terms, the confidentiality of health registration data in New Zealand has become a major legal issue with the Department of Health in Wellington.[62]

The Medicines Act of 1981 and statutory instruments passed thereunder (principally the Medicines Regulations 1984, and the Department of Health Guide, which arguably has statutory effect) require all applicants for licenses to manufacture and sell pharmaceutical products to file suitable safety and efficacy data in support of their applications. The law draws no distinction between original and generic drugs, and each class is to be accorded the same treatment under the Act. There is no statutory authority for the Department of Health to implement an "abridged" procedure.

The Medicines Act and Regulations thereunder impose strict obligations on applicants for health registration to supply cogent safety and efficacy data. The Department of Health is required by this legislation to consider such data before granting a health registration. This process cannot be circumvented by recourse to the Official Information Act, or by reliance on the innovator's data filed with the Department. Such an "abridged" procedure would lead to the impeachment of any registration granted to a generic applicant. There are also various common law remedies available to prevent the misuse of proprietary information belonging to the innovator. Breach of confidence is a possibility, but the most obvious remedy is a judicial review.

[62] *Pfizer Laboratories Limited and Another v. Director-General of Health and Another.*

IV. Conclusion

Companies need protection for the confidential information and data that they are required to submit to regulatory authorities. Otherwise, there is no incentive to undertake the large investment in time and money that is involved in preparing such data. Such protection has no necessary connection with the patent status of the product. In any event, in many cases patent protection may not exist because of the length of the regulatory approval process or for other reasons. This need for safeguards has to be balanced, however, against a strong public policy favoring full disclosure. As we have seen, the regulatory authorities and courts in the respective jurisdictions have not as yet been able to fully accommodate these competing policies. The underlying objectives in fashioning an adequate legal solution should be safety and fairness: safety to the consumer and fairness to the innovator.

Safety

Is it safe for health authorities to draw the inference that all the clinical, toxicological and other data generated for the innovator's product can be applied to generic versions, thereby relieving the generic companies from performing their own clinical and toxicological investigations to demonstrate the safety and efficacy of their own products?

Most health authorities require generic companies seeking a registration to submit certain limited information on the manufacture of the generic drug, and a bio-availability study comparing the proposed generic drug to the brand name drug. Bio-availability studies are done by assessing the blood levels of the drug in healthy volunteers at various times after drug ingestion. The blood levels of the drug allow the assessment of the rate of absorption, and the extent of absorption. If the rate and extent of absorption of the generic is not significantly different from the brand name drug, the two drugs are said to be "bio-equivalent." The inference which health authorities then make is that all the extensive clinical data generated for the brand name drug can be applied to the generic version, with the result that the generic company need not further demonstrate safety and efficacy. Hence, safety and efficacy are *inferred* for a generic product, and are not *proven* directly.

Differences in excipients, particle size, dispersion, pH, stability, tablet compression and so on, can result in generic pharmaceutical products being different—perhaps dangerously so—from the innovator's established product, even though, strictly speaking, they may be "bio-equivalent." Different formulations of

phenytoin, grisofulvin, digoxin, cimetidine, levothyroxine and enteric-coated ASA are samples of generic versions of drugs having had comparably decreased efficacy or increased toxic effects. A good example was a generic version of the analgesic ibuprofen in Canada, which was withdrawn from the formularies, after evidence was introduced that the generic version was absorbed into a patient's bloodstream significantly more slowly than the innovator's brand for which the health authority held all the safety and efficacy data.

It seems there have been problems with the studies themselves, as well. In 1987, doctors apparently were warned by the Australian Health Ministry not to prescribe 33 generic prescription pharmaceuticals to new patients pending further notice, because of concerns about the inadequacies of the bio-equivalent data generated by the testing laboratory involved. One year earlier, it also seems that 20 generic pharmaceuticals were recalled from the Australian market as a result of bio-inequivalence concerns, all based on data provided by the same testing laboratory.

On the other hand, most regulatory agencies take the position that for the large majority of chemical compounds bio-equivalence is sufficient proof of safety. They argue that the reported instances of problems with generic products are relatively few.

Fairness

The pursuit of cost savings in the health care sector is an important goal of any government. Consequently, in recent years, as we have seen, there has been an increasing inclination in many countries—either expressly or, more often, by implication—to grant government authorities the right to use and/or disclose to others scientific data submitted in support of applications for the registration of medicines and, in the United States, for the registration of other chemical products as well.

These moves to abolish or attenuate the confidentiality of registration data have been supported by manufacturers of generic products, who would, in the short term, benefit commercially from the free disclosure of the proprietary information involved. They have also been supported by some consumer organizations, which argue that the registration process should be made transparent so that members of the public have the opportunity to contribute their own findings or to raise objections.

The costs incurred by the originator in generating and assembling detailed pharmacological, toxicological and clinical data concerning a new medicine or other chemical are very high, and are increasing. The incentive to undertake this very high level of expenditure is the prospect that, if the product turns out to be a successful one, the originator will be able to recoup and earn a reasonable return on that investment by temporarily enjoying an exclusive position in the marketing of the product and/or by granting to other manufacturers royalty-bearing licenses to make and market the product. That prospect, in turn, depends at least partly on preserving the confidentiality of the registration data as well as on patent rights.

Abolition or attenuation of the confidentiality of the registration data would therefore weaken the incentive to invest in the discovery and development of new medicines and other useful chemical compounds, and discourage the diminishing band of innovating manufacturers from continuing to invest money in the risky venture of chemical research. Over the long term, any substantial reduction in the level of investment in R & D would inevitably lead to a diminishing flow of new compounds. This would, incidentally, operate against the long-term interests of the generic manufacturers, who would, in due course, have fewer products to copy. More importantly, however, it would involve heavy social costs, as there is ample evidence—contained in numerous published economic studies[63]—that the introduction and use of modern medicines yields very large net economic benefits for society.

The massive size and the upward trend of the costs incurred by innovating manufacturers in generating and assembling detailed pharmacological, toxicological and clinical data are confirmed by empirical evidence. On the basis of a study of the R & D expenditures of 14 U.S. pharmaceutical manufacturers,[64] it was calculated that, in 1976, the total cost of discovering and developing a marketed new chemical entity amounted on average to $54 million, and that, of this total cost, $23.6 million (i.e., 43.7%) was accounted for by the cost of post-IND tests and preclinical animal toxicity testing.

The laws of many countries provide protection against the unauthorized use of business secrets. Certain information generated by an applicant for registration of a chemical compound, in the course of the testing of that compound, represents commercially valuable scientific information, and is treated as strictly confidential by the applicant concerned. This information is equivalent to business secrets and should receive the same protection that business secrets are afforded.

[63] *(a)* H. Brungger, "Health in Cost-Benefit Analysis, the Case of the New Drug L-Dopa," *Schweizerische Zeitschrift für Volkswirtschaft und Statistik*, 1972, Vol. 108, pp. 347-375; *(b)* B. Lindholm, *"Poliovaccinets Samhällsekonomiska Lonsamhet," Statens Medicinska Forskningsråd*, Rapport No. 1, 1973; *(c)* Battelle-Institut, *Kosten-Nutzen-Analyse der Grippeschutzimpfung*, Frankfurt, 1973; *(d)* S. Peltzman, *Regulation of Pharmaceutical Innovation*, American Enterprise Institute, Washington, 1974, pp. 51-73; *(e)* Battelle-Institut, *Kosten-Nutzen-Analyse der Poliomyelitis*; *(f)* P. Stolz, *Psychopharmaka—Volkswirtschaftlich Analysiert*, Schulthess Polygraphischer Verlag, Zurich, 1974; *(g)* M. Brand *et al.*, *Kosten-Nutzen-Analyse Antidepressiva*, Springer-Verlag, 1975; *(h)* Netherlands Economic Institute, *Present Cost of Peptic Ulceration to the Dutch Economy and Possible Impact of Cimetidine on this Cost*, Rotterdam, 1977; *(i)* Robinson Associates Inc., *The Impact of Cimetidine on the National Cost of Duodenal Ulcers*, Bryn Mawr, Pennsylvania, 1978; *(j)* Swedish Institute for Health Economics, *"Magsårssjukdomen."*

[64] R.W. Hansen, "The Pharmaceutical Development Process, Estimates of Development Costs, Etc.," in R.I. Chien, ed., *Issues in Pharmaceutical Economics*, D.C. Health & Co., Lexington, Massachusetts, 1979, pp. 151-181.

In short, the competing policies facing governments would appear to be best accommodated by affording trade secret protection to those aspects of an applicant's filing that qualify as such. The consumer is best served where the safety and efficacy of each drug must be proven, and not inferred. Furthermore, in the long term, the consumer will be the direct beneficiary of the inventions that the incentives inherent in a fair system will foster.

The Protection of Confidential Data Communicated to Public Authorities, Particularly with Regard to Chemicals

A Selective Study of European Legislation

J.-M. DEVOS*

Foreword

Until just a few years ago, the protection of confidential data was seldom thought to constitute a specific legal discipline. In the majority of European legal systems, the "right of confidentiality" has not been developed as a self-contained set of provisions that is at once cohesive and complete. The protection of data has generally been provided for in the general provisions on the duty of civil servants to exercise discretion, or in specific regulations. As we shall see in the course of this study, a trend towards express recognition of the "confidentiality of data" is taking shape, notably under the influence of the international economic organizations responsible for promoting the movement of goods and trade between countries.

The exact nature of the rights held by the owners of data[1] is still a matter of controversy among writers. They generally agree, however, in their recognition that such rights do exist, and that it would be unacceptable for the owner of the data to lose the advantages conferred on him by knowledge acquired through his own inventiveness and industry. Unlike the patentee, the owner of data does not benefit from any public title affording him direct protection for his invention.

We shall see in this study to what extent the laws of a number of countries and the law of the European Economic Community (EEC) meet the need to protect information received by administrations.

The *first part* of the study will examine how the laws of several European countries provide for the protection of confidential information. We shall also see how the legislation of a number of countries deals with the question in the more specific context of the testing of chemicals prior to marketing. This examination will among other things cover Belgian law, which will serve here as an example of the application of the Community regime, but it will also take in the Dutch, French, German and British regimes. Certain questions have been deliberately omitted from the national accounts when they have been extensively harmonized at the international level.

The *second part* of the study deals with the measures adopted by a supranational group like the Common Market, which has achieved a very high degree of harmonization based on mutual trust and on recognition of the right of confidentiality in data exchanges between countries. We shall then see how—on a broader scale but with less binding force—the Organisation for Economic Co-operation and Development (OECD) has worked out principles common to all its members under its special Programme on the Control of Chemicals.

Part One
Consideration of Various National Legal Systems for the Protection of Confidential Data

Chapter I: The Law of Belgium

General Provisions on the Protection of Information Held by the Administration—Professional Secrecy and Duty of Discretion

The Belgian legislative system has long recognized the principle of mandatory respect by the authorities for information communicated to them.

The concepts of "confidential data" or "commercial or industrial secrecy" are not defined in the law, and are left to the discretion of the courts.

Without any doubt the Belgian legal order protects information supplied to an authority, either by a criminal sanction (Section 458 of the Criminal Code) or by virtue of the provisions applicable to State officials (Section 982 of the State Officials Regulations).

Section 458 of the Criminal Code obliges any person who is a "depositary by estate or by profession" not to disclose the secrets entrusted to him on pain of imprisonment or a fine. The only exceptions to that rule are the case in which the holder of the secret is called upon to testify in court and that in which the law obliges him to reveal the secrets. The provision is addressed not only to professional categories as different as physicians and pharmacists, but also to civil servants. The latter are in

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[1] We are using the word "owner" by design. It appears that a majority of legal writers of various countries now agree that the legal protection of industrial secrecy, like the protection of know-how, derives from a proprietary right. This approach was, for instance, used by the Group of Experts on Confidentiality of Data of the Organisation for Economic Co-operation and Development (OECD) which came down firmly in favor of intellectual property law.

addition subject to an express obligation of non-disclosure, which is repeated in Section 9, second paragraph, of the *State Officials Regulations* (Royal Order of October 20, 1937). Civil servants are not entitled to reveal facts that have come to their knowledge in the pursuance of their duties and which are of secret character "either by nature or by virtue of instructions from superiors." The prohibition applies to State officials who have ceased to perform their duties.

Violation of the secrecy obligation can result in disciplinary or criminal sanctions, but also in the civil liability of the official of the administration who has committed a wrongful indiscretion.

The general rule of the professional secrecy obligation and of the duty of discretion on the part of agents of the authorities is written into a very large number of legal texts. Specific rules on the control of goods involving the communication of data to the Administration are no exception to the rule. They even extend it to persons who are not subject to the State Officials Regulations and also to those members of commissions entrusted with such cases who are not civil servants. For instance, Section 5, sixth paragraph, of the Royal Order of May 24, 1982, provides that

> "any person taking part or called upon to take part in the work of the Dangerous Goods Commission shall exercise the most absolute discretion on any information or document that might have come to his knowledge in the course or at the time of that work."

Specific Provisions to Guarantee the Protection of Data in Chemicals Control Legislation

The rules laid down by Community law in the Directive on the testing of chemicals are to be found in the Royal Order of May 24, 1982, regulating the marketing of substances potentially dangerous to man or to his environment.[2]

Request for Confidential Treatment. The person or entity ("the notifier") who communicates a file to the Administration may specify the information whose disclosure could be prejudicial to him and which he consequently asks to be kept secret from any person other than the competent Belgian authorities and the other Member States of the European Communities, and also the Commission.[3]

The notifier does, however, have to provide the "necessary justification" in support of his request for confidential treatment.

Decision of the Authority. The Minister takes the decision to grant confidential treatment in the light of the report of the Dangerous Goods Commission, which has the task of examining notification files that are submitted to it. In the event of a dispute arising from refusal to grant confidential treatment, the ministerial decision may be the subject of an appeal for annulment before the Council of State. It should be pointed out that, if the notifier himself publicizes information recognized as requiring confidential treatment, he is bound to inform the Minister beforehand.

Information not Qualifying for Confidential Treatment. Under the provisions of Community Directive 79/831, a certain number of particulars concerning the health and safety of persons cannot be subject to secrecy and therefore do not qualify for confidential treatment. Those particulars have to be widely accessible.

The data concerned are the following:

- the trade name of the substance;
- certain physico-chemical properties of the substance;
- the possible ways of rendering the substance harmless;
- the interpretation of the toxicological and ecotoxicological tests and the name of the body responsible for the tests required in the notification file;
- recommended methods and precautions and emergency measures.

Communication to the Competent Authorities of the Other Countries of the Communities

Confidential information is communicated by the Belgian authority provided that its secrecy is as strictly safeguarded in the receiving country or countries as it is in Belgium. The relevant provisions provide that the notifier is given a hearing prior to the communication of secret information by the Belgian authority.

Therefore, in line with the principles of the OECD and in accordance with the Community system, a prior assessment is made of the conditions of confidentiality prevailing in the country whose authority has requested the communication of confidential data.

The notifier is involved in the assessment, which may relate to legal and regulatory provisions, but also to the practice and to the actual steps taken by the authority in the requesting country.

In the second part of this study we shall see in greater detail how the matter of exchange between States has been settled at the international level.

The reader is also referred to the second part of the study for an account of the regime applicable to the "second notifier" of a file. Belgian legislation has adopted the solutions written into Community law as they stand.

Chapter II: The Law of the Netherlands

General Provisions on the Protection of Information Held by the Administration—Professional Secrecy and Duty of Discretion—Potential Conflict with the Principle of Public Access

The law of the Netherlands provides in a general way that civil servants and officials of public departments

[2] Royal Order of May 24, 1982.

[3] Section 8 of the Royal Order of May 24, 1982.

are bound by the obligation of secrecy under the Law on Administration Personnel and the General Civil Service Regulations.

It should be noted that the obligation of secrecy imposed on the agents of the authority is to be found in a great many laws and regulations governing specific matters.

The position in the Netherlands, however, is a classic example of the potential antagonism of the obligation on civil servants to exercise discretion and the protection of data on the one hand, and the principle of the transparency of the Administration on the other.

The law on the "openness" of the Administration[4] provides that the authority has to communicate information in its possession when a request to do so is addressed to it. Individuals thus have an express right of access to the documents held by the Administration.

The law does, however, list a series of limitations and exceptions to the principles of transparency and openness. The public does not, for instance, have access to any information that might jeopardize the integrity of the Crown or State security. Neither may the authority reveal any data in its possession that has a bearing on the private life of individuals.

Section 4*(c)* of the law on openness provides expressly that data concerning the life of businesses that are communicated to the Administration in confidence by natural persons or legal entities may not be disclosed. Commercial or industrial information supplied to the Administration thus escapes the principle of openness on condition that the person who communicated it did so in confidence and requested that its secrecy be protected.

Disputes relating to refusal of a document or to unwarranted communication may be the subject of an appeal to a section of the Council of State.

Specific Provisions to Guarantee the Protection of Data and the Notifier in Connection with Chemicals Control

The decree on the protection of man and his environment against dangerous substances and preparations[5] implements the Directive of the Council of the European Communities dated September 18, 1979 (79/831/EEC), in Netherlands legislation.

The Notification File. In accordance with the Community system, any person who intends to produce or import a substance for marketing has to communicate to the Administration a set of data concerning the possible effects of the substance on man and on the environment. Those data relate among other things to the identity, characteristics and hazards of the substance, its use or uses, the means of neutralizing its harmful effects, recommendations for its use, etc.

The authority then publishes the notification in the *Government Gazette* of the Netherlands. In addition, a file containing a series of particulars is made accessible to the public. That file contains elements that cannot be considered confidential, however.

Request for Confidential Treatment. It is for the person who communicates the file to request expressly that the confidential information communicated to the authority be kept secret.

The notifier has to state his reasons for seeking confidential treatment. His request has to be justified by the need to protect trade secrets, and has no effect on data declared non-confidential by the law.

Information not Qualifying for Confidential Treatment. Netherlands law expressly rules out the protection of the chemical name of a substance at the stage of the announcement of a notification in the Government Gazette, or in connection with the file accessible to the public, or again in connection with the mandatory labelling that has to appear on the packaging of the substance.[6]

The other data that do not qualify for secrecy are taken over from Community law (trade name, physico-chemical data, methods of neutralization, recommendations for use, recommendations in the event of accident, names of persons responsible for testing the substance, etc.).

Decision of the Authority. It is for the administrative authority to decide that confidential treatment is granted or on the contrary that the data cannot be kept secret. The decision on confidential treatment cannot in any case apply to data that the law specifies at the outset as being non-confidential.

Dispute Between the Notifier and the Administration. In the event of refusal of confidential treatment by the Administration on the ground that the data concern the effects of a substance or preparation on the environment, the notifier is requested to submit a second file.

Netherlands law aims to be pragmatic, and suggests that the notifier should transmit a text that does not disclose secret data but provides sufficient information on the effects of the substance or preparation on man or on the environment.

The new request is subject to ministerial authorization.

Obligation to Respect Secrecy.[7] Agents of the Administration or even any person having responsibility in the implementation of the chemical substances legislation

[4] *"Wet openbaarheid van bestuur"*—Law of November 9, 1978.

[5] Chemical Substances Decree of December 5, 1985.

[6] There has been a great deal of controversy between industry and Community and national authorities on the question of the treatment of the chemical name of a substance. Industry declared itself decisively in favor of protecting the confidentiality of the chemical name when that same chemical name was a manufacturing secret.

[7] Section 57 of the chemical substances legislation of December 5, 1985.

are under the obligation to keep information brought to their notice secret, except where the law expressly provides otherwise.

For questions concerning the international exchange of data and the rights of the first notifier, the reader is referred to the second part of this study, on international harmonization.

Chapter III: The Law of the Federal Republic of Germany

General Provisions on the Protection of Data Held by the Administration—The Principle of Restricted Public Access

The law of the Federal Republic of Germany is characterized by the principle of restricted public access to administrative documents.[8]

By virtue of that principle, documents held by the Administration may be inspected, but only by persons who are engaged in specific administrative procedures. There is thus no generalized and indiscriminate right to consult data kept by the Administration. As a general rule, only those persons who have a definite and legitimate interest in the administrative file may acquaint themselves with it. In addition, the law provides expressly that the parties concerned by an administrative procedure have the right to request the non-disclosure of their data by the administrative authority, particularly in matters of private life but also in matters concerning industrial and commercial secrecy (Section 30 VwVfG).

Before disclosing data, the Government has to obtain the consent of the person who provided them, except where there is a legislative provision that expressly authorizes or specifies such disclosure.

The balance between "public access" and the "right to secrecy" varies according to the subject matter of the specific legislation of the Federal Republic of Germany. For instance, in the field of environmental law, the grant of an operating license for certain installations subject to authorization calls for a study of the implications for the immediate environment of the factory, to which it is compulsory that the public have access.

Professional Secrecy and Duty of Discretion. Agents of the authority but also a great many professions are subject to the obligation of professional secrecy. That is true of members of the medical profession, members of legal professions, including patent attorneys, members of consultancy companies, etc.

Such an obligation derives in particular from administrative law. Its violation is punished by criminal provisions: the Criminal Code provides that any person who discloses a secret fact in his possession, either on the private life of an individual or on a business or commercial matter, is liable to imprisonment for one year or to a fine.[9]

The secrecy obligation is also found in a great many specific laws and regulations.

The unlawful disclosure of data kept by the Administration may be prevented by means of an action instituted before the administrative courts.

Where such disclosure has occurred in a manner contrary to the law, the injured party who supplied the data may bring action for damages before the civil courts.

Specific Provisions Concerning the Secrecy of Data in Connection with Chemicals Control

This subject is governed by the Law on Protection Against Dangerous Substances, better known as the *"Chemikaliengesetz."*[10]

The Notification File. In accordance with Community provisions, manufacturers and importers are under the obligation to communicate a file to the Administration before they can market a new substance. The file contains a very large amount of information, notably the identification characteristics of the substance, information on its use, possible harmful effects, marketing quantities envisaged, methods of elimination, etc. The notifier is also bound to communicate the results of tests to determine the toxic effects and the physical and chemical properties of the substance.

Request for Confidential Treatment and Decision of the Authority. The person seeking confidentiality for industrial or commercial secrets contained in the file communicated to the Administration makes the appropriate request. The Administration grants confidentiality except in the case of data that cannot be considered secret under Community law and the *Chemikaliengesetz.* Those are in particular the trade name of the substance, its physico-chemical properties, methods of elimination, recommendations on precautions to be taken and on handling in cases of emergency, and also packaging, labelling, the evaluation of toxicological and ecotoxicological tests and the name of the person responsible for testing.

Other Aspects of the "Chemikaliengesetz." Apart from the provisions on the treatment by the Administration of data supplied to it by a notifier, the Chemicals Law deals extensively with two questions that have been very thoroughly dealt with at the European level (European Communities) and at the international level (OECD).

The one is the question of the "first and second notifier" of the data, and the other is the awkward problem of the international communication of data.

[8] Section 29 VwVfG *[Verwaltungsverfahrensgezetz]* (Law on Administrative Procedure).

[9] Section 203 StGB *[Strafgesetzbuch]* (Criminal Code).

[10] *Gesetz zum Schutz vor gefährlichen Stoffen, Bundesgesetzblatt* I, 1980, p. 1718.

International Exchange of Data. We shall go into greater detail on these questions in the second part of the study. We would merely mention here that German law fits into the pattern of international harmonization efforts in this area, notably the *OECD principles on the exchange of confidential data between member countries.*

Chapter IV: The Law of France

General Provisions on the Protection of Confidential Data

Professional Secrecy. In France, as in the majority of European countries, civil servants are expressly bound by the professional secrecy obligation. It is an obligation that forms an integral part of the Civil Service Regulations,[11] violation of which results in a criminal sanction.[12] As we shall see below, the obligation is to be found *expressis verbis* in specific legislation.

Public Access to Certain Administrative Documents and Exceptions—Secrecy in Industry and Commerce. The French Law of July 17, 1978, introduced a right of public access to certain administrative documents.[13] Those documents may take the form of writings, sound or visual recordings, electronically processed data, etc.

The Law lists a certain number of exceptions to the principle of free access. Section 6 refers in particular to documents "containing commercial and industrial secrets," but without specifying the actual content of the concept. That moreover is true of most comparable legislation in the other European countries, and it is an indication of the difficulty of encompassing the subject with sufficient comprehensiveness. In French law the concept seems to cover that of know-how. The Law provides that Orders determine the lists of administrative documents that may not be disclosed by reason of their nature or their subject.

The party injured by an illegal disclosure has the possibility of bringing an action claiming the civil liability of the person responsible for the prejudice. He may in addition invoke the criminal liability of the person responsible for the disclosure for breach of professional secrecy.

A "Commission on Access to Administrative Documents" rules on cases in which a dispute has arisen (refusal of the Administration to communicate a document).

Specific Provisions on the Protection of Data in Connection with Chemicals Control

The French Law of July 12, 1977,[14] on the Control of Chemicals introduced a system of declaration prior to the marketing of new substances and dangerous substances. The Law has undergone a number of amendments in order to accommodate the Community regime introduced by Directive 79/831/EEC of the Council of the European Communities. Section 6 of the Law of July 1977 provides that

> "the administrative authorities shall keep information on the exploitation and manufacture of substances and preparations secret, at the same time providing for the appropriate form of public access to information of toxicological character...."

The Law also provides that

> "persons having access to files and information shall be bound to observe professional secrecy according to the procedures specified in Section 378 of the Criminal Code, except in their relations with the judicial authorities."

An implementing decree sets the conditions that allow the secrecy of the complete formula of preparations to be protected, notably in poison treatment centers.[15]

The Notification File. The notification file is sent by registered mail to the competent administrative authority (the Environment Ministry). The file consists of a marketing declaration and a technical dossier. The latter contains a set of data similar to those required by Community law, notably the trade designation of the substance, the chemical formula, the physical and chemical properties, the effects of the substance, the conditions for its use, the results of toxicity tests, etc.

Confidential Treatment of Data. Section 4 of the Decree of February 13, 1985, enacted under the Law of July 12, 1977, provides that the declaring party has to enclose with his file on the one hand a summary of its contents and on the other hand a list of the data that he regards as qualifying for industrial and trade secrecy. The Decree specifies that secrecy cannot be claimed either for the chemical designation of a substance liable to be included in a list of substances classified as being dangerous to man and to the environment, or for information that the law disqualifies from industrial and commercial secrecy.

Request for Confidential Treatment. It is for the declaring party, more often than not a firm, to request the grant of confidential treatment.

Decision of the Authority. It is for the Administration to grant or not to grant confidential treatment when it is requested. Any disputes that may arise are settled in ordinary administrative appeals.

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[11] Ordinance of February 4, 1959.

[12] Section 378 of the Criminal Code. That provision also punishes members of the medical profession for breaches of professional secrecy. Article 418 of the Criminal Code protects manufacturing secrecy and prohibits the employees of a firm from knowingly disclosing manufacturing processes of which they have knowledge.

[13] Law No. 78-753 of July 17, 1978.

[14] Law No. 77-771 of July 12, 1977, on the Control of Chemicals.

[15] Decree No. 85-217 of February 13, 1985, on the Control of Chemicals.

Role of the "Commission for the Evaluation of the Ecotoxicity of Chemicals." The Commission for the Evaluation of the Ecotoxicity of Chemicals is solicited by the Environment Minister. The Commission is competent among other things to consider the technical dossiers concerning declared chemicals and also to deal with requests or proposals for classification in the list of dangerous products.

On completion of its consideration of a declaration file, the Commission proposes to the Environment Minister that he record the figures that it has given and the conclusions that it has drawn on a data card. That card has to be inserted in the *Journal officiel de la République française* not later than nine months after the matter was referred to the Commission. None of the particulars recorded on the cards may relate to data for which the declaring party has claimed and been granted industrial and commercial secrecy.

Rules Applicable to the Evaluation Commission for the Protection of Confidential Data. In practice, the Chairman designates from within the Commission a rapporteur who is entrusted with the consideration of the file. The rapporteur may call on an expert. Both are under the obligation of discretion. The Decree specifies that the rapporteur is bound to abstain from giving an account before the Commission of data for which a declaring party has claimed and been granted confidentiality. The system thus expressly limits the number of persons who have access to the secret, which is in line with one of the demands expressed by industry.

Communications between Administrations. When it has been judged acceptable, the technical dossier is sent to the Minister of Industry and to the Minister of Health and—in part—to the Ministers of the Interior and of Transport. The Decree contains interesting details regarding communication to "poison treatment centers." The Minister of Health may communicate the full chemical formula of a substance and the complete composition of preparations containing it to such centers. Any commercially confidential data that might be useful to those centers may also be communicated to them after the opinion of the Chairman of the Evaluation Commission has been sought.

The Minister of Health is, however, under the obligation to advise the declaring party of the nature of the information communicated to the centers. He also has to take all the necessary steps to ensure that the centers respect the confidentiality of the data communicated to them.

Other Questions. For questions concerning the international exchange of data and the "second notifier," the reader is referred to the second part of the study ("Efforts Towards International Harmonization of the Confidential Treatment of Data").

Chapter V: The Law of the United Kingdom

General Provisions on Professional Secrecy and Prohibition of Disclosure

The unauthorized disclosure of official information is punished by criminal provisions (Official Secrets Act 1911).

Specific laws expressly prohibit such disclosure in the most varied subject areas. For instance, the Statistics of Trade Act protects firms against the communication to third parties of items of information concerning them. The legislation on health and safety prohibits unauthorized disclosures of data provided by firms.

Common Law and Breach of Confidence. It should come as no surprise that common law should have made breach of confidence into a tort when confidential information has been disclosed without authorization and when that act has harmed the person from whom the information came.

The conditions required for there to be breach of confidence are the following: the plaintiff (hypothetically the person from whom the information came) has to show that:

- the information has the necessary quality of confidentiality;
- the information was disclosed by a third party who had an obligation to maintain confidentiality;
- there was unauthorized use of the information.

The obligation of confidentiality extends to the third party who receives or has knowlege of confidential information when he knows or ought to know that he has obtained them through a breach of confidence.

On application by the owner of the information, the British courts can grant injunctions prohibiting further unauthorized disclosure. They can also grant indemnification of the prejudice sustained by the owner of the data when the legal disclosure occurred.

Access to Public Documents. With certain exceptions that are written into specific laws, administrative documents are not accessible to the public. The legislation on public documents provides that, to be communicated, a document has to be classified as a "public document." As a general rule, a document becomes open to the public 30 years after its creation, subject to more extensive protection that may, where circumstances dictate, be adopted in special cases.

Some specific legislation nevertheless provides for the disclosure of certain information of industrial and commercial character. For instance, the provisions on town and country planning provide that persons seeking authorization for the siting of factories are bound to provide detailed information on the site and the installation.

Specific Provisions on the Protection of Data in Connection with Chemicals Control

The Health and Safety at Work Act 1974 authorizes the enactment of regulations requiring manufacturers and importers of chemicals to notify the authorities of certain properties of their products. The Notification of New Substances Regulations 1982 implement Directive 79/831/EEC in the United Kingdom.

The Notification File. Following the pattern set by the Community system, the manufacturer or importer is under the obligation to send the Health and Safety Executive a notification file within a period of 45 days prior to the supply of a quantity in excess of one tonne.

Among other things the notification contains:

- a technical dossier providing the information necessary for an assessment to be made of the potential hazards which the substance may present for man and for the environment, including the results of research and tests according to the Directive;
- a declaration on the adverse effects of the substance in relation to the envisaged uses;
- proposals and recommendations for the use of the substance, etc.

Confidential Treatment of Data. The 1982 Regulations provide that it is for the person who makes the notification to specify what information should be treated in confidence. The request has to be justified by the party making it. Its acceptance results in strict protection of the data. The competent authority is under the obligation to inform the notifier before any communication to a third party, should such communication be necessary.

Some information is not protected by confidentiality. Such is the case of the trade name of the substance, certain physico-chemical data, possible ways of rendering the substance harmless, the interpretation of toxicological and ecotoxicological tests, emergency measures, recommendations for use, etc.

Other Questions. For matters regarding the international exchange of data, the reader is referred to the second part of the study, on international harmonization. It is nevertheless useful to point out here that the Regulations provide expressly that the competent British authority, which is the Health and Safety Executive, may refuse to communicate confidential information concerning a notification to the competent authority of another Member State where that other authority does not apply legislation or administrative procedures ensuring protection for commercially sensitive information that are at least as strict as the provisions in the Directive (Articles 7(3) and 11(4)) but also those in the New Substances Regulations and its implementing procedures, and any provision of British law that is applicable to the disclosure of information.

The United Kingdom makes very extensive use of the possibility conferred on it by virtue of Community law, but also of the principles of the OECD.

Part Two
Efforts Towards International Harmonization of the Confidential Treatment of Data

Chapter I: The Law of the European Communities and the Testing of Chemicals

Community Law and Professional Secrecy

The authors of the Rome Treaty clearly stated the principle of professional secrecy that is strictly binding on the staff of the institutions.

Article 214 of the Treaty provides as follows:

> "The members of the institutions of the Community, the members of committees, and the officials and other servants of the Community shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost component."

The obligation is repeated in a very large number of Community texts. Several aspects deserve to be emphasized:

- The obligation is imposed on a very large number of persons, both officials and staff members but also "members of committees." The latter expression refers to persons who, without actually belonging to the European civil service, take part in the activities of committees and working groups set up for a specific purpose relating to the implementation of Community law. Article 214 is applicable to national officials and experts who are called upon to take part in such activities.
- The obligation is without any limitation in time, as it applies even after the duties have ceased.
- Article 214 expressly mentions information about undertakings, thereby unequivocally affording protection to secrets associated with business life.

The principle written in Article 214 of the Rome Treaty is repeated in Article 17 of the Staff Regulations of the European Communities. That provision specifies among other things that the staff member must not communicate, in any form, to a person not entitled to have knowledge of it, any document or any information that has not been made public. Thus the disclosure of information, even in a form other than the complete form, is prohibited.

The disciplinary sanctions for violation of secrecy can be a reprimand, demotion, forfeiture of pension rights, etc. The staff member may in addition be obliged to provide redress for the prejudice sustained by the European Communities on account of serious personal misdemeanors committed in the performance or at the time of the performance of his duties.

In civil terms, the victim of a breach of professional secrecy can invoke the liability of the European Communities if the act perpetrated is the necessary continuation of assignments entrusted to the Community institutions by virtue of a direct internal relationship. If the act does not meet the criteria of the necessary continuation of assignments entrusted to the institutions and of the direct internal relationship, the personal civil liability of the officer can be questioned before a competent national jurisdiction, as the immunity provided for in Article 12 of the Protocol on Privileges and Immunities does not protect the officer in that case.

In criminal terms, a distinction should be made as to whether or not the officer is acting in his official capacity. If he breaches his secrecy obligation in his official capacity, he is liable for his acts only towards the Communities, and he is protected by immunity from jurisdiction.[16] If, on the other hand, he is not acting in his official capacity, he is liable to the actions and sanctions of the country that he is in at the time of the perpetration of the acts.

Specific Provisions on the Protection of Data in Connection with Chemicals Control

The Notification of Data under the System of Directive 79/831/EEC. The Directive of September 18, 1979,[17] introduced a single system of control over the placing on the market of dangerous new substances on the territory of the Communities. The States are under the obligation to comply with the Directive. The system relies among other things on the obligation to notify "new" chemical substances 45 days before they are placed on the market. It also imposes precise obligations regarding the packaging and labelling of dangerous substances. The Directive presupposes the gathering of a very large amount of information and the compilation of a technical dossier by manufacturers or importers, who are bound to communicate them to the competent authorities. The national administration of the country of the Communities in which the substance is manufactured or into which it is imported is competent to receive and process the notification. It acts as national authority and Community authority at the same time. When the manufacturer has filed a notification in a member country, that notification is valid for the whole of the Communities, which avoids the need to engage more than once in procedures that are often costly and cumbersome. The competent authority therefore has a very important part to play, and is obliged to communicate all or part of the notification file to the Commission and to the other Member States. As the reader will gather from this summary outline, the Community system is responsible for considerable movements of data between the manufacturer or importer, on the one hand, and the competent authority on the other, but also between the administrative authorities of the States and the Commission. The problem of the protection of the secrecy of data is thus posed on two levels at the same time, the national and the inter-State. Article 7(3) of the Directive states the general principle according to which Member States and the Commission ensure that any information concerning commercial exploitation or manufacturing is kept secret.

Protection of Data Communicated to the Competent Authority. Once it has the file in its possession, the authority that has received the notification decides on its own responsibility which information is covered by industrial and trade secrecy.

It is for the notifier to indicate the information that he considers to be commercially sensitive and disclosure of which might harm him industrially or commercially, and which he therefore wishes to be kept secret from all persons other than the competent authorities and the Commission (Article 11(3)). The notifier has to justify his application.

The Directive excludes a certain number of data from industrial and commercial secrecy, either because those data are by their very nature alien to the concept of secrecy, or because they have a direct bearing on personal health or safety.

Thus industrial and commercial secrecy does not apply to:

- the trade name of the substance;
- physico-chemical data concerning the substance;
- the possible ways of rendering the substance harmless;
- the interpretation of the toxicological and ecotoxicological tests and the name of the body responsible for the tests;
- the recommended methods and precautions concerning handling, storage, transport, fire and emergency measures in the case of accidental spillage or in the case of injury to persons.

The protection of chemical identity (or chemical "name") has given rise to a great deal of controversy between the industry and the Community authorities. For a number of sectors of the chemical industry, the question is indeed very sensitive in commercial and competition terms. We would merely mention here that the Directive provides that the name of a substance may be included in encoded form in the list of substances in respect of which notifications have been made, provided that the substance is not classified as dangerous under the criteria specified in the Directive. Inclusion in the list in encoded form must not be for

[16] Article 12 of the Protocol on Privileges and Immunities of the European Communities.

[17] Council Directive of September 18, 1979, amending for the sixth time Directive 67/548/EEC (*Official Journal of the European Communities* (O.J.) No. L 259 of October 15, 1979, p. 10).

longer than three years (Article 11(3)). Contrary to what has been argued by the Community authorities, the industry has contended that this provision does not rule out other forms of protection, including, for instance, recourse to a generic name rather than the actual chemical identity.

The Protection of Data in Connection with the Communication of Files between States and the Commission. The Directive lays down a general principle according to which confidential information brought to the attention either of the Commission or of a Member State is kept secret. The Commission and the States are therefore, in principle, bound by the confidentiality claims accepted by the authority that has received the notification.

Article 11(4) provides, however, that confidential information may be divulged to persons directly involved in administrative or legal proceedings involving sanctions and undertaken for the purpose of controlling substances placed on the market. Such persons are, however, themselves bound by professional secrecy.

As we have said, the authority that receives the notification acts as Community authority and forwards the data to the Commission and to the other Member States, where appropriate in summary form. The competent authorities of a Member State and the Commission in principle have access to the notification file and to the complementary information. In the event of refusal to communicate to the authorities, the Directive has provided for a procedure that can result in a ruling by the Commission.

Equivalent Protection Requirement. The reader will be interested to note that the principle of mutual trust that underlies the Community system is subject to one important limitation. That limitation also exists in connection with the OECD principles. It has been made necessary by the dangers that there would be if the differences between the protection standards of the various Member States were too great.

The Directive does not oblige a Member State whose legislation or administrative practice impose stricter limits on the protection of industrial and commercial secrecy than are provided for in the Directive to supply information to another State if that State does not take steps to observe those stricter limits. The Community text thus expressly recognizes the precedence of the national protection standards of the State in which the notification has been received. This solution was to some extent a response to the concerns of industrial circles afraid that the Community system was bound to cause leaks of confidential information if nothing was done to lessen such a risk at the weakest links of the Community chain. A better solution would have been to harmonize completely the legal provisions and procedures designed to guarantee the confidential treatment of data. The industry has made suggestions to that effect, and has among other things insisted on the need to harmonize safety procedures.[18] As yet these questions have not been fully resolved owing to the difficulty of standardizing national legal and administrative traditions that are often quite ancient.

The Question of the First and Second Notifier. When a person wishes to place on the market a substance that has already been notified before by a competitor, and when that same person (known as the second notifier) wishes to refer to the data contained in the file of the first notifier, a question arises as to what rights the first notifier has in relation to the data that he has provided. The gathering of such data is often a long, difficult and costly task if one considers among other things the extent of the research and tests that are required in connection with a notification file.

It is thus very much in the first notifier's interest to ensure that the information communicated to the Administration is not misused by third parties, or that the mere fact of its having already been notified does not release competitors from the same obligation.

Community law has solved the problem by introducing the principle of the prior agreement in writing of the first notifier. This principle is valid for chemicals, but it is also written into the Community system for pharmaceutical specialities.[19]

It follows from this principle that any subsequent notifier of a chemical product who wishes to refer to the data contained in the file or files of the first notifier or notifiers is required to seek written authorization from the same notifier or notifiers for his use of the data. The first notifier gives such authorization provided that the second notifier grants him sufficient compensation, notably to cover any expense incurred.

It should be noted that the right of the first notifier is limited in time in that the subsequent notifier is relieved of the obligation to supply the prescribed information for the technical file[20] when the substance was initially notified more than 10 years previously.[21]

Chapter II: The OECD Program on the Control of Chemicals and the Confidential Character of Data

General Context

Since 1978 the OECD has been developing a program on the control of chemicals. The object of the

[18] The reader is referred among other things to the proposals submitted by the European Council of Chemical Manufacturers' Federations (CEFIC) ("Principles and Rules Guaranteeing the Protection of Confidential Data"—CEFIC document, 1982).

[19] Council Directive of December 22, 1986, amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (O.J. No. L 15 of January 17, 1987).

[20] Technical dossier provided for in Annex VII of the Directive.

[21] Second sentence of Article 6(3) of the Directive of September 18, 1979.

program was twofold. On the one hand, it was a question of promoting commercial exchanges between member countries by removing non-tariff barriers to the free movement of chemicals. On the other hand, it was a question of creating collaboration between countries by ensuring the circulation of information on the potential hazards of the products for man and the environment. The program resulted among other things in the definition of a system of mutual acceptance of data for the assessment of chemicals and in the adoption of guidelines for testing and principles concerning proper laboratory practice. This work was bound to come up against the question of the protection of industrial and commercial secrecy, and a group of experts was specially entrusted with studying the matter. Here we shall consider briefly what was the essential focus of the Group of Experts, and the principles that emerged, at the international level, for the exchange of confidential data between member countries. The reader is unlikely to be surprised at the similarities between the conclusions of the OECD and the binding solutions worked out by Community law.

Approaches Adopted for the Handling of Data

The Group of Experts on Confidentiality of Data pursued the twofold aim of improving the protection of man and the environment, and reducing barriers to international trade. The Group did not make any specific recommendation on the nature of a possible international instrument to govern the exchange of data. It did, however, draw up common approaches on three issues considered essential: non-confidential data, principles for the exchange of confidential information, and protection of proprietary rights of data.

(i) Non-Confidential Data

Certain data of value for hazard assessment of chemicals and other purposes connected with the protection of man and the environment should be susceptible of exchange without restriction and should be freely accessible to the public. It was on the basis of that assumption that the OECD Group of Experts drew up a list of non-confidential data that should be susceptible of transmittal from one member State to the other *on request*. It is not recommended that these procedures should be automatic, unlike what is provided for under Community law. Another characteristic is that the list applies equally to old and to new chemicals.

The list of non-confidential data is as follows:

- trade names or names commonly used;
- general data on uses (the uses need to be described only broadly, like: closed or open system, agriculture, domestic use, etc.);
- safe handling precautions to be observed in the manufacture, storage, transport and use of the chemical;
- recommended methods for disposal and elimination;
- safety measures in case of an accident;
- physical and chemical data with the exception of data revealing the chemical identity (e.g., spectra); if the physical and chemical data make it possible to deduce therefrom the chemical identity, only ranges of values need be given;
- summaries of health and safety data including precise figures and interpretations (the submitter of the health and safety data should participate in the preparation of the summaries).

(ii) Principles Governing the Exchange of Confidential Information between Member Countries

This is probably the major contribution made by the OECD Group of Experts to the question of the protection of the exchange of data between countries.

The text of the principles forms an integral whole which aims to promote exchanges provided that they are genuinely justified and, on the other hand, attempts to eliminate the risks of abuse that would be caused by unwarranted requests.

Principle No. 1

The exchange of confidential information on chemicals between the competent authorities of countries is intended solely to facilitate the hazard assessment of chemicals and the protection of man and the environment.

Principle No. 2

A country having received information in response to a request must in no circumstances use such information for any purpose other than the assessment of hazards of chemicals and the protection of man and the environment.

Principle No. 3

A country, whenever requesting information about a chemical, must substantiate the need for the information, on the ground that:

(a) the chemical is present or is shortly to be marketed in its territory, and

(b) the information is necessary for the assessment of its hazards and the protection of man and the environment.

Principle No. 4

A country requesting information

(a) must abide by the decision made by the transmitting country with respect to the confidential nature of the information;

(b) must treat the transmitted information with at least the same degree of confidentiality as is practiced in the country from which the information has been requested;

(c) may make the information available to national, regional or local authorities only when necessary for purposes of hazard assessment of chemicals or protection of man and the environment and only

when such authorities are able to guarantee the same level of confidential treatment;
(d) shall not transmit the information received to any other country.

Principle No. 5

The requesting country must not ask for the transmission of confidential information which it does not have the authority to collect and use under its legislation or in the normal course of its administration.

Principle No. 6

The solicited country should consult with the person who submitted the requested confidential data before transmitting them.

(iii) Protection of Proprietary Rights of Data

The OECD Group of Experts repeatedly stated that data submitted to governments were the property of the person obtaining and submitting them or agreeing that they be submitted by another person. There lies the foundation and justification for the protection of confidential data and also the legal machinery introduced in order to ensure that protection.

Conclusions

The international communication of data on products is tied up with the development of commercial exchanges. An approximation, or even a standardization of national legal systems is desirable if one wishes to create a climate of trust conducive to such exchanges.

As we have seen, the OECD principles are based on a wide international consensus in the achievement of which industry has been involved. There is no doubt but that the general approaches that have been worked out in that connection need to be made more specific, either at the multilateral level (in the case of Community law) or at the bilateral level (agreements between OECD member countries).

Such principles could unquestionably provide inspiration for pragmatic common solutions in much larger groupings and between countries with different socio-economic systems.

Yet the difficulties of such a task cannot be underestimated if one measures the scale of the effort that was necessary within the OECD and the European Economic Community for even this still very incomplete degree of harmonization to be achieved.

Utility Models: The Experience of the Federal Republic of Germany*

E. HÄUSSER**

To report on the experience of my country in the use of the utility model is an interesting task, particularly since the utility model, as an industrial property right, was "invented" in Germany. When the initial Utility Model Law was enacted on June 1, 1891, Germany became the first industrialized nation to introduce this particular form of protective right. Since then, nearly one hundred years have passed, in the course of which a legal tradition has been developed and consolidated, and extensive practical experience gained with utility models.

I.

1. The German Patent Law which entered into force on July 1, 1877, made it possible for the first time to have technical inventions protected by patents effective in all the states that constituted Germany at the time. Not long before that date, in January 1876, the Design Law had entered into force, affording protection to aesthetic creations. It was then assumed that these two types of protective rights would fully meet the practical needs of the economy.

However, it soon transpired that design protection covered only those models and designs that constituted an aesthetic creation, but not articles of everyday use of a technical nature and, as a rule, lesser inventive value or only temporary economic importance. The borderline, generally accepted today, between the protection of technical inventions by patents and utility models and the protection of aesthetic creations by copyright and registered designs only developed gradually through case law until it gained recognition in practical use. As a historical reminiscence, however, the term of "utility model" still contains the word "model."

At any rate, soon after the introduction of protection by patents, commerce, trade and industry called for the creation of a protective right for "minor inventions," a right which, compared with the patent, required less inventiveness, led—through a simple and rapid procedure—to full protection and, additionally, entailed less expense.

2. The Utility Model Law of June 1, 1891, entirely complied with those requirements. A protective right was created whose effects were fully comparable with those of the protection afforded by patents, i.e., an exclusive right securing sole use of the subject matter of the invention to the owner of the utility model. By restricting utility model protection to tools and implements, articles of everyday use or parts thereof, the Law demonstrated that this industrial property title was above all intended for inventions of minor inventive and economic importance. Accordingly, the term of protection was limited to a total of six years. A further basic difference, when compared with a patent, was that a utility model was not examined as to the substantive requirements for protection (novelty, technical progress, inventiveness), but was simply recorded under a registration procedure, if the formal requirements had been met.

3. These basic provisions have proved their value, and are still being applied. Unlike the Patent Law, the Utility Model Law underwent only minor change. Not until a recent date was it adapted to the modifications made to patents over the years, by the Law Amending the Utility Model Law, of August 15, 1986 (*Bundesgesetzblatt* (BGBl.) I, pp. 1446 *et seq.*)[1] without, however, abandoning the above-mentioned principles. At the same time, the consolidated Law was published with renumbered Sections, to which the references in this article apply. The Law entered into force on January 1, 1987, and now meets all the demands placed on an up-to-date utility model law, securing the protection which is an essential element of the industrial property system in the Federal Republic of Germany.

II.

The utility model has stood the test of practical use in the Federal Republic of Germany. As a "petty patent," it has assumed its place within the system of industrial property rights. This is explained by the fact that, despite a basically identical objective, there are clear and fundamental differences between it and patent protection.

1. Inventions Eligible for Utility Model Protection

Like the patent, the utility model is a protective right for technical inventions. Therefore, the subject matter

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** President of the German Patent Office.

[1] For the consolidated texts of the Utility Model Law and the Patent Law, see *Industrial Property Laws and Treaties*, GERMANY, FEDERAL REPUBLIC OF—Texts 2-003 and 2-002, respectively.

of the utility model has also to convey a technical teaching, i.e., information for the performance of technical actions. However, not every technical invention can be protected by a utility model.

Under Section 1(1) of the Utility Model Law, in force as of January 1, 1987, protection can be afforded only to those tools, implements, and articles of everyday use or parts thereof which

— embody a new configuration, arrangement, device or electrical circuitry,
— involve an inventive act and
— are susceptible of industrial application.

The subject matter of the utility model may also consist of several associated components (second sentence of Section 1(1) of the Utility Model Law).

Utility model protection—just as patent protection—is not available to inventions whose subject matter is a discovery, a scientific theory or a mathematical method, an aesthetic creation, a scheme, rules or a method for performing mental acts, playing games or doing business or a computer program, if sought for that subject matter or activity as such (Section 1(2) of the Utility Model Law).

Under the law of the Federal Republic of Germany, an important restriction on protectability is that only tools and implements, articles of everyday use or parts thereof may be protected as utility models. The point at issue here is not the size or complexity of the object; even large and complex objects such as excavators, engines and ships, can be protected by utility models if they are intended and suitable for handling by man. This means that the subject matter of a utility model application has to be a unitary, physically defined and coherent entity that is movable and transportable, whereby it is irrelevant whether this can be done by human muscular power.

Therefore, many inventions are not eligible for utility model protection:

— processes of any kind, particularly chemical processes;
— chemical substances;
— foodstuffs, stimulants and pharmaceuticals, as far as their properties are concerned;
— substances without defined shape, such as powder, emulsified preparations and fluids;
— immovables (e.g., buildings, bridges, dams);
— electrical circuits which are not connected with tools and implements, articles of everyday use or parts thereof.

Another serious restriction of protectability, which is a peculiarity of the law of the Federal Republic of Germany, has proved to be the requirement of a three-dimensional form which the court decisions derived from the provision that the subject matter of a utility model has to embody a new configuration, arrangement, device or circuitry (as an element of a tool or implement or of an article of everyday use).

The claims in a utility model application have therefore to convey a concrete teaching on the three-dimensional form and thus on the physical characteristics to be protected. It is not sufficient to state merely a principle according to which a tool or implement or an article of everyday use may be shaped in varying physical forms. Consequently, not only are claims for use excluded from protection, but also appropriations and uses of a known three-dimensional form. If, therefore, the invention concerns a new appropriation, the three-dimensional form has to be modified in conformity with the new purpose, which may then possibly become the subject matter of an independent application.

The extension of utility model protection to electrical circuits by the recent amendment to the Utility Model Law does not represent a departure from the requirement of three-dimensional form since the general part of the claim has to include the unmodified definition of the respective tool or implement or article of everyday use. Any circuit defined in the characterizing part no longer needs to be physically defined so that also genuine circuit layouts and circuit principles can be included in the utility model protection, provided they are elements of a tool or implement or of an article of everyday use.

The rules governing protectability, particularly the requirement of three-dimensional form, frequently lead in practice to considerable difficulties of delimitation and have resulted in numerous court proceedings. As a consequence, the procedure before the Patent Office is significantly prolonged in such cases. Both theoreticians and practitioners therefore rightly demand that the restriction on utility model protection be removed and that it be opened up to all technical inventions. This would not only mean a considerable speeding-up of the procedure for us, but would also promote technical and economic development, especially for small and medium-sized industry and independent inventors.

The legislative body (the *Bundestag*) was therefore right in directing that a study be made of the question whether such clear provisions are suited to the practical needs of today. In my opinion, we can expect this limitation of the access to utility model protection to be abandoned within the next few years.

2. Requirements of Protectability

The configuration, arrangement, device or circuitry of an object filed for utility model protection has to be new, involve an inventive act and be industrially applicable (Section 1(1) of the Utility Model Law).

Novelty

The subject matter of a utility model is considered new, if it does not form part of the state of the art. The state of the art comprises any knowledge made available to the public by means of a written description or of use

within the jurisdiction of the Utility Model Law before the date relevant for the priority of the application (Section 3(1), first and second sentences, of the Utility Model Law).

This means that—just as in the Patent Law—all domestic and foreign publications known before the date relevant for the priority of the utility model application are detrimental to novelty.

However, in other respects there are considerable differences with the Patent Law:

— only domestic acts of prior use are detrimental to novelty;

— public oral descriptions do not form part of the state of the art;

— description or use within six months before the date relevant for the priority of the application are not considered, if based upon the work of the applicant or his predecessor in title (Section 3(1), second sentence, of the Utility Model Law).

Finally, display of the subject matter of a utility model application at a public exhibition is not prejudicial to novelty, if the application is filed within six months of the opening of the exhibition (exhibition priority).

Hence, the rules governing novelty in the German Utility Model Law are quite independent and correspond largely to the former regulations under patent law. In contrast with the patent law, the maintenance of the period of grace for novelty and the exhibition priority, in particular, take into account the urgent needs of applicants from small and medium-sized enterprises and the independent inventors who—either out of ignorance or under the pressure of daily work—frequently disclose the subject matter of an invention prematurely and thus prevent the grant of patent protection.

This flexible and pragmatic concept of novelty in the Utility Model Law has been possible because the legislative body is not bound by the strict general conditions of international conventions, especially the obligations under the 1963 Strasbourg Convention on the Unification of Certain Points of Substantive Laws on Patents for Invention, to be observed by the European countries, which do not apply to the Utility Model Law. Although the re-introduction of the period of grace for novelty and of the exhibition priority is under discussion at international level, it cannot be predicted when these efforts will lead to a result. Until then, the Utility Model Law of the Federal Republic of Germany remains a "second line" of protection for inventions which have been inadvertently disclosed to the public at a premature stage.

Inventiveness

An invention capable of being protected by a utility model has also to possess a certain inventive quality, and may not be based purely on handicraft skill.

Even prior to the last amendment of the Utility Model Law, a lower level of inventiveness for utility models than for patents was required, both by Patent Office practice and court decisions. This now finds its expression in the Law which introduced "inventive act" *[erfinderischer Schritt]* as a separate term in law in the Federal Republic of Germany to distinguish the Utility Model Law from the Patent Law, which requires "inventive activity" *[erfinderische Tätigkeit]* as a prerequisite for patentability (Section 1(1) of the Patent Law). However, utility model law also holds that an inventive act is not involved if the subject matter of the invention is obvious from the prior art to a person skilled in the art (see Section 4 of the Patent Law).

Indeed, if requirement of a certain degree, albeit a small one, of inventive activity were to be waived altogether, this would have a detrimental effect on the national economy, since protective rights that are not justified in substance would hinder technical development and economic activity.

3. The Registration Procedure

An essential condition for the attractiveness of utility model protection is the simple registration procedure under which the applicant can rapidly obtain a complete protective right.

The utility model procedure also requires a formal application to be made containing a request for registration of the utility model, one or more claims, a description of the subject matter and a drawing (Section 4(2) of the Utility Model Law). Contrary to the requirements for a patent application, a drawing is compulsory for a utility model application.

The particularity of the procedure, however, is that the Patent Office does not examine the subject matter of the application as to the substantive requirements of protectability, i.e., novelty, inventive act and industrial applicability (Section 8(1), second sentence, of the Utility Model Law). If the application complies with the formal requirements and if the conditions of protectability of subject matter of the invention (tool, implement or article of everyday use, three-dimensional form) are met, the Patent Office orders registration in the Utility Model Register (Section 8(1), first sentence, of the Utility Model Law). On registration of the utility model, protection is immediately and fully effective.

Since this registration procedure with the German Patent Office requires only three to four months on average, as experience shows, the applicant for a utility model very quickly obtains a full protective right which he can use in technical and economic competition.

This uncomplicated and therefore rapid registration procedure is of special practical importance in view of another particularity of the Utility Model Law of the Federal Republic of Germany.

The Law permits a patent application to be filed as well as a utility model application for the same

invention. Under the former Law, up to December 31, 1986, a filing could be effected in the form of an auxiliary utility model application, which, as a rule was filed simultaneously with the patent application. Although this meant that a formal procedure was initiated, the registration of the utility model was suspended until the patent application had been processed.

As from January 1, 1987, the auxiliary utility model application has been replaced, under the new provisions, by the possibility of claiming the filing date of an earlier patent application for a (later) utility model application. This is not in fact a real priority right, but the possibility of deriving a utility model application from a patent application.

Thus, in parallel with a patent application, the applicant may file a utility model application simultaneously or later and obtain very rapidly—through a great variety of options—the flanking protection of a utility model for a pending patent application.

This provides an applicant with a possible stopgap during the frequently lengthy patent procedure and a means of securing early protection for subject matter which is the same as that of a patent application.

However, the applicant may also influence the course of the procedure by registering a utility model on the date of first publication of the patent application. He then not only enjoys the rather weak preliminary protection under the Patent Law, which is effective from the date of first publication, but also the full protection afforded by the registered utility model. He finally has the possibility of registering a utility model in order to take action against a competitor using the subject matter of the invention even before grant of the patent.

In the past, German applicants have made frequent use of these possibilities of securing the subject matter of a patent application by the flexible use of utility model protection. Almost 23,000 of the some 35,000 utility model applications in 1985 were auxiliary applications, and therefore concerned the subject matter of a corresponding patent application. This situation is not expected to change in the future and the possibility of derivation will be in great demand.

4. The Registered Utility Model

As already mentioned, the relevant protection becomes effective on registration of the utility model. The registration thus creates an instantaneous exclusive industrial right with its well-known effects.

The proprietor of the utility model is exclusively authorized to use the invention protected by the utility model (Section 11(1), first sentence, of the Utility Model Law). Any other person is prohibited from using, directly or indirectly, the subject matter of the utility model (Section 11(1), second sentence, and (2) of the Utility Model Law). This prohibitive right is enforced by the right given to the proprietor of the utility model to take action for injunction and for damages (Section 24 of the Utility Model Law).

The rapid execution of the registration procedure has the drawback that no examination as to novelty and inventive step is carried out and the proprietor of the utility model cannot therefore rely unreservedly on the legal validity of the registered protective right.

Indeed, registration does not afford utility model protection where the requirements of Sections 1 to 3 of the Utility Model Law are not complied with and any person may therefore assert a claim against the person registered as proprietor for cancellation of the utility model.

There is an absolute bar to protection, in particular, if the subject matter of the utility model is not new or does not involve an inventive act (Sections 13(1) and 15(1) of the Utility Model Law).

The lack of legal validity of the registered utility model may be invoked by anyone who is sued by the owner of the utility model or by his exclusive licensee for infringement of the utility model in litigation before the ordinary courts (objection of lack of legal validity). The ordinary court then examines the protectability of the utility model, including the absolute protection requirements, as a preliminary to its substantive decision.

As a rule, the party sued for infringement opts for a cancellation procedure before the Patent Office, which may be requested by anyone. These cancellation requests are dealt with by one of the Utility Model Divisions set up in the Patent Office and composed of two technical members and one legal member (Section 10(3), first sentence, of the Utility Model Law). These provisions mean that the task of technical member can be given to those Patent Office examiners who are competent for the technical field to which the contested utility model belongs. This ensures that the legal validity of the utility model is decided by the examiners who are also competent for the relevant patent application, so that a reliable assessment, in particular concerning novelty and inventive act, may be expected.

This uncertainty as to the legal validity of a registered utility model resulting from the registration procedure may evoke disadvantageous effects for its owner even prior to action in court. Although the proprietor of the registered utility model may invite the infringer to refrain from using it (under threat of legal proceedings), if the use of the protected invention is illegal and the utility model is a protectable one, such a threat may, however, result in the alleged infringer claiming compensation of damages from the proprietor of the utility model, if the substantive requirements of protection of the utility model are not complied with and the utility model is not registered legally. To avoid a claim for damages, the proprietor of the utility model must carefully examine the requirements of protection before threatening legal action. After a conscientious

examination on the basis of reasonable and fair considerations, he must determine whether the subject matter of the protected invention is new and involves an inventive act and therefore whether his protective right will be legally valid. Normally, this will require knowledge of the state of the art in the relevant technical field of activity. Ignorance is generally held against the utility model owner.

In this context, the new possibility provided by the utility model procedure of requesting the Patent Office to search those printed documents which are to be considered in assessing the protectability of the subject matter of the utility model application or of the (registered) utility model, applicable since January 1, 1987, appears to be of particular importance (Section 7(1) of the Utility Model Law). The request may be filed by the applicant or by the registered proprietor, but also by any third party; it must be submitted in writing and accompanied by a fee of DM 450 (Section 7(2) of the Utility Model Law).

Since this state-of-the-art search report is drawn up by the Patent Office examiner who would also be competent for the examination of a corresponding patent application, a very reliable search is to be expected and this can form the basis of the assessment of the legal validity of the utility model made by the applicant, the proprietor or an expert.

It is therefore advisable to use the possibility of a search request concerning the relevant printed documents in all cases where there is even the slightest doubt as to the eligibility for protection of the filed utility model. In this way, the value of the registered utility model can be considerably increased.

5. Cost and Term of Protection of a Utility Model

The utility model is a full protective right which may be obtained from the Patent Office on payment of the appropriate fees.

On filing of the utility model, a fee of DM 50 has to be paid to cover the first three-year term of protection (Section 23(1) of the Utility Model Law). The term of protection may be extended by a further three years to a total of six years on payment of a fee of DM 350 (Section 23(2), first sentence, of the Utility Model Law).

For utility models filed after January 1, 1987, the term of protection can be extended by a further two years on payment of DM 600 (Section 23(6) of the Utility Model Law).

The maximum eight-year term of protection available under the new provisions of the Utility Model Law on payment of altogether DM 1,000 goes a long way to satisfying the needs of the economy. Indeed, the term of protection of only six years available under the former regulations frequently proved too short for the transformation of protected inventions into new products. There are practitioners who demand a maximum duration of protection of 10 years. In my opinion, this would be the optimum term and would enhance the attractiveness of the utility model.

To sum up, it may be said that the structure and organization of utility model protection under German law possesses clear advantages which, however, also entail some drawbacks.

The following may be considered the advantages of the utility model:

— the simple and quick registration procedure;
— the low cost;
— the possibility of registering a utility model giving full protection to the subject matter of a patent application to bridge over the often lengthy period of patent procedure until protection becomes effective;
— the more favorable criteria for the novelty of the subject matter of the invention (only domestic prior public use, period of grace, exhibition priority) compared with a patent.

The drawbacks being that:

— utility model protection is not available for all inventions (in particular, for processes and chemical substances);
— the term of protection, six years or eight years as the case may be, can hamper the industrial exploitation of a protected invention;
— the utility model is registered without prior examination of the substantive requirements of protection, i.e., without examination as to novelty and inventive act, and therefore enforcement of the protective right against infringers requires a conscientious examination of the legal validity of the utility model by its proprietor, if he does not wish to be exposed to claims for damages for unwarranted threat of legal action.

III.

When weighing the advantages of utility model protection against its disadvantages, it would appear that the users of the industrial property system rate its advantages higher. This is proved, in particular, by the number of applications filed since the introduction of utility model protection nearly one hundred years ago.

Since 1891, 3,826,655 applications have been filed and 2,197,284 utility models registered at the German Patent Office. These figures prove that utility model protection is sought to almost the same extent as protection by patent for, since 1877, 4,516,493 inventions have been filed for patents and a total of 1,652,730 patents granted following the examination procedure.

It is remarkable in this context that utility model protection is of particular importance for domestic industry. From the very beginning, a significant proportion of utility model protection has been sought by domestic applicants. Up to now, more than 80

percent of utility model applications filed with the German Patent Office come from domestic applicants, whereas only about 50 percent of patent applications are domestic applications. When tracing the statistics of my Office back into the past, it will be seen that, until about 1955, even more utility model applications than patent applications were filed by domestic applicants. It was only after that date that patents began to prevail among the domestic applications.

A corresponding development can also be noted in Japan. Until 1980, each year domestic applicants filed many more applications for utility models than for patents. However, since 1981, the number of domestic utility model applications has stagnated, whereas the number of patent applications has increased rapidly.

A similar development is taking place in China, where a clear majority of domestic filings is to be noted among the utility model applications since the entry into force of the Patent Law on April 1, 1985.

It is therefore evident that utility model protection assumes particular importance for the domestic economy at the beginning of a country's industrialization and, even in Germany and Japan, industrialization took a number of decades. Utility model protection has proved, so to speak, that it provides an entry into a modern economic system and gives domestic industry the opportunity to develop its own creative efforts and to catch up with the technical and economic development achieved in other countries. Thus, the shift of emphasis from utility models to patents is the result of the growing technical status of a country and bears evidence of how an economy rates its own technical capacity. Germany (Federal Republic of) and Japan have set a good example for that process of development.

IV.

To sum up, it can be said that the utility model has proved its worth in practice in an impressive way. This pragmatic industrial property right is still an essential part of today's industrial property system in the Federal Republic of Germany. The utility model is of prime importance, above all, for small and medium-sized enterprises and independent inventors, for whom the inexpensive and simple registration procedure allows adequate protection for new technical developments. However, it is precisely these small and medium-sized enterprises and the independent inventors that are of special importance for the country's economy, since this sector produces a multitude of new technical ideas and is more effective in transforming inventions into new products and processes than are the less flexible large-scale companies.

So far, the utility model is a feature of the industrial property system in only a small number of countries. However, I am convinced that the utility model, as a pragmatic way to a full industrial property right, will increasingly be adopted by those countries that are ready to remunerate and protect inventive activities, thus rendering them effective for their economic development.

But attention should be paid, above all, to the basic concept of industrial property, namely, that industrial property rights are to be used as instruments in fair technical and economic competition.

News Items

History, Development and Main Provisions of the UPOV Convention

Thirty years ago, in February 1957, the Ministry of Foreign Afffairs of the French Republic invited the following 12 European States to participate in a diplomatic conference: Austria, Belgium, Denmark, Finland, Germany (Federal Republic of), Italy, Netherlands, Norway, Spain, Sweden, Switzerland, United Kingdom, together with the following intergovernmental organizations:

- United International Bureaux for the Protection of Intellectual Property (BIRPI);
- Food and Agriculture Organization of the United Nations (FAO);
- Organisation for European Economic Co-operation (OEEC).

The Conference's objective was to study the protection of breeders' rights in new plant varieties.

The first session of the Paris Diplomatic Conference was opened on May 7, 1957, by Mr. Loustau, Under-Secretary of State for Agriculture, and Mr. Ferru, Head of the French Delegation, was unanimously appointed President. The first session did not, however, lead to adoption of a convention, but only to adoption of a Final Act providing for continuation of the Diplomatic Conference at a later date following further preparatory work.

This further preparatory work lasted from 1957 to 1961 and a new draft international convention for the protection of plant varieties was drawn up during the course of a number of meetings of experts. Mr. Bustarret, Delegate of France and Chairman of the Committee of Experts, said, with regard to a second session of the conference, that the experts "saw no need to prolong discussions; because only the conference could decide upon the various matters on which they had not been able to reach unanimous agreement." Nevertheless, he stressed the "climate of mutual understanding and friendly cooperation that had reigned during the Committee's work."

On July 11, 1961, the Minister for Foreign Affairs of the French Republic invited the States and intergovernmental organizations that had participated in the first session to a second session of the Diplomatic Conference, together with the European Economic Community (EEC) and the following non-governmental organizations:

- International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL);
- International Association for the Protection of Industrial Property (AIPPI);
- International Community of Breeders of Asexually Reproduced Fruit Tree and Ornamental Varieties (CIOPORA);
- International Federation of the Seed Trade (FIS).

The second session of the Conference opened in Paris on November 21, 1961, at the International Conference Center of the Ministry of Foreign Affairs. Among participants in the Conference were the foremost experts of the time taking part as delegates, for example, Dirk Böringer, Jean Bustarret, Bernard Laclavière, Halvor Skov, Ludwig Pielen and Leslie Smith, as well as the following experts who participated as observers: Claude Hutin, René Royon, Ernest Tourneur and André de Vilmorin. On December 2, 1961, the 41 articles of the International Convention for the Protection of New Varieties of Plants were adopted and signed by plenipotentiaries of Belgium, France, Germany (Federal Republic of), Italy and the Netherlands. During the following year, in which it remained open for signature, the Convention was also signed by plenipotentiaries of Denmark and the United Kingdom on November 26, 1962, and by the plenipotentiary of Switzerland on November 30, 1962.

Article 27(2) of the Universal Declaration of Human Rights, adopted by the United Nations General Assembly in 1948, states that "Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."

Convinced of the importance attaching to the protection of new varieties of plants, not only for the development of agriculture but also for safeguarding the moral and material interests of breeders, the signatory States deemed that it was highly desirable for such a right to be guaranteed and recognized in accordance with uniform principles clearly defined in the Convention. The protection granted, or likely to be granted, to breeders of new plant varieties, whatever the legal system in force (special title of protection or patent), presumes that the new varieties fulfill the following criteria:

- they must be distinguishable by one or more important characteristics from the known varieties;

— they must be sufficiently homogeneous;
— they must be stable in their essential characteristics after repeated reproduction or propagation.

The effect of protection of new varieties is to make any sale of propagating material for the variety subject to the breeder's authorization.

Although the protection of new plant varieties was first instituted at the national level, the creation of the Convention and of UPOV has visibly contributed towards a global development that corresponds to Article 27 of the Universal Declaration of Human Rights in the field of plant breeding. Since the beginning of the twentieth century, with the help of the progress made in genetics, enterprises have specialized in the costly, difficult and painstaking work of creating new plant varieties.

The first instrument of ratification was deposited in 1965 by the United Kingdom, the second in 1967 by the Netherlands, and the Convention entered into force after ratification by the Federal Republic of Germany on August 10, 1968.

This was the origin of the International Union for the Protection of New Plant Varieties (UPOV).

Like many other international organizations, UPOV chose Geneva for its headquarters.

However, this account would not be complete without consideration of the Union's evolution through the Convention and of the persons who made valuable contributions to its development.

The Convention was revised twice: a first modification of limited scope was contained in the 1972 Additional Act; the second revision in 1978 stemmed from the realization that "certain amendments to the Convention [were] necessary to facilitate accession by States that had not yet acceded to the Convention."

Many persons contributed to the establishment of UPOV. But here it is necessary to make special mention of the Presidents of the UPOV Council, the Secretaries-General and the Vice Secretaries-General:

The Presidents of the Council were, in order:

— Mr. Leslie Smith, United Kingdom, 1968-1971;
— Mr. Ludwig Pielen, Federal Republic of Germany, 1971-1974;
— Mr. Bernard Laclavière, France, 1974-1977;
— Mr. Halvor Skov, Denmark, 1977-1980;
— Mr. Walter Gfeller, Switzerland, 1980-1983;
— Mr. Jean Rigot, Belgium, 1983-1986; and
— Mr. Stanley Schlosser, United States of America, the current President, for a period of three years until 1989.

The office of Secretary-General was occupied by Professor G.H.C. Bodenhausen from 1969 to 1973 and from then on by Dr. Arpad Bogsch.

The list of Vice Secretaries-General is almost as short: Halvor Skov, from August 1, 1970, to February 28, 1974, followed by the late Heribert Mast from March 4, 1974, to August 11, 1986, and then, since December 1, 1986, by Walter Gfeller.

The main provisions concerning protection contained in the International Convention for the Protection of New Varieties of Plants of December 2, 1961, revised at Geneva on November 10, 1972, and October 23, 1978, are the following:

Protection is granted to the breeder of a new variety or his successor in title, whatever may be the origin, artificial or natural, of the initial variation from which the new variety results (therefore also to a person who has discovered a new variety).

States party to the Convention are required to grant the breeder the right to make his prior authorization necessary for the following:

(a) production, for purposes of commercial marketing, of the reproductive or vegetative propagating material;
(b) offering such material for sale;
(c) repeated use of the variety for the commercial production of another variety;
(d) commercial use of ornamental plants or parts thereof as propagating material in the production of ornamental plants or cut flowers.

From the above, it can be seen that the use of the new variety as an initial source of variation for the purpose of creating other new varieties, as well as the marketing of such varieties, is free. However, repeated use as outlined in subparagraph (c), above, is not free.

The 1978 Diplomatic Conference recommended that where, in respect of any genus or species, the granting of more extensive rights than those described above was desirable to safeguard the legitimate interests of the breeders, the Contracting States should take adequate measures.

With regard to recognition and protection of breeders' rights, member States must grant to nationals of the other member States and to persons domiciled or having their registered office in one of those States the same treatment as is accorded by their respective laws to their own nationals. Any member State may, however, limit the right to claim protection for a variety to nationals of member States that apply the Convention for the same genus or species as that of the new variety and to persons domiciled or having their registered office in any of those States.

The effect of the right of priority which States party to the Convention must recognize is that a breeder may file his first application for protection of a new variety in the member State of his choice. If he files an application for the same variety in another member State within a period of 12 months from the filing of the first application, he enjoys, on request, a right of priority for the subsequent application. Where a right of priority is claimed, the breeder's rights cannot be affected by an application filed for the same variety by another person during the period between filing of the first application

and filing of the subsequent application by the breeder, nor by use of the variety during that same period.

Each new variety must have a variety denomination. The denomination is registered at the time of issuing the title of protection and becomes the generic designation of the variety. This rule is mainly intended to prevent the denomination of a new variety registered in a member State from being used in another member State as the denomination of another variety of the same botanical species or of a closely related species. Member States must also ensure that no rights in the designation registered as the denomination of the variety hamper free use of the denomination in connection with the variety, even after the expiration of the protection.

The Convention is in principle applicable to all botanical genera and species (taxa). Member States must do everything possible to apply it to the largest possible number of taxa. They must apply it to at least five taxa when they become bound by the Convention and subsequently extend this number to at least 10 within a period of three years, to at least 18 within a period of six years and to at least 24 within a period of eight years.

The Convention sets out the conditions to be fulfilled by each new variety for which protection is sought. It does not allow the granting of protection to be subject to other conditions, apart from the fulfillment of formalities and the payment of fees. The Convention provides that a new variety must be clearly distinguishable by one or more important characteristics from any other variety whose existence is a matter of common knowledge. At the time of application for protection, the new variety must not have been offered for sale or marketed, with the agreement of the breeder, in the member State where the application has been filed (or where the law of that State so provides, not for longer than one year nor longer than four years in any other State (six years in the case of vines and trees, including their rootstocks)). In addition, the new variety must be sufficiently homogeneous and stable in its essential characteristics.

The Convention provides that the period of protection, computed from the date of issue of the title of protection, must be at least 18 years for vines and trees, including their rootstocks, and 15 years for all other plants.

The Convention allows each member State to grant protection for a new plant variety in the form of a special title of protection or of a patent.

The Convention authorizes restriction of the free exercise of the exclusive rights provided for in the Convention solely for reasons of public interest. Where public interest consists of ensuring the distribution of the new variety, the member State having recourse to restrictions must take all measures necessary to ensure that the breeder receives equitable remuneration.

Member States must register the denomination of a new variety at the same time as the title of protection for the variety is issued. Although the denomination is chosen and proposed by the variety's breeder, it must conform to certain criteria laid down in some detail in the Convention. The denomination must enable the new variety to be identified and must not be liable to mislead or to cause confusion concerning the characteristics, value or identity of the new variety or the identity of the breeder. It must be different from every denomination which, in any member State, designates an existing variety of the same botanical species or of a closely related species. Except where there is a major obstacle, the new variety must be presented under the same denomination in all protection application procedures.

Member States must require that persons offering for sale or marketing reproductive or vegetative propagating material of a protected variety in that State use for this purpose the denomination of the variety and continue to do so even after the expiration of protection.

The International Union for the Protection of New Varieties of Plants has two permanent organs, the Council and the Office. The Council is comprised of representatives of member States. Each member State has one vote. The Council elects a President and at least one Vice-President from among its members.

The Council holds regular sessions at least once a year and its main tasks are the following:

(i) to establish and amend the Union's rules of procedure and administrative and financial regulations;

(ii) to examine and approve the budget of the Union and fix the contribution of each member State;

(iii) to appoint the Secretary-General and, if it finds necessary, a Vice Secretary-General and determine the terms of appointment of each;

(iv) to give to the Secretary-General all necessary directions for the accomplishment of the tasks of the Union;

(v) to examine the annual report on the activities of the Union and to approve the accounts;

(vi) to fix the program for the Union's future work, to fix the date and place of the Conferences on Revision of the Convention;

(vii) to study appropriate measures to safeguard and encourage the development of the Union;

(viii) take all necessary decisions to ensure the efficient functioning of the Union.

The Office of the Union is under the direction of the Secretary-General, who is also the Director General of the World Intellectual Property Organization (WIPO). The Secretary-General is assisted by a Vice Secretary-General, appointed by the Council, and by a small staff.

The Office carries out all the duties and tasks entrusted to it by the Council. It has its headquarters in Geneva and maintains close technical and adminis-

trative cooperation with the International Bureau of WIPO.

At July 1, 1987, UPOV comprised 17 member States: Belgium, Denmark, France, Germany (Federal Republic of), Hungary, Ireland, Israel, Italy, Japan, Netherlands, New Zealand, South Africa, Spain, Sweden, Switzerland, United Kingdom, United States of America.

BOLIVIA

Director General,
General Directorate of Standards and Technology

We have been informed that Ing. Felix Miranda Cuevas has been appointed Director General of the General Directorate of Standards and Technology.

ECUADOR

"Director Nacional de Propiedad Industrial"

We have been informed that Dr. Francisco Cucalón Rendón has been appointed *"Director Nacional de Propiedad Industrial."*

JAPAN

Director General, Japanese Patent Office

We have been informed that Mr. Kunio Ogawa has been appointed Director General of the Japanese Patent Office.

Calendar of Meetings

WIPO Meetings

(Not all WIPO meetings are listed. Dates are subject to possible change.)

1987

September 3 to 11 (Geneva) — Permanent Committee on Patent Information (PCPI) and PCT Committee for Technical Cooperation (PCT/CTC)

September 14 to 19 and 22 (Geneva) — Consultative Meeting on the Revision of the Paris Convention (Fourth Session)

September 21 to 30 (Geneva) — Governing Bodies (WIPO General Assembly, Conference and Coordination Committee; Assemblies of the Paris, Madrid, Hague, Nice, Lisbon, Locarno, IPC, PCT, Budapest, TRT, Vienna and Berne Unions; Conferences of Representatives of the Paris, Hague, Nice and Berne Unions; Executive Committees of the Paris and Berne Unions; Committee of Directors of the Madrid Union; Council of the Lisbon Union): Ordinary Sessions

October 5 to 9 (Geneva) — Committee of Governmental Experts on Works of Applied Art (convened jointly with Unesco)

November 2 to 6 (Geneva) — Committee of Experts on the Harmonization of Certain Provisions in Laws for the Protection of Inventions (Fourth Session)

November 23 to December 4 (Geneva) — Permanent Committee on Patent Information (PCPI): Working Group on Search Information

December 2 to 4 (Geneva) — Joint Unesco-WIPO Consultative Committee on the Access by Developing Countries to Works Protected by Copyright (convened jointly with Unesco)

December 7 to 11 (Geneva) — Committee of Governmental Experts on the Printed Word (convened jointly with Unesco)

UPOV Meetings

1987

October 6 to 8 (Geneva) — Technical Committee

October 8 and 9 (Geneva) — Administrative and Legal Committee

October 12 and 13 (Geneva) — Meeting with International Organizations

October 14 (Geneva) — Consultative Committee

October 15 and 16 (Geneva) — Council

1988

June 7 to 9 (Edinburgh) — Technical Working Party on Automation and Computer Programs

June 14 to 17 (Wageningen) — Technical Working Party for Vegetables

June 20 to 24 (Melle) — Technical Working Party for Ornamental Plants and Forest Trees

June 28 to July 1 (Hanover) — Technical Working Party for Fruit Crops, and Subgroups

July 5 to 8 (Surgères) — Technical Working Party for Agricultural Crops

Other Meetings Concerned with Industrial Property

1987

September 1 to 4 (Warwick) — British Library Japanese Information Service: International Conference on Japanese Information in Science, Technology and Commerce

September 4 to 6 (Stockholm) — International League for Competition Law: *Journées d'études*

September 22 to 25 (Strasbourg) — Center for the International Study of Industrial Property: Seminar on Licensing and the Transfer of Technology (second module: Strategy and Procedures for the Transfer of Technology)

November 8 to 11 (Budapest) — Pharmaceutical Trade Marks Group: 35th Conference entitled "Moscow to Madrid"

November 30 to December 4 (Strasbourg) — Center for the International Study of Industrial Property: Present Status of European Patent Law and Practice — Seminar on the Drafting of Claims and Oppositions

December 7 to 11 (Munich) — European Patent Organisation: Administrative Council

1988

January 25 to 30 (Strasbourg) — Center for the International Study of Industrial Property: Present Status of European Patent Law and Practice — Seminar on Legal Problems

March 24 (London) — Institute of Trade Mark Agents: International Conference on "New Vistas in Trade Marks"

June 27 to July 1 (Cannes) — International Federation of Industrial Property Attorneys: World Congress

September 15 to 18 (Angers) — International League for Competition Law: 30th Congress