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SENATE

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Action:

Introduced By Mr. Mathias:

"(D) provides for maximum utilization of existing services, including those offered by private, nonprofit service proriders; and

"(E) is administered by the same agency which administers the State plan under section 402, the same agency which administers the State plan approved under part B of this title, or the same agency which administers the block grant under title XX.

"(2) For purposes of this section, 'pregnant teenagers' and 'teenage mothers' means only pregnant women or mothers who are age 18 or under, or who are secondary school students.

"(c)(1) Any State receiving a grant under this section for a fiscal year shall provide a report to the Secretary at the close of such fiscal year which shall include the number and characteristics of individuals served by the State program, the services provided, and the results achieved. Such report shall also include data on the number of cases and the amounts of the aid to families with dependent children provided under this part for the fiscal year, broken down by the age of the parent or caretaker relative receiving such aid, by race, and by location within the State.

"(2) The Secretary shall establish a systematic reporting system capable of yielding comprehensive data on which service figures and program evaluations shall be based. On or before each January 1 the Secretary shall submit to the Congress a report describing the activities supported under this section during the fiscal year ending on the preceding September 30, including, at a minimum, the number and characteristics of persons served, the services provided, the results achieved, and the Secretary's plans and recommendations for the future.

"(d) For purposes of making grants to States under this section there are authorized to be appropriated $75,000,000 for fiscal year 1985 and for each fiscal year thereafter."

By Mr. MATHIAS:

S. 3085. A bill to amend the patent laws implementing the Patent Cooperation Treaty; to the Committee on the Judiciary.

PATENT COOPERATION TREATY

Mr. MATHIAS. Mr. President, the Patent Cooperation Treaty is a major multilateral convention under which 35 countries, including the United States, have joined together to facilitate the filing of patent applications for the same invention in a number of countries. U.S. inventors now rely on the convention to obtain protection for their technology in other countries.

At present under the treaty, U.S. applicants are able to file a single international patent application in English in the U.S. Patent and Trademark Office and have that application acknowledged in as many other countries as the applicant designates. Following the preparation of an international search report—prepared by the U.S. Patent and Trademark Office or the European Patent Office for U.S. applicants—citing relevant references, the applicant decides whether or not to proceed to perfect his or her applications in the countries designated by paying national fees and furnishing the necessary translations. This decision is not required until more than 1½ years after first filing the application.

This legislation that I introduce today, which accompanies and implements a planned withdrawal of a reservation by the United States to the application of the second chapter of the Patent Cooperation Treaty, will further increase the usefulness of the Patent Cooperation Treaty for U.S. interests. Adherence of the United States to chapter II will give the U.S. inventor access to an examination report, which related the references found in the search report to the invention.

It will also enable the applicant to defer the decision about paying national fees and preparing translations to perfect the applications until approximately 2½ years after the first filing of the international application. Before having to make this decision, the applicant will have in hand a report that cites the previous patents or publications that bear on the patentability of his or her invention. The applicant will also have a report that relates these references to the invention. With this information the applicant will be able to make an informed decisions about continuing to pursue protection in many other countries before having to underwrite the large costs of national fees and preparing translations.

In addition to giving the U.S. applicant more flexibility in pursuing protection for an invention in a number of countries, the proposed changes should increase the strength of the patents that are obtained in the various countries. Not only will these countries have all the resources they now have for evaluating the patentability of an invention, but, in addition, they will have a search report and an examination report prepared by a major patent office for each application. This should greatly aid U.S. inventors in obtaining stronger protection for their inventions abroad.

I have been informed that the U.S. Patent and Trademark Office will produce examination reports for international applications only after it achieves its important goal of reducing patent application pendancy time to an average of 18 months. This goal is expected to be achieved in 1987. Arrangements have been made to have the European Patent Office prepare the examination reports for U.S. inventors until that goal is achieved. Thereafter the U.S. Patent and Trademark Office will also be able to prepare these examination reports.

I introduce the bill today, not in the expectation that we will pass it in the 98th Congress, but to get the debate started and lay the groundwork for action in the 99th. I urge my colleagues to examine it closely and share it with interested constituents, and I request unanimous consent that it appear in the RECORD immediately following my remarks along with a statement of purpose.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

S. 3085

Be it enacted by the Senate and House of Representatives of the United States of America in Congress Assembled, That this Act may be cited as the "Act to Authorize the United States to Participate in Chapter II of the Patent Cooperation Treaty."

SEC. 2. (a) Section 351(a) of title 35, United States Code, is amended by striking out ", excluding chapter II thereof".

(b) Section 351(b) of title 35, United States Code, is amended by striking out "excluding part C thereof".

(c) Section 351(g) of title 35, United States Code, is amended by—

(1) striking out "term" and inserting in lieu thereof "terms";

(2) inserting "and 'International Preliminary Examining Authority'" after "Authority"; and

(3) striking out "means" and inserting in lieu thereof "mean".

SEC. 3. The item relating to section 362 in the analysis for chapter 36 of title 35, United States Code, is amended to read as follows: "362. International Searching Authority and International Preliminary Examining Authority."

SEC. 4. Section 362 of title 35, United States Code, is amended to read as follows:

"SEC. 362. INTERNATIONAL SEARCHING AUTHORITY AND INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

"(a) The Patent and Trademark Office may act as an International Searching Authority and International Preliminary Examining Authority with respect to international applications in accordance with the terms and conditions of an agreement which may be concluded with the International Bureau, and may discharge all duties required of such Authorities, including the collection of handling fees and their transmittal to the International Bureau.

"(b) The handling fee, preliminary examination fee, and any additional fees due for international preliminary examination shall be paid within such time as may be fixed by the Commissioner."

SEC. 5. Section 364(a) of title 35, United States Code, is amended by—

(a) striking out "or", first occurrence and inserting in lieu thereof ", ";

(b) inserting "International Preliminary Examining Authority" after "Authority, or"; and

(c) striking out "both".

SEC. 6. Section 368(c) of title 35, United States Code, is amended by—

(a) striking out the second occurrence of "or" and inserting in lieu thereof ", "; and

(b) striking out "both" and inserting in lieu thereof "International Preliminary Examining Authority".

SEC. 7. (a) Section 371(a) of title 35, United States Code, is amended to read as follows:

"(a) Receipt from the International Bureau of copies of international applications with any amendments to the claims, international search reports, and international preliminary examination reports including any annexes thereto may be required in the case of international applications designating or electing the United States."

(b) Section 371(b) of title 35, United States Code, is amended to read as follows:

"(b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39(1)(a) of the treaty."

(c) Section 371(c)(4) of title 35, United States Code, is amended by striking the "." and inserting in lieu thereof ";".

(d) Section 371(c) of title 35, United States Code, is amended by adding at the end thereof the following new paragraph (5):

"(5) a translation into the English language of any annexes to the international preliminary examination report, if such annexes were made in another language.".

(e) Section 371(d) of title 35, United States Code, is amended by adding at the end thereof the following sentence: "The requirement of subsection (c)(5) shall be complied with at such time as may be fixed by the Commissioner and failure to do so shall be regarded as cancellation of the amendments made under article 34(2)(b) of the treaty.".

(f) Section 371(e) of title 35, United States Code, is amended by inserting "or article 41" after "28".

Sec. 8. (a) Section 376(a) of title 35, United States Code, is amended by

(1) inserting "and the handling fee" after the first occurrence of "fee";

(2) striking "amount is" and inserting in lieu thereof "amounts are";

(3) redesignating paragraph (5) as paragraph (6); and

(4) inserting the following new paragraph (5):

"(5) A preliminary examination fee and any additional fees (see section 362(b))."

(b) Section 376(b) of title 35, United States Code, is amended by

(1) inserting "and the handling fee" after the first occurrence of "feet" in the first sentence; and

(2) inserting "the preliminary examination fee and any additional fees," after "fee," in the third sentence.

Sec. 9. Sections 2 through 8 of this Act shall come into force on the same day as the effective date of entry into force of chapter II of the Patent Cooperation Treaty with respect to the United States, by virtue of the withdrawal of the declaration under article 64(1)(a) of the Patent Cooperation Treaty. It shall apply to all international applications pending before or after its effective date.

Statement of Purpose

The purpose of this legislation is to authorize the Patent and Trademark Office to act as an International Preliminary Examining Authority and as an elected Office under chapter II of the Patent Cooperation Treaty. When the United States ratified the treaty in November 1975, it did so with a declaration that it was not bound by the provisions of chapter II thereof. This chapter calls for the establishment of an International Preliminary Examination Report with respect to an international application and provides for additional time before the application enters the national patent processing stage in various elected national offices.

The reason for non-adherence to chapter II by the United States in 1975, was the then-prevailing opinion that divergent patent examining methods in other member countries would have made adherence impracticable. Experience gained with the operation of the treaty during the ensuing years, as well as major steps taken by other countries to harmonize international patent processing procedures, such as the coming into force of the European Patent Convention in 1978, have largely eliminated this reason. Accordingly, it would be in the interest of U.S. industry and independent inventors alike, if the United States withdrew its reservation regarding chapter II of the treaty. In a letter dated July 27, 1984, the President has requested the Senate's advice and consent to that withdrawal. Because the treaty is not self-executing, adherence to chapter II requires implementing legislation, such as that proposed here.

Sectional Analysis

Introduction

Under chapter I of the Patent Cooperation Treaty, (hereinafter referred to as the "treaty"), a patent applicant is required to "designate" those member countries of the International Patent Cooperation Union in which he desires patent protection. The applicant receives an international search report from an International Searching Authority and is not required to undertake the expenses of translation, national filing fees and prosecution in each designated country until usually 20 months from the priority date of the international application.

Chapter II of the treaty offers a supplement to chapter I. If an applicant "elects" previously "designated" member countries which are also bound by chapter II, usually prior to the expiration of 19 months from the priority date, several additional features and procedures become effective. As explained in greater detail below, an International Preliminary Examining Authority will prepare an international preliminary examination report for the benefit of the applicant and the elected Offices. The elected Offices may agree or disagree with the conclusions reached by the International Preliminary Examining Authority. Further, the time limit for committing the expenses to enter the national stage in the elected Offices is postponed to usually 25 months from the priority date of the international application. Beginning on January 1, 1985, this time limit will be extended to 30 months, by virtue of a decision taken under Article 47 of the treaty by the Assembly of the International Patent Cooperation Union, at its seventh Extraordinary Session in February 1984.

Under chapter II of the treaty (article 31), an applicant files a "demand" with the appropriate International Preliminary Examining Authority, electing member countries as mentioned above. That Authority then conducts the international preliminary examination which essentially determines whether the claimed invention is new, involves an inventive step (is non-obvious), and is industrially applicable. The applicant and the Authority communicate with each other during the international preliminary examination and the applicant is given at least one opportunity to amend the claims, the description, and the drawings of his international application. Thereafter, an international preliminary examination report is established. The report does not contain any statement regarding the patentability of the claimed invention according to the law of any country; it merely states—by a "Yes" or "No"—in relation to each claim whether it seems to satisfy the three criteria set forth above. Each such statement is usually accompanied by citations of prior art references and other explanations. The report is communicated to the applicant and the national Offices of the elected countries, which then may use the report in connection with their patent granting process.

The national fees and translations, if any, must be paid before the expiration of the time period under article 39(1)(a) of the treaty, which will be 30 months from the priority date of the international application, beginning in 1985. Examination and other processing in the elected Offices can start only after the expiration of that time period, unless the applicant chooses to have it start earlier. If election of a country is made after the expiration of the 19th month from the priority date, the original time limits under chapter I of the treaty (article 22) must be observed.

Section 1. This section identifies the legislation as the "Act to Authorize the United States to Participate in Chapter II of the Patent Cooperation Treaty."

Section 2. This section amends section 351 of title 35, United States Code, by deleting the phrases ", excluding chapter II thereof" in subsection (a) and "excluding part C thereof" in subsection (b). These exclusions were placed in the original legislation, Public Law 94-131, 89 Stat. 685, since chapter II of the treaty was not implemented then. The exclusion of the articles and Regulations of the treaty relating to chapter II must be eliminated in existing legislation to permit the United States to participate in chapter II.

Subsection 351(g) is amended to refer to the "International Preliminary Examining Authority" in association with the current reference to the "International Searching Authority" in anticipation of the United States Patent and Trademark Office becoming an International Preliminary Examining Authority when that Office's workload is sufficiently current.

Section 3. This section amends the title of section 362 of title 35, in the analysis following the Chapter 36 title, to include reference to the International Preliminary Examining Authority, thus reflecting changes in section 362.

Section 4. Current section 362 of title 35 has been designated as subsection (a) and has been amended to permit the Patent and Trademark Office to act as an international Preliminary Examining Authority, should it desire to enter into an agreement with the International Bureau and perform the required functions. At present, this section only permits the Patent and Trademark Office to act as an International Searching Authority.

Subsection (a) of amended section 362 specifically provides for the collection of handling fees under article 31(5) of the treaty (and Rule 57 of the Regulations thereunder) and the transmittal thereof to the International Bureau, for whose benefit such fees are paid.

New subsections 362(b) gives the Commissioner authority to establish time periods, within the limits of the treaty and its Regulations, for the payment by applicants of the handling fee under Rule 57 of the Regulations and the preliminary examination fee under Rule 58 of the Regulations. The supplement to the handling fee under Rule 57.1(b) of the Regulations is paid by the applicant directly to the International Bureau and need not be provided for in the legislation.

Section 5. This section amends subsection 364(a) of title 35 by referring to the "International Preliminary Examining Authority" along with current references to "Receiving Office" and "International Searching Authority", in order to specify that all international processing functions, when performed by the Patent and Trademark Office, must be in accordance with the treaty, its Regulations, and title 35, United States Code.

Section 6. Subsection 368(c) of title 35 is amended to prevent the unauthorized disclosure of the contents of international applications by the Patent and Trademark Office when acting as an International Preliminary Examining Authority.

Section 7. Section 371 of title 35 requires a number of changes to facilitate the possibility of proceeding under chapter II of the treaty. Subsection 371(a) of title 35 is amended to authorize the Commissioner to

require the International Bureau to supply international preliminary examination reports, including annexes thereto. The annexes consist of amendments to the claims, description, or drawings of the international application made before the International Preliminary Examining Authority, as indicated in Rule 70.16 of the Regulations. The amended wording makes it possible for the Commissioner to require copies of all such documents or to exclude certain papers, such as those filed in or issued by the Patent and Trademark Office.

Subsection 371(b) of title 35 is amended to refer to the later time period under article 39(1)(a) of the treaty, at which an applicant may enter the national stage by virtue of having elected the Patent and Trademark Office under chapter II. As noted above, this time limit has been changed by the Assembly of the International Patent Cooperation Union from 25 months to 30 months, as of January 1, 1985.

Subsection 371(c) of title 35 is amended by adding a new paragraph (5) which requires the applicant to file, in addition to the requirements of paragraphs (1)-(4), a translation into the English language of any annexes to the international preliminary examination report, if such annexes are in a language other than English. Although the International Bureau is responsible under article 36(3)(a) of the treaty for communication to the Patent and Trademark Office of copies of these annexes in their original language, together with the international preliminary examination report, the applicant is responsible under article 36(2)(b) and (3)(b) of the treaty, to prepare a translation of the annexes if necessary and to transmit such translation to the Patent and Trademark Office.

Subsection 371(d) of title 35 is amended to include reference to the time period for submission of annexes to the international preliminary examination report. The amendment also provides the sanction of cancellation of the amendments for noncompliance.

Subsection 371(e) of title 35 is amended to ensure the right of the applicant to amend the application during the national stage before the elected Office, as provided in article 41 of the treaty.

Section 8. Subsection 376(a) of title 35 is amended to include reference to the handling fee to parallel the current reference to the international fee. The amounts of these fees are indicated in Rule 96 of the Regulations, which is titled "The Schedule of Fees."

A new paragraph (5) is added to subsection 376(a) to allow the Patent and Trademark Office to specify the amount of the preliminary examination fee and any additional fees thereto, referred to in subsection 362(b).

Subsection 376(b) of title 35 is amended to include reference to the fact that the amount of the handling fee is not prescribed by the Commissioner. Reference is also made to the preliminary examination fee and additional fees to the preliminary examination fee, as being refundable to the applicant where the Commissioner determines such a refund to be warranted.

Section 9. Section 9 specifies the effective date of the Act to be that of the entry into force of chapter II of the treaty with respect to the United States. When the United States ratified the treaty in November 1975, it did so with a declaration under article 64(1)(a) thereof, that it was not bound by the provisions of chapter II. Under article 64(6)(b) of the treaty, this declaration may be withdrawn at any time by notification to the Director General of the World Intellectual Property Organization and takes effect three months after the day on which the notification was received.

The Act applies to all international applications pending before or after its effective date. Accordingly, applicants whose applications have been pending less than 19 months from their priority date at the time chapter II becomes effective for the United States, will be able to make a "demand" for treatment under chapter II, thereby delaying the entry of the national stage in elected States to 30 months. Although there is no time limit in the treaty for submitting the "demand", its effects can only be guaranteed if it is submitted before the expiration of 19 months from the priority date of the international application. Submission of the "demand" after that date still entitles the applicant to receive an international preliminary examination report, but does not toll the applicable time limit under article 22 of the treaty.●

By Mr. CHAFEE:

S. 3086. A bill to require the National Institute of Child Health and Human Development of the National Institutes of Health to conduct research on, and develop, human contraceptives; to the Committee on Labor and Human Resources.

CONTRACEPTIVE RESEARCH

● Mr. CHAFEE. Mr. President, the disadvantages inherent in available birth control methods are the primary reason why many millions of American couples have difficulty avoiding unintended pregnancies. Effectiveness, convenience, and freedom from adverse health effects are all lacking in contraceptives on the market today. The result is unwanted pregnancy, and, all too frequently, abortion.

For example, the most serious side effect attributed to oral contraceptives—used by more than 8 million U.S. women—involves the cardiovascular system, specifically thromboembolism, stroke, and heart attack. Women of a higher risk are those who smoke, have diabetes or a family history of it, and high blood pressure or hypertension. An estimated 2.3 million women in the United States use intrauterine devices—IUD's. Risk of infection is the most serious drawback with IUD's, and with each infection, a women's risk of infertility increases. A total of 11.6 million U.S. women have chosen sterilization as their means of birth control. This method is irreversible and, therefore, not a reasonable alternative for those most vulnerable to unwanted pregnancies—2.1 million young women between the ages of 16 and 19, more than half of whom are estimated to have had sexual intercourse.

The limitations of current contraceptives cause 31 percent of the women who are not using birth control not to use it because they are concerned about health risks and side effects. One obvious result is the growth in the number of unwanted pregnancies. Over 3 million unplanned pregnancies occur annually, and 1 million of these are among teenagers. Forty-six percent of these pregnancies end in abortion, and approximately 29 percent of the teenage pregnancies end in abortion. The large number of abortions is one clear indicator of how badly safe and effective contraceptives are needed.

However, the U.S. Government—the largest single sponsor of reproductive and contraceptive research—spends, according to Malcom Potts, president of Family Health International, approximately "the cost of a small order of McDonald's french fries per person per year" on all aspects of reproductive research.

As recently as 30 years ago, no research was being done on contraception. It was not until 1968 that the Center for Population Research within the National Institutes of Health was created. In 1983 funding for the Center was $86 million; in 1972 it was $65 million. Only $8.6 million of this actually goes toward contraceptive development, the remainder toward basic research in reproductive sciences. The $8.6 million is a particularly insignificant sum when one considers that, according to Mr. Potts, it can "cost up to $50 million and take more than 10 years of research" to bring a new contraceptive to the market.

In the past, industry was largely responsible for the research and development of many of the currently available contraceptives. However, industry is now far less excited about expending the effort to conduct new research and development because the cost and time involved from initial development to approval of marketing by the Food and Drug Administration—FDA—is a deterrent. Pharmaceutical companies would rather concentrate on developing drugs to treat disease than drugs and devices to prevent pregnancies given the cost and the time.

Recently, the Ford Foundation and the Canadian International Development Research Council, which made major contributions to contraceptive research, have withdrawn their support in light of the dwindling concern about the relative importance of problems of population growth. There seems to be far more concern about abortion than about prevention of unwanted pregnancies. It's ironic that the abortion controversy works against contraceptive research instead of in its favor.

The future of contraceptive research is not bright, despite the need to make it a priority. That is why I am today introducing legislation which requires the National Institutes of Health to conduct research on and develop better means of contraception. Requiring the National Institute of Health's Institute of Child Health and Human Development—which includes the Center for Population Research—to use at least 10 percent of its budget for new research and development would spur the search for safe and effective means of birth control. The Office of Technology Assessment rec-