DRAFT INDUSTRIAL PROPERTY ACT FOR SAMOA AND COMMENTARY ON ITS MAIN PROVISIONS

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COMMENTARY ON THE MAIN PROVISIONS OF THE DRAFT INDUSTRIAL PROPERTY ACT FOR SAMOA

PART I

PATENTS

Section I

Subsection (1) defines what is a patent and subsection (2) what is an invention for the purposes of this Act, mentioning the two existing categories of inventions, namely product inventions and process inventions. Product inventions exist in tangible form, e.g., machines, equipment, devices, etc., and process inventions generally consist of a series of steps for producing a product or a desired result, e.g., artificially coloring citrus fruits.

Subsection (3) lists subject matter that is excluded from patent protection. The basic difference between a discovery, mentioned in item (i), and an invention is that a person who makes an invention "creates" something that has not existed before whereas the person who makes a discovery does not create but reveals the existence of something which was unknown up to then. Item (ii) concerns instructions to the human mind which cannot be patented. The exclusion of methods of treatment and diagnostic methods, in item (iii), clearly states that products for applying such methods (e.g., medical equipment) are not excluded. Art. 27(3)(b) of the TRIPS Agreement allows for the exclusion of plants and animals other than microorganisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, countries which exclude plant varieties from patent protection must provide for an effective sui generis system of protection. These permitted exceptions are contained in items (iv), (v) and (vi). Art. 27(2) of the TRIPS Agreement provides for the option of excluding from patentability, inventions, the prevention of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life, or health or to avoid seriously prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law. This exception and its requirements are set out under item (vii).

Subsection (3)(viii): This provision may be adopted by Least Developed Countries (LDCs) and is based on paragraph 7 of the Declaration on the TRIPS Agreement and Public Health (doc. ref. WT/MIN(01)/DEC/W/2), issued at the World Trade Organization (WTO) Ministerial Conference which was held in Doha from November 9 to 14, 2001. Paragraph 7 of the said Declaration provides that least-developed country Members of the WTO will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 (Patents) and 7 (Protection of Undisclosed Information) of Part II of the TRIPS Agreement or to enforce rights provided for under those Sections until 1 January 2016, without prejudice to the right of those Members to seek other extensions of the transition periods as provided for in Article 66.1 of the said Agreement. The TRIPS Council, was requested in the said Declaration, to take the necessary action to give effect to this decision pursuant to Article 66.1 of the TRIPS Agreement. In accordance with the said request, the TRIPS Council,

the [Authority] adopts the following Act:

PART I: PATENTS

Definitions of "Patent" and of "Invention";
Matter Excluded from Patent Protection

- 1.(1) For the purposes of this Act, "patent" means the title granted to protect an invention.
- (2)(a) For the purposes of this Act, "invention" means an idea of an inventor which permits in practice the solution to a specific problem in the field of technology.
- (b) An invention may be, or may relate to, a product or a process.
- (3) The following, even if they are inventions within the meaning of subsection (2), shall be excluded from patent protection:
 - (i) discoveries, scientific theories and mathematical methods;
 - (ii) schemes, rules or methods for doing business, performing purely mental acts or playing games;
 - (iii) methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced on the human or animal body; this provision shall not apply to products for use in any of those methods.
 - (iv) [plants and animals other than microorganisms]
 - (v) [essentially biological processes for the production of plants or animals other than non-biological and microbiological processes]
 - (vi) [plant varieties]

during its session on June 27, 2002, approved a decision to extend until January 1, 2016, the transition period during which LDCs are not obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under those Sections without prejudice to the right of those Members to seek other extensions of the transition periods as provided for in Article 66.1 of the said Agreement. The TRIPS Council also approved a waiver to exempt LDCs from having to provide exclusive marketing rights for pharmaceutical products in the period during which they do not provide patent protection for such products. The waiver was submitted to, and approved by, the WTO General Council on July 8, 2002.

LDCs which adopt this provision may need to introduce transitional provisions for patents granted in respect of pharmaceutical products under any previous or current legislation. It should also be noted, in this context, that Section 66.1 of the TRIPS Agreement provides that least-developed country Members of the WTO are not required to implement the TRIPS Agreement until January 1, 2006. As such, and in light of Paragraph 7 of the said Declaration, and the said decision of the TRIPS Council, an LDC is not obliged, under the TRIPS Agreement, to enforce patents granted in respect of pharmaceutical products under any previous or current legislation.

Section 2

This Section sets out and defines the three basic conditions for patentability of an invention, namely, novelty, inventive step and industrial applicability.

Subsection (2)(a) deals with the notion of novelty, providing that an invention is new if it is not anticipated by prior art, that is to say, if it does not form part of the state of the art.

Subsection (2)(b) defines prior art which is the sum of knowledge to be taken into account in evaluating the novelty of an invention and the inventive step at the decisive moment which is the filing date of the patent application or, where applicable, the filing date of the application on the basis of which priority is claimed under Section 6. The subsection provides for a requirement of universal novelty so far as publications in tangible form and so far as other forms of disclosure are concerned.

Subsection (2)(c) allows a "grace period" of twelve months for a patent application claiming an invention to be filed after the invention has been disclosed, either by the applicant or by his predecessor in title (e.g., at an official exhibition or through inexperience), or by reason of an abuse against the rights of the applicant or his predecessor in title (e.g., as a result of a theft of the invention or a breach of faith), without the disclosure being considered as prior art against the application.

Subsection (3) defines the second condition of patentability namely inventive step (sometimes called "non-obviousness").

In *subsection* (4), the third condition, industrial applicability, is defined, it being emphasized that "industry" is to be understood in its broadest sense.

- (vii) inventions, the prevention within Samoa of the commercial exploitation of which is necessary to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law.
- (viii) [pharmaceutical products, until January 1, 2016.]
- 2.(1) An invention is patentable if it is new, involves an inventive step and is industrially applicable.
- (2)(a) An invention is new if it is not anticipated by prior art.
- (b) Prior art shall consist of everything disclosed to the public, anywhere in the world, by publication in tangible form or by oral disclosure, by use or in any other way, prior to the filing or, where appropriate, the priority date, of the application claiming the invention.
- (c) For the purposes of paragraph (b), disclosure to the public of the invention shall not be taken into consideration if it occurred within twelve months preceding the filing date or, where applicable, the priority date of the application, and if it was by reason or in consequence of acts committed by the applicant or his predecessor in title or of an abuse committed by a third party with regard to the applicant or his predecessor in title.
- (3) An invention shall be considered as involving an inventive step if, having regard to the prior art relevant to the application claiming the invention and as defined in subsection (2)(b), it would not have been obvious to a person having ordinary skill in the art.
- (4) An invention shall be considered industrially applicable if it can be made or used in any kind of industry. "Industry" shall be understood in its broadest sense; it shall cover, in particular, handicraft, agriculture, fishery and services.

Patentable Inventions

To cater for the situation in which two or more persons have made the same invention independently of each other, *subsection (3)* applies the "first-to-file" system which is easier to apply than the "first-to-invent" system since it is not always easy to prove the date on which an invention was made.

Subsection (5) deals with the right to a patent for an invention made by an employee in execution of an employment contract

Subsection (6) establishes the inventor's moral right to be named as such in the patent and ensures that recognition is given to him. It is particularly important where, for example, the patent is granted not to the inventor but to his successor in title. Logically, the subsection states the right of the inventor to remain anonymous if he so wishes and, as a precaution against abuse, it provides that the wish of the inventor not to be named must be stated in a special written declaration signed by him and that any promise or undertaking by him to make such a declaration is devoid of legal effect.

Right to Patent; Naming of Inventor

- 3.(1) The right to a patent shall belong to the inventor.
- (2) If two or more persons have jointly made an invention, the right to the patent shall belong to them jointly.
- (3) If and to the extent to which two or more persons have made the same invention independently of each other, the person whose application has the earliest filing date or, if priority is claimed, the earliest validly claimed priority date shall have the right to the patent, as long as the said application is not withdrawn, abandoned or rejected.
- (4) The right to a patent may be assigned, or may be transferred by succession.
- (5) Where an invention is made in execution of an employment contract, the right to the patent shall belong, in the absence of contractual provisions to the contrary, to the employer.
- (6) The inventor shall be named as such in the patent, unless in a special written declaration signed by him and addressed to the Registrar he indicates that he wishes not to be named. Any promise or undertaking by the inventor made to any person to the effect that he will make such a declaration shall be without legal effect.

This Section deals with the requirements of a patent application and eventually should be supplemented by the Implementing Regulations.

The most frequent instance in which the applicant will have to furnish the statement referred to in subsection(2)(b) is where the inventor is his employee, in which case the statement will mention that the right of the applicant to the patent is based upon a contract of employment.

Subsection (3): The obligation to disclose the invention in a clear and complete manner in the description and to indicate, in particular, at least one mode for carrying out the invention is one of the fundamental obligations of the applicant. There is indeed no justification for the grant of an exclusive right with respect to an invention which does not contribute to the general wealth of technical knowledge because it has been insufficiently disclosed. Art. 29(1) of the TRIPS Agreement provides countries with the possibility of requiring applicants to indicate the best mode for carrying out their inventions at the filing date or, when priority is claimed, at the priority date of the application. Although it is often difficult to prove that the applicant had not complied with the best mode requirement, it may be that the authorities may wish to adopt the wording included in the said article of the TRIPS Agreement. It should also be noted that in countries applying the first-to-file system, the applicant, at the time of filing, often does not know what the best mode for carrying out the invention is.

Subsection (4): The function of the claim or claims is to determine the scope of protection. They alone are decisive in this respect. The description does not serve this function, nor does the abstract, as indeed subsection (6) makes clear. Consequently, each laim must be drafted in such a way as to enable the public and a court to know for certain the cope of the protection. However, the description and drawings may be used to interpret the laims, which often are drafted in highly technical language peculiar to particular fields of echnology. Moreover, the claims must be clear and concise and must be fully supported by ne description; it would be contrary to the public interest to permit the scope of protection of patent to be ambiguously defined or extended beyond any foundation for it in the description of the patent.

Subsection (6): The abstract has a limited but still important function. It provides echnical information on the subject matter of the invention, facilitates the classification of the oplication and, when the application is granted, it enables the reader (engineer, scientist, searcher) to quickly determine whether or not the subject matter of the patent is of interest to m.

- 4.(1) The application for a patent shall be filed with the Registrar and shall contain a request, a description, one or more claims, one or more drawings (where required), and an abstract. It shall be subject to the payment of the prescribed application fee.
- (2)(a) The request shall contain a petition to the effect that a patent be granted, the name of and other prescribed data concerning the applicant, the inventor and the agent, if any, and the title of the invention.
- (b) Where the applicant is not the inventor, the request shall be accompanied by a statement justifying the applicant's right to the patent.
- (3) The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art, and shall, in particular, indicate [at least one mode known to the applicant for carrying out the invention] [the best mode for carrying out the invention known to the applicant at the filing date or, where priority is claimed, at the priority date of the application].
- (4)(a) The claim or claims shall define the matter for which protection is sought. The description and the drawings may be used to interpret the claims.
- (b) Claims shall be clear and concise. They shall be fully supported by the description.
- (5) Drawings shall be required when they are necessary for the understanding of the invention.
- (6) The abstract shall merely serve the purpose of technical information; in particular, it shall not be taken into account for the purpose of interpreting the scope of the protection.
- (7) The applicant may, up to the time when the application is in order for grant, withdraw the application at any time during its pendency.

Subsection (1) is designed to prevent an applicant from including in a single application (and paying fees on the basis of one invention) claims relating to two or more different inventions; each invention must be the subject of a separate application.

Subsections (2) and (3) also allow the applicant, up to the time the application is in order for grant, to amend or divide the application on his own initiative, i.e., without being invited to do so by the Industrial Property Registry, in the course of the examination of the application.

Subsection (4): The purpose of the requirement of unity of invention under subsection (1) is to facilitate the administration and the search of applications and not to establish a standard or measure of the suitability of a subject-matter for patent protection. Accordingly, the failure to comply with the requirement of unity of invention cannot be a ground for the invalidation of the patent. Failure to comply with the requirement can only be redressed at the application stage. At that stage, the sanction for non-compliance is the refusal of the grant of a patent unless the application is restricted through the elimination of certain claimed subject matter. The subject matter so eliminated could then be included in one or more "divisional" applications.

Unity of Invention; Amendment and Division of Application

- 5.(1) The application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.
- (2) The applicant may, up to the time when the application is in order for grant, amend the application, provided that the amendment shall not go beyond the disclosure in the initial application.
- (3)(a) The applicant may, up to the time when the application is in order for grant, divide the application into two or more applications ("divisional applications"), provided that each divisional application shall not go beyond the disclosure in the initial application.
- (b) Each divisional application shall be entitled to the filing date and, where applicable, the priority date of the initial application.
- (4) The fact that a patent has been granted on an application that did not comply with the requirement of unity of invention under subsection (1) shall not be a ground for the invalidation of the patent.

This Section deals with the form in which an applicant, wishing to avail himself of the priority of an earlier application filed abroad for the same invention, must present his claim.

The substantive provisions on the right of priority are contained in Article 4 of the Paris Convention for the Protection of Industrial Property. That article provides, in particular, that any person who has duly filed an application for a patent in one of the countries party to the Paris Convention, or his successor in title, enjoys, for the purpose of filing a patent application for the same invention in other countries, a right of priority during a period of 12 months from the date of filing of the first application. Consequently, any subsequent filing, if made before the end of the 12 month period, cannot be "invalidated" by reason of any acts which occur in the interval, in particular, another filing or the publication or exploitation of the invention, and such acts cannot give rise to any third-party right or any right of personal possession.

According to Article 2.1 of the TRIPS Agreement, compliance with the substantive provisions of the Paris Convention is mandatory for all Members of the World Trade Organization even if they are not party to the Paris Convention.

Right of Priority

- 6.(1) The application may contain a declaration claiming the priority, as provided for in the Paris Convention, of one or more earlier national, regional or international applications filed by the applicant or his predecessor in title in or for any State party to the said Convention [or any Member of the World Trade Organization].
- (2) Where the application contains a declaration under subsection (1), the Registrar may request that the applicant furnish, within the prescribed time limit, a copy of the earlier application certified as correct by the Office with which it was filed.
- (3) The effect of the said declaration shall be as provided in the Paris Convention.
- (4) If the Registrar finds that the requirements under this Section and the Regulations pertaining thereto have not been fulfilled, the said declaration shall be considered not to have been made

The purpose of the provisions in this Section is to enable the Industrial Property Registry to request and obtain, from the applicant, information and documents concerning applications filed or grants made in other countries in respect of the same or essentially the same invention. Such information could, to a large extent, facilitate the processing of the patent application by the Registry. Having received the information requested under *subsection* (1), the Registry can select from among the foreign applications or grants, which one interests it most and apply the provisions of *subsection* (2) in respect thereof.

Information Concerning Corresponding Foreign Applications and Patents

- 7.(1) The applicant shall, at the request of the Registrar, furnish him with the date and number of any application for a patent filed by him abroad ("foreign application") relating to the same or essentially the same invention as that claimed in the application filed with the Industrial Property Registry
- (2)(a) The applicant shall, at the request of the Registrar, furnish him with the following documents relating to one of the foreign applications referred to in subsection (1):
 - (i) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;
 - (ii) a copy of the patent granted on the basis of the foreign application;
 - (iii) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application
- (b) The applicant shall, at the request of the Registrar, furnish him with a copy of any final decision invalidating the patent granted on the basis of the foreign application referred to in paragraph (a).

Subsection (1) deals with the filing date to be accorded to the application. The requirements imposed are not stringent since it is important that a filing date be fixed as soon as possible (the filing date being the decisive moment for evaluating the novelty of the purported invention and also the basis for a claim of priority for subsequent applications filed in respect of the same invention in a foreign country). Where a defect preventing a filing date from being accorded is corrected in time, the application, under paragraph (b), receives, as filing date, the date on which the correction was received by the Registry. If the defect is not corrected in time, the application is treated as if it had not been filed, except as regards drawings, in which case the application receives as filing date the date it was received by the Registry, and any reference to missing drawings shall be treated as non-existent (subsection (2)). The latter may, of course, eventually undermine the application, if the missing drawings prove to be necessary for the understanding of the invention. However, in such a case, the filing date is nevertheless retained, which may be useful for purposes of claiming priority for subsequent applications abroad for the same invention.

Subsection (3) requires the application to be examined for compliance with the prescribed formal requirements and as to whether information requested, if any, on corresponding foreign applications has been provided

[Under subsection (4), the Registry, having ascertained that the application complies with the formal requirements, proceeds to decide whether the application is in compliance with accordance with corresponding provisions to be incorporated in the Regulations, have the application examined. The facilities required for performance of such an examination comprise a substantial and fairly complete collection of patent documents published in various countries, patent applications covering all fields of technology, and equipment for storage and retrieval of documentation.]

Filing Date; Examination

8 (1)(a) The Registrar shall accord as the filing date the date of receipt of the application, provided that, at the time of receipt, the application contains:

- (i) an express or implicit indication that the granting of a patent is sought;
- (ii) indications allowing the identity of the applicant to be established;
- (iii) a part which, on the face of it, appears to be a description of an invention.
- (b) If the Registrar finds that the application did not, at the time of receipt, fulfill the requirements referred to in paragraph (a), he shall invite the applicant to file the required correction and shall accord as the filing date the date of receipt of the required correction, but if no correction is made, the application shall be treated as if it had not been filed.
- (2) Where the application refers to drawings which in fact are not included in the application, the Registrar shall invite the applicant to furnish the missing drawings. If the applicant complies with the said invitation, the Registrar shall accord as the filing date the date of receipt of the missing drawings. Otherwise, the Registrar shall accord as the filing date the date of receipt of the application and shall treat any reference to the said drawings as non-existent.
- (3) After according a filing date, the Registrar shall examine whether the application complies with the requirements of Section 4(1) and (2) and the Regulations pertaining thereto and those requirements of this Act and the Regulations which are designated by the Regulations as formal requirements for the purposes of this Act and whether information requested under Section 7, if any, has been provided.
- [(4) Where the Registrar is of the opinion that the application complies with the requirements indicated in subsection (3), the Registrar shall take a decision as to whether the requirements of Sections 1(2) and (3), 2, 4(3), (4) and (5) and 5 and the Regulations pertaining thereto are fulfilled and for this purpose may, as provided for in the Regulations, cause the application to be examined.]

[As regards the task of the Registrar to decide as to whether the application contains a patentable invention, subsection (5) enables him, for this purpose, to take into account and base his decision on the conclusions of the reports or decisions referred to or, where no such reports have been established or decisions rendered or have not been communicated or where he considers that the application needs to be further examined, on a search and examination report carried out on his behalf by an external authority which has at its disposal the required facilities. In this respect, it should be noted that WIPO provides services in the framework of its program of International Cooperation in the Search and Examination of Inventions (ICSEI) The ICSEI Program, which commenced in 1983, assists patent offices of developing countries in assessing novelty and inventive step of patent applications filed with them by residents of their respective countries. The ICSEI program is carried out in cooperation with donor countries with which WIPO has entered into agreements for the delivery of a specified number of reports per year. The ICSEI search and examination reports, prepared by highly skilled examiners of industrial property offices having at their disposal the required documentation, contain opinions on the novelty and inventive step of inventions claimed in the respective patent applications, which can, in turn, be used by the requesting industrial property office to decide whether or not the invention claimed in the application deserves a patent. In performing the search and examination of patent applications under the ICSEI Program, the examiners treat the applications as they would treat national applications filed with their offices. Consequently, they would detect non-compliance with requirements that are generally applied in patent granting procedures such as those relating to non-patentable matter, the requirements of the description, including drawings, the claims and in respect of unity of invention.]

- [(5) The Registrar shall take into account, for the purposes of subsection (4),
 - (i) the results of any international search report and any international preliminary examination report established under the PCT in relation to the application; and/or
 - (ii) a search and examination report submitted under Section 7(2)(i) relating to, or a final decision submitted under Section 7(2)(iii) on the refusal to grant a patent on, a corresponding foreign application; and/or
 - (iii) a search and examination report which was carried out upon his request by an external search and examination authority.]

The procedure under this Section is that patents are granted after the positive result of an examination as to [form] [substance], without any provision for the possibility of an opposition (which could entail the consideration of technically complicated issues). Invalidation proceedings may be instituted under *Section 14*.

Subsection (2): The publication of a reference to the grant of a patent, and making copies thereof available to the public, is an economical means of giving notice of the existence of the patent and making available to the public the technological information it contains. The patent is recorded in the patent register by inserting a copy of the patent in the register.

The certificate of grant issued to the applicant under *subsection* (2)(ii) is the legal document evidencing his ownership of the patent.

[Subsection (3)] establishes a time limit for granting or refusing the application, which necessarily implies a time limit for completing any substantive examination undertaken pursuant to Section 8(4). The time limit is two years from the date the substantive examination was started. It is to be noted that this time limit applies "wherever possible." The words, "wherever possible," are intended to indicate that some flexibility in the administration of the time limit is necessarily required in view of the dialogue which can take place between the Registrar and an applicant during the substantive examination. In the absence of a delay caused by such an extended dialogue, or other special circumstances, however, it should be "possible" for the Registrar to complete the substantive examination and thus reach a final decision on an application within the time limit prescribed.]

Subsection (4) establishes the right of the owner of a patent to request the Registrar to make changes in the text or drawings of the patent in order to limit the extent of protection conferred by the patent. A change limiting the extent of protection might be sought by the owner of the patent following the discovery by him of prior art, previously unknown to him, that affected the validity of the scope of protection granted by his patent. However, no change may be made to a patent if the change would result in the disclosure contained in the patent going beyond the disclosure contained in the application as filed. New matter might have the effect of extending the protection conferred by the patent to the potential detriment of competitors who may have relied on the extent of protection indicated in the patent as published.

Grant of Patent; Changes in Patents

- 9 (1) Where the Registrar finds that the conditions referred to in Section 8(3) [and (4)] are fulfilled, he shall grant the patent. Otherwise, he shall refuse the application and notify the applicant of that decision.
 - (2) When he grants a patent, the Registrar shall
 - (i) publish a reference to the grant of the patent,
 - (ii) issue to the applicant a certificate of the grant of the patent and a copy of the patent,
 - (iii) record the patent;
 - (iv) make available copies of the patent to the public, on payment of the prescribed fee
- [(3) The Registrar shall, whenever possible, reach a final decision on the application not later than two years after the commencement of the examination referred to in Section 8(4)]
- (4) The Registrar shall, upon request of the owner of the patent, make changes in the text or drawings of the patent in order to limit the extent of the protection conferred thereby, provided that the change would not result in the disclosure contained in the patent going beyond the disclosure contained in the initial application on the basis of which the patent was granted.

The effect of the grant of a patent is that the patented invention may not be exploited in the country by persons other than the owner of the patent, unless the owner agrees to such exploitation.

Subsection (2) lists those acts the performance of which require the agreement of the owner.

Subsection (3): The right to institute proceedings against any person exploiting the patented invention in the country without the owner's agreement is the owner's most important right, since it permits him to derive the material benefits to which he is entitled as a reward for his intellectual effort and work, and as compensation for the expenses which his research and experimentation leading to the invention have entailed. The performance of any act of exploitation falling within the scope of protection of the patent by a person, without the agreement of the owner, constitutes an infringement of the patent under subsection (3), subject to the exceptions provided in subsection (4) and Section 12 (see below).

Subsection (4): The first limitation contained in this subsection is usually called the "exhaustion" of patent rights. Under that principle, once a patent protected article (a patented product or a product made by a patented process) has been lawfully put on the market, the patent owner's rights in respect of that product are exhausted. This limitation assures free circulation of products. The TRIPS Agreement, in its Article 6, does not establish which level of exhaustion (i.e., national, regional or international) members shall adopt, subject to its provisions on national treatment and most-favored-nation treatment. Thus, under a law providing for a national level of exhaustion, the rights of the owner of the patent would be exhausted only in respect goods that have been put on the market in the country with its consent. In a system which provides for regional exhaustion (e.g., countries of the European Union) once goods are released with the consent of the owner of the patent in any country belonging to the region, the rights of the patent owner are exhausted and the goods may be imported to other countries within the region and trading in such goods would not constitute an infringement. Under a system of international exhaustion, goods put on the market by or with the consent of the patent owner anywhere in the world would result in the patent owner's rights being exhausted in the country concerned. Thus, goods imported into a country with a system of international exhaustion of rights cannot be considered as infringement so long as they were put on the market, originally, by the owner of the patent or with his consent. It is noteworthy, in this context, that TRIPS Article 28 (Rights Conferred) contains a footnote, as regards the right to prevent importation, stating that that right, "like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6." This means that parallel importation of goods into a country will not be permitted where that country's legislation provides for national exhaustion. Such importation will be permitted in a country with a regional system of exhaustion in so far as the goods were released in a country of the region by the owner of the patent or with his consent. In a country applying a system of international exhaustion, patented products put on the market by the owner of the patent or with his consent in any country, and under a parallel patent in force in the exporting country, may be imported into that country without constituting an infringement of the patent. As affirmed in paragraph 5(d) of the Declaration on the TRIPS Agreement and Public Health (doc. ref. WT/MIN(01)/DEC/W/2), issued at the November 2001 WTO Ministerial Conference in Doha, the effect of the provisions in the TRIPS Agreement that are relevant

Rights Conferred by Patent

- 10.(1) The exploitation of the patented invention in Samoa by persons other than the owner of the patent shall require the latter's agreement.
- (2) For the purposes of this Act, "exploitation" of a patented invention means any of the following acts:
- (a) when the patent has been granted in respect of a product:
 - (i) making, importing, offering for sale, selling and using the product;
 - (ii) stocking such product for the purposes of offering for sale, selling or using;
- (b) when the patent has been granted in respect of a process:
 - (i) using the process;
 - (ii) doing any of the acts referred to in paragraph (a) in respect of a product obtained directly by means of the process.
- (3) The owner of the patent shall, in addition to any other rights, remedies or actions available to him, have the right, subject to subsection (4) hereof and Section 12, to institute court proceedings against any person who infringes the patent by performing, without his agreement, any of the acts referred to in subsection (2) or who performs acts which make it likely that infringement will occur.
 - (4)(a) The rights under the patent shall not extend:
 - (i) to acts in respect of articles which have been put on the market in Samoa [any country] by the owner of the patent or with his consent; or

to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the Most-favored Nation (MFN) and national treatment provisions of Articles 3 and 4 of the said Agreement. Alternatively, however, because both national and international regimes of exhaustion have advantages and disadvantages (national exhaustion permits a better control of imports of counterfeit and pirated goods and encourages technology transfer, but international exhaustion puts some pressure on international, discriminatory prices), WTO Members may adopt a system of controlled international exhaustion. The second limitation is aimed at avoiding a situation in which the exercise of the exclusive right might be prejudicial to the public interest in maintaining free movement of vessels, aircraft, etc. The paragraph itself is limited in four ways. First, it is only the "use" of the article that cannot be affected by the patent rights (i.e., manufacture or sale would be affected). Secondly, only that use which is exclusively for the needs of the vessel is concerned. Thirdly, only vessels, etc., of other countries are concerned and, fourthly, only those vessels which temporarily or accidentally enter the airspace or territory or waters of the country are concerned. The third limitation concerns acts done only for experimental purposes, which implies that such acts must be for non-commercial purposes. The fourth limitation recognizes the so-called "prior user's" right. This right is established by "good faith" prior use or serious preparations for such use, within the territory of Samoa. The right does not extend to use which is different in nature (e.g. making a patented product as opposed to importing the product) or purpose (e.g., making the patented product on contract for another enterprise or for sale in general as opposed to making it for the internal use of the enterprise) from the actual prior use or, in the case of preparations, envisaged prior use. The right is further limited by paragraph (c). Paragraph (b) is based on the decision of a WTO Dispute Settlement Panel in a complaint filed by the European Communities and their Member States against Canada, "Canada - Patent Protection of Pharmaceutical Products" (adopted by the WTO Dispute Settlement Body on April 7, 2000, doc. ref. WT/DS114/R available on the WTO website at www.wto.org). The decision clarified that activities related to the development and submission of information required to obtain marketing approval for a generic product may take place during the patent term of the original product. In accordance with the decision, the purpose of the exception is to permit potential generic competitors to obtain government marketing approval during the term of the patent, so that they will have regulatory permission to sell by the date on which the patent expires. It is applicable to products such as pharmaceuticals whose marketing is subject to government regulation in order to assure their safety or effectiveness. To qualify for exemption under this provision, the activities concerned must be "solely for uses reasonably related to the development and submission of information required" by any law, of any country, that "regulates the manufacture, construction, use or sale of any product". Paragraph (c) restricts the transferability of the right of the prior user to those circumstances in which a transferee (assignee, heir, etc.) acquires also the enterprise or business, or that part of the enterprise or business, in which the prior use or preparations for use occurred.

- (ii) to the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Samoa; or
- (iii) to acts done only for experimental purposes relating to a patented invention; or
- (iv) to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted and in Samoa, was using the invention or was making effective and serious preparations for such use.
- (b) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Samoa or a country other than Samoa that regulates the manufacture, construction, use or sale of any product.
- (c) The right of prior user referred to in paragraph (a)(iv) may be transferred or devolve only together with the enterprise or business, or with that part of the enterprise or business, in which the use or preparations for use have been made.

[small roman (i) of subparagraph (a) can be deleted and replaced by the following language:

- (d) (i) The Minister shall have the authority, ex officio or at the request of any interested party, of permitting others to import the patented product or a product manufactured directly or indirectly by means of the patented invention from the territory of any other country in which the product has been put on the market by the owner of the patent or with his consent under a valid and enforceable patent in that other country for the same articles when that product is not available in the territory of Samoa or is available in the territory of Samoa with low quality standards or in a quantity that is not sufficient to meet the local demand or at prices that the Minister deems abusive or for any other reason of public interest, such as unreasonable restraint of trade.
- (ii) If the conditions that gave rise to the authorization to import above mentioned cease to exist, the Minister may, ex officio or at the request of the patent owner, cancel the authorization, provided that the legitimate interests of the importer are taken into account, including but not exclusively that the importer will retain the right to commercialize the patented articles that remain on stock.]