Annexure 1:

DOHA WTO MINISTERIAL 2001: TRIPS
Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.

Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

   a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

   b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

   c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
d. The effect of the provisions in the TRIPS Agreement that are relevant 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 MFN and
national treatment provisions of Articles 3 and 4.

6. We recognize that WTO members with insufficient or no manufacturing capacities in
the pharmaceutical sector could face difficulties in making effective use of compulsory
licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an
expeditious solution to this problem and to report to the General Council before the end
of 2002.

7. We reaffirm the commitment of developed-country members to provide incentives to
their enterprises and institutions to promote and encourage technology transfer to least-
developed country members pursuant to Article 66.2. We also agree that the least-
developed country members will not be 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 these Sections until 1 January 2016, without prejudice to the
right of least-developed country members to seek other extensions of the transition
periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council
for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the
TRIPS Agreement.

http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
Annexure 2:

Proposals relating to implementation of Paragraph 6 discussed at the Council for TRIPS (March 2002)

The EC and their Member States submitted two possible options to address the paragraph 6 problem:

1) an amendment to Article 31 of the TRIPS Agreement in order to carve out an exception to Article 31 (f) for exports under compulsory licences, under certain conditions, of products needed to combat serious public health problems; or

2) an interpretation of the limited exceptions clause of Article 30 of the TRIPS Agreement in a way to allow production for export, to certain countries and under certain conditions, of products needed to combat serious public health problems;

Option (1) would be subject to three conditions: criteria ensuring that importing countries actually face serious public health problems, safeguards against re-exportation of the cut-price generics, particularly to rich countries, and reporting requirements that would inform trading partners of such action.

Option (2) would be subject to two minimum conditions: the entirety of the product must be exported to the country with the public health problem, and re-export from the importing country would be prohibited.

3) The USA proposed a moratorium whereby WTO Members would agree not to bring a WTO complaint against countries that export some medicines to countries in need, so long as certain other conditions are met.

On behalf of the African Group, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Malaysia, Sri Lanka and Thailand, Kenya made a statement suggesting, as possible options, an amendment to Article 31 in order to eliminate paragraph "f", or to develop an authoritative interpretation that would recognize the right of Members to allow the production without the consent of the patent holder to address public health needs in another country, under Article 30 of the TRIPS Agreement.
Annexure 3:

Uruguay Round Agreement: TRIPS

Part II — Standards concerning the availability, scope and use of Intellectual Property Rights

Section 5

Article 31
Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent
authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.
Annexure 4:

TRIPS: Extract of the August 30th Decision (2003)

Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (Compulsory Licensing provision)

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s) has made a notification to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed;
(ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and
(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision;

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and
(iii) before shipment begins, the licensee shall post on a website the following information:
- the quantities being supplied to each destination as referred to in indent (i) above; and
- the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify the Council for TRIPS of the grant of the licence, including the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the licence...
has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.
Annexure 5:
Free trade Agreements with Participation of Latin American and Caribbean Countries

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<thead>
<tr>
<th>Country</th>
<th>Negotiated</th>
<th>Under Negotiation</th>
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<tbody>
<tr>
<td>USA with</td>
<td>- 1992: NAFTA</td>
<td>- Free Trade Agreement of the Americas (FTAA); Ecuador; Panama</td>
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<td>- 2003: Chile</td>
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<td>- 2006: Peru; Colombia</td>
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<td>- 2007: Uruguay</td>
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<td>EU with</td>
<td>- 1997: Mexico</td>
<td>- Andean Community****;</td>
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<td></td>
<td>- 2000: ACP Countries -Cotonou Agreement</td>
<td>- Mercosur**;</td>
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<td></td>
<td>- 2002: Chili 2003</td>
<td>- Regional bilateral economic partnership negotiations, built on Cotonou Agreement: Countries of CARIFORUM (Caribbean)</td>
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<tr>
<td>EFTA*** with</td>
<td>- 2000: Mexico</td>
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<td>- 2003: Chile</td>
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<td>Republic of</td>
<td>- 2005: Chile</td>
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<td>Korea with</td>
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<td>Japan with</td>
<td>2005: Mexico</td>
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<td>- 2007: Chile</td>
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<td>Taiwan with</td>
<td>- 2005: Panama</td>
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</tbody>
</table>

*Dates refer in general to the year of signing of the respective agreement
**Argentina, Brazil, Paraguay, Uruguay, Venezuela
***Norway, Lichtenstein, Iceland, Switzerland
****Bolivia, Colombia, Ecuador, Peru

Sources:
www.usestr.gov
http://ec.europa.eu/comtrade/issues/bilateral/index_en.htm
https://secretariatfta.int
www.bilaterals.org
Annexure 6:

Glivec case: Novartis Petition -
W.P.NO.24759 http://www.lawyerscollective.org/files/W.P.NO_24759.doc

Annexure 7:

Glivec Case: CPAA Affidavit -
WP24754 http://www.lawyerscollective.org/content/reply-novartis-24759-final-arguments
Annexure 8:

**Patents on Neem**

PATENTS ON NEEM

1.

**US PATENT NO.**
4,515,785 (Neem Bark Extracts)

**Inventors:** Masaki Shimizu, Todashi Sudo, Tokeo Nomura of Japan

**Assignee:** Terumo Corporation (Japanese Corporation)

**Date:** May 7, 1985

**Date field:** Sep. 13, 1983

The patent is for neem bark extracts which are obtained by subjecting neem bark to an extraction process using solvents such as benzene, toluene, etc. The original solvent is then removed from the solution with another organic solvent. The patent was sought because of the extract's ability to retard growth of sarcoma tumors in mice.

2.

**US PATENT NO.**
4,537,774 (Hot-water Extracts of Neem)

**Inventors:** Masaki Shimizu, Todashi Sudo, Tokeo Nomura of Japan

**Assignee:** Terumo Corporation (Japanese Corporation)

**Date:** August 27, 1985

This patent extension of the above patent. Neem bark is treated with water at a temperature between 0-40 C. and the residue is subject to a purification process by alcohol precipitation. The process yields a higher purity extract.

3.
Larson patented a process for deriving azadirachtin from neem seeds by ethanol extraction. The process also adds an emulsifier to aid in the equitable solution of azadirachtin and neem oil. This process is said to stabilise azadirachtin storage for up to a year period by minimising the breakdown of azadirachtin's biopesticide characteristics.

4.

The patent protects a process for deriving azadirachtin from neem seeds by ethanol extraction. The process also adds an emulsifier to aid in the equitable solution of azadirachtin and neem oil. This process is said to stabilise azadirachtin storage for up to a year period by minimising the breakdown of azadirachtin's biopesticide characteristics.

5.

The patent protects a process for deriving azadirachtin from neem seeds by ethanol extraction. The process also adds an emulsifier to aid in the equitable solution of azadirachtin and neem oil. This process is said to stabilise azadirachtin storage for up to a year period by minimising the breakdown of azadirachtin's biopesticide characteristics.

6.

The patent protects a process for deriving azadirachtin from neem seeds by ethanol extraction. The process also adds an emulsifier to aid in the equitable solution of azadirachtin and neem oil. This process is said to stabilise azadirachtin storage for up to a year period by minimising the breakdown of azadirachtin's biopesticide characteristics.
7.

US PATENT NO. 4,960,791 (Salannin derivation insect control agents)
Inventor: James F Walter
Assignee: W.R. Grace & Co. (US Corp.)
Date: August 7, 1990

8.

US PATENT NO. 5,001,146 (Storage stable azadirachtin formulation)
Inventors: James A. Klocke et. al.
Assignee: Native Plant Institute (NPI)(US Corporation)
Date: October 2, 1990

This is an extension of patent no. 4,556,562 (Larson Patent). The patent protects an improved process over the ethanol-water based formulation of stabilised azadirachtin extract. The patent covers novel pesticide formulations containing azadirachtin as the active ingredient and a non-degrading solvent system to enhance stable storage.

9.

US PATENT NO. 5,001,149 (Azadirachtin derivative insecticides)
Inventor: James A. Klocke et. al.
Assignee: NPI
Date: March 19, 1991

This patent protects on azadirachtin derived insecticide that inhibits and/or prevents part of the moulting process in insect (the ecdysis process). The patent describes derivative of azadirachtin which are more stable than naturally occurring azadirachtin and the subsequent insecticide and antifeedant compounds.

10.

US PATENT NO. 5,009,886 (Dentifrice)
Assignee: Floss Products Corp., Illinois (US Corp.)
This patent protects the development of toothpaste using neem root and branches. The patent covers the paste compound and the process of deriving microfibres from the branches and roots to include in the paste.

11.

US PATENT NO. 5,047,242 (Azadirachtn derivative insecticides)
Inventor: James A. Klocke et. al.
Assignee: NPI
Date: September 10, 1991

This patent builds on NPI's first patent. It covers a newly discovered azadirachtin derivative called 1-Cinnamoyl-meleaniolone and its derivatives. The patent protects the processes used to stabilise and extracts this derivative and compound in which the derivative in introduced.

12.

US PATENT NO. 5,110,591 (Neem oil Emulsifier)
Assignee: PPG, Inc., Pennsylvania(US Corp.)
Date: May 5, 1992

This patent protects an emulsifying agent, polyhydric alcohol and water, that will make azadirachtin stable for storage. The patent seeks particular protection for this neem emulsifying agent because it will be a "safe and acceptable" agent in any azadirachtin biopesticide by meeting approved use status under current US law for food additives.

13.

US PATENT NO. 5,124,49(Storage stable Azadirachtin formulation)
Inventor: Not known
Assignee: W. R. Grace & Co.
Date: 1992

This is another extension of the Grace patent series. The patent protects another novel azadirachtin solvent system for use in creating a stable azadirachtin derived biopesticide.

14.
EUROPEAN PATENT NO 0,436,257 B1 (Method for controlling fungi on plants by the aid of hydrophobic extracted neem oil)
Inventor: James Charles Locke, Hiram Gordon Larew II
Assignee: James Frederic Walter
Date: September 14, 1994.

This patent protects the method of controlling fungi on plants with the aid of a fungicide comprising a hydrophobic solvent extracted neem oil free of azadirachtin, possessing the ability to control the growth of serious fungal pathogens and kills fungal pest at various stages.

Annexure 9:

Other Controversial patents on Neem granted to U.S. Companies:

US patent No 4946681 - granted in 1990 for improving the storage stability of neem seed extracts containing azadirachtin (a naturally occurring substance that belongs to an organic molecule class called tetraortritenoids. Azadirachtin occurs in all parts of the neem tree but the majority of it is concentrated in the neem kernel. It is one of more than 70 limanoids produced by neem). The inventor is named as James F Walter of Ashton, Maryland.

US patent No 5124349 - granted in 1994 for storage of stable insecticidal composition comprising neem seed extract. The major contribution was increasing the shelf-life stability of azadirachtin solution. (Four people are named as the inventors).

Annexure 10:

Recent Indian Patents:

70/Bom/91 - 13.3.91 (171888) - A process for treating (Upgrading) Neem Oil - Hindustan Lever Ltd. Bombay, India

668/Mas/93 - 23.9.93 - A combination of hydroponicum and a spray to improve the survival of tissue cultured plants with specific references to Neem - Dalmia Cantre for Biotechnology

757/Del/93 - 20.7.93 Preparation of edible Neem oil - Rohm and Haas Co.

758/Del/93 - 20.7.93 Stable extract from Neem oil - Rohm and Hass Co.

759/Del/93 - 20.7.93 Preparation of Neem seed extract - Rohm and Haas Co.

1270,1271,1272 & 1273/Del/93 - 12.11.93 A process for preparation of a spermicidal agent from neem oil or extractives - National Research Development Corporation.

7/Mas/94 - 7-1-94 - A method for preparing ayurvedic antivirus compound comprising three oils mainly Neem seed oil - Girivas Vishwanath Seth.

9/Mas/94 - 10-1-94 - Nimbecidine - Vegetable oil including neem oil, enriched with azadirachtin and the same extracted from neem seed and other parts of neem. T. Stanes and Company Ltd.


Annexure 12:

International Human Rights Instruments Addressing Intellectual Property
Universal Declaration of Human Rights (UDHR) (1948)
Article 27:
1. Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.
2. 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.

Annexure 13:

Important International Covenants for the protection of Social and Cultural Rights
International Covenant on Economic, Social and Cultural Rights (ICESCR)
Article 15:
1. The States Parties to the present Covenant recognize the right of everyone:
   (a) To take part in cultural life;
   (b) To enjoy the benefits of scientific progress and its applications;
   (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

Convention on Biological Diversity (CBD)
Article 8(j):
Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;

International Labor Organization Convention No. 169
Article 15 (1):
The rights of the peoples concerned to the natural resources pertaining to their lands shall be specially safeguarded. These rights include the right of these peoples to participate in the use, management and conservation of these resources.

Annexure 14:

International Treaty on Plant Genetic Resources For Food and Agriculture

Article 1 – Objectives
1.1 The objectives of this Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security.
1.2 These objectives will be attained by closely linking this Treaty to the Food and Agriculture Organization of the United Nations and to the Convention on Biological Diversity.

Article 9 – Farmers’ Rights
9.1 The Contracting Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.

9.2 The Contracting Parties agree that the responsibility for realizing Farmers’ Rights, as they relate to plant genetic resources for food and agriculture, rests with national governments. In accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers’ Rights, including:
(a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
(b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and
(c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

9.3 Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate.

Article 10 – Multilateral System of Access and Benefit-sharing

10.1 In their relationships with other States, the Contracting Parties recognize the sovereign rights of States over their own plant genetic resources for food and agriculture, including that the authority to determine access to those resources rests with national governments and is subject to national legislation.

10.2 In the exercise of their sovereign rights, the Contracting Parties agree to establish a multilateral system, which is efficient, effective, and transparent, both to facilitate access to plant genetic resources for food and agriculture, and to share, in a fair and equitable way, the benefits arising from the utilization of these resources, on a complementary and mutually reinforcing basis.