INTERNATIONAL COURT OF JUSTICE

SPECIAL AGREEMENT

BETWEEN KURACA AND SENHAVA FOR SUBMISSION TO THE INTERNATIONAL COURT OF JUSTICE OF THE DIFFERENCES BETWEEN THEM CONCERNING THE VACCINE TRIALS

jointly notified to the Court on 1 December 1999

COUR INTERNATIONALE DE JUSTICE

COMPROMIS

ENTRE KURACA ET SENHAVA VISANT A SOUMETTRE A LA COUR INTERNATIONALE DE JUSTICE LES CONTESTATIONS QUI LES OPPOSENT CONCERNANT LES ÉPREUVES DE VACCIN

notifié conjointement à la Cour le 1 decembre 1999

JOINT NOTIFICATION
ADDRESSED TO THE REGISTRAR OF THE COURT:

The Hague, 1 December 1999

On behalf of Kuraca and Senhava, in accordance with Article 40(1) of the Statute of the International Court of Justice, and subject to the objections to the Court's jurisdiction reserved by the Republic of Senhava, we have the honour to transmit to you an original of the Special Agreement for Submission to the International Court of Justice of the Differences between Kuraca and Senhava Concerning the Vaccine Trials, signed at Washington, D.C., on 10 November 1999.

Ambassador of Kuraca
to the Kingdom of
the Netherlands.

Ambassador of Senhava
to the Kingdom of
the Netherlands.

SPECIAL AGREEMENT
BETWEEN KURACA AND SENHAVA
FOR SUBMISSION TO THE INTERNATIONAL COURT OF JUSTICE
OF THE DIFFERENCES BETWEEN THEM CONCERNING
THE VACCINE TRIALS

Kuraca and *Senhava*,

Considering that differences have arisen between them concerning the vaccine trials and other matters;

Recognizing that the Parties concerned have been unable to settle these differences by negotiation;

Recognizing that the Republic of Senhava objects to the jurisdiction of this Court, and that pursuant to Article 36(6) of its Statute, the Court is empowered to determine whether it has jurisdiction;

Desiring further to define the issues to be submitted to the International Court of Justice in the event that it determines that it is competent to hear the merits of this dispute;

have agreed as follows:

Article 1

The Parties submit the questions contained in the Statement of Facts to the International Court of Justice pursuant to Article 40(1) of the Statute of the Court.

Article 2

(a) The Court is requested to decide in the first instance whether it has jurisdiction to hear and to determine the merits of this case.

(b) In the event that the Court decides that it does have jurisdiction, the Court is requested to decide the Case on the basis of the rules and principles of general international law, as well as any applicable treaties.

(c) The Court is also requested to determine the legal consequences, including the rights and obligations of the Parties, arising from its judgment on the questions

presented in the case.

Article 3

(a) All questions of procedure and rules shall be regulated in accordance with the provisions of the Official Rules of the 2000 Philip C. Jessup International Law Moot Court Competition.

(b) The Parties request the Court to order that the written proceedings should consist of memorials presented by each of the parties not later than 10 January 2000.

Article 4

(a) The Parties shall accept any Judgment of the Court as final and binding upon them and shall execute it in its entirety and in good faith.

(b) Immediately after the transmission of any Judgment, the Parties shall enter into negotiations on the modalities for its execution.

In witness whereof, the undersigned, being duly authorized to do so, have signed the present Special Agreement and have affixed thereto their respective seals of office.

Done in Washington, D.C., this 10th day of November 1999, in triplicate in the English language.

Ambassador of Kuraca
to the Kingdom of
the Netherlands.

Ambassador of Senhava
to the Kingdom of
the Netherlands.

2000 Philip C. Jessup International Law Moot Court Competition

** *Compromis* **

The State of Kuraca v. The Republic of Senhava

THE CASE CONCERNING THE VACCINE TRIALS

1 The State of Kuraca is a large, industrial country with a developed economy, an extensive system of public and private higher education, and one of the world's leading biotechnology industries. With a gross domestic product of U.S. $70 billion, Kuraca is a foreign assistance donor country.

2 The Republic of Senhava is a developing country, a former colony, and a recipient of foreign assistance. Its gross domestic product in 1997 was U.S. $1 billion. It is an archipelagic state, thousands of miles from Kuraca. Senhava's population of approximately three million includes many different ethnic and language groups, several of which live in almost total isolation. Article XII of its Constitution defers to aboriginal law "where appropriate." Senhava's economy relies on agriculture, fishing, minerals extraction, biological resources, and foreign tourism, as well as foreign assistance.

3 Kuraca and Senhava have always maintained normal trading relations with each other. Both are members of the United Nations and the World Health Organization, and are parties to the Vienna Convention on the Law of Treaties, the Convention on the Rights of the Child, the Convention on the Elimination of All Forms of Discrimination Against Women, and the Convention against Torture and other Cruel, Inhuman or Degrading Treatment. Both have signed the Convention on Human Rights and Biomedicine, although their ratifications are pending. Senhava is a party to the International Covenant on Economic, Social and Cultural Rights; Kuraca has signed but has not deposited an instrument of ratification. Kuraca is a party to the International Covenant on Civil and Political Rights; Senhava has not signed it. They are also parties to a bilateral Treaty of

Amity and Commerce. Neither is a party to any other treaty relevant to this case.

4 Multivector Hepatic Viral Disease (MHVD) is a disabling and deadly contagious disease. There is no known cure.

5 The MHVD virus attacks the human liver, disrupts the digestive system, and nearly invariably leads to death within three years. Scientists have found that victims may carry the virus for a year or longer without suffering serious symptoms, and so may be unaware that they have been infected and are themselves infectious. The MHVD virus can be carried and transmitted by any of several vectors, including air, water, human bodily fluids, and several kinds of flies and mosquitoes. Accordingly, the disease spreads quickly through dirty water, inadequate sanitation or pest control, or unprotected intimate human contact.

6 MHVD was unknown to public health authorities until 1988, when its characteristic symptoms were first reported. The World Health Organization (WHO) declared the existence of a worldwide MHVD pandemic in 1996. Biomedical laboratories, public health agencies, and pharmaceutical companies in many parts of the world have been working to understand the disease and to develop means to prevent its spread. The MHVD virus has been identified and described in general biochemical terms, but no vaccine has yet been shown to be generally effective against it. A WHO Special Panel on MHVD reported in 1997 that clean water, sanitation, pest control, and avoidance of unsafe sex practices are the only reliable defenses currently available against the disease. The Panel urged scientists to develop a vaccine against MHVD.

7 Over 20% of Senhava's population is reported to be infected with MHVD. The disease has just begun to appear in Kuraca, with a few hundred cases reported to date.

8 Numerous Kuracan biomedical and pharmaceutical companies have been trying to develop an MHVD vaccine, which, considering the pervasiveness of the deadly disease, would be extraordinarily profitable. The two leading Kuracan companies in the race for a vaccine are Megaceutical Corporation and K-Biomed Corp.

9 Megaceutical Corporation is a multinational pharmaceutical company. It is incorporated and has its headquarters and principal laboratories and drug processing facilities in Kuraca. Megaceutical is the 49% owner of a subsidiary, Megaceutical-Senhava, Ltd., which is incorporated under the laws of Senhava. Megaceutical-Senhava has its headquarters, with small-scale laboratory and production facilities, in Senhava's capital city of Sencap . All of its operations are in Senhava.

10 Under Senhavan law, foreign corporations may operate only through entities incorporated in Senhava, with a majority of their equity ownership to be in the hands of Senhavans. There is no prohibition against maintaining foreign control through such devices as shareholders' agreements. Megaceutical-Senhava has been effectively controlled by its Kuracan parent through just such a device.

11 As it does for all foreign subsidiaries of Kuracan drug companies, the Kuracan Medical Product Regulation Agency contracted with a private, independent consultant to provide on-site reporting and advisory services with respect to Megaceutical-Senhava. In this case the consultant was George Smith, a citizen of the Republic of Nemin, who was stationed at Sencap. His job, performed with the consent of all concerned, was to report developments of potential importance to the Kuracan government regulatory process. Nemin is not a party to the compulsory jurisdiction of the Court, and has declined to intervene in this case or to participate otherwise in these proceedings.

12 Since 1998, Megaceutical Corporation has reported great progress in its efforts to develop a vaccine against MHVD. It conducted several small-scale tests of various formulas on people in Senhava, through Megaceutical-Senhava, Ltd. Megaceutical's MHVD vaccine project was headed by Maria Yukawa-Lopez, M.D., Ph.D., of the Biomedical Faculty of Kuraca Capital University. Dr. Yukawa-Lopez, who is licensed to practice in both Kuraca and Senhava, is the world's leading expert on MHVD. Kuraca Capital University is a world-renowned private research institution.

13 Working in collaboration at the Megaceutical-Senhava facility from January through March 1999, Megaceutical and Dr. Yukawa-Lopez conducted Phase I (toxicity) research on Investigational MHVD Vaccine 078b. The research results, based on studies of 30 apparently similar MHV-positive Senhavan volunteers, showed substantial improvement and no ill effects in 28. The other two patients developed an unusual kind of disabling asthma. Megaceutical and Dr. Yukawa-Lopez decided to accelerate the vaccine research, with a variant, 078c, thought to be safer, and planned to proceed as soon as practicable with Phase II (efficacy and dose-response ratio studies) and then Phase III (clinical trials in large populations).

14 Megaceutical announced that Phase II and Phase III trials would be conducted in Senhava by Megaceutical-Senhava, Ltd., for reasons of cost, as well as because of the easy availability of Senhavan test subjects and the prevalence of the disease in Senhava.

15 In June, 1999, Megaceutical-Senhava, Ltd. sought and received Senhavan Government permission to conduct Phase II and Phase III trials of Investigational MHVD Vaccine 078c as soon as possible at Megaceutical-Senhava's expense. In return, Megaceutical made an advance payment of the equivalent of Euros 2,000,000 to the Senhavan Health Ministry. The Ministry agreed to permit the trials where they would reach persons believed to be at the greatest risk: in orphanages, prisons, maternal and child health clinics, and outer island villages. Senhavan national police were commissioned to provide transportation to the Megaceutical-Senhava personnel supervising the vaccine trials, which were scheduled to commence in September 1999.

16 Neither Megaceutical nor its subsidiary sought or received any Kuracan Government funding in the vaccine development project. Dr. Yukawa-Lopez's salary and expenses were paid by Kuraca Capital University, and out of funds from private donors, foundations, industry contracts, and international governmental and non-governmental organizations. Megaceutical committed to paying an honorarium of U.S. $300,000 annually to Dr. Yukawa-

Lopez for her consultation on the project.

17 Kuracan physicians are licensed by the Kuracan Government Medical Board, which reviews complaints and may suspend or revoke a doctor's license on grounds, *inter alia*, of unethical conduct. The Medical Board bases its research ethics decisions on the Nuremberg Code[1] and the World Medical Assembly Declaration of Helsinki and its successor instruments.[2]

18 In Senhava, physicians are licensed by the Ministry of Health, which oversees all medical practice in the country. The Ministry mandates no specific professional ethical standard except for "the Hippocratic Oath," which is not otherwise defined.

19 Pursuant to Kuracan law,[3] in July 1999 Dr. Yukawa-Lopez submitted a copy of Megaceutical-Senhava's research protocol to the Kuraca Capital University Biomedical Ethics Review Board, among whose seven distinguished members was Dr. Francis Zeaklin, the President of K-Biomed Corp.

20 The research protocol designed by Dr. Yukawa-Lopez noted the kinds of populations that would be tested, and included a copy of the following "Informed Consent" form:

> CONSENT TO EXPERIMENTAL VACCINATION
>
> I, [name], hereby agree voluntarily to the injection of myself and/or [name], for whom I am legally responsible, with an experimental vaccine in order to help Megaceutical-Senhava, Ltd. and the Senhavan Ministry of Health to determine whether the vaccine is safe and effective in preventing Multivector Hepatic Viral Disease, and the effects of the vaccine at various doses. I understand that variants of this vaccine have already been tested, and that no

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[1] Excerpted in Annex A to the Compromis.

[2] Excerpted in Annex B to the Compromis.

[3] Kuracan laws and administrative regulations governing biomedical research on human beings include National Health Law 1006 and its implementing Regulations. Relevant portions are excerpted in Annex C to the Compromis.

ill effects have been found in 28 of the 30 human subjects. I understand that the other two persons in that test developed unexplained, debilitating asthma.

[signature] [date]

NOTE TO PERSON OBTAINING CONSENT: If the person from whom consent is sought is unable to read this form, then you must read it for him or her, and if necessary have it translated into that person's native language for consent to be considered valid.

21 On August 1, 1999, the Kuraca Capital University Biomedical Ethics Review Board announced its conclusion that, notwithstanding the seriousness of the MHVD problem, the Senhavan trials as proposed would not offer human subjects sufficient protection. Among the problems noted were the vulnerability of the proposed study populations, the small likelihood that any "voluntary consent" would be fully informed, the use of placebos in areas where there was active disease, and the absence of an indigenous credible and reliable biomedical ethics review function in Senhava. In light of its conclusions, the Board warned that Kuraca Capital University faculty and physicians who worked on the proposed vaccine trials in Senhava could risk revocation of their Kuracan medical licenses.

22 Meanwhile, George Smith, the independent consultant stationed with Megaceutical-Senhava, learned about the proposed study protocol and consent form, sent copies of those documents to the Kuracan Medical Product Regulation Agency, and recommended that the proposed clinical trials not be undertaken.

23 Having reviewed Smith's recommendation and the Biomedical Ethics Review Board's determination, the Administrator of the Kuracan Medical Product Regulation Agency called in the President of Megaceutical Corporation. Citing "humanitarian" grounds, she delivered a warning that the MHVD vaccine project had to stop, lest human rights be violated wholesale. Otherwise, she said, the Agency and other Kuracan Government bodies would not readily grant approval for drugs and biologics the company proposed to supply to Megaceutical-Senhava or to anyone else for use in MHVD vaccine development. The

conversation, reported in the industry newsletter "The Purple Sheet," was confirmed by the Agency, although further comment was declined.

24 Citing these developments, and deferring to her University's Ethics Review Board, Dr. Yukawa-Lopez immediately resigned from the MHVD vaccine project. Megaceutical declared that she had been indispensable to the project and in any event was indispensable to the company. In light of Dr. Yukawa-Lopez's withdrawal and the warning of the Medical Product Regulation Agency Administrator, Megaceutical directed its Senhavan subsidiary to terminate all MHVD vaccine activity. Thus, on August 10, 1999, Megaceutical-Senhava, Ltd. notified the Senhavan Ministry of Health that it had halted work on the project.

25 On August 12, the Senhavan National Police arrested George Smith, charging that in providing vaccine development documents to the Government of Kuraca he interfered with Senhavan public health measures. He continues to be held without bail, and no specific formal charges against him have been presented. No trial date has been scheduled.

26 In a diplomatic note dated August 15, 1999, the Senhavan Ministry of Foreign Affairs notified Kuraca's ambassador that the cessation of the MHVD vaccine project in Senhava by order of an agency of the Kuracan Government constituted an unacceptable extraterritorial application of Kuracan health legislation. The note further stated that the actions of the Administrator of the Medical Product Regulation Agency amounted to "a wealthy country's self-indulgence" and "cultural imperialism." The diplomatic note warned that, unless the Agency withdrew its order, Senhava would compel Megaceutical-Senhava to go ahead with the vaccine project, with or without the consent of Kuraca.

27 The Kuracan Ministry of Foreign Affairs responded by notifying Senhava's ambassador orally and in writing that Senhava was violating the rights of its one of its government contractors, George Smith, and had interfered with Kuraca's right to regulate the activities of its own corporations. Kuraca demanded that George Smith be freed.

28 The Senhavan Ministry of Foreign Affairs replied that the jailing of George Smith was purely a domestic matter, that the order of an agency of the Kuracan Government directing cessation of the MHVD vaccine project constituted an unacceptable extraterritorial application of Kuracan health legislation, and that Kuraca was violating Senhava's sovereign rights as well as international human rights law.

29 Kuraca's Minister of Foreign Affairs replied by diplomatic note that (1) Kuraca had a right to protect the welfare of its contractors engaged in lawful activity overseas; (2) the Kuracan law in question implements international obligations; (3) the Government has done nothing to interfere with anyone's sovereignty; and (4) Senhava's other accusations were too speculative to address.

30 Senhava announced publicly that it would arrange to go ahead with the vaccine project on its own. Using the police powers expressly provided to it by legislation, on September 16, 1999, Senhava's Ministry of Health declared an MHVD public health emergency, and ordered Megaceutical-Senhava, Ltd. to proceed with the vaccine project or face substantial fines and imprisonment of its officers, many of whom are citizens of Kuraca and other States.

31 Megaceutical, through its control of Megaceutical-Senhava, Ltd., continued to refuse to implement the Senhava vaccine project, notwithstanding the Senhavan Government's order to proceed. On September 21, Senhava shut down the offices of Megaceutical-Senhava, Ltd., and began to levy fines against it at a rate of U.S. $100,000 per day.

32 Senhava's Prime Minister called the Kuracan ambassador to his office. He delivered a written message stating that (1) Kuraca's termination of the vaccine project was unacceptable under the rules of international law, and all the moreso in "a society in which self-sacrifice for the ultimate good of the many was essential to social justice"; and (2) the Kuracan Government's use of "muscle" against Megaceutical and its Senhavan subsidiary was an inexcusable violation of Senhava's sovereign rights to govern its own commerce and

to protect its own public health.

33 Each country recalled its ambassador to the other, and the press in both nations reported, according to "well-placed sources," that a break in diplomatic relations was under active consideration in both capitals. In late October, 1999, an ad hoc group of 12 Nobel Peace laureates met with the presidents of the two countries, separately, and proposed to them that the dispute be referred to the International Court of Justice. "In order not to risk rupturing the historic good relations between their nations, with all of the consequences that might entail," the presidents stated in a joint press release that they would agree to do so, subject to Senhava's reservation of its objection to the jurisdiction of the Court.

34 Both Senhava and Kuraca have accepted the Court's compulsory jurisdiction. Kuraca's notice of acceptance, filed in 1946, is attached as Annex D; Senhava's, dated 1989, is at Annex E. Senhava maintains that the Court is without jurisdiction over the subject matter of this case, because: (1) the dispute exclusively concerns matters which are essentially within the domestic jurisdiction of Senhava as determined by Senhava, and (2) it arises under a multilateral treaty and some affected states are not parties to this case.

35 Kuraca now files this case before the International Court. Notwithstanding Senhava's position that the Court is without jurisdiction over this matter, it has agreed to the submission of this jointly-prepared Compromis to expedite proceedings.

ISSUES/CLAIMS

Kuraca requests that the International Court of Justice:

1) **assert** jurisdiction over the subject matter of this case;

2) **order** the immediate release of George Smith and the dropping of all charges against him;

3) **declare** that Kuraca, in promulgating and enforcing its laws and regulations governing foreign as well as domestic use of its Government's funds in respect

of the rights of human subjects in prospective vaccine trials, complied with its obligations under international law, notwithstanding any direct or indirect consequences on public health and commerce within Senhava, and in no way violated Senhava's sovereign rights;

4) **declare** that Kuraca did not violate international law when its Government official advised Megaceutical that human rights concerns warranted the company's action to halt its contemplated vaccine work; and

5) **declare** that Kuraca incurred no liability to Senhava in this matter.

Senhava requests that the International Court of Justice:

1) **decline** jurisdiction, inasmuch as the issues here are purely internal to Senhava; or, in the alternative:

2) **declare** that Kuraca violated international law by promulgating laws and regulations to operate extraterritorially in derogation of Senhava's sovereign rights to protect Senhavan public health and to govern internal Senhavan commerce;

3) **order** that Kuraca promptly remove all direct and indirect Kuracan legal and governmental obstacles to the conduct of MHVD vaccine trials in Senhava as proposed in the research protocol that led to this controversy;

4) in the alternative, **order** that Kuraca promptly remove all direct and indirect Kuracan legal and governmental obstacles to development and trials of MHVD vaccine by Megaceutical-Senhava, Ltd., a Senhavan corporation; and

5) in the further alternative, **award** monetary damages to compensate Senhava for public health expenses reasonably incurred because of failure to conduct vaccine trials in Senhava, including a percentage of the cost of treating future victims of the MHVD epidemic.

ANNEX A
EXCERPT FROM
THE NUREMBERG CODE (1947)

[From the judgment, in Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10 (1949)]:

. . . All agree . . . that certain basic principles must be observed in order to satisfy moral, ethical, and legal concepts:

1. The voluntary consent of the human subject is absolutely essential.

2. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

ANNEX B
EXCERPTS FROM
THE WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

Recommendations guiding physicians in biomedical research involving human subjects, adopted by the 18th World Medical Assembly (Helsinki, Finland, 1964), amended by the 29th (Tokyo, Japan, 1975), the 35th (Venice, Italy, 1983), the 41st (Hong Kong, 1989), and the 48th (Somerset, South Africa, 1996).

I. BASIC PRINCIPLES

* * * * *

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment, and guidance, to a specially-appointed committee independent of the investigator and the sponsor, provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

* * * * *

5. . . . Concern for the interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. . . .

* * * * *

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.

10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may

consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation. Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

* * * * *

II. MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE (Clinical Research)

* * * * *

3. In any medical study, every patient – including those of a control group, if any – should be assured of the best proven diagnostic and therapeutic method. This does not exclude the use of inert placebo in studies where no proven diagnostic or therapeutic method exists.

* * * * *

III. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (Non-Clinical Biomedical Research)

* * * * *

3. The investigator or the investigating team should discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

ANNEX C
EXCERPTS FROM:

I. KURACAN NATIONAL HEALTH LAW 1006.

Section 6. BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS:

(a) *FINDINGS*: THE NATIONAL LEGISLATURE

(1) RECOGNIZES Kuraca's continuing national and international obligations for the protection of the health and rights of all people subject to the actions of the Kuracan Government and its agencies;

(2) ACKNOWLEDGES the continuing obligations of Kuracan biomedical researchers, medical practitioners, health authorities, and the Government under international law and the customs of civilized nations, such law and customs including but not limited to biomedical ethical considerations expressed in the Nuremberg Code, the Helsinki Declaration, and successor and other instruments that have established international standards of care for the protection of prospective and actual human subjects of biomedical research;

(3) FURTHER ACKNOWLEDGES that all physicians are bound by professional ethical obligations under the aforesaid law and customs of civilized nations, notwithstanding the presence or absence of specific statutory provisions to that effect; and

(4) EXPRESSLY INTENDS that the principles enacted or acknowledged herein are binding notwithstanding any adverse economic effect that they may have upon persons (whether natural or juridical) subject to Kuracan jurisdiction.

(b) *DELEGATION AND JUDICIAL REVIEW*:

The Minister of Health shall promulgate regulations to effect the purposes of this Law, and those Regulations, as well as Government actions thereunder, shall be subject to judicial review.

(c) *FUNDING*:

No Kuracan Government funds shall be expended contrary to the purposes of this Law.

(d) *PENALTIES FOR VIOLATION:*

Individuals and institutions found by the Minister of Health or any competent court to be in violation of this Law, or the Regulations lawfully promulgated hereunder, shall be ineligible for Government funding, whether direct or indirect and whether by contract, grant, or otherwise, for five years, shall forfeit all relevant professional licenses for five years, and shall be ineligible during those five years to engage under anyone else's license in professional medical or biomedical research, administration, teaching, or care.

(e) *BIOMEDICAL ETHICS REVIEW BOARDS:*

The Minister of Health and each institutional recipient of Government funds for research or for medical care shall establish a Biomedical Ethics Review Board, in order to protect the rights of the human subjects of such research. Each Board shall consist of at least seven members, as follows: two scientists; two physicians; one lawyer; one biomedical ethicist or bioethicist; and one other person. No more than two members may be affiliated in any way with the institution itself, and no member may be from the sponsoring government agency. Members may serve no more than two consecutive two-year terms.

(f) *BIOMEDICAL ETHICS REVIEWS:*

(1) No agency, institution, or person subject to this Law may undertake medical experimentation upon human beings unless the appropriate Biomedical Ethics Review Board has reviewed such work, and has approved a protocol that requires at least the following: that information be given to each prospective subject as to the risks and benefits of participation in the study; that no subject participate except with that person's voluntary, informed consent; that any subject may withdraw from the study at any time without penalty; and provision for the best available treatment for each human subject in connection with the disease or condition under study.

(2) In the case of children of disabled individuals unable voluntarily and knowingly to give or withhold consent, such consent may be given by a parent or lawfully designated guardian unaffiliated with any sponsor or performer of the study. For good cause

shown, the head of the responsible agency or institution may overrule a Biomedical Ethics Review Board's approval of a proposed research protocol but under no circumstances may a Biomedical Ethics Review Board's disapproval be overruled.

(g) *PRIVACY*:

Records kept in studies subject to this Law will be kept in such a way as to preclude the disclosure of the identities of human subjects by researchers and affiliated care givers to any person or agency except at the voluntary request of the subject.

(h) *SUPERVISION BY PHYSICIANS*:

A duly licensed physician shall supervise any research involving human subjects.

II. KURACAN NATIONAL HEALTH REGULATIONS:

Section 1006(r). *INTERNATIONAL COLLABORATION IN BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS*:

No natural or juridical person subject to National Health Law 1006 ("the Law") may assist or collaborate with any foreign natural or juridical person or government or international agency in any biomedical research involving human subjects unless the proposed research protocol is approved in advance by the cognizant Kuracan Biomedical Ethics Review Board(s) or by a comparable host country ethics review board as satisfying biomedical ethical standards embodied in international law and custom, including but not limited to those listed in § b(a)(2) of the Law.

1006(s). *CLINICAL TRIALS*:

These Regulations apply not only to laboratory, in-hospital, and in-clinic studies, but also to field tests and clinical trials of experimental drugs, experimental vaccines, and other experimental biologics, whether such trials are Phase I (toxicity and biological action), Phase II (dose-response studies and other testing in relatively small groups of patients to ascertain possible effectiveness), or Phase III (large-scale trials, particularly those comparing the substance being tested with existing methods of prevention or treatment).

ANNEX D

I hereby declare that the State of Kuraca recognizes, in accordance with Article 36, paragraph 2, of the Statute of the International Court of Justice, as compulsory ipso facto and without special agreement, in relation to any other State accepting the same obligation, the jurisdiction of the International Court of Justice in all disputes arising or which may arise after the signature of the present Declaration. This declaration shall not apply to:

(a) disputes with regard to matters which are essentially within the domestic jurisdiction of Kuraca as determined by Kuraca; and

(b) disputes arising under a multilateral treaty, unless (1) all parties to the treaty affected by the decision are also parties to the case before the Court, or (2) Kuraca specially agrees to jurisdiction.

August 21, 1946

[Signed] Rafael Alvaro
President of the State of Kuraca

ANNEX E

I hereby declare that the Republic of Senhava recognizes, in accordance with Article 36, paragraph 2, of the Statute of the International Court of Justice, as compulsory ipso facto and without special agreement, in relation to any other State accepting the same obligation, the jurisdiction of the International Court of Justice in all disputes arising or which may arise after the signature of the present Declaration.

March 15, 1989

[Signed] Nena Kabua
President of the Republic of Senhava

2000 PHILIP C. JESSUP
INTERNATIONAL LAW MOOT COURT COMPETITION

CORRECTIONS AND CLARIFICATIONS TO THE COMPROMIS

The following corrections and clarifications have been agreed by the parties in response to many requests of Jessup Competitors, and the Compromis should be considered amended accordingly. In offering these, the parties remind all participants of the following:

a. The Compromis is, in essence, a stipulation of facts. Its words have been carefully chosen, and are the results of extensive negotiation. The parties decline to "clarify" the facts by providing conclusory characterizations, *e.g.* of the nature of their political systems. And, obviously, the parties will not stipulate as to what arguments are acceptable or unacceptable.

b. The response to any request for a clarification **not** addressed in the following paragraphs is already included in the Compromis or has been considered inappropriate or immaterial, or the parties were unable to reach agreement on a mutually acceptable answer.

c. Except to the extent that corrections and clarifications are set out below, participants are to assume that the Compromis is accurate and complete in all respects.

d. Participants should assume that any signature to or ratification of a treaty is without reservation unless the contrary is indicated.

Corrections

1. The "Convention on Human Rights and Biomedicine" referenced in ¶ 3 of the Compromis is the Convention adopted by the Council of Europe at Oviedo, Spain, on 4 April 1997. Both parties have signed it pursuant to Article 33.1, as both qualify as "non-Member States [of the Council of Europe] which have participated in its drafting."

2. Paragraph 34(2) should begin "the dispute arises . . . "

3. In Senhava's prayer for relief, paragraph (1) should read, "decline jurisdiction, inasmuch as the issues here are purely internal to Senhava, and also because Nemin, a state potentially affected by any decision herein, is not a party to the case."

4. In Kuraca's prayer for relief, paragraph (5) should read: order Senhava to rescind the order closing the offices of Megaceutical-Senhava, revoke the fines assessed against the company, and return the advance payment to the Ministry of Health of 2 million Euros.

5. In Annex C, part I, the first line of section 6(f)(2) of Law 1006 should begin: "In the case of children **or** [not **of**] disabled individuals . . . "

6. In Annex C, part II, section 1006(r) of the Regulation should refer to Section **6**(a)(2), not **b**(a)(2), of the Law.

Clarifications

1. Dr. Yukawa-Lopez is, and at all relevant times has been, a citizen of Kuraca.

2. Although the Compromis states that Senhava is a former colony, it was never a colony of Kuraca. Senhava gained its independence, and was admitted to the United Nations, in 1961. Kuraca and Senhava have had normal diplomatic, consular, and trading relations since early 1962.

3. Kuraca Capital University receives Kuracan Government money directly, as through the underwriting of specific programs and indirectly, such as through Government financial aid to students.

4. The 51% of the equity in Megaceutical-Senhava that is not owned by Megaceutical Corporation is held by a large number of private stockholders of Senhavan nationality.

5. Decisions of the Kuraca Capital University Biomedical Ethics Review Board are by majority vote. The vote on Megaceutical's proposed MHVD vaccine trials in Senhava was three in favor, four against. Individual members' votes are not attributed to them in the Board's records.

6. Megaceutical Corporation is acknowledged to be the furthest advanced of any company in the world in the race to develop a successful MHVD vaccine. The company has never publicly announced plans to conduct tests on human subjects in any other country.

7. As used in the Compromis, the word "vaccine" means a biological substance for the prevention, amelioration, or treatment of an infectious disease. An experimental vaccine is one whose doses and responses have yet to be determined.

8. Nemin is a party to all of the multilateral treaties and is a member of all of the international organizations listed in ¶ 3 of the Compromis.

9. George Smith has been given no bill of particulars citing the crimes with which he is charged.

10. The Treaty of Amity and Commerce between Kuraca and Senhava reads as follows: Natural and juridical persons that are nationals of either Party shall be permitted to carry on trade, and to perform any act incident to or necessary for the conduct of trade, upon the same terms and conditions as similarly situated nationals of the other party, submitting themselves to all laws and regulations applicable to them.