

705A

IN THE INTERNATIONAL COURT OF JUSTICE
AT THE PEACE PALACE
THE HAGUE, THE NETHERLANDS 2000

**THE
CASE CONCERNING
THE
VACCINE TRIALS**

KURACA
(Applicant)

V.

SENHAVA
(Respondent)

MEMORIAL FOR THE APPLICANT

Case Concerning the Vaccine Trials

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Statement of Jurisdiction

Kuraca and Senhava have submitted this dispute by Special Agreement to the International Court of Justice. Both Kuraca and Senhava have accepted the jurisdiction of the International Court of Justice pursuant to Article 36, paragraph 2 of the Statute of the International Court of Justice. However, jurisdiction in this dispute is contested. In its declaration pursuant to Article 36, paragraph 2, Kuraca has reserved its acceptance of jurisdiction with respect 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.”

Statement of Facts

Kuraca is a large, industrial country with one of the world's leading biotechnology industries. Medical research by Kuracan nationals is regulated by Kuracan Health Law 1006, which implements international law including ethical standards for medical research in accordance with the Helsinki Declaration and Nuremberg principles.

Senhava is a developing nation, with a diverse ethnic population, and an economy dependent on natural resources and foreign aid. Senhavan law requires foreign companies to incorporate locally and have majority Senhavan equity ownership. Megaceutical is a multinational pharmaceutical company based in Kuraca, and controls a subsidiary in Senhava, Megaceutical-Senhava, in which it has a 49% shareholding. There are no other major shareholders.

Megaceutical has led the development of a Multivector Hepatic Viral Disease ("M.H.V.D.") vaccine since 1998, and has tested vaccines in Senhava through Megaceutical-Senhava. Pursuant to Kuracan law, Megaceutical-Senhava's operations were monitored by George Smith, a citizen of Nemin, reporting to the Kuracan Medical Product Regulation Agency ("Agency"). Dr. Yukawa-Lopez, a Kuracan physician at Kuraca Capital University, and the world's leading M.H.V.D. expert, headed Megaceutical's M.H.V.D. project in Senhava. Phase I testing of an investigational M.H.V.D. vaccine 078b showed substantial improvement in many M.H.V.D.-infected subjects, but 2 of 30 developed an unusual kind of disabling asthma.

In June 1999, Megaceutical-Senhava received approval from Senhava to undertake Phase II and III trials of a variant vaccine 078c on Senhavan subjects, and arranged an advance payment of Euros 2,000,000 to the government. The trial was to target orphanages,

prisons, maternal and child health clinics and outer island villages. Senhavan police were to Megaceutical-Senhava's personnel during the trial.

In July, pursuant to Kuracan law, Dr. Yukawa-Lopez submitted the trial protocol to the Kuraca Capital University Biomedical Ethics Review Board ("Board"). The Board determined the trial would not sufficiently protect the subjects. It criticised the vulnerability of subjects, the small likelihood that any consent would be voluntary, and the absence of reliable ethical review within Senhava. It warned that physicians of the project risked losing their licences. George Smith also reported to the Agency that the protocol was inadequate.

The Agency's Administrator, having reports from the Board and Smith warned the President of Megaceutical the trial not go ahead, lest human rights be violated. She also advised Kuracan regulatory authorities may not grant the licences required for necessary biologic supplies should Megaceutical proceed. Yukawa-Lopez, deferring to the Board, resigned. Megaceutical, because of the resignation and the Agency's advice decided to halt the trial. Megaceutical-Senhava duly notified Senhava on August 10.

On August 12, Senhava detained George Smith, without granting bail, making formal charges, or setting a trial date.

On August 15, Senhava warned Kuraca that unless the trial was allowed to proceed it would compel Megaceutical-Senhava to do so. It claimed the cessation of the trial following recommendations of Kuracan authorities constituted an unacceptable application of Kuracan health laws. Kuraca responded that George Smith's detention was a violation of his human rights, and compulsion of the company would interfere with Kuraca's rightful regulation of its nationals. Senhava replied that George Smith's arrest was a domestic matter, and otherwise repeated its previous claims. Kuraca responded that it had a right to protect George

Smith, and that its laws implemented international human rights obligations which in no way breach Senhava's sovereignty.

Senhava announced it would proceed with the trial. Using police powers it declared a public emergency, and ordered Megaceutical-Senhava to perform the trial or face daily fines and imprisonment of its officers, many of them Kuracan. Megaceutical, through Megaceutical-Senhava, refused to bow to pressure.

On September 21, Senhava shut down Megaceutical-Senhava's offices, and levied fines at US\$100,000 per day. Each State recalled its ambassador, and a break in relations seemed imminent. In October, after meeting with an ad hoc group of Nobel Peace Laureates, the States jointly referred the dispute to the I.C.J.

Both States are members of the United Nations and the World Health Organization., and 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, Convention against Torture and other Cruel, Inhuman or Degrading Treatment, and a bilateral Treaty of Amity and Commerce. This dispute appears before the Court by Special Agreement of 10 November 1999. Senhava disputes jurisdiction as (1) the dispute is essentially within Senhava's domestic jurisdiction as determined by Senhava; and (2) it arises under a multilateral treaty and some affected states are not parties.

Questions Presented

1. Whether the Court has jurisdiction to hear this matter.
2. Whether Kuraca has standing to bring the claim.
3. Whether all indispensable States are parties to the case.
4. Whether George Smith has been arbitrarily detained in violation of international law.
5. Whether Kuracan National Health Law 1006 is valid at international law.
6. Whether Kuraca has breached international law by acting to halt the M.H.V.D. vaccine trials.
7. Whether Senhava has breached the Treaty of Amity and Commerce and obligations of national treatment.
8. Whether Senhava must refund Megaceutical's advance payment of 2 million Euros.
9. Whether the cost to Senhava of treating M.H.V.D. victims is compensable loss.

Summary of Pleadings

This Court possesses jurisdiction. This Court is invested with compulsory jurisdiction by virtue of the Declarations made by Kuraca and Senhava under Article 36(2) of the Statute of the International Court of Justice (“Statute”). Kuraca’s declaration under Article 36(2) contains a self-judging domestic jurisdiction reservation and a multilateral treaty reservation. Neither of these reservations limit the jurisdiction of the Court in this dispute.

Kuraca’s self-judging reservation, invoked by Senhava, is valid, but subject to an implied requirement of good faith. Senhava’s determination that the dispute concerns matters essentially within its domestic jurisdiction is made in bad faith. Senhava is estopped from denying that international law governs the dispute. If the self-judging reservation is not subject to a requirement of good faith, it is inconsistent with Article 36(6) of the Statute and the Court’s power to determine its own jurisdiction has priority. Alternatively, the reservation is invalid and severable. Additionally, the Court’s jurisdiction is not precluded by the multilateral treaty reservation. This reservation cannot be invoked reciprocally because it is a reservation *ratione personae*. If it applies, all affected states with a legal interest are already parties to the case. Further, because the dispute is governed by customary international law, the absence of affected parties is not a bar to jurisdiction. The Court also has jurisdiction under the bilateral Treaty of Amity and Commerce.

Kuraca has standing to bring this claim because under international law, Megaceutical-Senhava (“M.-S.”) is a national of Kuraca. Kuraca has standing in respect of George Smith because he is an effective national of Kuraca, and is an agent of the Kuracan State. Further, Senhava’s detention of Smith violates international human rights law, conferring standing on

Kuraca under the *erga omnes* principle. Nemin is not an indispensable party to the case, as its interests do not constitute the very subject matter for decision.

George Smith has been arbitrarily detained in violation of customary international law. Senhava has not provided a list of charges, has not fixed a trial date and has not judicially reviewed his detention. These are the well-accepted indices of arbitrary detention.

Kuracan Health Law 1006 codifies international human rights law concerning informed consent and is valid. It does not breach Senhavan sovereignty because it implements universally enforceable international law principles governing human experimentation. The Law implements the peremptory norms of non-discrimination and the prohibition on cruel and inhuman treatment. The Law is also a valid exercise of nationality jurisdiction and legitimately regulates Kuraca's pharmaceutical industry.

Kuraca's conduct has forestalled large-scale human rights violations by Senhava. Kuraca has not violated any purported right to health, as this notion has not crystallised in customary international law. If any right exists, Kuraca has fulfilled its obligations by balancing obligations to control disease with protection of the right to informed consent.

Senhava has breached the bilateral Treaty of Amity and Commerce and customary international law by discriminatorily injuring the property and commerce of Kuracan nationals.

Senhava must make reparations for its violations of international law. This Court can order the release of persons detained in violation of international law. Senhava must end the closure of M.-S. and revoke the fines imposed. Kuraca is not liable to pay damages for Senhava's public health costs, as the loss is speculative and contingent.

Written Pleadings

I. THE COURT HAS JURISDICTION

A. The Court's compulsory jurisdiction is not precluded by the self-judging reservation

Both Senhava and Kuraca have accepted the compulsory jurisdiction of the Court by lodging a declaration under Article 36(2) of the Statute of the Court. Kuraca's declaration contains a self-judging reservation, which excludes from the Court's jurisdiction matters essentially within the domestic jurisdiction of Kuraca as determined by Kuraca. The doctrine of reciprocity allows Senhava to invoke reservations relating to the scope and substance of Kuraca's declaration, and the Court must base itself on the narrower grant of jurisdiction.¹ Nevertheless, the Court has jurisdiction over this dispute because this reservation does not apply.

1. Kuraca's self-judging reservation is valid, but does not apply in this case

a) This reservation contains an implied obligation of good faith

Texts emanating from States must be interpreted as intending to produce effects in accordance with existing law.² In order to be valid, the self-judging reservation must be interpreted with an implied obligation that Senhava exercise its determination in good faith.³ This interpretation ensures that the declaration is not an illusory undertaking, but contains a genuine obligation.⁴ The interpretation is consistent with Senhava's obligation to apply the

¹ *Certain Norwegian Loans (Fr. v. Nor.)*, 1957 I.C.J. 9, 23 (July 6); *Anglo-Iranian Oil Co. (U.K. v. Iran)*, 1952 I.C.J. 93, 103 (July 22).

² *Rights of Passage Over Indian Territory (Port. v. Ind.)*, 1957 I.C.J. 125, 142 (Nov. 26).

³ Crabb, *On Judging the Connally Amendment*, 50 GEO. L.R. 529, 536 (1961-62).

⁴ *Id.* 536; Schlesinger, *The Connally Amendment - Amelioration by Interpretation?*, 48 VIRG. L.R. 685, 695 (1962).

self-judging reservation *pacta sunt servanda*,⁵ in accordance with Article 36(6) of the Statute of the Court and with the general rule of *compétence de la compétence* which entitles tribunals to determine disputes concerning their jurisdiction.⁶

b) Senhava cannot in good faith invoke the self-judging reservation

Senhava's determination that the matter is essentially domestic will accord with good faith only if the Court finds that this is consistent with international law.⁷ Once a matter is regulated by customary and conventional international law, it is no longer essentially domestic.⁸ In order to adjudicate on the issues surrounding Senhava's vaccine trial, the Court must interpret treaty and customary obligations.⁹ The existence of applicable international law therefore precludes Senhava from reasonably determining that such issues are essentially domestic. Moreover, the Senhavan Prime Minister's appeal to the rules of international law¹⁰ constitute an official recognition of this dispute's international character.¹¹ Senhava's assertion that the dispute "exclusively concerns matters which are essentially within the domestic jurisdiction of Senhava" is an act of bad faith which this Court should treat as null

⁵ Vienna Convention on the Law of Treaties, *opened for signature* May 23, 1969, 1155 U.N.T.S. 331 (entered into force Jan. 27, 1980), art 26; Crabb, *supra* n. 3, 536.

⁶ SHIHATA, THE POWER OF THE INTERNATIONAL COURT TO DETERMINE ITS OWN JURISDICTION (1965); Nottebohm (Prel. Obj.) (Liecht. v. Guat), 1953 I.C.J. 111, 119-20 (Apr. 6).

⁷ SHIHATA, *supra* n. 6, 290-1.

⁸ Tunis and Morocco Nationality Decrees, 1923 P.C.I.J. (ser. B) No. 4 (Feb. 7); Treatment of Polish Nationals in Danzig, 1932 P.C.I.J. (ser. A/B) No. 4 (Feb. 4); Fitzmaurice, *The Law and Procedure of the International Court of Justice, 1954-9*, 35 BRIT. Y.B. INT'L L. 183, 199 (1959).

⁹ See *infra* Pleadings, at 14-22.

¹⁰ *Compromis*, para 28, 32.

¹¹ Military and Paramilitary Activities (Jurisdiction) (Nicar. v. U.S.A.), 1984 I.C.J. 392, 410 (May 10).

and void.¹²

- c) **Senhava is estopped from determining that the matter is essentially within its domestic jurisdiction**

The recognition by Senhava's Prime Minister of the relevance of the rules of international law to the vaccine trial gives rise to an estoppel.¹³ International law prevents Senhava from acting contrary to its unilateral declaration that the dispute is international in character.¹⁴ Estoppel in international law reflects the need for consistency and good faith in States' behaviour, and is broader than the common law equivalent.¹⁵

2. **If Kuraca's self-judging reservation is invalid, it is either inoperative or is severable**

If the Court cannot guard against an arbitrary invocation of the self-judging reservation, the reservation conflicts with Article 36(6) and the objects and purposes of Article 36(2) of the Statute.¹⁶

- a) **The Court's power to determine its own jurisdiction prevails**

In the event that the self-judging reservation of domestic jurisdiction is incompatible

¹² *Certain Norwegian Loans*, *supra* n. 1, 73 (diss. op. Judge Basdevant); Schlesinger, *supra* n. 4, 688.

¹³ *Nuclear Tests (Aust. v. Fr.)*, 1974 I.C.J. 253, 267 (Dec. 20); MacGibbon, *Estoppel in International Law*, 7 INT'L & COMP. L. Q. 468, 487 (1958).

¹⁴ *Legal Status of Eastern Greenland (Den. v. Nor.)* 1933 P.C.I.J. (ser. A/B) No. 53, 71 (Apr. 5); Rubin, *The International Legal Effects of Unilateral Declarations*, 71 AM. J. INT'L L. 1, 16, 19-20 (1977).

¹⁵ *Temple of Preah Vihear (Cambod. v. Thail.)*, 1962 I.C.J. 6, 42 (sep. op. Judge Alfaro) (June 15); MacGibbon, *supra* n. 13, 477-8, 487.

¹⁶ *Certain Norwegian Loans*, *supra* n. 1, 44-8, 55 (sep. op. Judge Lauterpacht), 68-70 (diss. op. Judge Guerrero); *Interhandel (Switz. v. U.S.)*, 1959 I.C.J. 6 (sep. op. Judge Spender) 76-8 (diss. op. Pres. Klaestad), 91-4 (diss. op. Judge Armand-Ugon) (Mar. 21); Crawford, *The Legal Effect of Automatic Reservations to the Jurisdiction of the International Court*, 50 BRIT Y.B. INT'L L. 63, 80-1 (1979).

with Article 36(6), it is rendered inoperative by Article 103 of the U.N. Charter.¹⁷ The obligations under the Charter affix to declarations under Article 36(2) as well as treaties.¹⁸ The obligation to let the Court determine its jurisdiction is a Charter obligation, which is superior to the conflicting obligation to accept Senhava's determination under its reservation.¹⁹ Article 103 of the UN Charter does not speak of invalidity, but rather provides a rule for choosing which obligations prevail in the event of conflict. The Court need not declare the self-judging reservation invalid to avoid giving effect to it.

b) An invalid reservation is severable

If the Court declares that the self-judging reservation is invalid, the reservation is severable and does not disturb the validity of Kuraca's declaration as a whole. The Court should not allow its jurisdiction to be defeated by remediable defects which are not of an essential character.²⁰ Kuraca's intention to issue a real and effective declaration is evidence that its self-judging reservation was not essential.²¹ Once severed, Kuraca's declaration vests the Court with jurisdiction to hear the merits of the dispute.

B. Kuraca's multilateral treaty reservation is not a bar to jurisdiction

¹⁷ Gross, *Bulgaria Invokes the Connally Amendment*, 56 AM. J. INT'L L. 357, 381 (1962); *Interhandel*, *supra* n. 16, 93 (diss. op. Judge Armand-Ugon).

¹⁸ *Interhandel*, *supra* n. 16, 92 (diss. op. Judge Armand-Ugon); Case of the Free Zones of Upper Savoy and the District of Gex, 1930 P.C.I.J. (ser. A), No. 24, 33 (Mr. Kellogg) (Dec. 6).

¹⁹ U.N. CHARTER, art. 92; *Certain Norwegian Loans*, *supra* n. 1, 43 (sep. op. Judge Lauterpacht); *Interhandel*, *supra* n. 16, 76 (diss. op. Pres. Klaestad).

²⁰ *Certain Norwegian Loans*, *supra* n. 1, 57 (sep. op. Judge Lauterpacht).

²¹ *Id.* 64 (diss. op. Judge Guerrero); *Interhandel*, *supra* n. 16, 91 (diss. op. Armand-Ugon), 77 (diss. op. Pres. Klaestad).

Kuraca's second reservation excludes disputes arising under a multilateral treaty, unless all parties to the treaty affected by the decision are also parties to the case, or Kuraca specially agrees to jurisdiction. Kuraca submits that the multilateral treaty reservation, even if it has any relevance or validity, has no application to the claims of Kuraca based upon customary international law.²²

1. Senhava cannot reciprocally invoke a reservation *ratione personae*

A reservation must narrow the scope or substance of the Court's jurisdiction before it can be subject to reciprocity under Article 36(2).²³ Reservations which are the formal conditions of creation of the declaration cannot be invoked reciprocally.²⁴ The Court must be able to ascertain the reciprocal obligations at the time of seisin,²⁵ once the dispute and parties to the case have been defined.²⁶ A reservation *ratione personae* prevents the court from defining the parties at the time of seisin. Because Kuraca's reservation excludes disputes arising under multilateral treaties unless all affected parties are before the Court, it is a reservation *ratione personae*²⁷ which cannot be invoked reciprocally by Senhava.

²² *Military and Paramilitary Activities (Jurisdiction)*, *supra* n. 11, 392.

²³ STATUTE OF THE INTERNATIONAL COURT OF JUSTICE, art. 36, para. 2; Weiss, *Reciprocity and the Optional Clause*, in *THE INTERNATIONAL COURT OF JUSTICE AT A CROSSROADS*, 82, 90 (Damrosch ed., 1987).

²⁴ *Military and Paramilitary Activities (Jurisdiction)*, *supra* n. 11, 419; *Rights of Passage*, *supra* n. 2, 143; SZAFARZ, *THE COMPULSORY JURISDICTION OF THE INTERNATIONAL COURT OF JUSTICE* 57 (1993).

²⁵ *Rights of Passage*, *supra* n. 2, 143.

²⁶ Waldock, *Decline of the Optional Clause*, 32 *BRIT. Y.B. INT'L L.* 244, 257 (1957).

²⁷ Gross, *Compulsory Jurisdiction Under the Optional Clause: History and Practice*, in *THE INTERNATIONAL COURT OF JUSTICE AT A CROSSROADS* 19, 25 (Damrosch ed., 1987); Weiss, *supra* n. 23, 91.

2. Alternatively, the multilateral treaty reservation does not apply because all parties affected by the decision are present

The reservation prevents this Court from deciding the dispute when all parties to the treaty affected by the decision are not parties to the case before this Court. An “affected” party must demonstrate a legal interest under the reservation.²⁸ The dispute is confined to the rights and obligations of Kuraca, George Smith (Kuraca’s effective national or agent), Megaceutical Corporation (M.C. , a Kuracan national) and its subsidiary, and Senhava.

It is not for Senhava to determine which States are “affected” within the meaning of the reservation, as this denies the legal character of the reservation.²⁹ The contention that *all* treaty parties must be present for the Court to exercise jurisdiction contemplates an impossible situation and is without legal foundation.³⁰ Judicial interpretation of a treaty cannot affect the legal rights and duties of absent signatories.³¹ Nemin has demonstrated that it is not an “affected party” by declining to intervene in the proceedings.³²

3. The Court may apply other sources of law

Under Article 79(7) of the Court’s Rules, the Court must declare that Senhava’s objection based on the reservation “does not possess, in the circumstances of the case, an

²⁸ Wright, *The International Court of Justice and the Interpretation of Multilateral Treaties*, 41 AM. J. INT’L L. 445, 449 (1947); Wilcox, *The United States Accepts Compulsory Jurisdiction*, 40 AM. J. INT’L L. 699, 715 (1946).

²⁹ *Military and Paramilitary Activities (Jurisdiction)*, *supra* n. 11, 449 (sep. op. Pres. Nagendra Singh).

³⁰ Wilcox, *supra* n. 28, 716; *Nicaragua*, *supra* n. 11, 455 (sep. op. Judge Ruda), 469 (sep. op. Judge Mosler).

³¹ STATUTE OF THE INTERNATIONAL COURT OF JUSTICE, art. 59; Wilcox, *supra* n. 28, 716.

³² *Military and Paramilitary Activities (Jurisdiction)*, *supra* n. 11, 425; ALEXANDROV, RESERVATIONS IN UNILATERAL DECLARATIONS ACCEPTING THE COMPULSORY JURISDICTION OF THE INTERNATIONAL COURT OF JUSTICE 115 (1995).

exclusively preliminary character” as it is not possible to name with any precision the States whose presence is necessary to enable the Court to proceed further with the case.³³ The reservation is therefore no obstacle for the Court to consider the case.

The multilateral treaty reservation has no application to the claims of Kuraca based upon customary international law.³⁴ While the Court is prevented from applying relevant treaty provisions, certain norms exist separately as custom and can be applied separately.³⁵ Moreover, Senhava is bound to accept the compulsory jurisdiction of this Court over claims presented by Kuraca in so far as they imply violations of provisions of the bilateral Treaty of Amity and Commerce.³⁶

II. THE CLAIM IS ADMISSIBLE

A. Kuraca has standing to bring this claim, by its exercise of diplomatic protection

1. Kuraca has standing to claim on behalf of Megaceutical-Senhava

In extending diplomatic protection to Megaceutical-Senhava (M-S), Kuraca is asserting its sovereign right to protect its nationals and ensure respect for the rules of international law.³⁷ M-S is a national of Kuraca under international law, which accords the nationality of a corporation to the State with which it has a “substantial and effective

³³ *Military and Paramilitary Activities (Jurisdiction)*, *supra* n. 11, 448, 450; Damrosch, *Multilateral Disputes, in THE INTERNATIONAL COURT OF JUSTICE AT A CROSSROADS* 376, 396 (Damrosch ed., 1987).

³⁴ *Military and Paramilitary Activities (Jurisdiction)*, *supra* n. 11, 424.

³⁵ *Military and Paramilitary Activities (Merits) (Nicar. v. U.S.A.)*, 1986 I.C.J. 14, 94-96 (June 27).

³⁶ *Military and Paramilitary Activities (Jurisdiction)*, *supra* n. 11, 428.

³⁷ *Mavromatis Palestine Concessions*, 1924 P.C.I.J. (ser. A), No. 2, at 12 (Aug. 30); para 78 (judgment). *Barcelona Traction, Light and Power Co. Ltd. (Belg. v. Spain)*, 1972 I.C.J. 4, para. 78 (Feb. 5).

connection”,³⁸ evidenced by the location of the control, finance and management of the corporation.³⁹ Although incorporated in Senhava, M-S’s operations are effectively controlled by its Kuracan parent, M.C., which is its 49% owner and enforces a shareholder agreement. This dominant influence is confirmed by the absence of any other substantial shareholding in M-S. Such operational control is determinative of corporate nationality in international arbitration⁴⁰ and various bilateral taxation treaties.⁴¹ Moreover, because international rules determining nationality protect substantive rather than formal rights,⁴² the provision by M.C. of personnel and capital is also determinative of Kuracan nationality.⁴³

The place of incorporation is no longer decisive, as the Court has recognised that the this may not equate with the “true centre” of the corporation’s “political and economic interests”,⁴⁴ especially when a corporation has no “close and permanent connection” with the

³⁸ *Barcelona, supra* n. 37, para. 39 (sep. op. Judge Jessup); BORCHARD, *THE DIPLOMATIC PROTECTION OF CITIZENS ABROAD* 617-18 (1915); Vegts, *The Corporate Alien: Definitional Questions in Federal Restraints on Foreign Enterprise*, 74 HARV. L. REV. 1489, 1544-51 (1961).

³⁹ *Barcelona, supra* n. 38, para. 49; O’CONNELL, 2 INTERNATIONAL LAW 1041 (1970); AMERICAN LAW INSTITUTE, 2 RESTATEMENT OF THE LAW THIRD: FOREIGN RELATIONS LAW OF THE UNITED STATES, para. 213, Reporters Notes, para. 5 (1987) [hereinafter THIRD RESTATEMENT].

⁴⁰ *Sedco International Inc. v. National Iranian Oil Co & Iran*, 9 Iran-U.S.C.T.R. 248, 259 (1985); BROWNLIE, *PRINCIPLES OF PUBLIC INTERNATIONAL LAW* 486 (5th ed. 1998); THIRD RESTATEMENT, *supra* n. 39, para. 414, Comment e.

⁴¹ Agreement between the Commonwealth of Australia and the Federal Republic of Germany for the Avoidance of Double Taxation, Nov. 24, 1972 (entered into force Feb. 15, 1975) A.S.T. No. 8 (1975).

⁴² Harris, *The Protection of Companies in International Law in the Light of the Nottebohm Case*, 18 INT’L & COMP. L. Q. 275, 510 (1969).

⁴³ *Suez Canal Company, 1864*, cited in O’CONNELL, *supra* n. 39, 1044.

⁴⁴ *Barcelona, supra* n. 37, para. 283 (sep. op. Judge Gros); BORCHARD, *supra* n. 38, 617-18.

jurisdiction.⁴⁵ Moreover, Senhava's laws requiring local incorporation may not be used to force M-S to "surrender its right to protection by the State of its parent corporation or of the parent's shareholders".⁴⁶

2. Kuraca has standing to claim on behalf of Kuracan interests in Megaceutical-Senhava

M.C., a Kuracan national, can be afforded diplomatic protection by virtue of its substantial interest in M-S.⁴⁷ International law has evolved with international commerce to vest in foreign shareholders the right to bring an action for the defence of the company,⁴⁸ rather than leave shareholders "at the mercy" of the State of incorporation.⁴⁹ Judicial and State practice confirms that a shareholders' right of action is made more imperative when the company has been injured by its State of incorporation.⁵⁰ M-S has suffered the forced suspension of its operations, and the confiscation, through massive fines, of its assets. Such injuries found a right to diplomatic protection against Senhava. The fact that all other shareholders in M-S are of Senhavan nationality distinguishes Kuraca's claim from

⁴⁵ *Barcelona, id.*, para. 42; THIRD RESTATEMENT, *supra* n. 39, para. 213, Comment c.

⁴⁶ THIRD RESTATEMENT, *supra* n. 39, para. 213, Reporters' notes, para. 3.

⁴⁷ *Id.* para. 213.

⁴⁸ *Barcelona, supra* n. 37, paras. 33-4; Ruden Case, Moore, I.A. 1653 (1870) cited in O'CONNELL, *supra* n. 39, 1044; Spanish Zone of Morocco, Ziat, Ben Kiran Claim (Gt. Brit. v. Spain), 2. R.I.A.A. 729 (Spec. Arb. 1925); Cayuga Indians (Gt. Brit. v. U.S.), 6 R.I.A.A. 173 (Spec. Arb. 1926).

⁴⁹ Jones, *Claims of Behalf of Nationals Who are Shareholders in Foreign Companies*, 26 BRIT. Y.B. INT'L L. 225, 236 (1949).

⁵⁰ *Barcelona, supra* n. 37, paras. 92-3 and para. 51-2, 63 (sep. op. Judge Jessup); THIRD RESTATEMENT, *supra* n. 39, para. 213, Comment d.; Jones, *supra* n. 49, 236; United Kingdom Rules Regarding the Taking Up of International Claims by Her Majesty's Government, July 1983, *reprinted in* 54 BRIT. Y. B. INT'L L. 520 (1983).

Belgium's in *Barcelona*.⁵¹ The substantial interests of M-S will go unprotected if Kuraca is denied standing.

3. Kuraca has standing on behalf of George Smith

Kuraca is entitled to extend diplomatic protection to George Smith as an effective national or agent of Kuraca. George Smith is employed by a Kuracan government regulatory agency. Although a citizen of Nemin, he may be conferred Kuracan nationality by his allegiance to Kuraca. Importantly, "where a businessman has international connexions and social mobility, residence and interests may provide no choice and political ties may then take on particular significance."⁵² This satisfies the evidence of a "genuine connection",⁵³ the threshold for which is lower when only one disputing party is claiming nationality.⁵⁴ Senhava is estopped from denying the Kuracan nationality of George Smith, by its consent to his employment and activity.⁵⁵

There are recognised exceptions to the rule that a State may only exercise diplomatic protection on behalf of nationals.⁵⁶ If George Smith is not conferred effective Kuracan

⁵¹ *Barcelona*, *supra* n. 37, 6.

⁵² *Nottebohm (Second Phase) (Liech. v. Guat.)*, 1955 I.C.J. 4, 44-5 (diss. op. Judge Read) (Apr. 6); Brownlie, *Nationality in Public International Law*, 39 BRIT. Y.B. INT'L L. 284, 359 (1963).

⁵³ *Nottebohm*, *supra* n. 52, 23.

⁵⁴ SCHWARZENBERGER, 1 INTERNATIONAL LAW 362-3 (3d. 1957).

⁵⁵ *Compromis*, para. 11; BROWNLIE, *supra* n. 40, 335-7; *Expropriated Religious Properties (Fr. v. Spain)* 1 R.I.A.A. 7, 46 (Spec. Arb. 1920).

⁵⁶ *Reparations for Injuries Suffered in the Services of the United Nations* 1949 I.C.J. 174, 181 (Apr. 11); OPPENHEIM, INTERNATIONAL LAW 935-9 (9th ed., Jennings ed., 1992).

nationality, his employment by Kuraca is sufficient to base a right of diplomatic protection.⁵⁷ This arrangement, agreed to by Senhava, creates a sufficient interest for Kuraca to seek to protect.⁵⁸ Government agents of a State may, acting on behalf of the State, incur the liability of that State.⁵⁹ As rights and responsibilities are corollaries at international law,⁶⁰ George Smith's ability to attract Kuracan state responsibility entitles Kuraca to protect him.

4. Kuraca has standing in respect of breaches of obligations *erga omnes*

Obligations *erga omnes* are owed to the international community as a whole.⁶¹ In view of the importance of the basic rights of the human person, including protection from discrimination and denial of justice, Kuraca has a legal interest in their observance.⁶² Senhava's arbitrary detention of George Smith amounts to a flagrant violation of customary human rights norms, which injures Kuraca along with the rest of the international community. Moreover, Kuraca's standing to vindicate its own legislation protecting basic human rights in human experimentation logically derives from its *erga omnes* obligation.

B. No local remedies are available to Megaceutical-Senhava or George Smith

International law requires an individual to exhaust "effective"⁶³ local remedies.⁶⁴ In

⁵⁷ Fitzmaurice, *The Law and Procedure of the International Court of Justice*, *supra* n. 8, 24-6.

⁵⁸ BROWNIE, *supra* n. 40, 482.

⁵⁹ Caire Claim (Fr. v. Mex.) 5 R.I.A.A. 516 (1929); *Report of the Commission to the General Assembly on the Work of its 32d. Session*, [1980] 2 Y.B. Int'l L. Comm'n 31, A/CN.4/SER.A/1980/Add.1 (Part 2), art. 8.

⁶⁰ *Spanish Zone of Morocco Claims*, *supra* n. 48.

⁶¹ *Barcelona*, *supra* n. 37, para. 32.

⁶² *Id.* para. 47.

⁶³ *Certain Norwegian Loans*, *supra* n. 1, 39 (sep. op. Judge Lauterpacht); *Finnish Shipowners Arbitration (Fin. v. U.K.)*, 3 R.I.A.A. 1479 (Spec. Arb. 1934).

light of the laws and actions taken by Senhava, no remedies are available to M-S or to George Smith in this dispute. M-S is exempted from exhausting local remedies, as the closure of its offices renders it incapable of seeking municipal redress.⁶⁵ Its shareholders, including M.C, are unable to pursue a local remedy in the absence of the formal dissolution of M-S.⁶⁶ George Smith is held in Senhava without bail, in the absence of formal charges or a trial date. He has no means of challenging his arbitrary detention.

C. There are no indispensable third parties to bar the claim

The Court has declined jurisdiction if the interests of a State not party to the proceedings forms the very subject-matter of the decision.⁶⁷ In this case, all indispensable States are parties to the proceedings. Nemin's position is unlike that of Albania in the Monetary Gold case or Indonesia in the East Timor case. Nemin's interest is limited to the treatment of Smith, who is represented by Kuraca. Further, Nemin's waiver of its claim concerning Smith constitutes the removal of this interest.⁶⁸

III. GEORGE SMITH HAS BEEN ARBITRARILY DETAINED

Senhava's arrest of Smith constitutes arbitrary detention contrary to the principles of

⁶⁴ *Interhandel*, *supra* n. 16, 26-7.

⁶⁵ *Elettronica Sicula S.p.A. (ELSI) (U.S. v. Italy)*, 1989 I.C.J. 15, 47 (July 20) (majority), 114-5 (diss. op. Judge Schwebel).

⁶⁶ *Barcelona*, *supra* n. 37, 41.

⁶⁷ *Monetary Gold Removed from Rome in 1943 (Italy. v. Fr., U.S., U.K.)*, 1954 I.C.J. 32 (June 15); *East Timor (Port. v. Austl.)*, 1995 I.C.J. 90 (June 30).

⁶⁸ *Certain Phosphate Lands in Nauru (Prel. Obj.) (Nauru v. Austl.)*, 1992 I.C.J. 240, 324 (June 26) (diss. op. Judge Oda); BROWNLIE, *supra* n. 40, 507-8; BRIGGS, *THE LAW OF NATIONS: CASES, DOCUMENTS AND NOTES* (2d. ed, 1952).

customary international law.⁶⁹ “Arbitrary” is not restricted to “against the law”, but includes elements of inappropriateness, injustice and lack of due process.⁷⁰ Detention is arbitrary if, *inter alia*, it occurs on grounds not previously established in law,⁷¹ is supported by only a general warrant or is not accompanied by a notice of charges.⁷² Detention has been deemed arbitrary by the United Nations Working Group on Arbitrary Detention where charges have not been filed against the detainee within a reasonable period of time after arrest.⁷³ Detention is also arbitrary where the detainee is held for more than a brief period of time without being brought before a judicial authority to review the propriety of the detention.⁷⁴ Even during public emergencies, the State must provide some form of independent review.⁷⁵

By the date of the compromis, Smith had been held for almost four months without

⁶⁹ *Universal Declaration of Human Rights*, G.A. Res. 217, U.N. Doc. A/810, at 71 (1948), art. 9; THIRD RESTATEMENT, *supra* n. 39, para. 702, Reporters’ note 6; Rodriguez-Fernandez v. Wilkinson, 505 F. Supp. 787, 798 (D. Kan. 1980); *Commission on Human Rights: Report of the Working Group on Arbitrary Detention*, U.N. ESCOR, 48th Sess., Item 10, at 3, U.N. Doc. E/CN.4 (1993); *United States Diplomatic and Consular Staff in Tehran (U.S. v. Iran)*, 1980 I.C.J. 3, 42 (May 24).

⁷⁰ U.N. GAOR Hum. Rts Comm., 45th Sess., Supp. No. 40 at 108, U.N. Doc. A/45/40 (1990) (*Hugo van Alphen v. Neth.*).

⁷¹ UNITED NATIONS COMMISSION ON HUMAN RIGHTS, *STUDY OF THE RIGHT OF EVERYONE TO BE FREE FROM ARBITRARY ARREST, DETENTION AND EXILE* 27 (1964); U.N. GAOR Hum. Rts Comm., 38th Sess., Supp. No. 40 at 134, U.N. Doc. A/38/40 (1983) (*Daniel Mbenge v. Zaire*); FREEMAN, *THE INTERNATIONAL RESPONSIBILITY OF STATES FOR DENIAL OF JUSTICE* 196 (1938).

⁷² THIRD RESTATEMENT, *supra* n. 39, para. 702, Comment h.; UNITED NATIONS COMMISSION ON HUMAN RIGHTS, *supra* n. 71, 33.

⁷³ *Commission on Human Rights: Report of the Working Group on Arbitrary Detention*, Decisions 1-5/1993 (Phil.), U.N. Doc. E/CN.4/1994/27, Dec. 17, 1993.

⁷⁴ UNITED NATIONS COMMISSION ON HUMAN RIGHTS, *supra* n. 71, 39; *Hugo van Alphen v. Neth.*, *supra* n. 70.

⁷⁵ UNITED NATIONS COMMISSION ON HUMAN RIGHTS, *supra* n. 71, 195.

being presented with charges. When arrested, he was accused of having “interfered with Senhavan public health measures.” It is unclear whether this accusation constituted an offence under law at the time of the arrest; if it is a criminal offence, it is unacceptably vague, and adds to the detention’s arbitrariness. Smith has not yet been given the opportunity to have his detention reviewed by a judicial authority, nor has there been any review of eligibility for bail or other forms of release pending a trial. No trial date has been fixed.

If the declaration of public emergency is warranted, the actions taken must be strictly required by the threat. It is disingenuous of Senhava to claim that the Public Health Emergency entitles it to detain Smith, given that he was arrested more than a month before the state of emergency commenced. Smith’s detention does not in anyway assist in the control of the M.H.V.D. epidemic, and it is impossible to discern a public emergency rationale for his arrest. It is a vindictive, punitive action intended to inconvenience Kuraca after its decision to stop the vaccine trial.

IV. KURACAN NATIONAL HEALTH LAW 1006 IS VALID

International law compels the observance of ethical standards in human experimentation, including requirements of informed consent and non-discrimination. The Kuracan Health Law 1006 (“Law 1006”) is valid, as it implements these obligatory standards on the basis that they are universally enforceable. Alternatively, Law 1006 is valid as it regulates the actions of Kuracan nationals abroad, or because it legitimately regulates Kuraca’s pharmaceutical industry.

A. International law regulates human experimentation.

Customary norms protecting human rights set minimum standards for human

experimentation and are “beyond the reach of a national sovereign”.⁷⁶ These obligations signify a shift in the focus of international law from the protection of States to the protection of individual human rights.⁷⁷ The absolute sovereignty of States has necessarily been qualified in order to protect internationally recognised human rights.⁷⁸

1. States must protect informed consent in human experimentation

The requirement for informed consent specified in Law 1006 reflects customary international law. Custom arises where there is consistent State practice performed with the belief that such practice is legally required (*opinio juris*).⁷⁹ In human rights law, State practice is primarily evidenced by consistent reiteration of principles in human rights instruments, and their implementation in national legislation and policy.⁸⁰

International law recognises the inherent autonomy and dignity of the individual,⁸¹ and the inviolability of the person,⁸² through its prohibition against cruel, inhuman or

⁷⁶ King Jr, *Nuremberg and Sovereignty*, 28 CASE W. RES. J. INT’L L. 135, 136-7 (1996).

⁷⁷ Reisman, *Sovereignty and Human Rights in Contemporary International Law*, 84 AM. J. INT’L L. 866, 869-72 (1990).

⁷⁸ Sohn, *The New International Law: Protection of the Rights of Individuals Rather Than States*, 32 AM. U. L. REV. 1, 18 (1982).

⁷⁹ North Sea Continental Shelf (F.R.G. v. Den.; F.R.G. v. Neth.), 1969 I.C.J. 3, 42-3 (Feb. 20).

⁸⁰ THIRD RESTATEMENT, *supra* n. 39, para. 701; MERON, HUMAN RIGHTS AND HUMANITARIAN NORMS AS CUSTOMARY LAW 92-94 (1989).

⁸¹ LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 10, 70-1 (1981).

⁸² Verdun-Jones & Weisstub, *Consent to Human Experimentation in Québec: The Application of the Civil Law Principle of Personal Inviolability to Protect Special Populations*, 18 INT’L J. L. & PSYCH. 163 (1995).

degrading treatment, as articulated in foundational human rights treaties⁸³ and domestic constitutions.⁸⁴ Protection of bodily integrity has such importance and wide acceptance within the world community that it has achieved the status of a peremptory norm,⁸⁵ and has non-derogable status.⁸⁶ Article 7 of the International Covenant on Civil and Political Rights (I.C.C.P.R.) demonstrates that the prohibition extends to involuntary human experimentation: “in particular, no one shall be subjected without his free consent to medical or scientific experimentation.” Recourse to the I.C.C.P.R.’s *travaux préparatoires* reveals the broad consensus of participants that such a statement be included, given the atrocities perpetuated in Nazi concentration camps during the Second World War.⁸⁷ The two concepts

⁸³ *Universal Declaration of Human Rights*, *supra* n. 69, art. 3 (U.D.H.R.); International Covenant on Civil and Political Rights, G.A. Res. 2200 (XXI), Dec. 16, 1966, U.N. GAOR, 21st Sess., Supp. (No.16) at 52, U.N. Doc. A/6316 (1966), 999 U.N.T.S 171 (entered into force Mar. 23, 1976) art. 7; European Convention for the Protection of Human Rights and Fundamental Freedoms, Nov. 4, 1950, 213 U.N.T.S. 222 (entered into force Sept. 3, 1953); as amended by Protocol No.3, (entered into force Sept. 21, 1970, and Protocol No. 5, (entered into force Dec. 21, 1971), art. 3 (E.C.H.R.); American Convention on Human Rights, Nov. 22, 1969, O.A.S.T.S. No.36, at 1, OEA/Ser.L./V/II.23 doc. Rev. 2, (entered into force July 18, 1978) art. 5; African Charter on Human and Peoples’ Rights, O.A.U. Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982) (entered into force Oct.,1986) arts. 4-5.

⁸⁴ PHIL. CONST. (1987) art. 2, para. 11; TRIN. & TOBAGO CONST. (1980) art. 5, para. 2(b); NAMIB. CONST. (1990) art. 8; NETH. CONST., art. 11; S. AFR. CONST. (1996) art. 12, para. 1(e).

⁸⁵ THIRD RESTATEMENT, *supra* n. 39, para. 702; R.v. Bow Street Metropolitan Stipendiary Magistrate; Ex Parte Pinochet Ugarte (No 3) [1999] 2 WLR 272 (U.K.); Prosecutor v. Anton Furundzija, 38 I.L.M. 317 (1999); Sideman de Blake v. Republic of Argentina, 965 F 2d 699, 714-18 (9th Cir, 1992); Sohn, *supra* n. 78, 32.

⁸⁶ I.C.C.P.R., *supra* n. 83, art 4, para. 2, art. 7; E.C.H.R., *supra* n. 83, art. 3, art. 15, para. 2; Ireland v. United Kingdom, 2 E.H.R.R. 25 (1978), para. 162; Sohn, *supra* n. 78, 18.

⁸⁷ BOSSUYT, GUIDE TO THE “*TRAVAUX PRÉPARATOIRES*” OF THE INTERNATIONAL COVENANT ON CIVIL AND POLITICAL RIGHTS, 151-58 (1987).

are thus unified by their promotion of dignity of the individual;⁸⁸ experimentation without consent constitutes an affront to a person's autonomy and physical integrity and is cruel, inhuman and degrading.⁸⁹

Consent is the primary criterion by which to judge the lawfulness of experimentation, and requires that a competent individual, having received and adequately understood information about the procedure, voluntarily consents to it.⁹⁰ These basic requirements are confirmed by consistent acceptance into domestic laws and guidelines.⁹¹ Developed and developing nations have jointly drafted and implemented guidelines specifying how these

⁸⁸ BOSSUYT, *id.*; *Tyrer v. United Kingdom*, 1978 Y.B. Eur. Conv. on H. R. 612 (Eur. Ct. H. R.).

⁸⁹ SLOVN. CONST. (1991) art. 51; S. AFR. CONST. (1996) art. 12, para. 2(c); King, *A Proposal for the Effective International Regulation of Biomedical Research Involving Human Subjects*, 34 STAN. J. INT'L L. 163, 178 (1998).

⁹⁰ Nuremberg Code, *reprinted in* ANNAS AND GRODIN, *THE NAZI DOCTORS AND THE NUREMBERG CODE 2* (1992); Declaration of Helsinki, World Medical Association 18th Assembly (June 1964, am. 1975, 1983, 1989, 1996) (visited Jan. 19, 2000), <http://www.impactcg.com/info/helsinki.htm>; COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (C.I.O.M.S.) & WORLD HEALTH ORGANIZATION (W.H.O.), *INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS* (1993) [hereinafter C.I.O.M.S. GUIDELINES]; INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE, *GOOD CLINICAL PRACTICE* (1996).

⁹¹ Act on Practice of Medicine and Its Related Practices, No. 1219 (1928) (Turk.) art. 20; *Arzneimittelgesetz*, paras 40 *et. seq.*, *Medizinproduktegesetz*, paras. 17 & 18 (F.R.G.); Leflar, *Informed Consent and Patients' Rights in Japan*, 33 HOUS. L. REV. 1 (1996); Limpakarnjanarat et al, *Informed Consent for a Clinical Trial in Thailand*, 339 NEW ENG. J. MED. 1332 (1998); Decree No. 258/992 (1992), para. 30, *et. seq.* (Uru.); Préziosi et al, *Practical Experiences in Obtaining Informed Consent for a Vaccine Trial in Rural Africa*, 336 NEW ENG. J. MED. 370 (1997) (Sen.); Leach et al., *An Evaluation of the Informed Consent Procedure Used During a Trial of a Haemophilus influenzae Type B Conjugate Vaccine Undertaken in The Gambia, West Africa*, 48 SOC. SCI. & MED. 139 (1999); NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL, *NATIONAL STATEMENT ON ETHICAL CONDUCT IN RESEARCH INVOLVING HUMANS* (1999) (Austl.).

principles may be realised in practice.⁹² The recent Convention on Human Rights and Biomedicine (C.H.R.B.) - which articulates “common general standards for the protection of the human person”⁹³ - codifies the “already well-established rule”⁹⁴ of informed consent, and accords it a non-derogable status in the context of scientific research.⁹⁵

Aside from its customary obligation, Kuraca must not subvert the purpose of the C.H.R.B.:⁹⁶ to protect the rights of the human being over the sole interest of science or society.⁹⁷ In implementing Law 1006, Kuraca has ensured that human subjects are given information regarding the risks and benefits of the proposed research, that they are free to withdraw from research at any time, and that consent is voluntary.⁹⁸ It has also ensured that an independent, competent body examines its ethical standard and scientific merit.⁹⁹

2. States must not discriminate in human experimentation

As well as protecting the autonomy of the individual, research must integrate the

⁹² C.I.O.M.S. GUIDELINES, *supra* n. 90, 6, 9.

⁹³ Council of Europe, Explanatory Report to the Convention for the Protection of Human Rights and Biomedicine, DIR/JUR (97), *reprinted in* 36 I.L.M. 826, para.4 [hereinafter Explanatory Report (C.H.R.B.)].

⁹⁴ *Id.* para. 34.

⁹⁵ Convention on Human Rights and Biomedicine, (entered into force Dec. 12, 1999), E.T.S. No. 164, art. 16, para. 5, art. 17, para. 4, art. 26, para. 2 (C.H.R.B.).

⁹⁶ Vienna Convention on the Law of Treaties, *supra* n. 5, art. 18.

⁹⁷ C.H.R.B., *supra* n. 95, Preamble, art. 1, art. 2; Explanatory Report (C.H.R.B.), *supra* n. 93, paras. 21, 22.

⁹⁸ Nuremberg Code, *supra* n. 90, Principle 1; Declaration of Helsinki, *supra* n. 90, Pt. I, Principles 9-11; C.I.O.M.S. GUIDELINES, *supra* n. 90, Guidelines 1, 2; C.H.R.B., *supra* n.95, arts. 5, 16, 17.

⁹⁹ Declaration of Helsinki, *supra* n. 90, Part I, Principle 2; C.I.O.M.S. GUIDELINES, *supra* n. 90, Guideline 14; C.H.R.B., *supra* n. 95, art. 16, para. 3.

principles of beneficence (maximisation of benefits and minimisation of harms) and justice (fairness in the distribution of risks and benefits).¹⁰⁰ Certain populations, such as children and prisoners, lack the capacity or freedom to give informed consent due to economic, political or life circumstances.¹⁰¹ Because these groups “provide convenient, low-risk, low-cost subjects” they are particularly vulnerable to exploitation and may end up carrying a disproportionate burden of the risks of research.¹⁰² Targeting these groups for research violates the international law principle of non-discrimination.¹⁰³ Kuraca has legislated to protect vulnerable groups from exploitation through its implementation of informed consent standards.

B. Kuraca’s law is valid as it regulates the conduct of Kuracan nationals.

Kuraca’s law is valid as it requires only Kuracan nationals to act in accordance with customary norms relating to informed consent.¹⁰⁴ Kuraca’s competence to legislate with respect to the conduct of its nationals abroad is affirmed by its treaty obligations,¹⁰⁵ and is a

¹⁰⁰ The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, (visited Jan 19, 2000) at <www.impactcg.com/info/belmont.htm>.

¹⁰¹ Nuremberg Code, *supra* n. 90, Principle 1; Declaration of Helsinki, *supra* n. 90, Part I, Principles 4, 5; C.I.O.M.S., *supra* n. 90, commentary to Guideline 10; C.H.R.B., *supra* n.95, art. 16, para. ii.

¹⁰² King, *supra* n. 89, 194.

¹⁰³ U.N. CHARTER, art. 1, para. 3; art. 55, para. c; *Barcelona*, *supra* n. 37, para. 33; BROWNLIE, *supra* n. 40, 602; Sohn, *supra* n. 78, 25-8; SIMMA, THE CHARTER OF THE UNITED NATIONS: A COMMENTARY 776-93 (1995).

¹⁰⁴ *Compromis*, Annex C, Kuracan National Health Regulations, Section 1006(r).

¹⁰⁵ Convention against Torture and other Cruel, Inhuman or Degrading Treatment, G.A. Res. 39/46, annex, 39 U.N. GAOR Supp. (No. 51) at 197, U.N. Doc. A/39/51 (1984), (entered into force June 26, 1987) art. 5.

well-recognised basis of jurisdiction.¹⁰⁶ Kuraca's law is reasonable as it is solely directed towards Kuracan nationals in the light of universal obligations, and does not interfere with Senhava's national interest.¹⁰⁷

C. Alternatively, Kuracan law is a valid regulation within its territory

"Sovereignty ... is the right to exercise ..., to the exclusion of any other State, the functions of a State"¹⁰⁸ including the enactment and enforcement of laws within its own territory.¹⁰⁹ Kuraca is entitled to regulate its pharmaceutical industry, which operates "substantially within [Kuracan] territory".¹¹⁰ As Kuracan regulations are directed towards corporations within Kuraca's domestic jurisdiction, Kuraca is not responsible at international law for any indirect consequences such enforcement may have.

V. KURACA'S CONDUCT ACCORDS WITH INTERNATIONAL LAW

A. The trial cannot be justified at international law

Implementation of the proposed trial would breach fundamental human rights. The paucity of information in the informed consent form would have precluded an enlightened decision regarding participation in the trial.¹¹¹ The trial entailed unacceptable risk for

¹⁰⁶ Akehurst, *Jurisdiction in International Law*, 46 BRIT. Y. B. INT'L L. 46, 159 (1972-3).

¹⁰⁷ THIRD RESTATEMENT, *supra* n. 39, paras. 213, 403, 414.

¹⁰⁸ *Island of Palmas (Neth. v. U.S.)* 2 R.I.A.A 829, 838 (1928).

¹⁰⁹ BROWNLIE, *supra* n. 40, 299; Mann, *The Doctrine of International Jurisdiction Revisited After Twenty Years*, 186 RECEUIL DES COURS 13, 20 (1984-III).

¹¹⁰ THIRD RESTATEMENT, *supra* n. 40, para. 402.

¹¹¹ Nuremberg Code, *supra* n. 90, Principle 1; Declaration of Helsinki, *supra* n. 90 Part I, Principle 9; C.I.O.M.S Guidelines, *supra* n. 90, Guidelines 1, 2; C.H.R.B., *supra* note 95, art. 16, para. 5.

participants:¹¹² not only has the proposed Vaccine 078c never been tested in a Phase I study, but a variant, 078b, caused debilitating asthma in one out of fifteen subjects. The trial focused almost entirely on inappropriate subjects. Children should only be experimental subjects where the research entails minimal risk of harm and pertains to uniquely childhood disease.¹¹³ Prisoners are almost universally prohibited from experimentation due to the strong probability of coercion.¹¹⁴ The powerlessness of traditionally marginalised groups – women and poor people – would have been exacerbated by utilising police escorts and the inadequate consent procedure.¹¹⁵ Any consent obtained in this trial would not have met the requirements that it be truly voluntary and informed.

B. Kuraca is not obliged to cooperate in the trial

To be justiciable, relevant obligations must be clear and concrete. The right to health suffers from a want of conceptual clarity regarding both its scope and means of implementation;¹¹⁶ unlike civil and political rights, economic and social rights have rarely been the subject of significant jurisprudential consideration.¹¹⁷ The right to health is therefore too nebulous to constitute a norm of customary international law. Any technical obligations

¹¹² Nuremberg Code, *id.*, Principle 4; Declaration of Helsinki, *id.*, Part I, Principles 4, 5, 7; C.I.O.M.S. GUIDELINES, *id.*, Guideline 10; C.H.R.B., *id.*, art. 16, paras. i, ii.

¹¹³ Nuremberg Code, *id.*, Principle 1; C.I.O.M.S. GUIDELINES, *id.*, Guideline 5; C.H.R.B., *id.*, art. 17.

¹¹⁴ C.I.O.M.S. GUIDELINES, *id.*, commentary to guideline 7; ANNAS, GLANTZ & KATZ, INFORMED CONSENT TO HUMAN EXPERIMENTATION 103-38 (1977).

¹¹⁵ C.I.O.M.S. GUIDELINES, *id.*, guidelines 8, 10; Glantz et al, *Research in Developing Countries: Taking "Benefit" Seriously*, 28 HAST. CENTER REP. 38 (1998).

¹¹⁶ Alston, *Out of the Abyss: The Challenges Confronting the New U.N. Committee on Economic, Social and Cultural Rights*, 9 HUM. RTS Q. 332, 351 (1987).

¹¹⁷ Alston, *id.*

derived from the I.C.E.S.C.R. are not binding on Kuraca, as it has never ratified that treaty.¹¹⁸

Even if there were a customary obligation to respect the right to health, it has never been seen as an absolute right, but one which must be progressively realised.¹¹⁹ It addresses only the creation of conditions *conducive* to health, and not a right to health *per se*.¹²⁰ The right to personal autonomy and integrity remains paramount.¹²¹ Kuraca's conduct is justified as a balancing of obligations to control disease and to respect ethical standards. Kuraca has satisfied both obligations by disapproving the substandard protocol without obstructing the overall objective of developing a successful vaccine. Senhavan people should not be denied the protection of individual human rights merely because they live in a developing country.

VI. SENHAVA HAS BREACHED THE TREATY OF AMITY AND COMMERCE

Senhavan measures against M-S are breaches of international law and are a denial of justice. The traditional rights of an alien to treatment equal to nationals,¹²² as reflected in the Treaty of Amity and Commerce, are applicable.¹²³ The company thus has rights to the beneficial use of its property and to the protection of its interests, which cannot be abrogated

¹¹⁸ Vienna Convention on the Law of Treaties, *supra* n.5, art. 18.

¹¹⁹ International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 49, U.N. Doc. A/6316 (1966), 993 U.N.T.S. 3, (entered into force Jan. 3, 1976).

¹²⁰ Jamar, *The International Human Right to Health*, 22 S. U. L. REV. 1, 27 (1994).

¹²¹ Leary, *The Right to Health in International Human Rights Law*, 1 HEALTH & HUM. RTS. 25, 36-7 (1994).

¹²² BROWNLIE, *supra* n. 40, 526, 531; *Documentation of the 9th Session including the report of the Commission to the General Assembly*, [1957] 2 Y.B. Int'l L Comm'n, A/CN.4/SER.A/1957/Add.1.; Williams, *International Law and the Property of Aliens*, 9 BRIT. Y.B. INT'L L. 28 (1928).

¹²³ BROWNLIE, *supra* n.40, 529; *Documentation of the 9th Session including the report of the Commission to the General Assembly*, *id.* 112.

by national law or decree.¹²⁴ Senhava is also obliged to act in good faith with respect to foreign investment.¹²⁵ Senhavan measures were directed towards the company as a Kuracan national after Senhava's demands were refused; they are flagrantly discriminatory. The closure and fines render company management practically impossible.¹²⁶ They injure M-S's property and commerce, and injure M.C.'s foreign investment in bad faith.

VII. REMEDIES

A. The Court must order the release of George Smith

By virtue of its jurisdiction to make final determinations, this Court has the power to make orders which restore international law rights.¹²⁷ These orders can include declaratory relief¹²⁸ and mandatory orders.¹²⁹ Where a State is detaining persons in violation of international human rights law, the Court can order the State to terminate the detention, as it did in the *Tehran Hostages* case.¹³⁰ In ordering George Smith's release, the Court is not interfering with Senhava's criminal law processes, nor is it acting as a court of criminal appeal; it is merely restoring conditions which existed prior to Senhava's breach of

¹²⁴ U.D.H.R., *supra* n. 83, arts. 8, 17; I.C.C.P.R., *supra* n. 83, arts. 6, 14; *Documentation of the 9th Session including the report of the Commission to the General Assembly*, *id.* 113; FREEMAN, *supra* n. 71, 69.

¹²⁵ G.A. Res 1803, U.N. GAOR, 17th Sess., Supp. No. 17, at 15, U.N. Doc. A/5217 (1962); BROWNLIE, *supra* n. 40, 528, 543; Neer Claim (U.S. Mex.) 2 R.I.A.A. 60, 61 (Gen. Cl. Comm'n. 1926)

¹²⁶ *ELSI*, *supra* n. 65, 55.

¹²⁷ LAUTERPACHT, *THE DEVELOPMENT INTERNATIONAL LAW BY THE INTERNATIONAL COURT* 246 (1958); *Corfu Channel* (U.K. v. Alb.), 1949 I.C.J. Rep. 4, 26 (Apr. 9).

¹²⁸ GRAY, *JUDICIAL REMEDIES IN INTERNATIONAL LAW* 66 (1987).

¹²⁹ Mann, *The Consequences of An International Wrong in International and Municipal Law* 48 BRIT. Y. B. INT'L L. 1, 13 (1976-7).

international law, under the principle of *restitutio in integrum*.¹³¹

B. Senhava must remedy injuries to Megaceutical-Senhava and return the advance payment

Senhava has breached international law by causing direct injury to the property of Kuracan nationals, and by breaching the Treaty of Amity and Commerce. It is trite law that breaches of international law give the wronged party a right to restitution in kind, or, if that is not possible, to compensation corresponding to the value of restitution in kind¹³² - which in this case entails the rescission of orders closing the offices of M-S and the cancellation of fines levied against the company.

It is a general principle of law in national legal systems that, where circumstances render an undertaking impossible to perform, both parties must be returned to the position they were in prior to the commencement of the transaction.¹³³ Performance of the undertaking by M.C. to conduct the vaccine trial has been frustrated because of the incompatibility with international law of the trial procedures as currently proposed. Accordingly, M.C. is entitled to the return of the 2 million Euros paid to the Senhavan Ministry of Health as an advance payment.

C. Kuraca is not required to pay damages for Senhava's public health costs

Kuraca is not liable to compensate Senhava for health expenses or any percentage of

¹³⁰ United States Diplomatic and Consular Staff in Tehran (U.S. v. Iran) 1980 I.C.J. 3, 44-5 (May 24).

¹³¹ Chorzów Factory (Merits) (Ger. v. Pol.), 1928 P.C.I.J. (ser. A) No. 17, 47 (Sep. 13).

¹³² *Id.*

¹³³ Rapsomanikis, *Frustration of Contract in International Trade Law and Comparative Law*, 18 DUQ. L. REV. 551 (1980); Smit, *Frustration of Contract: A Comparative Attempt at Consolidation*, 58 COL. L. REV. 287 (1958); ZWEIGERT AND KÖTZ, AN INTRODUCTION TO COMPARATIVE LAW 516-65 (3d. ed, 1998).

the cost of treating future victims of the M.H.V.D. epidemic. Damage which is indirect, remote or uncertain cannot be the subject of damages award.¹³⁴ Senhava presumes the full therapeutic effectiveness of an experimental vaccine still in the early stages of development;¹³⁵ future losses claimed on the basis of the presumed success of the vaccine trial are contingent and indeterminate, and cannot be the basis of an award of damages.¹³⁶

VIII. PRAYER FOR RELIEF

The State of Kuraca respectfully requests this Honorable Court to:

- 1) assert jurisdiction over this case;
- 2) declare that Kuracan National Health Law 1006 complies with its obligations under international law and has not violated Senhava's sovereignty;
- 3) declare that Kuraca did not violate international law when it advised that human rights concerns warranted the halt of the vaccine trials;
- 4) order the immediate release of George Smith;
- 5) order Senhava to rescind the order closing the offices of M-S, revoke the fines assessed against the company, and return the advance payment of 2 million Euros.

Respectfully submitted on this day

Friday, 21 January, 2000

THE STATE OF KURACA

¹³⁴ Trail Smelter Arbitration (U.S. v.Can.) 3 R.I.A.A.1905 (Spec. Arb. 1938, 1941).

¹³⁵ KERNS, ETHICAL ISSUES IN HIV VACCINE TRIALS 72 (1997).

¹³⁶ Chorzow Factory, *supra* n. 131, 57.

